



BILLET D'ÉTAT

WEDNESDAY, 15th JANUARY, 2020

ELECTIONS AND APPOINTMENTS

1. Appointment of an Industrial Disputes Officer and Deputy Industrial Disputes Officer, P.2019/140

LEGISLATIVE BUSINESS

Legislation Laid Before the States

The Land Planning and Development (Fees) (Amendment) Regulations, 2019

Legislation for Approval

2. The Companies (Guernsey) Law, 2008 (Insolvency) (Amendment) Ordinance, 2020, P.2019/139

OTHER BUSINESS

- 3. Policy & Resources Committee Charities and Other Non Profit Organisations, P.2019/136
- 4. Policy & Resources Committee BBC Over-75 Licence Scheme: Extending Relevant Parts of the Communications Act 2003, P.2019/137
- 5. Policy & Resources Committee The Review of the Fiscal Policy Framework and Fiscal Pressures, P.2019/142
- 6. Committee *for* Health & Social Care Review of the Funding of Drugs, Treatments and Devices, P.2019/141
- 7. Committee *for* Home Affairs Police Support for Alderney and Sark, P.2019/138
- 8. Policy & Resources Committee Schedule for future States' Business, P.2019/145

BILLET D'ÉTAT

TO THE MEMBERS OF THE STATES OF THE ISLAND OF GUERNSEY

I hereby give notice that a Meeting of the States of Deliberation will be held at THE ROYAL COURT HOUSE, on WEDNESDAY, the 15th January, 2020 at 9.30 a.m., to consider the items listed in this Billet d'État which have been submitted for debate.

R. J. COLLAS Bailiff and Presiding Officer

The Royal Court House Guernsey

16th December, 2019

THE STATES OF DELIBERATION Of the ISLAND OF GUERNSEY

COMMITTEE FOR EMPLOYMENT & SOCIAL SECURITY

APPOINTMENT OF AN INDUSTRIAL DISPUTES OFFICER AND DEPUTY INDUSTRIAL DISPUTES OFFICER

The	States	are	asked	tο	decide

Whether, after consideration of the Policy Letter entitled 'Appointment of an Industrial Disputes Officer and Deputy Industrial Disputes Officer', dated 25th November 2019, they are of the opinion:

- 1. To appoint Mr Stuart Le Maitre as Industrial Disputes Officer, for the period 3rd February 2020 to 31st December 2024, and
- 2. To appoint Mr Boley Smillie as Deputy Industrial Disputes Officer, for the period 3rd February 2020 to 31st December 2024.

The above Propositions have been submitted to Her Majesty's Procureur for advice on any legal or constitutional implications in accordance with Rule 4(1) of the Rules of Procedure of the States of Deliberation and their Committees.

THE STATES OF DELIBERATION Of the ISLAND OF GUERNSEY

COMMITTEE FOR EMPLOYMENT & SOCIAL SECURITY

APPOINTMENT OF AN INDUSTRIAL DISPUTES OFFICER AND DEPUTY INDUSTRIAL DISPUTES OFFICER

The Presiding Officer States of Guernsey Royal Court House St Peter Port

25th November 2019

Dear Sir

1. Executive summary

- 1.1. Under the Industrial Disputes and Conditions of Employment (Guernsey) Law, 1993 ("the Law"), the States of Guernsey is required to appoint an Industrial Disputes Officer ("IDO") and a Deputy Industrial Disputes Officer ("DIDO").
- 1.2. The terms of appointment for the current Industrial Disputes Officer, Mr Neil Carrington, and Deputy Industrial Disputes Officer, Mr Stuart Le Maitre, expire on 31st December 2019. Mr Carrington is not seeking reappointment for a further term. The Committee is grateful to Mr Carrington for his terms of office, firstly, in the role as the DIDO, and subsequently as the IDO. Mr Carrington brought a wealth of knowledge and experience to the positions.
- 1.3. Following an open recruitment and assessment process to select an individual for each role the Committee *for* Employment & Social Security is recommending that the States appoint Mr Stuart Le Maitre as Industrial Disputes Officer and his nomination of Mr Boley Smillie, as Deputy Industrial Disputes Officer, both for the period 3rd February 2020 to 31st December 2024.

2. Background

2.1. Section 1 of the Industrial Disputes and Conditions of Employment (Guernsey)
Law, 1993 ("the Law") requires the States to appoint an Industrial Disputes
Officer. Section 2 of the Law requires the Industrial Disputes Officer to

appoint a Deputy Industrial Disputes Officer, whose appointment is subject to the approval of the States.

3. Recruitment and selection process

- 3.1. To ensure a strong element of independence and impartiality in the selection process for the posts of IDO and DIDO, the Committee advertised the roles and established a selection process for suitable applicants. The process was similar to that used in the previous selection and recruitment procedures for the IDO and DIDO in 2012 and 2016.
- 3.2. The shortlisted candidates for the role of IDO and DIDO were interviewed. Candidates were assessed against the key criteria and skills identified for the positions.

4. Term of appointment

4.1. The Law requires the States to appoint the officers "for such period as the States may direct." The Committee has concluded that a five year term would be appropriate. Subject to States approval, these appointments will take effect from 3 February 2020. The Committee will recommend the ending of the appointments on 31 December 2024, which will in effect be one month short of a five-year term.

5. Proposals

- 5.1. The Committee recommends that the States appoints Mr Stuart Le Maitre as Industrial Disputes Officer for the period 3rd February 2020 to 31st December 2024.
- 5.2. Mr Le Maitre proposes to appoint Mr Boley Smillie as Deputy Industrial Disputes Officer.
- 5.3. The Committee supports Mr Le Maitre's proposal and recommends the States to approve the appointment of Mr Boley Smillie for the period 3rd February 2020 to 31st December 2024.
- 5.4. A short profile for each nominee is included in the Appendix of this policy letter.

6. Conclusions

Compliance with Rule 4 of the Rules of Procedure

- 6.1. The Committee has consulted with the Law Officers regarding the legal implications and legislative drafting requirements resulting from the propositions set out in this policy letter.
- 6.2. The Committee has set out its proposals for Mr Le Maitre and Mr Smillie to be appointed to the roles of Industrial Disputes Officer and Deputy Industrial Disputes Officer, respectively, and seeks the States support for the propositions, which are based on the Committee's purpose:

"To foster a compassionate, cohesive and aspirational society in which responsibility is encouraged and individuals and families are supported through schemes of social protection relating to pensions, other contributory and non-contributory benefits, social housing, employment, re-employment and labour market legislation."

- 6.3. In particular, the propositions are aligned with the priorities and policies set out in the Committee's Policy Plan, which was approved by the States in June 2017 (Billet d'État XII, Article 1). The Committee's Policy Plan is aligned with the States objectives and policy plans.
- 6.4. In accordance with Rule 4(4) of the Rules of Procedure of the States of Deliberation and their Committees, it is confirmed that the propositions have the unanimous support of the Committee.

Yours faithfully

M K Le Clerc President

S L Langlois Vice-President

J A B Gollop E A McSwiggan P J Roffey

M J Brown Non-States Member

A R Le Lièvre Non-States Member

APPENDIX

7. Profile: Stuart Marcel Le Maitre

7.1. Mr Le Maître has completed an initial term of 3 years as Deputy Industrial Disputes Officer. He is currently Interim Chief Executive of the Medical Specialist Group, following a period of self-employment carrying out consultancy work. He has previously held positions of both Constable and Douzenier for the Vale Parish and holds non-executive director roles. Previously Mr Le Maître was a civil servant for over twenty years, both in the UK and Guernsey; including working in the Industrial Relations Service (now the Employment Relations Service) where he gained first-hand knowledge of working with the Industrial Disputes Officers at that time, and developed extensive experience of chairing conciliation meetings. He also has experience of working in the commercial sector locally, having held senior positions for more than five years.

8. Profile: Boley Smillie

8.1. Mr Smillie is currently Chief Executive of Guernsey Post Ltd, where he has been a member of the Board since 2007, having held a range of other senior roles since the Company was incorporated in 2002. He has over twenty years' experience of working with several established trade unions both at a local and national level and has successfully developed a culture of positive industrial relations in a challenging commercial environment. He has a background of effective employee engagement and leadership, recognised by the Investors in People Gold accreditation and has successfully managed numerous complex negotiations through the collective bargaining process.

THE STATES OF DELIBERATION Of the ISLAND OF GUERNSEY

COMMITTEE FOR EMPLOYMENT & SOCIAL SECURITY

APPOINTMENT OF AN INDUSTRIAL DISPUTES OFFICER AND DEPUTY INDUSTRIAL DISPUTES
OFFICER

The President
Policy & Resources Committee
Sir Charles Frossard House
La Charroterie
St Peter Port

25th November 2019

Dear Sir

Preferred date for consideration by the States of Deliberation

In accordance with Rule 4(2) of the Rules of Procedure of the States of Deliberation and their Committees, the Committee *for* Employment & Social Security requests that the Policy Letter entitled "Appointment of an Industrial Disputes Officer and Deputy Industrial Disputes Officer" be considered at the States' meeting to be held on 15th January 2020.

The current terms of office expire on 31st December 2019. To prevent the lapse of time between the terms of office being longer than necessary, the Committee *for* Employment & Social Security requests that the Policy Letter is discussed at the earliest possible opportunity, which is the States meeting scheduled for 15th January 2020.

Yours faithfully

Michelle Le Clerc

President

Shane Langlois
Vice President

John Gollop, Emilie McSwiggan, Peter Roffey

Mike Brown, Andrew Le Lievre Non-States Members

STATUTORY INSTRUMENTS LAID BEFORE THE STATES

The States of Deliberation have the power to annul the Statutory Instruments detailed below.

No. 113 of 2019

The Land Planning and Development (Fees) (Amendment) Regulations, 2019

In pursuance of section 12 of the Land Planning and Development (Fees and Commencement) Ordinance, 2008 and section 89 of the Land Planning and Development (Guernsey) Law, 2005, the "Land Planning and Development (Fees) (Amendment) Regulations, 2019", made by the Development and Planning Authority on 20th November, 2019, are laid before the States.

EXPLANATORY NOTE

These Regulations amend the Land Planning and Development (Fees and Commencement) Ordinance, 2008 ("the 2008 Ordinance"). They replace the whole of Schedule 1 to the 2008 Ordinance with the new Planning Fees Schedule set out in Schedule 1 to these Regulations. The Table of building control Fees in Part I of Schedule 2 to the 2008 Ordinance is also replaced with the new Table set out in Schedule 2 to these Regulations.

The Schedules to these Regulations set out new fees to accompany an application for planning permission or an application for approval of reserved matters under a planning permission (Schedule 1) and new fees to accompany a deposit of full plans made under building regulations (Schedule 2).

The new fees will apply to an application for planning permission, an application for approval of reserved matters or a deposit of full plans made under building regulations which is made on or after 1st January, 2020 (see regulation 3(1) of these Regulations).

The planning fee categories in Schedule 1 are also restructured and simplified. In particular, categories 3 and 4 in relation to domestic and non-domestic development are amended to include certain minor development included in former fee category 6 and definitions of "domestic development" and "non-domestic development" are included in Part II of the Schedule. Fees for placement of caravans and similar vehicles on land are now included in categories 3 and 4 where within the curtilage of a dwelling or a non-domestic building and in category 9 where not within the curtilage of a building.

Category 4, in relation to non-domestic development, no longer provides for separate fees for a list of specific development (former category 4B). Any such development will now generally fall under category 4H.

Development in relation to shop fronts is also now included in category 4 and removed from the category related to advertisements (now category 6).

Two categories relating to provision of public utility services and street furniture and development in relation to mobile telephone masts and antennas have been combined to form new category 5.

Consequential amendments, in relation to the restructuring and simplification of fee categories, have also been made to the notes in Part II of the Planning fees Schedule.

A change has also been made to the note 3 in Part II of the Planning fees Schedule which adjusts the fee payable where an application is for revised development which is still

substantially the same as that already approved. The condition that the application must be made within 12 months of the original grant has been replaced by a requirement that the original permission is still in effect i.e. development has started or the permission has not expired.

The building control fees in Schedule 2 are also increased and changes made to amalgamate former categories 2D and E and to split former category 2G into two categories with a higher fee for extensions of 50 square metres or more in floor area.

In accordance with section 4B and 4C of the 2008 Ordinance, the new fees also apply in relation to an appeal to the Planning Tribunal in relation to a planning decision or to an Adjudicator against a rejection of full plans under the building regulations, for which a fee is payable under the 2008 Ordinance.

The new fees will apply where the appeal fee is required to be calculated, under section 4B(2) or 4C(2) of the 2008 Ordinance, as if the appeal were made on or after 1st January, 2020 (see regulation 3(2) of these Regulations).

These Regulations come into force on the 1st January, 2020.

The full text of the legislation can be found at: http://www.guernseylegalresources.gg/article/90621/Statutory-Instruments

THE STATES OF DELIBERATION Of the ISLAND OF GUERNSEY

THE COMPANIES (GUERNSEY) LAW, 2008 (INSOLVENCY) (AMENDMENT) ORDINANCE, 2020

The States are asked to decide:-

Whether they are of the opinion to approve the draft Ordinance entitled "The Companies (Guernsey) Law, 2008 (Insolvency) (Amendment) Ordinance, 2020", and to direct that the same shall have effect as an Ordinance of the States.

This proposition has been submitted to Her Majesty's Procureur for advice on any legal or constitutional implications in accordance with Rule 4(1) of the Rules of Procedure of the States of Deliberation and their Committees.

EXPLANATORY MEMORANDUM

This Ordinance amends the Companies (Guernsey) Law, 2018 ("the Law") to make further provision relating to the insolvency of companies.

Sections 2 and 3 insert provisions into the Law exempting a company in liquidation from the requirement under section 255 of the Law to have its accounts audited.

Section 6 inserts a provision into the Law that an administrator may make distributions to creditors in specified circumstances.

Section 7 inserts a provision into the Law permitting the dissolution of a company, following the discharge of an administration order, where it appears to the Court that a company has no assets that might permit a distribution to creditors. Sections 4 and 5 insert consequential provisions.

Section 8 inserts a provision into the Law requiring administrators to call an initial meeting of creditors, and to send an explanation to creditors of the aims, and likely process of, the administration. Section 8 also inserts into the Law a power for the Committee for Economic Development to make regulations in respect of the initial meeting and for the calling and otherwise in respect of any further meetings of creditors.

Sections 9 and 20 insert new sections into the Law enhancing the powers of administrators and liquidators of companies to obtain information and documents from officers, employees and those involved in the formation of companies.

Sections 10 and 21 insert provisions into the Law requiring administrators and liquidators, respectively, to report delinquent officers of insolvent companies to the Registrar of Companies or, in the case of supervised companies, to the Guernsey Financial Services Commission.

Sections 11 to 15 insert provisions into the Law regarding the appointment, and conduct, of liquidators of insolvent companies which are being voluntarily wound up, to enhance creditor protection.

Sections 16 and 17 insert provisions into the Law relating to circumstances where a final meeting prior to the dissolution of a company is called but no quorum was present.

Section 19 inserts a new Part XXIIIA into the Law providing for the compulsory winding up, by the Court, of non-Guernsey companies in specified circumstances.

Section 21 inserts provisions into the Law giving liquidators a power to disclaim onerous property and making consequential provision.

Section 22 inserts a new Part XXIVA into the Law which contains miscellaneous provisions relating to the winding up and administration of companies including:

- Powers for the Committee for Economic Development to appoint an Insolvency Rules Committee and to make rules for the purpose or carrying into effects Parts XXI to XXIV of the Law and more generally relating to dissolution, winding up, liquidation or administration.
- A power for a liquidator or administrator to apply to the Court for an order setting aside transactions at an undervalue and extortionate credit transactions in specified circumstances.
- A power for the Committee for Economic Development to make regulations about the supply of specified services to companies in administration or liquidation, with the aim of enabling such supplies to continue.

Other sections of the Ordinance make miscellaneous minor, or consequential, amendments to the Law.

The Ordinance shall come into force on the day appointed by regulations made by the States Committee for Economic Development, and different days may be appointed for different provisions and different purposes.

The Companies (Guernsey) Law, 2008 (Insolvency) (Amendment) Ordinance, 2020

THE STATES, in pursuance of their Resolution of the 31st March, 2017^a, and in exercise of the powers conferred on them by sections 533 and 538 of the Companies (Guernsey) Law, 2008, as amended^b, and all other powers enabling them in that behalf, hereby order:-

Amendment of Law.

- 1. The Companies (Guernsey) Law, 2008 is further amended as follows.
- 2. In section 255 after "section 256" add "or section 256A".
- 3. After section 256 add the following section -

"Company in winding up exempt from audit.

256A. (1) Upon the appointment of a liquidator a company is exempt from the requirement under section 255 to have its accounts for a financial year audited.

a Article XIV of Billet d'État No. VII of 2017.

b Order in Council No. VIII of 2008; No. XIII of 2010; No. I of 2013; No. VI of 2014; No. VI of 2017; Ordinance No. XXV of 2008; No. LIV of 2008; No. VII of 2009; No. XIV of 2009; No. XI of 2010; No. XXXI of 2012; No. XXXI of 2013; No. IV of 2015; No. XII of 2015; No. XXVI of 2015; No. IX of 2016; No. XXIX of 2017; No. XXVII of 2018; G.S.I. No. 34 of 2009; G.S.I. No. 37 of 2013; G.S.I. No. 84 of 2014; G.S.I. No. 29 of 2016; G.S.I. No. 35 of 2016; G.S.I. No. 35 of 2017; G.S.I. No. 103 of 2017; G.S.I. No. 90 of 2018.

- (2) An exemption under subsection (1) will apply to each financial year of the winding up, including -
 - (a) the financial year in which the liquidator is appointed, and
 - (b) the company's final financial year,

but, for the avoidance of doubt, will not apply to any financial year prior to the one in which the liquidator was appointed (provided always that there is no obligation upon the liquidator to conduct an audit of the company's accounts for any such prior financial year in respect of which the company was in contravention of section 255).

- (3) An exemption under subsection (1) only has effect in relation to obligations under this Law and does not prejudice any other obligation of a company to have its accounts audited.".
- **4.** In sections 369 and 370(1)(a)(ii) after "section 111(2)(d)" insert "or 382A".
- 5. In section 371(3)(b) after subparagraph (ii) insert the following subparagraph -
 - "or (iii) dissolved under section 382A and removed from the Register of Companies, whether any person who was an administrator prior to the company's dissolution consents to be an administrator if the company is restored,"

6. After section 380, add the following section -

"Distributions to creditors.

- **380A.** (1) The administrator may make a distribution to a creditor of the company if he thinks it likely to assist the achievement of any purpose for which the administration order was made.
- (2) The administrator may not make a distribution to a creditor who is not -
 - (a) a creditor with a secured interest, including a security interest (within the meaning of the Security Interests (Guernsey) Law, 1993), or
 - (b) a creditor with a preferred debt within the meaning of the Preferred Debts (Guernsey) Law, 1983,

unless the Court gives permission.

- (3) For the avoidance of doubt, a distribution under this section to a creditor is not a distribution within the meaning of section 301 or for the purposes of section 303.".
- 7. After section 382, add the following section -

"Dissolution following discharge of administration order.

382A. (1) If an administration order is discharged under section

382, and it appears to the Court that the company has no assets which might permit a distribution to its creditors, the Court may, on such terms and conditions as it thinks fit, order that the company be dissolved on a specified date.

- (2) Where an order is made under this section the administrator shall -
 - (a) within 7 days after the day of the order, send a copy of the order that the company be dissolved to the Registrar, and
 - (b) within such time as the Court may direct, send a copy thereof to such other persons as the Court may direct.".
- **8.** After section 386, add the following section -

"Requirement for initial meeting of creditors.

- **386A.** (1) Each notice sent to creditors under section 386(1)(d)(i) shall be accompanied by -
 - (a) an invitation to an initial meeting of creditors, and
 - (b) an explanation of the aims of and the likely process of the administration.
 - (2) If the Court orders otherwise than for notices to be sent

to all creditors of the company under section 386(1)(d), the Court may at the same time order that the administrator must -

- (a) call an initial meeting of all such creditors by notice sent to them, and
- (b) send the explanation of the aims and process of the administration to all such creditors as set out in subsection (1)(b),

in each case so far as he is aware of their addresses.

- (3) The date set for an initial meeting of creditors must be within a period of 10 weeks from the date of the administration order, or such other period as the Court may direct.
- (4) The Committee may make regulations in respect of the initial meeting and for the calling and otherwise in respect of any further meetings of creditors which -
 - (a) shall be by way of company insolvency rules under section 426B, and
 - (b) may, without limitation, provide that -
 - (i) the initial meeting may be dispensed with where, in the opinion of the administrator, having regard to the provisions of section 419, there are no

assets available for distribution to the creditors, and

- (ii) this section and the regulations shall have effect in respect of the initial meeting and any further meeting of creditors subject to such exceptions, adaptations and modifications as may be specified in the regulations."
- **9.** In section 387 -
 - (a) after subsection (3)(d) add the following paragraph -
 - "(e) with the leave of the Court, any other person.",
 - (b) after subsection (7) add the following subsection -
 - "(7A) If a person fails to comply with any obligation imposed under this section the administrator may (without prejudice to any other remedy or sanction in respect of the failure to comply) apply to the Court, and upon such an application the Court may make such order on such terms and conditions and subject to such penalty as it thinks fit, including without limitation an order that the person in respect of whom the application is made must
 - (a) make out and submit a statement of affairs in accordance with the

provisions of this section, and

- (b) comply with any other obligation imposed under this section.".
- **10.** After section 387, add the following section -

"Duty to report delinquent officers of company.

- 387A. (1) If it appears to the administrator at any time when an administration order is in force that there are grounds for the Court to make a disqualification order under Part XXV in respect of any past or present officer of the company, he shall, before, or within a period of 6 months from, the day on which he vacates office report the matter to the Registrar of Companies and, in the case of a supervised company, to both the Registrar of Companies and the Commission.
- (2) Following a report under subsection (1), the administrator shall provide to the Registrar of Companies or (as the case may be) the Commission such additional information or documents in the possession of or under the control of the administrator and relating to the matter in question as the Registrar or (as the case may be) the Commission requires.
- (3) The provisions of this section are in addition to and not in derogation from the provisions of section 422.".
- 11. After section 391 add the following section -

"Declaration of solvency.

- **391A.** (1) Where it is proposed to wind up a company voluntarily, the board of directors may make a declaration of solvency, which is a declaration signed by a director stating that, in the opinion of the board, the company satisfies the solvency test.
- (2) To be effective, the declaration must be made within the period of 5 weeks immediately preceding the date of the resolution for winding up, or on the same date.
- (3) If a declaration of solvency is not made in accordance with this section, sections 395(1A) and 398B apply to the winding up, and for the avoidance of doubt, those sections do not apply to a winding up in respect of which a declaration of solvency has been made in accordance with this section.
- (4) A copy of a declaration of solvency made under this section shall be delivered by the company to the Registrar within a period of 30 days after the day of it being made.
 - (5) A company which fails to comply with subsection (4) -
 - (a) is guilty of an offence, and
 - (b) is liable to a civil penalty.".
- **12.** After section 395(1), add the following subsection -
 - "(1A) If a declaration of solvency has not been made in

accordance with section 391A, the company may not appoint a liquidator under subsection (1) who is -

- (a) a director, former director, shadow director, employee, manager, secretary or member of
 - (i) the company, or
 - (ii) any associated company,
- (b) a director, former director, shadow director, employee, manager, secretary or member of -
 - (i) any other company (company X) which is or has been a director, former director, shadow director, employee, manager, secretary or member of the company intended to be placed into voluntary liquidation, or
 - (ii) any associated company of company X, or
- (c) the parent, spouse, former spouse, child or stepchild of any of the persons referred to in paragraph (a) or (b)."
- 13. In section 396(1)(b), after "made with its creditors," add "and subject also to the provisions of section 395(1A),".

- **14.** In section 398, number the existing text as subsection "(1)" and add the following subsection -
 - "(2) For the avoidance of doubt, the Court may appoint a liquidator under this section who is a person referred to in section 395(1A)(a) or (b), whether or not a declaration of solvency has been made in accordance with section 391A.".
 - **15.** After section 398, add the following sections -

"Liquidator to resign in certain circumstances.

- **398A.** (1) If a liquidator ("A") is a person referred to in section 395(1A)(a) or (b), and it becomes apparent to him during the winding up that, notwithstanding the declaration of solvency made under section 391A, the company does not satisfy the solvency test, A shall -
 - (a) convene a meeting of all creditors of the company (so far as he is aware of their addresses) to which either or both of the following propositions shall be submitted -
 - (i) that A's appointment as liquidator be sanctioned,
 - (ii) that an alternative liquidator, who has expressed his willingness to act, be appointed on the same terms and conditions as A, or on such other terms

and conditions as may be set out in the proposition, and that A shall immediately resign, or

(b) make an application to the Court on notice to all creditors of the company (so far as he is aware of their addresses) for an order that A's appointment as liquidator be sanctioned,

and, where the appointment of a liquidator has been sanctioned by a meeting of creditors or by an order of the Court pursuant to paragraph (a)(i) or (b) or an alternative liquidator has been appointed pursuant to paragraph (a)(ii), section 398B applies to the winding up.

- (2) For the purposes of subsection (1) -
 - (a) a proposition mentioned in subsection (1)(a)(i)or (ii) must be passed by a simple majority in value of the creditors present and voting,
 - (b) if only one of the propositions mentioned in subsection (1)(a) is submitted to the meeting, and that proposition is not passed, A shall immediately resign and deliver notice of resignation to the Registrar within a period of 30 days immediately following the day of the meeting,
 - (c) if both propositions mentioned in subsection

- (1)(a) are submitted to the meeting –
- (i) the proposition mentioned in subsection(1)(a)(i) shall be voted on first,
- (ii) if that proposition is passed, then no vote shall be taken on the proposition mentioned in subsection (1)(a)(ii), and
- (iii) if neither of the propositions mentioned in subsection (1)(a) is passed, a vote having been taken on each, A shall immediately resign and deliver notice of resignation to the Registrar within a period of 30 days immediately following the day of the meeting,
- (d) if only the proposition mentioned in subsection(1)(a)(ii) is passed -
 - (i) A shall immediately resign and deliver notice of resignation to the Registrar within a period of 30 days immediately following the day of the meeting, and
 - (ii) notice of the appointment of the alternative liquidator shall be delivered to the Registrar within a period of 30 days immediately following the day of

the meeting (and the provisions of section 395(1) shall be deemed to have been complied with), and

- (e) notwithstanding the foregoing provisions of this section, if in any case -
 - (i) no creditor is present at the meeting mentioned in subsection (1)(a), or
 - (ii) no creditor votes at that meeting,

the proposition mentioned in subsection (1)(a)(i) shall be deemed to have been passed,

and a proposition passed or deemed to have been passed under this subsection shall have effect for the purposes of this Law and shall be complied with and acted upon accordingly.

(3) On hearing an application under subsection (1)(b), the Court may, if satisfied it would be just to so order, sanction the liquidator's appointment (on such terms and conditions as the Court may direct), or make such other order as the Court considers just.

Additional requirements on liquidator.

398B. (1) If -

(a) a declaration of solvency has not been made in accordance with section 391A,

- (b) the appointment of a liquidator has been sanctioned -
 - (i) by a meeting of creditors pursuant to section 398A(1)(a)(i), or
 - (ii) by an order of the Court pursuant to section 398A(1)(b), or
- (c) an alternative liquidator has been appointed pursuant to section 398A(1)(a)(ii),

the liquidator shall, unless in the opinion of the liquidator, having regard to the provisions of section 419, there are no assets available for distribution to the creditors, call at least one meeting of the company's creditors which meeting shall take place within one month of his appointment or (as the case may be) the sanctioning of his appointment.

- (2) Notice of the meeting shall be sent to all the company's creditors at least 7 days before the day on which the meeting is to be held, and shall contain -
 - (a) notice of the liquidator's appointment or (as the case may be) the sanctioning of his appointment, and
 - (b) an explanation of the likely process of the voluntary winding up.".

16. After section 400(2) add the following subsection -

"(2A) However, if a quorum is not present at such a meeting, the liquidator shall give notice to the Registrar that the meeting was duly called, specify the date on which it was due to take place and state that no quorum was present."

- 17. In section 400(3) after the words "publish the fact of this final meeting" insert ", or the fact that it was duly called and no quorum was present,".
- **18.** In section 407, for the expression "section 406(e)" substitute "sections 406(e) and 418B(2)(b)".
 - **19.** After section 418 insert the following Part -

"PART XXIIIA

WINDING UP OF NON-GUERNSEY COMPANIES

Meaning of "non-Guernsey company".

418A. In this Part of this Law "non-Guernsey company" means -

- (a) any overseas company,
- (b) any person or body prescribed by the Committee for the purposes of this section or of a class or description so prescribed,

and, for the avoidance of doubt, does not include a company registered in the

Register of Companies.

Winding up of non-Guernsey companies.

- 418B. (1) Subject to the provisions of this Part, any non-Guernsey company may be compulsorily wound up by the Court under this Law, and Parts XXIII and XXIV, other than section 420, apply (with the modification set out in subsection (2) and all other necessary modifications) to a non-Guernsey company as they apply in relation to a company registered in the Register of Companies, and the court or liquidator may exercise any powers or do any act in the case of a non-Guernsey company which might be exercised or done by it or him in winding up a company registered in the Register of Companies.
- (2) Section 409(1) applies with the modification that in the case of a non-Guernsey company which is -
 - (a) a licensee within the meaning of the Insurance Business (Bailiwick of Guernsey) Law, 2002, or
 - (b) a licensed institution within the meaning of the Banking Supervision (Bailiwick of Guernsey) Law, 1994,

the Court may not direct that the period specified in that section be reduced to a period of less than 7 days.

- (3) The circumstances in which a non-Guernsey company may be wound up by the Court are as follows -
 - (a) if the company is dissolved, or has ceased to

carry on business, or is carrying on business only for the purpose of winding up its affairs,

- (b) if the company is unable to pay its debts within the meaning given in section 407, or
- (c) if the Court is of the opinion that it is just and equitable that the company should be wound up.".
- **20.** After section 419, insert the following sections -

"Statement of affairs to be submitted to liquidator.

- **419A.** (1) Subject to this section, section 387 applies (with necessary modifications) to a winding up and a liquidator as it applies to an administration and an administrator, and accordingly a liquidator may (without prejudice to any other requirements imposed by or under that section) require all or any of the persons mentioned in section 387(3) to make out and submit to him a statement (a "**statement of affairs**") in such form as he may require as to the affairs of the company.
- (2) For the purposes of the application of section 387 to a statement of affairs to be submitted to the liquidator, "the preceding year" in section 387(3)(b) means the period of one year before the date of -
 - (a) the making of the application for the compulsory winding up of the company under section 408,
 - (b) the passing by the company of any resolution

mentioned in section 391(1) for the voluntary winding up of the company, or

(c) the making of an administration order in respect of the company,

as the case may be.

- (3) For the avoidance of doubt, a liquidator may require a statement of affairs from a person notwithstanding that that person has submitted a statement in respect of the company in a previous administration or voluntary winding up of the company.
- (4) The powers conferred on a liquidator by this section may be exercised only to the extent reasonably required by the liquidator for the purposes of the performance of his functions in respect of the winding up of the company.

Production of documents and information.

- **419B.** (1) The liquidator may at any time before the dissolution of the company apply to the Court for an order requiring all or any of the persons mentioned in subsection (3) to produce documents and information relating to the company.
- (2) The Court may, on such terms and conditions and subject to such penalties as it thinks fit, order a person who is the subject of an application under subsection (1) -
 - (a) to produce, in the form and manner specified in

the order, any documents that are specified or described in the order, and

- (b) to provide, in the form and manner specified in the order, such information as may be specified or described in the order.
- (3) The persons referred to in subsection (1) are -
 - (a) those who are or have been officers of the company,
 - (b) those who have taken part in the company's formation at any time within the preceding year within the meaning of section 419A(2),
 - (c) those who are in the company's employment or have been in its employment within the preceding year, and are in the liquidator's opinion capable of giving the information required,
 - (d) those who are or have within the preceding year been officers of or in the employment of a company which is, or within the preceding year was, an officer of the company,
 - (e) with the leave of the court, any other person.

(4) In subsection (3) -

- (a) "employment" includes employment under a contract for services, and
- (b) in the case of a cell of a protected cell company, references to company include references to the protected cell company.
- (5) This section only applies to documents and information reasonably required by the liquidator for the purposes of the performance of his functions in respect of the winding up of the company.
- (6) Nothing in this section compels the production or divulgence by an advocate or other legal adviser of an item subject to legal professional privilege (within the meaning of section 24 of the Police Powers and Criminal Evidence (Bailiwick of Guernsey) Law, 2003), but an advocate or other legal adviser may be required to give the name and address of any client.
- (7) An order of the Court under this section has effect notwithstanding any obligation as to confidentiality or other restriction on the disclosure of information imposed by statute, contract or otherwise, and accordingly the obligation or restriction is not contravened by the making of a disclosure pursuant to such an order.
- (8) A person who without reasonable excuse fails to comply with any obligation imposed by or under this section is (without prejudice to any other remedy or sanction in respect of the failure to comply) guilty of an offence.

Examination of officers.

- **419C.** (1) The liquidator may in the course of the winding up apply to the Court for the appointment of an Inspector of the Court to conduct an examination of any person who is or has been an officer of the company.
 - (2) The liquidator -
 - (a) unless the Court on the application of the liquidator directs otherwise, shall make an application under subsection (1) as soon as reasonably practicable if requested to do so by one half in value of the company's creditors, and
 - (b) may make such an application of his own motion at any time.
- (3) On an application under subsection (1), the Court shall if it thinks fit appoint an Inspector on such terms and conditions (including terms and conditions as to remuneration, costs and expenses and the recovery thereof) as the Court thinks fit and direct that an examination of the person to whom the application relates shall be held on a day to be appointed by the Inspector, and that person shall -
 - (a) attend on that day in the same way as if summonsed before the Court in civil proceedings, and
 - (b) be examined as to -

- (i) the formation, management or promotion of the company,
- (ii) the conduct of its business and affairs, or
- (iii) his conduct or dealings in relation to the company.
- (4) A person examined under subsection (3) has the same rights, powers and privileges, and is subject to the same duties, obligations, sanctions, penalties and proceedings, as a witness summonsed before the Court in civil proceedings (including, without limitation, duties to take the oath or affirmation, which shall be administered by the Inspector, to produce any document in his possession, custody or power, and to answer any question put to him).
- (5) An examination before an Inspector under this section shall be conducted in private.
- (6) A statement made by a person in the course of an examination before an Inspector under this section -
 - (a) may be used in evidence against him in proceedings other than criminal proceedings, and
 - (b) may not be used in evidence against him in criminal proceedings except -

- (i) where evidence relating to it is adduced, or a question relating to it is asked, in the proceedings by or on behalf of that person, or
- (ii) in proceedings for -
 - (A) any offence where, in giving evidence, he makes a statement inconsistent with it, but the statement is only admissible to the extent necessary to establish the inconsistency,
 - (B) perjury, or
 - (C) perverting the course of justice.
- (7) The Committee may make such rules of procedure in respect of examinations under this section and the conduct thereof as it thinks fit and in respect of the qualifications, appointment, functions, privileges and immunities of an Inspector.".
- **21.** After section 421, insert the following sections -

"Power to disclaim onerous property.

421A. (1) The liquidator may by giving notice under this section disclaim any onerous property of the company, and may do so

notwithstanding that he has taken possession of it, endeavoured to sell it, or otherwise exercised rights of ownership in relation to it.

- (2) For the purpose of this section, "onerous property" means -
 - (a) any unprofitable contract,
 - (b) any other personal property of the company which is unsaleable or not readily saleable or is such that it may give rise to a liability to pay money or perform any other onerous act, and
 - (c) any real property if it is situated outside the Bailiwick of Guernsey.
 - (3) A notice of disclaimer under subsection (1) must -
 - (a) contain a description of the property disclaimed which enables it to be easily identified,
 - (b) be signed and dated by the liquidator and served within 7 days of signing on -
 - (i) the Registrar,
 - (ii) Her Majesty's Receiver General,
 - (iii) any person who claims an interest in the

disclaimed property,

- (iv) any person who is under any liability in respect of the disclaimed property, not being a liability discharged by the disclaimer,
- (v) any other person prescribed by the Committee for the purposes of this subsection.
- (4) A disclaimer under this section -
 - (a) operates so as to determine, as from the date of the disclaimer, the rights, interests and liabilities of the company in or in respect of the property disclaimed, but
 - (b) does not, except so far as is necessary for the purpose of releasing the company from any liability, affect the rights or liabilities of any other person.
- (5) A notice of disclaimer shall not be given under this section in respect of any property if -
 - (a) a person interested in the property has applied in writing to the liquidator requiring the liquidator to decide whether he will disclaim or

not, and

- (b) the liquidator has not, within a period of 28 days after receipt of the application or such further period as may be allowed by the Court, given notice disclaiming the property.
- (6) Any person sustaining loss or damage in consequence of the operation of a disclaimer under this section is deemed a creditor of the company to the extent of the loss or damage and accordingly may prove for the loss or damage in the winding up.
- (7) Notwithstanding any other provision of this section, a notice of disclaimer of onerous property of a company under this section is not effective against any person not served with notice of the disclaimer.
- (8) Where the effect of a disclaimer of onerous property under this section is that the property would become bona vacantia, Her Majesty's Receiver-General may direct that the property is not bona vacantia and accordingly does not belong to the Crown.

Disclaimer of leaseholds.

- **421B.** (1) The disclaimer under section 421A of any property of a leasehold nature does not take effect unless a copy of the disclaimer has been served (so far as the liquidator is aware of their addresses) on every person claiming under the company as underlessee or mortgagee and either -
 - (a) no application under section 421C is made in respect of that property before the end of the

period of 14 days beginning with the day on which the last notice served under this subsection was served, or

- (b) where such an application has been made, the Court directs that the disclaimer shall take effect.
- (2) Where the Court gives a direction under subsection (1)(b) it may also, instead of or in addition to any order it makes under section 421C, make such orders in respect of fixtures, tenant's improvements and other matters arising out of the lease as it thinks fit.
 - (3) For the purposes of this section -

"mortgagee" means a person holding any, or any interest in any, security on assets of the company or any cell thereof,

"property of a leasehold nature" means -

- (a) any interest in or in respect of real property which confers or vests rights of possession, occupation or enjoyment and which is treated by law as or deemed to be personal property, or
- (b) any real property subject to such an interest,

Powers of court in respect of disclaimed property - general.

421C. (1) This section and section 421D apply where the liquidator has issued a notice disclaiming any property under section 421A.

- (2) An application may be made to the Court by -
 - (a) any person who claims an interest in the disclaimed property,
 - (b) any person who is under any liability in respect of the disclaimed property, not being a liability discharged by the disclaimer,
 - (c) Her Majesty's Receiver General,
 - (d) with leave of the Court, any other person.
- (3) Subject to subsection (4) the Court may, on an application under this section, make an order on such terms and conditions as it thinks fit, including without limitation one for the vesting of the disclaimed property in, or for its delivery to -
 - (a) a person entitled to it or a trustee for such a person, or
 - (b) a person subject to such a liability as is mentioned in subsection (2)(b) or a trustee for such a person.
- (4) The court shall not make an order under subsection (3)(b) except where it appears to the court that it would be just to do so for the purpose of compensating the person subject to the liability in respect of the

disclaimer.

- (5) The effect of any order under this section shall be taken into account in assessing for the purpose of section 421A(6) the extent of any loss or damage sustained by any person in consequence of the disclaimer.
- (6) An order under this section vesting property in any person need not be completed by conveyance, assignment or transfer.

Powers of court in respect of leaseholds.

- **421D.** (1) The Court shall not make an order under section 421C vesting property of a leasehold nature in any person claiming under the company as underlessee or mortgagee except on terms making that person -
 - (a) subject to the same liabilities and obligations as the company was subject to under the lease at the commencement of the winding up, or
 - (b) if the Court thinks fit, subject to the same liabilities and obligations as that person would be subject to if the lease had been assigned to him at the commencement of the winding up.
- (2) For the purposes of an order under section 421C relating to only part of any property comprised in a lease, the requirements of subsection (1) apply as if the lease comprised only the property to which the order relates.

(3) Where subsection (1) applies and no person claiming under the company as underlessee or mortgagee is willing to accept an order under section 421C on the terms required under subsection (1), the Court may, by order under section 421C, vest the company's estate and interest in the property in any person who is liable (whether personally or in a representative capacity, and whether alone or jointly with the company) to perform the lessee's covenants in the lease.

The Court may vest that estate and interest in such a person freed and discharged from all estates, incumbrances and interests created by the company.

(4) Where subsection (1) applies and a person claiming under the company as underlessee or mortgagee declines to accept an order under section 421C, that person is excluded from all interest in the property.

Duty to report delinquent officers of company.

- **421E.** (1) If it appears to the liquidator in the course of the winding up of a company that there are grounds for the Court to make a disqualification order under Part XXV in respect of any past or present officer of the company, he shall before, or within a period of 6 months from, the day on which the company is dissolved report the matter to the Registrar of Companies, and in the case of a supervised company, to both the Registrar of Companies and the Commission.
- (2) Following a report under subsection (1), the liquidator shall provide to the Registrar of Companies or (as the case may be) the Commission such additional information or documents in the possession of or under the control of the liquidator and relating to the matter in question as the

Registrar or (as the case may be) the Commission requires.

- (3) The provisions of this section are in addition to and not in derogation from the provisions of section 422.".
- 22. After section 426A insert the following Part -

"PART XXIVA

MISCELLANEOUS PROVISIONS APPLYING TO WINDING UP AND ADMINISTRATION

Company insolvency rules.

- **426B.** (1) The Committee may by regulation make rules ("company insolvency rules") for the purpose of carrying into effect Parts XXI to XXIV of this Law and any other provision of this Law relating to dissolution, winding up, liquidation or administration, including (without limitation) rules prescribing or otherwise in respect of -
 - (a) matters of practice and procedure to be followed in or in connection with those Parts and provisions,
 - (b) the administration of those Parts and provisions, including by the Committee and the Registrar,
 - (c) the means by which particular facts may be proved, and the way in which representations may be made or given,

- (d) ancillary, incidental, supplementary and related matters.
- (2) Company insolvency rules under subsection (1) may, without limitation -
 - (a) prescribe the circumstances where a creditor wishing to recover a debt from a company which is being wound up must submit a proof of that debt to the liquidator, and provide for a procedure for proving the debt,
 - (b) provide that the liquidator may accept or rejecta proof (in whole or in part),
 - (c) provide that, if a creditor is dissatisfied with a liquidator's decision to reject a proof, the creditor may apply to court for the decision to be reversed or varied,
 - (d) prescribe the form and content of the notice by which a liquidator may disclaim onerous property of the company under section 421A.
- (3) Company insolvency rules may, without limitation, make provision corresponding to that made in England and Wales by the Insolvency (England and Wales) Rules 2016 as from time to time amended or

re-enacted (with or without modification).^c

Company Insolvency Rules Committee.

- **426C.** (1) The Committee may from time to time establish an Insolvency Rules Committee for the purpose of being consulted by the Committee under subsection (3).
- (2) The Committee may appoint as members of the Insolvency Rules Committee any persons appearing to it to have qualifications or experience that would be of value to the Committee in considering any matter about company insolvency rules.
- (3) If an Insolvency Rules Committee has been established under subsection (1), the Committee must consult that Committee before making any company insolvency rules under section 426B.

Transactions at an undervalue.

- **426D.** (1) A liquidator or an administrator (as the case may be) of a company may apply to the Court for an order under this section if -
 - (a) the company has entered into a transaction with a person at an undervalue at any time after the commencement of a period of 6 months immediately preceding the relevant date, and
 - (b) the company -

c United Kingdom S.I. 2016/1024.

- (i) was unable to satisfy the solvency test when it entered into the transaction, or
- (ii) became unable to satisfy the solvency test as a result of entering into the transaction.
- (2) For the purposes of this section -
 - (a) a company enters into a transaction with a person at an undervalue if the company -
 - (i) makes a gift to that person or otherwise enters into a transaction with that person on terms that provide for the company to receive no valuable consideration, or
 - (ii) enters into a transaction with that person for a consideration the value of which, in money or money's worth, is significantly less than the value, in money or money's worth, of the consideration provided by the company,
 - (b) the "relevant date" is the earlier of -
 - (i) the date of the making of any application for the compulsory winding up of the company under section 408,

- (ii) the date of the passing by the company of any resolution mentioned in section 391(1) for the voluntary winding up of the company,
- (iii) the date of the making of any application for an administration order under section 375.
- (3) Subject to subsection (7), on an application by a liquidator or an administrator under subsection (1) the Court may make such order on such terms and conditions and subject to such penalty as it thinks fit for restoring the position to what it would have been if the company had not entered into the transaction.
- (4) Without prejudice to the generality of subsection (3) but subject to subsection (5), an order under this section may -
 - (a) require any property transferred as part of the transaction to be vested in the company,
 - (b) require any property to be so vested if it represents in any person's hands the application either of the proceeds of sale of property so transferred or of money so transferred,
 - (c) release or discharge (in whole or in part) any security given by the company,

- (d) require any person to pay, in respect of benefits received by him from the company or benefits received by him from the person who entered into the transaction with the company, such sums to the liquidator or administrator as the court may direct,
- (e) provide for any surety or guarantor whose obligations to any person were released or discharged (in whole or in part) under the transaction to be under such new or revived obligations as the Court thinks fit,
- (f) provide for -
 - (i) security to be provided for the discharge of any obligation imposed by or arising under the order,
 - (ii) such an obligation to be secured or charged on any property, and
 - (iii) such security or charge to have the same priority as a security or charge released or discharged (in whole or in part) under the transaction,
- (g) provide for the extent to which any person

whose property is vested by the order in the company, or on whom obligations are imposed by the order, is to be able to claim in the liquidation for debts or other liabilities which arose from, or were released or discharged (in whole or in part) by, the transaction.

- (5) An order under this section may affect the property of or impose obligations on any person, whether or not he is the person with whom the company entered into the transaction, but shall not -
 - (a) prejudice any interest in property acquired from a person other than the company in good faith, for value and without notice of the existence of circumstances by virtue of which an order under this section may be made,
 - (b) prejudice an interest deriving from such interest, or
 - (c) require a person who received a benefit from the transaction in good faith, for value and without notice of the existence of circumstances by virtue of which an order under this section may be made to pay any sum unless he was a party to the transaction.
- (6) In the application of this section to any case where the person who entered into the transaction with the company is connected with

the company, the reference in subsection (1) to 6 months is to be read as a reference to 2 years.

- (7) The Court shall not make an order under this section if it is satisfied -
 - (a) that the transaction at an undervalue was entered into by the company in good faith and for the purpose of carrying on its business, and
 - (b) that at the time the transaction was entered into there were reasonable grounds for believing that the transaction would be of benefit to the company.
- (8) In considering for the purposes of this section whether a person has acted in good faith, the court may, without limitation, take into consideration -
 - (a) whether the person was aware -
 - (i) that the company had entered into a transaction at an undervalue, and
 - (ii) that the company -
 - (A) was unable to satisfy the solvency test when it entered into the transaction, or

- (B) would as a likely result of entering into the transaction became unable to satisfy the solvency test, and
- (b) whether the person was an associated company of or was connected with either the company or the person with whom the company entered into the transaction.
- (9) In this section "**connected**" has the same meaning as in section 424(7).
 - (10) This section is without prejudice to any other remedy.

Extortionate credit transactions.

- **426E.** (1) A liquidator or an administrator of a company may apply to the Court for an order under this section if -
 - (a) the company is, or has been, a party to a transaction for, or involving, the provision of credit to the company,
 - (b) the transaction is or was extortionate, and
 - (c) the transaction was entered into during the period of 3 years immediately preceding the relevant date.

- (2) For the purposes of this section -
 - (a) a transaction is extortionate if, having regard to the risk accepted by the person providing the credit -
 - (i) the terms of it are or were such as to require grossly exorbitant payments to be made (whether unconditionally or in certain contingencies) in respect of the provision of the credit, or
 - (ii) it otherwise grossly contravened ordinary principles of fair dealing,
 - (b) "relevant date" has the same meaning as in section 426D(2)(b).
- (3) Unless the contrary is proved, it shall be presumed that a transaction with respect to which an application is made under this section is or, as the case may be, was extortionate.
- (4) An order under this section shall be made on such terms and conditions and subject to such penalties as the Court thinks fit, and may -
 - (a) set aside the whole or part of any obligation created by the transaction,

- (b) vary the terms of the transaction or vary the terms on which any security for the purposes of the transaction is held,
- (c) require any person who is or was a party to the transaction to pay to the liquidator or administrator (as the case may be) any sums paid to that person, by virtue of the transaction, by the company,
- (d) require any person to surrender to the liquidator or administrator (as the case may be) any property held by that person as security for the transaction,
- (e) make any other order with regard to the transaction as the Court thinks fit, (including, without limitation, one directing accounts to be taken between any persons).
- (5) This section is without prejudice to the provisions of the Ordonnance donnant pouvoir à la Cour de réduire les intérêts excessifs, 1930.

Supplies of gas, water, electricity, etc.

- **426F.** (1) The Committee may make regulations about the supply of -
 - (a) gas, water and electricity,

- (b) communications services, and
- (c) goods or services mentioned in subparagraphs(i) to (v), where the supply is for the purpose of enabling or facilitating anything to be done by electronic means -
 - (i) point of sale terminals,
 - (ii) computer hardware and software,
 - (iii) information, advice and technical assistance in connection with the use of information technology,
 - (iv) data storage and processing, and
 - (v) website hosting,

by a person who carries on a business which includes giving such a supply to a company in administration or liquidation with the aim of enabling that supply to continue.

(2) Without prejudice to the generality of subsection (1), regulations may provide that if a liquidator or administrator of a company (as the case may be) makes a request to a person who carries on a business which includes giving such a supply as is mentioned in subsection (1) in Guernsey for a supply to the company in liquidation or administration, the supplier -

- (a) may make it a condition of the supply that the liquidator or administrator (as the case may be) personally guarantees the payment of any charges in respect of the supply, but
- (b) may not make it a condition of the supply, or do anything which has the effect of making it a condition of the supply, that any outstanding charges in respect of a supply given to the company before the company entered liquidation or administration are paid.".
- **23.** In section 513(1)(b), after "391(4)," insert "391A(5)," and after "414(6)," insert "419B(8),".
 - **24.** In section 533 -
 - (a) in subsection (4)(b), repeal the word "and",
 - (b) in subsection (4)(c), for "enactment." substitute "enactment, and",
 - (c) add the following paragraph after subsection (4)(c) -
 - "(d) may empower the Committee or the Registrar, in specified circumstances, to make regulations."

Citation.

25. This Ordinance may be cited as the Companies (Guernsey) Law, 2008

(Insolvency) (Amendment) Ordinance, 2020.

Commencement.

26. This Ordinance shall come into force on the day appointed by regulations made by the States Committee for Economic Development, and different days may be appointed for different provisions and different purposes.

of the ISLAND OF GUERNSEY

POLICY & RESOURCES COMMITTEE

CHARITIES AND OTHER NON PROFIT ORGANISATIONS

The States are asked to decide:-

Whether, after consideration of the Policy Letter dated 12th November, 2019, of the Policy & Resources Committee, they are of the opinion:-

- 1. To agree to the introduction of a single register of NPOs and the repeal of the requirement for the Registrar to maintain a separate register of charities
- 2. To agree to amend the definition of NPOs by the introduction of a charitable purposes test, which may be amended by regulations made by the Committee after consultation with the Registrar
- 3. To agree to amend the criteria for registration to bring them in line with the risks posed by the NPO sector
- 4. To agree to the introduction of a power for the Committee to make regulations, after consultation with the Registrar, exempting types or classes of NPO from the requirement for registration or from particular obligations attaching to registration, including NPOs who register voluntarily, and making changes in respect of the thresholds or any exemptions that have been put in place
- 5. To agree to the widening of the Registrar's powers to refuse applications for registration
- 6. To agree to the introduction of restrictions on the persons who may act as owners, controllers or directors of NPOs
- 7. To agree to the introduction of a power for the Committee to make regulations, after consultation with the Registrar, in respect of governance measures applicable to NPOs, including in respect of ethical standards
- 8. To agree to the introduction of wider information-gathering and oversight powers for the Registrar and information sharing gateways between the Registrar and other parties
- 9. To agree to the introduction of an exemption from the requirement to provide information about the owners, controllers or directors of NPOs that are Guernsey or Alderney legal persons where that information has already been provided under the

registration requirements applicable to those legal persons upon and subsequent to incorporation, and to any amendments to the Beneficial Ownership of Legal Persons (Guernsey) Law, 2017 that may be necessary to ensure consistency of sanctioning powers

- 10. To agree to changes to the sanctions applicable for non-compliance with the registration requirements
- 11. To agree to the introduction of a reporting requirement in respect of certain categories of transaction and a power for the Committee to make regulations, after consultation with the Registrar, amending the categories of transaction exempt from this requirement
- 12. To agree to the repeal of the Law and the introduction of new legislation consolidating the registration framework applicable to Guernsey and Alderney as outlined in the Policy Letter; and
- 13. To direct the preparation of such legislation as may be necessary to give effect the foregoing, including any necessary consequential and incidental provision.

The above Propositions have been submitted to Her Majesty's Procureur for advice on any legal or constitutional implications in accordance with Rule 4(1) of the Rules of Procedure of the States of Deliberation and their Committees.

of the ISLAND OF GUERNSEY

POLICY & RESOURCES COMMITTEE

CHARITIES AND OTHER NON PROFIT ORGANISATIONS

Presiding Officer Royal Court St Peter Port Guernsey

12th November, 2019

Dear Sir

1. Executive Summary

- 1.1 The Bailiwick of Guernsey is fortunate to have a successful and healthy charitable sector involved with a wide variety of community activities. Many of these voluntary, non-profit and charitable organisations (referred to collectively in this policy letter as "NPOs"), work alongside the States of Guernsey ("the States") to deliver essential services and facilities. The States recognises and is grateful for the significant contribution NPOs make to the community. They are viewed across the States as an important partner in realising the vision to "be among the happiest and healthiest places in the world, where everyone has equal opportunity to achieve their potential. We will be a safe and inclusive community, which nurtures its unique heritage and environment and is underpinned by a diverse and successful economy", as set out in the Future Guernsey Plan, the plan for government. In this regard, the Policy & Resources Committee welcomes the input which has been provided by the Association of Guernsey Charities ("AGC") and the Guernsey Community Foundation. The Committee will work with the third sector as the legislative framework envisaged in this policy letter develops. The Committee is conscious of the importance for the framework governing NPOs to be proportionate.
- 1.2 This policy letter proposes a number of changes to the registration framework for NPOs that is currently set out in the Charities and Non Profit Organisations (Registration) (Guernsey) Law, 2008 ("the Law"). The Law applies to NPOs established in Guernsey and Alderney. The changes proposed by the Committee will help to strengthen the governance of NPOs and support them to more effectively manage risk, while enabling the States to comply with international financial regulations and standards. The changes fall into six categories.

- 1.3 The first category is aimed at facilitating a more targeted and risk based approach to compulsory registration, which requires the removal of the registration requirement from low risk NPOs and its extension to some which are currently exempt NPOs that are assessed as being higher risk. This may be done by raising the financial thresholds for registration and amending both the definition of NPO (including the introduction of a charitable test) and the exemptions from registration. It is envisaged that these changes will in turn enable the introduction of a single register for NPOs, to include charities, rather than the maintenance of two separate registers as currently required under the Law. This is dealt with in paragraphs 4.2 and 4.3 below.
- 1.4 The second category is aimed at preventing the registration framework being used inappropriately. This involves a widening of the power to refuse applications for registration and the introduction of a basic fit and proper test for the officers of NPOs. This is dealt with in paragraphs 4.4 and 4.5 below.
- 1.5 The third category concerns the quality of the controls that NPOs have in place and the information they obtain about parties with whom they deal. This involves an extension of the compulsory governance obligations applicable to registered NPOs and the introduction of a reporting requirement for overseas transactions above a specified threshold. This is dealt with in paragraphs 4.6 and 4.7 below.
- 1.6 The fourth category relates to the possible use of the registration framework to promote standards of ethical conduct in the charitable sector, particularly in relation to adult safeguarding and child protection requirements. This is dealt with in paragraph 4.6 below.
- 1.7 The fifth category is aimed at more effective enforcement. This involves both widening the information gathering and other oversight powers of the Registrar of Guernsey and Alderney NPOs ("the Registrar"), widening the range of sanctions available to the Registrar and raising the level of existing sanctions applicable for non-compliance with the obligations under the registration regime. These measures would be accompanied by the power for the Registrar to issue statutory guidance and standard forms, and enhanced information. This is dealt with in paragraphs 4.8 and 4.9 below.
- 1.8 The sixth category concerns clarity and ease of use. It involves the repeal of the Law and the introduction of new legislation consolidating and clarifying the registration framework applicable to Guernsey and Alderney. This is dealt with in paragraph 5 below.

2. Background

2.1 The current framework was introduced in order to address the standards of the Financial Action Task Force ("the FATF standards") in respect of money laundering and terrorist financing in place at that time, in line with the Bailiwick's longstanding commitment to meeting international standards in relation to financial crime. The framework has been revised from time to time. These revisions include the extension of the Law to Alderney in 2011, changes made in 2014 to clarify the language around

- criminal offences and to widen the information-sharing gateways in the Law, and the issue of joint guidance by the Policy & Resources Committee and the AGC in 2018.
- 2.2 The Committee has conducted a comprehensive review of the registration regime, which has taken into account a number of factors that point to the need for further changes.
- 2.3 First, there are two recommendations in the January 2016 MoneyVal report on Guernsey's compliance with the FATF standards which can only be met by revisions to legislation. These are the extension of the registration requirements to manumitted organisations (this term is explained in paragraph 3.1.5 below) and the strengthening of the sanctions for failure to comply with registration requirements. Second, the FATF has revised its standards on NPOs since the Law was introduced and these changes need to be considered in the context of any revisions to the legal framework. These changes include requirements for jurisdictions to identify, assess and understand risks as well as specific requirements in relation to the NPO sector. Third, although the Law was introduced to meet the FATF standards in force in 2008 and, therefore, the international anti-money laundering and terrorist financing ("AML/CFT") agenda at that time, it is recognised that there is a need to enhance governance standards in a proportionate way within NPOs generally, not only for AML/CFT purposes. Fourth, input by the AGC and the Registrar, and their experience with the legislation, has disclosed a need to simplify the current legislation on NPOs. Fifth, following the recent introduction of Guernsey and Alderney registers of beneficial ownership of legal persons, which are separate registers maintained under dedicated Guernsey and Alderney legislation, there is now a potential duplication issue for NPOs that are Guernsey or Alderney legal persons in respect of the information about their owners or controllers that must be included in their applications for registration as NPOs and the information that must be provided for the purposes of the beneficial ownership registers.
- 2.4 The ethical governance of the charitable sector (particularly in respect of child protection and adult safeguarding) has also become a matter of growing public concern; brought to light in particular through the Charity Commission's recent investigation into Oxfam's conduct¹. Many local charities, whether focused on Guernsey or overseas, work with especially vulnerable groups of people, and governments and regulators have an important role to play in establishing appropriate standards of ethical conduct, which prioritise the welfare of those people. In updating the current framework, the States of Guernsey has an opportunity to put measures in place that will enable such standards to be set for the local charitable sector, in an appropriate and proportionate way.

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¹ https://www.gov.uk/government/publications/charity-inquiry-oxfam-gb

3. The Current Position

3.1 Existing Framework

- 3.1.2 The existing legal framework requires NPOs based in Guernsey, Alderney, Herm or Jethou with gross assets and funds of, or over, £10,000 or gross annual income of, or over, £5,000 to be registered on the register of NPOs. The application for registration must include the full names of the persons who own, direct or control the activities of the organisation including its directors, officers and trustees. The application must also provide the current home addresses or registered offices of such persons, depending on whether they are natural or legal persons.
- 3.1.3 The register is maintained by the Registrar, who publishes the name and address of each NPO which solicits or accepts donations, funds and contributions from the public, or those that do not meet this criteria but which elect to be inscribed on the public Register. Registrations must be renewed at the commencement of each calendar year.
- 3.1.4 Registered NPOs are currently subject to a number of requirements under the Law. They must:
 - (a) make, keep and retain records of all financial transactions (with whosoever made) in order to evidence the application or use of the organisation's assets, funds and income. The records must be retained in a readily retrievable form for a period of no less than six years after the date of being made;
 - (b) file annual financial statements with the Registrar, in such form as the Registrar may specify (subject to an exemption for NPOs with assets of less than £100,000 or income of less than £20,000, or whose assets or income are applied exclusively in the Bailiwick); and
 - (c) inform the Registrar as soon as is reasonably practicable of any change to any of the matters required to be stated in the application for registration.
- 3.1.5 Apart from the record-keeping obligations referred to above, the current framework does not apply to manumitted organisations, that is, any NPO which is administered, controlled or operated by a person:
 - who holds or is deemed to hold a licence granted by the Guernsey Financial Services Commission under certain specified regulatory Laws; and
 - who administers, controls or operates the organisation in the course of his or her regulated activities.

3.2 **2014 Proposals**

3.2.1 In September 2014 the States of Guernsey considered a Policy Letter ("the 2014 Policy Letter")² from the (then) Policy Council which recommended a number of changes to the Law. These were as follows:

² Article VII of Billet d'État No. XX of 2014

- (a) remove the exemption for manumitted organisations, so that they would become subject to all existing and any future requirements in connection with registration;
- (b) amend the definition of NPOs to clarify its scope;
- (c) widen the regulation-making powers available to the Policy Council to permit the making in due course of regulations to cover all necessary matters regarding internal governance issues
- (d) make criminal sanctions for failing to comply with the different requirements imposed on NPOs explicit and consistent;
- (e) permit disclosures relating to NPOs to be made by the Registrar of NPOs to the Director of Income Tax and to corresponding authorities inside the Bailiwick as well as outside.
- 3.2.2 Recommendations (d) and (e) were addressed by the Charities and Non Profit Organisations (Registration) (Guernsey) Law, 2008 (Amendment) Ordinance, 2014. As part of its review the Committee has been considering how best to address recommendations (a) to (c) in the 2014 Policy Letter. In addition, the review has identified the need for a further amendment since the amendment giving effect to (e) came into force, namely to permit information to be shared with the proposed Social Investment Fund (SIF)³.
- 3.2.3 The 2014 Policy Letter also recommended that the Income Tax (Guernsey) Law, 1975 ("the Income Tax Law") be amended to permit information on NPOs to be disclosed to the Registrar of NPO. An amendment to implement this recommendation is pending and may conveniently be finalised at the same time as the consequential amendments to the Income Tax Law that are envisaged below.

4 Proposals for Change

4.1 As a result of its review, the Committee proposes various changes that are set out below. These changes are required to ensure that the jurisdiction continues to meet its objectives in terms of its international position as being highly regarded for providing a legal and operational framework for NPOs that promotes transparency, integrity and confidence in the sector and is clear, easy to understand and proportionate to the risks of the sector.

³ The proposal to establish a SIF (formerly referred to as the Social Investment Commission) was considered and approved by the States of Deliberation in the 2017 and 2018 budget. A policy letter, to be submitted in 2020, will detail the governance, structure and funding for the SIF. It is proposed that the SIF will provide funds to Bailiwick charities and third sector organisations for charitable and community purposes which address the themes of the Policy and Resources Plan "Future Guernsey".

4.2 **Definitions**

- 4.2.1 The 2014 Policy Letter recommended that the definition of NPOs should be amended so as to clarify its scope. However, the review by the Committee, and in particular discussion with the AGC, has identified that more significant revisions are required, in a number of respects.
- 4.2.2 The first revision concerns the fact that, while charities are a type of NPO, the Law includes separate definitions of charity and of NPO as different registration requirements are applicable to each entity. The definition of charity covers (a) any organisation established for charitable purposes only and (b) any person who has been entrusted with property or funds applicable to charitable purposes (or with any income from such property or funds). An NPO is defined as any organisation established (solely or principally) either for the non-financial benefit of its members or for the benefit of society or any class or part of society and, without limitation, includes any organisation established solely or principally for fraternal, educational, cultural or religious purposes, or for the carrying out of any other types of good works; this definition includes charities. The definition of organisation is wide ranging and includes a body of persons (corporate or unincorporated), a trust, any other legal entity, or any equivalent or similar structure or arrangement. It also extends to any person who comes within the situation outlined at (b) above in this paragraph.
- 4.2.3 The FATF standards refer to NPOs, which are defined as legal persons, arrangements or organisations that primarily engage in raising or disbursing funds for purposes such as charitable, religious, cultural, educational, social or fraternal purposes, or for the carrying out of other types of "good works". A registration requirement that applies only to charities would be considered as too narrow to meet these standards. The original reason for the separate definitions of charity and NPO in the Guernsey framework was to address this wider approach by the FATF and, in addition, it was felt useful for the Registrar to maintain separate registers of charities and NPOs as the tax consequences of registration for these two categories are different. However, in practice it is not always easy to distinguish between a NPO that is a charity and a NPO that is not. Therefore, the Committee recommends that the legal framework should be amended to include a charitable test to inform what should be considered to be a charity, and also to require only one register to be maintained, but which would be maintained in a way that enabled charities to be separately specified as such.
- 4.2.4 The Committee has reviewed whether or not legislation in the UK and in the other Crown Dependencies might be helpful in defining charities in the Guernsey context. It has concluded that a definition similar to that in the Charities (Jersey) Law, 2014 ("the Jersey Law") would be suitable for Guernsey. Under the Jersey Law, there is a charity test which an entity meets if all of its purposes are charitable (or ancillary or incidental to its charitable purposes) and if it provides public benefit in Jersey or elsewhere to a reasonable degree. The Jersey Law defines what a charitable purpose is by reference to an exhaustive list, which covers a wide range of activities including the relief of poverty, the advancement of education, the arts and community development, the provision of recreational facilities and the relief of those in need by reason of age, ill-

health, disability, financial hardship or other disadvantage. It is proposed that the same approach be taken in Guernsey, including a power for the Committee to make regulations after consultation with the Registrar to add to, or explain, the list of charitable purposes, in line with a corresponding power in the Jersey Law.

4.3 Registration and Provision of Financial Statements

- 4.3.1 Revisions to the thresholds for registration and the provision of financial statements are considered necessary for a number of reasons.
- 4.3.2 First, the FATF Standards now explicitly recognise that not all NPOs are inherently high risk. Therefore, they require countries to identify NPOs that are likely to be at risk of abuse and to put in place measures to address those risks. On that basis, the Committee considers that there are NPOs within the jurisdiction that no longer need to be covered by a registration framework aimed at meeting the FATF standards as they are considered to be low risk. Examples include sports and social clubs established by employers that operate purely for the benefit of their employees, and private residential associations that operate for the purposes of financing the upkeep of communal areas accessible to their members.
- 4.3.3 Second, the current threshold for registration is set so low that persons who hold a single fundraising event for use of funds within Guernsey or Alderney can inadvertently and needlessly be required to be registered. Linked with this, individuals involved with these events might not realise that registration is required. The Committee considers, therefore, that the current framework is not proportionate.
- 4.3.4 The Committee has undertaken analysis of the effects of changing the thresholds. Even quite significant modifications would have relatively minor effects on the number of registered entities. The Committee considers that, subject to a risk-based exception (see the following paragraph), the proportionate level at which the registration requirements should be set currently would be the same threshold at which financial statements are required to be provided to the Registrar i.e. it should apply to NPOs with assets or funds of, or over, £100,000, or gross annual income of, or over, £20,000.
- 4.3.5 It is also recommended that, separate from this, there should be a second criterion for registration on risk grounds so that, irrespective of the level of gross assets or funds, the registration requirement would also be applicable to all charities and other NPOs under whose constitutions the raising or distribution of assets outside the Bailiwick is envisaged, except where these overseas distributions are incidental to the activities of the NPO (e.g. the purchase of office equipment) or are *de minimis* (e.g. where an NPO provides funds to pay for refreshments at an event overseas). As the question of what constitutes an incidental or *de minimis* payment will vary depending on the activities of the NPO in question, it is envisaged that the Registrar will issue guidance on this.

- 4.3.6 No change is currently proposed to the threshold for the provision of financial statements, as it is considered appropriate in the future for all registered NPOs to provide financial statements to the Registrar and also for those NPOs generally to ensure that they have high governance standards. However, in some cases, based on risk, it will be appropriate for financial statements to be audited (i.e. subject to scrutiny by a professional third party) and it is proposed that the Committee should have the ability to make regulations on this matter. Governance is further addressed below at paragraph 4.6.
- 4.3.7 In order to ensure that the registration framework continues to be proportionate, the financial threshold and the new criterion relating to the use of assets outside the Bailiwick would be complemented by a power for the Committee to make regulations exempting certain types or classes of NPO from the need for registration, or from any specific obligations attaching to registration. The regulation-making power would also be wide enough to allow changes to be made in respect of the thresholds or any exemptions that have been put in place. Any such regulations would be made on the basis of consultation with the Registrar.
- 4.3.8 Under the above proposals manumitted NPOs will be required to be registered unless they are subject to regulations exempting them from registration.
- 4.3.9 For some NPOs that do not meet the criteria for compulsory registration, there may nonetheless be tax or other advantages to registration (for example, protection for deposits under the Banking Deposit Compensation Scheme (Bailiwick of Guernsey) Ordinance, 2008). Therefore, as is the case now, there would be nothing to prevent NPOs which are not required to register with the Registrar from doing so. However, the Committee does not wish NPOs in this category to be disadvantaged by the changes to the regime that are not necessary for them on AML/CTF risk grounds and would be disproportionate to the size and activities of many of them. Therefore, it is proposed that the power to make regulations exempting certain types or classes of NPO from the need for registration or from specific obligations referred to above will be wide enough to permit the Committee to disapply, in whole or in part, the obligations applicable to registered NPOs where those NPOs have registered on a voluntary basis.

4.4 Refusal to Register Organisations

4.4.1 The Registrar's current power to refuse an application for registration only applies where the Registrar is not satisfied that an organisation is an NPO. It is proposed to extend this power to situations where, in the opinion of the Registrar, no information, or insufficient information, has been provided about an NPO's purpose, control and governance, or where the Registrar believes that the proposed name of the NPO could be misleading as to its purpose, or where the Registrar considers that control and governance are not or will not be adequate, where there is a concern about its owners, directors or controllers which will have an effect on the NPO's ability to meet its responsibilities, or otherwise on public interest or similar grounds.

4.5 **Standards for Controllers of NPOs**

- 4.5.1 There are currently no requirements in the Law for the fitness and propriety of owners (i.e. beneficial owners, shareholders or similar), controllers or directors of NPOs or the control they exercise in relation to NPOs. Such individuals might have very significant control over the use of the assets of an NPO. This does not provide a credible framework either for the Guernsey or Alderney public or anybody else providing funds to NPOs, or to the international community. The Committee is not at this stage proposing the introduction of a full licensing regime for NPOs with the Registrar undertaking the kind of licensing functions which would normally be associated with a supervisory authority for financial services businesses. Such a licensing framework would be disproportionate to the current risks of the NPO sector, as well as being costly to implement.
- 4.5.2 Therefore, it is proposed that instead that the Law should provide that
 - persons with criminal convictions (other than convictions that are spent in line with the provisions of the Rehabilitation of Offenders (Bailiwick of Guernsey) Law, 2002);
 - those who do not meet the director eligibility criteria within the Company Law;
 and
 - minors

are not permitted to be owners, controllers and directors of the activities of NPOs (whether or not they are registered). This would be subject to a power for the Registrar to disapply the restriction in the case of criminal convictions if he or she considers it appropriate. This is to ensure that persons who have been convicted of offences that cannot sensibly be considered relevant to their fitness or propriety to own, control or direct an NPO are not prevented from doing so. In addition, as discussed below, regulations will be introduced to provide governance standards for NPOs. The particular parties responsible for complying with the regulations will vary according to the nature of the NPO in question but, in general terms, will be senior officers, board members, or trustees as the case may be, or those who otherwise exercise control over the activities of the NPO.

- 4.5.3 There will also be an exemption in respect of the provision of information about people who exercise managerial functions or are the beneficial owners of legal persons incorporated in the Bailiwick.
- 4.5.4 Information about those exercising managerial functions in respect of these legal persons, including Board members or other managing officials depending on the type of legal person in question, is already publicly available on the registers that govern incorporation. Under beneficial ownership legislation introduced in 2017, there are now also registration requirements in respect of the individuals who own or control these legal persons.

- 4.5.5 The effect of this is that, where an NPO constitutes one of these forms of legal person, the authorities will already have information about its managing officials and its underlying owners or controllers, as this will have been provided to the appropriate register and there is a continuing obligation to keep this information up to date.
- 4.5.6 In order to avoid the same information having to be provided to more than one register, it is proposed that, if an NPO is a Bailiwick legal person, it will not automatically have to provide the same information about the persons who own it or who direct or control its activities twice.
- 4.5.7 In addition, the Registrar is mindful of the importance of complying with the data protection framework established under the Data Protection (Bailiwick of Guernsey) Law, 2017. In this regard he or she will ensure that, where additional personal data is received and maintained a result of the amendments referred to in this Policy Letter, appropriate mechanisms will be in place to continue to comply with the framework.

4.6 **Governance**

- 4.6.1 Good governance is crucial for NPOs. Therefore, in addition to the basic fit and proper test proposed above, a number of other steps will be required to promote the transparency and integrity of NPOs. In order to achieve this, the current regulation-making power under the Law should be extended as envisaged in the 2014 Policy Letter to include governance. It is proposed that this should be done after consultation with the Registrar. It is also proposed that governance measures for these purposes should include ethical standards (such as requiring charities to have in place effective child protection and adult safeguarding policies). These standards must be proportionate; and, as a general principle, the Committee will consult with the sector wherever appropriate prior to introducing new regulations, in addition to consulting the Registrar.
- 4.6.2 The intention is for the regulations made under this power to impose high level requirements and for the Registrar to issue guidance providing the detail on how the requirements can be met. It is envisaged that the regulations would cover four aspects of governance. The first is the constitutional documents NPOs must have, which should address the basic minimum standards to be expected of them. This would include requirements regarding quorums for decision making, independent oversight of finances and disbursements, and record keeping. The second is risk mitigation measures, primarily aimed at identifying donors and beneficiaries where this is considered necessary on the basis of risk. The third is measures to ensure financial probity and transparency, such as a requirement for NPOs to pass funds over a certain limit through their bank accounts and for the proper division of functions to ensure that responsibility for the approval for the release of funds and the release of funds itself rests with separate and unconnected individuals. The fourth relates to establishing standards in respect of child protection, adult safeguarding or other forms of ethical conduct.

- 4.6.3 It is envisaged that the third aspect (financial probity and transparency) would also allow specification of categories or types of NPO required to put in place assurance measures in relation to their financial statements, whether through external audit or otherwise, and to provide for the provision of financial statements by NPOs to third parties on request and publication by the Registrar. The making of any regulations in relation to assurance and publication of financial statements might be sensitive and the Committee proposes to consult further on this point in particular and whether the exemption for NPOs not to file accounts with the Registrar where their assets or income are applied exclusively in the Bailiwick (referred to in paragraph 3.1.4(b) above) should be revised or removed.
- 4.6.4 The regulations should be enforceable so as to ensure that NPOs are treating them seriously and endeavouring to meet them. This means that the Registrar should be able to apply sanctions for breaches of them. The overall sanctions framework, including the sanctions proposed to apply for breaches of regulations, is specified below.

4.7 Reporting of Transactions

4.7.1 In order to monitor overseas payments and, therefore, assist the Registrar to monitor the risks posed by NPOs to the jurisdiction, it is proposed that a legal requirement should be introduced to report payments of a value, to be set by regulations made by the Committee, that are made to parties outside the Bailiwick. However, this would not apply to payments to affiliated organisations in Jersey, the Isle of Man or the UK, or to incidental payments such as payments for services provided to an NPO. No approval would be required but it is envisaged that the Registrar would be able to issue forms specifying the information about the transaction(s) and related information to be provided to it. In addition, the regulation-making power referred to above would include a power to amend the categories of transactions that are exempt from this requirement, to ensure that the legal framework can be updated quickly in line with any changes or developments in the risk profile of particular types of transactions.

4.8 **Sanctions and Enforcement**

- 4.8.1 The MoneyVal report states that the current sanctions for non-compliance with registration requirements are not effective or dissuasive. This echoes a comment which was made by the International Monetary Fund in the report following its evaluation of Guernsey's AML/CFT framework in 2010. Although the AML/CFT authorities had concluded, prior to the MoneyVal evaluation, that the sanctions framework was adequate for Guernsey's context, it is now apparent to the Committee that it should be revised and the level and range of sanctions increased.
- 4.8.2 In doing so, it is important to recognise the particular policy considerations that arise from the status of NPOs when determining the penalties that are appropriate, especially the fact that their assets are largely made up of donations from members of the public that are given for philanthropic or similar purposes. Against this

background, the Committee has considered whether it is appropriate for financial penalties to apply not only to NPOs but also persons who are senior officers or who direct or control the activities of NPOs. The Committee has decided that the legislation should provide both for the possibility of administrative financial penalties being applied to NPOs and the persons mentioned above by the Registrar. This would be in addition to the administrative financial penalties for NPOs specified below. It is important to recognise that the powers will be permissive rather than compulsory and that they should allow the right party or parties to be subject to penalties for a breach. In addition, the Registry should have publically available procedures so as to transparently demonstrate the proportionality of the sanctions and enforcement framework. Other penalties are specified below.

- 4.8.3 The Registrar may currently strike off a NPO for the following reasons:
 - the Registrar has reason to believe that the organisation is not a non-profit organisation,
 - the organisation fails to comply with any request for information by the Registrar,
 - the organisation fails to comply with any obligation or requirement imposed by or under the Law,
 - a person is found guilty of an offence under the Law in respect of statements made or information or documents produced or furnished for or on behalf of the organisation, or
 - the organisation fails to pay certain fees imposed by the Registrar,

provided in each case that the Registrar has given the organisation two weeks' notice of the intention to strike it off the Register. The Registrar may publish the fact of an organisation being struck off the Register in such manner as he or she thinks fit (including by publication in La Gazette Officielle).

- 4.8.4 It is proposed that the Law should be revised to allow the Registrar to also strike off a NPO:
 - where any of its officers has committed any criminal offence of any kind under any legislation (other than where a conviction is spent or not relevant – see above);
 - on public interest or similar grounds.
- 4.8.5 Looking at the issue of financial penalties, these are already in place under the Law in relation to the following criminal offences:
 - failure by an NPO to be registered (a fine of up to £10,000 on summary conviction);
 - provision of information which is false, deceptive or misleading (up to three months imprisonment and/or a fine of up to £10,000 on summary conviction and up to two years' imprisonment and/or an unlimited fine on indictment);

- failure to comply with duties in respect of annual statements and keeping of proper records (a fine of up to £10,000);
- failure to comply with a request for information made by the Registrar or with any obligation or requirement imposed under the Law (a fine of up to £500).
- 4.8.6 At the time of the drafting of the Law in 2008, any legislation on NPOs was breaking new ground. The level of the penalties took account of this and the financial and staff resource capacity of smaller NPOs. However, from the perspective of 2019, when compared with similar criminal offences in other legislation, it is recognised by the Committee that some of the penalties in the Law are too low both in absolute and relative terms. It is therefore proposed that the level of criminal financial penalties be brought in line with the penalties applicable to comparable offences elsewhere in the legal framework.
- 4.8.7 Administrative financial penalties can also be applied to an NPO by the Registrar. These are as follows:

Failure to register	£500
Failure to renew registration	
 1st month (whole or part) 	£20
 2nd month (whole or part) 	£40
 Each subsequent month (whole or part) 	£80
Failure to file annual financial statements	
 1st month (whole or part) 	£20
 2nd month (whole or part) 	£40
 Each subsequent month (whole or part) 	£80
Failure to respond to information request	
 1st month (whole or part) 	£0
 2nd month (whole or part) 	£0
 Each subsequent month (whole or part) 	£10

- 4.8.8 International assessors consider that these levels are too low to be dissuasive. The Committee believes that very high penalties would be inappropriate to the large majority of the very small NPOs which comprise Guernsey's third sector. However, in some cases the cost of imposing a financial penalty would be greater than the level of the penalty applied. Therefore, it is proposed that the levels should be increased.
- 4.8.9 The following increases are envisaged: the financial penalty for failure by an NPO to be registered would move from £500 to £2,000; the financial penalty for failure to renew registration or to file annual financial statements would be increased to £250 for each and every calendar month for which the NPO is in default of the obligation; a failure to respond to the Registrar's requests for information would increase to £250 for each calendar month for which the information is not provided. These increases

- are considered appropriate for penalties of an administrative nature, bearing in mind that criminal sanctions involving much higher financial penalties are also available.
- 4.8.10 In order to create a more dissuasive framework overall, rather than limiting the Registrar to powers of strike off and financial penalties, it is proposed that the Registrar's powers of sanction should also be increased by adding to them the ability to issue private (i.e. non-public) warnings to senior officers, controllers and directors of an NPO and an NPO itself; power to make public statements in relation to such persons; and the power to disqualify individuals from being owners, senior officers controllers or directors of NPOs. The exercise of these powers will be subject to appropriate safeguards including notice periods and appeal provisions, in line with the existing protections under the Law.
- 4.8.11 In order to support the legal framework, the Registrar should have additional powers, specifically the power to require documents, accounts and other information from NPOs, their owners, controllers or directors or from third parties. The Registrar should also have the power to visit the premises of NPOs and require information and documents to be provided to him or her. The information gathering powers should be wide enough to enable the Registrar to determine any matter relating to particular NPOs or their owners, controllers or directors (including whether all NPOs that should be registered are in fact registered). The powers should also cover wider issues such as risk (including the obtaining of statistics to enable the Registrar and other AML/CFT authorities to understand and assess the scope and scale of the activities of the NPO sector or of particular NPOs as necessary) and public interest or similar considerations. There should also be the necessary information sharing gateways in place for this purpose, as well as to enable information to be shared with other authorities such as the Guernsey Financial Services Commission to assist them in the discharge of their functions, and with any other parties that have functions relevant to the third sector, such as the SIF indicated above at paragraph 3.2.2.

4.9 **Guidance and Standard Forms**

4.9.1 In order to assist NPOs in the discharge of their various obligations, it is recommended that provision be made for the Registrar to issue statutory guidance and standard forms to be completed when submitting information to the Registrar, including forms confirming or describing adherence to the governance regulations.

5. Legal Framework

5.1 The way in which the NPO registration regime has evolved has given rise to a number of amendments to the Law, in particular its extension to Alderney in 2011. As a result of Alderney coming within its scope later than the other islands, it is not obvious from the title of the legislation that it includes Alderney. In addition, the changes to the regime that are now envisaged may make the legislation less easy to follow and therefore affect the ease with which the obligations on NPOs can be understood. For these reasons it is proposed that the Law be repealed and replaced with new legislation which is expressed to apply to both Guernsey and Alderney, and which

incorporates the features of the existing regime with the envisaged new provisions in a way that makes the entire framework readily understandable.

5.2 Consequential amendments will be needed to ensure that all necessary information-sharing gateways are in place across the legal framework, as indicated above. In addition, in view of the exemption from the obligation to provide information about the persons who own, direct or control the activities of an NPO where this has been provided under beneficial ownership legislation, it is recommended that the Beneficial Ownership of Legal Persons (Guernsey) Law, 2017 is amended as required, to ensure that the enforcement powers for failing to provide the necessary information which the Registrar of Beneficial Ownership may apply to legal persons that are NPOs are consistent with the enforcement powers which the Registrar may apply to NPOs that are not legal persons.

6. Transitional Provisions

6.1 Transitional provisions should be included to ensure that NPOs have time to make any changes necessary to meet the revised framework, including new regulations. Different provision may be made for different categories or types of NPO or on the basis of risk.

7. Engagement and Consultation

As indicated above, when reviewing the existing registration regime and considering the need for change the Committee liaised closely with members of the NPO Working Group (which includes representatives of the Committee, the Registrar, the Revenue Service, the Guernsey Financial Services Commission, the Law Officers Chambers and Law Enforcement) and the AGC. In addition, in January 2018 a consultation paper outlining proposed changes was issued by the Committee to the AGC (who shared it with individual NPOs), the Guernsey Association of Trustees and the Guernsey Bar. The consultation process has led to a two phased response. The first was the issuing of guidance for the NPO sector and the second was this Policy Letter. This Policy Letter takes into account the responses received, as well as further input provided in subsequent discussions between the Committee, the AGC, the Guernsey Community Foundation, the Overseas Aid & Development Commission, the Registrar, the Revenue Service, the Guernsey Financial Services Commission, GAT and the Guernsey Bar.

8. Alderney

As the Law applies to Alderney NPOs, the Policy & Finance Committee of the States of Alderney has also been consulted. This Committee supports the proposals in this Policy Letter.

9. Resources

9.1. The proposals above, including the provisions of the various regulations, will lead to new governance, control and other responsibilities for charities and other NPOs.

They will also lead to revised responsibilities for, and a new approach by, the Registry in conducting an oversight role. The Committee and the Registry are of the view that, in total, three additional staff will be required for the Registry, on a permanent basis, in order to exercise its oversight responsibilities properly. It is envisaged that these three additional members of staff will be recruited in stages with funding of £135,000 included in the 2020 Guernsey Registry budget and a further additional amount of £50,000 will be required in 2021. This approach should enable the Registry to ensure a smooth transition when the law comes into force. This increased expenditure will reduce the overall surplus of the Guernsey Registry which is transferred to General Revenue by a commensurate amount.

9.2. Additional IT resources will also be required for the Guernsey Registry so that it can exercise its new responsibilities efficiently. This includes enabling both it, and those acting on behalf of NPOs, to move from a mainly paper-based system to a system in which relationships can be managed through a comprehensive modern IT system, which will be sensitive to the profile of the third sector. Investment in IT is essential to the successful delivery of the changes proposed, which will help to strengthen the governance of NPOs and support them in more effectively managing risk, while enabling the States to comply with international standards. Initial market testing has taken place for the provision of the necessary IT in order to inform the accurate determination of detailed market costing/procurement processes. The requirements include the development of a comprehensive modern records system, which can be stand alone, incorporated into or work with the Registry's IT platform. It is estimated that the one-off cost of the new system will be no more than £300,000 and this would be funded through a minor capital vote.

10. Recommendations

- 10.1 The States are asked to decide whether they are of the opinion:-
- 10.1.1 to agree to the introduction of a single register of NPOs and the repeal of the requirement for the Registrar to maintain a separate register of charities;
- 10.1.2 to agree to amend the definition of NPOs by the introduction of a charitable purposes test, which may be amended by regulations made by the Committee after consultation with the Registrar;
- 10.1.3 to agree to amend the criteria for registration to bring them in line with the risks posed by the NPO sector;
- 10.1.4 to agree to the introduction of a power for the Committee to make regulations, after consultation with the Registrar, exempting types or classes of NPO from the requirement for registration or from particular obligations attaching to registration, including NPOs who register voluntarily, and making changes in respect of the thresholds or any exemptions that have been put in place;

- 10.1.5 to agree to the widening of the Registrar's powers to refuse applications for registration;
- 10.1.6 to agree to the introduction of restrictions on the persons who may act as owners, controllers or directors of NPOs;
- 10.1.7 to agree to the introduction of a power for the Committee to make regulations, after consultation with the Registrar, in respect of governance measures applicable to NPOs, including in respect of ethical standards;
- 10.1.8 to agree to the introduction of wider information—gathering and oversight powers for the Registrar and information sharing gateways between the Registrar and other parties;
- 10.1.9 to agree to the introduction of an exemption from the requirement to provide information about the owners, controllers or directors of NPOs that are Guernsey or Alderney legal persons where that information has already been provided under the registration requirements applicable to those legal persons upon and subsequent to incorporation, and to any amendments to the Beneficial Ownership of Legal Persons (Guernsey) Law, 2017 that may be necessary to ensure consistency of sanctioning powers;
- 10.1.10 to agree to changes to the sanctions applicable for non-compliance with the registration requirements;
- 10.1.11 to agree to the introduction of a reporting requirement in respect of certain categories of transaction and a power for the Committee to make regulations, after consultation with the Registrar, amending the categories of transaction exempt from this requirement;
- 10.1.12 to agree to the repeal of the Law and the introduction of new legislation consolidating the registration framework applicable to Guernsey and Alderney; and
- 10.1.13 to direct the preparation of such legislation as may be necessary to give effect the foregoing, including any necessary consequential and incidental provision.

11. Compliance with Rule 4

- 11.1 Rule 4 of the Rules of Procedure of the States of Deliberation and their Committees sets out the information which must be included in, or appended to, motions laid before the States.
- 11.2 In accordance with Rule 4(1), the Propositions have been submitted to Her Majesty's Procureur for advice on any legal or constitutional implications. She has advised that there is no reason in law why the Propositions should not to be put into effect.

11.3 In accordance with Rule 4(4) of the Rules of Procedure of the States of Deliberation and their Committees, it is confirmed that the propositions accompanying this policy letter are supported unanimously by the Policy & Resources Committee.

Yours faithfully

G A St Pier President

L S Trott Vice-President

A H Brouard J P Le Tocq T J Stephens.

of the ISLAND OF GUERNSEY

POLICY & RESOURCES COMMITTEE

BBC OVER-75 TV LICENCE SCHEME: EXTENDING RELEVANT PARTS OF THE COMMUNICATIONS ACT 2003

The States are asked to decide:-

Whether, after consideration of the Policy Letter dated 21st November, 2019, of the Policy & Resources Committee, they are of the opinion:-

To agree that section 365A, and such other provisions of the Communications Act 2003 as amended (including as amended by the Digital Economy Act 2017) relating to TV licence fee concessions by reference to age as it may be necessary or expedient to extend, should be extended by Order in Council to the Bailiwick with such modifications as appear to Her Majesty in Council to be appropriate, following consultation with the Policy & Resources Committee.

The above Proposition has been submitted to Her Majesty's Procureur for advice on any legal or constitutional implications in accordance with Rule 4(1) of the Rules of Procedure of the States of Deliberation and their Committees.

THE STATES OF DELIBERATION of the ISLAND OF GUERNSEY

POLICY & RESOURCES COMMITTEE

BBC OVER-75 TV LICENCE SCHEME: EXTENDING RELEVANT PARTS OF THE COMMUNICATIONS ACT 2003

The Presiding Officer States of Guernsey Royal Court House St Peter Port

21st November 2019

Dear Sir

1. Executive Summary

- 1.1. As a result of the UK Government's decision in 2015 to transfer responsibility to the BBC for both setting and funding the UK's over-75 age TV licence concession scheme ('the over-75 scheme') from June 2020, the States of Guernsey made similar arrangements with the BBC in December 2016. This was agreed by the Committee for Employment & Social Security following consultation with the Committee for Economic Development and the Policy & Resources Committee.
- 1.2. The States of Deliberation had earlier resolved, in October 2015, to close its own over-75 TV licence concession scheme to new entrants. The scheme, developed in 2001, was provided by the Committee *for* Employment & Social Security for Guernsey and Alderney residents and funded from General Revenue (at a cost of £624,000 in 2015). It was closed to new entrants from 1st September 2016. As part of the future policy and funding arrangements with the BBC, transitional provisions were agreed to share the cost of funding the scheme between the States of Guernsey and the BBC during 2018 and 2019, prior to the BBC taking full responsibility for setting and funding the over-75 scheme from 1st June 2020.
- 1.3. In June 2019, the BBC announced its decision on the future of the over-75 scheme for UK residents. From June 2020, the universal benefit will cease but a free TV licence will be issued to any household with someone aged over 75 who

receives Pension Credit. The BBC's decision does not automatically extend to the Bailiwick and therefore the broadcaster must make a separate decision regarding any future concession scheme for Bailiwick residents.

- 1.4. The UK Digital Economy Act 2017 ('the Digital Economy Act') amends the UK Communications Act 2003 ('the Communications Act') with effect from 1st June 2020 to provide the BBC with the necessary powers to set the policy for the provision of any age-related concessionary TV licences, including the power to amend the eligibility criteria for any such concession. Parts of the Communications Act, including provisions relating to TV licensing, already extend to the Bailiwick by Order in Council. The States are now asked to approve the further extension of relevant parts of the Communications Act (as amended by the Digital Economy Act) to provide the BBC with the necessary power to set the policy for the provision of any age-related concessionary TV licences within the Bailiwick, ensuring Bailiwick residents are treated on an equal basis to UK residents. This would enable the BBC to fulfil the commitments it made in 2016 when agreeing to take responsibility for setting and funding the over-75 age concession.
- 1.5. Outside the scope of the over-75 scheme, the States of Guernsey funds the provision of a TV licence to Guernsey and Alderney residents over pensionable age (currently 65) who are in receipt of income support. The Committee *for* Employment & Social Security has confirmed it has no plans to alter this separate scheme. Given the operation of this scheme, it is expected that the cost of providing free TV licences for residents over 75 years of age in Guernsey and Alderney who receive income support would fall to that Committee in the absence of any future BBC funding.

2.0. Background

2.1. In the United Kingdom, the Isle of Man and Channel Islands, any household watching or recording live television transmissions as they are being broadcast (terrestrial, satellite, cable or internet) is required to hold a television licence. A TV licence is also required to receive video-on-demand programme services provided by the BBC on its iPlayer catch-up service. The TV licence was introduced in 1946 with powers for its establishment contained within the Wireless Telegraphy Act 1904. This Act has since been amended and superseded, with relevant powers relating to TV licences extended to the Bailiwick over the years by the States of Deliberation – most recently by extending Part 4 of the Communications Act 2003.

- 2.2. In July 2015, during the UK post-election budget, the then Chancellor of the Exchequer announced that the UK Government would pass to the BBC the policy and funding responsibility for the age concession scheme whereby persons over the age of 75 were entitled to a free TV licence. A staged transition from 2018 to 2020 was agreed. The change to responsibility for the over-75 scheme captured UK licence fee payers only and did not extend to the Bailiwick of Guernsey (nor to Jersey nor the Isle of Man).
- 2.3. In October 2015¹, the States of Deliberation resolved² to end the Guernsey and Alderney over-75 age concession scheme to new entrants (Sark residents were not included in the scheme as that island is not part of the same benefits system). The scheme was closed to new entrants on 1st September 2016. Anyone aged 75 or more before 1st September 2016 who was already in receipt of a free TV licence has continued to receive one. The October 2015 policy letter stated:

"The appropriateness of continuing to provide universal benefits, such as the provision of free TV licences, was considered by the Social Security Department and the Treasury and Resources Department as part of the Personal Tax, Pensions and Benefits Review. As age is not necessarily an indicator of low income and this service is provided to many who could better afford a TV licence than some who do not receive one, it was the view of the Joint Board that this benefit could be withdrawn with minimal impact to the individuals concerned."

- 2.4. Following the UK Government's decision to transfer responsibility for setting and funding the over-75 age concession to the BBC, discussions were held between representatives of the States of Guernsey and the BBC about how best to ensure fairness for all licence fee payers, including those in the islands. An agreement was reached in December 2016 between the BBC and the States of Guernsey to transfer to the BBC responsibility for both funding and setting the terms of the over-75 scheme for Bailiwick residents from June 2020, replicating the decision made in the UK. This agreement preserved the principle of equal treatment for all British licence fee payers.
- 2.5. A transition arrangement was agreed whereby the BBC would part-fund the States of Guernsey's existing over-75 licence concession scheme. The BBC agreed to fund one-third in 2018 (£225,000) and two-thirds in 2019 (£452,000). This funding arrangement is due to stop in 2020 when the BBC takes on full cost and

¹ Billet d'Etat XVIII, 27th October 2015, Social Security Department – Benefit and Contribution Rates for 2016: https://gov.gg/CHttpHandler.ashx?id=98327&p=0

² Resolutions, Billet d'Etat XVIII, 27th October 2015: https://gov.gg/CHttpHandler.ashx?id=99104&p=0

policy setting responsibility. Below are extracts from a letter from the BBC to the President of the Committee *for* Economic Development, in December 2016, outlining the agreed position:

"An existing Agreement between the BBC and Guernsey for the provision of broadcasting services made on 15th December 2006 is due to expire on 31 December 2016. The BBC wishes to give assurances and express its intentions for the continued provision of broadcasting services in the Bailiwick in the future, express its expectations in relation to the continuation and updating of the licence fee framework in the Bailiwick by the States of Guernsey, and set out its intentions and expectations in relation to future arrangements for the determination and funding of age-related concessions for the television licence in the Bailiwick (excluding Sark). The BBC's proposals are offered in accordance with its obligations under the 2016 Charter and the 2016 Agreement. The BBC must be independent in all matters concerning the fulfilment of its Mission and the promotion of its Public Purposes, particularly as regards editorial and creative decisions, the times and manner in which its output and services are supplied, and in the management of its affairs.

Clause 78 of the 2006 Agreement provides for the BBC to receive compensation from the UK Department for Work and Pensions for issuing TV licences in the UK for which, in accordance with regulations made under section 365(1) of the 2003 Act, no fee is payable. The States of Guernsey compensate the BBC directly for concessionary licences issued under the Regulations in the Bailiwick too, i.e. for those in the Bailiwick (excluding Sark) who qualify having reached 75 by 1st September 2016. Direct compensation is not provided for TV licences issued under the Bailiwick's means tested scheme, as the States of Guernsey fund these licences via the Guernsey Post Office, allowing the BBC to collect payment through that route. Her Majesty's Government decided in July 2015 to transfer to the BBC, on a phased basis from 1 April 2018, the cost of providing free TV licences in the UK. In addition, the Digital Economy Act ("DEA") will, if enacted in its current form, provide for the BBC to have the power, and will remove from the Secretary of State the power, to set the policy for the provision of any age-related concessionary television licences, where the relevant age is 65 years or more, from 1 June 2020, currently in the UK only, including the power to amend the eligibility criteria for any such concession.

In the context of the above, and in return for seeking from the States of Guernsey the assurances and expression of intentions detailed below, the BBC gives assurances and expresses the following intentions. The expression of the following intentions by the BBC in this letter should not be taken to extend beyond the end of the period of the BBC's agreed funding settlement to 31 March 2022. Given the acknowledgement by the BBC (below) that the States of Guernsey cannot purport to bind the legislature of any Bailiwick jurisdiction or of any United Kingdom authority or body, in the event that the States of Guernsey fail to deliver on any of its assurances, the BBC reserves the right to choose not to honour one or more of the following assurances.

- (1) The BBC expresses its intention to share the cost on a phased basis of:
 - a. the age-related concession scheme for those persons in Guernsey and Alderney aged 75 years or more on 1st September 2016, and
 - b. the age-related, means-tested concessionary TV licences for those persons in Guernsey and Alderney who reach the age of 75 on or after 1st September 2016,

as this is reflected in the States of Guernsey note to the BBC dated 26th October 2016 ("Note"). BBC cost-sharing will be on a phased basis from 1 April 2018. The BBC will share one third of the cost of free TV licences in categories a. and b. above in 2018/2019, two thirds in 2019/2020 and be responsible for the full cost in 2020/2021.

The States of Guernsey will be responsible for reimbursing the BBC for the balance between the BBC contribution and the total cost of free licences. In effect, this means that the States of Guernsey would refund to the BBC the cost of the concessions, minus the BBC's share (see Guernsey assurance (5) below).

The BBC contribution for 2018/19 and 2019/20 will be £225,000 and £452,000 respectively (assessed on the basis of eligibility figures the BBC holds for 2015/16, adjusted to account for recent changes in eligibility as set out in the Note and to account for estimated growth in the number of households) but uprated for inflation in due course on the same basis as the licence fee. The figure for 2020/21 (to be assessed on the figures the BBC holds for 2015/16, recent changes in eligibility as set out in the

Note estimated growth in the number of households and uprated for inflation) will be subject to the BBC's power to reform eligibility from 1st June 2020."

- 2.6. Separate to the over 75-age scheme, the States of Deliberation agreed in October 2015 to continue funding a scheme whereby Guernsey and Alderney residents of pensionable age (currently 65) who are in receipt of income support receive a free TV licence. The then Social Security Department stated in its policy letter that the withdrawal of the universal over-75 concession scheme would be most keenly felt by low income households, so the retention of a means-tested scheme for those above pensionable age would help those most in need.
- 2.7. The Committee *for* Employment & Social Security has confirmed it has no plans to alter the separate scheme for those above pensionable age on income support, which currently costs about £18,000 per annum.

3.0. <u>June 2020 changes</u>

3.1. In June 2019, following the transfer of policy and funding responsibility from the UK Government to the BBC, the broadcaster announced its decision on the future of the over-75 TV licence fee concession scheme for UK residents. From June 2020, the universal benefit will cease but a free TV licence will be issued to any household with someone aged over 75 who receives Pension Credit. In its statement announcing its decision, the BBC stated³:

"The Government's current scheme comes to an end next year and Parliament - through legislation - gave the responsibility to the BBC Board to make this decision. From June 2020 any household with someone aged over 75 who receives Pension Credit will be eligible for a free TV licence funded by the BBC. Around 1.5 million households could be eligible. The BBC Board believes this is the fairest option to help the poorest pensioners. It is also the fairest option for all licence fee payers, as this means everyone will continue to receive the best programmes and services that the BBC can provide. The BBC will not be making judgements about poverty as that measure is set and controlled by Government. The new scheme will cost the BBC around £250 million by 2021/22 depending on the take-up of the new scheme. The cost of this new scheme will require the BBC to divert some spending on programmes and services, alongside continuing to find new savings while expanding its commercial revenue to cope. The decision does, however, prevent unprecedented

³ https://www.bbc.co.uk/mediacentre/latestnews/2019/over-75s-licence-fees-decision

closures of services which would have been required had we copied the Government's scheme."

- 3.2. The BBC's decision does not automatically extend to the Bailiwick. The broadcaster must make a separate decision regarding any future concession scheme for Bailiwick residents. Preliminary discussions have been held with the BBC, which has signalled its continued commitment to the principle of equal treatment for all British licence fee payers (including island residents). Guernsey and Alderney do not have a benefit which is directly equivalent to the UK's Pension Credit benefit. The BBC would need to consider this as part of its decision-making on any future concession scheme to apply in the islands. The decision about the scope of the scheme to be applied to the Bailiwick will be a matter for the BBC Board.
- 3.3. Sark has not previously been included in the over-75 age concession scheme, as it is not part of the Bailiwick's benefit system. Sark also does not have a like-for-like benefit to Pension Credit. It is intended to encourage the BBC to consult with Sark before making its final decision on the over-75 age concession for the Bailiwick.

4.0. Legal considerations

- 4.1. The Communications Act, as amended by the Digital Economy Act, provides the BBC with the necessary powers to set the policy for the provision of any agerelated concessionary TV licences from June 2020, including the power to amend the eligibility criteria for any such concession. Parts of the Communications Act have been extended to the Bailiwick by Order in Council, including provisions relating to TV licensing, but these recent amendments made by the Digital Economy Act (principally the insertion of section 365A, TV licence fee concessions by reference to age) have not been so extended. Therefore the BBC currently has no legal authority to either set or fund an over-75 age concession for any Bailiwick resident.
- 4.2. The transitional funding arrangement previously agreed, which has seen the BBC and States of Guernsey share the cost of the over-75 concessions, ends in 2020. Without the extension of section 365A and any other necessary related provisions, the BBC would not offer any further funding to Bailiwick residents. This would result in the closure of the existing over-75 scheme, which was closed to new entrants in September 2016, unless a new scheme were to be established and funded by the States of Guernsey.

- 4.3. However, given the Committee *for* Employment & Social Security currently operates a separate scheme for those over pensionable age (currently 65) on income support, it is expected that the cost of providing free TV licences for residents over 75 years of age in Guernsey and Alderney who receive income support would fall to that Committee in the absence of any future BBC funding.
- 4.4. The BBC has indicated its continued support for the principle of fair and equitable treatment of all British licence fee payers. The BBC has also indicated that it will not make a decision about the over-75 concession scheme for Bailiwick residents for the period from 1st June 2020 until it has the necessary legal authority to do so.
- 4.5. The States is asked to approve the extension to the Bailiwick by Order in Council of the relevant parts of the Communications Act as amended by the Digital Economy Act with any necessary minor modifications, with effect from 1st June 2020, to provide the BBC with the necessary power to set the policy for the provision of any age-related concessionary TV licences. This will enable the BBC to fulfil the commitments it made in 2016 when agreeing to take responsibility for setting and funding the over-75 age concession scheme within the Bailiwick.
- 4.6. The situation in the Bailiwick is replicated in Jersey in so far as any decision by the BBC with regards UK licence fee payers does not automatically extend to Jersey. As a result the Government of Jersey is currently in discussions with the BBC about the future provision of age related concessionary TV licenses.

5.0. Consultation

- 5.1. The Committee *for* Employment & Social Security approved in 2016 the transfer of responsibility for the over-75 age concession scheme (policy and funding) to the BBC to ensure the equal treatment of all BBC licence fee payers from 2020 onwards. That Committee's views have now been sought on the need to extend relevant parts of the Communications Act 2003, as amended (including as amended by the Digital Economy Act 2017). The Committee *for* Employment & Social Security stated it supported the proposition of this policy letter.
- 5.2. The Committee for Economic Development has mandated responsibility for broadcasting policy and agreed the transitional arrangements with the BBC for funding the scheme in Guernsey and Alderney for 2018 and 2019. That Committee's views have now been sought on the need to extend relevant parts of the Communications Act 2003, as amended (including as amended by the

- Digital Economy Act 2017). The Committee for Economic Development stated it supported the proposition of this policy letter.
- 5.3. The States of Alderney has been consulted about extending relevant parts of the Communications Act 2003 as amended (including as amended by the Digital Economy Act 2017) to Alderney. The Policy & Finance Committee said it supported the proposition of this policy letter.
- 5.4. The Chief Pleas of Sark has been consulted about extending relevant parts of the Communications Act 2003 as amended (including as amended by the Digital Economy Act 2017) to Sark. The Policy & Finance Committee said it is content for the legislation to be extended to Sark.

6. Compliance with Rule 4

- 6.1. Rule 4 of the Rules of Procedure of the States of Deliberation and their Committees sets out the information which must be included in, or appended to, motions laid before the States.
- 6.2. In accordance with Rule 4(1), the Propositions have been submitted to Her Majesty's Procureur for advice on any legal or constitutional implications. HM Procureur has advised that there is no reason in law why the Propositions should not be put into effect.
- 6.3. In regard to Rule 4(3) of the Rules of Procedure of the States of Deliberation and their Committees, it is not envisaged that additional resources will be required to fulfil the propositions of this policy letter.
- 6.4. In accordance with Rule 4(4) of the Rules of Procedure of the States of Deliberation and their Committees, it is confirmed that the Propositions above have the unanimous support of the Committee.
- 6.5. In accordance with Rule 4(5) of the Rules of Procedure of the States of Deliberation and their Committees, the Propositions relate to the duties of the Committee because its mandate includes responsibilities to, "external relations and international and constitutional affairs, which includes: 2. relations with the United Kingdom and other jurisdictions; 4. relations with the other islands of the Bailiwick; 5. representing, or overseeing the representation of, and negotiating for, the Island; [and] 7. executing and requesting the extension of international agreements to which the Island is invited to acquiesce;...".

6.6. The Committee's consultation with other parties is outlined in Section 5 above, in accordance with Rule 4(5).

7. Propositions

The States are asked to decide whether they are of the opinion:-

To agree that section 365A, and such other provisions of the Communications Act 2003 as amended (including as amended by the Digital Economy Act 2017) relating to TV licence fee concessions by reference to age as it may be necessary or expedient to extend, should be extended by Order in Council to the Bailiwick with such modifications as appear to Her Majesty in Council to be appropriate, following consultation with the Policy & Resources Committee.

Yours faithfully

G A St Pier President

L S Trott Vice-President

A H Brouard J P Le Tocq T J Stephens

of the ISLAND OF GUERNSEY

POLICY & RESOURCES COMMITTEE

THE REVIEW OF THE FISCAL POLICY FRAMEWORK AND FISCAL PRESSURES

The States are asked to decide:

Whether, after consideration of the Policy Letter entitled 'The Review of the Fiscal Policy Framework and Fiscal Pressures', dated 25 November 2019, they are of the opinion:

- 1) To adopt the Fiscal Policy Framework and its Principles as outlined in Section 5 of the Policy Letter.
- 2) To direct the Policy & Resources Committee, in consultation with all States Members and further to public engagement, to conduct a review to ensure that Guernsey's tax base is capable of raising sufficient revenues to meet long-term government expenditure needs in a sustainable manner within the boundaries of the Fiscal Policy Framework.
- 3) To agree that the review should be conducted in accordance with the Terms of Reference and methodology laid out in paragraphs 3.16 to 3.20 of the Policy Letter and be presented to the States for consideration by no later than June 2021.

The above propositions have been submitted to Her Majesty's Procureur for advice on any legal or constitutional implications in accordance with Rule 4(1) of the Rules of Procedure of the States of Deliberation and their Committees.

THE STATES OF DELIBERATION of the ISLAND OF GUERNSEY

POLICY & RESOURCES COMMITTEE

THE REVIEW OF THE FISCAL POLICY FRAMEWORK AND FISCAL PRESSURES

The Presiding Officer States of Guernsey Royal Court House St Peter Port

25 November 2019

Dear Sir

1. Executive summary

The Fiscal Policy Framework

- 1.1 The Fiscal Policy Framework (the Framework), first established in 2009, sets out the island's highest level of fiscal policy, including the boundaries within which more detailed fiscal policy should operate. The Framework provides a series of high-level principles which commit the States to an overarching theme of long-term permanent balance (not spending more than is received) and ongoing fiscal prudence. These principles define fiscal boundaries in terms of long-term fiscal balance and include limits on revenues, deficits and debt against which the States can be monitored and held accountable. It is designed to endure across multiple political terms to promote stability and consistency in fiscal policy.
- 1.2 This review of the Framework was made necessary by the revision of GDP¹ in 2017 and the beginning of the transition towards International Public Sector Accounting Standards (IPSAS) during 2018. The revised principles within the Framework reflect the evolution of fiscal policy-making since its inception. These principles are summarised as (see section 5 for details):

¹ Gross Domestic Product is a measure of the size of an economy. In Guernsey this is calculated as the sum of compensation of employees (such as wages and pension contributions), gross operating surplus (such as company trading profits), remuneration and profits of sole traders and the income of households.

- Principle 1: Guernsey's fiscal policy should operate on a principle of long-term permanent balance.
- Principle 2: The annual net deficit reported on the General Revenue accounts for any given year should not exceed 15% of operating revenues.
- Principle 3: Annual net deficits reported in the General Revenue accounts should not be allowed to persist for more than five consecutive years.
- Principle 4: Measures to address any identified or anticipated deficit must be incorporated in the States Medium Term Financial Plan (MTFP).
- Principle 5: The aggregate amount of States' revenue should not exceed 24% of GDP.
- Principle 6: Total capital expenditure over any States term should be maintained at a level which reflects the need for long and medium term investment in infrastructure and direct capital expenditure by the States should average no less than 1.5% of GDP per year averaged over a four year period.

Principle 7: The States' total debt should not exceed 15% of GDP.

- 1.3 The small size and open nature of Guernsey's economy means that long-term permanent balance is important and running a sustained deficit is not a realistic or prudent option. We must balance our long-term budget, which means that any increase in spending may need to be accompanied by an increase in taxation.
- 1.4 The Framework sets policy which should be applied in the long-term with few and infrequent changes. One of the core principles of the Framework (principle 5) is a limit on the aggregate revenues that can be taken from the economy through government taxes and charges. The review of the Framework is therefore an ideal opportunity for high level discussions about how large government revenues should be relative to the size of the economy. As such, this Policy Letter has been significantly expanded since its first publication in July 2019² in order to facilitate this discussion.
- 1.5 The States are facing a series of enduring fiscal pressures both through challenges to the sustainability of existing services as a result of the ageing population and growing demand for additional services (see table 2.1 for

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² In September 2019, the States agreed to the Policy & Resources Committee's request to withdraw the policy letter entitled "Review of the Fiscal Policy Framework" in light of the mounting fiscal pressures.

details). This policy letter includes provisional analysis of these pressures to facilitate a debate on one of the most fundamental questions of any community: what level of public services should be provided and how much tax are we prepared to take from the economy and the community in order to provide these?

- 1.6 The Framework sets the maximum amount of revenues that *could* be raised from the community given the growing clarity about the scale of these long-term pressures. This will define the boundaries on the total size of the public sector in Guernsey.
- 1.7 The 24% of GDP limit on aggregate revenues applied in the Framework is broadly equivalent in monetary terms to the limit applied prior to this review. This limit was set with acknowledgement of the projected increase in demand for public services as the population ages. It provided headroom to accommodate the anticipated need to increase aggregate revenues beyond their current level to meet this demand. The situation has now progressed to a point where we are going to need to begin to make use of this headroom. The States are asked to reaffirm the commitment to this limit now the projected fiscal pressures are becoming a reality.
- 1.8 The Framework does not define *how* revenues should be raised or what services should be provided.
- Once the principles of the Framework are agreed, the next stage of work in this area will be to review how the States might raise more money from the economy in a sustainable way within the limits agreed. The review will need to take into consideration both the parameters set in the Framework and the series of decisions States' Members will face in the coming months, which will have a significant impact on the scale of revenues required to support the provision of public services in the long-term.
- 1.10 Once the States have made in principle decisions on policy proposals (income and expenditure) there will need to be an iterative process of incorporating these into the MTFP and Annual Budgets. This will provide the States with the opportunity to approve the relative prioritisation of resources, and the speed and extent of the implementation of revenue raising measures and service developments on a rolling basis.

The Review of Revenues

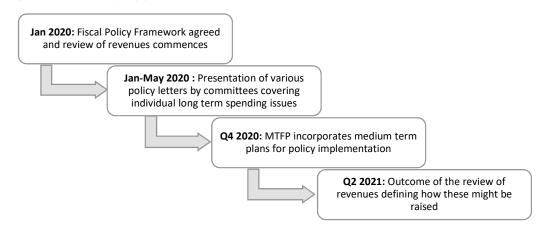
- 1.11 It has been clear for many years that Guernsey faces significant fiscal and policy challenges. As the current political term draws to a close, there are a number of key policy initiatives intended to manage various aspects of demographic and other pressures being developed (see section 2 for details). Some of these items may be brought forward for debate without an identified sustainable source of funding. Each decision to increase spending will place a further requirement on the next Assembly to raise revenues.
- 1.12 Each policy brought forward for debate is undoubtedly done so with the best of intentions. Individually, within each policy, there are likely to be persuasive arguments to be generous; to support more services and provide larger subsidies. However, Government services are not free, for example: it costs between £7,300 and £8,800 for each standard off-island knee replacement and up to £20,000 for a more complex joint replacement surgery; a year's education for a secondary school pupil costs on average £8,100 to £8,900 in revenue expenditure (in addition there are significant capital costs); and it costs an estimated £45,000 to keep a prisoner in custody for a year (see Appendix A). These services are funded by taxation and more services and larger subsidies require higher taxation.
- 1.13 Committees could be directed to present each of these policies with a recommended source of funding, but this type of piecemeal approach is unlikely to result in an optimal solution.
- 1.14 As highlighted in the 2020 Budget Report (Billet d'État XXI, November 2019) it has become evident that we cannot support the increasing demand for such services on our current, comparatively small and narrow tax base. Guernsey currently collects only 21% of its annual GDP in revenues compared to 26% in Jersey and 38% in the UK (see Appendix B). Within this smaller tax base the States of Guernsey currently provides a broadly similar level of services to those provided in Jersey, but will be unable to sustain this. If we are to continue to provide our community with the range and quality of services they would expect to receive, we will need to raise more revenue from the economy to pay for them.
- 1.15 In recent years it has been possible to balance the budget with fairly moderate changes to the current tax system, such as the withdrawal of tax allowances for higher earners and the expansion of domestic property tax revenues with increased rates and a more progressive structure. However, the scale of the

demands on public finances, estimated at between £79m and £132m (see table 2.1 for details), cannot, and should not, be met by a continual tweaking around the edges. Even at the lower end of the estimates, a substantial increase in funding would be required to support the complete profile of emerging policy. Therefore substantial changes to the tax base are needed.

- 1.16 Not all of this funding would be required immediately, but raising additional revenues on this scale from the local community over the medium term should be subject to careful consideration to ensure that it is done in a way that is both economically and socially sustainable and fair. Tax structures interact in complex ways and, without a wholesale approach to revenue raising, the risk of unintentionally introducing inequities and/or undermining the integrity of the tax base or the economy is high. A single, co-ordinated approach to revenue raising will create a more sustainable and equitable result.
- 1.17 The States has a commitment to transformation and ensuring the provision of public services is cost effective. As resolved in the 2020 Budget, public service reform activity must continue to generate reform dividends in order to contribute towards balancing the budget. However, it is unrealistic to expect that efficiency savings, transformation and economic growth could generate the amount of resources required to meet the demands of all of the policy initiatives listed in this policy letter, particularly given the small amount of revenue currently collected in Guernsey relative to the size of its economy.
- 1.18 Ordinarily policy regarding how to raise additional revenues would be determined through the Medium Term Financial Plan (MTFP) and the Annual Budget (see section 6), however, this is a structural issue which requires separate more detailed review and more careful implementation which will need to span more than one MTFP.

- 1.19 The Policy & Resources Committee therefore proposes commencing a review of potential long-term options for ensuring that the tax base has the *capacity* to raise the amount of revenues required to meet long-term needs, incorporating consideration of options for generating additional revenues from:
 - i. the taxation of company profits with due regard to the need to maintain a tax system which is competitive, internationally acceptable and maintains tax neutrality³;
 - ii. Extension or modification of the existing income tax and Social Security contribution system;
 - iii. A health tax;
 - iv. The addition of general or limited consumption taxes to the tax base.

Figure 1.1: Series of key publications and debates



- 1.20 The next MTFP, which will be published while this review is ongoing, will need to recognise and incorporate the likely impact of these policies in the medium term period (four years). This may include ensuring there are sufficient resources available to meet any interim funding requirements needed to support these policies in anticipation of longer term funding solutions to follow where this is appropriate.
- 1.21 The review and its recommendations will not be considered by the States until mid-2021 and implementation of revenue raising measures could take some time. The raising of significant revenues should not be implemented at a speed unnecessarily detrimental to the economy. As a result, the next and subsequent

³ Tax neutrality is important for the continuing operation of the finance sector in Guernsey, enabling Guernsey to competitively facilitate the movement of international capital flows in the absence of the extensive network of double tax agreements available to larger jurisdictions. Tax neutrality ensures that the products and clients of the finance sector are taxed appropriately in the jurisdictions of origin, residence or investment, as appropriate, without any additional tax cost being imposed in Guernsey. Tax neutrality does not generally impede the taxation of profits on the regulated providers of services in the finance sector as is currently the case under the 0/10 regime.

MTFPs will also need to ensure that implementation of policy is managed and coordinated within the available resources.

1.22 This means that funding may not be immediately available to support all in principle decisions made by the States on these policy areas. There will need to be a managed and co-ordinated programme of prioritisation and implementation of both revenue and expenditure aspects and the co-operation of all committees will be required achieve this.

2. Developing fiscal pressures

- 2.1 There are a number of policy initiatives in development which will be presented to the States in due course which could have very substantial long-term financial consequences. It is not the role of this policy letter to discuss the relative merits of each and each will require its own policy letter setting out the issues, intended outcomes, detailed analysis (including economic and social impact), options and conclusions. Instead the intention is to bring to members' attention the potential cumulative effect of these policies. It should be noted that some of these items will be brought forward for debate without an identified sustainable source of funding. Each decision to increase spending will place a further requirement on the next assembly to raise revenues.
- 2.2 Each policy brought forward for debate is undoubtedly done so with the best of intentions. In each area there are various options for progressing the policy which may change the scale and distribution of costs borne by individuals and the economy. Individually, within each policy, there are likely to be persuasive arguments to be generous; to support more services and provide larger subsidies. But Government services are not free. Whether these are funded via general taxation or through Social Security contributions, more services and larger subsidies require drawing more money from the population. As discussed in section 3, the small size and open nature of Guernsey's economy means that long-term permanent balance is important. We must balance our long-term budget, which means that increasing spending means increasing taxation.
- 2.3 The following sections are not intended to prejudge the developments which are underway, but to provide an indication of the likely cost scale of these and to summarise the potential magnitude of the aggregate consequences. It is hoped that this will aid members, both in the debate on the Framework (particularly the deliberation of the limit on the total size of the public sector) and to better understand the context and interrelationship of policies to be brought forward.

- 2.4 It was acknowledged in the 2020 Budget Report that we will need to raise more revenue to meet the long-term demand challenges. A series of decisions will be taken by the States in the coming months which will determine how much more revenue will be needed. The States have a collective responsibility for the overall impact of its decisions and the cumulative annual cost and resource implications of the decisions members will face during this period could be particularly large. Members should remain aware of these cumulative costs. The next Assembly will need to find long-term funding solutions for every spending commitment that is made by this one. Compromise and balance will be essential.
- 2.5 The policy initiatives covered in this section are, without exception, large and complex with far reaching consequences. They should not be rushed. Neither would it be practical or possible to make all decisions on all these policies at once, but it is important to avoid a position where resources are prioritised to one area of policy development at the expense of others simply because it was the first to be brought forward for decision.
- 2.6 The role of the proposed review of revenues will be to design a tax structure *capable* of raising revenues up to the limits of the Framework. It is not expected that all the potential revenues will be required at once (if at all).
- 2.7 Once the States have made in principle decisions on policy proposals there will need to be an iterative process of incorporating these into the MTFP and Annual Budgets. This will provide the States with the opportunity to approve the relative prioritisation of resources, and the speed and extent of the implementation of revenue raising measures and policy decisions on a rolling basis. In some cases this may mean that funding to implement decisions made in principle will not be available immediately. The aim of this process should be to ensure that the expansion of the tax base is balanced against the need to allocate appropriate amount of resources to key priorities at an appropriate time.
- 2.8 Cost estimates presented are based on the best estimates of the cost envelope available at the time of publication. It is to be expected that these will be changed and refined as the policies develop.

Drug Funding: supporting NICE recommendations

- The range of drug treatments available to local residents is under review following a Requête, laid by Deputy Roffey during 2018, entitled "Drug Funding" (Billet d'État XXVII, December 2018). The Requête sought to make all drugs approved for use in the UK NHS available to patients in Guernsey with public funding, but was successfully amended to facilitate a formal review of the matter.
- 2.10 The resulting review by the Committee for Health & Social Care, expected to be published concurrent with this policy letter, has considered a range of possible options for extending the range of drugs and treatments available from public funding. It is evident from this closer examination that the costs implications are significantly higher than the initial estimates quoted in the debate on the Requête. Current estimates suggest that, depending on the approach taken and the extent to which members wish to extend the availability of treatments, the long-term cost implications could be anywhere between £5m and £12m a year.

Review of primary care

- 2.11 In December 2017 the States approved the Partnership of Purpose (*Billet d'État XXIV, December 2017*), a ten year programme working across organisational boundaries, to evolve service delivery and create an integrated model designed to improve islanders' health and wellbeing, deliver user-centred care focused on prevention and early intervention and help mitigate rising health and care costs.
- 2.12 The review of primary care is part of the delivery of the Partnership of Purpose. Primary care is defined for these purposes as General Practice and the Emergency Department. This work will seek to realise a range of practical, organisational and financial benefits, all centred on facilitating patient-centred care in line with the agreed aims of the Partnership of Purpose.
- 2.13 The Committee *for* Health & Social Care intends to bring proposals to the Assembly recommending that all providers work within a technical and statutory framework which supports integrated working and the delivery of consistent high-quality care. Informed by improved health intelligence, the Committee intends to work with existing providers to trial new ways of working that reshape the primary care model to become increasingly cost effective and support direct access to services where appropriate. The key focus will be ensuring that all islanders have the ability to access the right professional at the right time in the right environment with the right information.

- 2.14 One of the key aims of the Partnership of Purpose is fair access to care: ensuring that low income is not a barrier to health through proportionate funding processes based on identified need. How best to achieve this aim in the context of primary care forms part of this work stream.
- 2.15 While improving cost effectiveness and efficient functioning of the system to mitigate long-term cost increase is an important part of this, there are cost implications, particularly in relation to the issue of affordable access to primary care for the user. For the purpose of illustration of the potential scale of the cost, without other reforms it is estimated that to provide all primary care services either at lower cost to the user or free of charge without any other changes could cost in the region of £9m to £20m per annum.

Supported living and ageing well: The Long Term Care Fund

- 2.16 The first stage of the Supported Living and Aging Well Strategy was brought to the States in 2016 (Billet d'État III, February 2016) and there were a number of work streams initiated to implement the recommendations. The most fiscally significant of these is the work stream undertaken by the Committee for Employment & Social Security to examine the future of the Long Term Care Fund.
- 2.17 This Fund, which receives income from Social Security contributions, was created in 2003 and provides a substantial subsidy towards the cost of residential and nursing care, primarily for older people. However, at its inception it was noted that in the long-term it would require more funding to make it financially sustainable. Despite the 0.5% increase in contributions applied in 2017 (Billet d'État XXVII, November 2016) current projections suggest that, without any change in policy, an increase in contributions of approximately 0.7% (valued at approximately £11m at 2019 prices) will be required to stabilise the Fund.
- 2.18 There are a number of policy options under discussion including:
 - bringing the funding of community based long-term care services into the scope of the scheme, which will increase the long-term financial demand on the Fund;
 - re-balancing the distribution of the costs between the Fund (and by implication contribution rates paid primarily by working age individuals) and individuals receiving the benefit; and
 - reviewing the mechanism by which an individual might contribute to the cost of their care.

- 2.19 The policy area is complex. There are a number of private sector and not-for-profit providers who supply the majority of current services and the projections show a very substantial increase in demand for these services in the medium and long-term. Any changes to the policy and funding structure need to consider the financial sustainability of the fund; the need to ensure continued participation and future investment by private sector providers; and the fairness and equity of the system for both contributors and beneficiaries.
- 2.20 Options currently under consideration include increases in contribution rates of between 0.4% and 1.2%. Including any General Revenue cost implications this could require a total value of additional funding of between £7m and £23m.

States pensions

- 2.21 The Guernsey Insurance Fund supports £130m of State's Pension⁴ expenditure as well as a number of smaller income replacement benefits. The most recent actuarial projections (Billet d'État XXVII, November 2016) suggest that, at the current central assumptions of earnings growth and investment return, an estimated increase in contributions of 0.5% would be required to fund the current uprating policy.
- 2.22 This would mean that in order to maintain a policy of increasing pensions by one third of the real (above inflation) increase in median earnings until 2025 and by RPIX thereafter a further £8m of income would be required. A more generous long-term up-rating policy would require further funding.
- 2.23 The existing policy to reduce the uprating of the pension to RPIX only by 2025 is contingent on the introduction of a secondary pension scheme to enhance personal provision. The implementation of this scheme has been delayed and the proposed phasing of its introduction means that it will be some years before members are making significant contributions. Therefore, the uprating policy will need to be reconsidered before 2025.
- 2.24 Investigations are underway to examine whether it might be possible to consolidate the governance of the Social Security Funds with the General Revenue Reserves. This may include options which could improve the investment performance of the Social Security Funds which may reduce the required funding. The next full actuarial review is due in 2020.

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⁴ Formally the Old Age Pension

Secondary pensions

- 2.25 The second policy letter on the Secondary Pensions project is also due to be brought to the States for debate in the first quarter of 2020. This will recommend the introduction of legislation to make it mandatory for employers to offer an auto-enrolment pension scheme to all qualifying employees. It will also recommend the launch of a States supported scheme which will be open to all employers and individuals to join. This will provide affordable access to pension products for small employers and lower income individuals, who are currently priced out of the market by the administrative cost of such schemes.
- 2.26 There are considerable long-term benefits of increasing pension saving in our community. Current estimates suggest the level of saving is wholly inadequate to support most people in a comfortable retirement and increasing the savings rate could reduce long-term reliance on the benefit systems. The administrative cost of existing schemes is such that their availability tends to be restricted to larger employers and those operating within the finance and professional sectors. As a result for many median and low income employees opportunities to save effectively for retirement are limited, which has a tendency to exaggerate income inequalities as people move in to retirement.
- 2.27 However, increasing pension saving in this way comes with both direct and indirect costs to the States. Estimates suggest that an additional £100,000 a year will be required to ensure employers are complying with the new legislation. There may also be an estimated £8m in lost tax revenue by 2029 from the tax relief granted on the contributions of people brought in to pension savings for the first time. A further £700,000 a year of additional income support costs may be incurred to compensate claimants for the reduction in their net income should they choose to remain enrolled in the scheme.
- 2.28 Increasing pensioner income in the long-term should raise tax receipts, reduce income support payments to retirees and will balance a large part of the indirect costs over time. However, these effects will take generations to rebalance and the States will need to replace the net lost income and fund net additional expenditure for an extended period. The total annual fiscal impact is estimated to peak at £9m in 2029.

Public Sector Terms and Conditions

- 2.29 The terms and conditions of the various public service pay groups have evolved organically over time. Some pay groups have reference groups in the UK. Others have evolved relative to private and/or industry sectors in Guernsey and the need to compete for staff resources. This has resulted in different working hours, leave entitlements, sickness management and pay arrangements in different pay groups.
- 2.30 The public sector workforce generally has a value set that includes a motivation to serve the community. Public sector remuneration packages meet or fall below comparable roles in the private sector but when roles are 'read across' or reviewed on the basis of a job evaluation scheme in some cases there are considerable differences in the value of the full terms and conditions packages offered by the States of Guernsey as the single employer. The achievability of many of the States' transition programmes is centred on the organisation being better able to manage its deployment of staff. This is hampered through this myriad of terms and conditions which often result in skilled service providers moving to the better remunerated roles in the public sector.
- 2.31 The Policy & Resources Committee has commissioned a review of the terms and conditions of all public sector pay groups including nursing and care staff, teachers and lecturers, public service employees and established civil servants. This work is examining pay, benefits, working hours, and leave entitlement and sickness arrangements with a view to enabling harmonisation.
- 2.32 An options appraisal should analyse the potential for job matching across the entire public service based on the principles of fair and equal pay. This would fundamentally change the pay structure and usher in very significant long-term cost implications. The Policy & Resources Committee intends to report the findings of the Review by March 2020. The current estimates for the annual, direct cost to General Revenue upon completing the full recommendations are circa £35m to £40m a year.

General Healthcare and other pressures

- 2.33 In addition to the above, there are more general pressures on the baseline budgets. Health and social care services in particular are beginning to feel the effects of increasing demand. The Committee *for* Heath & Social Care was awarded an additional £6.2m in the 2020 Budget to meet above inflation pressures on its baseline costs, and settlement of 2019 and 2020 pay awards for staff in the Agenda for Change pay group at a level substantially higher than inflation to address historic pay issues would push this significantly higher. While efforts are being made to manage the increasing demand efficiently to limit the increasing costs, it is likely to prove impossible to avoid a long-term real increase in the cost of providing health care services.
- 2.34 With the transfer of services provided via the Guernsey Health Service Fund to the Committee *for* Health & Social Care's formal mandate and cash limits anticipated in 2021, it will also be necessary to absorb the estimated £1.5m shortfall on the GHSF (currently supported from investment income and by drawing down the fund reserves) into General Revenue. While in the medium term the investment return on the Fund will still be available to support some of the projected cost, it is not a sustainable solution.
- 2.35 Current estimates, based on a detailed investigation of baseline costs of healthcare services and demographic pressures, suggest that net of possible savings from transformation these cost could exert an upward pressure of between £1m and £2m a year.
- 2.36 Demographic pressures are also likely to arise in other areas, including but not limited to Income Support, ambulance services and the provision of suitable accessible housing.
- 2.37 There are also non-demographic pressures to consider including: climate change; the proposed review of the basket of goods used to determine Income Support rates could put upward pressure on costs; ongoing financial support to Aurigny in order to protect the Bailiwicks' lifeline air links; and the funding of the sports strategy.

Funding Capital investment and replenishment of reserves

- 2.38 There is also a commitment to fund the Island's capital programme. The capital programme supports the investment in the key infrastructure which is required for the proper functioning of the economy and the provision of public services. Projects funded from the Capital Reserve include the redevelopment of the education estate, the capital elements of the implementation of the Future Digital Services Strategy and the maintenance of Guernsey's coastal defences.
- 2.39 The recommended minimum level of investment in capital to be supported by General Revenue presented in this Policy letter is set at 1.5% (see section 5) and this level of funding is the approved allocation for 2020. If this is increased to 2% it would require an additional £16m a year of funding.
- 2.40 The States are also under direction to increase the size of the Core Investment Reserve (previously Contingency Reserve) to the equivalent of one year's revenue income. This Reserve forms an important part of the States approach to long-term sustainable management of its finances. The Contingency Reserve was used to fund deficits over the period following the introduction of zero/10. To comply with the spirit of the principle of permanent balance this Reserve should be replenished and to achieve this the States will need to generate a surplus which can be transferred to the Reserve.
- 2.41 There are also directions in place to replenish the Transformation & Transition Fund and Future Guernsey Economic Fund using the return from the projects supported therefrom. The reinvestment of returns from such projects is key to ensuring the ongoing capacity of the States to invest in both transformation and economic growth.

Combined pressures

The combined impact of these developments, if they are all progressed, could require additional annual revenues of between £79m and £132m over a five to ten year period. Between £71m and £124m of this amount is required to cover additional costs and £8m to replace lost income from the implementation of the secondary pension scheme.

Table 2.1: Summary of known long-term fiscal pressures

	Estimated long-term funding		Notes
	requirements		
Policy Area	£m per annum	% GDP	
NICE treatment	£5m - £12m	0.1% - 0.4%	Policy letter
funding			Published 25 th Nov
			2019
Primary care	Provisional est.	0.3%-0.6%	
services	£9m - £20m		
Health and Social	£5m-£10m over 5	0.1%-0.3%	
care demand (net	years		
of savings)			
Long Term Care	£7m - £23m	0.2% - 0.7%	Pending Policy
funding			Letter in 2020
States Pension	£8m - £18m	0.2% - 0.6%	Pending actuarial
			review in 2020
Secondary pension	£8m lost revenue	0.2% lost revenue	Pending Policy
	£1m additional	0.03% additional	Letter Q1 2020
	costs	cost	
Public Sector terms	£35m-£40m	1.1% to 1.2%	Pending Policy
and conditions			Letter in Q1 2020
Total	£8m lost revenue	0.2% lost revenue	
	£71m-£124m	2.2%-3.8%	
	additional costs	additional costs	
Indicative Total		23.5%-25.1% of	
Revenues (without		GDP	
further savings)			

2.43 In 2019 Guernsey is expected to generate government revenue equal to approximately 21.3% of GDP. Without economic growth or transformation and cost saving elsewhere to alleviate some of this pressure, progression of all the policy areas outlined would raise the size of aggregate revenue in Guernsey to between 23.5% to 25.1% of GDP.

- 2.44 There are areas where money might be saved or pressures mitigated. The Partnership of Purpose (Billet d'État XXIV, December 2017), the Reform of Health Care Funding agreed in 2019 (Billet d'État X, June 2019) and the modernisation of the Princess Elizabeth Hospital provide opportunities to make more effective use of the resources we have and mitigate some of the upward pressure on healthcare costs.
- 2.45 Elsewhere, Public Service Reform includes a programme of service design initiatives which seek to improve organisational efficiency, freeing resources which can be used elsewhere. The policy letter debated in September 2019 entitled "Transforming education programme & putting into effect the policy decisions made by the States in 2018" (Billet d'État XVI, September 2019) identified net annual savings (after reinvestment) of £1.8m to £2.2m a year.
- 2.46 Economic growth would also provide additional revenues by increasing the employment, earnings and company profits which are taxed in Guernsey, albeit that the link between government revenues and GDP growth in any given year is an imperfect one.
- 2.47 The States can make further expenditure savings and will continue to prioritise these. However, it is unrealistic to assume that efficiency savings, transformation and economic growth could free up or generate the amount of resources required to meet the demands of all the policy initiatives listed above. Even at the lower end of the estimates, a substantial increase in funding would be required to support the complete profile of emerging policy.

3. A review of long-term revenue raising options: terms of reference

- 3.1 In total these known pressures summarised in the previous section could amount to a potential need for additional funding of between £79m and £132m over the next five to ten years. Without mitigating some of this pressure through expenditure savings and economic growth this would require an increase in the size of the tax base to between 23.5% and 25.1% of GDP. This level of additional funding cannot be met without making substantial changes to the existing tax base.
- 3.2 The options for raising revenues on this scale are in reality fairly limited. To give an indication of scale it is estimated that to raise the amount of revenue collected each year to 24% of GDP (the limit recommended in this Policy letter), or

approximately £84m at 2019 prices, from **existing** tax systems would require one of the following:

- i. An increase in the headline personal income tax rate (currently 20%) by 7%;
 or
- ii. An increase in Social Security contribution rates by 7%; or
- iii. An increase of an estimated 350% in all domestic and commercial TRP rates.
- 3.3 To raise the same amount through a change in the structure to the system might require either:
 - v. A higher earners rate applied to individuals earning over £50,000 of 45%; or
 - vi. A broad based GST of 8%.
- 3.4 The most appropriate course may be to choose a combination of measures, but the review will need to consider how such measures might interact. Provisional estimates of how much revenue would be raised by specific measures independently are included in Appendix C.
- 3.5 Corporate taxes are also included in the scope but substantially more work is required before realistic estimates of how much might be raise can be included. The corporate tax environment and other taxes charged against corporate have changed substantially since the introduction of Zero/10:
 - Commercial TRP rates were increased significantly in 2008 and have been increased further in subsequent budgets;
 - The Social Security contributions for employers have been subject to both
 a significant increase in the upper earnings limit and increases in the
 employer's contributions rate since 2007;
 - The coverage of the 10% and 20% tax rates have been extended significantly since 2012, and now cover most administrative and management functions within the regulated finance sector in addition to banking activity, large retailers, hydrocarbons, the aircraft registry and medicinal cannabis cultivation and use;
 - Companies are now required to exchange significantly more information on their activities under FATCA and UK Intergovernmental agreements made in 2014;
 - Guernsey adopted the OCED's minimum standards on Base Erosion and Profit Shifting requiring the introduction of exchange of tax rulings and country by country reporting in 2016 and 2017; and
 - Guernsey implemented substance legislation in 2019 following the screening exercise undertaken by the EU.

- 3.6 A full timeline of the changes made on the corporate and other tax systems is included in Appendix D.
- 3.7 These changes have recouped much of the revenue lost in the move to zero/10. The total real value of taxes and contributions paid by the corporate sector, including TRP, company fees and employer's Social Security contributions has reduced by less than 10% between 2006 and 2019 (see Appendix E).
- 3.8 The global and regulatory conditions in which the corporate tax system operates have also changed significantly since it was last subject to review in 2012. The corporate tax system is also subject to continual monitoring under the following resolution (Billet d'État IV, March 2015):
 - "To direct the Treasury and Resources Department, having due regard for the need to provide a stable platform, maintain business confidence, support and encourage financial services and to retain an internationally acceptable and competitive tax environment for the islands' businesses, to continue to closely monitor the appropriateness of the corporate tax regime, and to report back to the States should it consider any changes are necessary."
- 3.9 Any consideration of corporate taxes needs to carefully consider the impact on the local economy, Guernsey's competitive position as an off shore finance centre and changing international standards. At the current time no estimates are currently available of what revenues it might be possible to raise from the corporate sector. Given the extent to which 10% and 20% rates have already been extended and the tax already levied on distributions to local shareholders which captures most smaller, locally owned businesses, it is unlikely to be feasible to raise sufficient revenues to meet the all of the long-term revenue need from this source without undermining the sustainability of the Islands' economy or its international position.
- 3.10 Corporate income taxes do not operate in isolation from the personal tax and indirect tax system. Any changes in the corporate tax system which might impact levels of economic activity and, by implication employment and earnings on the Island, are likely to have a further impact on revenues from income taxes, contributions and consumption taxes. These interrelationships will be carefully considered before any proposals for change are made.
- 3.11 Other taxes which might be considered, such as excise taxes on motoring or alcohol; or environmental taxes, have a limited capacity to raise revenue. This is because the nature, and in most cases, the intent of these taxes is to change

consumer behaviour. Environmental taxes, for example, are specifically designed to encourage people to change their behaviour to avoid the tax. The higher the rates are set, the larger the behavioural change made in response. As measures applied to raise revenues to any significant extent they are likely to be self-defeating.

- 3.12 While some of these pressures identified present more obvious funding mechanisms (for example Long Term Care Funding and State Pensions tend to lend themselves to funding by increase in Social Security contribution rates) taking a piecemeal approach to raising revenues on this scale is unlikely to provide an optimal solution.
- 3.13 Each option, or combination of options, would have a different impact on individual households. The various elements of any package may also interact in complex ways. For example, an increase in direct taxes such as income tax will mean that households have less disposable income to spend and might negatively affect the amount raised through consumption and excise taxes
- 3.14 Substantial changes in taxation can also have a material impact on the economy which needs to be considered, an aspect which becomes more complex with the inclusion of taxes on corporate profits and the need to ensure that our corporate tax system remains internationally acceptable, competitive and maintains tax neutrality. The implications of such substantial changes are too wide reaching for such decisions to be made without extensive research and deliberation.
- 3.15 The Policy & Resources Committee is therefore proposing that a review be launched to investigate options for ensuring Guernsey's tax base is able to sustainably and fairly raise sufficient revenue to meet the Bailiwick's long-term funding requirements.

3.16 The terms of reference for this review will be as follows:

- To present options for restructuring the tax base so that it has the capacity
 to raise revenues up to the limits of aggregate revenues proposed in the
 Fiscal Policy Framework in a sustainable way within the boundaries of the
 Framework (to be agreed following consideration of this Policy Letter);
- To investigate mechanisms for raising additional revenues including:
 - the taxation of company profits with due regard to the need to maintain a tax system which is competitive, internationally acceptable and maintains tax neutrality⁵;
 - Extension or modification of the existing income tax and Social Security contribution system;
 - A health tax;
 - The addition of general or limited consumption taxes to the tax base:
- To investigate options for the implementation of these measures in such a way as to minimise the economic impact of changes to the tax structure; and
- To provide analysis of the financial, economic and social implications of any options presented.
- 3.17 This review will not consider any form of capital taxes which are considered incompatible with Guernsey's status as a finance centre.
- 3.18 The review will be led by the Policy & Resources Committee with engagement with States Members and Committees in the initial stages of the process to capture their views on potential options and before any final proposals are published. Further detailed engagement with the Committees *for* Employment & Social Security and Health & Social Care will be undertaken in relation to Social Security contributions and health taxes. The process will also include public engagement.
- 3.19 The Policy & Resources Committee will report back to the States on the outcome of the review by no later than June 2021.

⁵ Tax neutrality is important for the continuing operation of the finance sector in Guernsey, enabling Guernsey to competitively facilitate the movement of international capital flows in the absence of the extensive network of double tax agreements available to larger jurisdictions. Tax neutrality ensures that the products and clients of the finance sector are taxed appropriately in the jurisdictions of origin, residence or investment, as appropriate, without any additional tax cost being imposed in Guernsey. Tax neutrality does not generally impede the taxation of profits on the regulated providers of services in the finance sector as is currently the case under the 0/10 regime.

3.20 The work stream will incorporate the resolution made in the debate on Reforming Health Care Funding (Billet d'État X, June 2019) to:

"direct the Policy & Resources Committee in consultation with the Committee for Employment & Social Security to progress the second stage of the work stream, as described in section 10 of this Policy Letter, and review the structure of Social Security contributions collected for the support of health and social care services and ensure that these are appropriate, fair and sustainable, and to consider the prioritisation of this work stream for the new Assembly in the 2021-25 Policy & Resource Plan"

Resource requirements

3.21 Budget has already been allocated to expand the internal analytical capacity of the States and it is believed that the staffing requirements can be met within these resources. Further financial resources may be required to procure independent expert validation of analysis, external analysis where the skills are not available internally, to support the public consultation and to provide a suitable programme of public communications. If necessary, the Policy & Resources Committee will use its delegated authority to make funding of up to £150,000 available from the Budget Reserve.

4. History of the Fiscal Policy Framework

- 4.1 The original Framework was agreed by the States in 2009 (Billet d'État XI, April 2009) and was intended "to underline the credibility of fiscal policy and provide reassurance to taxpayers about the sustainability of future States spending plans". The Framework was presented and agreed in the context of an anticipated deficit following the restructure of the corporate income tax system and proposals laid by the Treasury & Resources Department to borrow in order to finance part of the capital programme. While the States did not issue any debt until 2014, the Framework was adopted in full.
- 4.2 While it has been extended and amended, the basic tenets of the Framework, those of fiscal prudence and control, remain.
- 4.3 The most significant change to the Framework since its inception was an extension to incorporate the Social Security system in 2015 (Billet d'État IV, March 2015) to promote a more co-ordinated approach to raising revenues. This extension formally recognised the role Social Security contributions play in

supporting public services, the flow of money between the Social Security system and General Revenue, and the common impact that contributions and general taxation have on the population. The extension also eliminated the potential for the Social Security system to become a vehicle for revenue raising outside the scope of the Framework. Further minor amendments were made to the Framework within the first Policy & Resource Plan in published 2016 (Billet d'État XXVIII, November 2016).

- 4.4 At the end of 2017, following a review of the methodology used to calculate GDP in Guernsey, undertaken with assistance from the Office of National Statistics, substantial revisions were made to the published GDP figures. Shortly after this, the first phase of work to transition the States Accounts towards the internationally accepted accounting framework, IPSAS, was implemented in 2018 with the publication of the 2017 accounts. This changed the definition of some of the income and expenditure measures reported in the accounts.
- 4.5 With the majority of the criteria outlined in the Framework comprising account data benchmarked against GDP (see section 5), these two changes combined prompted a need to conduct a full review of the Framework.
- 4.6 In addition to considering the Framework in light of the revisions to the data, the review also considers the development of Fiscal Policy in Guernsey over the decade since its first introduction, including clarifying how the Framework operates in the context of the medium term financial planning framework introduced in 2016.
- 4.7 In the 2017 Annual Independent Fiscal Policy Review the authors noted:

"The changes to the Island's GDP and the corresponding effect on the Fiscal Framework's rules... represents an opportunity for the island to re-evaluate its fiscal position, spending levels and core strategies"

5. Framework principles

Principle 1: Guernsey's fiscal policy should operate on a principle of long-term permanent balance.

- This has been the governing principle of the Framework since its introduction and all subsequent principles stem from this. It means that, over the long-term, Guernsey should not spend more money on public services than it receives in revenues. While larger countries can, and sometimes do, run deficits for a sustained period, this can have damaging consequences as amply demonstrated during the sovereign debt crisis with its interlinked banking crisis.
- 5.2 Countries such as Greece and Ireland, which had accumulated a significant amount of government debt, found themselves unable to meet the repayments on that debt when the economic crisis of the late 2000's put their economies into recession. For Guernsey, a micro-economy with a heavy reliance on international trade, this is a particular threat. Short periods of modest deficits may be necessary or unavoidable, but they should be balanced by periods of surplus.
- 5.3 Long-term balance is about more than just balancing the Annual Budget. It is about managing the States' resources in the long-term to ensure fiscal sustainability. This principle will be supported with indicators which monitor:
 - The value of the Core Investment Reserve, recognising that the value of these assets should be increased over time in line with the current policy of targeting one year's revenues as the balance of the Reserve (as approved in the Medium Term Financial Plan 2017-2021).
 - The long-term projections of the Guernsey Insurance Fund and the Guernsey Long Term Care Fund, recognising the planned drawdown of these funds to support demographic change and the aim to maintain these reserves with at least two years of expenditure (as referenced in the Personal Tax, Pensions and Benefits Review (Billet d'État IV, March 2015).

Principle 2: The annual net deficit reported on the General Revenue accounts for any given year should not exceed 15% of revenue income⁶.

- 5.4 This principle sets out the maximum value of any deficit the States might have in any given year. Previously, this criterion has been set relative to GDP but the review concluded that it would be more appropriate to benchmark the size of the deficit against the revenues raised from general taxation². This approach was broadly supported by those States Members who attended the engagement workshops on this review.
- 5.5 This principle is to govern the net deficit, the calculation of which is outlined in table 5.1. Under the revised accounting rules, internal transfers between States' reserves (such as the allocation to the Capital Reserve) are no longer included as expenditure but actual capital spending is included instead. This will eventually be replaced by a measure of depreciation in line with IPSAS.

Table 5.1: Illustration of accounting positions for 2019 accounts

General taxation	+
Committee operating income	+
Misc income	+
Revenue Income	+
Committee expenditure	-
Revenue Expenditure	-
Operating surplus/deficit	+/-
Investment return	+/-
Capital receipts	+
Accrued losses	-
Finance charges	-
Capital spending	-
(to be replaced with depreciation)	
Net Surplus/Deficit	+/-

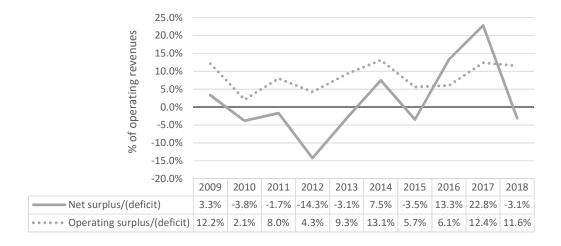
5.6 However, this definition of deficit is subject to some significant volatilities. The first is from the uncertainty of investment returns, which can rise and fall with the movement in financial markets. The second is the inclusion of actual capital spending, which in a jurisdiction of Guernsey's size can vary very significantly from one year to another.

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⁶ This definition excludes revenues from investment return or capital receipts

- 5.7 As the accounting policies progress further towards IPSAS, capital expenditure will be replaced by depreciation in the definition of the net deficit. This should smooth one source of volatility. However, given that the volatility of investment returns will remain, it is proposed that the operating position is also monitored as part of the Framework. This will ensure that any review is able to identify pressures developing within the operational income and expenditure of the States which might be otherwise disguised by movements in investment or capital spend.
- 5.8 The 15% of revenues income proposed is broadly equivalent in monetary terms to the 3% of GDP prior to the revisions. The current monetary value of this is approximately £75m. If the historical time series is restated to be consistent with the proposed definition, the deficit has never breached this level.

Figure 5.1: General Revenue surplus deficits as % of revenue income



Principle 3: Annual net deficits reported in the General Revenue accounts should not be allowed to persist for more than five consecutive years.

- 5.9 This principle recognises that, as well as limiting the size of deficits it is necessary to limit the length of time over which they can persist. Even relatively modest deficits can drain resources if allowed to persist over time.
- 5.10 Like previous versions of the Framework, this principle therefore restricts the maximum permitted length of a deficit to five years. Under the principle of long-term permanent balance, periods of deficit need to be balanced by periods of surplus to replenish reserves.

Principle 4: Measures to address any identified or anticipated deficit must be incorporated in the States Medium Term Financial Plan.

- This might include a combination of reductions in expenditure, revenueraising measures and measures to stimulate growth appropriate to the circumstances of the deficit.
- 5.11 Deficits can differ significantly in their nature and the response to a deficit needs to be tailored to the conditions prevailing at the time. There are numerous different responses to a deficit including cutting spending, raising revenues or stimulating growth (which may conceivably involve increasing spending) and each may be appropriate in different circumstances.
- 5.12 The intention of this principle is to require a formal response to a deficit, without pre-determining the most appropriate response. The principle ties the response to a deficit, actual or anticipated, into the process surrounding the MTFP. The MTFP includes forecasts of the expected financial position over the four-year period it covers and, if a deficit is anticipated, it should put in place appropriate measures to prevent or address it. While the MTFP is only routinely produced once every four years, it can be updated and amended in response to an unanticipated deficit should one arise in the intervening period.

Principle 5: The aggregate amount of States' revenue should not exceed 24% of GDP.

- This includes all forms of taxation from within General Revenue, Social Security contributions and the operating income of committees, but does not include the return on investments.
- 5.13 This principle governs the aggregate size of the public sector in Guernsey. Its intention is to provide a limit on the maximum amount of money it is deemed appropriate to take out of the general economy to be redirected to the provision of public services. With the exclusion of investment income, government revenue is generated from taxes and charges levied on local residents and businesses and Guernsey's status as a low tax jurisdiction is an important part of its competitive position as a finance centre.
- 5.14 In 2019, aggregate income of the States was estimated to be equal to 21.3% of GDP. Aggregate income has been at approximately the same level (between 21.0% and 21.5%) for most of the last twenty years. Only during 2005 and 2006, at the height of the property boom (when document duty receipts were some

- £10m larger in real terms they are expected to be in 2019), were aggregate receipts higher than those forecast for 2020.
- 5.15 The revenue lost in the move to the zero/10 corporate income tax regime in 2008 was largely replaced by the expansion of the Social Security contributions system and other smaller changes made to other taxes and duties since. None of the individual changes made to the tax base since the expansion of the Social Security system, including the increase in the Social Security contribution rate and the withdrawal of allowances for higher earners from 2017, has raised sufficient additional revenue to make a clearly visible difference to the graph presented in figure 5.2 below.

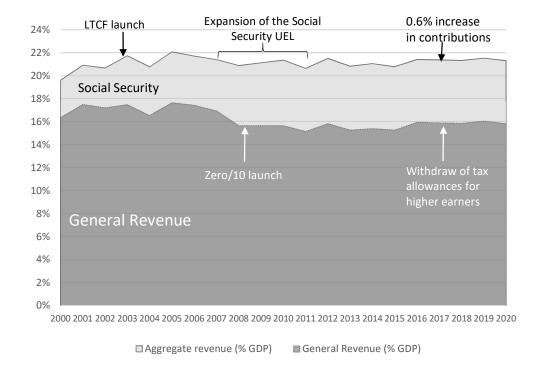


Figure 5.2: Aggregate income (excluding Investment returns) as a percentage of GDP

- 5.16 What has changed over this period is the distribution of revenues between the various taxes and other revenue sources. In 2007 20% of aggregate income was sourced from company income taxes compared to 10% of aggregate income in 2019 (including tax on distributions).
- 5.17 However, the decisions made at the time that zero\10 was introduced significantly increased the contribution from companies from other sources, including employers Social Security contributions and commercial TRP. As a result the *total* value of revenues from the corporate sector has declined in real

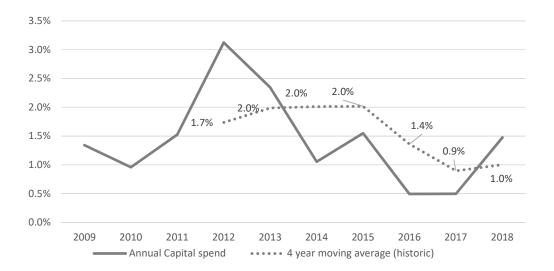
- terms (adjusted for inflation) from £201m in 2006 to £184m in 2019; a real decrease of less than 10%
- 5.18 Over the same period the proportion of revenues gained from Social Security contributions has increased from 21% to 26% as a result of the significant increase in the Upper Earnings Limit and increases in contribution rates. The proportion of funding gained from excise, motor and property taxes has increased from 9% to 13%. A further breakdown of how States revenues are generated is provided in appendix E.
- 5.19 The current aggregate revenues are about 2.7% of GDP (approx. £84m) below the proposed limit. This spare capacity is not designed to encourage additional spending. In the same manner as the previous iteration of the Framework, the limit recognises that Guernsey faces some significant long-term spending pressures as outlined in previous sections.
- 5.20 As described earlier in this Policy Letter, these pressures include those exerted on our pension provision, health and services because of the ageing of the population. The analysis suggests that known pressures will require an increase in aggregate revenues of between £79m and £132m of additional revenues (of which £8m is required to replace lost income) before consideration of measures to reduce spending elsewhere, mitigate the level of expenditure growth or growth the economy. With prudent and cautious management it should be possible to manage these long-term pressures within the recommended 24% of GDP envelope.
- 5.21 At 2019 prices, moving from revenues 21% of GDP to 24% of GDP will take up to £84m out of the economy. This is a substantial increase in the size of the public sector which could have a material impact on consumption levels and economic activity. Broad estimates suggest that an increase in taxation of this magnitude could supress GDP by up to 2%. The increase in the savings rate which is expected to accompany the launch of secondary pensions could reduce GDP by a further 1% (reducing over time as people draw on their pensions). The total negative impact on GDP could be as much as 3%.
- 5.22 While it would be easy to increase the size of the public sector beyond 24%, there is a need to maintain financial discipline and a focus on providing services in an efficient and cost effective manner. Acknowledging that there is a need to increase the size of the public sector should not be seen as a release on expenditure control. The Policy & Resources Committee is of the opinion that

setting a limit on revenues which is challenging but achievable is the best way to deliver this.

- 5.23 Long-term plans must be realistic and it has become clear that it will be necessary to increase revenues towards this limit to meet the demand for services. However, there remains scope for further savings and mitigation of expenditure growth to be achieved in the delivery of public services though Public Service Reform programmes such as the Partnership of Purpose, the Transformation of Education and the transformation of transactional and business support services and this must remain part of the solution. In light of the scale of the expenditure pressures faced by the States, it is more important than ever to continue efforts to deliver necessary services in a cost-effective way.
- 5.24 The States may also need to consider whether there are elements of its service provision that are no longer the best use of the resources dedicated to them. A review of Family Allowance is already underway and the States may wish to consider other areas where it might be possible to redirect resources to more effective areas.
- Principle 6: Capital expenditure over any States term should be maintained at a level which reflects the need for long and medium term investment in infrastructure and direct capital expenditure by the States should average no less than 1.5% of GDP per year averaged over a four year period.
 - This should be identified through the infrastructure plan and the medium term capital plan. The MTFP should ensure sufficient resources are allocated to deliver on these requirements.
 - Direct capital expenditure includes any capital spending supported with recourse to general taxation or reserves.
- 5.25 Previous iterations of the Framework have included a requirement for the States to spend 3% of GDP per annum on capital expenditure. However, in practice a number of difficulties were encountered in effectively monitoring this:
 - Because of the small size of the economy, capital expenditure is very volatile and even maintaining a consistent medium term average is challenging.
 - ii. The definition of capital expenditure was unclear. The Capital Reserve is no longer the only source of capital funding for the States and their

- unincorporated entities: the Belle Greve outfall, for example, was refinanced from the Bond Reserve. Neither was it clear whether investment via the States unincorporated entities, over which the States have full control, should be included within the scope.
- iii. The 3% target was chosen based on "international norms" but, in reality, levels of capital investment vary enormously between countries and the infrastructure needs of a jurisdiction like Guernsey may be substantially different to those of larger economies.
- 5.26 The target has been met in only one year of the ten years since the first edition of the Framework was published. That year was 2012 (see figure 5.3) when there was an exceptionally large amount of development (the Guernsey Airport pavements project and the final stage of the build of the Les Beaucamps High School). Beyond the financial considerations, the management and labour required to sustain this level of development year on year would be incredibly challenging, which suggests the target set was too high to be realistically attainable on a long-term basis. The upward revision of GDP in 2017 amplified this issue.

Figure 5.3: Direct Capital spending as a % of GDP



5.27 The Policy & Resources Committee considered the revision of this criteria at length and concluded that a tightly defined target for capital spend, even at a lower level, was not constructive. The recommendation was instead to formally embed within the Framework the principle that there should be a continual review of the infrastructure needs of the islands within the infrastructure plan and the Medium Term Capital Plan. The MTFP should make available the

resources to meet these needs. This will bring the requirement to continually assess and adequately fund capital development within the scope of the assessment of the States performance against the Framework as discussed in section 5.

- 5.28 Because of the volatile nature of capital spending in Guernsey, one of the functions of the MTFP will be to ensure that enough money is appropriated into the Capital Reserve each year to meet the necessary costs of the capital programme in the medium term and smooth the effect of the "lumpy" in year capital spend on the States cash flow.
- 5.29 However, reflecting on the feedback from the workshops held with States Members, it is also proposed that the principle should include a minimum level of investment which should be financed from General Revenues. The proposed minimum, 1.5% of GDP, will incorporate capital spend financed directly by general taxation (i.e. from the Capital Reserve). This minimum is set slightly higher than the 1.4% achieved in the 10-year period analysed in figure 5.3, and the 1.0% achieved in the last four years. Setting the minimum slightly above that achieved over the last ten years is intended to recognise the under investment in infrastructure over the last three years in particular.

Principle 7: The States' total debt should not exceed 15% of GDP.

- Gross debt can be deployed only to finance the investment in infrastructure or assets.
- Any project or acquisition supported with recourse to government debt must be able to generate sufficient revenue to meet the repayment of that debt.
- The definition of debt includes any direct borrowing and contingent liabilities associated with guaranteeing the borrowing of States trading entities, States owned enterprises and Non-Government Organisations (NGOs)
- Guarantees or assurances offered on the operational cash flow arrangements of the States trading entities and states owned enterprises (for example the guarantee of overdraft facilities) are excluded.
- 5.30 The approach to and practicalities of government debt and the investment in infrastructure has changed significantly since the original iteration of the Framework. This principle broadens the definition of debt and provides greater clarity of what direct government debt might be used for and in doing so recognises the evolution of financial management and the way in which infrastructure development is managed in Guernsey,.

- 5.31 Under this principle government debt can only be used to buy, develop or improve assets which have both a community and commercial value.
- 5.32 It also allows for the fact that these assets may not necessarily be directly owned by government. The States have increasingly sought to place revenue generating services in a more commercial context. For instance, Guernsey Water is operated as a trading entity, managed and operated on a commercial basis at arm's length from government. The Belle Greve outfall, which is a key part of the waste water disposal infrastructure, was refinanced from the Bond issue in 2014 recognising that, as a revenue generating long-term asset, this was a more appropriate source of financing than the Capital Reserve.
- 5.33 The principle as now drafted also places a clearer and tighter restriction that projects funded by debt must be able to generate sufficient revenue to service their share of that debt.
- 5.34 As well as the issue of external debt in 2015 the States act as a guarantor or otherwise provided surety for debt held by a number of States associated entities and NGOs, including Cabernet Ltd (the company which owns Aurigny Airlines) and the Guernsey Housing Association. Recognising that the States' hold ultimate liability for these debts and that these entities are investing in assets which have value to the community, this principle has been expanded so that the limit on borrowing encapsulates these contingent liabilities.
- 5.35 The States also offer surety on some of the short-term cash flow arrangements for these associated entities. For example the States offer surety on behalf of Aurigny to Barclaycard regarding unflown flights. These are short term financing arrangements required for the day to day operations of these entities and do not represent long-term debt or investment in assets. They are therefore excluded from this definition.
- 5.36 This addresses concerns raised in the review of the bond issue commissioned by the Scrutiny Management Committee in 2017 (States Bond Issue, KPMG) regarding the clarity of the definition of borrowing used in the Fiscal Policy Framework.
- 5.37 The level of direct debt and contingent liabilities which would be captured by this definition are detailed below. The figure states the maximum liability possible for these agreements.

Table 5.2: Maximum liability for current loans and contingent liabilities

Direct liabilities	£m	% GDP
States of Guernsey Bond	330	
Captured Indirect and contingent liabilities		
Cabernet limited (pending loan for aircraft		
purchase guarantee maximum value)	51	
Guernsey Housing association (letter of		
comfort re revolving credit facility, maximum)	15	
Total	£396	13.0%

6. Relationship with the MTFP and Annual Budgets

- 6.1 The Framework sets high level, long-term fiscal policy and is intended to define the boundaries within which more detailed and shorter-term policies should operate.
- 6.2 Policies which need to be more adaptable to the prevailing circumstances, requiring more frequent revision, should be set within the more detailed, shorter term policy vehicles. For example, the detailed response to a period of economic stress should be defined within the MTFP and implemented through the Annual Budget.
- 6.3 The States more detailed fiscal policy setting vehicles, the MTFP, the Medium Term Capital Plan (MTCP), the Annual Budget and the Annual Benefit and Contribution Rates Report, should operate subject to the principles of the Framework. These fiscal policy vehicles are intended to work cohesively, setting progressively more detailed policy covering progressively shorter time frames.
- 6.4 This structure is designed to ensure continuity and certainty in the application of long-term fiscal policy, while retaining the flexibility to adjust to conditions as they arise within the boundaries set. This provides some assurance to islanders about Guernsey's commitment to fiscal prudence, while retaining the freedom for each States to pursue more detailed objectives about how this is achieved.

Figure 6.1: Hierarchy of fiscal policy formation

Fiscal Policy Framework

Long term policy setting principles to be upheld across multiple States terms

Medium Term Financial Plan & Medium Term Capital Plan

Medium term policy setting fiscal and capital investment objectives for one States term

Annual Budget and
Benefit and
Contribution
Rates

- 6.5 For example, the Framework sets a limit on aggregate income. The 2020 MTFP will incorporate the States agreed policy objectives and present a plan to make sufficient resources available in the medium term within the principles of the framework to begin delivering these. The 2021 and subsequent Annual Budgets will begin the implementation this plan.
- 6.6 The Framework will equally apply in relation to the Annual Benefit and Contribution Rates reports laid by the Committee *for* Employment & Social Security. For example, the Committee *for* Employment & Social Security has active work streams investigating policy surrounding the States' Pension and the Long-Term Care scheme, both of which have been highlighted as potentially requiring an increase in revenues to sustain them. Any proposals to increase contribution rates to fund these will need to take the limitation on aggregate income into consideration.
- 6.7 The next and subsequent MTFPs will need to consider the medium term impact of the policies discussed in this policy letter to ensure that implementation is managed and co-ordinated within the available resources. The proposed review of revenues is not due to return to the States until mid-2021 and implementation of revenue raising measures could take a substantial amount of time. Neither

- should the raising of significant revenues be implemented at a speed unnecessarily detrimental to the economy.
- 6.8 This means that sustainable funding for these policies may not be immediately available to fund all "in principle" decisions made by the States on these policy areas. There will need to be a managed and co-ordinated programme of prioritisation and implementation of both revenue and expenditure aspects and the input from all committees will be required achieve this.

7. Reviewing compliance with the Framework

- 7.1 Prior to the restatement of GDP at the close of 2017, Guernsey's performance against the Framework was subject to an annual external review. This added a level of assurance and credibility to the Framework and provided an opportunity for external assessment of the fiscal and economic risks Guernsey faces. However, at a strategic level, economic and fiscal risks typically change slowly and as a result such annual reviews can become repetitive and lose value over time.
- 7.2 The annual review process is also costly in both financial and staff resources. The last annual review cost £45,000 and managing and co-ordinating the process and providing the necessary information required an estimated 150 hours of staff time.
- 7.3 Compliance with the specific criteria of the Framework is straightforward to assess, requiring only the extraction of the relevant information from the Accounts. It is therefore proposed that this be incorporated into the Annual Budget. This would ensure the metrics to assess performance against the Framework would be available on an annual basis.
- 7.4 Areas where the States have diverged from the Framework will be clearly identified and the reasons for the divergence explained.
- 7.5 A periodic external review is proposed to fulfil the more detailed and nuanced role, including more subjective analysis. This review, which will be conducted every four years at the outset of the new political term. It will be timed for publication shortly after the election of a new States, to help inform the production of the MTFP for the next four years which will govern States fiscal policy making for that term.
- 7.6 It is proposed that the first review in the new format should take place in 2020 and that it should be timed so that it might help inform the debate on the next

MTFP. It is also proposed that the terms of reference be extended to incorporate assessment of the delivery of the 2017-2021 MTFP. External reviewers will be tasked with:

- Assessing compliance with the principles of the Fiscal Policy Framework
- To identify short, medium- and long-term threats to compliance with the Fiscal Framework:
- To assess performance of recent finances against the objectives of the current MTFP;
- To identify risks and issues which should be addressed in the subsequent MTFP;
- Identify any structural change which may suggest that review of the Framework may be necessary.
- 7.7 Conducting an annual review is estimated to cost £180,000 over a four year period. It is estimated that the more detailed review, conducted once every four years, would cost £70,000, representing a saving to General Revenue of £110,000 over a four year period.
- 7.8 Should an economic or fiscal shock make a significant impact on the States' ability to operate within the principles of the Framework outside of this timetable, provision could be made for an ad-hoc review.

8. Consultation and engagement

- 8.1 A series of workshops were organised for States Members to discuss provisional propositions through March 2019. All members were invited and, excluding members of the Policy and Resources Committee, 23 States Members and Alderney Representatives attended across five sessions.
- 8.2 Members were given a presentation of draft proposals and given the opportunity to provide feedback. This feedback was used to further refine the principles contained within this policy letter.
- 8.3 Officers have also engaged with the authors of previous Annual Independent Fiscal Policy Reviews for advice and feedback on draft proposals. This feedback has also been incorporated in to this policy letter.

9. Compliance with Rule 4

9.1 Rule 4 of the Rules of Procedure of the States of Deliberation and their Committees sets out the information which must be included in, or appended to, motions laid before the States.

9.2 In accordance with Rule 4(1), the Propositions have been submitted to Her Majesty's Procureur for advice on any legal or constitutional implications. She has advised that there is no reason in law why the Propositions should not to be put into effect.

9.3 In accordance with Rule 4(3), the Propositions are not requesting the States to approve funding but the Policy & Resources Committee will use its delegated authority to make funding of up to £150,000 available from the Budget Reserve to undertake the review.

9.4 In accordance with Rule 4(4) of the Rules of Procedure of the States of Deliberation and their Committees, it is confirmed that the propositions have the unanimous support of the Committee.

9.5 In accordance with Rule 4(5), the Propositions relate to the duties of the Committee to advise the States and to promote and facilitate cross-committee policy development and to develop policies relating to fiscal policy and the financial resources of the States.

Yours faithfully

G A St Pier President

L S Trott Vice-President

A H Brouard
J P Le Tocq
T J Stephens

APPENDIX A: TAX LIABILITY AND THE COST OF SERVICE PROVISION

Individuals in the local community pay a proportion of their gross income in taxes and contributions and also pay other taxes and duties. These in turn are used to pay for public services and benefits including schools, hospitals, roads, police and fire services, contributory and universal benefits.

This appendix is intended to illustrate the extent of the taxes an individual might be expected to pay both on an annual and lifetime basis.

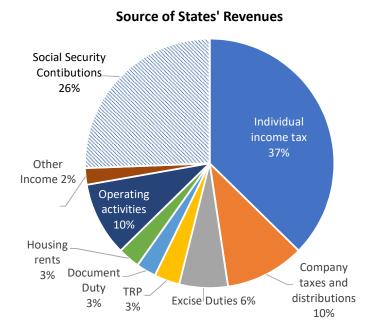
It also illustrates the average value of services consumed by households.

The analysis has been simplified given that tax liabilities and service use can vary hugely depending on personal circumstances.

REVENUES RAISED

The government collects approximately £700million in revenues (or 21% of GDP) each year including income tax, Social Security contributions and other taxes and duties. Approximately 63% of this revenue is generated from income taxes and contributions that are charged against people's income made up of 37% from income tax and 26% from Social Security contributions (including contributions paid by employers).

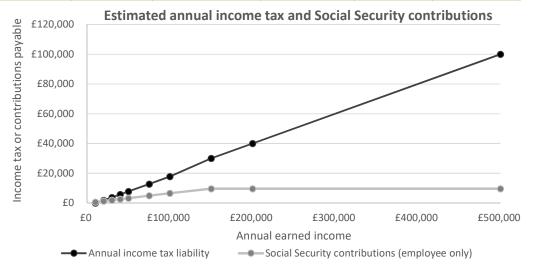
The remaining income is generated from a variety of sources. 10% is generated from income taxes charged on company profits (compared to 7% in the UK) and on the distribution of profits and 6% from excise duties. TRP and document duty each comprise 3% of total revenues as summarised in the chart below:



Guernsey's tax take is unusually small relative to the size of the economy. Guernsey collects aggregate revenues (excluding investment return) of 21% of its GDP. Jersey collects revenues equal to 26%⁷ of their GDP while the UK collects 38%.

The table and chart following show the total amount of income tax and Social Security contributions a single individual might pay in the course of a year depending on their level of income. The estimates assume an individual receives their income from employment, are under the States' pension age and entitled to only the basic personal tax allowance. In practice, many people are entitled to other allowances such as relief on mortgage interest or pension contributions which would reduce their tax liability.

Individual annual income	Annual income tax liability	Social Security contributions (employee only)	Other taxes	Estimated total taxes paid	% of gross income
£10,000	£0	£660	£770	£1,430	14%
£20,000	£1,800	£1,320	£770	£3,890	19%
£30,000	£3,800	£1,980	£780	£6,560	22%
Median Earnings					
(£33,600)	£4,500	£2,200	£790	£7,490	22%
£40,000	£5,800	£2,640	£800	£9,240	23%
£50,000	£7,800	£3,300	£820	£11,920	24%
£75,000	£12,800	£4,950	£875	£18,625	25%
£100,000	£17,800	£6,600	£930	£25,330	25%
£150,000	£30,000	£9,658	£970	£40,628	27%
£200,000	£40,000	£9,658	£1050	£50,708	25%
£500,000	£100,000	£9,658	£1,200	£110,858	22%



⁷ Calculated from published consolidated revenues and published GDP for 2018 available at www.gov.je

Over the course of a lifetime annual payments can total a very significant amount.

Example 1:

A low income working couple who each enter the workforce in jobs paying below the median for their age group. One member of the couple leaves the workforce to care for the couple's two children for a period of ten years, returning to work part time when their youngest child begins school and increasing their working hours over time. Their combined gross household income before benefits peaks at about £40,000.

If we assume both members of the couple live to average life expectancy, between them a couple in these circumstances might pay in the region of £260,000 in income taxes, social insurance contributions and other taxes over their lifetime.

Example 2:

A similar couple with a shorter break from the workforce and an income closer to the median household income, peaking at around £55,000, would be expected to pay in the region of £440,000 over the course of their lifetime.

Example 3:

A couple in more affluent circumstances peaking at a gross household income of £100,000, might have a total lifetime contribution in terms of taxes and contributions of £920,000.

Example 4:

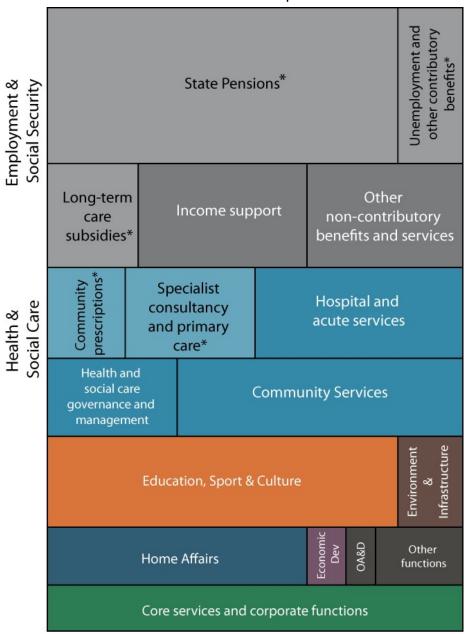
A very high income couple, with a joint income peaking at around £750,000 could make a total lifetime contribution of as much as £5,000,000 if they were resident in Guernsey for their whole working life.

SERVICE PROVISION

The revenues collected through taxes and duties is used to provide the community with public services. The diagram overleaf shows how the money collected from the community is spent each year, with the size of each box proportional to the annual spend in that area.

In total, 38% of the total amount of money spent on services each year is on Social Security benefits of which the largest item (more than £120m in 2019) is the payment of pensions. 21% of total spending is dedicated to health and social care services. This means that in total almost 60% of States' expenditure is in areas that are highly sensitive to the ageing of the population.

Distribution of States' expenditure



^{*} These benefits and services are funded from the Social Security System and are not directly funded from general revenue OA&D = Overseas Aid & Development

The table below provides estimates of the cost of providing some public services on an annual basis, both *per capita* for entire service areas and the unitary cost of specific services:

Health and Social Care services (including long term	
care)	
Total per capita cost per annum	£3,000
One year of nursing care subsidies	£44,200
One year of residential care subsidies	£23,700
One year of insulin prescriptions	£1,300
One year prescription of a rare cancer drug	£530,000
Heart transplant ⁸	Up to £140,000
Standard knee replacement surgery (provided off island)	£7,300-£8,800
Complex knee or hip operation ⁸	Up to £20,000
Pace maker implant ⁸	£4,500
Average cost of oncology day care case 8	£1,176
Average cost of other day care case 8	£955
Cost per day of a neonatal intensive care bed 8	£3,500
Average subsidy on a prescription	£9.31
Education services	
Total cost per capita per annum	£1,100
One year of primary education per pupil ⁹	£4,800-£6,300
One year of secondary education per pupil ⁹	£8,100-£8,900
One year grant to Student at university in South of	£14,000
England on a standard course at high level of subsidy ¹⁰	
Pensions and contributory benefits	
Total per capita cost of pensions and contributory	£2,300
benefits	
One year's state pension at full rate	£11,300
One year of severe disability benefit	£5,532
Average death grant	£565

⁸ Partnership of Purpose (*Billet d'État XXIV, December 2017*)

⁹ States costing and benchmarking report, BDO, May 2017

 $^{^{10}}$ Committee for Education, Sport & Culture guidance for students

Universal benefits (including legal aid)	
Total per capita cost of all universal benefits	£900
Family allowance for a family with two children for one	£1,500
year	
Average annual cost of an income support claim for a pensioner household	£7,400
Average annual cost of an income support claim for a	£12,700
working family	
Law and order	
Total <i>per capita</i> cost of policing, fire and rescue, prison, probation and border services	£400
Cost of prison services per prisoner 8	£45,000
Border costs per passenger ⁸	£2.25
Average cost of a fire and rescue service call out	£3,600

Across the course of a person's life time they may benefit from a significant level of public services. Some of these, like education provision, they might benefit from directly. Others, like the provision of law and order provide a more indirect benefit to the community as a whole.

The analysis overleaf outlines the direct services an average couple with two children might be expected to utilise across their lifetime. This assumes that they attend school on the island to the age of 18, require a fairly typical amount of health care and require, between them, approximately five years of long-term care services.

Some of the most costly services provided are used by only a very small minority of households. Such services include the provision of care and support services for very vulnerable children, treatment of rare or complex health conditions or off island placements for individuals with complex long-term care needs. Lifetime costs for households requiring such services could significantly exceed the upper estimates presented.

Estimate lifetime direct service costs of a couple with two children

Estimated cost of education: £190,000
Estimated receipt of family allowance for 2 children: £27,000
Estimate cost of free pre-school: £7,000
Estimated health care costs¹¹: £200,000-£600,000
Estimated long-term care costs: £150,000
Estimated pension receipt: £261,000
Estimated total cost of direct services: £835,000 - £1,235,000

Households are also able to access financial support for periods of their life when their income is insufficient to meet their needs. A low income working family, who require an income support top-up to their income while their children are living at home, and again in their retirement, might claim an estimated £430,000 across their lifetime.

A household closer to the median might be expected to claim for periods when their income might be restricted. For example they may need assistance while they have young children, if one member of the household were to find themselves temporarily unemployed or to support them during retirement if they have insufficient savings or if they need to continue paying rent after they retire. A median income household such as that described earlier might claim in the region of £150,000 of financial support during their lifetime.

¹¹ These are very broad estimates derived from aggregate accounting data cross checked against estimates made in other jurisdictions. Insufficient data is available to make accurate estimates of lifetime healthcare cost in Guernsey.

APPENDIX B: COMPARISON OF REVENUES WITH OECD COUNTRIES

Guernsey currently raises aggregate revenues, excluding investment return equal to 21.3% of its GDP. The analysis presented below details how this compares to OECD jurisdictions (with the addition of Jersey). Guernsey has a high level of GDP per capita and does not need to provide national defence services which make it more practical to sustain a relatively low level of revenues relative to GDP. A low level of revenues relative to GDP provides a competitive advantage in competing for international business which in turn enables Guernsey to sustain its high level of GDP per capita. Countries that collect high levels of revenues for their economy, such as France and Denmark, typically offer a more comprehensive range of public services than those with a smaller tax base.

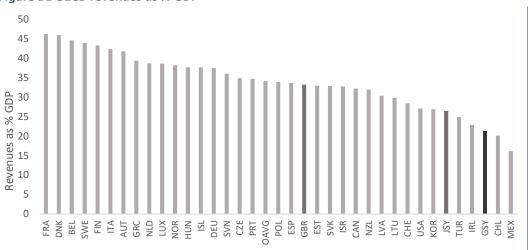


Figure B1 OECD revenues as % GDP

Jurisdiction	Revenues as % GDP	Jurisdiction	Revenues as % GDP	Jurisdiction	Revenues as % GDP
FRA ¹²	46.2	DEU	37.5	NZL	32.0
DNK	46.0	SVN	36.0	LVA	30.4
BEL	44.6	CZE	34.9	LTU	29.8
SWE	44.0	PRT	34.7	CHE	28.5
FIN	43.3	OAVG	34.2	USA	27.1
ITA	42.4	POL	33.9	KOR	26.9
AUT	41.8	ESP	33.7	JSY	26.5
GRC	39.4	GBR	33.3	TUR	24.9
NLD	38.8	EST	33.0	IRL	22.8
LUX	38.7	SVK	32.9	GSY	21.3
NOR	38.2	ISR	32.7	CHL	20.2
HUN	37.7	CAN	32.2	MEX	16.2
ISL	37.7				

 $^{^{12}}$ Data source: https://data.oecd.org/tax/tax-revenue.htm. Note that the data source for this data is different to that used in the 2020 budget and that figures may vary

APPENDIX C: ESTIMATED REVENUES RAISED BY TAX MEASURES

This appendix provides provisional estimates of the indicative amount of revenue that might be raised from various measures. Whilst some allowance has been made for the dynamic effects they would have on the economy, significantly more work is required before these can be presented as formal options for raising revenues.

These estimates do not take into account any of the complex cross relationships between various forms of taxation and government spending. For example, in increase in the income tax rate would reduce the capacity to raise revenues from a consumption tax; and increases in tax rates and Social Security contributions place an upward pressure on income support costs.

Headline income tax rates

Income	Additional
Tax	Revenues
Rate	£m
20.5%	6.8
21.0%	13.5
21.5%	20.3
22.0%	27.1
23.0%	40.0
24.0%	53.0
25.0%	66.0
26.0%	79.6
27.0%	93.2

Domestic and commercial TRP rates

Commercial and Domestic TRP rates	
(increase)	£m
50%	12.7
100%	25.3
150%	38.0
200%	50.7
250%	63.3
300%	76.0
350%	88.7
400%	101.3

Withdrawal of personal allowances

The state of personal another section of the state of the	
Keeping threshold at £100,000, reducing ratio to 1:4	£600,000
Marginal rate (employed): 31.6 % (self-employed): 36 %	
Keeping threshold at £100,000, reducing ratio to 1:3	£1.4m
Marginal rate (employed): 33.3% (self-employed): 37.7%	
Keeping threshold at £100,000, reducing ratio to 1:2	£2.3m
Marginal rate (employed): 36.6% (self-employed): 41%	
Reducing threshold to £90,000, keeping ratio at 1:5	£900,000
Marginal rate (employed): 30.6 %	Additional taxpayers
Marginal rate (self-employed): 35%	subject to WOPA: 400
Reducing threshold to £90,000, reducing ratio to 1:4	£1.6m
Marginal rate (employed): 31.6 % (self-employed): 36 %	
Reducing threshold to £90,000, reducing ratio to 1:3	£2.5m
Marginal rate (employed): 33.3 % (self-employed): 37.7 %	
Reducing threshold to £90,000, reducing ratio to 1:2	£3.6m
Marginal rate (employed): 36.6 % (self-employed): 41 %	
Reducing threshold to £80,000, keeping ratio at 1:5	£2m
Marginal rate (employed): 30.6 %	Additional taxpayers
Marginal rate (self-employed): 35%	subject to WOPA: 1,000
Reducing threshold to £80,000, reducing ratio to 1:4	£2.9m
Marginal rate (employed): 31.6% (self-employed): 36%	
Reducing threshold to £80,000, reducing ratio to 1:3	£4m
Marginal rate (employed): 33.3% (self-employed): 37.7%	
Reducing threshold to £80,000, reducing ratio to 1:2	£5.2m
Marginal rate (employed): 36.6 % (self-employed): 41 %	

Broad based GST (based on work completed in 2014)

GST rate	Revenue raised (£m)
3%	30
4%	41
5%	51
6%	61
7%	71
8%	81
9%	92
10%	102

Higher personal income tax rate

Income		Additional	Number
Tax	Threshold	Revenues	Taxpayers
Rate	£	£m	Affected
25%	50,000	20.0	8,600
30%	50,000	40.0	8,600
35%	50,000	60.0	8,600
40%	50,000	80.0	8,600
45%	50,000	100.0	8,600
50%	50,000	120.0	8,600
25%	75,000	13.6	4,100
30%	75,000	27.2	4,100
35%	75,000	40.8	4,100
40%	75,000	54.4	4,100
45%	75,000	68.0	4,100
50%	75,000	81.6	4,100
25%	100,000	10.6	2,500
30%	100,000	21.3	2,500
35%	100,000	31.9	2,500
40%	100,000	42.5	2,500
45%	100,000	53.1	2,500
50%	100,000	63.7	2,500
25%	150,000	7.2	1,200
30%	150,000	14.5	1,200
35%	150,000	21.7	1,200
40%	150,000	28.9	1,200
45%	150,000	36.1	1,200
50%	150,000	43.3	1,200
25%	200,000	5.5	700
30%	200,000	11.1	700
35%	200,000	16.6	700
40%	200,000	22.1	700
45%	200,000	27.6	700
50%	200,000	33.1	700

APPENDIX D: TIMELINE OF REVENUE RAISING CHANGES TO THE TAX BASE AND OTHER EVENTS

Corporate taxes, commercial TRP and employer social security contributions		Personal income tax, employee and self- employed social security contributions and domestic TRP and excise duties
Zero/10 approved (Billet d'État XI, June 2006)	2006	Personal allowances frozenAbove inflation increases in excise duties
 Employers upper earnings limit increased for £36k to £54k 100% increase in commercial TRV (Tax on Rateable Value) (replaced with TRP in 2008) 	2007	 Personal allowances frozen Above inflation increases in excise duties including 20% increase on alcohol Above inflation increase in domestic TRV Employee/ self-employed upper earnings limit increased for £36k to £54k
 Zero/10 introduced (0% standard rate, 10% applied to banking activity, 20% applied to CICRA regulated entities and ownership of buildings) Employer contribution rates increased by 1.0% Upper earnings limit for employers contributions increased to £108k 100% increase in commercial TRP on commercial properties and 400% increase on TRP on regulated finance and land approved for development. 	2008	 Personal allowances frozen Above inflation increases in excise duties including 20% increase on alcohol Replacement of TRV with TRP Employee/ self-employed upper earnings limit increased to £65k
50% increase in TRP for regulated finance	2009	 Above inflation increases in excise duties Employee/ self-employed upper earnings limit increased to £80k
Above inflation increases in commercial TRP	2010	 Above inflation increases in excise duties Above inflation increases in domestic TRP Employee/ self-employed upper earnings limit increased to £92k
	2011	 Personal allowances frozen Above inflation increases in domestic TRP Employee/ self-employed upper earnings limit increased to £105k

Corporate taxes, commercial TRP and employer social security contributions		Personal income tax, employee and self- employed social security contributions and domestic TRP and excise duties
	2012	 Above inflation increases in excise duties Above inflation increases in domestic TRP Employee/ self-employed upper earnings limit increased to £120k
 10% rate extended to provision of fiduciary services, domestic insurance business, insurance manager and insurance intermediary business Deemed distribution regime repealed 	2013	 Above inflation increases in excise duties Employee/ self-employed upper earnings limit increased to £132k (completing alignment with employers limit increased by inflation since 2008)
FATCA and the UK Intergovernmental agreement introduced	2014	 Above inflation increases in excise duties Above inflation increases in domestic TRP
 10% rate extended to provision of fund administration services Exempt application fee doubled from £600 to £1,200 Above inflation increase in commercial TRP (lower increase applied to retail) 	2015	 Personal allowances frozen Above inflation increases in domestic TRP
 10% rate extended to provision of custody services 20% rate extended to the importation and/or supply of hydrocarbon oil or gas in Guernsey and to large retail business (taxable profit of more than £500,000) Above inflation increase in commercial TRP (excluding retail) Guernsey joined the BEPS Inclusive Framework in June 2016 introducing country by country reporting (a minimum standard) Guernsey adopted the Common Reporting Standard on Automatic Exchange of Information 	2016	 Personal allowance frozen Above inflation increases in domestic TRP Above inflation increases in excise duties Reduction in mortgage interest relief

Corporate taxes, commercial TRP and employer social security contributions		Personal income tax, employee and self- employed social security contributions and domestic TRP and excise duties
 Above inflation increase in commercial TRP 0.1% increase in employer contribution rates Introduction of Exchange of Tax Rulings (BEPS minimum standard) 	2017	 Age related tax allowance reduced to balance real increase in personal tax allowance Above inflation increases in Domestic TRP Above inflation increases in excise duties Withdrawal of personal allowances from higher earners 0.6% increase in employee contribution rates 0.5% increase in self-employed and non-employed contribution rates Reduction in mortgage interest relief
 10% rate extended to provision of investment manager services (except where those services are provided to Common Investment Vehicles) Introduction of higher TRP rate for legal services Above inflation increase in commercial TRP 	2018	 Age related tax allowance reduced to balance real increase in personal tax allowance Above inflation increases in domestic TRP Withdrawal of other allowances from higher earners Reduction in mortgage interest relief
 10% rate extended to income from operating an investment exchange and income from compliance and other related activities provided to regulated financial services business Introduction of a higher commercial TRP rate for accountancy services and non-regulated financial services Introduction of economic substance requirements 	2019	 Age related tax allowance reduced to balance real increase in personal tax allowance Real increases in domestic TRP Introduction of progressive domestic TRP (for properties with TRP value >500) Reduction in threshold and rate of withdrawal of allowances from higher earners Reduction in mortgage interest relief Increase in tax caps to restore real value

Corporate taxes, commercial TRP and employer social security contributions		Personal income tax, employee and self- employed social security contributions and domestic TRP and excise duties
 10% rate extended to income from the activity of operating an aircraft registry 20% rate extended to income from the licensed activity of cultivation/use of cannabis plants Commence phased process to align commercial TRP for all office accommodation with rates charged on regulated finance activity. 	2020	 Real increase in personal tax allowance and Age related tax allowance removed Above inflation increases in excise duties Real increases in domestic TRP Continuation of introduction of progressive domestic TRP (for properties between TRP values of 200 and 499) Reduction in mortgage interest relief

APPENDIX E: HISTORY OF REVENUES IN GUERNSEY

This appendix details how revenues in Guernsey have changed between 2006 and 2019. The data shows the extent to which the distribution of Guernsey's tax base has changed and demonstrates the relative scale and volatility of various income streams.

Aggregate revenues have remained broadly constant relative to GDP for almost 20 years. The loss of revenue incurred at the introduction of zero/10 in 2008 have been recovered from other income sources. However, there has been a significant shift in the underlying distribution of States' revenues.

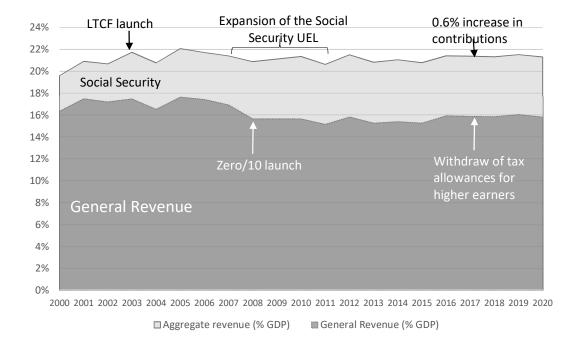


Figure E1: Aggregate income (excluding Investment returns) as a percentage of GDP

The most evident change is in the degree of reliance placed on taxes on corporate profits (including distributions). In 2007, 23% of Guernsey's aggregate revenue was from corporate income taxes, reducing to 11% in 2008 after the introduction of zero/10 and to 10% by 2019 (see table E4). It should be noted that the expansion of the employer Social Security contributions and significant increases in commercial TRP mean that the reduction in the total contribution from the corporate sector is smaller; falling from 31% in 2006¹³ to 26% in 2019. Expressed in 2019 prices, the total revenue from the corporate sector has fallen from £201m in 2006 to £184m in 2019; a real decrease across this period of less than 10%.

¹³ Changes to the Social Security system were commenced a year ahead of the move to zero/10

As a revenue stream, taxes on company profits are highly volatile. Year by year, shifts in the annual revenues gained from corporate taxes in excess of 10% in either direction are not unusual (see table E3). These revenues are very sensitive to economic conditions and in periods of strong growth they tend to rise sharply, but fall again in times of economic stress.

The lower reliance on company taxes within the current tax base has undoubtedly reduced the overall volatility of revenues making these more stable and predictable. However, it has also weakened the link between Government revenues and GDP growth on a year by year basis.

To recover the lost revenues the States have increased reliance on other sources of revenues, primarily through the expansion of the Social Security system. Social Security contributions from employers increased in real terms by 33% between 2007 and 2008 as a result of a substantial increase in the upper earning limit applied and a 1.0% increase in the contribution rate for employers with effect from January 2008 (States' Economic and Taxation Strategy 2006, Billet d'État XI, June 2006).

Contributions for other classes were also increased over a five year period by way of a matching increase in the upper earnings limit. A further increase in the contribution rate to meet various policy objectives was applied from January 2017 (Billet d'État XXVII, November 2016) (see appendix D). As a result the total amount of money collected from the contributions system has increased in real terms from £131m (at 2019 prices) in 2006 to £184m in 2019 – a cumulative real increase of 40.5%.

As a result of these changes the reliance on Social Security contributions has increased from 20.3% of aggregate revenues in 2007 to 25.5% in 2019. Combined with revenues from the personal income tax system, this mean that Guernsey has an unusually high reliance on taxes charged against income (which includes employer's Social Security contributions). In 2019 Guernsey, 63% of Guernsey's revenues were gained from the personal income tax and Social Security contributions compared to 56% in 2007. This has reduced slightly from its peak of 65% in 2015¹⁴ as a result of the expansion of other revenue streams. These revenues are subject to cyclical variation, but tend to be more stable in nature than taxes charged on company profits.

Elsewhere the States has seen significant shifts in revenues over this period as a result of changes in the housing market. Nominal receipts of document duty in 2007 at the

¹⁴ This figure is lower than that which was quoted in the 2015 Personal Tax, Pensions and Benefits review because States accounting practices now include gross rental income from the social housing stock (as opposed to income net of rent rebates) and operating income attributable to the funds earmarked within the General Reserve as revenues.

height of the housing boom totalled £26.4m (or £32.5m at 2019 prices). The following year these had fallen to only £15.4m, reducing government revenues by £11m in one year. As an indication of scale this loss of revenue was equal to approximately 20% of the fall in corporate tax revenues between 2007 and 2008 and approximately 67% of the revenue recouped from employer's contributions as described above. The contraction of the housing market and the loss of document duty receipts has therefore played a more significant role in the changes in the States fiscal position than has been widely recognised.

The housing market has yet to recover to its peak level of activity. Between 2014 and 2016 document duty receipts were, in real terms, less than half their peak value and while receipts increased in both 2017 and 2018 they are at only 55% of their peak. The portion of aggregate revenues derived from document duties has fallen from 5.2% in 2007 to 2.4% in 2019.

TRP is one of the most stable and easily forecast revenue streams in the profile of aggregate revenues since it is less subject to cyclical economic factors. As has been widely discussed TRP on both commercial and domestic properties has been increased significantly. Substantial increase to commercial TRP were made between 2007 and 2008 and increases in both commercial and domestic TRP rates have been applied since. As a result TRP's contribution to the aggregate States revenues has increased in real terms by £17.5m in real terms between 2007 and 2019. However, despite its prominence in debate it represents only 3.5% of aggregate revenues in 2019.

Revenues from excise (including motor tax prior to 2008) have also increased. Increases relate to measures applied both to raise additional revenues and those explicitly applied in order to discourage damaging behaviours (for example the increase in taxes on tobacco products in line with the recommendations of the tobacco strategy). The nature of these taxes is that consumers tend (and in some cases are specifically intended to) change their behaviour to avoid the tax. As such that their capacity to raise significant revenues is limited. Raising rates significantly typically has the effect of reducing the demand for the taxed goods, so they become self-defeating if applied for the purpose of raising revenues to any extent.

Table E1: Revenues by source at current prices (nominal £m)¹⁵

Table Li. Nevendes by	500.00		pcco	1	<u> </u>									
	2006	2007	2008	2009	2010	2011	2012	2013	2014	2015	2016	2017	2018	2019
Individual income taxes	160.7	178.4	218.1	209.1	204.8	218.1	227.5	227.1	236.8	238.4	245.8	253.8	260.8	272.5
Company taxes	109.4	118.0	59.2	64.2	52.8	51.9	53.4	54.5	61.3	51.6	56.9	70.3	71.7	69.8
Excise and motor taxes	19.8	22.7	28.0	29.2	31.9	33.2	35.1	35.5	36.8	37.5	41.8	42.2	45.2	45.9
Document duty	20.8	26.4	15.4	13.9	17.8	17.1	17.1	15.5	13.1	12.3	12.7	17.0	17.6	17.0
TRP/TRV	6.3	6.2	10.5	12.7	13.9	14.9	16.0	16.3	17.2	19.0	20.0	20.7	22.9	25.1
Misc revenue ¹⁶	23.7	27.8	29.1	28.2	26.2	28.7	31.0	30.5	30.6	35.1	35.6	34.6	34.2	39.0
Operating income ¹⁷	37.2	38.8	42.0	44.3	48.3	51.2	51.0	52.5	50.0	54.4	55.1	60.9	66.5	67.9
SS Contributions Employer	37.7	43.4	59.8	61.7	63.0	65.1	66.5	67.1	69.3	68.1	70.8	73.6	76.4	78.7
SS Contributions Employee	40.6	47.3	52.2	54.0	55.9	58.5	60.3	61.3	63.6	62.5	64.9	73.1	75.7	77.9
SS Contributions Self- employed	8.4	10.5	11.2	11.5	12.4	13.3	14.0	14.5	15.8	16.0	15.9	16.3	16.8	17.3
SS contributions Non- employed	4.3	5.3	6.1	6.8	6.9	7.1	7.5	7.9	8.5	8.7	8.5	9.5	9.9	10.2
Total	468.8	524.8	531.6	535.6	533.9	559.1	579.3	582.7	602.9	603.5	628.1	671.9	697.7	721.4

¹⁵ These represent actual monetary values presented in a given year

¹⁶ Misc income was restated in the 2017 account to incorporate gross housing income. Gross housing rents were not recorded in the accounts prior to 2016. For 2007 to 2015 this value has been inferred from historic series

¹⁷ Operating income was amended in the 2017 accounts to include income generated on accounts held within the general reserve. Prior to 2006 the value of this has been inferred

Table E2: Revenues by source at constant 2019 prices (real £m)¹⁸

Table Ez. Revellues by S	ource at	Consta	110 2013	prices (i	Cai Liii)				ı			ı		
	2006	2007	2008	2009	2010	2011	2012	2013	2014	2015	2016	2017	2018	2019
Individual income taxes	219.3	219.3	258.2	249.6	241.9	251.3	256.2	250.5	256.0	256.1	262.1	265.8	265.8	272.5
Company taxes	145.1	145.1	70.1	76.7	62.4	59.8	60.2	60.2	66.2	55.4	60.7	73.6	73.1	69.8
Excise and motor taxes	27.9	27.9	33.1	34.8	37.6	38.2	39.6	39.2	39.8	40.2	44.5	44.2	46.1	45.9
Document duty	32.5	32.5	18.2	16.6	21.1	19.7	19.3	17.1	14.2	13.2	13.6	17.8	17.9	17.0
TRP/TRV	7.6	7.6	12.4	15.1	16.4	17.2	18.0	18.0	18.6	20.4	21.3	21.6	23.4	25.1
Misc revenue ¹⁹	34.1	34.1	34.4	33.7	30.9	33.0	34.9	33.7	33.1	37.7	38.0	36.3	34.8	39.0
Operating income ²⁰	47.7	47.7	49.8	52.9	57.0	59.0	57.4	57.9	54.1	58.4	58.7	63.8	67.8	67.9
SS Contributions Employer	53.4	53.4	70.8	73.7	74.3	75.1	74.9	74.0	74.9	73.2	75.5	77.1	77.9	78.7
SS Contributions Employee	58.2	58.2	61.8	64.5	66.0	67.4	67.9	67.6	68.7	67.2	69.2	76.5	77.1	77.9
SS Contributions Self- employed	12.9	12.9	13.2	13.8	14.7	15.3	15.8	16.0	17.1	17.2	16.9	17.1	17.1	17.3
SS contributions Non- employed	6.6	6.6	7.3	8.1	8.1	8.2	8.4	8.8	9.1	9.3	9.1	9.9	10.1	10.2
Total	645.1	645.1	629.3	639.5	630.4	644.2	652.6	642.8	651.7	648.4	669.7	703.7	711.2	721.4
Total personal/domestic taxes and charges ²¹	294.6	326.2	355.2	349.1	348.2	358.7	364.8	357.2	362.0	360.6	369.2	386.3	387.8	395.6
Total corporate/employer taxes and charges ²²	200.5	215.9	164.1	176.5	164.3	165.8	166.2	164.7	173.1	162.4	171.2	185.2	185.9	184.3

¹⁸ These represent the monetary values in any given year adjusted for the effects of inflation. For example figures presented for 2007 represent the monetary value of revenues in that year multiplied by the cumulative effect of inflation between 2007 and 2019.

¹⁹ Misc income was restated in the 2017 account to incorporate gross housing income. Gross housing rents were not recorded in the accounts prior to 2016. For 2007 to 2015 this value has been inferred from historic series

²⁰ Operating income was amended in the 2017 accounts to include income generated on accounts held within the general reserve. Prior to 2006 the value of this has been inferred

²¹ Personal income taxes + employee & non-employed Social Security contributions + self-employed contributions up to the employee rate + domestic TRP

²² Corporate income taxes + distributions + employer Social Security contributions + self-employed contributions above the employee rate + commercial TRP + company fees

Table E3: Change in revenues by source at constant 2019 prices (real annual % change)²³

	2006	2007	2008	2009	2010	2011	2012	2013	2014	2015	2016	2017	2018	2019
Individual income taxes		8%	18%	-3%	-3%	4%	2%	-2%	2%	0%	2%	1%	0%	3%
Company taxes		5%	-52%	9%	-19%	-4%	1%	0%	10%	-16%	9%	21%	-1%	-5%
Excise and motor taxes		11%	19%	5%	8%	2%	4%	-1%	2%	1%	11%	-1%	4%	0%
Document duty		23%	-44%	-9%	27%	-7%	-2%	-11%	-17%	-7%	3%	31%	1%	-5%
TRP/TRV		-5%	63%	22%	9%	5%	5%	0%	3%	10%	4%	2%	8%	7%
Misc revenue ²⁴		14%	1%	-2%	-8%	7%	6%	-4%	-2%	14%	1%	-5%	-4%	12%
Operating income ²⁵		2%	4%	6%	8%	3%	-3%	1%	-7%	8%	1%	9%	6%	0%
SS Contributions Employer		12%	33%	4%	1%	1%	0%	-1%	1%	-2%	3%	2%	1%	1%
SS Contributions Employee		13%	6%	4%	2%	2%	1%	0%	2%	-2%	3%	11%	1%	1%
SS Contributions Self-employed		22%	3%	4%	7%	4%	3%	2%	7%	1%	-2%	1%	0%	1%
SS contributions- Non-employed		22%	11%	11%	0%	1%	3%	4%	4%	2%	-2%	9%	1%	1%
Total		9%	-2%	2%	-1%	2%	1%	-1%	1%	-1%	3%	5%	1%	1%

²³ These are the annual changes in revenues adjusted to remove the effects of inflation

²⁴ Misc income was restated in the 2017 account to incorporate gross housing income. Gross housing rents were not recorded in the accounts prior to 2016. For 2007 to 2015 this value has been inferred from historic series

²⁵ Operating income was amended in the 2017 accounts to include income generated on accounts held within the general reserve. Prior to 2006 the value of this has been inferred

Table E4: Distribution of revenues by source (% of total revenues)

Table L4: Distribution of							1		ı	1				
	2006	2007	2008	2009	2010	2011	2012	2013	2014	2015	2016	2017	2018	2019
Individual income taxes	34.0%	34.0%	41.0%	39.0%	38.4%	39.0%	39.3%	39.0%	39.3%	39.5%	39.1%	37.8%	37.4%	37.8%
Company taxes	22.5%	22.5%	11.1%	12.0%	9.9%	9.3%	9.2%	9.4%	10.2%	8.5%	9.1%	10.5%	10.3%	9.7%
Excise and motor taxes	4.3%	4.3%	5.3%	5.4%	6.0%	5.9%	6.1%	6.1%	6.1%	6.2%	6.6%	6.3%	6.5%	6.4%
Document duty	5.0%	5.0%	2.9%	2.6%	3.3%	3.1%	3.0%	2.7%	2.2%	2.0%	2.0%	2.5%	2.5%	2.4%
TRP/TRV	1.2%	1.2%	2.0%	2.4%	2.6%	2.7%	2.8%	2.8%	2.9%	3.1%	3.2%	3.1%	3.3%	3.5%
Misc revenue ²⁶	5.3%	5.3%	5.5%	5.3%	4.9%	5.1%	5.3%	5.2%	5.1%	5.8%	5.7%	5.2%	4.9%	5.4%
Operating income ²⁷	7.4%	7.4%	7.9%	8.3%	9.0%	9.2%	8.8%	9.0%	8.3%	9.0%	8.8%	9.1%	9.5%	9.4%
SS Contributions														
Employer	8.3%	8.3%	11.3%	11.5%	11.8%	11.7%	11.5%	11.5%	11.5%	11.3%	11.3%	11.0%	11.0%	10.9%
SS Contributions														
Employee	9.0%	9.0%	9.8%	10.1%	10.5%	10.5%	10.4%	10.5%	10.5%	10.4%	10.3%	10.9%	10.8%	10.8%
SS Contributions Self-														
employed	2.0%	2.0%	2.1%	2.2%	2.3%	2.4%	2.4%	2.5%	2.6%	2.7%	2.5%	2.4%	2.4%	2.4%
SS contributions- Non-														
employed	1.0%	1.0%	1.2%	1.3%	1.3%	1.3%	1.3%	1.4%	1.4%	1.4%	1.4%	1.4%	1.4%	1.4%
Total	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%
Total personal/domestic														
taxes and charges ²⁸	45.7%	50.6%	56.4%	54.6%	55.2%	55.7%	55.9%	55.6%	55.5%	55.6%	55.1%	54.9%	54.5%	54.8%
Total corporate/employer														
taxes and charges ²⁹	31.1%	33.5%	26.1%	27.6%	26.1%	25.7%	25.5%	25.6%	26.6%	25.0%	25.6%	26.3%	26.1%	25.5%

²⁶ Misc income was restated in the 2017 account to incorporate gross housing income. Gross housing rents were not recorded in the accounts prior to 2016. For 2007 to 2015 this value has been inferred from historic series

²⁷ Operating income was amended in the 2017 accounts to include income generated on accounts held within the general reserve. Prior to 2006 the value of this has been inferred

²⁸ Personal income taxes + employee & non-employed Social Security contributions + self-employed contributions up to the employee rate + domestic TRP

²⁹ Corporate income taxes + distributions + employer Social Security contributions + self-employed contributions above the employee rate + commercial TRP + company fees

THE STATES OF DELIBERATION Of the ISLAND OF GUERNSEY

COMMITTEE FOR HEALTH & SOCIAL CARE

REVIEW OF THE FUNDING OF DRUGS, TREATMENTS AND DEVICES

The States are asked to decide:-

Whether, after consideration of the Policy Letter entitled 'Review of the Funding of Drugs, Treatments and Devices', dated 25th November, 2019 they are of the opinion:-

- 1. To agree, in principle, that the States of Guernsey should adopt, on a non-statutory basis, a policy of funding drugs and treatments in receipt of a Technology Appraisal from the National Institute for Health and Care Excellence, including those drugs approved for funding from the Cancer Drug Fund.
- 2. To direct that the Committee *for* Health & Social Care should adopt a phased approach to the implementation of Proposition 1 above, starting with those drugs and treatments with an incremental cost effectiveness ratio (ICER) value of up to £30,000 in Year 1, followed by an increase to an ICER value of up to £40,000 in Year 2, as set out in this Policy Letter, at an estimated cost of £5.6m in Year 1 and £8.3m from Year 2.
- 3. To agree that the costs associated with implementation of Propositions 1 and 2 will be funded from General Revenue until such time as the legislative changes are in place to enable this expenditure to be funded from the Guernsey Health Reserve.
- 4. To agree that when the legislative changes referred to in Proposition 3 are in place, a transfer should be made from the Guernsey Health Reserve to the General Revenue Reserve of the value of expenditure which has been incurred by General Revenue under Proposition 3.
- 5. To direct the Committee for Health & Social Care, with the support of the Policy & Resources Committee, to report back to the States with a review of the practical application of the policy referred to in Proposition 1 in the first two years of its operation, together with proposals recommending or otherwise the introduction of drugs and treatments with an ICER value greater than £40,000, to be submitted to the States for consideration as close to the end of Year 2 as possible, but in any event, no more than six months following the end of Year 2. The review should include:

- a) details of the long-term funding arrangements necessary for the continuance of drugs and treatments with an ICER value of up to £40,000;
- b) proposals recommending or otherwise the introduction of drugs and treatments with an ICER value greater than £40,000, to include identifying the associated financial and resource implications; and
- c) details of the long-term funding arrangements including any capital and/or additional infrastructure necessary for the introduction of drugs and treatments with an ICER value greater than £40,000.
- 6. To direct the Policy & Resources Committee to use its delegated authority to approve the use of a maximum of £150,000 from the Budget Reserve to fund the review set out in Proposition 5 above.

The above Propositions have been submitted to Her Majesty's Procureur for advice on any legal or constitutional implications in accordance with Rule 4(1) of the Rules of Procedure of the States of Deliberation and their Committees.

THE STATES OF DELIBERATION Of the ISLAND OF GUERNSEY

COMMITTEE FOR HEALTH & SOCIAL CARE

REVIEW OF THE FUNDING OF DRUGS, TREATMENTS AND DEVICES

The Presiding Officer States of Guernsey Royal Court House St Peter Port

25th November, 2019

Dear Sir

1 Executive Summary

- 1.1 This Policy Letter summarises the outcomes of a comprehensive review of drug funding policy. The Committee *for* Health & Social Care (*Cf*HSC) has considered a number of options for changes to current policy and makes a series of recommendations to the States of Deliberation to increase the availability of drugs and treatments to Bailiwick residents.
- 1.2 Following approval of an amendment to the Requête "Drug Funding" in December 2018¹, the States agreed that it would await the findings of such a review before agreeing any changes to existing funding arrangements. The amendment, laid by Deputies Soulsby and Le Clerc, was formed on the basis of the existing commitment in 'A Partnership of Purpose: Transforming Bailiwick Health and Care'² to evaluate the current funding process and ensure consistency of approach across all decision-making bodies in relation to drug and treatment funding.
- 1.3 A copy of the Requête, together with the successful amendment and the Terms of Reference for the review, are provided in **Appendices 1 and 2**.
- 1.4 The review was carried out by Solutions for Public Health (SPH) on behalf of the Committees for Health & Social Care (CfHSC) and Employment & Social Security (CfESS) between January and July 2019. SPH is a National Health Service (NHS) public health consultancy that consists of a multidisciplinary team offering public

¹ Requête "Drug Funding" - Billet d'État XXVII of 2018

² Committee *for* Health & Social Care - 'A Partnership of Purpose: Transforming Bailiwick Health and Care'- <u>Billet d'État XXIV of 2017</u>

health, clinical, research and analytical expertise. The input of SPH has provided impartial and expert evidence to enable the CfHSC to make the recommendations set out in this Policy Letter.

- 1.5 SPH was tasked with reviewing the availability of drugs, treatments and devices ("treatments") in receipt of a Technology Appraisal (TA)³ from the National Institute for Health and Care Excellence⁴ (NICE) for Guernsey and Alderney residents.
- SPH has produced two reports summarising the findings of the review, which should be read alongside this Policy Letter. The first, entitled "The Review of Drugs and Treatments: Options Appraisal" (Appendix 3), summarises the methodological approach taken to the review and provides an overview of current drug funding arrangements. This report evaluates six possible options for moving towards the adoption of TAs and includes an indication of the financial implications of broadening the range of treatments available to Guernsey and Alderney residents. This includes the costs associated with meeting the 'backlog' expenses, together with an assessment of the anticipated number of new patients that would be eligible on an ongoing basis. The reports take into account the views of health professionals, elected representatives and members of the public following a series of workshops and interviews undertaken during the review period.
- 1.7 Appendix 3 also provides further information about NICE and the processes it adopts to review the clinical and cost effectiveness of drugs and treatments available. It sets out the arrangements in place in England in relation to the use of promising cancer drugs in the Cancer Drugs Fund (CDF) and in respect of those treatments which are classified as Highly Specialised Technologies (HSTs), which are used for rare conditions.
- 1.8 A second report entitled "Additional Costs for the Implementation of NICE TAS" (Appendix 4) summarises the findings of a detailed benchmarking exercise to compare the existing 'white list' of treatments with new treatment pathways for TA-approved drugs (up to the 31st December 2018) that would become available if a change in funding policy was agreed. This was matched against the anticipated local demand for any new treatments.

³ 'Technology Appraisals' are recommendations made by NICE on the use of new and existing medicines and treatments. They are mostly medicines, but can also be medical devices, diagnostic techniques, surgical procedures and health promotion activities. See Section 5 of this Policy Letter.

⁴ NICE is a national advisory body offering guidance, information and advice to maximise improvements in health and social care. See Section 5 of this Policy Letter.

- 1.9 Appendix 4 describes the anticipated one-off 'set up' costs of working in new ways and the associated running costs of wider service delivery implications on an ongoing basis. This includes, but is not limited to: managing the demand on outpatient appointments; ward attendances and associated nurse time; the administration of NICE-approved drugs by intravenous infusion; an extension of pharmacy services to make up and deliver treatments; diagnostics to monitor progression and monitor side-effects; and hospital admissions that may be required to treat side-effects.
- 1.10 In the time that was available for the second stage of work, it was not possible to look at the full implications of introducing treatments approved by NICE with an 'Incremental Cost-Effectiveness Ratio' (ICER) threshold above £40,000. An ICER value is a measure of the difference in the mean costs of an intervention compared with the next best alternative. ICERs are expressed as a cost (in £) per QALY gained. A Quality-Adjusted Life Year (QALY) is a single unit of health gain that combines both expected years of life gained and quality of life gained.
- 1.11 The implementation and ongoing running costs of treatments approved by NICE with an ICER value above £40,000 are unknown at this time as these have not been assessed.
- 1.12 The CfHSC has carefully considered the findings of the review and, in discussion with the Policy & Resources Committee and the Committee for Employment & Social Security (CfESS), has shaped its recommendations to the States, which can be summarised as follows:
 - That, in principle, the States of Guernsey should move towards the funding of all drugs, treatments and devices with a TA from NICE, including those approved for funding from the Cancer Drug Fund.
 - The move towards funding TAs should happen in stages based on a universally accepted method of differentiating drugs, known as the incremental cost effectiveness ratio (ICER).

The Committee recommends the introduction of TAs with an ICER up to £30,000 in Year 1^5 and the further introduction of those TAs with an ICER up to £40,000 in Year 2.

5

⁵ This Policy Letter refers to Year 1 and Year 2 rather than to a specific calendar year. This is because the new policy (if approved by the States in January 2020) would be introduced part the way through the year. It is therefore expected that the expenditure required to fund the first 12 months of any change in policy would be incurred across the 2020 and 2021 financial years.

To enable sufficient time for the CfHSC to present to the States the findings of a review of Years 1 and 2, it is also recommending that the policy of funding TAs with an ICER up to £40,000 should continue into Year 3 until such time as the States debates and approves any further changes to drug funding policy and makes funding available for TAs with a higher ICER value.

An ICER threshold of £40,000 has been selected for implementation in these early years as it would capture 93 of the 160 treatments currently unfunded. It is also considered manageable from an operational perspective in the short-to-medium term, if the necessary funding is made available.

• The estimated amount of funding required is expected to be in the region of £5.6m in Year 1 and £8.3m from Year 2.

The complexity of this work has meant that it has been necessary to make a number of assumptions about the anticipated costs of adopting TAs. Section 10 of this Policy Letter provides further information about the assumptions that have been made in determining the estimated financial implications of the Committee's recommendations as these factors will, to a greater or lesser extent, affect future expenditure.

In particular, it has not been possible to determine an accurate way to understand how the backlog costs may reduce over time to take account of mortality rates and neither has it been possible to account for the addition of new TAs in future years and their associated costs. The review has only considered those TAs available to 31st December 2018. No allowances have been made for drug cost inflation in future years and no account has been taken of the potential impact of an ageing demographic on future demand. Nor, conversely, possible cost savings to existing services.

The figures in this Policy Letter must therefore be accepted as the best available estimates at this time.

• The additional funding required from Year 1 and 2 should be made available from the Guernsey Health Reserve (GHR).

Given the recent changes that have been agreed by the States to the GHR, the associated work required to amend the legislation and depending on the timing of the introduction of any change to drug funding policy, it may be necessary for the costs to be met on a temporary basis from General Revenue and later refunded by the GHR.

It will not be sustainable to use the GHR to fund TAs on an ongoing basis.

A review, to be carried out towards the end of Year 2, will assess both the
practical application of TAs and help to determine the approach to the next
stages of work to introduce drugs and treatments with an ICER value above
£40,000.

This will enable the CfHSC to report back to the States to secure the necessary funding and, with the support of the Policy & Resources Committee, to develop a sustainable funding approach for future years.

The sum of £150,000 is being requested to enable the CfHSC to obtain the specialist input required to complete this review.

 The ability to include non-NICE TAs within drug funding policy should be retained to ensure best value for money.

A non-statutory approach to drug funding will enable the CfHSC to continue to benefit from the best aspects of its current processes and retain flexibility in its decision-making processes to ensure that it is able to access the most clinically effective and cost-effective treatments.

- 1.13 The SPH reports also identified a number of areas where improvements to communication about current policy could be made and steps have been taken to address these recommendations to ensure greater transparency.
- 1.14 It is important to note that many of the drugs and treatments approved by NICE and which would become newly available to Guernsey and Alderney residents are life extending rather than curative treatments. As such, they cannot be considered as life-saving. However, some of the newer treatments do have the effect of reducing often uncomfortable side effects and enable patients to maintain a greater quality of life during treatment than some of the existing treatment pathways, depending on the nature of the condition. These improvements, calculated and measured by the QALY of each drug, are expected to be one of the major benefits of adopting TAs.
- 1.15 The CfHSC acknowledges that Islanders are generally able to enjoy good health and experience positive health outcomes compared to other jurisdictions. Current policy has been effective for many years in controlling the rate of increase in health costs during a period of considerable budgetary restraint. However, this has created significant disparity with England in terms of the range of treatments available to Islanders which has become too great and which the Committee does not consider can be justified. Islanders receiving treatment off-Island are not always currently able to receive the same treatment as a resident in England with the same condition due to the existing funding arrangements.

The introduction of TAs seeks to address this, albeit through an incremental approach.

- 1.16 However, the CfHSC would not wish for such an investment into new treatments to be at the expense of the other important aspects supporting the wider transformation of health and care. Investing in prevention, early intervention and other new service developments would equally give rise to improvements in patient care and may have more far-reaching benefits in improving the long-term health of the population and help to mitigate against rising health care costs in the future. By example, one of the Committee's current ambitions is to progress towards the elimination of cervical cancer as a public health issue in the Bailiwick. The recently introduced free Cervical Screening Programme together with a gender-neutral Human Papillomavirus (HPV) immunisation programme will help to achieve this. Such preventative measures should be given equal importance to the treatment of cervical cancer.
- 1.17 In presenting these proposals the Committee is also keen to highlight that it would not be possible to fund additional treatments from HSC's existing budget without significant cuts to services elsewhere. This would not be an acceptable compromise and would be untenable. The health and care pressures arising from an ageing demographic, a growing demand for increasingly specialist services, together with general developments in modern healthcare, are having a very real impact on the services being delivered by the Committee and on the requirement for revenue funding. It is becoming progressively more difficult each year to meet increasing demands within budgetary constraints.
- 1.18 As such, if the Propositions to extend the range of drugs and treatments available to Guernsey and Alderney residents are agreed by the States of Deliberation, it would be necessary to make funding available from an alternative source.

2 Introduction and Background

- 2.1 The CfHSC and the CfESS currently have in place a policy for determining funding prioritisation for access to drugs and treatments. This policy has, to a large extent, been in existence for the last 17 years and has been very effective in controlling the rate of increase in health costs over a period of considerable budgetary restraint.
- 2.2 Whilst the community generally experiences positive health outcomes, for example, enjoying longer life expectancy than England, this approach has created disparity between the drugs available to patients in England and those available locally.
- 2.3 Following approval of an amendment to the Requête "Drug Funding" in December 2018, the States agreed that it would await the findings of a

comprehensive review of the funding of drugs, treatments and devices before agreeing any changes to existing funding arrangements. The review was carried out by Solutions for Public Health (SPH) between January and July 2019 and has provided an impartial and expert evidence-base to enable changes to existing policy to be recommended.

- 2.4 The objectives of the review, set out in the Terms of Reference (Appendix 2), were as follows:
 - Consider the most effective and equitable system of drug, treatment and device availability that aligns with the relevant key aims of the Partnership of Purpose;
 - Consider the guiding principles underpinning resource allocation and the ethical considerations surrounding the funding of new drugs and treatments locally;
 - Provide an overview of the model for drug, treatment and device availability
 in other jurisdictions, most notably other small island jurisdictions (for
 example Jersey and the Isle of Man), as well as England, Wales and Scotland,
 and compare these to the current situation in Guernsey and Alderney;
 - Specifically consider which NICE TA-approved drugs and treatments are and are not funded in Guernsey and Alderney and analyse the impact, both health and economic, using an example of a NICE TA-approved drug that is not currently funded;
 - Outline a process for the move towards the presumptive funding of NICE TAapproved drugs and treatments;
 - Specifically consider whether Guernsey and Alderney should participate in, or create its own Cancer Drug Fund and consider the health and economic impact of this;
 - Specifically consider the health and economic impact of funding for end of life care drugs / indications (i.e. an ICER of £50,000);
 - Specifically consider equity of access to all NICE-approved drugs and treatments, irrespective of whether these were initiated in a UK tertiary referral centre or in Guernsey or Alderney;
 - Obtain input from Primary and Secondary Care, as well as CareWatch; and
 - Produce a report evaluating current approach and options for the future provision of drugs and treatment locally.
- 2.5 The review has resulted in the production of two reports by SPH. The first, entitled "The Review of Drugs and Treatments: Options Appraisal" (Appendix 3), summarises the methodological approach taken to the review and provides an overview of current arrangements. It presents six options for change which have been carefully considered by the Committee.

- 2.6 A second report entitled "Additional Costs for the Implementation of NICE TAs" (Appendix 4) summarises the findings of a detailed benchmarking exercise to compare existing treatments with new treatment pathways for NICE TA-approved drugs (up to the 31st December 2018) that would become available if a change in funding policy was agreed. This was matched against the anticipated local demand for any new treatments.
- 2.7 This Policy Letter summarises the findings of the review, considers the possible options for changes to drug funding policy and the financial implications of doing so. It makes a number of recommendations for an incremental approach to the adoption of TAs, with a requirement to report back to the States with funding proposals to enable the continuance of TAs with an ICER up to £40,000 in future years and to present proposals to fund a second phase to make available treatments with an ICER greater than £40,000.

3 The Strategic Context of the Review

- 3.1 The need for a review of the funding arrangements for drugs and treatments was highlighted in the Committee's Policy Letter to the States in December 2017: "A Partnership of Purpose: Transforming Bailiwick Health and Care." A subsequent amendment to the Policy & Resource Plan in June 2018 defined the scope of such a review to assess the guiding principles which should underpin resource allocation in health and social care and to take into account the need to ensure that limited resources are used fairly and equitably, maximizing the value of care delivered to the population as a whole.
- 3.2 The Partnership of Purpose sets out an ambitious programme to transform health and care services in the Bailiwick, based on the following aims:
 - Prevention: supporting islanders to live healthier lives;
 - User-centred care: joined-up services, where people are valued, listened to, informed, respected and involved throughout their health and care journey;
 - Fair access to care: ensuring that low income is not a barrier to health, through proportionate funding processes based on identified needs;
 - Proportionate governance: ensuring clear boundaries exist between commissioning, provision and regulation;
 - Direct access to services: enabling people to self-refer to services where appropriate;
 - Effective community care: improving out-of-hospital services through the development of Community Hubs for health and wellbeing, supported by a

⁶ Policy & Resource Plan – "2017 Review and 2018 Update" – Resolution 1o) - <u>Billet</u> d'État XV of 2018

- Health and Care campus at the PEH site delivering integrated secondary care and a Satellite Campus in Alderney;
- Focus on quality: measuring and monitoring the impact of interventions on health outcomes, patient safety and patient experience;
- A universal offering: giving islanders clarity about the range of services they can expect to receive, and the criteria for accessing them;
- Partnership approach: recognising the value of public, private and third sector organisations, and ensuring people can access the right provider; and
- o **Empowered providers and integrated teams**: supporting staff to work collaboratively across organisational boundaries, with a focus on outcomes.
- 3.3 Of most significance to the review of drugs and treatments are the proposals set out in this Policy Letter to move to a presumption of funding TAs to ensure that income is not a barrier to accessing the latest treatments, which may currently only be available to private patients.
- 3.4 The workstreams that arise from the Partnership of Purpose are an important element of the Future Guernsey Plan, which are being brought together in the 'Future Model of Care' Policy Priority Area. The Review of Drugs and Treatments was identified as a key policy priority for 2019.
- 3.5 The 20 year vision of the Policy & Resource Plan sets out the ambition for the Bailiwick "to be one of the healthiest and happiest places in the world, where everyone has an equal opportunity to achieve their potential."
- 3.6 Good health is one of the most important factors influencing our quality of life and therefore access to the newest treatments for Guernsey and Alderney residents supports the achievement of the health-related outcomes, upholding the values of the Policy & Resource Plan and contributing to the achievement of the 20 year vision.

4 Existing Arrangements of Drug Funding Prioritisation

- 4.1 Since the first prescription was dispensed on 4th June 1973, advances in medical science and the increase in the choice of treatments available has resulted in increasing costs which both the CfHSC and CfESS have made concerted efforts to fairly and responsibly manage in a way which best meets locally identified needs and priorities.
- 4.2 The commissioning of the Priorities Support Unit (a specialist NHS Public Health Consultancy) by the CfHSC in 2011 to review how health care decisions are made both for services for the population and for individuals shaped the current ethical framework used by Health & Social Care to inform and guide funding prioritisation for its wide range of services.

- 4.3 In respect of prioritising funding of drugs and treatments, the CfHSC works with the CfESS to maintain a 'white list' of drugs that are routinely funded locally and to manage a process that considers individual funding requests (IFRs) for drugs which are not. This is because some of the drugs and treatments are made available whilst care is being delivered within the Princess Elizabeth Hospital; others are dispensed through Community Pharmacies, which is overseen by the CfESS, and paid for through the GHR.
- 4.4 Further information about the current arrangements are available from: https://www.gov.gg/whitelist and https://www.gov.gg/fundingprioritisation
- 4.5 Since May 2018, in order to streamline processes, new drug approval processes for Primary Care have been unified in the Prescribing and Formulary Panel, with the CfHSC and the CfESS approving its terms of reference based on the funding policy 'Priority Setting in Health and Social Care' (G1033). The Prescribing and Formulary Panel, supported by the Prescribing Support Unit (PSU), works to disinvest in less effective and poor value treatments as well as approving new drugs. It takes a very conservative approach to the latter. As a result, increases in drugs costs have been limited and there are effective processes in place for working with Primary Care to manage expenditure responsibly, which has served the community well. For example, in the 12 months ending July 2019, the restricting of, and removal from, prescribing of five drugs is on course to save over £300,000 per year going forward. Quality improvements made by the PSU have also led to a 40% reduction in opioid prescribing and a 12% reduction in antibiotic prescribing.
- 4.6 At its meeting held on 12th June 2019⁷ the States agreed a series of Resolutions for the transfer of functions of the GHR to the CfHSC. This will allow aspects of health care policy presently resting with the CfESS to be taken by the CfHSC in the future and is the most recent measure taken to address the complexity of drug funding. Legislative changes are being prioritised to give effect to these Resolutions.
- 4.7 One of the key arguments for maintaining the status quo arrangements is that there is little evidence that investing in NICE TA-approved treatments will improve patient outcomes, in terms of offering a curative treatment. Islanders generally enjoy good health and experience positive health outcomes compared to other jurisdictions, evidenced by lower age-standardised deaths compared with England (843.7 per 100,000 population in the Bailiwick versus 968.7 per 100,000 in England).8

⁷ Policy & Resources Committee – "Reform of Health Care Funding" – <u>Billet d'État X of</u> 2019

⁸ Public Health Services. *Health Profile for Guernsey and Alderney 2013-2015*. Guernsey

- 4.8 However, there is evidence that some of the new medical technologies do have the benefit of improving patient experience during treatment, by reducing often uncomfortable or painful side effects, than existing treatment pathways. This is explored further in this Policy Letter.
- 4.9 Furthermore, the current system in the Bailiwick has also allowed clinicians to prescribe drugs without marketing authorisation, that are of equal clinical efficacy to TA-approved alternatives, at a much reduced cost. For example, a drug called Bevacizumab used for age-related macular degeneration has demonstrated similar clinical-effectiveness to the TA-approved drug Ranibizumab but at a significantly reduced cost (c.28 times less). In order to retain this flexibility and cost saving measure, it is not recommended that any change in the funding policy of TA-approved treatments in Guernsey is embedded in legislation.
- 4.10 The CfHSC wishes to retain the flexibility in the future to prescribe non-NICE TA approved drugs which are clinically effective, but to ensure that Bailiwick residents are also able to access new drugs and treatments evaluated by NICE, where beneficial.

5 Key Terminology

5.1 A brief explanation of some of the key terminology used in the SPH Report is set out below. A full glossary of key terms is also provided in Appendix 3 (Section 9).

What is NICE?

- 5.2 The National Institute for Health and Care Excellence, known as NICE⁹, is a national advisory body offering guidance, information and advice to maximise improvements in health and social care. In the UK, NICE seeks to improve outcomes for people using the NHS and other public health and social care services by evidence-based guidelines, developing quality standards and performance metrics, and providing a range of information services for commissioners and providers of health and care.
- 5.3 NICE guidelines all have the status of 'guidance' in the NHS in England and are adopted to varying extents according to local wants, needs and available budget. However, in 2012, in an attempt to tackle the 'postcode lottery' in health, it was made mandatory in law for health service commissioners in England to fund those drugs recommended via the NICE TA process.
- 5.4 Section 1.2.1. of Appendix 3 provides further information about the NICE and its role in assessing the clinical and cost effectiveness of health technologies.

⁹ National Institute for Health and Care Excellence - www.nice.org.uk

What is a Technology Appraisal (TA)?

- 5.5 TAs are recommendations made by NICE on the use of new and existing medicines and treatments. They are mostly medicines, but can also be medical devices, diagnostic techniques, surgical procedures and health promotion activities.
- The assessment associated with a TA relies upon significant investment from the drug company, which is required to make a submission compliant with the NICE TA process. NICE does not select new drugs to be included in its TA process and neither is it able to ask a drug company to submit a product for assessment.
- 5.7 NICE carries out a detailed and lengthy process to determine whether the clinical and cost effectiveness of the product justifies a recommendation for use. The evaluation process is undertaken in three stages; collecting evidence for submission, a review of the evidence by an Evidence Review Group (ERG) and the production of an appraisal with its recommendation.
- 5.8 Reviewed technologies are classified into one of five recommendation categories:
 - 1. Recommended for routine use in the NHS
 - 2. Recommended for use under strict criteria
 - 3. Recommended for use in the Cancer Drug Fund
 - 4. Recommended for use only for research purposes
 - 5. Not recommended for use
- 5.9 Technologies that are classified into categories 1 and 2 are, by law in England, required to be available for prescribing within 90 days of the recommendation being published. These treatments have met the very strict criteria set out by NICE, demonstrating both clinical and cost effectiveness. They are mostly life extending, not curative, treatments.
- 5.10 Cancer drugs which have not met the TA requirements for commissioning but are considered to have clinical potential by NICE can be recommended for use as part of the Cancer Drug Fund (CDF).
- 5.11 Treatments that are recommended for use in the CDF are those that have not yet met the threshold to receive a recommendation under categories 1 or 2 above but can demonstrate promising clinical effectiveness. The CDF therefore allows clinicians to prescribe the treatment, at a significantly reduced cost to the NHS, for a period of usually 24 months so further data can be gathered on its clinical and cost effectiveness. After this period of further data gathering, the treatment will undergo a full appraisal by NICE and will either be recommended for use or not. NICE do not agree a second cycle in the CDF.

- 5.12 In England, 39 of the currently unfunded TAs in Guernsey and Alderney have been recommended for funding through the CDF.
- 5.13 Categories four and five are not usually recommended for routine prescribing and their use would not be extended to the Bailiwick.

What is a QALY?

- 5.14 A Quality-adjusted life year (QALY) takes into account the length of life and the quality of life.
- 5.15 It is a measure of the state of health in which the benefits, in terms of life expectancy, are adjusted to reflect the quality of life. As described in Section 9 of Appendix 3, a QALY takes into account both the **quantity** of life (how long an individual will live for) and the **quality** of their life (the quality of those remaining years). In this respect, QALYs provide a means to benchmark and compare the benefits that each medicine may offer to a patient.
- 5.16 They are calculated using an estimate of years of life remaining for a patient following a particular treatment and a quality-of-life score. The quality-of-life score considers areas such as the person's ability to carry out the activities of daily life, free from pain and mental disturbance and estimate the effect of the new drug on these aspects to come up with an estimate of the quality of life improvement expected from the new drug.
- 5.17 QALYs allow a comparison to be made between different interventions and their expected outcomes.

What is meant by 'Cost per QALY?'

- 5.18 This is the cost of the treatment for an additional QALY per annum. For example:
 - Medicine A costs £10,000 per annum and provides 5 QALYs.

It has a cost per QALY of £2,000 (£10,000/5 QALYs).

Medicine B costs £20,000 per annum and provides 8.4 QALYs.

It has a cost per QALY of £2,380 (20,000/8.4 QALYs).

5.19 In some instances, NICE may not indicate a precise cost per QALY, but suggest that a treatment falls within a range of costs per QALY, or it may suggest a maximum cost per QALY for a drug used for different clinical indications.

What is an ICER?

- 5.20 The term incremental cost effectiveness ratio, or ICER, enables a comparison to be made between the costs of a new treatment compared to that of an existing treatment pathway. Where a new intervention appears more effective than the current comparator treatment, NICE compares them by calculating the ICER because the use of a QALY alone does not indicate the cost-effectiveness of a drug.
- 5.21 The ICER is the amount of money that needs to be spent to achieve 1 additional QALY with medicine B compared to medicine A and is calculated as the difference between the costs and the QALYs of two treatments:

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ICER = (Cost B - cost A) / (QALY B - QALY A)
ICER = (20,000 - 10,000) / (8.4 - 5)
ICER = 10,000 / 3.4
ICER = £2,941
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- 5.22 This means that Treatment B has an ICER of £2,941 per additional QALY gained when compared with Treatment A.
- 5.23 This calculation provides the amount (£) that will need to be spent on the new treatment per additional QALY when compared to the current treatment.
- 5.24 ICER's are particularly relevant to Option 5 of Appendix 3, discussed in full detail in section 7, as it provides a means of incrementally introducing additional treatments with a NICE TA.
- 5.25 This approach has helped to shape the Committee's proposals in this Policy Letter, which uses ICER as the basis for a phased implementation of TAs.

6 Methodology of the Review

(Section 2 of Appendix 3)

- 6.1 SPH undertook quantitative and qualitative analyses to inform its review, which included extensive research and stakeholder engagement. The methodology adopted by SPH comprised four linked programmes of work:
 - Quantitative analysis;
 - Engagement and qualitative analysis;
 - iii) Example of a different treatment pathway; and
 - iv) Comparison and learning from Jersey and the Isle of Man.

Stage 1) Quantitative Analysis

(Section 4 of Appendix 3)

- 6.2 In the first instance a review of the NICE TA-approved treatments available to residents in Guernsey was undertaken.
- 6.3 This concluded that of 480 TA recommendations approved by NICE up until 31st December 2018, 320 are funded by the States of Guernsey under existing policy.
- 6.4 Of the 160 TA recommendations that are presently not funded, 39 have previously been denied funding; the funding of three treatments were agreed but at the time of the review had not been made available; and the final 128 treatments had never been requested. The treatments that are not presently funded relate to the management of a range of health conditions.
- 6.5 Treatments that meet the definition of 'life extending at the end of life,' are considered differently by NICE and in 2009, a higher threshold for automatic funding of up to an ICER of £50,000 was introduced. NICE justifies this difference by stating that society places a higher value on quality adjusted life years at the end of life compared with any other time during the lifespan but there is not a strong evidence base to support this. 51 approved treatments that fall into this category are currently unfunded locally.
- 6.6 Highly Specialised Technologies (HSTs) are treatments that are used for very rare conditions. Due to their rarity, they are subject to different rules in the NICE TA process in that they carry the highest ICER threshold of all treatments. The threshold for which automatic funding is provided for HSTs is £100,000, with the potential for funding agreement above this amount at the discretion of the HST Evaluation Committee¹⁰. The gross cost of an HST for one patient per annum ranges from £100,000 to £500,000. Of the 160 TA treatments which are presently not funded, eight are HSTs.
- 6.7 HSTs will not routinely¹¹ be available until after the States has agreed the next stage of work following the completion of the review of Years 1 and 2. However, it is acknowledged that the introduction of HSTs in future years may present a risk of budget volatility due to the high cost of such technologies, even if there are only a small number of isolated cases. The review will therefore consider how best to fund HSTs in the future and may present a number of options for the States to consider.

¹⁰ The HST Evaluation Committee is an independent advisory Committee that supports the evaluation of highly specialised technologies by NICE. More information is available from: <u>NICE - Highly Specialised Technologies Evaluation Committee</u>

¹¹ Requests may still be made by clinicians for individual cases to the Individual Funding Request Panel during this time.

Stage 2) Engagement and Qualitative Analysis

(Section 3 of Appendix 3)

- 6.8 Stakeholder engagement events took place during March and April 2019 and were attended by 145 people from many different stakeholder groups. The purpose of these events was to seek the community's views about the principles that should be applied in drug funding policy decisions and direct feedback was sought by SPH in two ways: i) via facilitated discussion 'CHAT (Choosing Health Plans All Together)-boards'; and ii) from their written responses to two direct questions.
- 6.9 Feedback from the discussion CHAT-boards demonstrated a consensus of opinion in regards to the community's view that personal and social characteristics, disease characteristics and health setting should not be considered in the decision making for funding treatments within a finite resource. 20% of participants were in favour of prioritising NICE TA-approved treatments. Of particular concern to many was the possibility of cuts to existing services, particularly those focusing on prevention and early intervention, in order to fund this option.
- 6.10 The most popular decision making principle expressed by attendees through the second exercise was to make prioritisation decisions for drug funding based on the cost effectiveness of the treatment. This was followed by a strong preference not to prioritise cancer treatments¹² and the principle of treating all conditions equally regardless of the number of people affected by them. The full list of decision-making principles and their ranking from the stakeholder engagement events can be found in Section 3 of Appendix 3.
- 6.11 SPH also met with several individuals who shared their experiences of the current arrangements. A number expressed their frustrations around the current decision-making processes and how they are communicated. The Committee acknowledges that improvements can be made to existing arrangements. Some changes have already been made but further steps will be taken to improve current processes to support greater transparency of decision-making.

report as an option for prioritisation.

¹² Prioritising clinical effectiveness of treatments was ranked highly as a principle by which funding decisions should be made. All treatments which have received a TA recommendation from NICE have demonstrated clinical effectiveness through the thorough TA review process. Therefore clinical effectiveness is not included in the

6.12 Further detail surrounding the current funding process can be found in Section 3 of Appendix 3¹³.

Stage 3) Example of different treatment pathways

(Section 6 of Appendix 3)

- 6.13 In order to consider the costs of implementation beyond the direct cost of purchasing the treatments, a workshop was organised with relevant clinicians and providers in the care and service delivery of patients with lung cancer. The currently unfunded NICE TA-approved drug 'Pembrolizumab', used for two specific conditions in the treatment of lung cancer, was used as an example drug. 109 people died in the Bailiwick between 2012 and 2014 due to this disease.
- 6.14 Pembrolizumab has two TA recommendations; for locally advanced or metastatic PD-L1-positive non-small-cell lung cancer in adults who have had at least one chemotherapy or for untreated PD-L1-positive metastatic non-small-cell lung cancer.
- 6.15 As by way of a detailed worked example, Section 6.5 of Appendix 3 tabulates the differences between hospital resources, life expectancy, treatment duration, required monitoring services, adverse hospital events and other care required to provide a service using the current available treatment for these lung cancer indications and those for Pembrolizumab, should it become available.
- While it is acknowledged that some savings from a reduction in supportive nursing care would be made by using a newer treatment, as patients would likely experience fewer side effects and adverse hospital events such as neutropenic sepsis, these potential savings are difficult to estimate and are unlikely to offset the significant cost required in this case. It is not easy to quantify these benefits for individuals but improving the health, general wellbeing and patient experience for those suffering serious health conditions would be one of the key benefits of the recommendations arising from the review.

Stage 4) Comparison and learning from Jersey and the Isle of Man (Section 5 of Appendix 3)

6.17 When considering policy change in the Bailiwick, it is useful to consider the approach in other jurisdictions with a similar population size in order to identify any challenges and learning opportunities for Guernsey. With this in mind, SPH

¹³ Further information is also available from the States of Guernsey website: https://www.gov.gg/whitelist and https://www.gov.gg/fundingprioritisation

reviewed how both Jersey and the Isle of Man manage access to treatments that have been recommended through the NICE TA process. The main difference in Jersey is that HSTs which are approved are funded differently from other TAs. Jersey also does not routinely fund those cancer drugs which are classified by NICE as 'promising' treatments, which are funded in England from the CDF.

6.18 A summary of the funding arrangements in Jersey and the Isle of Man is provided in Section 5.2 and 5.3 of Appendix 3.

7 Summary of Options

(Section 1 of Appendix 3)

- 7.1 The SPH review offers a detailed appraisal of six options for possible changes to drug funding policy, together with cost estimates of: extending the options available to existing patients (i.e. the backlog); and the expected net cost for new patients per annum.
- 7.2 The options range from routine full adoption of all TA-approved treatments (Option 1) through to maintaining the status quo of current policy (Option 6), with a number of options for implementation in between.
- 7.3 The six options are summarised in Table 1:
 - 1. Fund all TA-approved treatments;
 - 2. Prioritise all TA-approved treatments for cancer;
 - 3. Prioritise TA-approved for life extending, at the end of life treatments;
 - 4. Prioritise TA-approved treatments for common diseases;
 - 5. Prioritise TA-approved treatments on the basis of (clinical and) cost effectiveness; and
 - 6. Status quo continue with the current system.

Table 1: A summary of six possible options for the implementation of TAs

		Number of TA recommendations,			ber of ients	Net cost impact		
Option	ICER	TA	TAs	Backlog	New	Backlog	New	
	banding	recommendations			patients		patients	
					per		per	
					annum		annum	
1		160	145	3,348	782	£7.6m	£5.5m	
2		88	84	114	98	£3.3m	£3.2m	
3		51	49	74	62	£1.8m	£1.8m	
4		44	40	3,221	679	£3.6m	£1.3m	
5	<20k ICER	27	24	1,928	338	£1.3m	£0.5m	
	<30k ICER	71	67	2,769	630	£3.1m	£1.5m	
	<40k ICER	93	88	3,073	678	£4.7m	£2.5m	
	<50k ICER	124	119	3,120	721	£5.9m	£3.8m	
	<100K ICER	138	130	3,141	737	£6.7m	£4.4m	
6		0	0	0	0	£0m	£0m	

- 7.4 The assumptions which support Table 1 above are as follows:
 - The calculations are based on treatments that have received a TA from NICE up until 31st December 2018;
 - The number of 'TAs' refers to the number of treatments that have received
 a TA from NICE. The figure for 'TA recommendations' represents clinical
 indications and is therefore higher because some treatments carry more than
 one clinical indication for prescribing and therefore may be used for more
 than one purpose; and
 - The number of new patients per annum has been calculated with reference to local clinicians' estimates of the expected prevalence of conditions that would be treated using alternative treatments, rather than with reference to trends elsewhere.
- 7.5 A detailed explanation of the six options together with a comprehensive analysis of their respective strengths and weaknesses are explained in Appendix 3 (Section 1 and Section 7).
- 7.6 The Committee has carefully reviewed the options set out by SPH above and the feedback received from stakeholders. The CfHSC considers that **Options 2, 3 and 4**, which prioritise a group of drugs or illness over another would create a 'disease lottery' for funding. The Partnership of Purpose emphasises the need to address inequalities in access to services and therefore these options are not supported.

- 7.7 **Option 6** retaining the status quo is also not supported by the Committee. The background to the Requête and the amendment, together with the feedback received from stakeholders, has evidenced a significant appetite for change to current policy. As such, Option 6 is not recommended for further consideration.
- 7.8 In shaping its recommended approach in this Policy Letter, the Committee has further considered the detailed implications associated with the implementation of **Option 1** and **Option 5**.

8 Shortlist of Options

Option 1

- 8.1 Option 1 would result in the funding of all treatments that have received a positive TA from NICE for patients in Guernsey and Alderney who meet the inclusion criteria specified in each NICE TA recommendation.
- 8.2 Option 1 shows the greatest alignment with the strategic objectives for health care provision set out in the Partnership of Purpose. Patients would be treated regardless of: i) their ability to pay; ii) the cost of their treatment; iii) whether treatment is provided on or off island; and iv) irrelevant of how common or rare their condition.
- 8.3 However, significant investment will be required to fund this option and new inequalities will be introduced. The approach which is inherent in the NICE TA methodology is that it targets manufacturer sponsored drug therapies. Although the Committee is recommending that the States retains flexibility within policy to fund treatments without a TA, to maximise cost-effectiveness where the evidence suggests that this is possible, treatments that have proven to be effective but which have not been through the review process by NICE would be less likely to secure funding (as in England).
- The use of treatments for wider indications beyond those in receipt of a TA was out of the scope for the review.

Option 5

8.5 Option 5 is based on the merits of individual treatments for specific indications, rather than patient attributes or disease characteristics and uses ICER thresholds to determine drug funding. An ICER is calculated as the difference between the costs and the QALYs of two treatments, which offers an indication of the financial cost of an additional year in good health for an individual between different treatment pathways.

- 8.6 Option 5 presents the cost of treating new patients on an ongoing basis and addressing the backlog on the basis of clinical and cost effectiveness using five different ICER thresholds.
- 8.7 This has provided the Committee with the information required to recommend an incremental approach to the introduction of new treatments locally, using the ICER thresholds, as set out in this Policy Letter.

9 Implementation Costs and Ongoing Expenditure

- 9.1 In addition to the high level indicative costs for each option presented in Table 1, there will be additional costs beyond the procurement cost of the treatments.
- 9.2 To support the findings of the initial options appraisal report, SPH were commissioned to provide an indicative estimate of the associated first year implementation costs for the currently unfunded treatments that have received TA recommendations up until 31st December 2018 with an ICER up to £40,000.
- 9.3 A breakdown of the currently unfunded TAs and their disease category is shown in Table 2 below. This is reproduced from Section 3.1 of Appendix 4.

Table 2: Approved TAs unfunded as at 31st December 2018 with an ICER of up to £40,000 per QALY

Specialty	Number of TA recommendations	% of total TA recommendations	Estimated Guernsey Patients Year 1	% of total estimated patients Year 1	Estimated Guernsey New Patients Per Annum	% of Estimated New Patients Per Annum
Cancer	42	46%	46.2	2%	40.3	6%
Cardiac Services	6	7%	2030	66%	240	35%
Colorectal Services	2	2%	110	4%	23	3%
Dermatology	5	5%	12	0%	10	1%
Ear and Ophthalmology Services	3	3%	21	1%	15.2	2%
Endocrinology	6	7%	305	10%	49	7%
Hepatobiliary and Pancreas	1	1%	2	0%	1	0%
Immunology and Allergy Services	1	1%	4	0%	1	0%
Infectious Diseases	2	2%	2	0%	2	0%
Mental Health	3	3%	95	3%	22	3%
Neurosciences	3	3%	5	0%	3	0%
Urology	1	1%	150	5%	40	6%
Pain	1	1%	100	3%	100	15%
Respiratory	5	5%	100	3%	49	7%
Rheumatology	5	5%	16	1%	7	1%
Trauma and Orthopaedics	5	5%	60	2%	60	9%
Vascular Disease	1	1%	15	0%	15	2%
Total	92	100%	3073.2	100%	677.5	100%

- 9.4 If a change in policy is agreed, it is the above treatments, plus those additional treatments with an ICER up to £40,000 per QALY approved in the interim stages, that would be eligible to receive funding in Year 2. It can be seen from the above that the TAs relate to the management of a wide range of conditions.
- 9.5 Table 2 above shows the number of TAs that are presently not funded and their clinical indication. It also shows that whilst 42 of the 92 TA recommendations (46%) relate to cancer, only 6% of patients, 40.3 of 677.5 (2%) of new patients per annum are expected to require these treatments.
- 9.6 The second report provided by SPH (Appendix 4) describes the anticipated one-off 'set up' costs of working in new ways to implement the above in Years 1 and 2 and the associated running costs of wider service delivery implications on an ongoing basis, as follows.

i) Assessment of Resource Requirements (Section 4 of Appendix 4)

- 9.7 When compared with the current treatments available locally, the introduction of TAs will impact health care services in many ways.
- 9.8 Where possible, SPH considered the implications for the Bulstrode Oncology Unit, Pharmacy Services, Diagnostic Services (Pathology and Radiology), Palliative and Community Care, Respiratory Services, off-island commissioning and treatment set-up costs. This includes the increasing demand for managing outpatient appointments; ward attendances and associated nurse time; an extension of pharmacy services to make up and deliver treatments; diagnostics to monitor progression and monitor side-effects, and hospital admissions that may be required to treat side-effects.
- 9.9 A detailed analysis, as set out in Appendix 4, was based on categorising treatments and estimating the likely number of patients involved:

Group 1: oral non-chemotherapy drugs

Group 2a: oral chemotherapy drugs, drugs by infusion, drugs by injection and

non-drug treatments with 1 or more patients estimated for year 1

Group 2b: oral chemotherapy drugs, drugs by infusion, drugs by injection and

non-drug treatments with <1 patient estimated for year 1

- 9.10 Specifically, across these services, the analysis of current treatment pathways and provision compared to the new treatment pathways and future workload for extending access to additional TAs, showed that additional resources and funding (including some minor capital expenditure) would be required for:
 - Oncology clinics and infusion costs;
 - Pharmacy cost for drug supply set up and management;
 - Pharmacy infusion and oral drug costs;

- The cost of additional diagnostic testing;
- Off-island costs:
- Respiratory Nursing costs;
- Palliative Care and Community Nursing; and
- A one off cost for specialist oncology scheduling software.
- 9.11 For example, to introduce new treatments with an ICER of up to £40,000 in Years 1 and 2 would require provision within the existing oncology unit at Bulstrode House to be extended to provide more infusion treatments. This is estimated at an additional 300-400 infusions per annum to accommodate increasing patient numbers and different treatment pathways. Allowances have been made for the additional staff that will be required to support this extended provision, which has been based on extending the opening hours and staffing accordingly. Pharmacy Services will also need to be available to prepare these new treatments, which often have a limited shelf-life, in a timely way.
- 9.12 Further information about the new demand on the Oncology and Pharmacy Services is provided in Section 4.2 of Appendix 4.
- 9.13 A high level estimation of these costs in their entirety for the first year of implementation is approximately £700,000 in Year 1 and £900,000 in Year 2. Further detail is available in Section 5 of Appendix 4.
- 9.14 The States of Deliberation recently agreed to commit significant funds to modernise the Princess Elizabeth Hospital campus¹⁴. Some of the developments which form part of the Hospital Modernisation Programme, particularly in its later phases, will provide additional facilities that will support the implementation of changes to drug funding policy.
- 9.15 As stated when the Hospital Modernisation Programme was agreed by the States, every effort will be made to maximise the impact of the investment into the PEH infrastructure through the Programme to ensure that it can accommodate new and innovative ways of working in the future.

ii) Project Management, Audit and Review

- 9.16 A move towards introducing TAs on an ongoing basis will require significant coordination and dedicated Project Management resource to manage the implementation of this change in policy. This will include managing the availability of the backlog of unfunded TAs and reviewing the introduction and implementation of additional TAs on an ongoing basis.
- 9.17 Investment will also need to be made in an ongoing audit and review function. As referenced above, NICE continually reviews and assesses the clinical effectiveness of new drugs and grants a TA for approximately 70 new drugs each year. Although as

¹⁴ Committee for Health & Social Care - "Hospital Modernisation Programme" - Billet d'État V of 2019

new treatments become available some will cease to be prescribed, the impact of the change in funding policy will extend new treatments to an increased number of Islanders.

- 9.18 The two commissioned reports from SPH only consider the costs of those treatments that have received a TA recommendation up until 31st December 2018. Therefore it is likely that a backlog of work will be present for the set up and implementation of drugs approved through the TA process during the entire 2019 calendar year, and in 2020 to the implementation date.
- 9.19 In the light of this, the CfHSC will need to develop its resources for the ongoing audit and implementation of new treatments into clinical practice. This will be supported by digital transformation within health and care. The audit function will also include reviewing the effectiveness of drugs and treatments that have not been evaluated by NICE.
- 9.20 If the Propositions are approved by the States, the stages of work associated with implementing new treatments in an incremental way, as proposed, would involve the following:
 - The development of a comprehensive communications plan for engagement with service-users and Primary and Secondary Care providers, both on and off-Island;
 - Negotiation with drug companies to develop procurement pathways for new treatments;
 - Development of new internal policies setting out eligibility for new treatments during the introductory phases;
 - Audit of newly introduced TAs;
 - The recruitment of new members of staff; and
 - New computer software for pharmacy management.
- 9.21 To ensure that the above can be adequately resourced, the Committee is requesting an additional sum of £300,000 in Year 1 and £200,000 in Year 2.
- 9.22 Although the review of drugs and treatments would be the catalyst for the above changes, these investments will have wider benefits to improve patient care and efficiency of service delivery that extend beyond those receiving new treatments.

10 Summary of the Financial Implications

- 10.1 The two reports prepared by SPH in Appendices 3 and 4 provide details of the anticipated costs of proposals for changes to drug funding policy.
- 10.2 The requirement for additional funding can be broken down into four main areas:
 - i) The cost of extending the range of treatments to existing patients. This is termed the 'backlog' cost in the SPH reports;

- ii) The anticipated number of new patients each year that may require each treatment, which were agreed in discussion with local clinicians;
- iii) One-off 'readiness' costs associated with implementation of changes to policy; and
- iv) Ongoing running costs, including additional resources for ongoing administration, audit and review.
- 10.3 The anticipated costs in Years 1 to 4 are summarised in Tables 3 and 4.

Table 3: An overview of the anticipated costs of introducing TAs from Years 1 and 2

	ICER R	lange		i) New patie	nts		ii) Backlo	g	iii) Additional	Sub-	iv)	
Year	In-year addition	Cumulative	In-year addition	Brought forward	Cumulative	In-year addition	Brought forward	Cumulative	Running costs	Total	Project Management	Total
			£m	£m	£m	£m	£m	£m	£m	£m	£m **	£m
1	<£30k	<£30k	1.5	0	1.5	3.1	0	3.1	0.7	5.3	0.3	5.6
2	£30k-£40k	<£40k	1.0	1.5	2.5	1.6	3.1	4.7	0.9	8.1	0.2	8.3

Table 4: An overview of the anticipated costs of introducing TAs

	ICER R	Range	i) New patients			ii) Backlo	g	iii) Additional	Sub-	iv)		
Year	In-year addition	Cumulative	In-year addition	Brought forward	Cumulative	In-year addition	Brought forward Cumulative		Running costs		Project Management	Total
			£m	£m	£m	£m	£m	£m	£m	£m	£m **	£m
3	£40k-£50k	<£50k	1.3	2.5	3.8	1.2	4.7	5.9	0.9*	10.6	0.15	10.75
4	£50k-£100k	<£100k	0.6	3.8	4.4	0.8	5.9	6.7	0.9*	12.0	0.15	12.15

^{*} The additional running costs (iii) for years 4 and 5 relate only to those drugs and treatments with an ICER of up to £40,000 introduced in years 1 and 2. The ongoing running costs for drugs and treatments with an ICER value above £40,000 are unknown at this time. The £0.9m figure shown above therefore represents the minimum expected running costs in years 4 and 5.

^{**} The Project Management, Audit and Review (iv) costs are those associated with the implementation of TAs with an ICER of up to £40,000 in years 1 and from year 2. Any further Project Management resources required for future years will be included in the Review to be progressed towards the end of Year 2. At this stage, an allowance of £150,000 is suggested for years 3 and 4 to ensure that the Committee has sufficient resources to manage the introduction of TAs on an ongoing basis and to support the audit function.

- 10.4 The above shows that changes to drug funding policy to adopt TAs will come at a significant cost; estimated at £5.3m in Year 1 and £8.1m in Year 2, and thereafter on an annual basis, in addition to the identified project management costs. To help to put this into context, in 2018, the cost of the drugs provided in the PEH amounted to £2.0m.
- 10.5 In October 2019¹⁵, in its annual report to the States, the CfESS advised that "Drugs, medicines and appliances, cost a total of £19.1m in 2018, before netting off prescription charges of £2.2m paid by patients, and rebates and discounts. Therefore the total cost of the service in 2018 was £16.8m."
- 10.6 The latter cost (Pharmaceutical Benefit) is funded from the GHR¹⁶.

Modelling assumptions

- 10.7 Although the Committee, with the support of SPH, has carried out a detailed exercise to understand the financial and other implications of making TAs available to Bailiwick residents, the expected annual costs **must be recognised as the best available estimates at the time of writing.**
- 10.8 This is because, in compiling Tables 3 and 4 above, a number of working assumptions have had to be made. The following factors described in i) to vi) below, are likely, to a greater or lesser extent, to affect the estimated annual costs of funding TAs.
- 10.9 The assumptions which have informed the modelling work are as follows:
 - i) It is assumed that there is no decrease in the backlog costs moving forward It is acknowledged that this is an inaccurate assumption as regrettably some of those patients in receipt of newly introduced TAs will pass away over time and will not require treatment on a long-term basis.

It is challenging to make any accurate assumptions around expected mortality rates, which would reduce the number of patients receiving treatments in successive years and therefore reduce the associated costs. Different modelling assumptions would need to be applied to the expected mortality rates for the range of health conditions requiring TA drugs and treatments, mapped against the associated cost of these treatments, in order to determine what the net financial impact could be in the future.

¹⁵ Paragraph 6.5 "Contributory Benefit and Contribution Rates for 2020" – Committee for Employment & Social Security - <u>Billet d'État XX of 2019</u>

¹⁶ In June 2019 the States agreed to transfer responsibility for the Guernsey Health Service Fund – now renamed the 'Guernsey Health Reserve' - from the Committee *for* Employment & Social Security to the Committee *for* Health & Social Care - <u>'Reform of Health Care Funding'</u> - <u>Billet d'État X of 2019</u>

Some initial work was completed in an effort to understand the impact of a reduction in backlog patient numbers over time, but the complexity of this work and the number of assumptions supporting this analysis makes it particularly challenging to do so with any accuracy and therefore no allowance has been made for mortality rates. That said, this early modelling work revealed reducing backlog numbers **could** reduce costs by an estimated £250,000 per annum.

ii) No allowance has been made for the procurement costs or the ongoing running costs associated with new TAs introduced after 31st December 2018 Approximately 70 additional TAs are approved by NICE each year. Although it has not been possible to make any accurate assumptions about the net effect of these additional TAs, newly approved drugs tend to be more expensive and is therefore anticipated to increase expenditure over time. Only a proportion of the newly available TAs will fall under the £40,000 ICER threshold in Years 1 and 2 but this could be anticipated to increase costs by as much as 40%, based on the proportion of TAs falling within this range.

Some of these new TAs may replace existing TAs for the same condition and will therefore offer an alternative or replacement drug or treatment, rather than being an entirely new treatment offered to an additional cohort of patients.

As it is not known in advance which TAs will be approved, the responsive nature of this is such that the detail and true impact of this factor on future costs is difficult to predict with certainty.

Furthermore, the increased costs of new TAs may be counterbalanced to some extent by the financial impact of a reduction of backlog patient numbers outlined in i) above.

iii) It is assumed that Guernsey can obtain the same discount as the NHS for procuring drugs

If a lesser discount is available, purchasing costs will be higher than shown in Tables 3 and 4. Up until now, Guernsey has been able to negotiate competitive discounts on drug prices. However, if similar levels of discounts could not be negotiated in the future, this could be expected to increase drug procurement costs by an estimated 30%.

iv) There are limitations to the input data feeding the modelling

The anticipated patient numbers that are expected to present with certain conditions over time has been estimated. It can be expected that there will be variations to the input figures feeding this aspect of the modelling because, as is the current situation, there will be a need to respond to patients' needs as they present themselves.

As a small jurisdiction with a small population, the Bailiwick is also vulnerable to significant statistical anomalies in terms of the incidence or prevalence of a particular clinical condition. For example, HSC currently experiences budgetary challenges when a patient with a complex condition presents late in the financial year for off-Island treatment, such as an organ transplant. Such treatment tends to be costly and cannot be predicted in advance¹⁷.

It is therefore tentatively suggested that margins of error could be up to 30%, which would impact on future expenditure.

v) There is no allowance for inflation of drug costs in future years Inflation for purchasing drugs and treatments is a recurring pressure on HSC's General Revenue budget and will affect drug procurement costs in the future.

In the UK, NHS Improvement assumes 4.1% per annum for inflation in drug costs and the CfHSC has typically allowed this sum when building its budget request for the forthcoming financial year. However, many of the new TAs will be used in the community, where the CfESS has previously used a higher figure of 10% for expected inflation.

No allowance has been made for the potential loss of private patient income At present, access to a broader range of drugs and treatments, including those presently unfunded TAs, are available to private patients. Whilst it is the view that some patients would continue to opt to receive their treatment privately, the move to routinely fund TAs is expected to reduce private patient income into HSC's revenue budget.

No data has been collected to support the above assumption and further analysis would be required to accurately assess what this financial impact could be. It is however estimated that this may be in the region of £0.5m per annum, which would impact on HSC's ability to manage within its annual revenue budget allocation.

It is suggested that this financial impact will be monitored by the Committee following the introduction of TAs and reported to the States as part of the review to be completed towards the end of Year 2.

10.10 An additional sum of money, up to £150,000, is also being requested to enable the CfHSC to obtain the specialist input required to complete the review in Year 2 to inform the next stages of work. This cost has not been included in Table 3 above.

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¹⁷ This becomes a particularly relevant consideration if Highly Specialised Technologies are introduced in future years (see also Section 6).

11 Competing Priorities for Funding

- 11.1 The Committee has carefully considered the relative merits of an increased investment into a wider range of drugs and treatments versus investing in other areas of the health service, such as prevention, early intervention and other new service developments that would equally give rise to improvements in patient care.
- 11.2 The CfHSC recognises the benefits of adopting TAs and considers that the disparity with England has become too great and is not justifiable. However, it does not wish for such a significant long-term investment into a broader range of drugs and treatments to be at the expense of HSC's plans for the wider transformation of health and care that will have longer-term and far-reaching benefits to improving the overall health and wellbeing of the population.
- 11.3 For example, as part of its commitment to improve outcomes through prevention and early intervention, as outlined in the Partnership of Purpose, in January 2019 the Committee introduced free cervical screening for women aged between 25 and 65 years of age. There is evidence of an increased take-up in screening in the first six months of the year. The total cost of this investment in 2019 is expected to be in the region of £200,000. This programme will provide free cervical screening annually to approximately 3,800 women living in the Bailiwick.
- 11.4 This measure, together with the HPV vaccination programme, will help to move towards eliminating cervical cancer in our community, with the long-term effect of reducing the prevalence of the disease and the associated cost of expensive treatments for cervical cancer in the future. Funding new drugs at the expense of such programmes of prevention would thus be counterproductive and more costly in the long-term. Likewise the inclusion of hepatitis B vaccine as part of the childhood immunisation programme will protect children from becoming infected with the hepatitis B virus with the possible risk of developing cirrhosis of the liver and liver cancer.
- 11.5 The proposals set out in this Policy Letter also need to be considered in in the context of HSC's considerable budget pressures and the increasing demand for health and care services within our community. The ageing demographic, a growing demand for increasingly specialist services, together with general developments in modern healthcare, are also having a very real impact on the service being delivered by the Committee and on revenue expenditure. It is becoming progressively more difficult to meet increasing demands within budgetary constraints. For example, some individual service areas within the PEH reach capacity at various times across the year and there has also been increasing demand for services such as radiology.
- 11.6 Increased demand means increased activity and the need for more staff and other resources. Furthermore, the Committee receives numerous bids from across HSC for additional funding for services that would improve patient care, which have had to be prioritised. It is not possible to fund all new innovations or service developments. In addition, cases are becoming increasingly complex and people are living longer with

multiple conditions. The health and care pressures arising from an ageing population are having a real and tangible impact on costs, presently estimated to be resulting in additional expenditure of £1m year on year. This should not come as a surprise. The modelling work completed by KPMG in 2017 highlighted that an additional £20.6m would be required by 2027 to meet the needs for additional services arising from the demographic challenges alone.

- 11.7 In presenting these proposals the Committee is keen to highlight that it would not be possible to fund additional drugs and treatments from within its existing general revenue budget without significant cuts to services elsewhere in HSC. It is the Committee's strong view that this would be a highly unsatisfactory solution and would be untenable.
- 11.8 As such, if the Propositions to extend the range of drugs and treatments available to Guernsey and Alderney residents are agreed by the States of Deliberation, it would be necessary to make funding available from an alternative source.

12 Proposed Interim Source of Funding: The Guernsey Health Reserve

- With the above in mind, and having discussed and agreed this approach with the Policy & Resources Committee, it is proposed to use part of the GHR to meet the cost of those TAs introduced in Years 1 and 2. The requirement for funding is estimated to be in the region of £5.6m in Year 1 and £8.3m from Year 2. It is also assumed that funding of drugs with an ICER up to £40,000 will continue until a decision has been made on the policy approach for drugs with an ICER greater than £40,000, following the review undertaken towards the end of Year 2.
- 12.2 The GHR is part of the contributory benefits system designed to make primary and secondary medical care more accessible to the population. In 2019, it held an estimated £120m of reserves, which provide health and care services under the provisions of the Health Service (Benefit) (Guernsey) Law.
- 12.3 The States has, upon consideration of a Policy Letter entitled "Reform of Health Care Funding" (Billet d'État X of 2019) already agreed a series of Resolutions for the transfer of functions of the GHR from the CfESS to the CfHSC to bring the governance of all health services provision unambiguously under the mandate of the CfHSC and the legislative changes required to give effect to these Resolutions is underway. As part of these changes this fund will be transferred to General Revenue.
- 12.4 In approving Resolution 13) of the above Policy Letter, the States agreed:
 - "13) To delegate authority to the Policy & Resources Committee to approve use of the Guernsey Health Reserve for the following purposes:
 - a. to fund unanticipated expenditure pressures in providing health services that arise outside of the normal budgetary process and cannot be met within that year's budget of the Committee for Health & Social Care;

- to fund revenue or capital expenditure on health transformation projects aimed at improving the efficiency, quality or capacity of health services in Guernsey which demonstrate long term benefits to the sustainability of Guernsey's health care system, subject to the same application process and governance conditions pertaining to the Transformation and Transition Fund or Capital Reserve;
- c. to manage any transitionary costs associated with implementing healthrelated transformational programmes; and
- d. to fund revenue or capital expenditure on management of cost pressures developing within the health service provision over the long term associated with the aging of the population."
- 12.5 The recommendation to fund TAs on an interim basis using the GHR is therefore consistent with this Resolution. Although this would not offer a sustainable long-term funding arrangement, this would allow TAs to be introduced on an incremental basis as described and for a review to take place towards the end of Year 2 which will help to inform future funding requirements. At this time, and informed by work to be carried out by the Policy & Resources Committee to review the Fiscal Policy Framework¹⁸ and the intended review of long-term revenue raising options referenced in the 2020 budget¹⁹, the CfHSC and the Policy & Resources Committee will recommend to the States a more sustainable, long-term funding solution for drugs and treatments in receipt of a TA.
- 12.6 Given the transfer of functions associated with the GHR which have been agreed by the States, and the timing of the associated legislative work to give effect to those decisions, together with the timing of making newly approved drugs and treatments available (if approved), it may be necessary for the costs to be met initially from General Revenue and then for the value of the expenditure incurred to be transferred from the Fund at a later date, once the legal changes have been made and governance structures are in place.
- 12.7 Proposition 2 of this Policy Letter has therefore been drafted to ensure that, if approved by the States, TAs can be introduced as soon as possible, whilst ensuring that the necessary funding is in place to enable this to happen, with the GHR being the proposed funding source, albeit that the costs may be met in the short-term by General Revenue.

¹⁸ At the time of writing, it is expected that the Policy & Resources Committee will present to the States a Policy Letter entitled "Long Term Fiscal Pressure and the Review of the Fiscal Policy Framework" for debate in January 2020, at the same States meeting as this Policy Letter on drugs and treatments.

¹⁹ Policy & Resources Committee "The States of Guernsey Annual Budget for 2020" – <u>Billet</u> d'État XXI of 2019

13 Overview of the Recommendations

- 13.1 The CfHSC has carefully considered the findings of the review and recommends to the States the following:
 - That, in principle, the States of Guernsey should move towards funding all drugs, treatments and devices with a TA from NICE, including those approved for funding from the CDF;
 - The move towards funding TAs should happen in stages based on a universally accepted method of differentiating drugs, known as the incremental cost effectiveness ratio (ICER). Year 1 should see the introduction of TAs with an ICER of up to £30,000 and Year 2 should introduce further drugs and treatments with an ICER of up to £40,000, which will continue until such time that the States is presented with the information necessary to debate and agree any change in policy;
 - The costs, which are estimated at £5.6m in Year 1 and £8.3m from Year 2 are to be met from the GHR, subject to the legislative changes to the Fund being completed, or from General Revenue on an interim basis;
 - The ability to include non-NICE TAs within drug funding policy should be retained to ensure best value for money. A non-statutory approach to drug funding on an ongoing basis will enable the Committee to continue to benefit from the best aspects of its current processes and retain flexibility in its decision-making processes; and
 - A review should be carried out towards the end of Year 2 to assess both the
 practical application of TAs in Years 1 and 2 and enable a full assessment of the
 introduction of TAs locally. The review will help to determine the approach to the
 next stages of work to introduce drugs and treatments with an ICER value greater
 than £40,000 and to report back to the States to secure the necessary funding to
 do so.
- 13.2 The sum of £150,000 is being requested to enable the CfHSC to obtain the specialist input required to complete this review.

14 Potential Risks and Issues

14.1 The Committee holds the view that, if approved by the States of Deliberation, it would be sensible and manageable to approach the introduction of TAs in an incremental way. Not only would this allow the necessary infrastructure to be put in place and to staff the services accordingly, but would also allow time for a review of the first phase so that a later phase/s could benefit from the organisational learning and feedback of service-user experience.

- 14.2 However, during the transition period, the proposed approach which prioritises treatments with an ICER value of up to £40,000 will introduce a new inequality for those people who would benefit from a treatment falling into a higher ICER banding which would not be available during the first stage.
- 14.3 As already described, to successfully manage the change in policy will also require sufficient funding to be allocated to the Committee to ensure that the necessary processes are in place to engage fully with staff, service-users, Primary and Secondary Care and off-Island providers. Effective communication and stakeholder engagement will be particularly important during the transition phases.

15 Consultation and Engagement

- 15.1 The CfHSC has discussed its proposals with the Policy & Resources Committee and the Committee for Employment & Social Security.
- 15.2 The review process has been informed by the views of a wide range of stakeholder groups, including members of the public, service-users, community groups, GPs, representatives from the Medical Specialist Group and other clinicians. This feedback is summarised in Section 6 of this Policy Letter and in detail in Appendix 3 (Section 3).
- 15.3 With permission, a copy of the correspondence received from Island Health in relation to these proposals is provided in **Appendix 5**.

16 Compliance with Rule 4

- 16.1 Rule 4 of the Rules of Procedure of the States of Deliberation and their Committees sets out the information which must be included in, or appended to, motions laid before the States.
- 16.2 In accordance with Rule 4(1), the Propositions have been submitted to Her Majesty's Procureur for advice on any legal or constitutional implications.
- 16.3 In accordance with Rule 4(3), the Committee has included Propositions which request the States to approve funding of not less than £5.6m in Year 1 and £8.3m from Year 2. Further details about the financial implications and the assumptions which relate to the estimate of the likely costs which arise from these Propositions are provided in Section 10.
- 16.4 In accordance with Rule 4(4) of the Rules of Procedure of the States of Deliberation and their Committees, it is confirmed that the propositions above have the unanimous support of the Committee.
- 16.5 In accordance with Rule 4(5), the Propositions relate to the duties of the Committee for Health & Social Care to protect, promote and improve the health and wellbeing of individuals and the community.

16.6 Also in accordance with Rule 4(5), as set out in Section 6 of this Policy Letter, the Committee *for* Health & Social Care has consulted with a wide range of stakeholder groups. It has also sought the views of the medical practice groups in the Island and the Medical Specialist Group.

Yours faithfully

H J R Soulsby President

R H Tooley Vice-President

R G Prow D A Tindall E A McSwiggan

R H Allsopp, OBE Non-States Member

of the ISLAND OF GUERNSEY

REQUÊTE

DRUG FUNDING

THE HUMBLE PETITION of the undersigned Members of the States of Deliberation SHEWETH THAT:

- 1. In the context of Europe as a whole the UK tends to be a late funder of new drugs and other medicinal treatments due to the rigorous cost/benefit analysis carried out by the National Institute for Health and Care Excellence ("NICE").
- Guernsey maintains its own white list of the drug treatments it will fund publically under the Health Service (Benefit) (Guernsey) Law, 1990. This is narrower than the list of drugs which can which can legally be prescribed in Guernsey on a self-funded basis.
- In its early years the Guernsey white list would automatically include any drugs approved for public funding within the UK National Health Service ("NHS") by NICE with the local clinical committee considering whether Guernsey wished to fund any additional drugs.
- 4. In recent years that practice has been reversed with many drugs which are publically funded in the UK not being included on the Guernsey white list.
- 5. Over the years since this change of policy the list of medications which are publically funded in the UK and the Guernsey white list have gradually diverged to the point that there is now a significant number of Guernsey people who find that, at the most vulnerable time of their lives, they are denied funding for the drugs their consultants would like to prescribe and which they would be able to prescribe had that patient lived elsewhere in the British Isles.
- Given that the expertise within NICE, on both drug efficacy and costeffectiveness, well exceeds that of the local clinical committee your petitioners
 presume that the driver for this major policy change was the simple need to
 save money.

- 7. While your petitioners applaud the desire of the Committee *for* Health & Social Care [and its predecessors] to bear down on rising costs we have major concerns over the way it has been done in this instance.
- 8. Ideally your petitioners would like to see the Guernsey policy on funding medicinal drugs return to one where the local white list contains all of the drugs approved for public funding in the UK meaning that local people are not denied important treatments which they could access elsewhere in the British Isles.
- 9. As an interim step your petitioners believe it is vital that Guernsey patients sent to the UK for treatment/consultation are not disadvantaged compared to UK resident patients with the same conditions.
- 10. Guernsey's health service is not a wholly separate entity but relies very heavily on NHS hospitals to provide tertiary care.
- 11. Very many Guernsey patients are sent to Southampton and other major UK hospitals for treatments which are not available in Guernsey. Others are referred to a UK based consultant for one or more consultations.
- 12. Your petitioners regard it as perverse and politically/ethically unsustainable that having referred Guernsey patients to the UK for treatment or consultation they are then denied the same range of treatment options available to all of the other patients in those same hospitals or being cared for by the same consultants.
- 13. Your petitioners note that other Crown Dependencies recognise the imperative to allow their patients to be treated under the same protocols as UK patients when in UK hospitals. [See appendix 1]
- 14. Your petitioners welcome the decision of the States to agree that the Committee for Health & Social Care shall review the funding considerations of all treatments, services and other interventions. [Partnership of purpose policy letter Resolution 14 on item XII of Billet d'État No. XXIV of 2017¹]

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¹ Resolution dated 13th December, 2017

- 15. Your petitioners further welcome the later direction that this review be completed within this political term [Policy & Resource Plan debate 2018 Resolution 1 o) on item I of Billet d'État No. XV of 2018²].
- 16. Since the initial drafting of this requete your petitioners have learned that HSC intend to report back with the findings of their review in the third quarter of 2019.
- 17. Your petitioners, however, feel that the States should commit now to the pledge that as a minimum the outcome of such a review should lead to Guernsey patients referred for tertiary treatment in the UK being able to access the same range of medicines and treatments as other patients with the same conditions in the same hospitals or medical centres.
- 18. Your petitioners also believe that such equality of treatment must extend to the ongoing treatment of those same patients after they have returned to Guernsey.
- 19. Your petitioners believe that by resolving now to implement such policies it will guide the review as what is or is not a politically acceptable outcome of the review.
- 20. Your petitioners, while understanding the financial considerations involved, would urge that such a limited development should be brought forward and implemented ahead of the conclusion of the general review if at all possible.
- 21. Your petitioners understand that providing equality of access to treatments between Guernsey patients and UK patients in the same hospitals and medical centres in the UK does nothing to address the limited access to treatments currently experienced by Guernsey patients who are not referred to the UK.
- 22. Your petitioners accept that this could be seen as somewhat inconsistent but believe it addresses the most glaring unfairness which the current policy creates.
- 23. Your petitioners believe that eventually there should be a far wider relaxation of the Guernsey white list so that it returns to the working within the previous

² Resolution dated 6th June, 2018

policy of automatically accepting all drugs approved for funding in the UK by NICE.

24. The proposals attached to this requete should be, therefore, be viewed not as aspirational targets but as the bare minimum acceptable.

THESE PREMISES CONSIDERED, YOUR PETITIONERS humbly pray that the States may be pleased to resolve:

- To direct the Committee for Health & Social Care and the Committee for Employment & Social Security that as a minimum outcome the current wideranging review of the funding of treatments, services and other interventions should result in Guernsey patients who are referred to the UK for tertiary treatment having access to the same range of medicines and treatments as NHS funded patents being treated in the same hospitals or medical centres for the same conditions.
- 2. That such equality of access should also apply to those same Guernsey patients post-discharge or when they have returned to Guernsey after a tertiary treatment episode.
- 3. To direct the Committee for Health & Social Care and the Committee for Employment & Social Security to consider if there is any practical way to bring forward such a development ahead of the outcome of the general review.
- 4. That, in principle, in the medium term Guernsey should return to the policy of including all NICE approved drugs on the local white list.

AND YOUR PETITIONERS WILL EVER PRAY GUERNSEY

This 26th day of September 2018

AA

Deputy Peter Rothery

Deputy JEREMY SMITHIES

Vepty havid Deny

The original signed copy of this Requete is held at the Greffe.

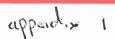
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DEPARTMENT OF HEALTH AND SOCIAL CARE (DHSC)



Funding Arrangements for Cancer Drugs (Interim Policy)

The Department of Health and Social Care (DHSC) <u>WILL FUND</u> cancer drugs for Isle of Man residents in line with the Cheshire and Merseyside Chemotherapy protocols available on-line at:

http://www.nwcscnsenate.nhs.uk/strategic-clinical-network/our-networks/cancer/chemotherapy-protocols/ (last accessed 15 June 2017)

DHSC **WILL FUND** new cancer drugs once these have been approved for routine use in the NHS in England by the National Institute of Health and Care Excellence (NICE), as these are included in the Cheshire and Merseyside protocols.

DHSC **WILL FUND** drugs recommended by NICE for use within the new (2016) Cancer Drug Fund (CDF). NICE recommends use within the CDF when there is considered to be plausible potential for a drug to satisfy criteria for routine commissioning, but where there is significant remaining uncertainty. The new CDF is a managed access scheme with clear entry and exit criteria for each drug/indication. It provides an opportunity to gather additional data on clinical and cost effectiveness which will enable NICE to make a final decision on appropriateness of routine funding within the NHS. DHSC will fund patients to receive drugs included within the new CDF where the patient will receive treatment with the drug within the NHS England arrangements. That is, DHSC will be able to access the drug at the price agreed between NICE and the manufacturer, the patient will be managed according to the protocol agreed within the CDF, and the patient's clinical data will be reported into the CDF and thus contribute to the understanding of clinical and cost effectiveness.

Note:

Isle of Man residents requiring specialist cancer treatment funded by DHSC receive this through hospitals within Cheshire and Merseyside. It is therefore appropriate for DHSC to fund treatment in line with the protocols followed by these hospitals.

The revised arrangements for the CDF in England were introduced in 2016. The NHS England budget to cover the costs of drugs used within CDF arrangements is £340 million per year. Pro-rata'd for the Isle of Man population, this would indicate an expected cost to the DHSC of around £500,000 per year. In practice, because the Isle of Man population is small, the number of patients eligible for CDF drugs will fluctuate widely year on year, simply due to statistical chance. It is, therefore, important that DHSC monitors spend on CDF. While it is desirable to fund clinical studies to confirm clinical and cost effectiveness, it should be remembered that money spent on treatments of uncertain effectiveness is not available to spend on other areas of care where effectiveness may already be established. In order to better understand the value DHSC, and the population of the Isle of Man, will derive from inclusion within CDF arrangements, this policy will be interim and will be fully reviewed for clinical benefit and cost utility at the review date.

¹ Based on an England population of 55 million, an Isle of Man population of 83,000 and assuming similar patterns of cancer incidence and progression.

Reason for policy:

Existing cancer drug policies needed revision in the light of changed arrangements for NICE assessments and the Cancer Drug Fund in England.

This policy replaces the CRC Recommendations:

- Cancer Drug Treatments Consideration of Funding for New Treatments Outside Currently Agreed Pathways (July 2015);
- · Chemotherapy Protocols (January 2011); and
- Expensive End of Life Treatments (April 2009)

Further information contact:

Tel: +44 (0)1624 642646

Email: clinicalcommissioning.dhsc@gov.im
Website: www.gov.im/dhscclinicalcommissioning

Date for policy review: June 2018



Note.

Your petitions confirm that this this requete has been submitted to the law officers for advice as required by rule 4(1)

In respect to rule 4(2) your petitions request that this requete be debated as soon possible.

In respect to rule 4(3) your petitions requested estimates of the financial implications of each of the propositions attached to this requete several weeks before submitting it. At the time of submission no such estimates had been provided but hopefully they will be during the statutory consultation on the requete.

of the ISLAND OF GUERNSEY

12th December, 2018

Proposition No. P2018/91

AMENDMENT

Proposed by: Deputy H.J.R. Soulsby Seconded by: Deputy M.K. Le Clerc

Requête Drug Funding

To delete the propositions and substitute:

"EITHER:-

1)

- a) To direct the Committee *for* Health & Social Care and the Committee *for* Employment & Social Security to commission a wide ranging review of the funding of drugs, treatments and devices in accordance with the Terms of Reference attached under Rule 24(1) and to direct the Policy & Resources Committee to make funding available from the 2019 Budget Reserve. The review should consider, as a minimum, the implementation of a policy for the availability of all drugs, treatments and devices approved by NICE Technology Appraisals. The findings of the review should be published no later than the end of the second quarter of 2019.
- b) To direct the Policy & Resources Committee to present future funding options to meet any increase in expenditure arising from any changes recommended to existing drug and treatment funding policy from the review, and to report back to the States as part of the 2020 Budget.

OR

2)

a) To make available, as soon as practically possible, drugs, treatments and devices recommended via NICE Technology Appraisals for Guernsey and Alderney patients, including end of life premium drugs.

- b) To establish a Guernsey and Alderney equivalent of the England Cancer Drug Fund, with the aim of making promising cancer drugs available to patients before fully approved for use in the NHS. Such Cancer Drug Fund to be established on an interim basis and to be reviewed before the end of 2021.
- c) To direct the Policy & Resources Committee to meet any additional costs arising from the introduction of 2) a) and 2) b), on an interim basis, as soon as practically possible; and
- d) To direct the Policy & Resources Committee to determine long-term future funding arrangements and to report back to the States as part of the 2020 Budget."

Explanatory note

This amendment asks the States to make a choice between two options in relation to the provision of drugs, treatments and devices.

The first option seeks to ensure that any changes to current policy are evidence-based and informed by a full review with independent, specialist healthcare public health input. In accordance with the principles of good governance, it also allows time for a range of future funding options to be prepared to ensure that the financial implications for the States of Guernsey are known when deciding if new drugs and treatments should be publicly funded.

The review will consider the equitable access to drugs, treatments and devices for all patients in Guernsey and Alderney regardless of where such treatment is being delivered (i.e. off-Island or on-Island). The Prayer of the Requête emphasises the needs of those patients who are referred to the UK for treatment and the drugs that are available to them on their return to the Islands, to the exclusion of those patients who remain on-Island for treatment.

Option 1 also asks the Policy & Resources Committee to prioritise the allocation of resources to expedite the review to enable the findings to be published no later than the end of the second quarter of 2019. It is anticipated that the cost of the specialist healthcare public health input required to carry out the review will not exceed £100,000. This timescale will provide sufficient time to enable the Budget of the States for 2020 to be informed by the review.

While the review is ongoing, the Committees will continue to apply their current policy, under which doctors may apply for any NICE-approved drug to be funded by the Committee for Health & Social Care or the Committee for Employment & Social Security (as applicable). The Committees commit to consider all applications extremely carefully and as quickly as possible.

The second option enables all drugs, treatments and devices supported by NICE Technology Appraisals to be made available and to introduce a Cancer Drugs Fund on an interim basis, to direct Policy & Resources to fund any additional costs needed for 2019 and consider future funding as part of the 2020 Budget. The additional cost relating to pharmaceuticals only is estimated to be not less than £4-5 million per annum.



TERMS OF REFERENCE

THE REVIEW OF DRUGS, TREATMENTS AND DEVICES

Project Ambitions

The project ambitions are as follows:

- To review the principles and criteria that are used by the States of Guernsey to decide if new drugs and treatments should be publically funded and to suggest any changes that may be necessary to better support the relevant key aims of the Partnership of Purpose.
- To consider the cost and health impact expected to arise from any changes to the current approach.
- To produce a report outlining the findings of the review for consideration by the Committee *for* Health & Social Care (HSC).
- To outline a process for moving towards the presumptive funding of NICE Technology Appraisal-approved drugs and treatments.
- To use this report to inform a policy letter to be published no later than the end of Quarter 2 in 2019.

Background

Resource allocation in health and care is a complex area of health care policy making, ensuring that resources are committed in a way which best meets locally identified health needs and priorities. The success of this requires various factors to be carefully balanced including the need to consider services available, the level and standards of such services, access and eligibility to such services, and their design and quality.

Current processes adopted with the Bailiwick of Guernsey have evolved as one way to fairly and responsibly manage the health budget, such processes are not without their challenges as they have inevitably resulted in some drugs and treatments being turned down and public understanding of the process is limited. The procedures are outlined in HSC Policy 1033 "Priority setting in Health & Social Care" and Policy G1002 "Individual funding requests"

In the UK, the National Institute for Health and Care Excellence (NICE) seeks to improve outcomes for people using the NHS and other public health and social care services by evidence-based guidelines, developing quality standards and performance metrics, and



providing a range of information services for commissioners and providers of health and care.

NICE guidelines all have the status of 'guidance' in the NHS in England, and are adopted to varying extents according to local wants, needs and available budget. However, in 2012, in an attempt to tackle the 'postcode lottery' in health, it was made mandatory for health service commissioners in England to fund those drugs recommended via NICE Technology Appraisals (TAs).¹

In England the funding of cancer drugs has recently been reviewed. The new Cancer Drug Fund (CDF) was established in 2016 and is the product of partnership working between NHS England, NICE, Public Health England, and the Department of Health and has been informed by further engagement with patient groups and industry. It is a managed access scheme to cancer drugs with the aim of making promising cancer drugs available to patients before they are fully approved for use in the NHS. The changes were introduced to the way in which cancer drugs are appraised and funded and are designed to:

- provide patients with faster access to the most promising new cancer treatments
- drive stronger value for money for taxpayers in drugs expenditure;
- offer those pharmaceutical companies that are willing to price their products responsibly, a new fast-track route to NHS funding for the best and most promising drugs via an accelerated NICE appraisal process and a new CDF managed access scheme.

As a result a modified appraisal process for cancer drugs was introduced on 1st April 2016 and now allows NICE to make one of three recommendations:

- Recommended for routine commissioning- 'yes';
- Not recommended for routine commissioning- 'no';
- Recommended for use within the CDF.

The new recommendation available to NICE - 'recommended for use within the CDF' – can be used when NICE considers there to be plausible potential for a drug to satisfy the criteria for routine commissioning, but where there is significant remaining clinical uncertainty. This fund is managed centrally. At the end of the managed access period, NICE will re-appraise

-

¹ The technology appraisal processes are designed to produce recommendations in the form of NICE guidance, on the use of new and existing medicines, products and treatments in the NHS. An appraisal is based on a review of clinical and economic evaluation. Clinical evidence shows how well the technology works – the health benefits. The evidence includes the impact on the quality of life (for example, pain and disability), and the likely effects on mortality. Economic evaluation shows how well the technology works in relation to how much it costs the NHS and whether it represents value for money.



the drug with a view to deciding whether or not the drug can be recommended for routine commissioning.

In 2009 NICE issued supplementary advice to its Technology Appraisal Committees which set out how the Committee can recommend a treatment in relation to end of life care. This treatment is indicated for patients with a short life expectancy, usually less than 24 months where there is sufficient evidence to indicate that treatment offers an extension to life (more than 3 months). This resulted in an adjustment of the relevant cost effectiveness threshold (i.e. £20k-£30k per QALY² or up to £50k per QALY for end of life care drugs / indications). The concern of this policy is that NICE has given preferential treatment to those interventions that provide palliation at the end of life, so potentially displacing treatments with a greater health benefit.

The Committee *for* Health & Social Care's Partnership of Purpose policy letter was unanimously approved by the States of Deliberation in December 2017. This Policy Letter contained 22 wide ranging resolutions designed to support the transformation of health and care services physically, virtually and financially.

As part of the Partnership of Purpose, there was unanimous agreement by the Assembly to carry out a review of the funding of drugs and treatments. More details were provided in an HSC-led amendment to the Policy & Resources Plan in June 2018 which stated that:

"the review of processes used to consider whether new drugs and medical treatments should be funded, as set out in Resolution 14 of Art XII, Billet d'Etat No XXIV of 2017 should:

- Assess the guiding principles which should underpin resource allocation in health and social care;
- Take into account the need to ensure that limited resources are used fairly and equitable, maximizing the value of care delivered to the population as a whole and the processes followed;
- Incorporate the experience of other jurisdictions, including guidance produced by the (UK's) National Institute of Health & Care Excellence;
- Consider whether a Guernsey and Alderney resident being treated in a UK tertiary centre should have access to all drugs and treatments normally available in that tertiary centre."

² A measure of the state of health of a person or group in which the benefits, in terms of length of life, are adjusted to reflect the quality of life. One QALY is equal to 1 year of life in perfect health. QALYs are calculated by estimating the years of life remaining for a patient following a particular treatment or intervention and weighting each year with a quality-of-life score (on a 0 to 1 scale). It is often measured in terms of the person's ability to carry out the activities of daily life, and freedom from pain and mental disturbance.



The current policy direction for funding drugs and treatments in Guernsey and Alderney is set out in Art III, Billet d'Etat XIII of 2003 and the Committee's internal policy (G1033) is available online at www.gov.gg/fundingprioritisation. There is a separate policy and process for 'Individual Funding Requests' (G1002) – which are not the subject of this Requête, but will be in scope for the review – also available online.

In addition to HSC the Committee *for* Employment & Social Security (ESS) has a significant role in drug-funding decisions under the Health Service (Benefit) (Guernsey) Law, 1990. While HSC is responsible for determining which drugs should be funded for use within its premises, ESS is responsible for deciding which drugs should be funded in the community, at the subsidised prescription rate.

The two Committees agree that there should be consistency in their decision-making processes, and have already consolidated two separate advisory committees (HSC's former Drugs & Therapeutics Committee and ESS's former Prescribing Benefit Advisory Committee) into a single body, responsible for advising both Committees on drug funding decisions. It must, however, be noted that one of these groups is currently governed by legislation which is due to be amended or repealed to ensure that there are no obstacles to alignment with a common policy direction.

Scope of the Review

The scope of this review will consider the process by which drugs and treatments should be publically funded; the costs arising from any changes to the current approach; equity of access to care and the possible benefit to islanders' health of any such change. The review will consider the approach in other jurisdictions and will specifically consider the funding of cancer drugs and end of life care. The resulting report will consider possible future models for drug and treatment provision. The review will outline a process for moving towards the presumptive funding of NICE TA-approved drugs and treatments.

Objectives of the Review

The objectives of the review are to:

- Consider the most effective and equitable system of drug, treatment and device availability that aligns with the relevant key aims of the Partnership of Purpose.
- Consider the guiding principles underpinning resource allocation and the ethical considerations surrounding the funding of new drugs and treatments locally.
- Provide an overview of the model for drug, treatment and device availability in other
 jurisdictions, most notably other small island jurisdictions (for example Jersey and
 the Isle of Man), as well as England, Wales and Scotland, and compare these to the
 current situation in Guernsey and Alderney.



- Specifically consider what NICE TA-approved drugs and treatments are and are not funded in Guernsey and Alderney and analyse the impact, both health and economic, using an example of a NICE TA-approved drug that is not currently funded.
- Outline a process for the move towards the presumptive funding of NICE TAapproved drugs and treatments.
- Specifically consider whether the Guernsey and Alderney should participate in, or create its own Cancer Drug Fund and consider the health and economic impact of this.
- Specifically consider the health and economic impact of funding for end of life care drugs / indications (i.e. a QALY of £50,000).
- Specifically consider equity of access to all NICE-approved drugs and treatments, irrespective of whether these were initiated in a UK tertiary referral centre or in Guernsey or Alderney.
- Obtain input from Primary and Secondary Care, as well as CareWatch.
- Produce a report evaluating current approach and options for the future provision of drugs and treatment locally.

Preparatory Work in Progress

A workshop will be conducted with local politicians on the 11th December 2018, led by Dr Henrietta Ewart, Director of Public Health from the Isle of Man. The aim of this to provide information for local politicians on options for drug funding and approval.

A potential provider for the formal review has been identified and discussions are currently in progress.

An assessment of interdependencies with other related work streams is currently in progress.



Timeframe

Quarter 4 2018	Workshop with local politicians on the 11 th December 2018 which will be facilitated by Dr Henrietta Ewart from the Isle of Man. This will include consideration and exploration of approaches in other jurisdictions. Commissioning of external provider of the review.
Quarter 1 2019	Review conducted to include an analysis of the local situation and an options appraisal for future provision. This should also include exploring the views of Primary and Secondary Care and CareWatch. To be completed by the external reviewer. Background information drafting for policy paper for the States of Deliberation. To be completed by Health & Social Care.
Quarter 2 2019	May 2019: Results of the external review preview presented to the Committee for Health & Social Care and circulated to key stakeholders. To be presented by external reviewer. By the end of June 2019: Publication of the results of the review

Related Workstreams

Partnership of Purpose

Key Stakeholders

- Committee for Health & Social Care
- Health & Social Care Services
- Committee for Employment & Social Security
- Primary Care, Medical Specialist Group
- Clinical Reference Group
- Policy & Resources Committee



Next Steps

• Progress with workstreams outlined above in the time frame

Open Issues / Risks

• Resource allocation continues to be available

Link to Key Aims of the Partnership of Purpose

Prevention: supporting islanders to live healthier lives	Υ
User-centred care: joined-up services, where people are valued, listened to, informed, respected and involved throughout their health and care journey	Υ
Fair access to care: ensuring that low income is not a barrier to health, through proportionate funding processes based on identified needs	Y
Proportionate governance: ensuring clear boundaries exist between commissioning, provision and regulation	Y
Direct access to services: enabling people to self-refer to services where appropriate	
Effective community care: improving out-of-hospital services through the development of Community Hubs for health and wellbeing, supported by a Health and Care Campus at the PEH site delivering integrated secondary care and a Satellite Campus in Alderney	
Focus on quality: measuring and monitoring the impact of interventions on health outcomes, patient safety and patient experience	Y
A universal offering: giving islanders clarity about the range of services they can expect to receive, and the criteria for accessing them	
Partnership approach: recognising the value of public, private and third sector organisations, and ensuring people can access the right provider	
Empowered providers and integrated teams: supporting staff to work collaboratively across organisational boundaries, with a focus on outcomes	Y



The Review of Drugs and Treatments: Options Appraisal

A Report for The States of Guernsey Committee for Health & Social Care

Final report

www.sph.nhs.uk

May 2019



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1 Options Appraisal Summary

The primary focus of this Review is to provide the best estimate of the impact of funding all 160 currently unfunded treatments for specific indications approved by the National Institute for Clinical Effectiveness (NICE) Technology Appraisal (TA)¹ for all patients eligible for State funded healthcare in Guernsey and Alderney. These include 156 drug treatments (of which 88 are for the treatment of cancer) and 4 non-drug treatments.

Our approach and methodology was designed to deliver a report to the Committee for Health and Social Care (CfHSC) by the end of May 2019 which would present a range of commissioning options for the committee for to consider for adoption. These options range from routine full adoption of all NICE TA-approved treatments (approved up to 31st December 2018 and ongoing) through to maintaining the status quo, with a number of part- or phased- implementation options in between should it be decided that full implementation is unjustified or unaffordable.

Qualitative interviews and engagement meetings with stakeholders from the States of Guernsey, Jersey and the Isle of Man (further detail in Sections 3 and 5 respectively) and quantitative analysis of patient numbers and estimated expenditure (reported in Section 4) informed the selection of the options, which are:

- Fund all NICE TA-approved treatments
 - 1a. Fund NICE TA-approved treatments except Highly Specialised Technologies
- 2. Prioritise all NICE TA-approved treatments for cancer over treatments for other conditions
 - 2a. Prioritise NICE TA-approved treatments for cancer excluding those in the Cancer Drugs Fund
 - 2b. Prioritise NICE TA-approved treatments for cancer only from the Cancer Drugs Fund
- 3. Prioritise NICE TA-approved life extending, at the end of life treatments
- 4. Prioritise NICE TA-approved treatments for common diseases so that the greatest number of people will benefit
- 5, Prioritise NICE TA-approved treatments on the basis of (clinical and) cost effectiveness
- Status quo continue with the current system of individually reviewing the NICE evidence of clinical and cost effectiveness, if requested by a Consultant or GP

All the options, apart from option 6 (status quo), if adopted may conflict with a number of principles and rules in the CfHSC policy document 'G1033, Priority Setting in Health and Social Care' (2017a). Adoption of any of the options, apart from option 6 (status quo), would therefore require a review of the principles, rules and processes used by CfHSC for resource allocation.

-

¹ Published up to 31st December 2018



Table 1: Principles from G1003 which may conflict with selected options

Conflicting Existing Principles and Rules (in addition to the common set detailed above)	Option 1	Option 1a	Option 2	Option 2a	Option 2b	Option 3	Option 4	Option 5
General principles								
3.1 CfHSC will make investments that aim to maximise the value of care delivered to the population it serves.	•	•	•	•	•	•	•	
3.2.1 When making an investment decision, CfHSC will consider all potential and competing use of the funds in order to come to a view about the best option for investing limited funds. CfHSC will not, save in the exceptional circumstances set out in this policy, make isolated decisions about investments	•	•	•	•	•	•	•	•
3.3 CfHSC will only invest in interventions that are cost-effective	•	•	•	•	•	•	•	•
3.4 CfHSC will not fund treatments of unproven clinical effectiveness unless it is in the context of a well-designed clinical study					•			
3.5 CfHSC will live within the budget allocated to it by the States of Guernsey								
3.5.3 Where an adopted policy turns out to exceed the budget allocated for it, CfHSC will review the future access criteria	•	•	•	•	•	•	•	•
3.7 CfHSC must not allow third parties to determine priorities or make funding decisions on its behalf	•	•	•	•	•	•	•	•
Principles regarding NICE guidance								
6.1 All guidance produced by the NICE is considered advisory only	•	•	•	•	•	•	•	•
6.2 Treatments recommended by the NICE technology appraisal programme will not automatically be funded. Furthermore:								
6.2.1 Treatments whose cost-effectiveness is estimated to be above £30,000 per quality adjusted life years will not be funded, unless exceptional circumstances apply	•	•	•	•	•	•	•	•
6.2.2 Treatments whose cost-effectiveness is estimated to be below £30,000 per quality adjusted life years will be further assessed to determine whether or not they should be forwarded for prioritisation								



Conflicting Existing Principles and Rules (in addition to the common set detailed above)	Option 1	Option 1a	Option 2	Option 2a	Option 2b	Option 3	Option 4	Option 5
End of life treatments								
6.3 CfHSC will commission end of life treatments using the same decision making principles and processes as are applied to the commissioning of other treatments. An 'end of life premium' will therefore not be adopted when considering cost-effectiveness	•	•	•	•		•		
Treatments for orphan diseases								
6.4 CfHSC will commission treatments for orphan disease using the same decision making principles and processes as are applied to the commissioning of other treatments.	•	•		•				
The English Cancer Drugs Fund								
6.5 Cancer treatments funded through the Cancer Drugs Fund established by the Department of Health (England) and now operated by NICE will not routinely be funded by CfHSC.	•	•	•	•	•			
6.6 An equivalent of the English Cancer Drugs Fund will not be operated in Guernsey.								

Tables 2 to 10 summarise each of the options.

- The estimates of costs for each option are explained in Section 4 and reflect the likely discounts that the islands can achieve for the new treatments, as well as the cost offset of replacing existing drugs with the TA-approved treatments.
- The estimates are based purely on the likely number of patients who meet all the treatment criteria specified in each NICE TA recommendation. The use of the treatments for wider indications beyond the NICE TA is outside of the scope of this Review.
- It is important to note that the estimated financial provision of each option is for unfunded TA-approved treatments published before 2019. It does not include provision for the 70+ TAs expected to be published during 2019.
- The estimated cost impact for each option does not include associated service delivery costs (staff, equipment, diagnostics, facilities) or hospital revenue loss from patients who currently pay for treatment via private insurance or private means.
- It was not possible to estimate the difference in health gain (or loss) for each option as this information is missing or redacted in a large proportion of the NICE TA supporting documentation.



• The number of patients reflects estimates provided by on and off-island consultants. This approach was adopted because the NICE TAS do not consistently contain the patient numbers for England which could be pro-rata'd for the Guernsey and Alderney population. Relying on NICE for this information was therefore less useful than employing local clinicians' estimates.



Table 2: Summary of Option1

Option 1

Fund all NICE TA-approved treatments

Number of TA recomme TAs	endations /	Number o	of patients	Net cos	t impact
TA recommendations	TAs	Backlog	New patients per annum	Backlog	New patients per annum
160	145	3,348	782	£7.6m	£5.5m

Strengths

All patients who meet the NICE TA patient selection criteria will be treated regardless of:

- the location of their treatment
- their ability to pay
- the cost of the treatment
- how many other people have the same condition

This will result in equity of access to treatments already funded by the NHS for patients in England.

There is potential to re-focus some prescribing and formulary panel activity towards planning, implementation and audit rather than the funding decision process.

Weaknesses

Significant investment will be required in order to deal with the backlog of unfunded TAs. The estimated financial provision is for unfunded TAs published before 2019. It does not include provision for the 70+ TAs expected to be published during 2019. Some treatments are very high cost (up to £500,000 per patient per year).

72 (45%) NICE TA-approved treatments are not cost effective within an ICER<£30,000 per QALY.

New inequities will be introduced:

- Treatments not reviewed by NICE TAs are less likely to be able to secure funding.
 The opportunity costs will be borne by patients with treatments/conditions not covered by a NICE TA.
- Since the NICE TA programme is targeted at manufacturer sponsored drug therapies, this will exaggerate the inequity between priority for drugs and non-drug treatments.

The process for making funding decisions about treatments will need to continue to consider requests for treatments that the NICE TA guidance will not cover. This could be using drugs for a different indication, devices, surgical interventions, new services, screening or prevention interventions etc.

The health economy would lose the flexible approach to adopting NICE TA guidance. This might mean paying more for treatments when an alternative is available for a much lower cost e.g. intravitreal drug treatments for age related macular degeneration.

This option values new treatments, particularly new drugs, recommended by NICE more highly than all other treatments.



Table 3: Summary of Option 1a

Option 1a

Fund NICE TA-approved treatments except Highly Specialised Technologies

Number of TA recomme TAs	endations /	Number o	of patients	Net cos	t impact
TA recommendations	TAs	Backlog	New patients per annum	Backlog	New patients per annum
152	137	3,344	777	£6.9m	£4.5m

Strengths

Except for highly specialised technologies HSTs, all patients who meet the NICE TA patient selection criteria will be treated regardless of:

- the location of their treatment
- their ability to pay

This will result in equity of access to these treatments already funded by the NHS for patients in England.

There is potential to re-focus some prescribing and formulary activity toward planning, implementation and audit rather than funding decision.

Budget will not be reserved unnecessarily for rare conditions where there may be no uptake due to the absence of patients residing in Guernsey and Alderney.

Weaknesses

HST approved treatments excluded in this option

- The HST appraisal route is reserved for treatments for orphan diseases only and consequently the cost of treatment is very high. There may be no patients on the islands for some of the treatments and associated indications recommended in the seven HSTs.
- Even after discount, the gross cost of an HST treatment for one patient per annum ranges from over £100,000 to c.£500,000.
- Patients with a very rare disease for which there is a high cost treatment recommended in a NICE TA will be denied funding on the basis of the:
 - cost of the treatment
 - o rarity of the condition
- This will create inequity between patients who receive care under the NHS in England and patients who rely on the States of Guernsey for their health care.
- The high cost of treatment, combined with the need to be taken by the patient for the
 rest of their life means that it is unlikely that any patient would be able to fund
 treatment privately.

Funding for TA-approved treatments included in this option:

 Significant investment will be required in order to deal with the backlog of unfunded TAs.



- 68 (44%) NICE TA-approved treatments are not cost effective within an ICER<£30,000 per QALY.
- New inequities will be introduced:
 - treatments not reviewed by NICE TAs are less likely to be able to secure funding. The opportunity costs will be borne by patients with treatments/conditions not covered by a NICE TA.
 - since the NICE TA programme is targeted at manufacturer sponsored drug therapies, this will exaggerate the inequity between priority for drugs and non-drug treatments.

The process for making funding decisions about treatments will need to continue to consider requests for treatments that the NICE TA guidance will not cover. This could be using drugs for a different indication, devices, surgical interventions, new services, screening or prevention interventions etc.

This option considers the merits of treatments and values cost effectiveness more highly. Patients whose condition is, by chance, rare are not favoured.



Table 4: Summary of Option 2

Option 2

Prioritise all NICE TA-approved treatments for cancer over treatments for other conditions

Number of TA recomme TAs	Number of TA recommendations / TAs			Net cos	t impact
TA recommendations	TAs	Backlog	New patients per annum	Backlog	New patients per annum
88	84	114	98	£3.3m	£3.2m

Strengths

All patients with cancer who meet the NICE TA patient selection criteria will be treated regardless of:

- the location of their treatment
- their ability to pay
- · the cost of the treatment
- how many other people have cancer

Cancer treatments for patients at the end of life (EoL) or approved for funding from the CDF are included.

This will result in equity of access to treatments for cancer already funded by the NHS for patients in England.

There is potential to re-focus some prescribing and formulary panel activity toward planning and implementation rather than the funding decision process.

Over half of the unfunded TA recommendations would be approved for funding in Guernsey [88/156(56%) of the TA-approved drugs are for cancer].

Weaknesses

Significant investment will be required in order to deal with the backlog of unfunded TAs for treatments for cancer.

59 (67%) NICE TA-approved treatments for cancer which would be funded within this option are not cost effective within an ICER<£30,000 per QALY.

Prioritising funding for one category of disease only i.e. cancer may be considered irrational as it does not take into account the needs of patients with other diseases, their prognosis, alternative treatment options, the extent to which their condition is lifechanging etc.

Support for this option from the stakeholders consulted during this Review was equivocal.

44% of unfunded TAs are for treatments for conditions other than cancer. These treatments could be equally or more clinically and cost effective than the 88 cancer drugs identified in this option, but would not be funded within this option.

Patients who do not have cancer would not have funding for treatments recommended by NICE TA. This creates inequity solely on the basis of the category of their disease.

This option values one disease only, rather than the merits of the individual treatments.



Table 5: Summary of Option 2a

Option 2a

Prioritise NICE TA-approved treatments for cancer <u>excluding</u> those in the Cancer Drugs Fund

Number of TA recomme TAs	Number o	of patients	Net cos	t impact	
TA recommendations	TAs	Backlog	New patients per annum	Backlog	New patients per annum
49	47	61	52	£1.2m	£1.2m

Strengths

This option offers:

- equitable access for cancer treatments proven to meet the NICE criteria for clinical and cost effectiveness
- access to EoL cancer treatments which have a higher cost per QALY

It excludes treatments approved in the CDF due to the uncertainty about the evidence and cost effectiveness.

It will provide access to these selected cancer drugs regardless of:

- the location of treatment
- the patient's ability to pay
- · the cost of the treatment
- how many other people have the same condition

Weaknesses

This option excludes TA-approved drugs likely to be part of the CDF for 24 months. This means that this option would delay access to treatment with these drugs for approximately 2 years whilst patients treated in England are routinely treated with these drugs. In addition, funding these drugs at the agreed discounted price during the CDF period, contributes to post-hoc data collection and evidence.

This option excludes funding for all other conditions, even those recommended in a NICE TA.

32 (65%) NICE TA-approved treatments for cancer are not cost effective within an ICER<£30,000 per QALY.

44% of unfunded TAs are for treatments for other conditions. These treatments could be equally or more clinically and cost effective than the 49 cancer drugs identified in this option.

Patients who do not have cancer would not have funding for treatments recommended by a NICE TA, solely on the basis of the category of disease.

There was no consensus from the engagement feedback that EoL cancer treatment should be prioritised over other treatments.

This option values one disease only and selectively values the merits of individual treatments.



Table 6: Summary of Option 2b

Option 2b

Prioritise NICE TA-approved treatments for cancer <u>only</u> from the Cancer Drugs Fund

Number of TA recommendations / TAs		Number of patients		Net cost impact	
TA recommendations	TAs	Backlog	New patients per annum	Backlog	New patients per annum
All CDF treatments only 39	38	53	46	£2.1m	£2.0m

Strengths

Funding treatments in the CDF would contribute to improving the evidence base for these drugs. Patients would have early access to these treatments regardless of:

- the location of treatment
- the patient's ability to pay
- the cost of the treatment
- how many other people have the same condition
- current uncertainty about the clinical and cost effectiveness of the treatment.

Weaknesses

Significant investment will be required in order to deal with the backlog of unfunded TAs for CDF cancer drugs.

These treatments have insufficient evidence of clinical and cost effectiveness for NICE to approve them in a TA.

30 (77%) NICE TA-approved treatments are not cost effective within an ICER<£30,000 per QALY. There are other treatments for cancer and other conditions which have been approved by NICE for which there is stronger evidence of clinical and cost effectiveness.

It is not logical to fund research, but deny access to treatments already proven to be clinically and cost effective by NICE.

New inequities will be introduced:

- Patients who do not have cancer would not have funding for treatments recommended by a NICE TA, solely on the basis of the category of disease.
- Treatments not reviewed by NICE TAs are less likely to be able to secure funding.
 The opportunity costs will be borne by patients with treatments/conditions not covered by a NICE TA.
- Since the NICE TA programme is targeted at manufacturer sponsored drug therapies, this will exaggerate the inequity between priority for drugs and non-drug treatments.

The process for making funding decisions about treatments will need to continue to consider requests for treatments that the NICE TA guidance will not cover. This could be using drugs for a different indication, devices, surgical interventions, new services, screening or prevention interventions etc.

This option values one disease only, rather than the merits of individual treatments.



Table 7: Summary of Option 3

Prioritise NICE TA-approved life extending, at the end of life treatments

Number of TA recommendations / TAs		Number of patients		Net cost impact	
TA recommendations	TAs	Backlog	New patients per annum	Backlog	New patients per annum
51	49	74	62	£1.8m	£1.8m

Strengths

Patients with cancer or other terminal illnesses who may benefit from life extending treatment near the end of their life will have access to the same treatments as patients in England regardless of:

- the location of treatment
- the patients ability to pay
- the cost of the treatment
- how many other people have the same condition

Weaknesses

Significant investment will be required in order to fund the backlog and future requirement for unfunded life extending treatments for patients at the end of life. The estimated financial provision is for unfunded TAs published before 2019. It does not include provision for the 70+ TAs expected to be published during 2019.

Prioritising treatments for the EoL was not identified as a priority for funding by stakeholders during engagement interviews and events.

EoL treatments usually have an ICER between £30,000 and £50,000 per QALY i.e. they are less cost effective than non EoL cancer drugs and treatments for other conditions.

New inequities will be introduced:

- All unfunded EoL TA treatments currently approved by NICE are for cancer. Patients
 who do not have cancer would not have funding for treatments recommended by a
 NICE TA, solely on the basis of the category of disease.
- Treatments not reviewed by NICE TAs are less likely to be able to secure funding.
 The opportunity costs will be borne by patients with treatments/conditions not covered by a NICE TA.
- Since the NICE TA programme is targeted at manufacturer sponsored drug therapies, this will exaggerate the inequity between priority for drugs and non-drug treatments.

The process for making funding decisions about treatments will need to continue to consider requests for treatments that the NICE TA guidance will not cover. This could be using drugs for a different indication, devices, surgical interventions, new services, screening or prevention interventions etc.

This option values the late stage of disease for one disease only, rather than the merits of the individual treatments.



Table 8: Summary of Option 4

Prioritise NICE TA-approved treatments for common diseases so that the greatest number of people will benefit

Number of TA recommendations / TAs		Number o	of patients Net cost im		t impact
TA recommendations	TAs	Backlog	New patients per annum	Backlog	New patients per annum
44	40	3,221	679	£3.6m	£1.3m

Strengths

There is no definition of 'common'. In this Review, a common condition is one where there are 5 or more backlog patients across Guernsey and Alderney who meet the patient selection criteria for that intervention.

All patients who meet the NICE TA treatment criteria for a 'common' condition will be treated regardless of:

- the location of their treatment
- their ability to pay
- the cost of the treatment

This will result in equity of access to TA-approved treatments for common conditions already funded by the NHS for patients in England.

For these patients (the majority), the ICER for treatments for common indications is usually below £30,000 per QALY indicating that the treatment is considered by NICE to be cost effective.

There is potential to re-focus some prescribing and formulary panel activity towards planning, implementation and audit rather than the funding decision process.

Weaknesses

Significant investment will be required in order to deal with the backlog of unfunded TAs.

Although the ICER is low and well within the accepted range used by NICE, the cost impact is high due to the likely numbers of patients expected to be eligible for treatment.

New inequities will be introduced:

- This option will discriminate against people who need treatment for rarer conditions or who need life-extending treatments at the end of their life.
- Treatments not reviewed by NICE TAs are less likely to be able to secure funding.
 The opportunity costs will be borne by patients with treatments/conditions not covered by a NICE TA.
- Since the NICE TA programme is targeted at manufacturer sponsored drug therapies, this will exaggerate the inequity between priority for drugs and non-drug treatments.

The process for making funding decisions about treatments will need to continue to consider requests for treatments not covered by NICE TAs e.g. different indications, devices, surgical interventions, new services, screening or prevention interventions etc.

This option values the number of patients with the disease, rather than the merits of the treatment itself.



Table 9: Summary of Option 5

Prioritise NICE TA-approved treatments on the basis of (clinical and) cost effectiveness

	Number of TA recommendations / TAs		Number of patients		Net cost impact	
	TA recommend - ations	TAs	Backlog	New patients per annum	Backlog	New patients per annum
ICER <£20k per QALY	27	24	1,928	338	£1.3m	£0.5m
ICER <£30k per QALY	71	67	2,769	630	£3.1m	£1.5m
ICER <£40k per QALY	93	88	3,073	678	£4.7m	£2.5m
ICER <£50k per QALY	124	119	3,120	721	£5.9m	£3.8m
ICER <£100k per QALY	138	130	3,141	737	£6.7m	£4.4m

Strengths

NICE already uses cost effectiveness of a treatment as a decision criterion since it was established in 2001. This has been proven to be a rational and defensible decision support criterion in England.

This option does not discriminate on the basis of the patients disease category. This option offers some flexibility as the threshold is set according to the budget identified.

Below an agreed ICER threshold, NICE TA-approved treatments will be funded regardless of:

- the category of disease
- the location of treatment
- the patient's ability to pay
- the cost of the treatment
- how many other people have the same condition

The net cost impact model is a helpful planning tool for budgeting for a new ICER threshold for the States of Guernsey and Alderney.

Prioritising funding for the most cost effective treatments will result in equity of access to treatments considered to provide the most value for money.

There is potential to re-focus some prescribing and formulary panel activity towards planning, implementation and audit rather than the funding decision process.

Weaknesses

For treatments with an ICER above £20k per QALY, significant investment will be required in order to deal with the backlog of unfunded TAs.

It is unknown what the ICER threshold should be for Guernsey in order to avoid opportunity costs for other patients and services.

This was the most favoured option suggested by engagement participants.



This option is based on the merits of individual treatments for specific indications, rather than patient attributes or disease characteristics.

New inequities will be introduced:

- Above an ICER threshold selected by the States, treatment will not be funded. This
 option will mean that treatments for rarer diseases or life-extending treatments for
 patients at the end of their life are especially unlikely to be funded.
- Treatments not reviewed by NICE TAs are less likely to be able to secure funding.
 The opportunity costs will be borne by patients with treatments/conditions not
 covered by a NICE TA.
- Since the NICE TA programme is targeted at manufacturer sponsored drug therapies, this will exaggerate the inequity between priority for drugs and non-drug treatments.

The process for making funding decisions about treatments will need to continue to consider requests for treatments that the NICE TA guidance will not cover. This could be using drugs for a different indication, devices, surgical interventions, new services, screening or prevention interventions etc.

This option values the merits of individual treatments for specific indications, rather than patient attributes or disease incidence or category of disease.



Table 10: Summary of Option 6

Status quo - continue with the current system of individually reviewing each NICE-approved TA, if requested by a Consultant or GP

Number of TA recommendations / TAs		Number o	f patients	Net cos	Net cost impact	
TA recommendations	TAs	Backlog	New patients per annum	Backlog	New patients per annum	
0	0	0	0	£0m	£0m	

Strengths

Existing process has resulted in funding for 320 out of 480 (66%) NICE TA recommendations published to the end of 2018.

Process attempts to balance the needs of all patients regardless of whether the treatment that they need has been reviewed by NICE.

Decisions are made by the States of Guernsey for the local population.

Decisions should be based on maximising health within the allocated budget and be consistent with the health needs of the Guernsey population.

Retains a selective approach to adopting NICE TA guidance e.g. paying far less for a clinically and cost effective non-NICE reviewed treatment instead of paying for the NICE approved treatment e.g. intravitreal treatment for age related macular degeneration.

Weaknesses

Patients can only access some NICE TA-approved treatments on the basis of their ability to pay.

Lack of transparency about the fact that many treatments are not funded by the States, which is unwelcome news for individual patients at a time when they are vulnerable and planning for such an eventuality, is too late.

Dissatisfaction with the apparent rigid application of cost effectiveness threshold and apparent rejection of some treatments which appear to have ICER below £20k to £30k per QALY threshold.

IFR process is unresponsive to individual patient request as it cannot be approved if there are other patients with similar need. The service development route is too slow.

Key operational issues would still need to be resolved in order to regain regard and confidence in the decision process and rules:

- consistency between different decision making bodies e.g. Prescribing and Formulary (PAF) panel and Corporate Management Team (CMT)
- consistency in funding being available following a PAF decision
- variation between consultant applications both content and enthusiasm
- facilitation of applications from off island consultant
- policy decisions and the rationale for them need to be easily retrievable and publically accessible

This option values the merits of individual treatments for specific indications, rather than patient attributes or disease incidence or category of disease.



1 Introduction

Solutions for Public Health (SPH)² has been commissioned to undertake an independent review (referred in this document as the 'Review') of National Institute of Health and Care Excellence (NICE) technology appraisal (TA) and Highly Specialised Technology appraisal (HST) approved treatments and their availability and funding in Guernsey and Alderney.

1.1 Background and context

1.1.1 A Partnership of Purpose

In November 2017, the States of Deliberation adopted a new model of health and social care provision described in the Policy Letter entitled 'A Partnership of Purpose: Transforming Bailiwick Health and Care' (CfHSC 2017b). It required health and social care providers and organisations to partner with the Committee for Health & Social Care (CfHSC) and to work together with the community to improve the health and wellbeing of all islanders. In relation to the scope of this Review, item 14 clearly asked the States to decide if 'they were of the opinion:-

14. To agree that the Committee for Health & Social Care shall review the processes used to:

Consider the merits of whether new drugs or medical treatments should be funded to ensure that a consistent approach is used across all decision making bodies (including the Committee for Employment and Social Security's Prescribing Benefit Advisory Committee)'

(CfHSC 2017b)

1.1.2 Requête

Further to that commitment, the Requête which was debated at the States of Deliberation meeting on 12th December 2018 proposed that treatments that had been recommended by NICE, particularly those appraised as a TA or HST should be funded by the States of Guernsey. The Requête was proposed by Deputy Peter Roffey and signed by an additional six Deputies. The key concerns that prompted the Requête are summarised below:

 the list of publically funded drug treatments is narrower than the list of drug treatments available to Guernsey patients who pay for their treatment privately; resulting in significant inequality of access to treatment based solely on patients' ability to pay.

² SPH is a team of public health consultants, researchers, analysts and associates, within Arden and GEM Commissioning Support Unit (part of NHS England). The team has extensive experience and a proven track record in supporting health care commissioners to make evidence based commissioning decisions.



- the limitations of the treatments available via public funds are not transparent, and often only realised by individuals at a time of personal need when they or a family member need a treatment recommended by a Consultant, which is denied by the States.
- Guernsey patients treated in England experience a different standard of care to patients resident in England.
 - Even when the island has approved referral to a Specialist Consultant in England, the States does not routinely accept and fund the treatment recommended by that Consultant.
 - Patients treated on-island are not able to access all the same drugs as English patients treated in England, although these patients may not be aware that they are receiving different care, or know the reasons why.
- The CfHSC procedures for deciding which treatments should or should not be funded appears to duplicate the NICE appraisal process, but without access to expertise or industry information.

Each of these points will be addressed in this report.

Following extensive debate, the States of Deliberation approved option 2 of an amendment to the Requête which sought to:

'... ensure that any changes to current policy are evidence-based and informed by a full review with independent, specialist healthcare public health input. In accordance with the principles of good governance, it also allows time for a range of future funding options to be prepared to ensure that the financial implications for the States of Guernsey are known when deciding if new drugs and treatments should be publicly funded.

The review will consider the equitable access to drugs and treatments for all patients in Guernsey and Alderney regardless of where such treatment is being delivered (i.e. off-Island or on-Island). The Prayer of the Requête emphasises the needs of those patients who are referred to the UK for treatment and the drugs that are available to them on their return to the Islands, to the exclusion of those patients who remain on-Island for treatment.

Option 2 also asks the Policy & Resources Committee to prioritise the allocation of resources to expedite the review to enable the findings to be published no later than the end of the second quarter of 2019. This will provide sufficient time to enable the Budget of the States for 2020 to be informed by the review.'

(CfHSC 2018)

The budget impact estimate is based on the presumptive funding for all NICE TA-approved treatments from 2020 onwards. The outline methodology is described in Section 2 and the details of Terms and Reference and Scope of the Review are described in Appendix 5.



This Review goes some way to meeting the task described in 'A Partnership of Purpose' in that the proposed methodology:

- requires the bringing together of multiple stakeholders to work together to improve the health and wellbeing of all islanders
- will include a review of the processes used to 'consider the merits of whether new drugs or medical treatments should be funded to ensure that a consistent approach is used across all decision making bodies (including the Committee for Employment and Social Security's Prescribing Benefit Advisory Committee)'

(CfHSC 2017b)

It is important to note that not all new drugs or medical treatments are included in the NICE TA guidance process. There are many which will be included in other NICE publications (mentioned below) or guidance from other clinical institutions, as well as treatments that will not be included in formal policies or guidance at all but administered at the clinician's discretion.

1.2 About the National Institute for Health and Clinical Excellence (NICE)

As this Review is tasked specifically with 'the implementation of all drugs recommended via NICE Technology Appraisals (TAs)' (Appendix 5), it is important to explain in this Review what NICE is, the different types of guidance that it publishes and the status of its guidance.

NICE provides national guidance and advice to improve health and social care in England. It was originally set up in 1999 to reduce variation in the availability and quality of NHS treatments and care. Following the Health and Social Care Act 2012, NICE became a Non Departmental Public Body (NDPB) which is accountable to the Department of Health and Social Care, but is operationally independent of government. The Committees which make guidance and other recommendations are independent.

NICE guidance is officially for England-only (DHSC 2015), although NICE does provide certain guidance to Wales, Scotland and Northern Ireland.

The guidance published by NICE takes several forms.

1.2.1 Technology appraisal guidance (TA)

The NICE TA and HST processes review, classify and publish guidance on health technologies. This guidance assesses the clinical and cost effectiveness of health technologies, such as new pharmaceutical and biopharmaceutical products, but may also include procedures, devices and diagnostic agents. This is to ensure that all NHS patients have equitable access to the most clinically and cost-effective new treatments as close to their launch as possible. NICE TAs are usually published as a single intervention for a single indication; however, some are reviewing more than one intervention for the same or different (but similar) indications. A small number of TAs are classified as 'Highly Specialised Technologies guidance' (HST – described



in more detail below) where the intervention being considered is for a rare condition. In this report, NICE TAs will be used to describe both TAs and HSTs.

The reviewed health technologies are classified into one of five recommendation categories:

- 1. recommended for routine use in the NHS
- 2. recommended for use under strict criteria (patient selection criteria and/or price reduction)
- 3. recommended for use in the Cancer Drugs Fund
- 4. recommended for use only for research purposes
- 5. not recommended for use

(NICE Technology Appraisal Guidance webpage)

If a technology falls into one of the top three categories, it is considered a positive TA or HST recommendation and will be referred to in this report as 'NICE TA and HST approved'. In this case, NHS commissioners have a statutory duty to make the technology available to patients within 90 days of publication (or 30 days for those appraised via the Fast Track Appraisal process).

When reviewing a specific technology, NICE will consider if the technology in question fits the criteria for End of Life treatment, Highly Specialised Technology or the Cancer Drugs Fund. Most technologies have a cost threshold of £20,000 to £30,000 per additional quality adjusted life year (QALY)³ gained (NICE 2013a). However, End of Life treatment and Highly Specialised Technologies have different and higher cost thresholds applied.

There is a statutory requirement which requires clinical commissioning groups, NHS England and, with respect to their public health functions, local authorities to comply with the recommendations in this appraisal within three months of its date of publication(NHS England 2013). There are similar directions to the NHS in Wales on implementing NICE technology appraisal guidance. When a NICE technology appraisal recommends the use of a drug or treatment, or other technology, the NHS in Wales must usually provide funding and resources for it within two months of the first publication of the final appraisal document.

This means that if a patient meets all the clinical criteria specified in a NICE recommendation and the clinician and patient have discussed and agreed that the treatment is suitable, then the NHS in England and Wales must make funding available. However, there is an exception to this rule. When a new drug costs more than the cost impact threshold of £20 million per year at any point in the first three years, a two stage mechanism to make the drug more affordable is triggered:

³ A measure of the state of health of a person or group in which the benefits, in terms of length of life, are adjusted to reflect the quality of life. One QALY is equal to 1 year of life in perfect health. QALYs are calculated by estimating the years of life remaining for a patient following a particular treatment or intervention and weighting each year with a quality-of-life score (on a 0 to 1 scale). It is often measured in terms of the person's ability to carry out the activities of daily life, and freedom from pain and mental disturbance.



- 1. discussions with pharmaceutical company to reduce financial burden
- 2. phasing the entry of the new drug to spread the costs

1.2.2 The Cancer Drugs Fund

The Cancer Drugs Fund (CDF) was set up in 2011 as a temporary solution to help patients and their clinicians to gain access to cancer treatments that were not routinely available to all patients treated by the NHS across England. Due to unclear entry and exit criteria, it later became financially unsustainable. The annual budget was initially set at £200 million for 2011/12, rising to £340 million in 2015/16, yet still overspent by £126 million by the end of 2015/16. Following a full public consultation the new, more sustainable CDF was launched in 2016 (NHS England 2016).

Since July 2016, all cancer drugs (new drugs or new indications) are reviewed by the NICE appraisal process and can either be fully recommended for routine use, recommended for use in the CDF, or not recommended for use. Recommendation for use in the CDF applies to those drugs which fall short of the requirements for routine commissioning due to clinical uncertainty, yet have plausible potential to meet them through further data collection or clinical studies.

The CDF budget is a fixed funding envelope set annually by NHS England Board. For 2018/19, the CDF budget was set at £340 million as it has been since 2015/16 (NHS England CDF Team 2019). The budget covers the cost of the drugs and the administration of the CDF. Individual clinicians or a nominated trust coordinator will submit an online request for funding of CDF listed drugs to the local CDF regional team who process the request. Confirmation of funding will be received within two working days and treatment should commence within a month of confirmation of funding. A joint NHS England and NICE CDF Investment Group is responsible for managing the overall budget.

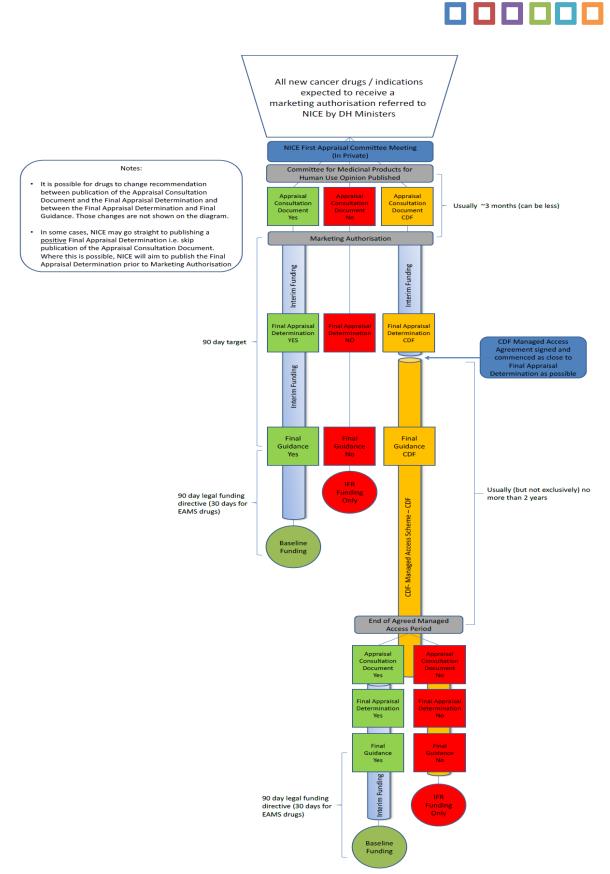
Treatments recommended for use in the CDF are subject to a managed access scheme. The managed access scheme is an agreement between NHS England and the manufacturing pharmaceutical company. This will usually mean that for a period of 24 months, a NICE TA will recommend the drug for a clearly specified patient group and the NHS will be required to make the funding available. During this CDF period, the company will be required to collect additional data to further confirm the case for clinical and cost effectiveness and the cost of the drug to the NHS is subject to an agreed reduced price (commercial access agreement). Treatments on a managed access scheme are typically (but not exclusively) re-appraised within two years. At the point of re-appraisal, NICE will review the additional information collected and issue a clear recommendation for the treatment to be routinely commissioned or not. If recommended for routine commissioning, the drug will continue to be interim funded out of the CDF for 90 days, after which it will go on to be funded from NHS England's Specialised Commissioning budget. In England, all anti-cancer drugs are funded by NHS England Specialised Services commissioning rather than by individual Clinical Commissioning Groups.

One of the aims of the CDF is to facilitate rapid access to new, licensed anti-cancer drugs for patients across England. The CDF interim funding arrangements of cancer



treatments considered by NICE to be 'promising' (i.e. not yet sufficiently proven to be clinically and cost effective to warrant a recommendation in a TA) is estimated to reduce the time taken for a new anti-cancer drug to be routinely funded across England by up to eight months.

Figure 1: Cancer Drugs Approval Process Diagram



Source: NHS England 2016

1.2.3 Life extending treatments at the end of life (EoL)

Treatments that extend life, close to the end of life are valued differently by NICE compared to other treatments (NICE 2009).



In 2009, NICE introduced a new higher indicative threshold for End of Life treatments of up to £50,000 per additional QALY (the standard cost per additional QALY threshold is £20,000 to £30,000) (NICE 2009). This means that if a treatment meets the definition of 'life extending treatment at the end of life', the NICE Technology Appraisal Committee may use its discretion and approve the treatment even though the cost per additional QALY exceeds £30,000 per QALY (Barham et al 2016). Life extending treatment at the end of life is defined as "treatment indicated for patients with a short life expectancy, normally less than 24 months," and with "sufficient evidence to indicate that the treatment has the prospect of offering an extension to life, normally of a mean value of at least an additional 3 months, compared with current NHS treatment" (NICE 2013a).

It is not clear whether the higher cost per QALY threshold for EoL treatments is justifiable. NICE states in its 'Social Value Judgements' (NICE date not specified) that ... 'society places higher value on quality adjusted life years at the end of life compared to at other points in life and that this in turn, justifies a higher cost per additional QALY'. However, the evidence on how society values end of life is unclear and contradictory.

A choice-based experiment (Linley et al 2013) found it was unclear if extending life at the end of life was particularly valued, and there was no evidence to support an end of life premium. It did find, however, that quality of life gain with no life expectancy gain was preferred to its inverse – that is, life expectancy gain with no quality of life gain. Another choice experiment (Shah et al 2012) also showed very limited evidence that the public valued extending life at the end of life over any other time. Contradictory to the 2013 study, it did show a slight preference for life expectancy gain without quality of life gain over quality of life gain without life expectancy gain.

This lack of clarity over how end of life is valued by the public has led some academics to question if the QALY is even an appropriate measure in valuing end of life. The two main arguments levied against the use of QALYs at the end of life are:

- 1. the evaluation methodology combining a measure for quality of life and life extension does not apply to end of life patients. This is because quality of life is valued differently when death is imminent, and most end of life treatments do not extend life by much, or even at all (Coast et al 2009)
- 2. the public supports interventions for the end of life that do not generate sufficient QALYs to be considered cost effective (Hughes 2005, Normand, 2009)

In his paper, 'Is a QALY still a QALY at the end of life?' Round (2012) argues that although QALYs have severe limitations specific to valuing end of life, there are nonetheless currently no "viable proposed alternatives [....] for the purposes of resource allocation". As such, QALYs are at present expected to continue to be used by NICE in End of Life Treatment appraisals.

1.2.4 Highly specialised technologies

Highly specialised technologies are treatments for very rare conditions. Often there are no or very few alternative treatments and patients are few in number. A cost per



additional QALY gained threshold for automatic funding has been set at £100,000 per QALY (five times greater than the lower end of NICE's standard threshold range) (NICE and NHS England 2016). In certain circumstances the HST evaluation committee would have the discretion to approve treatments over this threshold by applying QALY weighting that progressively advantages treatments that offer higher number of QALY gains. This allows for higher cost per additional QALY gained but only when there are more QALYs to be gained (NICE 2017). Even after discount, the gross cost of an HST-approved treatment for one patient per annum ranges from over £100,000 to c.£500,000.

1.2.5 Other NICE guidelines

NICE guidelines make evidence-based recommendations to improve the health of communities. They cover a wide range of topics, for example:

- · preventing and managing specific conditions
- improving population level health and wellbeing
- managing medicines in different settings
- providing social care to adults and children
- the planning of broader services and interventions

These aim to promote integrated care where appropriate, by covering transitions between services, such as, children and adult services and between health and social care. For example, the NICE guideline (CG156) Fertility Problems: Assessment and Treatment, covers a wide range of services and interventions from weight loss, smoking cessation and HIV management to sperm donation, egg sharing and IVF (NICE 2013b).

1.2.6 Interventional procedures guidance

Interventional procedures guidance recommends whether interventional procedures, such as laser treatments for eye problems or deep brain stimulation for chronic pain, are effective and safe enough for use in the NHS. NICE interventional procedures guidance does not address cost effectiveness.

1.2.7 Medical technologies evaluation programme

The medical technologies evaluation programme (MTEP) selects and evaluates new or innovative medical technologies (including devices and diagnostics). MTEP helps the NHS adopt efficient and cost effective medical devices and diagnostics more rapidly and consistently. The diagnostics guidance focuses on the evaluation of innovative medical diagnostic technologies in order to ensure that the NHS is able to rapidly and consistently adopt clinically and cost effective technologies.

1.2.8 Evidence summaries

Drugs which do not meet the criteria for a technology appraisal may be referred for an 'evidence summary'. The summary might be for new medicines; for unlicensed or off-label medicines; where a manufacturer's submission does not comply with the NICE TA process; or the new NICE appraisal fee is not paid. Evidence summaries



are not classified by NICE as guidance and are not subject to a statutory requirement for the NHS to make funding available.

1.2.9 Complications that arise with prioritising NICE TA-approved treatments

Since not all treatments are evaluated through the NICE TA or HST process, it is important to understand the limitations of the NICE TA and HST selection and appraisal process. The restrictions which affect which treatments are appraised in a NICE TA may result in an opportunity cost when TA-approved treatments are prioritised for funding over other treatments and services.

• Marketing authorisation A drug that has not been granted a marketing authorisation (or equivalent) will not be considered for technology appraisal. This might occur when drugs are used in children or when an existing drug is used for new indication. An example of this is guidance in development-TA421: quetiapine for the treatment of generalised anxiety disorder (NICE 2016). This TA was started and later suspended because the manufacturer decided not to pursue a license for the indication. This means that there is no NICE TA and if clinicians wish to use it for this group of patients, funding may not be available.

The States of Guernsey were early adopters of a drug called bevacizumab for age-related macular degeneration (AMD). It should be noted that the company did not have marketing authorisation for AMD, and the statutory requirement for the NHS in England to follow NICE TA guidance, meant that the NHS in England was required by law to treat AMD with a NICE TA-approved, licensed drug called ranibizumab (c.28 times more expensive), despite published evidence that bevacizumab has similar efficacy to ranibizumab, but is far more cost effective (The Lancet 2018).

- **Company investment** Each TA relies upon significant investment from the company which is seeking to market the drug in England.
 - The company is required to make a costly manufacturer submission which is compliant with the NICE TA process.
 - In addition, from April 2019, NICE charges companies for technology appraisals (in addition to requiring the company to make a manufacturer submission) (NICE 2019). The charges range from £88,000 to £126,000 plus VAT for a cancer drug fund review and a single technology review respectively. Multiple technology appraisals, for instance, where three technologies are appraised for the same indication will be £188,000 plus VAT (split between participating companies). The charges for small companies will be discounted by 75%. It is not clear if these charges will change the rate of published TAs from NICE in the future, but the charge to manufacturers for the NICE appraisal costs is intended to increase NICE's capacity to publish up to 75 TAs per annum (NICE 2018a).
- Focus on pharmacological interventions The NICE TA programme is intended to consider all new significant drugs and indications, and they state that health



technologies referred to the NICE technology appraisals programme could include any of the following:

- medicinal products
- medical devices
- diagnostic techniques
- surgical procedures or other therapeutic techniques
- therapeutic technologies other than medicinal products
- systems of care
- screening tools

However, we noted that of the 480 TA recommendations for specific indications up to 31st December 2018, 441 (92%) were for pharmacological interventions. This bias toward drug treatments has an opportunity cost for investment in conditions which require non-pharmacological management.

- The relationship between the accepted QALY and affordability. The primary outcome used by NICE is the quality-adjusted life year (QALY). A QALY is a single unit of health gain that combines both expected years of life gained and quality of life gained. The QALY is a 'common currency' which allows different interventions to be compared for different conditions. Where a new intervention appears to be more effective than the current comparator treatment, NICE usually compares the interventions by calculating the incremental cost-effectiveness ratio (ICER). The ICER is the ratio of the difference in the mean costs of an intervention compared with the next best alternative (which could be no action or treatment) to the differences in the mean health outcomes. ICERs are expressed as cost (in £) per QALY gained.
- Currently NICE uses a upper limit (or threshold) of £30,000 per QALY to gauge
 whether the health benefits offered by a new drug are greater than the health
 likely to be lost because the additional resources required are not available to
 offer effective treatments to other NHS patients.
- It should be noted that NICE has never formally identified a firm cut-off ICER above which interventions should not be recommended and below which they should. Despite this, the NICE Social Values Judgements states that 'in general, interventions with an ICER of less than £20,000 per QALY gained are considered to be cost effective ... [If the] ... most plausible ICER ... [is above] ... £30,000 per QALY gained, advisory bodies will need to make an increasingly stronger case for supporting the intervention as an effective use of NHS resources ...' (NICE, Social Values Judgements, Second Edition).
- There is no evidence to suggest that the NICE indicative ICER ceilings can be adopted by the NHS in England without incurring opportunity costs for other services (Claxton et al 2015). The authors found that the 'threshold' used by NICE would need to be approximately £13,000 per QALY if opportunity costs for other patients were to be avoided.



- The research showed that the approval of a new drug that costs the NHS in England an additional £10 million each year would offer benefits of 333 QALYs (at the current NICE threshold). This would also result in the loss of 773 QALYs for other NHS patients with increased mortality in cancer, circulatory, respiratory or gastro-intestinal diseases and reduced quality of life in neurological diseases and mental health (a net loss of 440 QALYs for every £10m of additional NHS costs).
- Treatments at the end of life. Since 2009, where a treatment is for a condition where the patient group is likely to have a life expectancy of less than two years, and the evidence suggests that the drug will 'normally' increase life expectancy by 3 months or more, NICE may approve an ICER cost per QALY which exceeds the usually accepted limit of up to £30,000 per QALY (NICE 2009). A review of 18 positive NICE TAs for EoL treatments published between 2009 and 2015 showed that the average ICER for EoL treatments was approximately £49,000 per QALY. There is no fixed ceiling for the ICER for EoL treatments (Barham et al 2016).
- It should be noted that as of 7th May 2019, NICE have published 24 new TAs (TA555 to TA578) since 1st January 2019. All of these are pharmacological treatments apart from the appraisal of 'Cochlear implants for children and adults with severe to profound deafness' (NICE 2019, TA566). Due to the date of issue, these TAs are outside the scope of this Review. We have not assessed what proportion of these are positive recommendations, assessed which of these would be in scope for inclusion as part of the Cancer Drugs Fund or assessed cost impact. Five of the 24 technology appraisals appear to be a 'terminated appraisal', although we have not checked the recommendations in each TA. Based on 24 TAs in the first 4 months of 2019, it is not inconceivable that NICE might publish 70 TAs in the 12 months period up to 31st December 2019.

2 Methodology

The Review timeline was determined by the States of Deliberation end goal to enact new policy from January 2020 onwards. This required time to consider the resource needs of adopting all NICE TA-approved treatments in line with the NHS in England and to make the necessary budgetary adjustments.

Our approach and methodology was therefore designed to deliver a Review report to the Committee *for* Health and Social Care by the end of May 2019 which would present a range of commissioning options for the Committee for Health and Social Care to consider for adoption. These options range from routine full adoption of all NICE TA-approved treatments (approved up to 31st December 2018 and ongoing) through to maintaining the status quo, with a number of part- or phased-implementation options in between.

For each option, we show the number of TAs from the 'backlog', the breakdown of disease categories, the estimated number of Guernsey patients affected, the



estimated health gain (where possible) and the expected annual cost impact. For each option, we also identified which of the current decision-making principles in policy document G1033 (CfHSC 2017a) would be challenged and key ethical considerations.

2.1 Outline approach

In order to arrive at the options for implementation, we conducted four linked programmes of work (Figure 2).

Figure 2: Overview of the Review methodology

1. Quantitative Analysis

- •Identify all NICE TAs published up to 31st December 2018
- Review the White List/DTC/PAF and liaise with pharmacists to confirm treatments not funded
- Detailed review of each unfunded TA
- Estimates of outcomes for each option: patient numbers, cost impact, health gain

2. Engagement & Qualitative Analysis

- •Interviews and desktop review:
- understand the health system
- identify key treatments which clinicians & service users cannot access, and the reasons why
- inform the design of the events
- Events
- gain wider engagement
- explain the Review methodology and output
- elicit key preferences to inform the options appraisal

OPTIONS APPRAISAL

3. Pathway example

- •Review one drug agreed by CfHSC in more detail to identify wider implementation considerations:
- patient benefit
- cost effectiveness
- service delivery issues
- associated costs of delivery
- management of side effects

4. Comparison & Learning from Jersey & IOM

- Interviews and document review
- decision process for funding NICE TAs
- budget impact
- equity
- learning points for Guernsey & Alderney

2.1.1 Quantitative analyses

The aim of the quantitative analysis was to confirm and clarify which NICE TA-approved treatments are *not* currently funded in Guernsey; to estimate the cost and benefits of those treatments not funded; and to enable the financial and health impact of routine adoption of all NICE TA-approved treatments to be estimated).

In addition, the health and financial impact of a number of different groups of TAapproved treatments were to be estimated, and presented in an options appraisal for



the States of Guernsey to consider. The options were informed by the findings of the qualitative analysis of the stakeholder engagement and the learning from other island jurisdictions. In all, six main groups were identified:

- 1. Fund all NICE TA-approved treatments
- 2. Prioritise NICE TA-approved treatments for cancer
- 3. Prioritise NICE TA-approved life extending, at the end of life treatments
- 4. Prioritise NICE TA-approved treatments for common diseases so that the greatest number of people will benefit
- 5. Prioritise NICE TA-approved treatments on the basis of (clinical and) cost effectiveness
- 6. Status quo continue with the current system of individually reviewing the NICE evidence of clinical and cost effectiveness

2.1.2 Qualitative analysis

The aims of the engagement and qualitative analysis work were to:

- 1. review the existing system of drug, treatment and device ("treatments") prioritisation and availability
- 2. use feedback from stakeholders and other jurisdictions to help develop recommendations for equitable policy options which are consistent with a move towards presumptive funding of all NICE TA-approved treatments

Our approach was to:

- review existing documentation (e.g. Partnership of Purpose, Priority Setting in Health and Social Care G1033) and identify existing underpinning equity and access principles
- undertake semi-structured interviews with stakeholders in Guernsey in order to understand the principles and decision processes which prevent TA-approved treatments being funded, the current equity of access issues to NICE TAapproved treatments for Bailiwick of Guernsey patients treated in UK off-island centres and the impact on patients and their families
- design and conduct engagement events to elicit from large groups of consultees their preference for funding NICE TA-approved treatments, and the principles and values which they prefer to be retained or rejected in order to allow NICE TAapproved treatments to be routinely funded
- to use the outcomes from the engagement events to directly inform and influence the options for implementation presented in Section 3
- propose changes that may be necessary to the current principles and processes described in 'Priority Setting in Health and Social Care'

2.1.3 Exemplar treatment pathway

For one currently unfunded NICE TA-approved treatment relevant to Guernsey population, we undertook a more detailed analysis of health and economic impact, taking into account required changes to the local treatment pathway and highlighting



wider service delivery implications. The Committee *for* Health & Social Care agreed that the exemplar treatment would be Pembrolizumab, a new anti-cancer drug for recommended by NICE for advance non-small cell lung cancer.

Pathway details from the two relevant NICE TAs were presented to a multidisciplinary group of clinicians in order to discuss and confirm numbers of patients affected, likely health outcomes, diagnosis and monitoring requirements, nursing requirements and pharmacy services. We have reported in the quantitative analysis section those TAs which are likely to require service delivery planning and possibly additional resource beyond that of the incremental cost of the drug therapy alone.

2.1.4 Comparison with Jersey and the Isle of Man

We undertook desktop research and semi-structured interviews to develop an overview of the existing processes for NICE TA-approved treatment availability, including those approved under the Cancer Drugs Fund, and the NICE End of Life criteria in the jurisdictions of Jersey, the Isle of Man and England. We have identified possible learning points highlighting key differences in approach, finance, equity of access and health outcome consequences from these in Section 5.

The detailed methodology is described in the relevant sections of this Review.

2.1.5 Limitations of the methodology

The methodology described above was adopted as the most appropriate pragmatic approach to deliver the review within the time and budget available, given the availability of key information to inform the findings. There are inevitably some key limitations and these are discussed in more detail in the relevant sections below.

The scope of the review is limited to reviewing unfunded NICE TA-approved treatments as at 31st December 2018 only. It is therefore a snapshot based on the position at the end of December 2018 and does not take into account any NICE TA recommendations published in 2019.

TA recommendations are a defined subset of all the NICE recommendations from a range of NICE publications. Nearly all the TA-approved treatments are drug therapies, over half of which are for cancer. The methodology is therefore unable to fully assess the relative value of prioritising and funding NICE TA-approved treatments against all other treatments or health interventions for which there may be demand in Guernsey and Alderney.

The source of the funding to implement adoption of all currently unfunded NICE TA recommendations is outside of the scope of this review.

Stakeholder engagement events are focussed on discussing NICE TAs only. This directly appeals to patients who are unable to access treatments that NICE has recommended in a NICE TA. Therefore patients with other diseases are indirectly excluded, even though presumptive funding of all NICE TA-approved treatment may adversely disadvantage investment in services that they need.



Qualitative information is descriptive and often comes from interviews, focus groups or artistic depictions. This type of data offers an approximation for an outcome but it does not provide a definitive measure. The feedback collected from the interviews and engagement events is therefore subjective, and is subject to censorship by the interviewees or participants.

In relation to the quantitative analysis, the data gathered was expected to be imprecise. This is due to the lack of complete information available in the public domain, including:

- the lack of transparency of both intervention and comparator drug prices due to confidential commercial arrangements between NICE and manufacturers
- incomplete or missing or out of date NICE costing templates for unfunded TAs
- NICE TA information goes out of date quite quickly in particular in relation to the cost of the intervention and comparator and this may render the estimated ICER obsolete
- only the drug acquisition cost (both intervention and comparator) has been included in the analysis. Staffing or other resource costs that may be associated with implementation of the currently unfunded NICE TA recommendations were outside the scope of the Review. However, the potential for significant resource implications should not be ignored. These are anticipated to include clinical and support staff (such as those in pharmacy, pathology, community and palliative care), equipment, facilities and revenue from privately funded patients.

In addition, the lack of complete costing templates in the TAs meant that estimating the number of people who might be eligible for treatment with a NICE TA-approved treatment, was impossible to undertake consistently based on information within the TAs. The initial approach to apply a crude pro-rata of England patient numbers (published by NICE) was therefore abandoned in favour of seeking local clinician estimates for each TA-approved treatment and indication.

3 Engagement and qualitative analysis

3.1 Aims and objectives

The aims were to:

- review the existing system of drug, treatment and device ("treatments") prioritisation and availability
- to use feedback from stakeholders and other jurisdictions to help develop recommendations for an equitable and effective process (assuming secured funding of all NICE TA-approved treatments)

The objectives were to:



- understand how the health care system operates in Guernsey and Alderney, particularly the principles and processes for policy development
- gain an understanding of treatments that are not funded by the States, the causes of this and the impact that this has on clinicians, patients and their families
- design and conduct a series of engagement events to elicit the preferences of attendees for a range of values and principles for future funding of NICE TAapproved treatments and listen to suggestions for implementation
- develop implementation options for the States to consider, as part of the options appraisal for presumptive funding of all NICE TA-approved treatments

3.2 Methodology

In order to understand how the health care system works in Guernsey and Alderney, as well as how policy decisions are made about new treatments, we conducted a desktop review of key documents. These included the recent Requête, the 'A Partnership of Purpose', but particularly, the principles and processes described in "Priority Setting in Health and Social Care" (CfHSC 2017a) and "Individual Funding Requests" (CfHSC 2017c).

This was combined with a series of semi-structured interviews and ongoing liaison with key staff involved in operating the States policy development processes described in G1033 and G1002. Semi-structured interviews were conducted to ensure key questions were covered during the interview and allow for flexibility in following new lines of enquiry as they arose during the conversation. Interviews were conducted face to face. An interview guide with a set list of questions was developed, covering the following areas:

- introduction
- understanding of the scope of the Review, the deliverables and the timelines
- your role and relevance to the Review
- specific interest in NICE TA-approved drugs
- key health care access issues affecting your clinical practice
- your experience of applying to use new drugs or treatments
- key unfunded treatments that you wish to be funded
- suggested options for prioritisation if presumptive funding all treatments is not adopted

In order to gain candid information from the interviewees, the interviews were conducted under the stated agreement that information given would be non-attributable and that we would use the information to draw together common themes which in turn would inform the design of the wider stakeholder engagement events.

Key informant sampling was used to target individuals or groups who were particularly knowledgeable about treatment accessibility and management, or alternatively, who were likely to have a direct interest in the outcome across a range of clinical specialties and services. The initial list of interviewees was discussed and



agreed with Dr Nicola Brink, Director of Public Health. We were grateful for the time and contributions from 22 interviewees including GPs, Consultants employed by the Medical Specialist Group (MSG) and the States of Guernsey, nurses involved in cancer care, managers involved in off-island care arrangements and pharmacists.

In addition to the interviews, we attended meetings with four different groups:

- CareWatch
- Cancer Services Group
- HEAL (representing a group of patients and families all of whom were directly affected by current unfunded treatments)
- Committee for Health & Social Care (CfHSC)

The purpose was to share the scope and methodology of the Review, answer questions about the Review, gain further insight of examples of unfunded treatments and the impact on patients and their families, and raise awareness of the up-coming engagement events described below.

3.2.1 Engagement events

Engagement events were held to understand stakeholder views about principles to apply in funding decisions.

The Department of Public Health Services was responsible for the logistics for the stakeholder engagement events (advertising, letters to charities, event management and press enquiries). With their support, we were able to run six separate engagement events in Guernsey and Alderney between 18th March and the 4th April 2019. The details are listed in Table 11. We were particularly grateful to colleagues from the Department of Public Health who volunteered to facilitate the tables at all the events.

Table 11: List of engagement events

Date	Venue	Attendees	Number of participants
18 th March	Les Cotils	Health and social care	48
Conference Centre,		professionals	
20 th March Guernsey		Public and Patients	46
21 st March		Deputies of the States of Guernsey	16
3 rd April	Island Hall, Alderney	Members of the State of Alderney	12
3 rd April		Public and Patients	4
4 th April	Princess Elizabeth Hospital, Guernsey	Public Health Services	19

In the engagement events we:

- provided an explanation of the Review, and NICE's function
- through discussion, enabled stakeholders to develop an understanding of the complexities associated with funding NICE TA and HST approved treatments
- listened to concerns about lack of access to treatment and ideas for resolution.



used these ideas to inform the options

Our intention was to engage with as many people as possible and to treat all contributions equally. Therefore, each engagement event followed the same agenda and invited all attendees to contribute in the same way, regardless of the date, location or status of the participants. In order to prevent the views of any individual or any one group of islanders being identified, the feedback from all six evens was collated and presented together in the findings in this Section.

The interviews and meetings we had already attended informed the content and structure of the engagement events. The design of the events was adapted from the 'Choosing Healthplans All Together' (CHAT) exercise which is a small group decision exercise that has been used for to elicit public opinion about what should be included in health insurance packages. It was initially created as a board game funded by the National Institutes of Health and the Robert Woods Foundation in the USA (Danis et al 2002).

The CHAT exercise is an interactive decision tool designed to facilitate deliberation by small groups about prioritisation of health care resources within a finite budget. The exercise has been shown to be understood by professionals and non-professionals alike and has been used for professionals and graduate students to expand their reasoning about priority setting. The underlying premise is that barriers to public participation - complexity of insurance, clinically exclusive language, disinterested or deferential healthcare consumers - can be overcome if an engaging, highly interactive process is developed to promote thoughtful communal decisions (Danis et al 2010).

Each stakeholder engagement event started with a presentation delivered by SPH. This introduced the scope and deliverables of the Review. It went on to describe what NICE is and briefly outline the different guidance that it publishes, to outline the engagement event design, and explain how the outcomes would feed into the options identified for appraisal in the final Review report.





Our adapted CHAT engagement event required participants to sit around a table with a facilitator (volunteers from the Department of Public Health from Guernsey, briefed in advance by SPH). During the session, the facilitator guided the participants to



consider which features were important to decision making at a population level in four rounds.

Round 1: Each participant was asked to read three of six scenarios. Each scenario painted a fictitious patient picture describing their:

- age
- family
- wealth, and employment circumstances
- a story about their diagnosed disease
- the NICE TA-approved treatment that is currently not funded by the States
- the expected benefit of the treatment and the cost

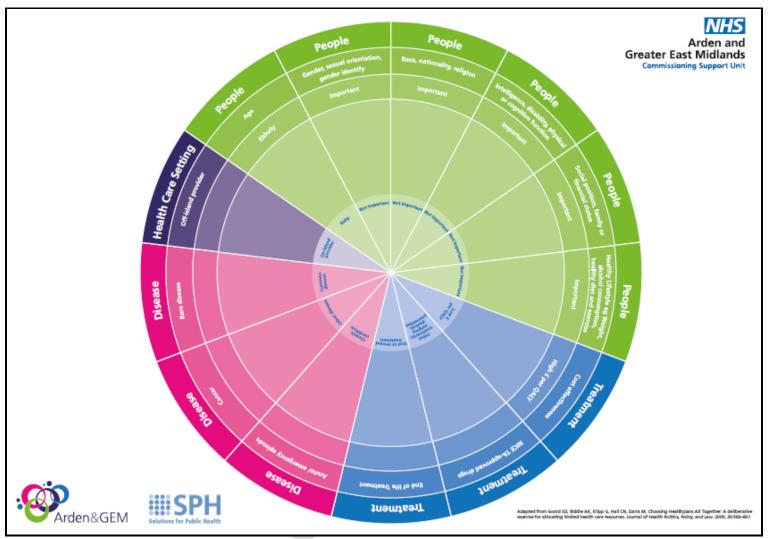
In order to encourage participants to read all three scenarios, each participant was asked to individually rank the three scenarios in order of which they would fund first if they could not afford to fund all three. These rankings were not analysed as the sole purpose was to encourage the participants to fully read the scenarios. Although each table only discussed three scenarios, there were six scenarios available for use during the events. All six scenarios were used by at least one table during each event. All of the scenarios featured treatments that have been recommended by NICE TAs which are not currently funded by the States of Guernsey. The six scenarios were purposefully selected to provoke discussion about patient age, common versus rare diseases, the different cost of drugs, cancer and chronic diseases such as diabetes or heart failure and treatments for early stage treatment or the end of life. See Appendix 3 for scenarios.

Round 2: During the second round of the event, an in-depth table discussion about the scenarios and why participants had made their prioritisation choices was facilitated. The participants were introduced to the CHAT-board (Figure 3), which presented various features of decision making in separate segments. The decision-making features were identified during the review of the current policy making decision framework (G1033) and during interviews and included people, disease characteristics, treatments and health care setting.

Round 3: At the end of the table discussions in round 2, each individual was given 13 small stickers (one for each segment on the CHAT-board) which they could use to express their post-discussion preference for the values and principles that they thought should determine policies for funding NICE TA-approved treatments. The pie chart provided an opportunity for participants to visually express their preference for whether or not a feature should influence a treatment funding decision.



Figure 3: Principles discussion CHAT-board



Adapted from Goold et al 2005.



Round 4: The final round was a plenary session facilitated by SPH. During this session, we asked each table to report back to the whole room, on one characteristic where there was broad agreement amongst the group members and one characteristic where there was a range of opinion. For the characteristics where there was a range of opinion, we probed the rapporteur and their fellow participants for more detail about the views and also checked with the other tables to see if the range of opinion was replicated in other small groups. We captured the key characteristics where there was agreement and disagreement so that we could use this to inform the options in the options appraisal reported in Section 1 of the Review.

At the end of each event before the close, we asked the participants to complete a 'postcard', and explained that the answers would be treated as a temperature gauge (rather than a 'vote') for treatment funding preferences.

Question 1 invited individual participants to express how strongly they agreed that all NICE TA-approved treatments should be prioritised for funding (Figure 4).

Question 2 invited suggestions for how to prioritise NICE TA-approved treatments should the States consider part-implementation (Figure 5). The anonymously completed postcards were collected at the end of each event and the results collated in the findings section of this chapter. The completion of the postcards at the end of the event was deliberate; it was intended to elicit the views of individuals only after they:

- had been provided with the opportunity to understand what NICE technology appraisals are (and the fact that they are nearly all pharmacological interventions)
- had considered a wide range of different clinical and social scenarios
- had participated in small group and plenary discussion about the consequences of using different decision criteria



Figure 4: Opinion postcard question 1

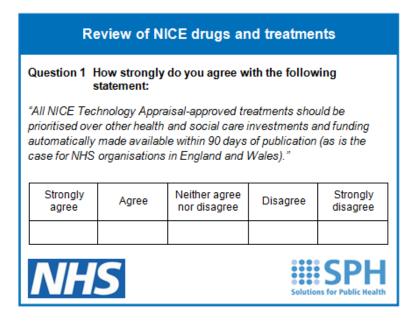
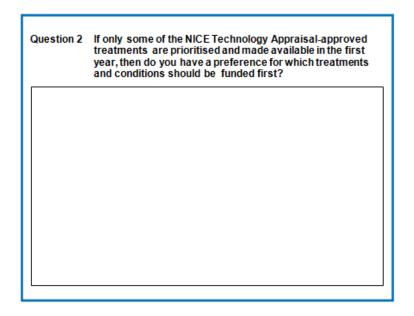


Figure 5: Opinion postcard question 2



3.3 Strengths and limitations of the engagement event approach and adapted CHAT methodology

One particular feature of CHAT was the ability to customise it to the needs of the scope of this Review for the States of Guernsey and Alderney (Ginsburg et al 2006).

For example, instead of the segments representing options, such as hospital care and pharmacy, we presented various health conditions such as cancer and chronic illness, personal characteristics such as intelligence, social position and lifestyle, different treatment features such as end of life, cost effectiveness and whether it should make a difference if the health care is received on-island or off-island.



Preparations before the engagement events based on interviews and meetings already conducted, enabled us to develop relevant patient scenarios which reflected a range of access issues reported by patients and clinicians, realistic costs for Guernsey and estimated benefits derived from the NICE TA.

A number of features of the CHAT-board exercise are designed both to inform participants about the issue of priority setting and to facilitate their ability in order to set priorities in an informed manner. This allowed the events to both inform participants as well as elicit their preferences.

The advantage of choosing to use the same progressive, highly structured approach for every event is that it guaranteed an output in a format that was usable, and that regardless of the status of the attendees, it ensured common outputs for each event which could then be collated once all events were completed (two were for politicians only, two were for service users and representatives of service users and two were for people involved in providing health care services for Guernsey and Alderney residents).

The colourful CHAT-boards where used in A1 size to encourage participation; facilitators encouraged lively debate amongst participants on each table, and the task of expressing preferences by placing allocated stickers on the CHAT-board (one per segment) pushed individual participants to make difficult choices. The views of each participant were given equal weight. However, it is possible that some individuals might have placed their stickers close to others in order to fit in with the group. To mitigate against this, facilitators were briefed to promote independence and to prevent individuals being unduly influenced by other participants.

Informal verbal feedback from some participants indicated that they found the discussion and CHAT-board approach to be positive and enjoyable. In contrast, we know that it created conflict between individuals on a table on one occasion.

A limitation of the stakeholder events is that in order to express a view, one had to be able to attend. Attendance may have been dependent on seeing or hearing the adverts, personal diary commitments and ability to get to the venue.

Another limitation is that the decision to attend might have been influenced by a vested interest in a specific NICE TA-approved treatment. We did not ask for personal information from attendees so cannot quantify the extent to which the event attendees might or might not be representative of the health care needs of the wider community in Guernsey and Alderney.

3.4 Current position from the document review

When making resource allocation decisions about commissioning specific services or interventions The Committee *for* Health & Social Care (CfHSC) abides by a set of principles and processes published in 'G1033: Priority Setting in Health and Social Care' (CfHSC 2017a) and 'G1002: Individual Funding Requests' (CfHSC 2017c).



These principles, rules and policy statements explain the decision making framework that the CfHSC has ratified for allocating resources regardless of the type of treatment or care, the disease or the patient group.

'A Partnership of Purpose: Transforming Bailiwick Health and Care identifies that the combination of an aging population and fewer working age tax payers will result in increased real terms public spending on health and care of £21m by 2027(CfHSC 2017b). This cost pressure does not take into account major service development such as adopting all NICE TA-approved treatments. As CfHSC is required not to exceed its annual budget, it is inevitable that routine adoption of all new TA-approved treatments for the population of Guernsey and Alderney will require additional budget provision.

The key principles from G1033 that are applied to all CfHSC resource allocation decisions are:

- "3.1 CfHSC will make investments that aim to maximise the value of care delivered to the population it serves.
- 3.2 That in order to deliver maximum value to its population, CfHSC will adopt prioritisation as the primary methodology for all its decisions making around resources. This means:

3.2.1 ...

3.2.2 ...

3.2.3 Care professionals including secondary healthcare practitioners, general practitioners, nurses and allied health care professionals must not introduce any new treatments, diagnostics or initiatives (including expanding access to treatment) which will increase CfHSC costs unless this has been sanctioned by CfHSC. Neither should they raise patient or client expectations about care to be provided, or refer publicly funded patients for treatments or interventions, not currently funded.

3.2.4 ...

- 3.3 CfHSC will only invest in interventions that are cost-effective.
- 3.4 CfHSC will not fund treatments of unproven clinical effectiveness unless it is in the context of a well-designed clinical study.
 - Section 5: Experimental and unproven treatments of this policy sets out the circumstances in which experimental and unproven treatments might be funded outside the context of a clinical study. Such requests are dealt with through CfHSC policy G1002: Individual funding requests.
- 3.5 CfHSC will live within the budget allocated to it by the States of Guernsey.

3.5.1 ...

3.5.2 ...

3.5.3 ...

- 3.6 CfHSC will not fund one individual if others with the same need cannot be funded
 - 3.6.1 ...
 - 3.6.2 ...
- 3.7 CfHSC must not allow third parties to determine priorities or make funding decisions on its behalf.



- 3.7.1 CfHSC may seek guidance and advice from a number of organisations when deciding its priorities. All such guidance has the status of being advisory. This includes guidance issued by The National Institute for Health and Care Excellence and professional health bodies.
- 3.8 CfHSC will not make an unjust or prejudicial distinction in the treatment of different categories of people, especially on grounds of personal characteristics, such as age, gender, sexual orientation, gender identity, race, nationality, religion, lifestyle, social position, family or financial status, intelligence, disability, physical or cognitive functioning.

Health care: In some instances, personal characteristics may be relevant to the clinical effectiveness of an intervention and the capacity of an individual to benefit from the treatment. For example a disease can behave differently in different age groups. Some personal characteristics therefore have a role in differentiating subgroups of patients from each other. It may also be the case that services may be enhanced to address unmet need within a service for vulnerable or disadvantaged groups.

Social care: Personal characteristics will influence what services are provided to individuals."

(CfHSC 2017a)

In addition to the principles above G1033 also gives more detailed rules about how CfHSC will consider treatments recommended by NICE. These explicitly state that:

- guidance (of any category) published by NICE is advisory rather than mandatory
- treatments recommended by the NICE technology appraisal programme will not automatically be funded and
 - treatments with a cost-effectiveness estimate above £30,000 per QALY 'will not be funded'
- treatments for people near the end of life or who have an orphan⁴ disease will not be considered preferentially
- cancer treatments funded through the Cancer Drugs Fund established by the Department of Health (England) and now operated by NICE will not routinely be funded by CfHSC
- an equivalent of the English Cancer Drugs Fund will not be operated in Guernsey

Whilst G1033 focuses on the principles, rules and process for priority setting within the available resources at a population level, the IFR system described in G1002 (CfHSC 2017c) considers applications for funding for treatments for individual patients. It specifically rejects all applications which might represent a potential service development explaining that IFRs are screened;

⁴ Orphan disease: life-threatening rare disease affecting fewer than 5 in 10,000



"to exclude requests which represent potential service developments including ...

3.6 New treatments including medicines, surgical procedures and medical devices ..."

(CfHSC 2017c)

G1002 goes on to explain, that if a funding request has been classified as a potential service development, the IFR Panel has no jurisdiction to consider the application. In those circumstances "the application... for funding for a NICE TA-approved treatment for a specific patient ...will not be submitted to the IFR Panel but will be subject to the usual business planning and priority setting processes of CfHSC."

- "3.9 CfHSC may, where the request has been classified as a service development:
 - 3.9.1 refuse funding, and refer the case back to the provider organisation (which may be the provider arm of CfHSC) and take no further action;
 - 3.9.2 refuse funding, and request the provider organisation to prioritise an application for that service development and, if supported by *CfHSC*, invite the provider organisation to submit a business case as part of the yearly cycle for considering service developments;
 - 3.9.3 refuse funding, and refer the request to the appropriate director within CfHSC for an assessment with a view to determining its priority for funding as a service development proposal in the next financial year;
 - 3.9.4 refuse funding, and refer the request to the appropriate director within CfHSC for an immediate workup of proposals as a potential candidate for funding as a service development in the current financial year."

(CfHSC 2017c)

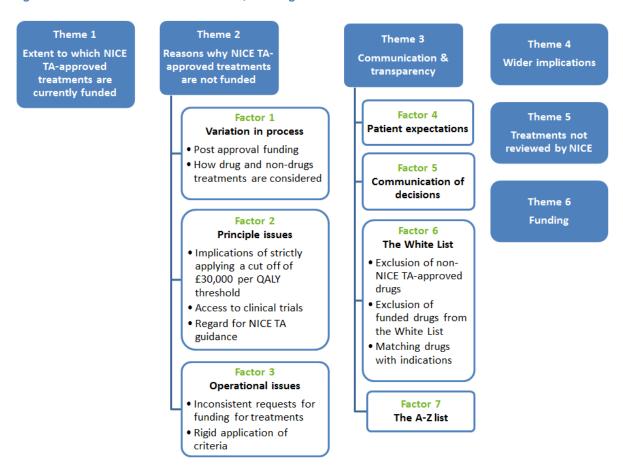
This process is potentially lengthy, and does not appear to be able to respond quickly to individual patient need. In the scenario where there is a NICE TA-approved treatment not previously requested, a patient who meets the criteria specified in the TA, and a treatment where the cost per additional QALY is below £30,000 but where there may be more than one patient on the island, it seems that the IFR panel would refuse funding on the basis of the need for the treatment to be considered as a 'service development'.

3.5 Themes from document review, meetings and interviews

The issues and factors around the allocation of funding that were identified from the document review, interviews and individual and small group meetings are organised into themes as shown in Figure 6.



Figure 6: Themes from document review, meetings and interviews

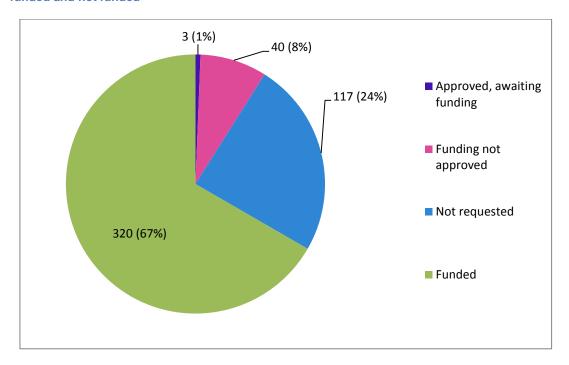


3.5.1 Theme 1: Extent to which NICE-TA-approved treatments are currently funded in Guernsey

Despite the restrictions of G1033 and G1002, it is important to note that a number of NICE TA-approved treatments are funded by the States. Of the 480 NICE TA recommendations for specified indications published by 31st December 2018, 320 are funded by the CfHSC (285 drugs and 35 non-drug treatments). 160 NICE TA-approved treatments, 156 of which are drug treatments, are not routinely funded by the States. These include 39 treatments which were requested but not approved, 114 treatments which have never been requested and 3 that have been approved by the DTC/PAF but are awaiting prioritisation for funding, as shown in Figure 7. A more detailed description of funded and unfunded treatments is reported in the quantitative analyses in Section 4.



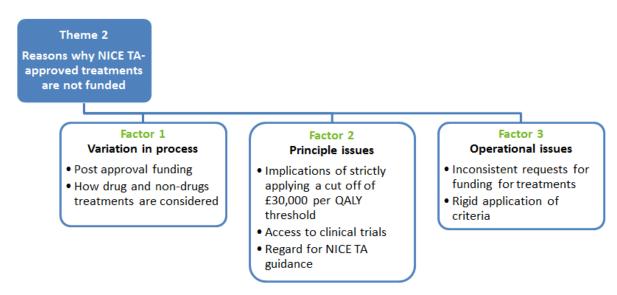
Figure 7: The proportion of NICE TA-approved treatments for specific indications which are funded and not funded



3.5.2 Theme 2: Reasons why not all NICE TA-approved treatments are funded in Guernsey

Reasons why the application of the principles described in G1033 may lead to variation in funding decisions, along with some of the wider, longer-term implications are shown in Figure 8.

Figure 8: Factors contributing to unfunded NICE TA-approved treatments in Guernsey.





Factor 1: Variation in process

Post-approval funding

Principle 3.2 in 'Priority Setting for Health and Social Care' states that "in order to deliver maximum value to its population, CfHSC will adopt prioritisation as the primary methodology for all its decisions making around resources" (CfHSC 2017a).

However it is not clear that this is uniformly applied, even for NICE TA-approved treatments.

Prior to May 2018, there were two committees responsible for assessing new drugs – the Drug and Therapeutics Committee (DTC) and the Pharmaceutical Benefits Advisory Committee (PBAC). Although they both used the same principles and processes for appraising a new drug i.e. those described in G1033, there were two different routes for funding the drugs after they were recommended by the respective Committees. Those drugs recommended by DTC, such as ipilimumab (an intravenous anti-cancer drug) for melanoma were submitted to the Corporate Management Team for consideration in the 'Prioritisation round' where the drug treatments are assessed against all other calls on resources which could include additional nurses, prevention, facilities. The result is that ipilimumab has still not been funded. In contrast, drugs approved by PBAC (such as oral anti-cancer drugs) were funded immediately from the Social Security budget.

This inconsistent application of the principle of prioritisation appears to discriminate between treatments on the basis of how they are administered. The recent establishment of the single Prescribing and Formulary Panel (PAF) in 2018 goes some way to promote equitable consideration of new treatments for funding. While HSC is responsible for determining which drugs should be funded for use within its premises, the Committee for Employment & Social Security (ESS) is responsible for deciding which drugs should be funded in the community, at the subsidised prescription rate. Since the issue of the two funding routes is not yet resolved, (the role of ESS in drug-funding decisions is subject to the Health Service (Benefit) (Guernsey) Law, 1990), there remains an illogical difference in securing funding for drugs recommended by PAF. We are aware that the changes to the States governance arrangements which bring together Health and Social Care and Social Security under one Office may facilitate a more unified process for securing funding for PAF approved drugs.

How requests for drug and non-drug treatments are considered.

NICE TA-approved interventions which are not pharmacological, such as specific surgical procedures, or devices, cannot be considered for funding by the PAF. These are reviewed by the CMT, alongside other competing business cases (staff, facilities etc.). The different funding routes potentially compound the inequity between funding drugs and non-drug treatments as the NICE TA programme already preferentially selects drugs for inclusion.



Factor 2: Principle issues

Implications of strictly applying a cut-off of a £30,000 cost per QALY threshold

Principle 3.3 in G1033 states that 'CfHSC will only invest in interventions that are cost-effective'.

This principle is not clearly defined in G1033. There is no definition of what is considered cost-effective for the States of Guernsey for all treatments regardless of whether or not they are recommended in a NICE TA. For treatments recommended by a NICE TA, Section 6 states that:

"6.2.1 Treatments whose cost-effectiveness is estimated to be above £30,000 per quality adjusted life years will not be funded, unless exceptional circumstances apply."

and that

6.2.2 Treatments whose cost-effectiveness is estimated to be below £30,000 per quality adjusted life years will be further assessed to determine whether or not they should be forwarded for prioritisation."

(CfHSC 2017a)

In practice, this means that drug treatments for which the incremental cost effectiveness ratio is over £30,000 per QALY compared to the standard NHS treatment, are always 'not approved' by PAF or its predecessor Committees. This is consistent with the Terms of Reference for the PAF and the rules (6.2.1, 6.2.2) specified in G1033. However, the ICER ceiling of £30,000 per QALY has not been established to be the limit of affordability for the States of Guernsey. In addition, the NICE estimate of the ICER may not apply (if the comparator treatment considered by NICE is not the standard treatment in Guernsey or if the price of the treatment differs from that used in the NICE calculation of the ICER estimate. It is well documented that the NICE cost effectiveness ceiling is an arbitrary indicative threshold, and in 2015, Claxton et al estimated that for the NHS to incur minimal opportunity costs when new treatments are introduce, the ICER should be far less (c.£13,000 per QALY).

Further, it is not clear if the cost effectiveness principle is applied to non-drug resource allocation decisions in health and social care. This potential inequality of access is outside of the scope of this review, but might impact on the credibility of decisions made for health and social care.

Clinical trials

There is a principle (Principle 3.4, G1033) that "treatments of unproven clinical effectiveness" will not be funded "unless it is in the context of a well-designed clinical study". This principle is perceived as unfair by some clinicians and patients as it compounds the difficulty in accessing newer treatments already approved by NICE and routinely funded by the NHS in England. This is particularly the case for accessing new treatments approved by NICE under the CDF arrangements which are not funded by The States. The CDF is in effect a national 2 year NHS funded phase IV trial where the NHS pays for the drugs at a significantly discounted price,



whilst the manufacturer collects more data about the treatment, prior to re-appraisal by NICE.

The States currently demand that the commercial sponsor should pick up all costs associated with the clinical trial. For non-commercial trials, patients can only access treatment by participating in a non-commercial trial if they are approved as an IFR or if the trial is considered an approved service development.

The geographical constraints of living on an island mean that far fewer clinical trials are accessible to patients who are unwell and may be unable to comply with the arduous requirements of participating in a clinical trial on the mainland.

In addition, all applications for funding for treatment as part of a clinical trial depend upon the patient's Consultant making a compelling case. There may be further inequity due to variation in the enthusiasm and ability of Consultants (particularly offisland Consultants unfamiliar with the Guernsey Health system) to apply on the patients' behalf for treatments that they can use routinely in England.

Regard for NICE TA Guidance

One of the core principles in G1033 which is relevant to this Review is 3.7 which states that "CfHSC must not allow third parties to determine priorities or make funding decisions on its behalf."

It goes on to explain that guidance from NICE and elsewhere has the status of being advisory only. Since NICE has no formal jurisdiction over any health care system other than England, it is logical to refer to the NICE guidance but selectively adopt its recommendations. The NICE guidance is published for the NHS in England, which is paid for by a much larger population, with completely different levels of state-funded coverage.

A number of clinicians and patients believed that the PAF and its predecessor committees attempted to replicate the NICE decision process but without the same level of resource either in terms of access to clinical and academic expertise, access to the same level of information or funding to run the review process. The recent change by NICE to charge commercial companies for the TA process of between £88,000 and £126,000 plus VAT is indicative of the complexity of the TA process and associated costs.

Having reviewed a number of requests for funding considered by PAF, it is clear that the Guernsey PAF Committee take a pragmatic approach and refer directly to the NICE TA to extract key information about the intervention, the comparator, the clinical effectiveness, the cost effectiveness, estimated numbers of patients and the generalisability of the outcomes to the Guernsey population and island health system. There is no attempt to replicate or replace the NICE appraisal process.



Rather a summary document⁵ of approximately four pages is produced (in contrast to the hundreds of pages of documentation on the NICE website) for each drug/indication for the PAF Committee members to consider. Even if all NICE TA's were to be routinely adopted in Guernsey, it is unlikely that this could be done without producing briefing documents to explain the clinical, service and budgetary provision required, to plan and inform any changes required to how services are provided.

Factor 3: Operational issues

The principles and rules for the policy development process described in document G1033 are clearly written and unambiguous. They support the stated intent of the CfHSC "to maximise the value of care delivered to the population".

However, a range of factors were identified which can act as enablers or barriers to arranging funding for treatments, relating both to policy and to the implementation of policy. Consideration of these could improve patient and clinician satisfaction with the processes used and improve efficiency and transparency. These are described here.

Inconsistent requests for funding for treatments

Although G1033 describes clearly the principles and rules for allocating health care resources, it does not describe to clinicians or to patients how they might be able to navigate the system if there is a treatment which they wish to be considered.

It seems that getting approval for funding new treatments already approved by NICE TA is highly dependent on the relevant speciality Consultants. Anecdotally, there is variable enthusiasm and familiarity with the process of applying for a treatment to be reviewed by PAF. This is consistent with our finding that of the 160 NICE TA-approved treatments which are not routinely funded in Guernsey, 117 had not been requested. In contrast, 40 had been requested and not approved, and three had been requested and approved but were still awaiting funding through the prioritisation process, as described in Section 4. It should be highlighted that a proportion of the 117 unrequested and three unfunded treatments may not have been needed by patients and clinicians either due to there being good alternative treatments options (also recommended by NICE TA) or due to there being no patient resident in Guernsey who needed the treatment.

A number of issues may contribute to the inconsistent requests or treatments:

- Some on-island clinicians are unfamiliar with the PAF process.
- Some on-island clinicians are more successful than others at 'making' a successful case for funding.
- Clinicians may be deterred from asking for treatments to be used because of previous unsuccessful experience of the process.
- Clinicians are unable to balance the perceived bureaucracy of the process of applying for funding with their clinical workload.

⁵ The key data are taken from the original study or the Summary of Product Characteristics. Additional data may be sourced from documents published by NICE, the Scottish Medicines Committee or the All Wales Medicines Group.



 Diseases which are treated by an off-island Consultant or MDT who are not familiar with the Guernsey health care system and do not realise that they need to make an individual patient case to PAF (or are too busy to prioritise this). In this instance it is not clear if someone else should ask for the case to be considered: the patient, the patient's GP or another on-island Consultant?

Rigid application of criteria

We noted that a number of interviewees found that the process for applying for funding for NICE TA-approved treatments was too rigid, and that it was impossible to get funding for treatments which did not meet the criteria (this was particularly an issue for drugs where the incremental cost effectiveness ratio was greater than £30,000 per QALY). We do not know if any of the 320 funded TA-approved treatments have a cost per QALY higher than the £30,000 per QALY threshold. We do know that a number of the TA-approved drugs which have an ICER of less than £30,000 per QALY have been considered for funding and 'not approved'.

There are no clear published reasons for these decisions. Conducting an audit of decisions made, and the rationale for the decisions, was outside of the scope of this Review which focuses on estimating the cost impact of treatments that are currently unfunded by the States but recommended as a treatment option in a NICE technology appraisal.

However the decisions to fund or not fund NICE TA-approved treatments are consistent with the rules which state:

- "6.2.1 Treatments whose cost-effectiveness is estimated to be above £30,000 per quality adjusted life years will not be funded, unless exceptional circumstances apply.
- 6.2.2 Treatments whose cost-effectiveness is estimated to be below £30,000 per quality adjusted life years will be further assessed to determine whether or not they should be forwarded for prioritisation."

(CfHSC 2017a)

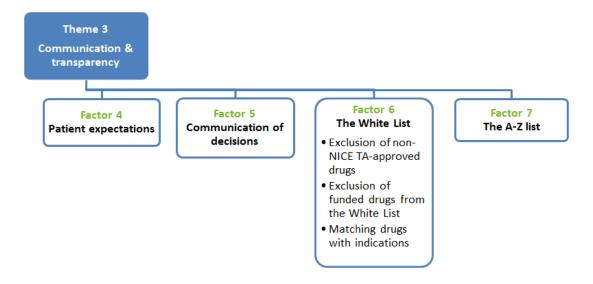
The PAF and its predecessor Committees appear to have operated the policy in line with the principles and process described, although the decisions and rationale for decisions are not in the public domain.

3.5.3 Theme 3: Communication and Transparency: Information about funded or not approved treatments

Issues and factors around communication on allocating resources are shown in Figure 9.



Figure 9: Factors contributing to communication and transparency in resource allocation



Factor 4: Patient expectations

Patients reported that they did not know that a significant proportion of the treatments recommended in NICE TAs are not funded until they needed treatment for themselves or a family member. Unless patients already have a private health insurance scheme it is too late for them to take out private insurance, so the only option is to accept the standard treatment funded in Guernsey (this may be a chemotherapy drug rather than a newer immunotherapy anti-cancer drug for instance), or to pay for the treatment (and related costs) privately.

Factor 5: Communication of decisions

Some clinicians and patients reported dissatisfaction with how the decisions about treatments are communicated after the PAF committee. In some instances patients reported that they had no written communication of the decision or the rationale for the decision. Currently, there is no publicly available and easily retrievable list of policy decisions following PAF or CMT which explains the intervention, the specific indication, the decision about routine funding and the rationale for that decision. This is consistent with our experience of data gathering for this Review; we were not able to verify the funding status of the NICE TA-approved treatments and indications without extensive liaison with and help from the Prescribing Advisor, the Chief Pharmacist and the Pharmacy Services Manager. The information could not be retrieved from publicly available sources.

Factor 6: The White List

The White List (Committee for Health and Social Care 2019) is published on the States of Guernsey website and described as a list of medicines and medical appliances which are funded by the States of Guernsey. It is a list of medicines and medical appliances with no introductory or explanatory text describing what is included or excluded and why.



Exclusion of certain non-NICE TA drugs from the White List

The published list is extensive although a number of clinicians raised the issue of drugs which they thought should be on the list which were not subject to a NICE TA. The drugs mentioned were all off-patent, were for chronic conditions and low cost compared to the cost of the treatments recommended by NICE TAs. In some instances, the availability of drugs might have a beneficial impact on the cost of the care pathway as well as the patient i.e. if a drug could be prescribed by the GP instead of a consultant or if the formulation of the drug might prevent an admission to hospital. It was not clear if non-NICE TA-approved drugs had been considered by PAF and rejected or if the clinicians had not applied to PAF in the first instance.

Exclusion of certain funded drugs from the White List

Not all drugs funded by the States are on the White List. For example, rituximab monotherapy or in combination with other drugs has been recommended by a NICE TA for a number of indications (non-Hodgkins lymphoma, chronic lymphocytic leukaemia, rheumatoid arthritis, vasculitis), and has been confirmed as being available by the pharmacists in Guernsey but it is not on the White List for any indication. In seeking to understand the reasons for the exclusion of rituximab, we noted that the White List includes a range of drugs prescribed by secondary care only such as oral cancer drugs which are dispensed by the hospital, drugs administered by injection, as well as oral heart failure drugs dispensed by community pharmacy. If the reason that rituximab is excluded from the list is because it is administered to patients via intra-venous infusion, it is not logical to selectively exclude funded drugs from the White list on the basis of the formulation. The information on the website about the White List does not explain such omissions.

Matching of drugs with indications

Although the White List is very specific about the drug, the dose and the formulation that is funded, and in some instances limitations on who may prescribe, we noted that the list does not specify the indications for which the drug can be used. Some prescribers identified that this would be helpful, particularly where there are drugs which can be used for more than one indication.

The introduction of related indications might facilitate the addition of drugs for selected indications only, and circumvent the use of new drugs for widespread use across a range of (severities and) diseases.

Factor 7: The A-Z List

As well as the White List of funded medicines, there is a 44 page 'A-Z list of funded and non-funded treatments on the list of treatments' on the States of Guernsey website (CfHSC date not specified). This list does not specify the majority of the 160 NICE TA-approved treatments which the gap-analysis by SPH shows are not funded. The A-Z list does appear to be largely focused on excluded surgical and device interventions but at least two drugs are listed as not routinely funded (eculizumab and for paroxysmal nocturnal haemoglobinuria or atypical haemolytic uremic syndrome, and enzyme replacement therapy for Fabry Disease). It is not clear why some drug treatments approved by NICE (HST1 eculizumab for treating atypical



haemolytic uraemic syndrome) are on the list and why others are not e.g. TA319 and TA268 (ipilimumab for previously untreated/treated advanced unresectable or metastatic melanoma). We note that all the treatments listed except for one are due to be reviewed by CfHSC in 2020.

3.5.4 Theme 4: Wider implications of the current systematic late adoption of new treatments

One of the principles cited in 'Priority Setting in Health and Social Care' states that

"3.2.3 Care professionals including secondary healthcare practitioners, general practitioners, nurses ... must not introduce any new treatments... which will increase CfHSC costs unless this has been sanctioned by CfHSC. Neither should they raise patient or client expectations about care to be provided, or refer publicly funded patients for treatments or interventions, not currently funded"

(CfHSC 2017a)

We note that it is important that service developments need to be managed but the States may need to be mindful that a long term position of late or never adoption of newer, effective interventions will not only affect patients but may also have an indirect, adverse effect on the ability of clinical staff to be able to maintain their professional standards, or for younger doctors to take full clinical responsibility for prescribing older treatments with which they may be less experienced. In the longer term, this may also adversely affect the ability of the States of Guernsey to successfully attract and recruit clinical staff.

3.5.5 Theme 5: Treatments not reviewed by NICE Technology Appraisal

We heard from clinicians and patients⁶ of specific examples of treatments that they wished to be routinely funded by the States which are not recommended by a NICE TA and are therefore out of scope of this Review. It was not clear for all of these examples if the treatments had been requested and turned down or if the treatment was not funded and the request to fund was never made.

The treatments included drug treatments for the management of chronic respiratory conditions, mental health, substance misuse, pain, as well as surgical interventions. Many of the treatments were low cost, for which it would be unlikely that there would be a cost-effectiveness study showing the ICER. Some of the drugs were off patent and without strong commercial interest to push. There was a concern that the prioritisation of funding for new treatments approved by a NICE TA, might adversely affect the availability of funding for other treatments which may have a lower overall cost impact and be more cost effective.

⁶ The HEAL group (Health Equity for ALL) is a group of patients, family members and carers, all of whom have experienced difficulty in accessing treatments that has been recommended by clinical specialists. These include both drugs and other interventions (surgery). Some patients have received treatment privately because they were able to access private funds (loan, savings or charitable donation), whilst others remain untreated or on an alternative, inferior treatment funded by the States of Guernsey.



3.5.6 Theme 6: Funding issues

The primary outcome of this Review was to estimate the budget impact of implementing the currently unfunded NICE TA-approved treatments. The task of assessing whether all NICE TA-approved treatments (current and future) could be routinely funded within the existing CfHSC budget or from another identified source was outside of the scope of this Review.

Despite this, many interviewees and participants at the stakeholder engagement events expressed their views about funding sources. Anecdotally, the views included:

- making sure that people with private health care insurance used their own insurance to access health care
- raising taxes
- a desire to make sure that existing services are not cut in order to fund TAapproved treatments

3.6 Recommendations based on the themes from document review, interviews and meetings

The key themes identified following the document review, meetings and interviews, are:

- the extent to which NICE TA-approved treatments are currently funded
- the reasons why not all NICE TA-approved treatments are funded
- communication & information about unfunded treatments

In this section, we have identified recommendations which may address some of the issues discussed above.

3.6.1 The extent to which NICE-TA-approved treatments are currently funded

The primary purpose of this Review is to estimate in the Options Appraisal the cost impact of funding all NICE TA-approved treatments and indications published to 31st December 2018. The source of the funding required to fulfil this ambition is out of scope of this Review. It is recommended that the implications of each of the options presented in this Review are fully considered, taking into account the financial considerations, the numbers of patients affected and the strengths and weakness of each option.

It should be noted that this Review has not included the treatments recommended by NICE TAs published from 1st January 2019. NICE plan to publish over 70 TAs in 2019.

3.6.2 The reasons why some NICE TA-approved treatments are not funded

This is due in part to the current principles and processes adopted by CfHSC.

Dissatisfaction with the principles, rules and process described in G1033 (CfHSC 2017a) and the decisions of the relevant committees (PAF Panel, Corporate Management Team) indicate that it is timely to review the principles and process



which determine both policy and the framework against which individual funding request decisions are made.

- The policy development criteria and process described in G1033 would benefit from a diagrammatic description of the end-to-end process starting with a clinician (or other party) submitting a request for a new treatment to be funded, through to the treatment being approved and funded, or not approved.
- There is a need for clear and publicly available information about the appeals process for both decisions about IFR and service developments (drugs and non-drugs). This would improve transparency and regard for the policy development process. There is already a description of the appeals process for treatments turned down by the IFR panel (CfHSC 2017c), but the appeals process for treatments regarded as service developments is not published in the policy "G1033: Priority setting in Health and Social Care" (CfHSC 2017a), rather it is written into the Terms of Reference of the PAF. These are not published on the States of Guernsey website for clinicians to refer to if they believe that a policy development decision for a treatment or drug needs to be reviewed. There is no published appeals process for non-drug service development decisions made by CMT.
- A clear process needs to be developed and described for considering treatments
 that an off-island Consultant has recommended where that Consultant has not
 complied with the Guernsey request process. If no such process exists e.g. for
 the GP or an on-island Consultant to apply on their behalf, then the patient is left
 without a clinical advocate. They may resort to funding the treatment themselves
 or remaining untreated or inappropriately treated.
- The policy development process needs to ensure that the different policy committees apply the same principles and rules when making decisions. The online publication of minutes (both the decisions and decision rationale) of all policy development committees (PAF and CMT) would facilitate transparency and confidence in the process adopted by CfHSC and the people responsible for delivering the process.
- A unified process for funding treatments approved by PAF Panel or CMT needs to be developed, in order to be able to be able to implement the decisions made using the principles described in G1033.

Together these improvements to the policy development process aim to improve the transparency and understanding of the process and decisions for patients and clinicians. They may also encourage clinicians from a wider range of clinical specialties who are unfamiliar with the process to engage with it and submit objective and competent proposals. In operating a restrictive policy development process, it is important to fund the approved treatments in order to gain buy-in and due regard for decisions not to approve other treatments.



3.6.3 Communication & information

- Investment in communication and a single online source of policy decisions and rationale would alleviate the dissatisfaction and misunderstanding about which treatments are or are not funded.
- The omissions, and the lack of an explanation that the White List is not a definitive list of funded and unfunded drug treatments, appear to contribute to clinician and patient dissatisfaction about the transparency of funding for treatments. The A-Z list of funded and non-funded treatments is also difficult to comprehend. There are a large number of NICE TA-approved drug treatments which are not funded and not on the A-Z list. There are also treatments which are funded and not listed on the White List. We were only able to verify the funding arrangements for each of the individual 160 NICE TA-approved treatments and indications by liaising directly with individual professionals in Guernsey. This confirms that there is a lack of transparency about treatments which are funded and unfunded by the States of Guernsey

3.7 Themes from Engagement Events

Engagement events were held to understand stakeholder views about principles to apply in funding decisions.

The Public Health Services were responsible for the logistics for the stakeholder engagement events (advertising, letters to charities, event management and press enquiries) and helped to facilitate at each of the six engagement events in Guernsey and Alderney.

In addition to the 22 interviews and four meetings, 145 people attended the engagement events listed above. Following the review of three scenarios, discussion in small groups and as a whole, we gathered and collated three key outcomes:

- agreement and disagreement about principles for deciding which treatments should be funded
- the responses to postcard question 1
- the responses to postcard question 2

3.7.1 Themes from event CHAT-boards

In reviewing and discussing the 27 completed CHAT-boards from all the tables, we found that there were a number of principles where there was strong agreement that the existing principle should remain. In contrast, there were a number of principles where there was a spread of opinion. We focused the plenary discussions on identifying these principles and understanding the reasons for the lack of consensus. When aggregated together, none of the segments had 145 stickers. The number of participants for each segment ranged from 130 to 141.



Table 12: Strength of agreement regarding existing principles and prioritisation for funding

Principle for decision-making and sticker count	Strength of consensus / range of opinion	Outcome and discussion
Personal characteristic principles		
Age - Not important 105 - Young 18 - Old 8 - Total 131	Over 80% consensus	There was a strong consensus that the age of the patient or patient group should not be used as a criterion for deciding which treatments should be prioritised for funding.
Gender, sexual orientation, gender identity - Important 0 - Not important 130 - 'Middle' 4 - Total 134	Over 80% consensus	There was a strong consensus that the gender, sexual orientation or gender identity of the patient or patient group should not be used as a criterion for deciding which treatments should be prioritised for funding.
Race nationality religion - Important 2 - Not important 131 - 'Middle' 4 - Total 137	Over 80% consensus	There was a strong consensus that the race, nationality or religion of the patient or patient group should not be used as a criterion for deciding which treatments should be prioritised for funding.
Intelligence, disability, physical or cognitive function - Important 4 - Not important 123 - 'Middle' 7	Over 80% consensus	There was a strong consensus that the intelligence, disability, physical or cognitive function of the patient or patient group should not be used as a criterion for deciding which treatments should be prioritised for funding. Differing interpretations contributed to variances in preferences. Plenary discussion points included concern that if these factors were
- Total 134		over-treatment or treatment for people who have other co-morbidities which affect their ability to benefit from the treatment e.g. cancer treatment

The Review of Drugs and Treatments



Principle for decision-making and sticker count	Strength of consensus / range of opinion	Outcome and discussion
		for people with dementia, people with disorders of consciousness
		 individuals who lack capacity to consent being denied treatment on an equitable basis
		The group agreed that these factors should not be decision criteria for policy development even though these factors may be important considerations for clinicians, patients and their families when making decisions about their own care.
Social position, family or financial status	Over 80% consensus	There was strong consensus that the social position, the family or financial status of a patient should not be relevant criteria for policy development.
Important 4Not important 110		The criterion about financial status was raised by participants who wished to explore:
Neither 18Total 132		 if "people who can afford to pay should actually pay, rather than the States pay for everyone to get treatment free regardless of whether they are rich or poor?"
		if personal wealth should be taken into account?
		 if those with private means did not pay for their own treatment, then would this mean fewer drugs being funded for those who cannot pay? Should treatment be means tested?
		Although it was discussed, the consensus was that personal financial status should not be a decision criterion for policy development.
Healthy lifestyle e.g. weight, alcohol consumption, smoking status, healthy diet and exercise - Important 53 - Not important 47 - Neither 35	Range of opinion	There was extensive debate about the extent to which one's lifestyle should affect whether or not treatment should be funded. Healthy lifestyle behaviours were the most controversial personal characteristics. Approximately 40% of participants thought lifestyle was an important factor; 60% thought that it was either not important or were undecided. Comments from the plenary discussion included:
- Total 135		 "Individuals should be encouraged to make changes in behaviour before treatment in order to maximise the effectiveness of the treatment."
		"For lifestyle affected diseases give drugs based on making changes to

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Strength of consensus / range of opinion	Outcome and discussion
	lifestyle to gain increased benefit from treatment."
	 "Prevention measures should be considered alongside NICE TA-approved drugs in case they are a better use of money than drugs afterwards."
	 "Policy makers should be cautious about 'judging' how people live. The pathway of how people got to where they are and how much choice they have is unknown."
	"The level of 'compliance' to engage in a healthy lifestyle pre-post treatment should be taken into account."
	"People have a personal responsibility to keep healthy."
	"Some people do not have control/choice e.g. alcoholism."
	Following discussion, there was general agreement that lifestyle should not be a principle used to make funding decisions about NICE TA-approved treatments for the population of Guernsey and Alderney.
er 80% consensus	The majority of participants favoured prioritising the most cost effective NICE TA-approved treatments first i.e. those with a lower cost per QALY. The CHAT-boards and the discussion indicated that almost half the participants were in favour of the CfHSC increasing the current cost per QALY ceiling above £30,000 per QALY.
ange of opinion	The majority of the unfunded NICE TAs in Guernsey and Alderney are drug therapies (156 out of 160). There was range of opinion about the priority of NICE TA-approved drugs over other types of treatments including other drugs therapies not considered by the NICE TA programme, surgery or devices. Approximately 20% of participants favoured prioritising NICE TA-approved drugs, 30% thought that funding for other treatments should be prioritised e.g. treatment for pain, mental health, surgery for osteoarthritis, prevention and alternative treatments to drugs.
	er 80% consensus

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Principle for decision-making and sticker count	Strength of consensus / range of opinion	Outcome and discussion
		to fund NICE TA-approved drugs.
Life-extending, end of life treatments - EoL treatments 11 - Equal 73 - First or second line treatments 50 - Total 134	Over 80% consensus	There was a strong consensus that treatments classed by NICE as life-extending for patients with a short life expectancy (for which NICE gives a greater weight to QALYs) should not be considered a higher priority for funding than other NICE TA-approved treatments
Disease principles		
Cancer compared to other diseases - Cancer 16 - All diseases equal 105 - Non-cancer 9 - Total 130	Over 80% consensus	There was a strong consensus that treatments for cancer should not be prioritised over treatments for other diseases.
Rare vs common - Common 40	Range of opinion	There was range of opinion about whether treatments for rare conditions should be prioritised for funding over treatments for common conditions.
Equal 96Rare 4		The majority of participants favoured treating all conditions equally regardless of how many other people are also affected.
- Total 140		The plenary discussion comments included a comment that "rare diseases can mean spending huge amounts of money on one person. This has a big impact on a small health economy" but there was general agreement that whilst prioritising treatments for rare diseases was not favoured, nor was making these treatments a low priority simply because fewer other people were affected.
Emergency vs lifelong treatments - Emergency 13 - Lifelong 12 - Neither 108 - Total 133	Over 80% consensus	There was a strong consensus that prioritising funding for treatments for emergency or acute health needs over treatments for lifelong conditions was not supported.

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Principle for decision-making and sticker count	Strength of consensus / range of opinion	Outcome and discussion
Healthcare setting principles		
Off-island provider vs. on-island provider	Over 80% consensus	There was a strong consensus that the funding for some treatments should be available to all Guernsey and Alderney residents regardless of whether or not
 On island 16 Neither 115 Off island 6 Total 137 		the treatment was recommended by an on or off-island consultant and regardless of whether the patient receives treatment in a hospital in England or in Guernsey or Alderney.
		There was very little support for prioritising treatments that were administered off-island. There was some concern that this might create a perverse incentive to refer patients to off-island providers (with associated additional costs) rather than treat them locally.



The key findings from the CHAT-board discussions were that there was a strong consensus that personal characteristics should not be used to determine funding policy for NICE TA-approved treatments, although there may be a consideration at an individual patient level about whether the patient is able to benefit from the treatment. Such personal characteristics included:

- age
- gender, sexual orientation, gender identity
- race nationality religion
- intelligence, disability, physical or cognitive function
- · social position, family or financial status
- healthy lifestyle e.g. weight, alcohol consumption, smoking status, healthy diet and exercise

Some of the decision principles that were discussed generated a wider range of opinion. In addition there were principles for which there was consensus in favour of them being used as a decision criterion for prioritising funding for NICE TA-approved treatments. These are listed in Table 13.

Table 13: Summary of discussion of decision principles for resource allocation

Q2: If only some of the NICE Technology Appraisal-approved treatments are prioritised and made available in the first year, then do you have a preference for which treatments and conditions should be funded first?

Principle	CHAT-board Summary	Number of responses	Rank	
Cost effectiveness	Strong consensus that the most cost effective treatments should be prioritised.	37	1	
Circulation		[plus 25 for 'strength of evidence of effectiveness']	[2]	
Cancer	Strong consensus that treatments for cancer should not be prioritised over treatments for other diseases.	25	2	
Common diseases /	Majority of participants favoured treating all conditions equally regardless of how many	22	3	
largest number	other people are also affected.		Chronic disease	
of people benefit	Strong consensus that rare conditions should		including CVD,	
	not be prioritised for funding over treatments for common conditions.		diabetes, LTC: count 19, rank 4	
Life-extending, end of life	Strong consensus that treatments classed by NICE as life-extending, end of life treatments	5 against	rank 9	
treatments	(for which NICE gives a greater weight to QALYs) should not be considered a higher priority for funding than other NICE TAapproved treatments	1 in favour	rank 12	
Fund all NICE	Range of opinion about the priority of NICE TA-	9	7	
TA-approved treatments	approved drugs over other treatments including other drugs therapies not considered by the NICE TA programme, surgery or devices.			
Status Quo	Not on the CHAT-board	2	11	



3.7.2 Themes from postcard question 1

In response to the two questions on the postcards, 139 participants out of the 145 people who attended the engagement events returned a postcard with Question 1 completed. Question 1 asked "How strongly do you agree with the following statement: 'all NICE technology appraisal approved treatments should be prioritised over other health and social care investments and funding automatically made available within 90 days of publications (as is the case for NHS organisations in England and Wales)?"

Figure 10 shows that of the 139 responses, 64 people (46%) answered in favour of NICE TA-approved treatments being funded over other health and social care investments, compared to 51 (37%) who disagreed with the statement and 24 (17%) who neither agreed nor disagreed.

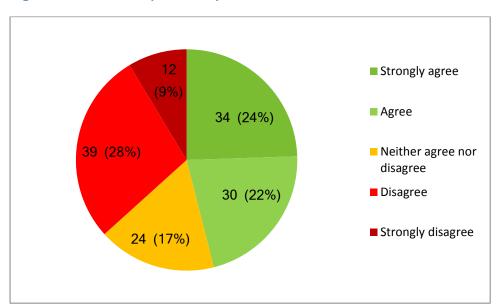


Figure 10: answers to postcard question 1

3.7.3 Themes from postcard question 2

Question 2 was an open question, which sought the views of individual participants about their ideas and preferences for which NICE TA-approved treatments or conditions should be prioritised if funding was not available for all treatments initially.

The narrative format of the feedback was captured and counted. Where multiple suggestions were written, we captured all the suggestions, before we grouped and ranked the feedback.

The key principles that the stakeholders preferred for the prioritisation of NICE TAapproved treatments are shown in Table 14 below. The suggestions have been categorised into 'decision principles' which include features about the patient group, the condition and stage of disease and the treatment.



The other two categories are 'decision comments' which largely refer to who should make the decision about prioritisation or what the decision should be and 'funding comments'.

Although the greatest consensus for how NICE TA-approved treatments should be prioritised was for those treatments which are the most cost effective, the counts for themed principles were relatively low compared to the number of participants (145) who attended the stakeholder engagement events.

Key findings included:

- 37 participants suggested that priority should be given to those treatments which are most cost–effective (highest ranking principle).
- There were 25 suggestions that those treatments which had the strongest evidence should be prioritised.
- A number of people suggested that treatments for cancer (25), and common or chronic diseases (22 and 19 suggestions respectively) should be prioritised.
- Although treatments which are life extending for people near the end of their life were prominent in the Requête, we noted that only one participant suggested these treatments should be prioritised and four participants suggested that they should not be prioritised.

Further detail is given in Table 14.



Table 14: Responses to postcard question 2

Principles and priorities for decision making	Number of responses	Rank
Decision principles		
Cost effectiveness / cost/QALY/value for money/ potential for efficiency or savings	37	1
Cancer	25	2
Clinically effective - LY/QoL/independence – strongest evidence	25	2
Common diseases / largest number of people benefit	22	3
Chronic disease including CVD, diabetes, LTC	19	4
Children and younger people	11	5
Treatments related to early stage/prevention	10	6
Not EoL	4	9
Off-island treatments	3	10
No other treatment option available/better than current treatment	2	11
EoL	1	12
Childhood obesity, Lifestyle related conditions e.g. addiction/mental	1	
health, Acute/emergencies, Fit people, High	(per	12
profile cases,	suggestion)	
Decision comments		
Professionals decide/ Professionals decide on individual patient basis Professionals plus expert groups decide, Guernsey authorities decide	7	8
Don't know/not qualified to answer/too subjective	3	10
No preference	2	11
Funding comments		
Fund all	9	7
Fund without reducing other health and social care spend	4	9
Too costly/ Avoid exceeding overall budget	3	10
Continue as now, consider on merit - status quo	2	11
Make sure people are aware that not all are funded	1	12

3.8 Issues to consider in interpreting findings

3.8.1 Interviewees and participants

The stakeholder engagement events to 'inform the future provision of National Institute for Health and Care Excellence (NICE) approved treatments for islanders' were advertised as being "your opportunity to have your say on the crucial issue of routinely making all NICE TA-approved treatments available for Guernsey and Alderney residents."

The advertisements went on to state that SPH would be seeking participants views on:

• making all NICE TA-approved treatments available



- prioritising particular NICE TA-approved treatments over others (for example, anti-cancer medication, end of life treatments, treatments for long term conditions or for childhood illnesses)
- the values and principles that you would like to be used when considering whether or not to fund a healthcare intervention or treatment

Although there was no analysis of participants (we did not ask participants to declare their professional or personal interests), it is likely that many of the interviewees and engagement event attendees had an interest in favour of NICE TA-approved treatments being funded and were not representative of the wider population of Guernsey and Alderney. It should also be noted that discussions, and 'counts' of preference about common and rare conditions are inevitably influenced by the likelihood that people with an interest in rare conditions are outnumbered by those with an interest in a common condition during the interview and engagement exercise.

Of particular note was the fact that we did not have access to off-island Consultant Specialists to whom Guernsey and Alderney residents are referred for conditions for which there is no on-island Consultant or for treatments which cannot be administered on-island. This means that their experience of treating patients from Guernsey and Alderney has not contributed to this Review. It might have been useful to understand their views on:

- their ability to comply with the Guernsey system for applying for funding for NICE TA-approved treatments
- the impact of not being able to treat patients with NICE TA-approved treatments on clinical outcomes and clinical governance have not been gathered

3.8.2 Focus of the Review

The primary focus of this Review is limited to the adoption of NICE TA-approved treatments so treatments which are outside the narrow remit of the NICE TA programme were marginalised in the discussions. All six scenarios used as the basis for generating discussion were based on NICE TA-approved treatments for diseases which are not currently funded by the States. There was therefore limited awareness about the relative clinical and cost effectiveness of NICE TA-approved treatments compared to other treatments which clinicians or patients also want to be funded. Discussions about any potential impact of adopting NICE TA-approved treatments on wider health services were outside of the scope of the Review.

3.8.3 Collecting data

The colourful CHAT-boards were designed to engage participants and to facilitate discussion about prioritising funding for treatments at a policy and population level rather than based on individual patient stories. Once participants had placed their stickers in each segment, the CHAT-board format also offered a visual indication of the strength and range of preference amongst participants.



We were aware that the placing of stickers by participants varied in a few instances. The way that stickers were applied varied as some individuals placed more than one sticker in a segment, and none in others. Of the 145 participants, when reviewing the segments across the 27 CHAT-boards, we found that the number of stickers in each segment ranged from 130 to 141. The missing or over-expressed preferences may have been due to the time constraints of the agenda, concern that the event was not worth engaging with or a desire to 'game' the numbers in order to exert influence.

The stickers on the CHAT-boards show that the majority of participants contributed to the outcomes in the same way.

Many participants did not complete question 2 on the postcard, whilst others offered several suggestions all of which we counted. The counts for the suggestions, even after collating into groups, are relatively low compared to the total number of participants. Although the second most frequent suggestion was to prioritise the most clinically effective treatments, we did not include this as an option for prioritisation for three reasons:

- 1. cost effectiveness (the most frequently suggested method of prioritisation) is already dependent on a treatment being clinically effective
- the outcomes data published by NICE usually redacts the estimated QALY gain from the publicly available evidence in order to protect commercially sensitive information about the extent to which drug treatments are discounted for the NHS
- 3. NICE considers that all of the TA-approved treatments are clinically effective

Nevertheless, the collated suggestions offered in response to question 2 on the postcard do offer an indication of the most popular ways of prioritisation of NICE TA-approved treatments, if it is not possible to fund all at once.

For all of the reasons above, the outcomes of the qualitative and engagement part of this review should be treated as indicative rather than definitive findings.

3.9 Summary of findings from stakeholder engagement

Following all stakeholder engagement discussions and feedback, the logical options identified for inclusion in this review are to:

- 1. Fund all NICE TA-approved treatments
 - Fund NICE TA-approved treatments except Highly Specialised Technologies
- 2. Prioritise all NICE TA-approved treatments for cancer over treatments for other conditions
 - 2a. Prioritise NICE TA-approved treatments for cancer excluding those in the Cancer Drugs Fund
 - 2b. Prioritise NICE TA-approved treatments for cancer only from the Cancer Drugs Fund
- 3. Prioritise NICE TA-approved life extending, at the end of life (EoL) treatments



- 4. Prioritise NICE TA-approved treatments for common diseases so that the greatest number of people will benefit
- 5. Prioritise NICE TA-approved treatments on the basis of (clinical and) cost effectiveness
- Status quo continue with the current system of individually reviewing the NICE evidence of clinical and cost effectiveness, if requested by a Consultant or GP

These six key options reflect the primary scope of the Review (i.e. presumptive funding of all NICE TA-approved treatments) as well as the decision-making principles for which there was the most support.

The implications and key considerations associated with each option are described in more detail in the Options Appraisal Summary at the start of this report.



4 Quantitative Analysis

4.1 Aims and objectives

The aims of the quantitative analysis were to:

- clarify which NICE TA-approved treatments are not funded by the States of Guernsey
- understand how many patients in the States of Guernsey would be likely to receive currently unfunded TA treatments, should funding be made available
- provide indicative estimates of the gross and net costs of funding the currently unfunded TA treatments
- summarise available information in the NICE TAs about health benefit and cost effectiveness

The objectives were to:

- identify which NICE TA-approved treatments were recommended by NICE, still current, and not routinely funded by the States of Guernsey
- use the information on eligibility and uptake in England within the TA documentation to estimate likely patient numbers in Guernsey for each TAapproved treatment
- extract information on cost, dosage and treatment duration from the TA documentation and use this information to calculate a cost per annum for each TA-approved treatment
- obtain discounted pricing information where nationally agreed commercial discounting arrangements had been agreed by the NHS in England
- review and summarise the available information in the NICE TAs in relation to life years gained, number of quality adjusted life years gained, and incremental cost effectiveness ratios (ICERs)

4.2 Methodology

4.2.1 Identifying a list of relevant NICE TAs

We downloaded a list of published NICE TA guidance from the NICE website and updated it to include all NICE TAs published up to 31st December 2018.

The list included 544 TAs, which between them made 864 separate sets of TA recommendations. In addition, eight TAs relating to Highly Specialised Technologies (HSTs) were also included in the analysis.

From the list we identified which TA recommendations related to TAs that had been withdrawn or replaced by NICE, or related to terminated appraisals (usually where the manufacturer has not submitted sufficient evidence to NICE for the appraisal to continue). We also identified TA recommendations where NICE determined that the treatment being appraised should not be recommended for routine funding.

We checked both the recommendation status and whether the TA had been withdrawn or replaced by a manual search of the NICE website to ensure that the



information from the downloaded list was as up to date as we would make it (as at January 2019).

The States of Guernsey Pharmacy Advisor provided SPH with a list of NICE TA guidance prepared by the Chief Pharmacist in late 2018, which included information on the funding status of each TA in the States of Guernsey. We used this information to populate our list of current and approved NICE TA recommendations with a provisional funding status by the States of Guernsey for each TA recommendation.

We shared our updated list, with the States of Guernsey Pharmacy Advisor, who reviewed the provisional funding status for each TA recommendation and advised us of any changes that had been made to the funding status since the Chief Pharmacist's list had been compiled. For a small number of TA recommendations that related to non-drug treatments we asked the Director of Public Health for the States of Guernsey to confirm the current funding position.

4.2.2 Recording details about each TA recommendation to support quantitative analysis

Having finalised the list of TA recommendations that were currently approved by NICE, but were not routinely funded by the States of Guernsey, we then augmented the list with further details about the TA treatment from the NICE TA documentation. These details were intended to make it possible to categorise the TA recommendations into different groups based on the outcome of the interviews and events discussed in the qualitative analysis section. The details also enabled us to estimate gross and net costs of the TA-approved treatments. These details included:

- the dosage and treatment duration of the TA treatment
- whether the treatment population included children or adults or both
- how many people NICE estimated would be eligible for treatment in England and of these how many would receive treatment per annum
- the price given in the NICE TA and whether any discounted pricing had been agreed via a Patient Access Scheme (PAS)
- NICE's assessment of cost effectiveness, including the Incremental Cost Effectiveness Ratio (ICER) which indicates how cost effective the TA treatment is likely to be compared with an existing treatment
- the comparator treatment(s) cited in the NICE TA documentation in relation to cost effectiveness

In addition to extracting information from the NICE TA documentation, we also sought information from the States of Guernsey on:

- which TA recommendations would be likely to have a significant impact on pharmacy services resources
- which TA recommendations would be likely to have a significant impact on laboratory and genomic testing services
- which comparator treatments were most commonly used in Guernsey, where multiple comparator treatments were cited in the NICE TA



 whether the comparator treatment cited in the NICE TA documentation was routinely funded by the States of Guernsey and if it was, whether a discounted price is paid (and what the discounted price is)

These data fields were discussed and agreed with senior representatives of Health and Social Care in the States of Guernsey during a visit to the island in late January 2019.

The final list of data fields included in the database is shown in Appendix 6.

4.2.3 Estimating patient numbers for TA-approved treatments

At the outset of the project, the intention was to estimate the number of patients in the States of Guernsey likely to receive the TA-approved treatments by taking the estimated number of patients for England as set out in the TA documentation and pro-rating it by the England and States of Guernsey populations. We considered whether we needed to take account of the population differences between the States of Guernsey and England, but concluded that this would not be necessary due to the large difference in the size of the respective 2017 Guernsey (64,048) and 2017 England populations (55.6 million). This difference meant that for every 1,000 patients in England pro-rating by the two populations would result in only 1.2 patients in the States of Guernsey. Many of the TA documents suggested that fewer than 1,000 patients in England would be eligible for the TA-approved treatment, suggesting that there would be negligible benefit in age-standardisation or using other methods to take better account of any population differences.

However, during the course of populating the database of NICE TA recommendations, it became clear that information on the number of patients likely to be eligible for and to take up the recommended treatment in England was absent from a significant proportion (about 65%) of the TA recommendations of interest to this review.

Therefore, we adopted two additional methods to generate estimates of patient numbers:

- we reviewed the documentation produced by the Scottish Medicines Consortium (SMC) who make recommendations on the funding of drug treatments for the population of Scotland for the TA recommendations relevant to this review
- we asked Guernsey clinicians to provide indicative estimates of:
 - the number of patients potentially eligible for each TA-approved treatment
 - of these the number that would potentially switch to or start on the TAapproved treatment
 - the expected number of new patients per year who would receive this TAapproved treatment
 - if this was likely to be less than one new patient per year, to provide the estimated number of new patients over a five year period



Our request to Guernsey clinicians was supported and co-ordinated by the Director of Public Health for the States of Guernsey who engaged directly with relevant clinicians on our behalf and collated the responses received.

The proforma used to collect patient numbers from Guernsey clinicians is shown in Appendix 7.

Having reviewed the results achieved by these three different methods of estimating patient numbers, we decided to:

- use the figures provided by Guernsey clinicians where these were available as there were relatively few gaps
- where these were not available, use the pro-rata estimates based on England numbers
- where both the above were not available, to use pro-rata estimates based on the SMC patient numbers and the Scottish population

4.2.4 Pricing

The pricing information contained within the NICE TA documentation enabled us to calculate a price for each TA treatment per patient per annum, but this price was based on the price of the treatment at the time at which the TA was published.

Around two thirds of the TA recommendations (and a higher proportion of the more recently published TAs) had some variety of commercially agreed discount agreed between the manufacturer and the NHS in England that made the treatment available in England at a lower price. Our colleagues in the Medicines Management team at NHS Arden and Greater East Midlands Commissioning Support Unit (AGEM CSU) obtained these discounted prices at their current 2019 values on our behalf. However, there are a small number (seven TA recommendations) where it was not possible to obtain the discounted price, in which case the original TA published price has been used.

For the TA recommendations which were not part of a commercial discounting arrangement in England, we have checked and updated the TA pricing where necessary, using prices published in the British National Formulary (BNF).

Due to the commercial sensitivities of the discounted pricing we have received via our Medicines Management colleagues, we have only used the real discounted prices in the high level options appraisal table, where a sufficient number of TA recommendations have been grouped together to ensure that the commercial pricing has not been revealed.

In most of the data tables in the analysis sections below, we have used an average indicative discounted price rather than the actual discounted price. This modified discounted price has been created by calculating the aggregate percentage discount across all the TA recommendations of interest to this review and then applying this fixed percentage discount to each individual TA recommendation that has a



commercial discount arrangement in place. We then adjusted the aggregate percentage discount to closely match the total price of all the TA recommendations when the pricing is applied to the estimated number of Guernsey patients to be treated in the first year. When looking at the total gross or net cost impact of each of the options presented below the modified fixed percentage discounted price will be very close to the real discounted price, but at individual TA recommendation level the modified discounted price will differ from the real discounted price, in either direction, by as much as 20% - 30%.

4.2.5 Calculations to support options appraisal

In Section 4.3 we present the results of our analysis of the TA recommendation database for each of the potential options for future NICE TA funding to be considered by the States of Guernsey.

These results are based on a number of calculations we performed on the completed TA recommendation database. Specifically, we have calculated:

- 1. the number of TA recommendations and TAs that fall within each of the different options
- 2. the number of Guernsey patients likely to start on the TA treatment in the first year. This number is based on the number of prevalent patients that Guernsey clinicians considered would be likely to switch to or start the TA treatment. For five TA recommendations where this information is not available, we have used the pro-rata number of patients expected to be treated in the first year by NICE or the SMC
- 3. the number of new patients treated per annum, or over 5 years if less than one patient is likely to receive the treatment per year. This number has been provided by the Guernsey clinicians. Neither NICE nor the SMC routinely provide a number of new patients per year within their guidance, so we have not been able to plug any gaps with pro-rata numbers for England and Scotland as we have with patients treated in the first year
- 4. **the gross cost of the TA treatment in Guernsey**. This has been calculated separately for patients being treated in the first year and for new patients per year. The cost has been calculated by multiplying the price per patient per annum of the TA drug by the estimated number of Guernsey patients
- 5. the net cost of TA treatment in Guernsey. This has been calculated separately for patients being treated in the first year and for new patients per year. The cost has been calculated by multiplying the price per patient per annum of the TA drug by the estimated number of Guernsey patients and subtracting the price per patient per annum of an existing comparator treatment applied to the same number of Guernsey patients
- the number of TA recommendations (and estimated patient numbers) where
 patients may switch from oral drugs (the current treatment) to infused or
 injected drugs (the TA-approved treatment) or vice versa



- 7. the number of TA recommendations (and estimated patient numbers) where there is likely to be significant impact on pharmacy services. The Pharmacy Advisor for the States of Guernsey advised that this was likely to be any drug treatment that needed infusion or injection
- 8. the number of TA recommendations (and estimated patient numbers) where there is likely to be significant impact on laboratory testing services. TA recommendations with a significant impact on laboratory services have been identified by pathology department at Princess Elizabeth Hospital on Guernsey

4.2.6 Assumptions and caveats

The estimates of both costs and benefits for the options presented in Section 4.3 and elsewhere in this report are subject to a number of significant constraints and limitations.

All NICE TAs published since 1st January 2019 have been excluded from our analyses. As of 1st May 2019, this amounts to 24 new TAs.

All costings are exclusive of VAT.

The drug treatment pricing is based on a number of assumptions including:

- all weight based drug pricing has been calculated based on a 70kg patient (man or woman)
- all body surface area based medication pricing has been based on the assumption that an average individual has a BSA of 1.7/m²
- for paediatric patients, a regimen weight recommended by the NICE TA has been used (where available). If there is a weight range stated, then the highest weight has been used. However, if none of those parameters are available, then the maximum dose allowance (per day) has been used as per the BNF/SPC
- if the drug involves a titration regimen (e.g. methadone), then the highest dose will be used on a pro-rata basis
- if a drug is available in in different strengths, the price has been calculated by using the highest strength
- if a drug is available as liquid and solid dosage form, the price is calculated based
 on the most cost effective dosage form available. If there is no preference stated
 on NICE TA, then the solid form has been used to calculate the pricing.
- if the TA states that the drug should be used in combination with another drug, then the cost is based on the NICE TA DRUG ONLY (e.g. TA418 Dapagliflozin in combination with metformin and a sulfonylurea where only Dapagliflozin has been costed).
- pricing calculations have taken account of "excess" or "wastage". For example, if a new vial needs to be used to make up the full dose and 80% of the vial is not used, then that would be classed as "excess" or "wastage"
- where two different prices were quoted by NICE in the TA e.g. TA157 Dabigatran etexilate where different prices are quoted for use in hips and knees, an average of the two prices has been used



- where it was not possible to obtain a price for the comparator or usual treatment described in the NICE TA guidance, we have used the gross price of the TAapproved treatment when calculating the net cost impact to the States of Guernsey of funding that TA
- the gross and net cost pricing relates to the acquisition drug treatment prices only and does not take into account any manpower or pathway related treatment costs

The data on ICERs published in the NICE TAs is sometimes explicitly without the commercial discount applied and sometimes explicitly with the commercial discount applied, but sometimes this is unclear. We are aware that for some TA recommendations the price of the comparator treatment will have changed since the publication of the NICE TA. It has not been possible to re-calculate the ICER for these TA recommendations using updated pricing information on the comparator treatment, largely because of the absence of QALY gain information in the published TA guidance. The ICER values presented in this report therefore are those published by NICE at the time they carried out their appraisal of each TA-approved treatment.

Whilst concerted efforts have been made to obtain complete information for each of the TA recommendations of interest to this review, inevitably there are some gaps in the data we have been able to obtain in the timescales of this review. These gaps include:

- We found the vast majority of TAs did not have health benefit information such as years of life gained or QALY gain available in the TA documentation. This information had often been redacted from the published versions for commercial sensitivity reasons.
- There are 60 TA recommendations where we have been unable to provide a net cost of adopting these TA-approved treatments and a gross cost figure has been used instead. This is due to the expected or actual current treatment being described in the TA documentation as "best supportive care" or "treatment of clinician's choice" where we have been unable to provide a costing and because the States of Guernsey does not always fund the existing treatment cited in the NICE TA
- 17 TA recommendations where no ICER was quoted in TA documentation and we were unable to find this information from equivalent guidance published by the SMC in Scotland.
- Seven TA recommendations where we were not able to obtain discounted prices.
- Five TA recommendations where we were not able to obtain patient number estimates for those likely to switch of start on the TA treatment from Guernsey clinicians.
- Four TA recommendations where we were not able to obtain numbers of new patients per annum from Guernsey clinicians.



4.3 Analysis

4.3.1 What is currently funded

Out of a total of 480 NICE TA recommendations relating to current TAs (excluding those which have been withdrawn or replaced) and which are approved by NICE exactly two-thirds, 320 are already funded by the States of Guernsey and 160 are currently unfunded.

These TA recommendations relate to a diverse range of different conditions, as shown in Table 15 below:

Table 15: Number of NICE TA-approved treatments approved and not approved for funding by the States of Guernsey by disease group

	Number of TA Recommendations			
Disease Group	Funded	Not Funded		
Cancer	74	87		
Rheumatology	39	14		
Dermatology	31	6		
Cardiac Services	26	6		
Infectious Diseases	21	2		
Neurosciences	19	3		
Ear and Ophthalmology Services	18	3		
Trauma and Orthopaedics	16	5		
Colorectal Services	15	2		
Vascular Disease	13	1		
Renal Services	11	1		
Respiratory	10	5		
Endocrinology	8	9		
Mental Health	4	3		
Paediatric Medicine	4	3		
Women's Services	3	0		
Blood Disorders	3	1		
Other	2	1		
Hepatobiliary and Pancreas	1	1		
Pain	1	1		
Child and Adolescent Mental Health Services (CAMHS)	1	0		
Children and Young Adult Cancer Services	0	1		
Medical Genetics	0	4		
Immunology and Allergy Services	0	1		
Total	320	160		

Table 15 shows that cancer has the largest number (74) of NICE TA recommendations already funded by the States of Guernsey, followed by Rheumatology (39) and Dermatology (31). Conversely, Child and Adult Mental Health Services (CAMHs), Pain Management and Hepatobiliary and Pancreas each only have a single TA recommendation funded. However, it should be noted that this pattern is likely to reflect the number of TA recommendations published for each



disease area by NICE, as well as local funding decisions. For funded TA-approved treatments, Cancer has the largest number of TA recommendations that are funded (87). This means that more than half of NICE TA recommendations for cancer are funded by the States and that more than half of the unfunded NICE TA recommendations also relate to cancer.

Figure 11 below shows the number of NICE TA recommendations that have been approved or not approved by NICE and the funding status in Guernsey of those TA recommendations that have been approved up to 31st December 2018.

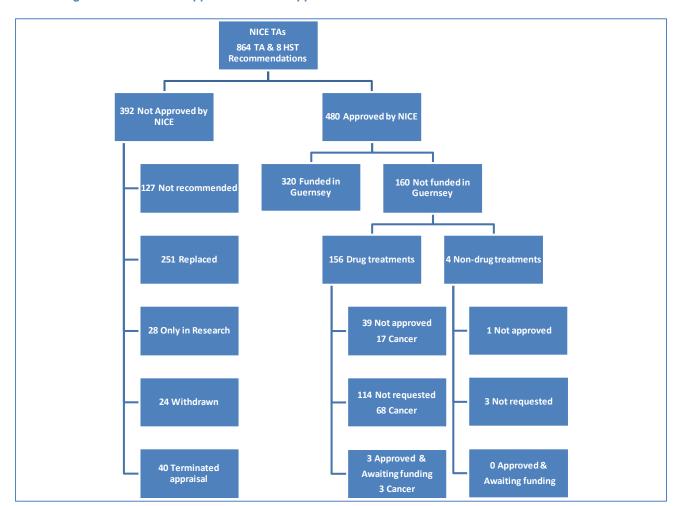


Figure 11: Number of approved and not approved TA recommendations

Figure 11 shows that of the 480 TA recommendations approved by NICE, 320 are funded by the States of Guernsey and 160 are not funded. The majority of the TA recommendations not funded by the States of Guernsey have not yet been requested for routine funding. This reflects local arrangements in Guernsey whereby NICE TA-approved treatments are not considered for funding until they have been formally requested by a clinician. The 160 currently unfunded NICE TA and HST recommendations are the subject of further analysis in the remainder of this section.

It is worth noting that the 392 NICE TA recommendations not approved by NICE include those where the appraisal was terminated, where TA recommendations have



been replaced by more recent TA or other NICE guidance and where NICE did not recommend treatment. It is possible for a TA recommendation to have been both not recommended and subsequently replace or withdrawn, so the numbers in the not approved by NICE boxes in Figure 11 do not sum to 392.

4.3.2 What is not currently funded

We have identified a total of 160 NICE TA recommendations (from 145 TAs) that are not routinely funded by the States of Guernsey. This includes NICE TA recommendations that have not been approved for funding (39), have not been asked for (128), and those that have been approved, but for which funding has yet to be made available (3).

Further details of these 160 currently unfunded TA recommendations are shown in Section 4.4 below.



4.3.3 Summary of analysis/options appraisal

Table 16: Summary of number of TA recommendations, numbers of Guernsey patients and net cost impact of potential funding policy options

Option	Number of TA Recommendations/TAs		Number of Patients		Net Cost Impact	
	No of TA Recommendations	Number of TAs	Backlog patients ⁷ *	New per annum	Backlog patients	New patients per annum
1. Fund all Inc. HST	160	145	3,348	782	£7,572,196	£5,486,944
1a. Fund all exc. HST.	152	137	3,344	777	£6,861,669	£4,499,953
2. Fund all cancer	88	84	114	98	£3,252,085	£3,207,102
2a. Fund all non-CDF	49	47	61	52	£1,191,011	£1,230,086
2b. Fund all CDF	39	38	53	46	£2,061,075	£1,977,016
3. Fund all end of life	51	49	74	62	£1,765,069	£1,759,270
4. Fund only common conditions	44	40	3,221	679	£3,613,662	£1,255,342
5. Fund according to cost effectiveness						
<20k <30k <40k <50k >100k	27 71 93 124 138	24 67 88 119 130	1,928 2,769 3,073 3,120 3,141	338 630 678 721 737	£1,253,455 £3,132,167 £4,726,920 £5,871,939 £6,703,689	£456,718 £1,523,265 £2,522,646 £3,764,477 £4,416,348
6. Status quo	0	0	0	0	03	£0

⁷ Backlog refers to the number of currently known people who Guernsey clinicians have indicated they would switch to or start on the TA-approved treatment should funding become available. In many cases, this number is larger than the number of new patients per annum that Guernsey clinicians provided.



4.4 Analysis of potential options

This section summarises the key data extracted from the NICE TAs and other sources, for the different groups of TAs that form each of the potential options for consideration by the States of Guernsey.

A list of which TA recommendations have been included in each option is available in Appendix 8.

For each option, we present the number of TA recommendations and individual TAs included in that option along with the estimated number of Guernsey patients likely to receive the TA treatment in the first year (the backlog) and the number of new patients per year likely to be treated thereafter. We also present the estimated gross and net costs for funding the TAs included in each option, along with the cost effectiveness of the TA recommendations included in each option. Finally, we indicate where adopting the TA treatment is likely to result in a change of drug administration method (from oral to infusion or injection or vice-versa) and how many TA recommendations in each option are likely to have a significant impact on pharmacy service resources or laboratory testing services.

4.4.1 Option 1: All NICE TA-approved treatments

This option would involve the States of Guernsey funding all of the 160 separate TA recommendations from 145 TAs that are currently approved by NICE for funding in England, but are not routinely funded in the States of Guernsey.

Table 17 shows the estimated number of patients likely to receive the TA-approved treatments for the TAs within this option and the estimated gross and net cost impact of the States of Guernsey funding these TA recommendations, broken down by different disease groups.



Table 17: Option 1 - Estimated Guernsey patient numbers and gross/net costs by disease group

	Estimated Guernsey Patient Numbers		Gross Cost Impact (PAS fixed discount)		Net Cost Impact (PAS fixed discount)	
Disease Group	Estimated Number of Patients Treated in Year 1		Cost Impact of Patients Treated in Year 1	Cost Impact of New Patients Treated per Annum	Cost Impact of Patients Treated in Year 1	Cost Impact of New Patients Treated per Annum
Blood Disorders	1	1	£384,300	£384,300	£384,300	£384,300
Cardiac Services	2,030	240	£2,140,122	£202,527	£2,083,950	£192,720
Cancer	114	98	£3,780,755	£3,559,553	£2,883,022	£2,794,266
Colorectal Services	110	23	£181,443	£42,085	£60,803	£5,893
Dermatology	14	11	£177,264	£138,024	£163,710	£130,902
Ear and Ophthalmology Services	21	15	£160,000	£83,500	£160,000	£83,500
Endocrinology	485	76	£370,728	£148,690	£184,033	£88,722
Hepatobiliary and Pancreas	2	1	£32,041	£16,021	£30,303	£15,151
Immunology and Allergy Services	4	1	£600	£150	£600	£150
Infectious Diseases	2	2	£89,654	£89,654	£89,654	£89,654
Medical Genetics	3	3	£340,200	£335,411	£340,200	£335,411
Mental Health	95	22	£36,941	£9,165	-£43,724	-£6,263
Neurosciences	5	3	£52,662	£34,356	£21,117	£18,584
Paediatric Medicine	0	1	£0	£221,058	£0	£221,058
Pain Management	100	100	£66,240	£66,240	£64,001	£64,001
Renal Services	0	2	£0	£17,640	£0	£17,640
Respiratory	100	49	£857,302	£472,583	£851,470	£468,938
Rheumatology	37	19	£215,281	£108,947	£150,408	£69,802
Trauma and Orthopaedics	60	60	£132,338	£132,338	£132,338	£132,338
Urology	150	40	£56,550	£15,080	£6,300	£1,680
Vascular Disease	15	15	£9,308	£9,308	£9,308	£9,308
Total	3,348	782	£9,083,728	£6,086,627	£7,571,793	£5,117,753

The NICE TA recommendations have been categorised into different disease groups based on the target treatment population stated in each TA. The disease categories were developed by the SPH team but are closely based on the Clinical Reference Groups within the NHS Specialised Services directorate in NHS England.



Table 17 shows that should the States of Guernsey choose to fund all of the TA recommendations within this option, 3,348 patients would be likely to switch to the TA treatment or start treatment within the first year (the backlog) and an estimated 782 further patients per annum would start treatment in subsequent years. The reason for the disparity in these two figures is the backlog of patients potentially eligible for TA recommendation treatment that would be likely to be treated within the first 12 months of funding being approved. Given this is a relatively large number of patients, the States of Guernsey may wish to consider adopting a phased approach to the implementation of this option.

Cardiac patients make up an estimated 2,030 patients out of the total of 3,348 patients (60.6%) likely to be treated in the first 12 months. The disease groups with the next highest number of estimated patients likely to be treated in the first 12 months are Endocrinology with 485 patients and Urology with 150 patients (accounting for 14.5% and 4.5% of the 3,348 total number of patients respectively). For new patients likely to be treated per annum, Cardiac services (240), Pain Management (100) and Cancer (98) have the highest numbers of patients, accounting for 30.7%, 12.8% and 12.5% respectively of the total number of new patients estimated to be treated each year (782).

As previously described in Section 4.2.4, the gross and net cost impact figures included in Table 17 have been based on an indicative discount to prevent commercially sensitive pricing available to the NHS in England being revealed. Table 17 shows that the gross estimated cost of funding all 160 TA recommendations in this option, for a total treatment population of 3,348 patients in the first year is around £9.1m. This figure reduces to a net cost impact of around £7.6m when the estimated costs of existing treatments are subtracted. However, it should be noted that the cost of existing treatments has not been deducted for 60 of the TA recommendations and in these cases the gross price of the TA-approved treatments has been included in the net cost impact figures. The main reasons for there not being a net cost impact for a TA recommendation are that the usual comparator was described in the TA was "best supportive care" or "treatment of physician's choice" which was not defined within the TA documentation and which we therefore have not been able to cost or where the comparative treatment stated in the TA is not currently funded by the States of Guernsey.

Cancer accounts for approximately £3.8m (41.8%) of the £9.1m gross cost impact, despite there being only an estimated 114 patients (3.4%) likely to received TA-approved treatments in the first year. Cardiac Services account for a further £2.1m (23.1%) of the gross cost impact of funding all the TA recommendations in this option. Cancer and Cardiac Services also have the highest net cost impacts, though the gap between them is smaller, with Cancer accounting for approximately £2.9m (38.2%) and Cardiac Services £2.1m (27.6%) of the total net cost impact of approximately £7.6m.



The gross and net cost impacts of funding the estimated 782 new patients per year for the TA-approved treatments in this option are approximately £6.1m and £5.1m respectively. With a gross cost impact of approximately £2.9m and a net cost impact of approximately £2.8m, TA-approved treatments in the Cancer disease group account for about half of both of these figures (47.5%) and (54.9%).

Table 18 shows the number of TA recommendations and the estimated number of patients likely to be treated in the first 12 months along with the number of new patients treated per annum for £10,000 bands of ICER values. The ICER values have been taken from the TA documentation and reflect the prices of both the TA-approved treatment and the comparator treatment at the time NICE carried out their appraisal.

Table 18: Option 1 - Number of TA recommendations and estimated patient numbers by NICE TA ICER bandings plus funding status in Guernsey for TA recommendations with an ICER of less than £30,000 per additional QALY gained

ICER Bandings from NICE TA	Number of TA Recommendations	Estimated Number of Patients Treated in Year 1	Estimated Number of New Patients Per Annum	TA Recommendations Not approved	TA Recommendations Not requested	TA Recommendations Awaiting Funding
Under £10,000	13	335	84	4	9	0
£10,000 - £20,000	14	1,593	254	6	8	0
£20,000 - £30,000	44	841	291	7	36	1
£30,000 - £40,000	22	304	48			
£40,000 - £50,000	31	47	43			
£50,000 - £60,000	9	14	12			
£60,000 - £100,000	5	7	4			
£100,000 plus	5	2	4			
ICER Not Available	17	205	41			
Total	160	3,348	782			

Table 18 shows that 71 (44.4%) of the TA-approved treatments were assessed by NICE as being within the less than £30,000 additional cost per QALY bandings usually considered to be cost effective by NICE. In terms of number of patients, 82.7% of the estimated 3,348 patients likely to be treated in the first 12 months were likely to receive TA-approved treatments that were assessed by NICE as being below the £30,000 per additional QALY funding threshold. For new patients likely to be treated per annum, 80.5% of patients fell within the ICER bandings below the £30,000 threshold. Of the 71 TA-approved treatments with an ICER of less than £30,000 additional cost per QALY, 53 (74.6%) have not been requested for routine funding, 17 (23.9%) have been considered for routine funding, but have not been approved and 1 (1.4%) has been approved, but is awaiting funding.



There are relatively few patients that would be likely to receive TA-approved treatments with a cost per additional QALY of greater than £60,000 per additional QALY gained (9 patients in the first year and 8 new patients per annum).

Table 19 indicates where patients may experience a change in how their medication is administered if the TA-approved treatments within this option are funded by the States of Guernsey. Table 19 shows how many patients and TA recommendations are likely to involve changes from taking oral drugs currently to having injected or infused drugs if a TA-approved treatment in this option is funded or vice versa. Where the existing treatment is an oral drug and the TA-approved treatment is an infused or injected drug there are likely to be additional costs associated with the administration of the drug that we have not been able to capture in our gross and net cost impact calculations. Conversely, where the existing treatment is a drug that is infused or injected and patients are switched to an oral TA-approved drug, there may be some savings that have not been captured in our gross and net cost impact calculations.

Table 19: Option 1 - Number of TA recommendations and estimated patient numbers, where patients are likely to switch to a different method of treatment administration, if they receive the TA treatment

Change of Treatment	Number of TA Recommendations	Estimated Number of Patients Treated in Year 1	Estimated Number of New Patients Per Annum
Patients would switch from oral drug (comparator) to infused drug (TA)	4	3	3
Patients would switch from oral drug (comparator) to injected drug (TA)	3	405	24
Patients would switch from infused drug (comparator) to injected drug (TA)	0	0	0
Patients would switch from injected drug (comparator) to infused drug (TA)	3	14	4
Patients would switch from infused drug (comparator) to oral drug (TA)	11	19	11
Patients would switch from injected drug (comparator) to oral drug (TA)	3	6	4
Patients would remain on current drug formulation	78	2,607	608
Patients would switch from non drug treatment (comparator) to oral drug (TA)	20	220	71
Patients would switch from non drug treatment (comparator) to infused drug (TA)	15	10	14
Patients would switch from non drug treatment (comparator) to injected drug (TA)	15	43	21
Patients would switch from oral drug treatment (comparator) to non drug (TA)	0	0	0
Patients would switch from infused drug treatment (comparator) to non drug (TA)	0	0	0
Patients would switch from injected drug treatment (comparator) to non drug (TA)	0	0	0
TA and Comparator are non drug treatments	8	21	21
Total	160	3,348	782



Table 19 shows that there are seven TA-approved treatments, involving an estimated 408 patients in the first 12 months and 27 patients per annum thereafter, that would be likely to involve a change from an existing oral drug treatment to either an infused or injected TA-approved drug treatment. Conversely there are 14 TA recommendations, involving an estimated 33 patients in the first 12 months and 15 patients per annum thereafter, where patients would be likely to switch from an injected or infused drug to a TA-approved oral drug.

Table 20 indicates the number of TA recommendations and estimated numbers of patients, where pharmacy and laboratory services in Guernsey have suggested that local funding approval for the TA-approved treatment(s) would have resource implications beyond the simple acquisition cost of the drug or treatment for their respective services. It has not been possible to include these resource costs in our gross and net cost calculations.

Table 20: Option 1 - Number of TA recommendations and number of patients where TA is expected to have significant impact on pharmacy and/or laboratory services

Impact of TA Approval	Number of TA Recommendations	Estimated Number of Patients Treated in Year 1	Estimated Number of New Patients Per Annum
TA has impact on Pharmacy Services	84	590	137
TA does not have impact on Pharmacy Services	76	2,758	645
TA has impact on Laboratory Services	90	1,489	387
TA does not have impact on Laboratory Services	1	0	0
Impact of TA on Laboratory Services unknown	69	1,859	394

Table 20 shows that 84 (52.5%) of the 160 TA-approved treatments in this option were considered likely to have an impact on local pharmacy services resources. These TA-approved treatments were estimated to involve 590 patients in the first year and 137 patients per annum thereafter. For laboratory services, there were 90 TA-approved treatments which were believed to be likely to have an impact on local resources, involving 1,489 patients in the first year and 387 new patients per annum thereafter.



4.4.2 Option 1a: All NICE TA-approved treatments, minus Highly Specialised Technologies (HSTs)

This option would involve the States of Guernsey funding 152 separate TA recommendations from 137 TAs that are currently approved by NICE for funding in England, but are not routinely funded in the States of Guernsey. These are the same TA recommendations as shown in Option 1 above, excluding 8 TAs relating to NICE Highly Specialised Technologies (HST) guidance. These are usually very expensive treatments but involve only small numbers of patients because they relate to very rare conditions.

Table 21 shows the estimated number of patients likely to receive the TA-approved treatments for the TAs within this option and the estimated gross and net cost impact of the States of Guernsey funding these TA recommendations, broken down by different disease groups.



Table 21: Option 1a - Estimated Guernsey patient numbers and gross/net costs by disease group

	Estimated Guernsey Patient Numbers		Gross Cost Impact (PAS fixed discount)	Net Cost Impact (PAS Fixed Discount)	
Disease Group	Estimated Number of Patients Treated in Year 1	Estimated Number of New Patients per Annum	Cost Impact of Patients Treated in Year 1	Cost Impact of New Patients Treated per Annum	Cost Impact of Patients Treated in Year 1	Cost Impact of New Patients Treated per Annum
Blood Disorders	0	0	£0	£0	£0	£0
Cardiac Services	2,030	240	£2,140,122	£202,527	£2,083,950	£192,720
Cancer	114	98	£3,780,755	£3,559,553	£2,883,022	£2,794,266
Colorectal Services	110	23	£181,443	£42,085	£60,803	£5,893
Dermatology	14	11	£177,264	£138,024	£163,710	£130,902
Ear and Ophthalmology Services	21	15	£160,000	£83,500	£160,000	£83,500
Endocrinology	485	76	£370,728	£148,690	£184,033	£88,722
Hepatobiliary and Pancreas	2	1	£32,041	£16,021	£30,303	£15,151
Immunology and Allergy Services	4	1	£600	£150	£600	£150
Infectious Diseases	2	2	£89,654	£89,654	£89,654	£89,654
Medical Genetics	0	0	£0	£0	£0	£0
Mental Health	95	22	£36,941	£9,165	-£43,724	-£6,263
Neurosciences	5	3	£52,662	£34,356	£21,117	£18,584
Paediatric Medicine	0	0	£0	£0	£0	£0
Pain Management	100	100	£66,240	£66,240	£64,001	£64,001
Renal Services	0	2	£0	£17,640	£0	£17,640
Respiratory	100	49	£857,302	£472,583	£851,470	£468,938
Rheumatology	37	19	£215,281	£108,947	£150,408	£69,802
Trauma and Orthopaedics	60	60	£132,338	£132,338	£132,338	£132,338
Urology	150	40	£56,550	£15,080	£6,300	£1,680
Vascular Disease	15	15	£9,308	£9,308	£9,308	£9,308
Total	3,344	777	£8,359,228	£5,145,858	£6,847,293	£4,176,984

Table 21 shows that should the States of Guernsey choose to fund all of the TA recommendations within this option, 3,344 patients would be likely to switch to the TA treatment or start treatment within the first year (the backlog) and an estimated 777 further patients per annum would start treatment in subsequent years. This reflects the fact that very few patients in Guernsey are likely to have the conditions covered by NICE HST guidance.



As with Option 1, Cardiac patients make up the majority of patients likely to be treated in the first 12 months (an estimated 2,030 patients out of the total of 3,344 patients or 60.7%). Endocrinology (485 patients) and Urology (150 patients) were the disease categories with the next highest numbers of patients likely to be treated in the first year, accounting for 14.5% and 4.5% of the total. For new patients, Cardiac services (240), Pain Management (100) and Cancer (98) have the highest numbers of patients, accounting for 30.9%, 12.9% and 12.6% respectively of the total number of new patients estimated to be treated each year (777).

As previously described in Section 4.2.4, the gross and net cost impact figures including in Table 21 have been based on an indicative discount to prevent commercially sensitive pricing available to the NHS in England being revealed. Table 21 shows that the gross estimated cost of funding all 152 TA recommendations in this option, for a total treatment population of 3,344 patients in the first year is around £8.4m. This is about £700,000 less than the equivalent gross cost for Option 1. The net cost impact is estimated to be approximately £6.8m when the estimated cost of existing treatments is subtracted (around £800,000 lower than Option 1).

Cancer accounts for approximately £3.8m (45.2%) of the £8.4m gross cost impact, despite there being only an estimated 114 patients (3.4%) likely to received TA-approved treatments in the first year. Cardiac Services account for a further £2.1m (25.0%) of the gross cost impact of funding all the TA recommendations in this option. Cancer and Cardiac Services also have the highest net cost impacts, with Cancer accounting for approximately £2.9m (42.6%) and Cardiac Services £2.1m (30.9%) of the total net cost impact of approximately £6.8m.

The gross and net cost impacts of funding the estimated 777 new patients per year for the TA-approved treatments in this option are approximately £5.1m and £4.2m respectively. With a gross cost impact of approximately £3.6m and a net cost impact of approximately £2.8m, TA-approved treatments in the Cancer disease group account for over two-thirds of both of these figures (70.6%) and (66.7.9%).

Table 22 shows the number of TA recommendations and the estimated number of patients likely to be treated in the first 12 months along with the number of new patients treated per annum for £10,000 bands of ICER values. The ICER values have been taken from the TA documentation and reflect the prices of both the TA-approved treatment and the comparator treatment at the time NICE carried out their appraisal.



Table 22: Option 1a - Number of TA recommendations and estimated patient numbers by NICE TA ICER bandings plus funding status in Guernsey for TA recommendations with an ICER of less than £30,000 per additional QALY gained

ICER Bandings from NICE TA	Number of TA Recommendations	Estimated Number of Patients Treated in Year 1	Estimated Number of New Patients Per Annum	TA Recommendations Not approved	TA Recommendations Not requested	TA Recommendations Awaiting Funding
Under £10,000	13	335	84	4	9	0
£10,000 - £20,000	14	1,593	254	6	8	0
£20,000 - £30,000	44	841	291	7	36	1
£30,000 - £40,000	22	304	48			
£40,000 - £50,000	31	47	43			
£50,000 - £60,000	9	14	12			
£60,000 - £100,000	5	7	4			
£100,000 plus	1	2	1			
ICER Not Available	13	201	39			
Total	152	3,344	777			

Table 22 shows that 71 (46.7%) of the TA-approved treatments were assessed as being within the less than £30,000 additional cost per QALY bandings usually considered to be cost effective by NICE. In terms of number of patients, 82.8% of the estimated 3,344 patients likely to be treated in the first 12 months were likely to receive TA-approved treatments that were assessed by NICE as being below the £30,000 per additional QALY funding threshold. For new patients likely to be treated per annum, 81.0% of patients fell within the ICER bandings below the £30,000 threshold. Of the 71 TA-approved treatments with an ICER of less than £30,000 additional cost per QALY, 53 (74.6%) have not been requested for routine funding, 17 (23.9%) have been considered for routine funding, but have not been approved and one (1.4%) has been approved, but is awaiting funding.

There are six TA recommendations within this option with an ICER of more than £60,000 per additional QALY gained. These six TA recommendations are estimated to involve nine patients being treated in the first 12 months and five patients per annum thereafter.

Table 23 indicates where patients may experience a change in how their medication is administered if the TA-approved treatments within this option are funded by the States of Guernsey.



Table 23: Option 1a - Number of TA recommendations and estimated patient numbers, where patients are likely to switch to a different method of treatment administration, if they receive the TA treatment

Change of Treatment	Number of TA Recommendations	Estimated Number of Patients Treated in Year 1	Estimated Number of New Patients Per Annum
Patients would switch from oral drug (comparator) to infused drug (TA)	4	3	3
Patients would switch from oral drug (comparator) to injected drug (TA)	3	405	24
Patients would switch from infused drug (comparator) to injected drug (TA)	0	0	0
Patients would switch from injected drug (comparator) to infused drug (TA)	3	14	4
Patients would switch from infused drug (comparator) to oral drug (TA)	9	16	11
Patients would switch from injected drug (comparator) to oral drug (TA)	3	6	4
Patients would remain on current drug formulation	78	2,607	608
Patients would switch from non drug treatment (comparator) to oral drug (TA)	19	220	69
Patients would switch from non drug treatment (comparator) to infused drug (TA)	13	9	13
Patients would switch from non drug treatment (comparator) to injected drug (TA)	13	43	21
Patients would switch from oral drug treatment (comparator) to non drug (TA)	0	0	0
Patients would switch from infused drug treatment (comparator) to non drug (TA)	0	0	0
Patients would switch from injected drug treatment (comparator) to non drug (TA)	0	0	0
TA and Comparator are non drug treatments	7	21	20
Total	152	3,344	777

Table 23 shows that there are seven TA-approved treatments, involving an estimated 408 patients in the first 12 months and 27 patients per annum thereafter, that would be likely to involve a change from an existing oral drug treatment to either an infused or injected TA-approved drug treatment. Conversely there are 12 TA recommendations, involving an estimated 22 patients in the first 12 months and 15 patients per annum thereafter, where patients would be likely to switch from an injected or infused drug to a TA-approved oral drug.

Table 24 indicates the number of TA recommendations and estimated numbers of patients, where pharmacy and laboratory services in Guernsey have suggested that local funding approval for the TA-approved treatment(s) would have resource implications beyond the simple acquisition cost of the drug or treatment for their respective services. It has not been possible to include these resource costs in our gross and net cost calculations.



Table 24: Option 1a - Number of TA recommendations and number of patients where TA is expected to have significant impact on pharmacy and/or laboratory services

Impact of TA Approval	Number of TA Recommendations	Estimated Number of Patients Treated in Year 1	Estimated Number of New Patients Per Annum
TA has impact on Pharmacy Services	79	589	135
TA does not have impact on Pharmacy Services	73	2,755	642
TA has impact on Laboratory Services	85	1,485	384
TA does not have impact on Laboratory Services	1	0	0
Impact of TA on Laboratory Services unknown	66	1,859	394

Table 24 shows that 79 (52.0%) of the 152 TA-approved treatments in this option were considered likely to have an impact on local pharmacy services resources. These TA-approved treatments were estimated to involve 589 patients in the first year and 135 patients per annum thereafter. For laboratory services, there were 85 TA-approved treatments which were believed to be likely to have an impact on local resources, involving 1,485 patients in the first year and 384 new patients per annum thereafter.

4.4.3 Option 2: All NICE TA-approved treatments for cancer

This option would involve the States of Guernsey funding 88 separate TA recommendations from 84 TAs that are currently approved by NICE for funding in England, but are not routinely funded in the States of Guernsey where the target treatment population is cancer. The TA recommendations in this option will be a mixture of TAs within the Cancer Drugs Fund (CDF) in England and not within the CDF. The breakdown between these two groups of TAs is shown in the analysis for Options 2a and 2b below.

Table 25 shows the estimated number of patients likely to receive the TA-approved treatments for the TAs within this option and the estimated gross and net cost impact of the States of Guernsey funding these TA recommendations, broken down by different disease groups.



Table 25: Option 2 - Estimated Guernsey patient numbers and gross/net costs by disease group

	Estimated Guernsey Patient Numbers		Gross Cost Impact (PAS fixed discount)		Net Cost Impact (PAS fixed discount)	
Disease Group	Estimated Number of Patients Treated in Year 1	Estimated Number of New Patients per Annum	Cost Impact of Patients Treated in Year 1	Cost Impact of New Patients Treated per Annum	Cost Impact of Patients Treated in Year 1	Cost Impact of New Patients Treated per Annum
Anti cancer - Bladder	8	4	£346,719	£173,360	£272,199	£136,100
Anti cancer - Breast	15	9	£272,518	£159,344	£272,278	£159,200
Anti cancer - Cervical	1	1	£3,492	£2,794	£3,492	£2,794
Anti cancer - Colorectal	10	6	£116,445	£69,867	£17,515	£10,509
Anti cancer - Gastric	2	1	£18,333	£9,167	£5,153	£2,577
Anti cancer - Head and Neck	4	2	£128,964	£52,977	£86,342	£38,059
Anti cancer - Hepatocellular	4	2	£110,000	£55,000	£110,000	£55,000
Anti cancer - Hodgkin lymphoma	2	3	£121,475	£159,826	£121,475	£159,826
Anti cancer - Leukaemia	8	11	£738,916	£885,543	£714,249	£849,241
Anti cancer - Lung	23	17	£701,078	£528,826	£569,493	£440,504
Anti cancer - Lymphoma	0	1	£0	£12,459	£0	£10,656
Anti cancer - Melanoma	2	7	£69,760	£296,564	£69,760	£296,564
Anti cancer - Multiple Myeloma	14	10	£648,778	£448,144	£386,078	£185,754
Anti cancer - Neuroblastoma	0	0	£0	£8,523	£0	£8,523
Anti cancer - Non Hodgkin's lymphoma	2	3	£61,811	£94,948	£61,811	£94,948
Anti cancer - Other	0	0	£0	£13,013	£0	£12,764
Anti cancer - Pancreatic	1	2	£4,959	£7,439	-£7,501	-£11,251
Anti cancer - Prostate	10	6	£147,363	£90,739	£98,859	£59,065
Anti cancer - Renal cell carcinoma	5	7	£172,805	£244,456	-£15,520	£37,298
Anti cancer - Sarcoma	0	1	£0	£6,641	£0	£6,641
Anti cancer - Skin	2	5	£88,368	£203,626	£88,368	£203,197
Anti cancer - Thyroid	1	1	£28,970	£23,530	£28,970	£23,530
Children and Young Adult Cancer Services	0	0	£0	£12,768	£0	£12,768
Total	114	98	£3,780,755	£3,559,553	£2,883,022	£2,794,266

Table 25 shows that should the States of Guernsey choose to fund all of the TA recommendations within this option, 114 cancer patients would be likely to switch to the TA treatment or start treatment within the first year (the backlog) and an estimated 98 further cancer patients per annum would start treatment in subsequent years.



Patients with lung cancer (25), breast cancer (15) and multiple myeloma (14) cancers make 47.4% of the cancer patients likely to be treated in the first 12 months. For new patients treated per annum, lung cancer, leukaemia and multiple myeloma patients account for 17.3%, 11.2% and 10.2% respectively of the total number of new patients estimated to be treated each year (98).

As previously described in Section 4.2.4, the gross and net cost impact figures including in Table 25 have been based on an indicative discount to prevent commercially sensitive pricing available to the NHS in England being revealed. Table 25 shows that the gross estimated cost of funding the 88 TA recommendations in this option, for a total treatment population of 114 patients in the first year is around £3.8m. This means that the 88 TA recommendations in this option make up 41.8% of the total gross cost of funding all 160 TA recommendations (Option 1), but only account for 3.4% of the estimated number of patients likely to be treated in the first year. The net cost impact is estimated to be approximately £2.9m when the estimated cost of existing treatments is subtracted, accounting for 38.2% of the estimated net cost of funding all the TAs in Option 1.

The gross and net cost impacts of funding the estimated 98 new patients per year for the TA-approved treatments in this option are approximately £3.6m and £2.8m respectively. With a gross cost impact of approximately £0.89m and a net cost impact of approximately £0.85m, leukaemia accounts for 24.9% of the gross cost impact and 30.4% of the net cost impact of treating the estimated number of new patients per annum within this option.

Table 26 shows the number of TA recommendations and the estimated number of patients likely to be treated in the first 12 months along with the number of new patients treated per annum for £10,000 bands of ICER values. The ICER values have been taken from the TA documentation and reflect the prices of both the TA-approved treatment and the comparator treatment at the time NICE carried out their appraisal.



Table 26: Option 2 - Number of TA recommendations and estimated patient numbers by NICE TA ICER bandings plus funding status in Guernsey for TA recommendations with an ICER of less than £30,000 per additional QALY gained

ICER Bandings from NICE TA	Number of TA Recommendations	Estimated Number of Patients Treated in Year 1	Estimated Number of New Patients Per Annum	TA Recommendations Not approved	TA Recommendations Not requested	TA Recommendations Awaiting funding
Under £10,000	1	1	1	0	1	0
£10,000 - £20,000	3	7	6	0	3	0
£20,000 - £30,000	23	24	22	0	22	1
£30,000 - £40,000	16	14	11			
£40,000 - £50,000	30	47	41			
£50,000 - £60,000	9	14	12			
£60,000 - £100,000	3	3	2			
£100,000 plus	1	2	1			
ICER Not Available	2	2	1			

98

Table 26 shows that 27 (30.7%) of the TA-approved treatments were assessed as being within the less than £30,000 additional cost per QALY bandings usually considered to be cost effective by NICE. In terms of number of patients, 36.4% of the estimated 88 patients likely to be treated in the first 12 months were likely to receive TA-approved treatments that were assessed by NICE as being below the £30,000 per additional QALY funding threshold. For new patients likely to be treated per annum, 29.6% of patients fell within the ICER bandings below the £30,000 threshold. Of the 27 TA-approved treatments with an ICER of less than £30,000 additional cost per QALY, 26 (96.3%) have not been requested for routine funding, none (0.0%) have been considered for routine funding, but have not been approved and one (3.7%) has been approved, but is awaiting funding.

There are four TA recommendations within this option with an ICER of more than £60,000 per additional QALY gained. These four TA recommendations are estimated to involve five patients being treated in the first 12 months and three patients per annum thereafter.

Table 27 indicates where patients may experience a change in how their medication is administered if the TA-approved treatments within this option are funded by the States of Guernsey.

Total

88

114



Table 27: Option 2 - Number of TA recommendations and estimated patient numbers, where patients are likely to switch to a different method of treatment administration, if they receive the TA treatment

Change of Treatment	Number of TA Recommendations	Estimated Number of Patients Treated in Year 1	Estimated Number of New Patients Per Annum
Patients would switch from oral drug (comparator) to infused drug (TA)	4	3	3
Patients would switch from oral drug (comparator) to injected drug (TA)	0	0	0
Patients would switch from infused drug (comparator) to injected drug (TA)	0	0	0
Patients would switch from injected drug (comparator) to infused drug (TA)	1	2	1
Patients would switch from infused drug (comparator) to oral drug (TA)	7	4	6
Patients would switch from injected drug (comparator) to oral drug (TA)	0	0	0
Patients would remain on current drug formulation	51	76	59
Patients would switch from non drug treatment (comparator) to oral drug (TA)	10	15	12
Patients would switch from non drug treatment (comparator) to infused drug (TA)	13	9	13
Patients would switch from non drug treatment (comparator) to injected drug (TA)	2	5	4
Patients would switch from oral drug treatment (comparator) to non drug (TA)	0	0	0
Patients would switch from infused drug treatment (comparator) to non drug (TA)	0	0	0
Patients would switch from injected drug treatment (comparator) to non drug (TA)	0	0	0
TA and Comparator are non drug treatments	0	0	0
Total	88	114	98

Table 27 shows that there are four TA-approved treatments, involving an estimated three patients in the first 12 months and three patients per annum thereafter, that would be likely to involve a change from an existing oral drug treatment to either an infused or injected TA-approved drug treatment. Conversely there are seven TA recommendations, involving an estimated four patients in the first 12 months and six patients per annum thereafter, where patients would be likely to switch from an infused drug to a TA-approved oral drug.

Table 28 indicates the number of TA recommendations and estimated numbers of patients, where pharmacy and laboratory services in Guernsey have suggested that local funding approval for the TA-approved treatment(s) would have resource implications beyond the simple acquisition cost of the drug or treatment for their respective services. It has not been possible to include these resource costs in our gross and net cost calculations.



Table 28: Option 2 - Number of TA recommendations and number of patients where TA is expected to have significant impact on pharmacy and/or laboratory services

Impact of TA Approval	Number of TA Recommendations	Estimated Number of Patients Treated in Year 1	Estimated Number of New Patients Per Annum
TA has impact on Pharmacy Services	53	72	60
TA does not have impact on Pharmacy Services	35	42	38
TA has impact on Laboratory Services	58	91	76
TA does not have impact on Laboratory Services	0	0	0
Impact of TA on Laboratory Services unknown	30	23	22

Table 28 shows that 53 (60.2%) of the 88 TA-approved treatments in this option were considered likely to have an impact on local pharmacy services resources. These TA-approved treatments were estimated to involve 72 patients in the first year and 60 patients per annum thereafter. For laboratory services, there were 58 TA-approved treatments which were believed to be likely to have an impact on local resources, involving 91 patients in the first year and 76 new patients per annum thereafter.

4.4.4 Option 2a: All NICE TA-approved treatments for cancer which are not part of the Cancer Drugs Fund in England

This option would involve the States of Guernsey funding 49 separate TA recommendations from 47 TAs that are targeted at Cancer patients, but have not been considered by the Cancer Drugs Fund in England. These TA recommendations are therefore a further subset of all the cancer NICE TA recommendations presented in Option 2 above.

Table 29 shows the estimated number of patients likely to receive the TA-approved treatments for the TAs within this option and the estimated gross and net cost impact of the States of Guernsey funding these TA recommendations, broken down by different disease groups.



Table 29: Option 2a - Estimated Guernsey patient numbers and gross/net costs by disease group

	Estimated Guernsey Patient Numbers		Gross Cost Impact (PAS fixed discount)		Net Cost Impact (PAS fixed discount)	
Disease Group	Estimated Number of Patients Treated in Year 1	Estimated Number of New Patients per Annum	Cost Impact of Patients Treated in Year 1	Cost Impact of New Patients Treated per Annum	Cost Impact of Patients Treated in Year 1	Cost Impact of New Patients Treated per Annum
Anti cancer - Bladder	2	1	£72,498	£36,249	£41,830	£20,915
Anti cancer - Breast	13	8	£223,341	£134,756	£223,101	£134,612
Anti cancer - Cervical	1	1	£3,492	£2,794	£3,492	£2,794
Anti cancer - Colorectal	0	0	£0	£0	£0	£0
Anti cancer - Gastric	2	1	£18,333	£9,167	£5,153	£2,577
Anti cancer - Head and Neck	0	0	£0	£0	£0	£0
Anti cancer - Hepatocellular	2	1	£57,940	£28,970	£57,940	£28,970
Anti cancer - Hodgkin lymphoma	0	0	£0	£0	£0	£0
Anti cancer - Leukaemia	6	7	£171,933	£254,490	£147,285	£218,188
Anti cancer - Lung	17	12	£470,549	£349,475	£359,208	£281,386
Anti cancer - Lymphoma	0	0	£0	£4,080	£0	£2,277
Anti cancer - Melanoma	1	5	£38,293	£200,732	£38,293	£200,732
Anti cancer - Multiple Myeloma	5	3	£322,959	£207,014	£322,339	£206,704
Anti cancer - Neuroblastoma	0	0	£0	£8,523	£0	£8,523
Anti cancer - Non Hodgkin's lymphoma	0	0	£0	£2,232	£0	£2,232
Anti cancer - Other	0	0	£0	£13,013	£0	£12,764
Anti cancer - Pancreatic	1	2	£4,959	£7,439	-£7,501	-£11,251
Anti cancer - Prostate	5	3	£46,077	£30,114	-£579	-£636
Anti cancer - Renal cell carcinoma	5	7	£172,805	£244,456	-£15,520	£37,298
Anti cancer - Sarcoma	0	1	£0	£6,641	£0	£6,641
Anti cancer - Skin	0	0	£0	£0	£0	£0
Anti cancer - Thyroid	1	0	£28,970	£5,794	£28,970	£5,794
Children and Young Adult Cancer Services	0	0	£0	£12,768	£0	£12,768
Total	61	52	£1,632,148	£1,558,707	£1,204,010	£1,173,288

Table 29 shows that should the States of Guernsey choose to fund the 49 TA recommendations within this option, 61 cancer patients would be likely to switch to the TA treatment or start treatment within the first year (the backlog) and an estimated 52 further cancer patients per annum would start treatment in subsequent years.



Patients with lung cancer (17) and breast cancer (13) make up 49.2% of the patients likely to be treated in the first 12 months for this option. For new patients treated per annum, lung cancer, breast cancer and both leukaemia and renal cell carcinoma account for 23.1%, 15.4% and 13.5% respectively of the total number of new patients estimated to be treated each year (52).

As previously described in Section 4.2.4, the gross and net cost impact figures including in Table 29 have been based on an indicative discount to prevent commercially sensitive pricing available to the NHS in England being revealed. Table 29 shows that the gross estimated cost of funding the 49 TA recommendations in this option, for a total treatment population of 61 patients in the first year is around £1.6m. This equates to 43.2% of the gross cost of funding all of the approved NICE TAs for cancer shown in Option 2. By comparison this option includes slightly under half (61) of the 114 estimated cancer patients likely to receive treatment within the first 12 months of local funding approval shown in Option 2. The gross cost of £1.6m is estimated to reduce to a net cost of approximately £1.2m, once the available costs of existing treatment have been taken into consideration.

The gross and net cost impacts of funding the estimated 52 new patients per year for the TA-approved treatments in this option are approximately £1.6m and £1.2m respectively. With a gross cost impact of approximately £0.36m and a net cost impact of £0.28m lung cancer accounts for 29.8% of the gross cost impact and 24.0% of the net cost impact of treating the estimated number of new patients per annum within this option.

Table 30 shows the number of TA recommendations and the estimated number of patients likely to be treated in the first 12 months along with the number of new patients treated per annum for £10,000 bands of ICER values. The ICER values have been taken from the TA documentation and reflect the prices of both the TA-approved treatment and the comparator treatment at the time NICE carried out their appraisal.



Table 30: Option 2a - Number of TA recommendations and estimated patient numbers by NICE TA ICER bandings plus funding status in Guernsey for TA recommendations with an ICER of less than £30,000 per additional QALY gained

ICER Bandings from NICE TA	Number of TA Recommendations	Estimated Number of Patients Treated in Year 1	Estimated Number of New Patients Per Annum	TA Recommendations Not approved	TA Recommendations Not requested	TA Recommendations Awaiting funding
Under £10,000	0	0	0	0	0	0
£10,000 - £20,000	3	7	6	0	3	0
£20,000 - £30,000	16	14	12	0	16	0
£30,000 - £40,000	8	8	5			
£40,000 - £50,000	19	27	26			
£50,000 - £60,000	1	3	2			
£60,000 - £100,000	0	0	0			
£100,000 plus	1	2	1			
ICER Not Available	1	0	0			
Total	49	61	52			

Table 30 shows that 19 (38.8%) of the TA-approved treatments were assessed as being within the less than £30,000 additional cost per QALY bandings usually considered to be cost effective by NICE. This is a higher proportion than for the TA recommendations for all cancer patients shown in Option 2 (30.7%). In terms of number of patients, 34.4% of the estimated 61 patients likely to be treated in the first 12 months would receive TA-approved treatments that were assessed by NICE as being below the £30,000 per additional QALY funding threshold. For new patients likely to be treated per annum, 34.6% of patients fell within the ICER bandings below the £30,000 threshold. Of the 19 TA-approved treatments with an ICER of less than £30,000 additional cost per QALY, all 19 (100.0%) have not been requested for routine funding.

There is only one TA recommendation within this option with an ICER of more than £60,000 per additional QALY gained. This TA recommendation is estimated to involve two patients being treated in the first 12 months and one patient per annum thereafter.

Table 31 indicates where patients may experience a change in how their medication is administered if the TA-approved treatments within this option are funded by the States of Guernsey.



Table 31: Option 2a - Number of TA recommendations and estimated patient numbers, where patients are likely to switch to a different method of treatment administration, if they receive the TA treatment

Change of Treatment	Number of TA Recommendations	Estimated Number of Patients Treated in Year 1	Estimated Number of New Patients Per Annum
Patients would switch from oral drug (comparator) to infused drug (TA)	4	3	3
Patients would switch from oral drug (comparator) to injected drug (TA)	0	0	0
Patients would switch from infused drug (comparator) to injected drug (TA)	0	0	0
Patients would switch from injected drug (comparator) to infused drug (TA)	0	0	0
Patients would switch from infused drug (comparator) to oral drug (TA)	3	3	2
Patients would switch from injected drug (comparator) to oral drug (TA)	0	0	0
Patients would remain on current drug formulation	29	40	31
Patients would switch from non drug treatment (comparator) to oral drug (TA)	4	3	3
Patients would switch from non drug treatment (comparator) to infused drug (TA)	8	7	10
Patients would switch from non drug treatment (comparator) to injected drug (TA)	1	5	3
Patients would switch from oral drug treatment (comparator) to non drug (TA)	0	0	0
Patients would switch from infused drug treatment (comparator) to non drug (TA)	0	0	0
Patients would switch from injected drug treatment (comparator) to non drug (TA)	0	0	0
TA and Comparator are non drug treatments	0	0	0
Total	49	61	52

Table 31 shows that there are four TA-approved treatments, for this option that would be likely to involve a change from an existing oral drug treatment to an infused TA-approved drug treatment. These four TA recommendations are estimated to involve three patients in the first 12 months and three patients per annum thereafter. However, there are three TA recommendations, involving three estimated patient in the first 12 months and two estimated patients per annum thereafter, where patients would be likely to switch from an infused drug to a TA-approved oral drug.

Table 32 indicates the number of TA recommendations and estimated numbers of patients, where pharmacy and laboratory services in Guernsey have suggested that local funding approval for the TA-approved treatment(s) would have resource implications beyond the simple acquisition cost of the drug or treatment for their respective services. It has not been possible to include these resource costs in our gross and net cost calculations.



Table 32: Option 2a - Number of TA recommendations and number of patients where TA is expected to have significant impact on pharmacy and/or laboratory services

Impact of TA Approval	Number of TA Recommendations	Estimated Number of Patients Treated in Year 1	Estimated Number of New Patients Per Annum	
TA has impact on Pharmacy Services	29	39	33	
TA does not have impact on Pharmacy Services	20	22	19	
TA has impact on Laboratory Services	30	45	37	
TA does not have impact on Laboratory Services	0	0	0	
Impact of TA on Laboratory Services unknown	19	16	15	

Table 32 shows that 29 (59.2%) of the 49 TA-approved treatments in this option were considered likely to have an impact on local pharmacy services resources. These TA-approved treatments were estimated to involve 39 patients in the first year and 33 patients per annum thereafter. For laboratory services, there were 30 TA-approved treatments which were believed to be likely to have an impact on local resources, involving 45 patients in the first year and 37 new patients per annum thereafter.

4.4.5 Option 2b: All NICE TA-approved treatments for cancer which are part of the Cancer Drugs Fund in England

This option would involve the States of Guernsey funding 39 separate TA recommendations from 38 TAs that are currently approved for funding in England following approval from the Cancer Drugs Fund. These TA recommendations are therefore a sub-set of all the cancer NICE TA recommendations presented in Option 2 above.

Table 33 shows the estimated number of patients likely to receive the TA-approved treatments for the TAs within this option and the estimated gross and net cost impact of the States of Guernsey funding these TA recommendations, broken down by different disease groups.



Table 33: Option 2b - Estimated Guernsey patient numbers and gross/net costs by disease group

	Estimated Guernsey Patient Numbers		Gross Cost Impact (PAS	fixed discount)	Net Cost Impact (PAS fixed discount)	
Disease Group	Estimated Number of Patients Treated in Year 1	Estimated Number of New Patients per Annum	Cost Impact of Patients Treated in Year 1	Cost Impact of New Patients Treated per Annum	Cost Impact of Patients Treated in Year 1	Cost Impact of New Patients Treated per Annum
Anti cancer - Bladder	6	3	£274,221	£137,110	£230,369	£115,184
Anti cancer - Breast	2	1	£49,177	£24,589	£49,177	£24,589
Anti cancer - Cervical	0	0	£0	£0	£0	£0
Anti cancer - Colorectal	10	6	£116,445	£69,867	£17,515	£10,509
Anti cancer - Gastric	0	0	£0	£0	£0	£0
Anti cancer - Head and Neck	4	2	£128,964	£52,977	£86,342	£38,059
Anti cancer - Hepatocellular	2	1	£52,060	£26,030	£52,060	£26,030
Anti cancer - Hodgkin lymphoma	2	3	£121,475	£159,826	£121,475	£159,826
Anti cancer - Leukaemia	2	4	£566,983	£631,053	£566,964	£631,053
Anti cancer - Lung	6	5	£230,530	£179,351	£210,286	£159,117
Anti cancer - Lymphoma	0	0	£0	£8,378	£0	£8,378
Anti cancer - Melanoma	1	2	£31,468	£95,832	£31,468	£95,832
Anti cancer - Multiple Myeloma	9	7	£325,819	£241,130	£63,739	-£20,950
Anti cancer - Neuroblastoma	0	0	£0	£0	£0	£0
Anti cancer - Non Hodgkin's lymphoma	2	3	£61,811	£92,716	£61,811	£92,716
Anti cancer - Other	0	0	£0	£0	£0	£0
Anti cancer - Pancreatic	0	0	£0	£0	£0	£0
Anti cancer - Prostate	5	3	£101,286	£60,625	£99,438	£59,701
Anti cancer - Renal cell carcinoma	0	0	£0	£0	£0	£0
Anti cancer - Sarcoma	0	1	£0	£0	£0	£0
Anti cancer - Skin	2	5	£88,368	£203,626	£88,368	£203,197
Anti cancer - Thyroid	0	0	£0	£17,736	£0	£17,736
Children and Young Adult Cancer Services	0	0	£0	£0	£0	£0
Total	53	46	£2,148,607	£2,000,846	£1,679,012	£1,620,978

Table 33 shows that should the States of Guernsey choose to fund the 39 TA recommendations within this option, 53 cancer patients would be likely to switch to the TA treatment or start treatment within the first year (the backlog) and an estimated 46 further cancer patients per annum would start treatment in subsequent years.



Patients with colorectal cancer (10), multiple myeloma (nine), bladder cancer (six) and lung cancer (six) make up 58.5% of the patients likely to be treated in the first 12 months for this option. For new patients treated per annum, multiple myeloma, colorectal cancer and both lung cancer and skin cancers account for 15.2%, 13.0% and 10.9% respectively of the total number of new patients estimated to be treated each year (46).

As previously described in Section 4.2.4, the gross and net cost impact figures including in Table 33 have been based on an indicative discount to prevent commercially sensitive pricing available to the NHS in England being revealed. Table 33 shows that the gross estimated cost of funding the 39 TA recommendations in this option, for a total treatment population of 53 patients in the first year is around £2.1m. This equates to 56.8% of the gross cost of funding all of the approved NICE TAs for cancer shown in Option 2. By comparison this option includes slightly under half (53) of the 114 estimated cancer patients likely to receive treatment within the first 12 months of local funding approval shown in Option 2. The gross cost of £2.1m is estimated to reduce to a net cost of approximately £1.7m, once the available costs of existing treatment have been taken into consideration.

The gross and net cost impacts of funding the estimated 46 new patients per year for the TA-approved treatments in this option are approximately £2.0m and £1.6m respectively. With a gross and net cost impact of approximately £0.63m leukaemia accounts for 31.5% of the gross cost impact and 38.9% of the net cost impact of treating the estimated number of new patients per annum within this option.

Table 34 shows the number of TA recommendations and the estimated number of patients likely to be treated in the first 12 months along with the number of new patients treated per annum for £10,000 bands of ICER values. The ICER values have been taken from the TA documentation and reflect the prices of both the TA-approved treatment and the comparator treatment at the time NICE carried out their appraisal.



Table 34: Option 2b - Number of TA recommendations and estimated patient numbers by NICE TA ICER bandings plus funding status in Guernsey for TA recommendations with an ICER of less than £30,000 per additional QALY gained

ICER Bandings from NICE TA	Number of TA Recommendations	Estimated Number of Patients Treated in Year 1	Estimated Number of New Patients Per Annum	TA Recommendations Not approved	TA Recommendations Not requested	TA Recommendations Awaiting Funding
Under £10,000	1	1	1	0	1	0
£10,000 - £20,000	0	0	0	0	0	0
£20,000 - £30,000	7	10	10	0	6	1
£30,000 - £40,000	8	6	6			
£40,000 - £50,000	11	20	15			
£50,000 - £60,000	8	11	10			
£60,000 - £100,000	3	3	2			
£100,000 plus	0	0	0			
ICER Not Available	1	2	1			
Total	39	53	46			

Table 34 shows that only eight (20.5%) of the TA-approved treatments were assessed as being within the less than £30,000 additional cost per QALY bandings usually considered to be cost effective by NICE. This is a lower proportion than for the TA recommendations for all cancer patients shown in Option 2 (30.7%). In terms of number of patients, 20.7% of the estimated 53 patients likely to be treated in the first 12 months would receive TA-approved treatments that were assessed by NICE as being below the £30,000 per additional QALY funding threshold. For new patients likely to be treated per annum, 23.9% of patients fell within the ICER bandings below the £30,000 threshold. Of the eight TA-approved treatments with an ICER of less than £30,000 additional cost per QALY, seven (87.5%) have not been requested for routine funding, none (0.0%) have been considered for routine funding, but have not been approved and one (12.5%) has been approved, but is awaiting funding.

There are three TA recommendations within this option with an ICER of more than £60,000 per additional QALY gained. These three TA recommendations are estimated to involve three patients being treated in the first 12 months and two patients per annum thereafter.

Table 35 indicates where patients may experience a change in how their medication is administered if the TA-approved treatments within this option are funded by the States of Guernsey.



Table 35: Option 2b - Number of TA recommendations and estimated patient numbers, where patients are likely to switch to a different method of treatment administration, if they receive the TA treatment

Change of Treatment	Number of TA Recommendations	Estimated Number of Patients Treated in Year 1	Estimated Number of New Patients Per Annum
Patients would switch from oral drug (comparator) to infused drug (TA)	0	0	0
Patients would switch from oral drug (comparator) to injected drug (TA)	0	0	0
Patients would switch from infused drug (comparator) to injected drug (TA)	0	0	0
Patients would switch from injected drug (comparator) to infused drug (TA)	1	2	1
Patients would switch from infused drug (comparator) to oral drug (TA)	4	1	4
Patients would switch from injected drug (comparator) to oral drug (TA)	0	0	0
Patients would remain on current drug formulation	22	36	28
Patients would switch from non drug treatment (comparator) to oral drug (TA)	6	12	9
Patients would switch from non drug treatment (comparator) to infused drug (TA)	5	2	3
Patients would switch from non drug treatment (comparator) to injected drug (TA)	1	0	1
Patients would switch from oral drug treatment (comparator) to non drug (TA)	0	0	0
Patients would switch from infused drug treatment (comparator) to non drug (TA)	0	0	0
Patients would switch from injected drug treatment (comparator) to non drug (TA)	0	0	0
TA and Comparator are non drug treatments	0	0	0
Total	39	53	46

Table 35 shows that there are no TA-approved treatments, for this option that would be likely to involve a change from an existing oral drug treatment to either an infused or injected TA-approved drug treatment. However, there are four TA recommendations, involving one estimated patient in the first 12 months and four estimated patients per annum thereafter, where patients would be likely to switch from an infused drug to a TA-approved oral drug.

Table 36 indicates the number of TA recommendations and estimated numbers of patients, where pharmacy and laboratory services in Guernsey have suggested that local funding approval for the TA-approved treatment(s) would have resource implications beyond the simple acquisition cost of the drug or treatment for their respective services. It has not been possible to include these resource costs in our gross and net cost calculations.



Table 36: Option 2b - Number of TA recommendations and number of patients where TA is expected to have significant impact on pharmacy and/or laboratory services

Impact of TA Approval	Number of TA Recommendations	Estimated Number of Patients Treated in Year 1	Estimated Number of New Patients Per Annum	
TA has impact on Pharmacy Services	24	33	26	
TA does not have impact on Pharmacy Services	15	20	19	
TA has impact on Laboratory Services	28	46	39	
TA does not have impact on Laboratory Services	0	0	0	
Impact of TA on Laboratory Services unknown	11	7	7	

Table 36 shows that 24 (61.5%) of the 39 TA-approved treatments in this option were considered likely to have an impact on local pharmacy services resources. These TA-approved treatments were estimated to involve 33 patients in the first year and 26 patients per annum thereafter. For laboratory services, there were 28 TA-approved treatments which were believed to be likely to have an impact on local resources, involving 46 patients in the first year and 39 new patients per annum thereafter.

4.4.6 Option 3: All NICE TA-approved treatments which satisfy NICE criteria for assessing end of life care interventions

This option would involve the States of Guernsey funding 51 separate TA recommendations from 49 TAs that meet the NICE criteria for assessing end of life care treatments (NICE, 2009). These TA recommendations are all concerned with treatments for cancer and are therefore a further sub-set of all the cancer NICE TA recommendations presented in Option 2 above.

Table 37 shows the estimated number of patients likely to receive the TA-approved treatments for the TAs within this option and the estimated gross and net cost impact of the States of Guernsey funding these TA recommendations, broken down by different disease groups.



Table 37: Option 3 - Estimated Guernsey patient numbers and gross/net costs by disease group

	Estimated Guernsey Patient Numbers		Gross Cost Impa	ct (PAS Fixed Discount)	Net Cost Impact (PAS Fixed Discount)	
Disease Group	Estimated Number of Patients Treated in Year 1	Estimated Number of New Patients per Annum	Gross Cost Impact of Patients Treated in Year 1	Gross Cost Impact of New Patients Treated per Annum	Net Cost Impact of Patients Treated in Year 1	Net Cost Impact of New Patients Treated per Annum
Anti cancer - Bladder	8	4	£346,719	£173,360	£272,199	£136,100
Anti cancer - Breast	7	4	£135,095	£76,139	£135,095	£76,139
Anti cancer - Cervical	0	0	£0	£0	£0	£0
Anti cancer - Colorectal	10	6	£116,445	£69,867	£17,515	£10,509
Anti cancer - Gastric	2	1	£18,333	£9,167	£5,153	£2,577
Anti cancer - Head and Neck	2	1	£76,702	£26,846	£34,080	£11,928
Anti cancer - Hepatocellular	2	1	£52,060	£26,030	£52,060	£26,030
Anti cancer - Hodgkin lymphoma	1	2	£50,075	£88,426	£50,075	£88,426
Anti cancer - Leukaemia	5	7	£154,691	£207,511	£132,488	£177,788
Anti cancer - Lung	22	15	£662,304	£462,874	£538,723	£382,556
Anti cancer - Lymphoma	0	0	£0	£0	£0	£0
Anti cancer - Melanoma	1	5	£38,293	£200,732	£38,293	£200,732
Anti cancer - Multiple Myeloma	2	1	£49,750	£24,875	£49,130	£24,565
Anti cancer - Neuroblastoma	0	0	£0	£0	£0	£0
Anti cancer - Non Hodgkin's lymphoma	0	0	£0	£0	£0	£0
Anti cancer - Other	0	0	£0	£6,507	£0	£6,257
Anti cancer - Pancreatic	0	0	£0	£0	£0	£0
Anti cancer - Prostate	5	3	£83,847	£48,999	£37,467	£18,387
Anti cancer - Renal cell carcinoma	5	7	£172,805	£226,822	-£15,520	£38,497
Anti cancer - Sarcoma	0	1	£0	£6,641	£0	£6,641
Anti cancer - Skin	1	4	£38,293	£153,551	£38,293	£153,121
Anti cancer - Thyroid	1	1	£28,970	£23,530	£28,970	£23,530
Children and Young Adult Cancer Services	0	0	£0	£0	£0	£0
Total	74	62	£2,024,383	£1,831,876	£1,414,022	£1,383,783

Table 37 shows that should the States of Guernsey choose to fund the 51 TA recommendations within this option, 74 end of life cancer patients would be likely to switch to the TA treatment or start treatment within the first year (the backlog) and an estimated 62 further end of life cancer patients per annum would start treatment in subsequent years.



Patients with lung cancer (22) and colorectal cancer (10) make up 43.2% of the patients likely to be treated in the first 12 months for this option. For new patients treated per annum, lung cancer, leukaemia and renal cell carcinoma account for 24.2%, 11.3% and 11.3% respectively of the total number of new patients estimated to be treated each year (62).

As previously described in Section 4.2.4, the gross and net cost impact figures including in Table 37 have been based on an indicative discount to prevent commercially sensitive pricing available to the NHS in England being revealed. Table 37 shows that the gross estimated cost of funding the 51 TA recommendations in this option, for a total treatment population of 74 patients in the first year is around £2.0m. This equates to 53.5% of the gross cost of funding all of the approved NICE TAs for cancer shown in Option 2. By comparison this option includes slightly under two-thirds (74) of the 114 estimated cancer patients likely to receive treatment within the first 12 months of local funding approval shown in Option 2. The gross cost of £2.0m is estimated to reduce to a net cost of approximately £1.4m, once the available costs of existing treatment have been taken into consideration.

The gross and net cost impacts of funding the estimated 52 new patients per year for the TA-approved treatments in this option are approximately £1.8m and £1.4m respectively. With a gross cost impact of approximately £0.46m and a net cost impact of £0.38m lung cancer accounts for 25.3% of the gross cost impact and 27.6% of the net cost impact of treating the estimated number of new patients per annum within this option.

Table 38 shows the number of TA recommendations and the estimated number of patients likely to be treated in the first 12 months along with the number of new patients treated per annum for £10,000 bands of ICER values. The ICER values have been taken from the TA documentation and reflect the prices of both the TA-approved treatment and the comparator treatment at the time NICE carried out their appraisal.



Table 38: Option 3 - Number of TA recommendations and estimated patient numbers by NICE TA ICER bandings plus funding status in Guernsey for TA recommendations with an ICER of less than £30,000 per additional QALY gained

ICER Bandings from NICE TA	Number of TA Recommendations	Estimated Number of Patients Treated in Year 1	Estimated Number of New Patients Per Annum	TA Recommendations Not approved	TA Recommendations Not requested	TA Recommendations Awaiting funding
Under £10,000	0	0	0	0	0	0
£10,000 - £20,000	1	5	5	0	1	0
£20,000 - £30,000	4	3	3	0	4	0
£30,000 - £40,000	8	6	5			
£40,000 - £50,000	28	46	39			
£50,000 - £60,000	7	10	8			
£60,000 - £100,000	2	2	1			
£100,000 plus	1	2	1			
ICER Not Available	0	0	0			
Total	51	74	62			

Table 38 shows that five (9.8%) of the TA-approved treatments were assessed as being within the less than £30,000 additional cost per QALY bandings usually considered to be cost effective by NICE. This is a much lower proportion than for the TA recommendations for all cancer patients shown in Option 2 (30.7%). All five of these TA-approved treatments have not been requested for routine funding.

Over half (54.9%) of the TA-approved treatments in this option were assessed by NICE as having ICERs in the £40,000 - £50,000 range. In terms of number of patients, 62.2% of the estimated 74 patients likely to be treated in the first 12 months would receive TA-approved treatments that were assessed by NICE as being in the £40,000 - £50,000 range per additional QALY gained. For new patients treated per annum, 62.9% of patients fell within the £40,000 - £50,000 ICER range. There are only three TA recommendations within this option with an ICER of more than £60,000 per additional QALY gained. These TA recommendations are estimated to involve four patients being treated in the first 12 months and two patients per annum thereafter.

Table 39 indicates where patients may experience a change in how their medication is administered if the TA-approved treatments within this option are funded by the States of Guernsey.



Table 39: Option 3 - Number of TA recommendations and estimated patient numbers, where patients are likely to switch to a different method of treatment administration, if they receive the TA treatment

Change of Treatment	Number of TA Recommendations	Estimated Number of Patients Treated in Year 1	Estimated Number of New Patients Per Annum
Patients would switch from oral drug (comparator) to infused drug (TA)	2	0	1
Patients would switch from oral drug (comparator) to injected drug (TA)	0	0	0
Patients would switch from infused drug (comparator) to injected drug (TA)	0	0	0
Patients would switch from injected drug (comparator) to infused drug (TA)	0	0	0
Patients would switch from infused drug (comparator) to oral drug (TA)	5	3	5
Patients would switch from injected drug (comparator) to oral drug (TA)	0	0	0
Patients would remain on current drug formulation	29	51	37
Patients would switch from non drug treatment (comparator) to oral drug (TA)	7	8	6
Patients would switch from non drug treatment (comparator) to infused drug (TA)	7	7	11
Patients would switch from non drug treatment (comparator) to injected drug (TA)	1	5	3
Patients would switch from oral drug treatment (comparator) to non drug (TA)	0	0	0
Patients would switch from infused drug treatment (comparator) to non drug (TA)	0	0	0
Patients would switch from injected drug treatment (comparator) to non drug (TA)	0	0	0
TA and Comparator are non drug treatments	0	0	0
Total	51	74	62

Table 39 shows that there are two TA-approved treatments, for this option that would be likely to involve a change from an existing oral drug treatment to an infused TA-approved drug treatment. These two TA recommendations are estimated to involve no patients in the first 12 months and one patient per annum thereafter. However, there are five TA recommendations, involving three estimated patient in the first 12 months and five estimated patients per annum thereafter, where patients would be likely to switch from an infused drug to a TA-approved oral drug.

Table 40 indicates the number of TA recommendations and estimated numbers of patients, where pharmacy and laboratory services in Guernsey have suggested that local funding approval for the TA-approved treatment(s) would have resource implications beyond the



simple acquisition cost of the drug or treatment for their respective services. It has not been possible to include these resource costs in our gross and net cost calculations.

Table 40: Option 3 - Number of TA recommendations and number of patients where TA is expected to have significant impact on pharmacy and/or laboratory services

Impact of TA Approval	Number of TA Recommendations	Estimated Number of Patients Treated in Year 1	Estimated Number of New Patients Per Annum	
TA has impact on Pharmacy Services	31	52	42	
TA does not have impact on Pharmacy Services	20	22	20	
TA has impact on Laboratory Services	34	61	48	
TA does not have impact on Laboratory Services	0	0	0	
Impact of TA on Laboratory Services unknown	17	13	14	

Table 40 shows that 31 (60.8%) of the 51 TA-approved treatments in this option were considered likely to have an impact on local pharmacy services resources. These TA-approved treatments were estimated to involve 52 patients in the first year and 42 patients per annum thereafter. For laboratory services, there were 34 TA-approved treatments which were believed to be likely to have an impact on local resources, involving 61 patients in the first year and 48 new patients per annum thereafter.

4.4.7 Option 4: NICE TA-approved treatments aimed at more common conditions

This option would involve the States of Guernsey funding 44 separate TA recommendations from 40 TAs that are targeted at more common conditions. We have chosen to define a common condition as one where there are an estimated five or more patients likely to be treated with the TA-approved treatment in the first year.

Table 41 shows the estimated number of patients likely to receive the TA-approved treatments for the TAs within this option and the estimated gross and net cost impact of the States of Guernsey funding these TA recommendations, broken down by different disease groups.



Table 41: Option 4 - Estimated Guernsey patient numbers and gross/net costs by disease group

	Estimated Guernsey Patient Numbers		Gross Cost Impact	(PAS Fixed Discount)	Net Cost Impact (PAS Fixed Discount)		
Disease Group	Estimated Number of Patients Treated in Year 1	Estimated Number of New Patients per Annum	Gross Cost Impact of Patients Treated in Year 1	Gross Cost Impact of New Patients Treated per Annum	Net Cost Impact of Patients Treated in Year 1	Net Cost Impact of New Patients Treated per Annum	
Blood Disorders	0	0	£0	£0	£0	£0	
Cardiac Services	2,030	240	£2,140,122	£202,527	£2,083,950	£192,720	
Cancer	40	28	£938,195	£694,616	£282,440	£121,001	
Colorectal Services	110	23	£181,443	£42,085	£60,803	£5,893	
Dermatology	6	5	£114,751	£95,626	£114,751	£95,626	
Ear and Ophthalmology Services	20	15	£80,000	£67,500	£80,000	£67,500	
Endocrinology	485	76	£370,728	£148,690	£184,033	£88,722	
Hepatobiliary and Pancreas	0	0	£0	£0	£0	£0	
Immunology and Allergy Services	0	0	£0	£0	£0	£0	
Infectious Diseases	0	0	£0	£0	£0	£0	
Medical Genetics	0	0	£0	£0	£0	£0	
Mental Health	95	22	£36,941	£9,165	-£43,724	-£6,263	
Neurosciences	0	0	£0	£0	£0	£0	
Other	150	40	£56,550	£15,080	£6,300	£1,680	
Paediatric Medicine	0	0	£0	£0	£0	£0	
Pain	100	100	£66,240	£66,240	£64,001	£64,001	
Renal Services	0	0	£0	£0	£0	£0	
Respiratory	100	49	£857,302	£472,583	£851,470	£468,938	
Rheumatology	10	6	£51,142	£30,685	£51,142	£30,685	
Trauma and Orthopaedics	60	60	£132,338	£132,338	£132,338	£132,338	
Vascular Disease	15	15	£9,308	£9,308	£9,308	£9,308	
Total	3,221	679	£5,035,059	£1,986,441	£3,876,811	£1,272,147	

Table 41 shows that should the States of Guernsey choose to fund the 44 TA recommendations within this option, 3,221 patients would be likely to switch to the TA treatment or start treatment within the first year (the backlog) and an estimated 679 new patients per annum would start treatment in subsequent years. This means that the 44 TA recommendations in this option account for 96.2% of the estimated number of patients to be treated in the first year and 86.9% of the number of new patients estimated to be treated per annum thereafter shown in Option 1.



Cardiac patients (2,030) make up 63.0% of the estimated number of patients likely to be treated in the first 12 months and 35.3% of the estimated number of new patients to be treated per annum for this option. Endocrinology patients (including those with diabetes) account for a further 15.1% of the estimated number of patients expected to be treated in the first year and pain management patients account for a further 14.7% of the estimated number of new patients likely to be treated per annum.

As previously described in Section 4.2.4, the gross and net cost impact figures including in Table 41 have been based on an indicative discount to prevent commercially sensitive pricing available to the NHS in England being revealed. Table 41 shows that the gross estimated cost of funding the 44 TA recommendations in this option, for a total treatment population of 3,221 patients in the first year is around £5.0m. This equates to 55.4% of the gross cost of funding all of the approved NICE TAs in the first year shown in Option 1. With an estimated gross cost expenditure of £2.1m, Cardiac Services accounts for 42.5% of the total estimated gross cost of this option. The gross cost of £5.0m is estimated to reduce to a net cost impact of approximately £3.9m, once the available costs of existing treatment have been taken into consideration.

The gross and net cost impacts of funding the estimated 679 new patients per year for the TA-approved treatments in this option are approximately £2.0m and £1.3m respectively. These figures are 32.6% and 24.9% of the gross and net cost of funding all 160 TA recommendations included in Option 1. With a gross cost impact of approximately £0.69m Cancer accounts for 35.0% of the gross cost impact of this option. Respiratory accounts for the highest proportion of net cost impact (36.9%) of treating the estimated number of new patients per annum within this option.

Table 42 shows the number of TA recommendations and the estimated number of patients likely to be treated in the first 12 months along with the number of new patients treated per annum for £10,000 bands of ICER values. The ICER values have been taken from the TA documentation and reflect the prices of both the TA-approved treatment and the comparator treatment at the time NICE carried out their appraisal.



Table 42: Option 4 - Number of TA recommendations and estimated patient numbers by NICE TA ICER bandings plus funding status in Guernsey for TA recommendations with an ICER of less than £30,000 per additional QALY gained

ICER Bandings from NICE TA	Number of TA Recommendations	Estimated Number of Patients Treated in Year 1	Estimated Number of New Patients Per Annum	TA Recommendations Not approved	TA Recommendations Not requested	TA Recommendations Awaiting funding
Under £10,000	8	330	81	4	4	0
£10,000 - £20,000	7	1,580	248	3	4	0
£20,000 - £30,000	17	817	271	7	10	0
£30,000 - £40,000	3	284	34			
£40,000 - £50,000	5	25	15			
£50,000 - £60,000	0	0	0			
£60,000 - £100,000	0	0	0			
£100,000 plus	0	0	0			
ICER Not Available	4	185	30			
Total	44	3,221	679			

Table 42 shows that 32 (72.7%) of the TA-approved treatments in this option were assessed as being within the less than £30,000 additional cost per QALY bandings usually considered to be cost effective by NICE. These 32 TA recommendations would involve an estimated 2,727 (84.7%) patients to be treated in the first year and 600 (88.4%) new patients per annum thereafter. Of the 32 TA-approved treatments with an ICER of less than £30,000 additional cost per QALY, 18 (56.3%) have not been requested for routine funding, and 14 (43.8%) have been considered for routine funding, but have not been approved.

There are no TA recommendations within this option with an ICER of more than £60,000 per additional QALY gained.

Table 43 indicates where patients may experience a change in how their medication is administered if the TA-approved treatments within this option are funded by the States of Guernsey.



Table 43: Option 4 - Number of TA recommendations and estimated patient numbers, where patients are likely to switch to a different method of treatment administration, if they receive the TA treatment

Change of Treatment	Number of TA Recommendations	Estimated Number of Patients Treated in Year 1	Estimated Number of New Patients Per Annum
Patients would switch from oral drug (comparator) to infused drug (TA)	0	0	0
Patients would switch from oral drug (comparator) to injected drug (TA)	3	405	24
Patients would switch from infused drug (comparator) to injected drug (TA)	0	0	0
Patients would switch from injected drug (comparator) to infused drug (TA)	1	10	2
Patients would switch from infused drug (comparator) to oral drug (TA)	1	10	3
Patients would switch from injected drug (comparator) to oral drug (TA)	0	0	0
Patients would remain on current drug formulation	25	2,541	559
Patients would switch from non drug treatment (comparator) to oral drug (TA)	6	204	55
Patients would switch from non drug treatment (comparator) to infused drug (TA)	1	5	3
Patients would switch from non drug treatment (comparator) to injected drug (TA)	4	26	13
Patients would switch from oral drug treatment (comparator) to non drug (TA)	0	0	0
Patients would switch from infused drug treatment (comparator) to non drug (TA)	0	0	0
Patients would switch from injected drug treatment (comparator) to non drug (TA)	0	0	0
TA and Comparator are non drug treatments	3	20	20
Total	44	3,221	679

Table 43 shows that there are three TA-approved treatments, for this option that would be likely to involve a change from an existing oral drug treatment to an infused TA-approved drug treatment. These three TA recommendations are estimated to involve 405 patients in the first 12 months and 24 patients per annum thereafter. However, there is only one TA recommendation, involving 10 estimated patients in the first 12 months and three estimated patients per annum thereafter, where patients would be likely to switch from an infused drug to a TA-approved oral drug.

Table 44 indicates the number of TA recommendations and estimated numbers of patients, where pharmacy and laboratory services in Guernsey have suggested that local funding approval for the TA-approved treatment(s) would have resource implications beyond the simple acquisition cost of the drug or treatment for their respective services. It has not been possible to include these resource costs in our gross and net cost calculations.



Table 44: Option 4 - Number of TA recommendations and number of patients where TA is expected to have significant impact on pharmacy and/or laboratory services

Impact of TA Approval	Number of TA Recommendations	Estimated Number of Patients Treated in Year 1	Estimated Number of New Patients Per Annum	
TA has impact on Pharmacy Services	15	506	73	
TA does not have impact on Pharmacy Services	29	2,715	606	
TA has impact on Laboratory Services	24	1,410	319	
TA does not have impact on Laboratory Services	0	0	0	
Impact of TA on Laboratory Services unknown	20	1,811	360	

Table 44 shows that 15 (34.1%) of the 44 TA-approved treatments in this option were considered likely to have an impact on local pharmacy services resources. These TA-approved treatments were estimated to involve 506 patients in the first year and 73 patients per annum thereafter. For laboratory services, there were 24 TA-approved treatments which were believed to be likely to have an impact on local resources, involving 1,410 patients in the first year and 319 new patients per annum thereafter.

4.4.8 Option 5: NICE TA-approved treatments grouped by estimated cost effectiveness

This option would involve the States of Guernsey deciding to fund TA recommendations based on the cost effectiveness as assessed by NICE in the TA documentation. NICE most commonly assesses the cost effectiveness of TA-approved treatments using incremental cost effectiveness ratios (ICERs) which assess how much it costs to obtain one additional year of good quality life with the TA treatment compared with the cost of obtaining one additional year of good quality life using an existing comparator treatment. It is important to note that the ICERs stated in the NICE TA documentation (and used here) will be based on the pricing of both the TA-approved treatment and the comparator treatment at the time at which the TA was published.

The number of TA-approved treatments, and associated patient numbers and gross and net cost impacts, will depend on the precise ICER threshold that the States of Guernsey decides to set for this option. As an aid to thinking about this we have presented a number of possible ICER thresholds below:

- TA Recommendations with an ICER of under £20,000 per additional QALY gained
- TA Recommendations with an ICER of under £30,000 per additional QALY gained



- TA Recommendations with an ICER of under £40,000 per additional QALY gained
- TA Recommendations with an ICER of under £50,000 per additional QALY gained
- TA Recommendations with an ICER of under £100,000 per additional QALY gained

TA Recommendations with an ICER of under £20,000 per additional QALY gained

Applying this ICER threshold value would result in the States of Guernsey funding 27 NICE TA recommendations from 24 separate TAs.

Table 45 shows the estimated number of patients likely to receive the TA-approved treatments for the TAs within this option and the estimated gross and net cost impact of the States of Guernsey funding these TA recommendations, broken down by different disease groups.



Table 45: Option 5 - Estimated Guernsey patient numbers and gross/net cost impact by disease group for TA recommendations with an ICER of less than £20,000 per additional QALY gained

	Estimated Guernsey Patient Numbers		Gross Cost Impact (PAS Fixed Discount)		Net Cost Impact (PAS Fixed Discount)	
Disease Group	Estimated Number of Patients Treated in Year 1	Estimated Number of New Patients per Annum	Gross Cost Impact of Patients Treated in Year 1	Gross Cost Impact of New Patients Treated per Annum	Net Cost Impact of Patients Treated in Year 1	Net Cost Impact of New Patients Treated per Annum
Blood Disorders	0	0	£0	£0	£0	£0
Cardiac Services	1,280	110	£786,125	£65,550	£751,435	£58,420
Cancer	8	7	£226,505	£301,780	£36,056	£110,331
Colorectal Services	110	23	£181,443	£42,085	£60,803	£5,893
Dermatology	0	0	£0	£0	£0	£0
Ear and Ophthalmology Services	0	0	£0	£0	£0	£0
Endocrinology	240	36	£113,120	£16,968	£58,640	£8,796
Hepatobiliary and Pancreas	0	0	£0	£0	£0	£0
Immunology and Allergy Services	4	1	£600	£150	£600	£150
Infectious Diseases	2	2	£89,654	£89,654	£89,654	£89,654
Medical Genetics	0	0	£0	£0	£0	£0
Mental Health	15	7	£7,741	£3,690	£6,313	£3,119
Neurosciences	3	2	£31,203	£23,626	£19,176	£17,613
Paediatric Medicine	0	0	£0	£0	£0	£0
Pain Management	100	100	£66,240	£66,240	£64,001	£64,001
Renal Services	0	0	£0	£0	£0	£0
Respiratory	0	0	£0	£0	£0	£0
Rheumatology	11	5	£67,556	£29,459	£67,556	£29,459
Trauma and Orthopaedics	5	5	£50,000	£50,000	£50,000	£50,000
Urology	150	40	£56,550	£15,080	£6,300	£1,680
Vascular Disease	0	0	£0	£0	£0	£0
Total	1,928	338	£1,676,736	£704,283	£1,210,534	£439,116



Table 45 shows that should the States of Guernsey choose to fund the 27 TA recommendations within this option with an ICER of less than £20,000 per additional QALY gained, 1,928 patients would be likely to switch to the TA treatment or start treatment within the first year (the backlog) and an estimated 338 new patients per annum would start treatment in subsequent years. This means that the 27 TA recommendations in this option account for 57.6% of the estimated number of patients to be treated in the first year and 43.2% of the number of new patients estimated to be treated per annum thereafter shown in Option 1.

Cardiac patients (1,280) make up 66.4% of the estimated number of patients likely to be treated in the first 12 months and 32.5% of the estimated number of new patients to be treated per annum for this option.

As previously described in Section 4.2.4, the gross and net cost impact figures including in Table 45 have been based on an indicative discount to prevent commercially sensitive pricing available to the NHS in England being revealed. Table 45 shows that the gross estimated cost of funding the 27 TA recommendations in this option, for a total treatment population of 1,928 patients in the first year is around £1.7m. This equates to 18.7% of the gross cost of funding all of the approved NICE TAs in the first year shown in Option 1. With an estimated gross cost expenditure of £0.8m, Cardiac Services accounts for 46.9% of the total estimated gross cost of this option. The gross cost of £1.7m is estimated to reduce to a net cost impact of approximately £1.2m, once the available costs of existing treatment have been taken into consideration.

The gross and net cost impacts of funding the estimated 338 new patients per year for the TA-approved treatments in this option are approximately £0.7m and £0.4m respectively. These figures are 11.6% and 8.6% of the gross and net cost of funding all 160 TA recommendations included in Option 1. With a gross cost impact of approximately £0.3m Cancer accounts for 42.8% of the gross cost impact of this option. Cancer also accounts for the highest proportion of net cost impact (25.1%) of treating the estimated number of new patients per annum within this option.

Table 46 shows the number of TA recommendations and the estimated number of patients likely to be treated in the first 12 months along with the number of new patients treated per annum for £10,000 bands of ICER values. The ICER values have been taken from the TA documentation and reflect the prices of both the TA-approved treatment and the comparator treatment at the time NICE carried out their appraisal.



Table 46: Option 5 - Number of TA recommendations and estimated patient numbers by NICE TA ICER bandings plus funding status in Guernsey for TA recommendations with an ICER of less than £20,000 per additional QALY gained

ICER Bandings from NICE TA	Number of TA Recommendations	Estimated Number of Patients Treated in Year 1	Estimated Number of New Patients Per Annum	TA Recommendations Not approved	TA Recommendations Not requested	TA Recommendations Awaiting funding
Under £10,000	13	335	84	4	9	0
£10,000 - £20,000	14	1,593	254	6	8	0
£20,000 - £30,000	0	0	0			
£30,000 - £40,000	0	0	0			
£40,000 - £50,000	0	0	0			
£50,000 - £60,000	0	0	0			
£60,000 - £100,000	0	0	0			
£100,000 plus	0	0	0			
ICER Not Available	0	0	0			
Total	27	1,928	338			

Table 46 shows that all of the TA-approved treatments in this option were assessed as being within the less than £30,000 additional cost per QALY bandings usually considered to be cost effective by NICE. These 27 TA recommendations would involve an estimated 1,928 (57.6%) patients to be treated in the first year and 338 (43.2%) new patients per annum thereafter. Of the 27 TA-approved treatments with an ICER of less than £30,000 additional cost per QALY, 17 (63.0%) have not been requested for routine funding, 10 (37.0%) have been considered for routine funding, but have not been approved.

Table 47 indicates where patients may experience a change in how their medication is administered if the TA-approved treatments within this option are funded by the States of Guernsey.



Table 47: Option 5 - Number of TA recommendations and estimated patient numbers, where patients are likely to switch to a different method of treatment administration, if they receive the TA treatment

Change of Treatment	Number of TA Recommendations	Estimated Number of Patients Treated in Year 1	Estimated Number of New Patients Per Annum
Patients would switch from oral drug (comparator) to infused drug (TA)	0	0	0
Patients would switch from oral drug (comparator) to injected drug (TA)	0	0	0
Patients would switch from infused drug (comparator) to injected drug (TA)	0	0	0
Patients would switch from injected drug (comparator) to infused drug (TA)	0	0	0
Patients would switch from infused drug (comparator) to oral drug (TA)	1	10	3
Patients would switch from injected drug (comparator) to oral drug (TA)	2	3	2
Patients would remain on current drug formulation	12	1,724	287
Patients would switch from non drug treatment (comparator) to oral drug (TA)	5	173	35
Patients would switch from non drug treatment (comparator) to infused drug (TA)	1	1	1
Patients would switch from non drug treatment (comparator) to injected drug (TA)	3	12	5
Patients would switch from oral drug treatment (comparator) to non drug (TA)	0	0	0
Patients would switch from infused drug treatment (comparator) to non drug (TA)	0	0	0
Patients would switch from injected drug treatment (comparator) to non drug (TA)	0	0	0
TA and Comparator are non drug treatments	3	5	5
Total	27	1,928	338

Table 47 shows that there are no TA-approved treatments, for this option that would be likely to involve a change from an existing oral drug treatment to an infused or injected TA-approved drug treatment. However, there is one TA recommendation, involving 10 estimated patients in the first 12 months and three estimated patients per annum thereafter, where patients would be likely to switch from an infused drug to a TA-approved oral drug.

Table 48 indicates the number of TA recommendations and estimated numbers of patients, where pharmacy and laboratory services in Guernsey have suggested that local funding approval for the TA-approved treatment(s) would have resource implications beyond the simple acquisition cost of the drug or treatment for their respective services. It has not been possible to include these resource costs in our gross and net cost calculations.



Table 48: Option 5 - Number of TA recommendations and number of patients where TA is expected to have significant impact on pharmacy and/or laboratory services

Impact of TA Approval	Number of TA Recommendations	Estimated Number of Patients Treated in Year 1	Estimated Number of New Patients Per Annum
TA has impact on Pharmacy Services	8	50	22
TA does not have impact on Pharmacy Services	19	1,878	316
TA has impact on Laboratory Services	9	235	47
TA does not have impact on Laboratory Services	1	0	0
Impact of TA on Laboratory Services unknown	17	1,693	291

Table 48 shows that eight (29.6%) of the 27 TA-approved treatments in this option were considered likely to have an impact on local pharmacy services resources. These TA-approved treatments were estimated to involve 50 patients in the first year and 22 patients per annum thereafter. For laboratory services, there were nine TA-approved treatments which were believed to be likely to have an impact on local resources, involving 235 patients in the first year and 47 new patients per annum thereafter.

TA-approved treatments with an ICER of under £30,000 per additional QALY gained

Applying this ICER threshold value would result in the States of Guernsey funding 71 NICE TA recommendations from 67 separate TAs.

Table 49 shows the estimated number of patients likely to receive the TA-approved treatments for the TAs within this option and the estimated gross and net cost impact of the States of Guernsey funding these TA recommendations, broken down by different disease groups.



Table 49: Option 5 - Estimated Guernsey patient numbers and gross/net cost impact by disease group for TA recommendations with an ICER of less than £30,000 per additional QALY gained

	Estimated Guernsey Patient Numbers		Gross Cost Imp	act (PAS Fixed Discount)	Net Cost Impact (PAS Fixed Discount)	
Disease Group	Estimated Number of Patients Treated in Year 1	Estimated Number of New Patients per Annum	Gross Cost Impact of Patients Treated in Year 1	Gross Cost Impact of New Patients Treated per Annum	Net Cost Impact of Patients Treated in Year 1	Net Cost Impact of New Patients Treated per Annum
Blood Disorders	0	0	£0	£0	£0	£0
Cardiac Services	1830	230	£1,549,535	£172,998	£1,501,029	£163,574
Cancer	32	30	£1,044,325	£1,095,543	£544,584	£587,692
Colorectal Services	110	23	£181,443	£42,085	£60,803	£5,893
Dermatology	12	10	£157,104	£127,944	£143,550	£120,822
Ear and Ophthalmology Services	21	15	£160,000	£83,500	£160,000	£83,500
Endocrinology	245	40	£256,321	£131,528	£152,666	£84,016
Hepatobiliary and Pancreas	0	0	£0	£0	£0	£0
Immunology and Allergy Services	4	1	£600	£150	£600	£150
Infectious Diseases	2	2	£89,654	£89,654	£89,654	£89,654
Medical Genetics	0	0	£0	£0	£0	£0
Mental Health	95	22	£36,941	£9,165	-£43,724	-£6,263
Neurosciences	3	2	£31,203	£23,626	£19,176	£17,613
Other	150	40	£56,550	£15,080	£6,300	£1,680
Paediatric Medicine	0	0	£0	£0	£0	£0
Pain	100	100	£66,240	£66,240	£64,001	£64,001
Renal Services	0	0	£0	£0	£0	£0
Respiratory	76	34	£510,373	£255,752	£504,541	£252,107
Rheumatology	14	6	£84,974	£35,265	£84,974	£35,265
Trauma and Orthopaedics	60	60	£132,338	£132,338	£132,338	£132,338
Vascular Disease	15	15	£9,308	£9,308	£9,308	£9,308
Total	2769	630	£4,366,907	£2,290,176	£3,429,799	£1,641,350

Table 49 shows that should the States of Guernsey choose to fund the 71 TA recommendations within this option with an ICER of less than £30,000 per additional QALY gained, 2,769 patients would be likely to switch to the TA treatment or start treatment within the first year (the backlog) and an estimated 630 new patients per annum would start treatment in subsequent years. This means that the 71 TA recommendations in this option account for 82.7% of the estimated number of patients to be treated in the first year and 80.6% of the number of new patients estimated to be treated per annum thereafter shown in Option 1.



Cardiac Services patients (1,830) make up 66.1% of the estimated number of patients likely to be treated in the first 12 months and 36.5% of the estimated number of new patients to be treated per annum for this option.

As previously described in Section 4.2.4, the gross and net cost impact figures including in Table 40 have been based on an indicative discount to prevent commercially sensitive pricing available to the NHS in England being revealed. Table 40 shows that the gross estimated cost of funding the 71 TA recommendations in this option, for a total treatment population of 2,769 patients in the first year is around £4.4m. This equates to 48.1% of the gross cost of funding all of the approved NICE TAs in the first year shown in Option 1. With an estimated gross cost expenditure of £1.5m, Cardiac Services accounts for 35.5% of the total estimated gross cost of this option. The gross cost of £4.4m is estimated to reduce to a net cost impact of approximately £3.4m, once the available costs of existing treatment have been taken into consideration.

The gross and net cost impacts of funding the estimated 630 new patients per year for the TA-approved treatments in this option are approximately £2.3m and £1.6m respectively. These figures are 37.6% and 32.1% of the gross and net cost of funding all 160 TA recommendations included in Option 1. With a gross cost impact of approximately £1.1m Cancer accounts for 47.8% of the gross cost impact of this option. Cancer also accounts for the highest proportion of net cost impact (35.8%) of treating the estimated number of new patients per annum within this option.

Table 50 shows the number of TA recommendations and the estimated number of patients likely to be treated in the first 12 months along with the number of new patients treated per annum for £10,000 bands of ICER values. The ICER values have been taken from the TA documentation and reflect the prices of both the TA-approved treatment and the comparator treatment at the time NICE carried out their appraisal.



Table 50: Option 5 - Number of TA recommendations and estimated patient numbers by NICE TA ICER bandings plus funding status in Guernsey for TA recommendations with an ICER of less than £30,000 per additional QALY gained

ICER Bandings from NICE TA	Number of TA Recommendations	Estimated Number of Patients Treated in Year 1	Estimated Number of New Patients Per Annum	TA Recommendations Not approved	TA Recommendations Not requested	TA Recommendations Awaiting funding
Under £10,000	13	335	84	4	9	0
£10,000 - £20,000	14	1,593	254	6	8	0
£20,000 - £30,000	44	841	291	7	36	1
£30,000 - £40,000	0	0	0			
£40,000 - £50,000	0	0	0			
£50,000 - £60,000	0	0	0			
£60,000 - £100,000	0	0	0			
£100,000 plus	0	0	0			
ICER Not Available	0	0	0			
Total	71	2,769	630			

Table 50 shows that all of the TA-approved treatments in this option were assessed as being within the less than £30,000 additional cost per QALY bandings usually considered to be cost effective by NICE. These 71 TA recommendations would involve an estimated 2,769 (82.7%) patients to be treated in the first year and 630 (80.6%) new patients per annum thereafter. Of the 71 TA-approved treatments with an ICER of less than £30,000 additional cost per QALY, 53 (74.6%) have not been requested for routine funding, 17 (23.9%) have been considered for routine funding, but have not been approved and one (1.4%) has been approved, but is awaiting funding.

Table 51 indicates where patients may experience a change in how their medication is administered if the TA-approved treatments within this option are funded by the States of Guernsey.



Table 51: Option 5 - Number of TA recommendations and estimated patient numbers, where patients are likely to switch to a different method of treatment administration, if they receive the TA treatment

Change of Treatment	Number of TA	Estimated Number of Patients	Estimated Number of New
ŭ	Recommendations	Treated in Year 1	Patients Per Annum
Patients would switch from Oral drug (comparator) to infused drug (TA)	3	3	2
Patients would switch from Oral drug (comparator) to injected drug (TA)	2	205	14
Patients would switch from infused drug (comparator) to injected drug (TA)	0	0	0
Patients would switch from injected drug (comparator) to infused drug (TA)	1	10	2
Patients would switch from infused drug (comparator) to oral drug (TA)	3	12	5
Patients would switch from injected drug (comparator) to oral drug (TA)	2	3	2
Patients would remain on current drug formulation	33	2,302	528
Patients would switch from non drug treatment (comparator) to oral drug (TA)	7	178	38
Patients would switch from non drug treatment (comparator) to infused drug (TA)	5	2	3
Patients would switch from non drug treatment (comparator) to injected drug (TA)	9	33	16
Patients would switch from oral drug treatment (comparator) to non drug (TA)	0	0	0
Patients would switch from infused drug treatment (comparator) to non drug (TA)	0	0	0
Patients would switch from injected drug treatment (comparator) to non drug (TA)	0	0	0
TA and Comparator are non drug treatments	6	21	20
Total	71	2,769	630

Table 51 shows that there are five TA-approved treatments, for this option that would be likely to involve a change from an existing oral drug treatment to an infused or injected TA-approved drug treatment. These five TA-approved treatments would involve 208 patients in the first year and 16 new patients per annum thereafter. However, there are also five TA recommendations, involving 15 estimated patients in the first 12 months and seven estimated patients per annum thereafter, where patients would be likely to switch from an infused drug to a TA-approved oral drug.

Table 52 indicates the number of TA recommendations and estimated numbers of patients, where pharmacy and laboratory services in Guernsey have suggested that local funding approval for the TA-approved treatment(s) would have resource implications beyond the simple acquisition cost of the drug or treatment for their respective services. It has not been possible to include these resource costs in our gross and net cost calculations.



Table 52: Option 5 - Number of TA recommendations and number of patients where TA is expected to have significant impact on pharmacy and/or laboratory services

Impact of TA Approval	Number of TA	Estimated Number of Patients	Estimated Number of New	
impact of TA Approval	Recommendations	Treated in Year 1	Patients Per Annum	
TA has impact on Pharmacy Services	31	310	67	
TA does not have impact on Pharmacy Services	40	2,459	563	
TA has impact on Laboratory Services	31	954	269	
TA does not have impact on Laboratory Services	1	0	0	
Impact of TA on Laboratory Services unknown	39	1,815	361	

Table 52 shows that 31 (43.7%) of the 71 TA-approved treatments in this option were considered likely to have an impact on local pharmacy services resources. These TA-approved treatments were estimated to involve 310 patients in the first year and 67 patients per annum thereafter. For laboratory services, there were 31 TA-approved treatments which were believed to be likely to have an impact on local resources, involving 954 patients in the first year and 269 new patients per annum thereafter.

TA-approved treatments with an ICER of under £40,000 per additional QALY gained

Applying this ICER threshold value would result in the States of Guernsey funding 93 NICE TA recommendations from 88 separate TAs.

Table 53 shows the estimated number of patients likely to receive the TA-approved treatments for the TAs within this option and the estimated gross and net cost impact of the States of Guernsey funding these TA recommendations, broken down by different disease groups.



Table 53: Option 5 - Estimated Guernsey patient numbers and gross/net cost impact by disease group for TA recommendations with an ICER of less than £40,000 per additional QALY gained

	Estimated Guernsey Patient Numbers		Gross Cost Imp	act (PAS Fixed Discount)	Net Cost Impact (PAS Fixed Discount)	
Disease Group	Estimated Number of Patients Treated in Year 1	Estimated Number of New Patients per Annum	Gross Cost Impact of Patients Treated in Year 1	Gross Cost Impact of New Patients Treated per Annum	Net Cost Impact of Patients Treated in Year 1	Net Cost Impact of New Patients Treated per Annum
Blood Disorders	0	0	£0	£0	£0	£0
Cardiac Services	2030	240	£2,140,122	£202,527	£2,083,950	£192,720
Cancer	46	40	£1,859,393	£1,864,913	£1,340,788	£1,348,930
Colorectal Services	110	23	£181,443	£42,085	£60,803	£5,893
Dermatology	12	10	£157,104	£127,944	£143,550	£120,822
Ear and Ophthalmology Services	21	15	£160,000	£83,500	£160,000	£83,500
Endocrinology	305	49	£284,881	£135,812	£181,226	£88,300
Hepatobiliary and Pancreas	2	1	£32,041	£16,021	£30,303	£15,151
Immunology and Allergy Services	4	1	£600	£150	£600	£150
Infectious Diseases	2	2	£89,654	£89,654	£89,654	£89,654
Medical Genetics	0	0	£0	£0	£0	£0
Mental Health	95	22	£36,941	£9,165	-£43,724	-£6,263
Neurosciences	5	3	£52,662	£34,356	£21,117	£18,584
Other	150	40	£56,550	£15,080	£6,300	£1,680
Paediatric Medicine	0	0	£0	£0	£0	£0
Pain	100	100	£66,240	£66,240	£64,001	£64,001
Renal Services	0	0	£0	£0	£0	£0
Respiratory	100	49	£857,302	£472,583	£851,470	£468,938
Rheumatology	16	7	£98,302	£41,929	£98,302	£41,929
Trauma and Orthopaedics	60	60	£132,338	£132,338	£132,338	£132,338
Vascular Disease	15	15	£9,308	£9,308	£9,308	£9,308
Total	3073	678	£6,214,880	£3,343,604	£5,229,985	£2,675,635

Table 53 shows that should the States of Guernsey choose to fund the 93 TA recommendations within this option with an ICER of less than £40,000 per additional QALY gained, 3,073 patients would be likely to switch to the TA treatment or start treatment within the first year (the backlog) and an estimated 678 new patients per annum would start treatment in subsequent years. This means that the 93 TA recommendations in this option account for 91.8% of the estimated number of patients to be treated in the first year and 86.7% of the number of new patients estimated to be treated per annum thereafter shown in Option 1.



Cardiac Services patients (2,030) make up 66.1% of the estimated number of patients likely to be treated in the first 12 months and 35.4% of the estimated number of new patients to be treated per annum for this option.

As previously described in Section 4.2.4, the gross and net cost impact figures including in Table 53 have been based on an indicative discount to prevent commercially sensitive pricing available to the NHS in England being revealed. Table 53 shows that the gross estimated cost of funding the 93 TA recommendations in this option, for a total treatment population of 3,073 patients in the first year is around £6.2m. This equates to 68.4% of the gross cost of funding all of the approved NICE TAs in the first year shown in Option 1. With an estimated gross cost expenditure of £2.1m, Cardiac Services accounts for 34.4% of the total estimated gross cost of this option. The gross cost of £6.2m is estimated to reduce to a net cost impact of approximately £5.2m, once the available costs of existing treatment have been taken into consideration.

The gross and net cost impacts of funding the estimated 630 new patients per year for the TA-approved treatments in this option are approximately £3.3m and £2.7m respectively. These figures are 54.9% and 52.3% of the gross and net cost of funding all 160 TA recommendations included in Option 1. With a gross cost impact of approximately £1.9m Cancer accounts for 55.8% of the gross cost impact of this option. Cancer also accounts for the highest proportion of net cost impact (50.4%) of treating the estimated number of new patients per annum within this option.

Table 54 shows the number of TA recommendations and the estimated number of patients likely to be treated in the first 12 months along with the number of new patients treated per annum for £10,000 bands of ICER values. The ICER values have been taken from the TA documentation and reflect the prices of both the TA-approved treatment and the comparator treatment at the time NICE carried out their appraisal.



Table 54: Option 5 - Number of TA recommendations and estimated patient numbers by NICE TA ICER bandings plus funding status in Guernsey for TA recommendations with an ICER of less than £40,000 per additional QALY gained

ICER Bandings from NICE TA	Number of TA Recommendations	Estimated Number of Patients Treated in Year 1	Estimated Number of New Patients Per Annum	TA Recommendations Not approved	TA Recommendations Not requested	TA Recommendations Awaiting funding
Under £10,000	13	335	84	4	9	0
£10,000 - £20,000	14	1,593	254	6	8	0
£20,000 - £30,000	44	841	291	7	36	1
£30,000 - £40,000	22	304	48	4	18	0
£40,000 - £50,000	0	0	0			•
£50,000 - £60,000	0	0	0			
£60,000 - £100,000	0	0	0			
£100,000 plus	0	0	0			
ICER Not Available	0	0	0			
Total	93	3,073	678			

Table 54 shows that 71 of the TA-approved treatments in this option were assessed as being within the less than £30,000 additional cost per QALY bandings usually considered to be cost effective by NICE. These 71 TA recommendations would involve an estimated 2,769 (82.7%) patients to be treated in the first year and 630 (80.6%) new patients per annum thereafter. There are 22 TA recommendations with an ICER of between £30,000 and £40,000, involving 304 patients treated in the first year and 48 new patients per annum thereafter. Of the 93 TA-approved treatments with an ICER of less than £40,000 additional cost per QALY, 71 (76.3%) have not been requested for routine funding, 21 (22.6%) have been considered for routine funding, but have not been approved and one (1.1%) has been approved, but is awaiting funding.

Table 55 indicates where patients may experience a change in how their medication is administered if the TA-approved treatments within this option are funded by the States of Guernsey.



Table 55: Option 5 - Number of TA recommendations and estimated patient numbers, where patients are likely to switch to a different method of treatment administration, if they receive the TA treatment

Change of Treatment	Number of TA Recommendations	Estimated Number of Patients Treated in Year 1	Estimated Number of New Patients Per Annum
Patients would switch from oral drug (comparator) to infused drug (TA)	3	3	2
Patients would switch from oral drug (comparator) to injected drug (TA)	3	405	24
Patients would switch from infused drug (comparator) to injected drug (TA)	0	0	0
Patients would switch from injected drug (comparator) to infused drug (TA)	2	12	3
Patients would switch from infused drug (comparator) to oral drug (TA)	4	14	6
Patients would switch from injected drug (comparator) to oral drug (TA)	2	3	2
Patients would remain on current drug formulation	46	2,376	546
Patients would switch from non drug treatment (comparator) to oral drug (TA)	9	202	53
Patients would switch from non drug treatment (comparator) to infused drug (TA)	8	2	4
Patients would switch from non drug treatment (comparator) to injected drug (TA)	10	35	17
Patients would switch from oral drug treatment (comparator) to non drug (TA)	0	0	0
Patients would switch from infused drug treatment (comparator) to non drug (TA)	0	0	0
Patients would switch from injected drug treatment (comparator) to non drug (TA)	0	0	0
TA and Comparator are non drug treatments	6	21	20
Total	93	3,073	678

Table 55 shows that there are six TA-approved treatments, for this option that would be likely to involve a change from an existing oral drug treatment to an infused or injected TA-approved drug treatment. These five TA-approved treatments would involve 408 patients in the first year and 26 new patients per annum thereafter. However, there are also six TA recommendations, involving 17 estimated patients in the first 12 months and eight estimated patients per annum thereafter, where patients would be likely to switch from an infused drug to a TA-approved oral drug.

Table 56 indicates the number of TA recommendations and estimated numbers of patients, where pharmacy and laboratory services in Guernsey have suggested that local funding approval for the TA-approved treatment(s) would have resource implications beyond the simple acquisition cost of the drug or treatment for their respective services. It has not been possible to include these resource costs in our gross and net cost calculations.



Table 56: Option 5 - Number of TA recommendations and number of patients where TA is expected to have significant impact on pharmacy and/or laboratory services

Impact of TA Approval	Number of TA Recommendations	Estimated Number of Patients Treated in Year 1	Estimated Number of New Patients Per Annum	
TA has impact on Pharmacy Services	45	523	87	
TA does not have impact on Pharmacy Services	48	2,550	591	
TA has impact on Laboratory Services	41	1,226	295	
TA does not have impact on Laboratory Services	1	0	0	
Impact of TA on Laboratory Services unknown	51	1,847	383	

Table 56 shows that 45 (48.4%) of the 71 TA-approved treatments in this option were considered likely to have an impact on local pharmacy services resources. These TA-approved treatments were estimated to involve 523 patients in the first year and 87 patients per annum thereafter. For laboratory services, there were 41 TA-approved treatments which were believed to be likely to have an impact on local resources, involving 1,226 patients in the first year and 295 new patients per annum thereafter.

TA-approved treatments with an ICER of under £50,000 per additional QALY gained

Applying this ICER threshold value would result in the States of Guernsey funding 124 NICE TA recommendations from 119 separate TAs.

Table 57 shows the estimated number of patients likely to receive the TA-approved treatments for the TAs within this option and the estimated gross and net cost impact of the States of Guernsey funding these TA recommendations, broken down by different disease groups.



Table 57: Option 5 - Estimated Guernsey patient numbers and gross/net cost impact by disease group for TA recommendations with an ICER of less than £50,000 per additional QALY gained

	Estimated Guernsey Patient Numbers		Gross Cost Imp	act (PAS Fixed Discount)	Net Cost Impact (PAS Fixed Discount)	
Disease Group	Estimated Number of Patients Treated in Year 1	Estimated Number of New Patients per Annum	Gross Cost Impact of Patients Treated in Year 1	Gross Cost Impact of New Patients Treated per Annum	Net Cost Impact of Patients Treated in Year 1	Net Cost Impact of New Patients Treated per Annum
Blood Disorders	0	0	£0	£0	£0	£0
Cardiac Services	2030	240	£2,140,122	£202,527	£2,083,950	£192,720
Cancer	93	82	£2,992,012	£2,986,390	£2,195,280	£2,270,270
Colorectal Services	110	23	£181,443	£42,085	£60,803	£5,893
Dermatology	12	10	£157,104	£127,944	£143,550	£120,822
Ear and Ophthalmology Services	21	15	£160,000	£83,500	£160,000	£83,500
Endocrinology	305	49	£284,881	£135,812	£181,226	£88,300
Hepatobiliary and Pancreas	2	1	£32,041	£16,021	£30,303	£15,151
Immunology and Allergy Services	4	1	£600	£150	£600	£150
Infectious Diseases	2	2	£89,654	£89,654	£89,654	£89,654
Medical Genetics	0	0	£0	£0	£0	£0
Mental Health	95	22	£36,941	£9,165	-£43,724	-£6,263
Neurosciences	5	3	£52,662	£34,356	£21,117	£18,584
Other	150	40	£56,550	£15,080	£6,300	£1,680
Paediatric Medicine	0	0	£0	£0	£0	£0
Pain	100	100	£66,240	£66,240	£64,001	£64,001
Renal Services	0	2	£0	£17,640	£0	£17,640
Respiratory	100	49	£857,302	£472,583	£851,470	£468,938
Rheumatology	16	7	£98,302	£41,929	£98,302	£41,929
Trauma and Orthopaedics	60	60	£132,338	£132,338	£132,338	£132,338
Vascular Disease	15	15	£9,308	£9,308	£9,308	£9,308
Total	3120	721	£7,347,500	£4,482,721	£6,084,478	£3,614,615

Table 57 shows that should the States of Guernsey choose to fund the 124 TA recommendations within this option with an ICER of less than £50,000 per additional QALY gained, 3,120 patients would be likely to switch to the TA treatment or start treatment within the first year (the backlog) and an estimated 721 new patients per annum would start treatment in subsequent years. This means that the 124 TA recommendations in this option account for 93.2% of the estimated number of patients to be treated in the first year and 92.2% of the number of new patients estimated to be treated per annum thereafter shown in Option 1.



Cardiac Services patients (2,030) make up 65.1% of the estimated number of patients likely to be treated in the first 12 months and 33.3% of the estimated number of new patients to be treated per annum for this option.

As previously described in Section 4.2.4, the gross and net cost impact figures including in Table 57 have been based on an indicative discount to prevent commercially sensitive pricing available to the NHS in England being revealed. Table 57 shows that the gross estimated cost of funding the 124 TA recommendations in this option, for a total treatment population of 3,120 patients in the first year is around £7.3m. This equates to 80.9% of the gross cost of funding all of the approved NICE TAs in the first year shown in Option 1. With an estimated gross cost expenditure of £2.1m, Cardiac Services accounts for 29.1% of the total estimated gross cost of this option. The gross cost of £7.3m is estimated to reduce to a net cost impact of approximately £6.1m, once the available costs of existing treatment have been taken into consideration.

The gross and net cost impacts of funding the estimated 721 new patients per year for the TA-approved treatments in this option are approximately £4.5m and £3.6m respectively. These figures are 73.6% and 70.6% of the gross and net cost of funding all 160 TA recommendations included in Option 1. With a gross cost impact of approximately £3.0m Cancer accounts for 66.6% of the gross cost impact of this option. Cancer also accounts for the highest proportion of net cost impact (62.9%) of treating the estimated number of new patients per annum within this option.

Table 58 shows the number of TA recommendations and the estimated number of patients likely to be treated in the first 12 months along with the number of new patients treated per annum for £10,000 bands of ICER values. The ICER values have been taken from the TA documentation and reflect the prices of both the TA-approved treatment and the comparator treatment at the time NICE carried out their appraisal.



Table 58: Option 5 - Number of TA recommendations and estimated patient numbers by NICE TA ICER bandings plus funding status in Guernsey for TA recommendations with an ICER of less than £50,000 per additional QALY gained

ICER Bandings from NICE TA	Number of TA Recommendations	Estimated Number of Patients Treated in Year 1	Estimated Number of New Patients Per Annum	TA Recommendations Not approved	TA Recommendations Not requested	TA Recommendations Awaiting funding
Under £10,000	13	335	84	4	9	0
£10,000 - £20,000	14	1,593	254	6	8	0
£20,000 - £30,000	44	841	291	7	36	1
£30,000 - £40,000	22	304	48	4	18	0
£40,000 - £50,000	31	47	43	10	20	1
£50,000 - £60,000	0	0	0			
£60,000 - £100,000	0	0	0			
£100,000 plus	0	0	0			
ICER Not Available	0	0	0			

721

Table 58 shows that 71 of the TA-approved treatments in this option were assessed as being within the less than £30,000 additional cost per QALY bandings usually considered to be cost effective by NICE. There are 22 TA recommendations with an ICER of between £30,000 and £40,000, involving 304 patients treated in the first year and 48 new patients per annum thereafter. There are 31 TA-approved treatments with an ICER of between £40,000 and £50,000, involving an estimated 47 patients to be treated in the first year and 43 new patients per annum thereafter. Of the 124 TA-approved treatments with an ICER of less than £50,000 additional cost per QALY, 91 (73.4%) have not been requested for routine funding, 31 (25.0%) have been considered for routine funding, but have not been approved and two (1.6%) has been approved, but is awaiting funding.

3,120

Table 59 indicates where patients may experience a change in how their medication is administered if the TA-approved treatments within this option are funded by the States of Guernsey.

Total

124



Table 59: Option 5 - Number of TA recommendations and estimated patient numbers, where patients are likely to switch to a different method of treatment administration, if they receive the TA treatment

Change of Treatment	Number of TA Recommendations	Estimated Number of Patients Treated in Year 1	Estimated Number of New Patients Per Annum
Patients would switch from oral drug (comparator) to infused drug (TA)	4	3	3
Patients would switch from oral drug (comparator) to injected drug (TA)	3	405	24
Patients would switch from infused drug (comparator) to injected drug (TA)	0	0	0
Patients would switch from injected drug (comparator) to infused drug (TA)	2	12	3
Patients would switch from infused drug (comparator) to oral drug (TA)	7	15	8
Patients would switch from injected drug (comparator) to oral drug (TA)	2	3	2
Patients would remain on current drug formulation	61	2,402	567
Patients would switch from non drug treatment (comparator) to oral drug (TA)	16	210	61
Patients would switch from non drug treatment (comparator) to infused drug (TA)	12	9	13
Patients would switch from non drug treatment (comparator) to injected drug (TA)	11	40	20
Patients would switch from oral drug treatment (comparator) to non drug (TA)	0	0	0
Patients would switch from infused drug treatment (comparator) to non drug (TA)	0	0	0
Patients would switch from injected drug treatment (comparator) to non drug (TA)	0	0	0
TA and Comparator are non drug treatments	6	21	20
Total	124	3,120	721

Table 59 shows that there are seven TA-approved treatments, for this option that would be likely to involve a change from an existing oral drug treatment to an infused or injected TA-approved drug treatment. These seven TA-approved treatments would involve 408 patients in the first year and 27 new patients per annum thereafter. However, there are also nine TA recommendations, involving 18 estimated patients in the first 12 months and 10 estimated patients per annum thereafter, where patients would be likely to switch from an infused drug to a TA-approved oral drug.

Table 60 indicates the number of TA recommendations and estimated numbers of patients, where pharmacy and laboratory services in Guernsey have suggested that local funding approval for the TA-approved treatment(s) would have resource implications beyond the simple acquisition cost of the drug or treatment for their respective services. It has not been possible to include these resource costs in our gross and net cost calculations.



Table 60: Option 5 - Number of TA recommendations and number of patients where TA is expected to have significant impact on pharmacy and/or laboratory services

Impact of TA Approval	Number of TA Estimated Number of Patien		s Estimated Number of New	
impact of intripprotai	Recommendations	Treated in Year 1	Patients Per Annum	
TA has impact on Pharmacy Services	63	559	119	
TA does not have impact on Pharmacy Services	61	2,561	602	
TA has impact on Laboratory Services	65	1,272	333	
TA does not have impact on Laboratory Services	1	0	0	
Impact of TA on Laboratory Services unknown	58	1,848	388	

Table 60 shows that 63 (50.8%) of the 124 TA-approved treatments in this option were considered likely to have an impact on local pharmacy services resources. These TA-approved treatments were estimated to involve 559 patients in the first year and 119 patients per annum thereafter. For laboratory services, there were 65 TA-approved treatments which were believed to be likely to have an impact on local resources, involving 1,272 patients in the first year and 333 new patients per annum thereafter.

TA-approved treatments with an ICER under £100,000 per additional QALY gained

Applying this ICER threshold value would result in the States of Guernsey funding 138 NICE TA recommendations from 130 separate TAs.

Table 61 shows the estimated number of patients likely to receive the TA-approved treatments for the TAs within this option and the estimated gross and net cost impact of the States of Guernsey funding these TA recommendations, broken down by different disease groups.



Table 61: Option 5 - Estimated Guernsey patient numbers and gross/net cost impact by disease group for TA recommendations with an ICER of less than £100,000 per additional QALY gained

	Estimated Guernsey Patient Numbers		Gross Cost Imp	act (PAS Fixed Discount)	Net Cost Impact (PAS Fixed Discount)	
Disease Group	Estimated Number of Patients Treated in Year 1	Estimated Number of New Patients per Annum	Gross Cost Impact of Patients Treated in Year 1	Gross Cost Impact of New Patients Treated per Annum	Net Cost Impact of Patients Treated in Year 1	Net Cost Impact of New Patients Treated per Annum
Blood Disorders	0	0	£0	£0	£0	£0
Cardiac Services	2030	240	£2,140,122	£202,527	£2,083,950	£192,720
Cancer	110	96	£3,653,410	£3,497,173	£2,786,369	£2,747,220
Colorectal Services	110	23	£181,443	£42,085	£60,803	£5,893
Dermatology	12	10	£157,104	£127,944	£143,550	£120,822
Ear and Ophthalmology Services	21	15	£160,000	£83,500	£160,000	£83,500
Endocrinology	305	49	£284,881	£135,812	£181,226	£88,300
Hepatobiliary and Pancreas	2	1	£32,041	£16,021	£30,303	£15,151
Immunology and Allergy Services	4	1	£600	£150	£600	£150
Infectious Diseases	2	2	£89,654	£89,654	£89,654	£89,654
Medical Genetics	0	0	£0	£0	£0	£0
Mental Health	95	22	£36,941	£9,165	-£43,724	-£6,263
Neurosciences	5	3	£52,662	£34,356	£21,117	£18,584
Other	150	40	£56,550	£15,080	£6,300	£1,680
Paediatric Medicine	0	0	£0	£0	£0	£0
Pain	100	100	£66,240	£66,240	£64,001	£64,001
Renal Services	0	2	£0	£17,640	£0	£17,640
Respiratory	100	49	£857,302	£472,583	£851,470	£468,938
Rheumatology	20	9	£124,958	£55,257	£105,662	£42,393
Trauma and Orthopaedics	60	60	£132,338	£132,338	£132,338	£132,338
Vascular Disease	15	15	£9,308	£9,308	£9,308	£9,308
Total	3141	737	£8,035,553	£5,006,832	£6,682,926	£4,092,028

Table 61 shows that should the States of Guernsey choose to fund the 138 TA recommendations within this option with an ICER of less than £100,000 per additional QALY gained, 3,141 patients would be likely to switch to the TA treatment or start treatment within the first year (the backlog) and an estimated 737 new patients per annum would start treatment in subsequent years. This means that the 138 TA recommendations in this option account for 93.8% of the estimated number of patients to be treated in the first year and 94.2% of the number of new patients estimated to be treated per annum thereafter shown in Option 1.



Cardiac Services patients (2,030) make up 64.6% of the estimated number of patients likely to be treated in the first 12 months and 32.6% of the estimated number of new patients to be treated per annum for this option.

As previously described in Section 4.2.4, the gross and net cost impact figures including in Table 61 have been based on an indicative discount to prevent commercially sensitive pricing available to the NHS in England being revealed. Table 61 shows that the gross estimated cost of funding the 138 TA recommendations in this option, for a total treatment population of 3,141 patients in the first year is around £8.0m. This equates to 88.5% of the gross cost of funding all of the approved NICE TAs in the first year shown in Option 1. With an estimated gross cost expenditure of £3.7m, Cancer accounts for 45.5% of the total estimated gross cost of this option. The gross cost of £8.0m is estimated to reduce to a net cost impact of approximately £6.7m, once the available costs of existing treatment have been taken into consideration.

The gross and net cost impacts of funding the estimated 737 new patients per year for the TA-approved treatments in this option are approximately £5.0m and £4.0m respectively. These figures are 82.3% and 80.0% of the gross and net cost of funding all 160 TA recommendations included in Option 1. With a gross cost impact of approximately £3.5m Cancer accounts for 69.8% of the gross cost impact of this option. Cancer also accounts for the highest proportion of net cost impact (67.1%) of treating the estimated number of new patients per annum within this option.

Table 62 shows the number of TA recommendations and the estimated number of patients likely to be treated in the first 12 months along with the number of new patients treated per annum for £10,000 bands of ICER values. The ICER values have been taken from the TA documentation and reflect the prices of both the TA-approved treatment and the comparator treatment at the time NICE carried out their appraisal.



Table 62: Option 5 - Number of TA recommendations and estimated patient numbers by NICE TA ICER bandings plus funding status in Guernsey for TA recommendations with an ICER of less than £100,000 per additional QALY gained

ICER Bandings from NICE TA	Number of TA Recommendations	Estimated Number of Patients Treated in Year 1	Estimated Number of New Patients Per Annum	TA Recommendations Not approved	TA Recommendations Not requested	TA Recommendations Awaiting funding
Under £10,000	13	335	84	4	9	0
£10,000 - £20,000	14	1,593	254	6	8	0
£20,000 - £30,000	44	841	291	7	36	1
£30,000 - £40,000	22	304	48	4	18	0
£40,000 - £50,000	31	47	43	10	20	1
£50,000 - £100,000	14	21	16	3	10	1
£100,000 plus	0	0	0		•	
ICER Not Available	0	0	0			

737

Table 62 shows that 71 of the TA-approved treatments in this option were assessed as being within the less than £30,000 additional cost per QALY bandings usually considered to be cost effective by NICE. There are 14 TA recommendations with an ICER of between £50,000 and £100,000 involving 21 patients treated in the first year and 16 new patients per annum thereafter. Of the 138 TA-approved treatments with an ICER of less than £100,000 additional cost per QALY, 101 (73.2%) have not been requested for routine funding, 34 (24.6%) have been considered for routine funding, but have not been approved and three (2.2%) has been approved, but are awaiting funding.

Table 63 indicates where patients may experience a change in how their medication is administered if the TA-approved treatments within this option are funded by the States of Guernsey.

Total

138

3,141



Table 63: Option 5 - Number of TA recommendations and estimated patient numbers, where patients are likely to switch to a different method of treatment administration, if they receive the TA treatment

Change of Treatment	Number of TA Recommendations	Estimated Number of Patients Treated in Year 1	Estimated Number of New Patients Per Annum
Patients would switch from oral drug (comparator) to infused drug (TA)	4	3	3
Patients would switch from oral drug (comparator) to injected drug (TA)	3	405	24
Patients would switch from infused drug (comparator) to injected drug (TA)	0	0	0
Patients would switch from injected drug (comparator) to infused drug (TA)	3	14	4
Patients would switch from infused drug (comparator) to oral drug (TA)	9	16	11
Patients would switch from injected drug (comparator) to oral drug (TA)	2	3	2
Patients would remain on current drug formulation	69	2,417	576
Patients would switch from non drug treatment (comparator) to oral drug (TA)	17	212	64
Patients would switch from non drug treatment (comparator) to infused drug (TA)	13	9	13
Patients would switch from non drug treatment (comparator) to injected drug (TA)	12	41	20
Patients would switch from oral drug treatment (comparator) to non drug (TA)	0	0	0
Patients would switch from infused drug treatment (comparator) to non drug (TA)	0	0	0
Patients would switch from injected drug treatment (comparator) to non drug (TA)	0	0	0
TA and Comparator are non drug treatments	6	21	20
Total	138	3,141	737

Table 63 shows that there are seven TA-approved treatments, for this option that would be likely to involve a change from an existing oral drug treatment to an infused or injected TA-approved drug treatment. These seven TA-approved treatments would involve 408 patients in the first year and 27 new patients per annum thereafter. However, there are also 11 TA recommendations, involving 19 estimated patients in the first 12 months and 13 estimated patients per annum thereafter, where patients would be likely to switch from an infused drug to a TA-approved oral drug.

Table 64 indicates the number of TA recommendations and estimated numbers of patients, where pharmacy and laboratory services in Guernsey have suggested that local funding approval for the TA-approved treatment(s) would have resource implications beyond the simple acquisition cost of the drug or treatment for their respective services. It has not been possible to include these resource costs in our gross and net cost calculations.



Table 64: Option 5 - Number of TA recommendations and number of patients where TA is expected to have significant impact on pharmacy and/or laboratory services

Impact of TA Approval	Number of TA	Estimated Number of Patients	Estimated Number of New	
impact of 1A Approval	Recommendations	Treated in Year 1	Patients Per Annum	
TA has impact on Pharmacy Services	73	577	129	
TA does not have impact on Pharmacy Services	65	2,564	608	
TA has impact on Laboratory Services	76	1,291	348	
TA does not have impact on Laboratory Services	1	0	0	
Impact of TA on Laboratory Services unknown	61	1,850	389	

Table 64 shows that 73 (52.9%) of the 138 TA-approved treatments in this option were considered likely to have an impact on local pharmacy services resources. These TA-approved treatments were estimated to involve 577 patients in the first year and 129 patients per annum thereafter. For laboratory services, there were 76 TA-approved treatments which were believed to be likely to have an impact on local resources, involving 1,291 patients in the first year and 348 new patients per annum thereafter.

4.4.9 Option 6: Status Quo – no additional NICE TA-approved treatments funded

This option would involve the States of Guernsey with continuing the existing arrangements for approving new drugs and other treatments and therefore none of the currently unfunded NICE TAs presented in this report would be routinely funded. This would result in their being no gross or net cost impact of funding currently unfunded NICE TA-approved treatments.



5 Other island jurisdictions

This chapter is a review of how other island state crown dependencies, namely, States of Jersey and the Isle of Man, manage access to treatments recommended by NICE TAs. It begins by describing the methods used before describing the findings, providing an overview of their current policies. The discussion will draw out some of the challenges and learning opportunities for Guernsey.

5.1 Methodology

Semi-structured interviews were conducted to ensure key questions were covered during the interview and allow for flexibility in following new lines of enquiry as they arose during the conversation. Interviews were conducted by phone. An interview guide with a set list of questions was developed, covering the following subjects:

- current policy
- background to the policy
- cancer treatments and Cancer Drugs Fund
- End of Life Treatments
- Highly Specialised Technologies
- cost per QALY thresholds
- process for accessing new treatments
- logistics
- issues and complications
- forward vision

Key informant sampling was used to target individuals who are particularly knowledgeable about treatment accessibility and management on their respective islands. Interviewees were asked to recommend other potential interviewees (snowballing method), however, this proved unsuccessful as other interviewees were contacted but were not available to participate.

On initial contact with interviewees and at time of interview, relevant documents, information or links to relevant documents were requested. A search of Jersey and the Isle of Man's respective government websites was conducted for background information on relevant policies.

In Jersey, interviews were conducted with the Chief Pharmacist, the Group Medical Director, and the Pharmacy Advisor. In the Isle of Man, interviews were conducted with Director of Public Health and Chief Pharmacist.

The right for interviewees to withhold information, refuse to answer questions or withdraw information was explicitly stated. We did not have access to or review the financial provision for funding of NICE TA-approved treatments for each jurisdiction.



5.2 Jersey

5.2.1 Jersey process and approach

Current policy and process

There are two parallel systems in Jersey for considering the introduction of new drugs and treatments; one for the hospital services and one for the primary care services.

Hospital Services. Jersey's hospital services have a policy⁸ to approve all NICE TA and HST approved treatments (other than the CDF treatments), with the caveat that there is no time limit on when the treatment has to be made available. If a TA or HST approved treatment has not yet been used in Jersey, the clinician who wants to use the new treatment is required to complete a treatment request form. This form is used for all new treatment requests (NICE TA and HST approved or not). Completion of the form requires information about the intervention and the specific indication. These forms are reviewed weekly by a clinical review panel. NICE TA-approved treatments are usually approved for funding and made available with immediate effect. However, if the treatment is particularly expensive, for example an HST treatment, it may take longer to be made available since the funding will need to be sourced. Once a treatment has been approved on the island, it enters onto a pharmaceutical list and is then available for routine prescribing.

NICE TA-approved cancer treatments are routinely adopted and funded by the States of Jersey. Cancer treatments that are not fully approved by NICE are not approved for funding. This includes treatments approved by NICE for funding from the CDF due to the outstanding uncertainty about their clinical and cost effectiveness.

The Department for Health and Social Care in Jersey has considered introducing a policy to fund all CDF treatments, but the estimated cost (calculated by applying the England cost of the CDF to Jersey population on a pro-rata basis) and the perceived lack of demand for such treatments has resulted in requests for CDF treatments only being considered for individual patients following consideration using the individual funding request (IFR) process.

Both HST and EoL treatments are considered the same as any other NICE TA-approved treatments despite them having a higher cost per QALY threshold. The cost per QALY is not used to discriminate between TAs. Jersey's view is that if it is NICE TA-approved it is considered cost effective by NICE and that is accepted by Jersey.

Primary Care Services. The second process for considering the introduction of new drugs and treatments in primary care works in a similar way to Guernsey. A clinician may make a treatment request to the Pharmaceutical Benefits Advisory Committee (PBAC) which will then review the evidence. If the PBAC approves the drug, a

⁸ We did not have access to the written policy



recommendation goes to the Jersey Social Security Minister for ministerial approval. Approved treatments are usually added to the formulary list (Products Available as Pharmaceutical Benefit Under the Health Insurance Jersey Law) and made available for routine prescribing (funded by social security).

The PBAC typically approves drugs that are NICE TA-approved. The exception to this is if:

- a) the drug cannot be accessed for the same price stated in the NICE TA guidance (e.g. if the drug is subject to a patient access scheme or price reduction, primary care will not be able to secure the lower price) or
- b) there is inadequate service infrastructure to support the treatment being made available in the community setting (e.g. biological treatments).

If PBAC rejects a NICE TA-approved treatment request due to lack of access to the NICE agreed discounted price, provision by hospital services will be explored (as their contracting allows access to NICE negotiated discounted price).

The PBAC takes into account clinical effectiveness, affordability and cost effectiveness in their decision making. However, since the primary care services typically do not provide any HSTs or EoL treatments, the cost per QALY does not rise above the lower NICE threshold of £20,000-£30,000 per QALY, so there is no great fluctuation in the cost effectiveness of the treatments requested.

How the current policy was developed

Before the current hospital services policy to agree all NICE TA- and HST- approved treatments (excluding CDF treatments) was introduced, Jersey had a process of requesting treatments through Individual Funding Requests (IFR) and via application to the Drug and Therapeutics Committee. Over time a large proportion of TA- and HST-approved treatments had been approved and made available on the island. This meant that when the question of whether to fund all NICE TA- and HST-approved treatments arose on the island, it was not such a leap from current practice to do so. As a result, there was smooth transition from the old way of working to the new, largely determined by the fact that the island was already funding the majority of treatments.

Financing

Jersey does not have a provider-commissioner split, which means that for hospital services budget lines are managed by clinicians. Annual budgets are planned by using historic budgets in combination with horizon scanning for future additional costs. If a request for new treatment appears to place an unexpected burden on the current budget, there are mechanisms through which additional funds can be accessed, for example, money from the contingency fund can be bid for. This takes time to organise and Jersey does not set a time by which they have to make treatment available after request. Despite this, even for the most expensive treatments, treatments are generally available within a year.



Although in hospital services, all NICE TA- and HST-approved treatments (except treatments funded from the CDF) are always approved, clinicians are still required to submit a request form for new treatments. This is partly to provide clinical oversight of the treatments being used, and partly to support financial management and planning.

For primary care, the cost of drugs is funded by social security. The Prescribing Advisor manages the primary care budget.

Jersey's hospital system is subject to the same pricing structure for treatments as the South of England Region and has never had an issue accessing the regional price. However, should an issue arise with accessing the regional price, the policy of approving the NICE TA and HST treatments would not apply – as it assumes access to the same prices as England to make the cost effective estimate relevant. Primary care can only access list prices of drugs.

Logistics

We were advised that if the existing infrastructure to support prescribing and administration of treatments in the community setting is inadequate the treatment may be provided by the hospital. This means that a patient may be receiving outpatient treatment at the hospital and treatment from their General Practitioner for the same illness at the same time. For example, patients with rheumatoid arthritis might receive biological treatment in the hospital outpatient clinic and other drug prescriptions from their General Practitioner.

In addition, some clinical tests associated with treatments have to be performed offisland and some clinical pathways lead to Southampton. Neither factor is considered problematic and integration with key off-island providers such as Southampton is well managed.

There were no marked resource issues noted from the interviews.

Forward vision

For the foreseeable future the current policy regarding NICE TA-approved treatment is likely to continue.

5.2.2 Reflections on the Jersey approach

Benefits of having an approve-all policy

By hospital services having a clear policy of approving all NICE TA- and HST-approved treatments, interviewees reported the need for fewer layers of administration and resources that would be otherwise required to review and approve all the treatments individually. All interviewees acknowledged that as a small island, they cannot replicate the complicated and resource intensive appraisal that NICE performs, and there is a general agreement amongst the clinical review panel and PBAC that NICE's recommendations should be accepted.



Another reported benefit of the hospital services policy was how it ensures an equitable and objective approach to prioritising resources which can be justified under scrutiny.

Issues and complications

Both interviewees reported that there were no specific issues or complications due to the policy Jersey has adopted. Patient satisfaction data was not available but it was noted that there was little to no public agitation around treatment availability.

5.3 Isle of Man

5.3.1 Isle of Man process and approach

The Isle of Man Department of Health and Social Care (DHSC) is responsible for the funding of all drugs and treatments offered to residents through the island's NHS. The process (Figure 12) through which funding decisions are made starts with a request for policy consideration to the Clinical Recommendations Committee (CRC comprising senior clinicians from acute, mental health and general practice, allied health professions, management and lay representation) which considers evidence for clinical and cost effectiveness.

Where the CRC makes a positive recommendation, the request progresses to the Commissioning Committee for prioritisation against other options for investment and identification of funds. Where priority and funding are confirmed, a draft policy is submitted to the DHSC Department meeting (comprising the minister, political members and senior DHSC management) for confirmation and implementation. Clinicians are able to request to introduce a new treatment into the clinical pathway by completing a request form that is sent to the CRC for consideration. Topics for policy consideration can also be identified by other routes, e.g. audits of prescribing data.

Figure 12: Isle of Man treatment policy process





As with Jersey, National Institute of Health and Care Excellence (NICE) guidance has no legal status on the island. This means that NICE TA and HST approved treatments are not automatically funded or implemented on Isle of Man. Similarly, treatments commissioned by NHS England under a specialised services commissioning policy are also not automatically funded on island.

The Isle of Man treatment pathways link to services in the North West of England (for tertiary and specialist elements), and in some situations treatments available in the North West of England pathways are not automatically funded for Isle of Man patients – either as part of care on island or within the North West England service.

The Isle of Man DHSC recognises NICE appraisals as best available evidence and accepts NICE conclusions regarding clinical and cost effectiveness (provided DHSC can access treatments at the price agreed for the NHS in England – which to date has been the case). However, in the current financial climate, DHSC has not been able to achieve assurance that a policy of routinely funding in line with NICE and NHS E would be affordable. In addition, DHSC remains unsure as to whether there are gaps in current clinical pathways which would be a higher priority to fund in comparison to some NICE TA and HST approved treatments.

The current processes have limited ability to mitigate these concerns. CRC does not hold a budget and is a 'single issue consideration' body. Thus, it can check each treatment considered for evidence of clinical and cost effectiveness but it cannot prioritise between all treatments that pass the effectiveness threshold or assess whether there are other gaps in pathways which could be higher priority. Where a NICE TA assessment is available, the work on clinical and cost effectiveness has already been done and there is little that the CRC can add to this.⁹

One treatment category where DHSC has taken a blanket approach to implementing NICE TAs is cancer drugs. The interim policy agreed in 2017 (Isle of Man, Department of Health and Social Care, 2017) confirms that funding will be in line with the protocols in place for the Cheshire and Merseyside Cancer Network (now one of the North West Coast Strategic Clinical Networks) through which oncology and chemotherapy is commissioned and delivered to Isle of Man patients. Aligning Isle of Man cancer treatment with the network protocols effectively means that Isle of Man will automatically fund all cancer drugs recommended through a NICE TA and drugs funded in England through the (new) Cancer Drug Fund, until they progress to a NICE TA decision. The 2017 interim policy was required to update and clarify earlier policy which had already committed to fund in line with the North West Coast cancer network protocols. The DHSC believed it was not possible to robustly model the likely financial impact of the interim policy prior to implementation. For that reason the policy was designed to be interim to enable review once the impact could be assessed. This review is currently ongoing. DHSC has not identified a separate ringfenced budget either for cancer drugs generally or for drugs covered by the CDF in

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⁹ Information on the CRC process is available here: https://www.gov.im/dhscclinicalcommissioning and a list of current commissioning policies is also available via this link.



England. The reason for this is that with a small population, demand will fluctuate year on year to such an extent that a budget is difficult to set and manage on a year on year basis.

Forward vision

The Isle of Man is currently going through a review of clinical pathways, and considering what their approach should be to approving all NICE TA-, HST- and NHS England specialised commissioning approved treatments.

5.4 Discussion and conclusion

Ostensibly, Jersey and the Isle of Man are similar in the fact that they have a health system independent of the UK and they are not mandated to follow NICE guidance, but are still, to a certain degree, reliant on the UK NHS because their clinical pathways feed into it. There are, however, some notable differences. Namely the Isle of Man has a policy to provide all NICE TA-approved cancer treatments (including those on the CDF) but other NICE TA- and HST-approved treatments have to go through a long process of approval. This can lead to inequity of treatment access between patient groups.

On the other hand, Jersey's primary care services typically fund all NICE TA-approved treatments and hospital services have a policy to fund all NICE TA- and HST-approved treatments (excluding CDF treatments). There are mechanisms in place to manage more expensive treatments albeit with a delay. CDF treatments in Jersey are not considered fully NICE approved but there does not appear to be dissatisfaction with the lack of routine commissioning of these treatments.

Since both Jersey and the Isle of Man have clinical pathways that feed into England, both may find that if they do not approve all NICE TA and HST approved treatments they will increasingly diverge from the England clinical pathways and treatments. This might also impact clinical staff recruited from England who will be less familiar with older treatments and could expect to access NICE approved treatments and find it difficult to adapt.

Prioritisation is complicated by the fact that most new NICE TA-approved drugs are for end of pathway indications and the issues along the whole clinical pathway might not always be fully understood. Prioritising a new drug for funding when potential issues and improvements further upstream in the clinical pathway are not fully understood, is problematic.

There could be unknown opportunity costs to approving all NICE TA-approved treatments. For example, Sacubitril Valsartan (Entresto™) is a TA-approved drug (TA388) for patients with heart failure who meet very specific patient selection criteria and who are assessed and managed by a heart failure specialist with access to a heart failure MDT. Ideally, investment in a treatment for advanced heart failure needs to be considered alongside prevention, early intervention and optimal treatment of heart failure. Therefore, under these circumstances, it is difficult to assess whether



funding Sacubitril Valsartan (Entresto™), a relatively expensive drug, is the most cost effective investment along the heart failure pathway.

In summary, the States of Jersey and the Isle of Man offer interesting and contrasting examples of how to respond to issues of equity and accessibility to NICE TAs and HSTs, with one routinely funding all except for CDF treatments while the other routinely funds all cancer treatments including CDF treatments, but not other NICE TAs of HSTs. Thus, neither the States of Jersey nor the Isle of Man currently routinely fund all NICE TA and HST approved treatments. Nonetheless, there are several learning points that could be useful for The States of Guernsey to reflect on.

Learning points that could be useful for Guernsey include:

- 1. Divergence from the England NHS treatment regime can prove problematic particularly if clinical pathways feed into clinical pathways funded by the NHS in England. Patients expect equal access to treatments (to their English counterparts) and can be left dissatisfied if they are aware that access to treatment is restricted. In addition, clinicians recruited from England can struggle with being limited in their treatment options and not having access to evidence based treatments that they could routinely use in the NHS in England.
- 2. Consideration of the whole clinical pathway is important. TA- and HST-treatments are often second or third line treatments, or treatments for when a disease has relapsed or advanced. Therefore, to be able to fully assess the costs and benefits of funding these treatments, it is important to have an understanding of the full clinical pathway (including all treatment options, diagnostics, early interventions and optimal management) and to consider whether funding of the NICE TA- or HST-approved treatment might be at the expense of good care earlier in the pathway.
- 3. There was a contrast in views about the CDF treatments. Jersey does not routinely fund CDF treatments whereas the Isle of Man does. Jersey did not feel any urgency to bring in a policy to approve CDF treatments. They do not view CDF treatments as NICE approved since they are not recommended by NICE for routine commissioning and the cost of funding CDF treatments was roughly estimated and considered to have a significant budgetary impact (although exact information on this was withheld). The Isle of Man, on the other hand, does include them in their Cancer treatment policy.
- 4. Fairness and equity is an important consideration. If some TAs are automatically approved and some are not, as is the case in the Isle of Man, then inequity can emerge between patient groups. For example, cancer patients can access all the newest treatments, but non-cancer patients and their clinicians cannot routinely access NICE TA-approved treatments for other conditions.
- 5. There are costs associated with managing a system to review each NICE TA and HST treatment request (such as review committees) that may not be required when a policy to approve all NICE TAs and HSTs is instituted. However, cost savings may be dependent on the system in place to review treatments that are not covered by NICE TAs and HST appraisals. For example, if the same



committee and panel reviews NICE TA- and HST- approved treatments and other treatments, then the savings associated by routinely approving all NICE TA and HST approved treatments may not be significant. Nonetheless, any cost savings associated with not having a policy to approve all NICE TAs and HSTs should be balanced against the costs of the alternative system that reviews each treatment request.

To conclude, any decision to increase funding of NICE TA- and HST-approved treatments is likely to incur opportunity costs that should be considered. If Guernsey opts to fund only some NICE TA- and HST-approved treatments, further implications, such as the introduction of inequity of access to treatment between patient or disease groups will also need to be considered.

6 Pathway exemplar

6.1 Introduction

As part of the NICE TA-approved drug and treatment review for Guernsey, there was a need to provide a case study to illustrate considerations (other than the direct cost of the drug or treatment) which may require consideration when deciding on a policy of routine adoption of NICE TA-approved treatments.

Following discussions with clinicians, pharmacists and the Director of Public Health, it was decided that a suitable case study would be Pembrolizumab for non-small cell lung cancer (NSCLC).

There are two relevant TAs:

- TA531: Pembrolizumab for untreated PD-L1 positive metastatic non-small cell lung cancer (NICE 2018b)
- TA 428: Pembrolizumab for treating PD-L1 positive non-small cell lung cancer after chemotherapy (NICE 2017b).

Pembrolizumab is not routinely funded in Guernsey, and as recently as January 2019, a request for its use for non-small-cell lung cancer was 'not approved' by the Prescribing and Formulary Panel.

In order to develop a common understanding of current treatment options, and identify the implications of adopting Pembrolizumab for the treatment of NSCLC, a workshop style meeting was set up to bring together key relevant professionals and service providers involved in the care and delivery of health services to people with non-small cell lung cancer.



6.2 Lung Cancer

There are two main types of primary lung cancer. These are classified by the type of cells in which the cancer starts. They are:

- **non-small-cell lung cancer** the most common type, accounting for more than 80% of cases; can be either squamous cell carcinoma, adenocarcinoma or large-cell carcinoma
- **small-cell lung cancer** a less common type that usually spreads faster than non-small-cell lung cancer

There are usually no signs or symptoms in the early stages of lung cancer, but many people with the condition eventually develop symptoms including:

- · a persistent cough
- coughing up blood
- persistent breathlessness
- unexplained tiredness and weight loss
- · an ache or pain when breathing or coughing

Treatment depends on the type of cancer, how far it's spread and how good your general health is.

If the condition is diagnosed early and the cancerous cells are confined to a small area, surgery to remove the affected area of lung is usually recommended.

If surgery is unsuitable due to your general health, radiotherapy to destroy the cancerous cells may be recommended instead.

If the cancer has spread too far for surgery or radiotherapy to be effective, chemotherapy is usually used.

For patients diagnosed with NSCLC, the treatment used will be dependent on the proteins expressed by the tumour. Not all patients with NSCLC will be eligible for Pembrolizumab as the treatment is targeted at NSCLC which expresses a protein called PD-L1. Treatments for PD-L1-positive non-small-cell lung cancer are limited and on average patients diagnosed with NSCLC have a life expectancy of less than 24 months.

Prognosis

As lung cancer has few symptoms until it becomes advanced and has spread through the lungs or into other parts of the body, people are often diagnosed with advanced disease. Approximately one third of people live for at least a year after they're diagnosed and about 1 in 20 people live at least 10 years. However, survival rates vary widely, depending on how far the cancer has spread at the time of diagnosis.

Epidemiology

Lung cancer is one of the most common and serious types of cancer. Around 44,500 people are diagnosed with the condition every year in the UK. Lung cancer is rare in



people younger than 40, and the rates of lung cancer rise sharply with age. It is most commonly diagnosed in people aged 70-74 (NHS Choices, Lung Cancer). Smoking is the main cause of lung cancer (accounting for over 85% of cases).

The incidence of lung cancer in Guernsey is similar to England (c.100 per 100,000 population). There were 140 new cases reported in 2014. Between 2012 and 2014, 109 people died due to lung cancer (Public Health England 2017).

In an audit conducted in Guernsey for the years 2010 to 2012, 70% of the 120 lung cancer cases were found to be non-small-cell lung cancer (84 cases) (Health and Social Care Information Centre 2012). More recently, an on-island consultant oncologist estimated that the annual numbers of non-small-cell lung cancer to be around 34 patients a year (80% of the estimated total cases a year).

6.3 Pembrolizumab

There are two NICE Technology Appraisals for Pembrolizumab for non-small cell lung cancer (NSCLC) published before 31st December 2018.

TA 428: Pembrolizumab for treating PD-L1-positive non-small-cell lung cancer after chemotherapy

- 1.1 Pembrolizumab is recommended as an option for treating locally advanced or metastatic PD-L1-positive non-small-cell lung cancer in adults who have had at least one chemotherapy (and targeted treatment if they have an epidermal growth factor receptor [EGFR]- or anaplastic lymphoma kinase [ALK]-positive tumour), only if:
 - pembrolizumab is stopped at 2 years of uninterrupted treatment and no documented disease progression, and
 - the company provides pembrolizumab in line with the commercial access agreement with NHS England.

TA 531: Pembrolizumab for untreated PD-L1-positive metastatic non-small-cell lung cancer

- 1.1 Pembrolizumab is recommended as an option for untreated PD-L1-positive metastatic non-small-cell lung cancer (NSCLC) in adults whose tumours express PD-L1 (with at least a 50% tumour proportion score) and have no epidermal growth factor receptor- or anaplastic lymphoma kinase-positive mutations, only if:
 - pembrolizumab is stopped at 2 years of uninterrupted treatment or earlier in the event of disease progression and
 - the company provides pembrolizumab according to the commercial access agreement.

Pembrolizumab is a drug that helps the body's immune system to recognise and destroy cancer cells. It is generally well tolerated by patients but a small proportion of people have immune-related adverse effects such as rash and colitis. The side



effects reported for pembrolizumab are more tolerable than those associated with existing platinum based combination chemotherapy treatments which tend to produce more significant side effects in more patients. During the NICE Technology Appraisal process, the NICE 'patient experts' explained that "symptoms can be debilitating, so improving quality of life, even with small extensions in length of life are of considerable importance to this patient group" (NICE 2018b).

For the indications in both TA428 and TA531, pembrolizumab provides a statistically significant median overall survival gain compared with the alternative (more detail in Tables 65 to 68).

Due to the short life expectancy of patients with PD-L1-positive NSCLC (average under 24 months), pembrolizumab is considered by NICE to meet the NICE 'life extending, end of life treatment' criteria. As such, it qualifies for a higher cost per QALY threshold. NICE concluded that pembrolizumab is a cost effective use of NHS money compared to standard care.

During the workshop, the clinicians estimated that on average, 13 patients per year are likely to meet the patient selection criteria for TA428 and TA531 above.

6.4 Workshop

The purpose of the workshop was to bring together a range of specialists all of whom are involved in the delivery of services for patients with NSCLC and create a common understanding of:

- 1. current treatment
- 2. planning implementation of the new treatment

The following points were explored:

- the current treatment pathway for patients with NSCLC (assuming no access to pembrolizumab via private health insurance or personal funding)
- the NSCLC disease burden in Guernsey and Alderney
- the evidence of clinical and cost effectiveness presented in the NICE TA documentation e.g. life years gained and quality of life
- the potential numbers of patients in Guernsey and Alderney
- drug acquisition costs
- off-setting of costs associated with the introduction of Pembrolizumab
- the service delivery and support services required, including human resource
- unique considerations to the States of Guernsey

The workshop was attended by nine stakeholders including two oncologists, a cancer nurse specialist, two pathologists, three pharmacists and a finance officer for the hospital.

6.5 Findings

The workshop held on Friday 5th April achieved the key aims of identifying the current treatment, and estimating high level financial and service delivery resource



required for both current treatments and future treatment (assuming pembrolizumab is adopted). In lieu of confirmed figures, the workshop group also came to an agreement on estimated patient numbers (see below tables).

TA428: Pembrolizumab for treating PD-L1-positive non-small-cell lung cancer after chemotherapy

Tables 65 and 66 present the findings associated with TA428 for locally advanced or metastatic PD-L1-positive non-small-cell lung cancer after previous treatment with chemotherapy. It presents the estimated resource and financial costs for the current standard platinum based chemotherapy treatment funded by the States of Guernsey compared to the associated resource and financial costs for treatment with pembrolizumab.

For this indication, pembrolizumab is more costly (estimated at £194,000 total a year for all patients) and requires eight more infusions annually than the current treatment. Some of the financial and staff cost may be offset by a reduction in supportive care required due to fewer and less severe side-effects. The cost offset may be modest in terms of service delivery resource. The median overall survival increases by approximately 2 months and there is an increase in quality of life experienced by the patients due to reduction in debilitating side-effects.



Table 65: Comparison of annual treatment and costs between current and future treatment if Pembrolizumab is routinely adopted for previously chemotherapy treated locally advanced or metastatic PD-L1-positive non-small-cell lung cancer (TA428)

TA 428 Indication: locally advanced or metastatic PD-L1-positive non-small-cell lung cancer in adults who have had at least one chemotherapy

chemothe	erapy			· ·			
	Estimated number of Patients	Treatment	Dose per cycles	Average no of Infusions/ cycles	Estimated cost of drug per cycle	Pathology Tests Initial	Pharmacy Services Required
Current Treatment	6+	Docetaxel	Average 75 mg /m² every 21 days	6	c.£1,000 per cycle Total cost of treatment: £6000	EGFR ALK PD-L1 These are one off Not currently funded	1.5 hours per bag
NICE recommended treatment (pembrolizumab)	6+	Pembrolizumab monotherapy	2mg / kg every 21 days	14 (stop at disease progression or 2 years)	c. £2735 per cycle ¹⁰ . Estimated Total cost per patient: £38,293	FBC U&E Ca LFT CEA Fewer Blood transfusions less frequent blood tests	1.5 hours per bag PLUS only one bag of monoclonal antibody drug can be made up at a time. The isolator needs to be sterilised before and after each bag is made up.
Per patient comparison	Same	n/a	n/a	8 more infusions	Total Cost increases by an average £32,293 per patient	More test but possibly less blood transfusions	At least 12 more hours pharmacy required per patient
Total annual comparison (all patients)	0	n/a	n/a	8 more infusions	£193,758	More test but possibly less blood transfusions	72 hours

¹⁰ Pembrolizumab has a confidential commercial arrangement. Therefore, costs have been estimated by applying the average reduction of all commercial arrangements (44%) to the list price.



Table 66: Comparison of resource usage and outcome between current and future treatment if Pembrolizumab is routinely adopted for previously chemotherapy treated locally advanced or metastatic PD-L1-positive non-small-cell lung cancer (TA428)

TA 428 I chemoth	•	y advanced or i	metastatić l	PD-L1-positive r	non-small-cell lui	ng cancer in adults who have had at least one
	Hospital Resources	Life Expectancy	Duration of treatment	Monitoring -radiology -MDT -pathology	Adverse events hospital - Other treatments	Other care - Palliative care - home support - radiotherapy
Current Treatment	c.2 hours nurse time each cycle	Median Overall Survival 8.6 months	4-5 months	No set protocol Chest x-ray CT Scan	More blood transfusions required due to neutropenic sepsis	Drug support Prophylactic antibiotics More nursing care in between cycles in view of side effects e.g. nausea / vomiting / neutropenia / stomatitis / constipation/ neuropathy / fatigue.
NICE recommended treatment (pembrolizumab)	c.2 hours nurse time each cycle	Median Overall Survival 10.5 Months	Median 10.5 months	No set protocol Chest x-ray CT Scan	Avoids neutropenic sepsis	The improved tolerance to treatment with pembrolizumab (an immune therapy) compared to chemotherapy is associated with improved of quality of life. This is expected to require less supportive nursing care. After disease progression and stopping treatment with pembrolizumab, the palliative care support for all patients is likely to be similar.
Per patient comparison	As 8 more infusions are needed, 16 hours of additional nurse time	Median additional survival 1.9 months	4.5 to 5.5 additional months of treatment	Similar	Less severe side effects e.g. neutropenic sepsis are experienced by fewer patients.	Quality of life is improved on future treatments (pembrolizumab), therefore less supportive nursing care required. After disease progression or at the end of the treatment with pembrolizumab, the palliative care requirements are expected to be similar to patients who were treated with chemotherapy.
Total annual comparison (all patients)	c. 128 hours additional nurse time needed	Median improvement in survival : 1.9 months	4.5-5.5 additional months of treatment	Similar	Less severe side effects experienced by fewer patients.	Fewer side-effects means less supportive nursing care and treatment of adverse events will be required while undergoing treatment. Patients treated with pembrolizumab are expected to live for an additional 2 months, requiring health services for that duration.



TA 531:Pembrolizumab for untreated PD-L1-positive metastatic non-small-cell lung cancer

Tables 67 and 68 present the findings associated with TA531 for previously *untreated PD-L1-positive metastatic non-small-cell lung cancer*. It presents the estimated resource and financial costs for the current standard platinum based chemotherapy treatment funded by the States of Guernsey compared to the associated resource and financial costs for treatment with pembrolizumab.

The implementation of pembrolizumab for the estimated 7 patients who are likely to meet the criteria in TA531 is estimated to cost over £574,574 per annum. Although this reflects the net cost of the drugs, this may over-estimate the actual funding required. This is because the financial cost may be further offset by the reduction in supportive care required due to fewer and less severe side-effects but it is unlikely to offset a major proportion of the additional drug costs. Pembrolizumab is associated with increased survival as well as increased quality of life due to reduction in debilitating side-effects. Patients treated with pembrolizumab are expected to live for an additional 16 months, requiring health services for that duration.



Table 67: Comparison of annual treatment and costs between current and future treatment if Pembrolizumab is adopted for previously untreated PD-L1-positive metastatic non-small-cell lung cancer (TA531)

		TA531 li	ndication: untreated F	PD-L1-positive m	netastatic non-small-o	cell lung cancer	
	Estimated number of Patients	Treatment	Dose - Cycles	No of Infusions	Estimated cost of drug per cycle	Pathology Tests Initial	Pharmacy Services Required
Current Treatment	7+	GEMCarbo (gemcitabine and carboplatin) Plus maintenance pemetrexed	4 - 6 cycles Every 3 weeks	8-12 (2 infusions per cycle) 8 ¹¹	£153 per cycle Total cost £600- £900 c.£12,000	Blood tests required every 2-3 weeks Blood transfusions	1.5 hours per bag
NICE recommended treatment (pembrolizumab)	7+	Pembrolizumab	200mg every 3 weeks up to disease progression or 2 years	34 based on 2 years	£2767 per cycle Total for 1 year: £47,041 ¹² Total for 2 years: £94,082	Every 3 weeks for up to 2 years	Individual prescriptions need to be made up in isolation: 1.5 hours per bag. In addition, the isolator needs to be sterilised before and after each bag is made up.
Per patient comparison	same	n/a	n/a	c.22	Additional c.£82,082 per patient	As patient live longer on average 8 months extra treatment. 11 additional pathology tests per patient	Additional 8 months of input means 16.5 additional input per patient.
Total annual comparison (all patients)	0	n/a	n/a	22	Additional £574,574 per annum	77 additional pathology tests	Additional 115.5 hours of pharmacy time required each year

¹¹ Taken from TA190: https://www.nice.org.uk/guidance/ta190/chapter/4-Consideration-of-the-evidence

¹² Pembrolizumab has a confidential commercial arrangement. Therefore, costs have been estimated by applying the average reduction of all commercial arrangements (44%) to the list price.



Table 68: Comparison of resource usage and outcome between current and future treatment if Pembrolizumab is adopted for previously untreated PD-L1-positive metastatic non-small-cell lung cancer (TA531)

		TA531 Indication	on: untreate	d PD-L1-positi	ve metastatic non-small-cell lung can	cer
	Hospital Resources	Life Expectancy	Duration of treatmen t	Monitoring -radiology - MDT -pathology	Adverse events hospital - Other treatments	Other care - Palliative care - home support - radiotherapy
Current Treatment	3 hours nurse time for each cycle.	14.2 months (Median Overall Survival)	3-4 months (GEMCar bo) 10 months Pemetrex ed	4 scans	Most patients experience adverse effects. 20% of patients require hospital admission within the first 3 months. Blood transfusions Home appointments. Fatigue / breathless / constipation.	Prophylactic antibiotics Growth factor: Neutropenic to prevent admission Radiotherapy not available on the island so some patients as unable to travel will not get it.
NICE recommended treatment (pembroliz- umab)	1.5 / 2 hours nurse time each cycle	30 months (Median Overall Survival)	2 years	4 scans in a year 8 scans in 2 years	Less likely to require admission. After treatment they have less adverse effects. If there is going to be any admissions it is usually 10% of the patients within first 3 months	Patients treated with pembrolizumab are expected to live for an additional 16 months, requiring health services for that duration.
Per patient comparison	Additional 31 hours required per patient (if no extra resources required for Pemetrexed).	16 month improvement in median overall survival.	2 years	additional 4 scans per patient	Less severe side effects e.g. neutropenic sepsis are experienced by fewer patients.	Quality of life is improved on treatment with pembrolizumab - less supportive nursing care is required. After disease progression or at the end of the treatment with pembrolizumab, the palliative care requirements are expected to be similar to patients who were treated with chemotherapy.
Total annual comparison (all patients)	Based on assumptions, an additional 217 hours nurse time would be required per year	The median overall survival for pembrolizumab is 30 months, which is c. 16 months longer than the median OS associated with treatment with platinum based chemotherapy combination.	2 years	Additional 42 scans per year	Savings from reduced adverse events (unquantified)	Fewer side-effects means less supportive nursing care and treatment of adverse events will be required while undergoing treatment. Patients treated with pembrolizumab are expected to live for an additional 16 months, requiring health services for that duration.



6.6 Conclusion

This example makes clear that drug acquisition costs alone are not the only consideration when adopting NICE TA-approved treatments. Other service delivery resources need to be taken into account when implementing new treatment pathways.

Outpatient appointments, ward attendances and associated nurse time, pharmacy services required to make up and deliver intravenous treatments, hospital admissions required to treat adverse events are all factors that should all be included in the decision making process.

In this example, the same drug (pembrolizumab) is used to treat the same disease (PD-L1-positive non-small cell lung cancer) with two slightly different indications.

TA428 recommends pembrolizumab as an option for treating locally advanced or metastatic PD-L1-positive non-small-cell lung cancer in adults who have had at least one chemotherapy (and targeted treatment if they have an epidermal growth factor receptor [EGFR]- or anaplastic lymphoma kinase [ALK]-positive tumour).

TA 531 recommends pembrolizumab as an option for untreated PD-L1-positive metastatic non-small-cell lung cancer (NSCLC) in adults whose tumours express PD-L1 (with at least a 50% tumour proportion score) and have no epidermal growth factor receptor- or anaplastic lymphoma kinase-positive mutations.

The price of pembrolizumab for both indications is subject to the same commercial access agreement for both indications. However, not all NICE TAs should be considered equal in clinical effectiveness. The improvement in median survival for patients previously treated with chemotherapy is less than 2 months, whereas the increased median survival those patients who meet the criteria specified in TA531 is 16months. This is indicative of how vastly different TA-approved treatments can be, both in terms of clinical effectiveness and net cost.

Although out of scope of this review, we noted that NICE published a further set of recommendations in January 2019: <u>Pembrolizumab with pemetrexed and platinum chemotherapy for untreated, metastatic, non-squamous non-small-cell lung cancer (TA557)</u>.

In this recommendation, pembrolizumab is an add on therapy and does not replace standard treatment with pemetrexed and platinum chemotherapy. This would minimise the potential cost offset of drug treatment and side effect management. It is unknown if there would be additional patients further to those already identified.



- 1.1 Pembrolizumab, with pemetrexed and platinum chemotherapy is recommended for use within the Cancer Drugs Fund, as an option for untreated, metastatic, non-squamous non-small-cell lung cancer (NSCLC) in adults whose tumours have no epidermal growth factor receptor (EGFR)- or anaplastic lymphoma kinase (ALK)-positive mutations. It is only recommended if:
 - pembrolizumab is stopped at 2 years of uninterrupted treatment or earlier if disease progresses and
 - the company provides pembrolizumab according to the <u>managed access</u> <u>agreement</u>.

6.7 Recommendation

Currently, the Guernsey Prescribing Advisor produces summaries of NICE TA-approved treatments which have been requested by clinicians for the PAF Panel to review. Even if a 'fund all' NICE TA-approved treatments policy is adopted, a consolidation of the key health benefits, adverse events, and cost-effectiveness information could still be valuable for planning funding and access to new treatments approved by NICE. The tables above could offer a standard approach to presenting the information to make comparison with current treatment easy.



7 Summary of findings and recommendations

7.1 Findings – Impact of funding currently unfunded NICE TAs:

The primary focus of this Review is to provide the best estimate of the impact of funding all 160 currently unfunded treatments for specific indications approved by the NICE Technology Appraisal (TA) process, if these were funded for all patients eligible for State funded healthcare in Guernsey and Alderney. These include 156 drug treatments (of which 88 are for the treatment of cancer) and 4 non-drug treatments. Our analysis shows that 320 NICE TA-approved treatments are already funded for patients in Guernsey and Alderney.

Direct recommendations arising from the impact of funding currently unfunded NICE TAs are outside the scope of this Review, and are a matter for the States.

By combining both qualitative and quantitative approaches, we have identified a range of commissioning options for the Committee for Health and Social Care to consider for adoption. These options range from routine full adoption of all NICE TA-approved treatments (approved up to 31st December 2018 and ongoing) through to maintaining the status quo, with a number of part- or phased- implementation options in between should it be decided that full implementation is unjustified or unaffordable.

The 6 key options identified were:

- 1. Fund all NICE TA-approved treatments
- 2. Prioritise all NICE TA-approved treatments for cancer
- 3. Prioritise NICE TA-approved life extending, at the end of life (EoL) treatments
- 4. Prioritise NICE TA-approved treatments for common diseases
- 5. Prioritise NICE TA-approved treatments on the basis of (clinical and) cost effectiveness
- 6. Status quo continue with the current system of individually reviewing the NICE evidence of clinical and cost effectiveness

The estimates of costs for each option are explained in Section 4. These reflect the likely discounts that the islands can achieve for the new treatments, as well as the potential cost offset of replacing existing drugs with the TA-approved treatments. The estimates are based purely on the estimated number of patients who meet all the treatment criteria specified in each NICE TA recommendation. The use of the treatments for wider indications beyond the NICE TA is outside of the scope of this Review.

It is important to note that the estimated financial provision of each option is for unfunded TA-approved treatments published before 2019. It does not include provision for the 70+ TAs expected to be published during 2019.



The estimated cost impact for each option does not include associated service delivery costs (staff, equipment, diagnostics, facilities) or hospital revenue loss from patients who currently pay for treatment via private insurance or private means. It was not possible to estimate the difference in health gain (or loss) for each option as this information is missing or redacted in a large proportion of the NICE TA supporting documentation.

The number of patients reflects estimates provided by on and off-island consultants. This approach was adopted because the NICE TAs do not consistently contain the patient numbers for England which could be pro-rata'd for the Guernsey and Alderney population. Relying on NICE for this information was therefore less useful than employing local clinicians' estimates.

The strengths and the weaknesses of each option are highlighted in Table 69 below.



Table 69: Summary of options and implications for the implementation of funding NICE TA-approved treatments in Guernsey and Alderney.

	Recomm	er of TA nendations/ TAs		ber of ients	Net Co	st Impact		
Option	Number of TA Recommendations	Number of TAs	Backlog	New patients per annum	Backlog patients	New patients per annum	Strengths	Weaknesses
Option 1: Fund all NICE TA-approved treatments All new treatments reviewed and recommended in a NICE TA will be funded by the States for all patients who meet the patient selection criteria	160	145	3,348	782	£7.6m	£5.5m	All patients who meet the NICE TA selection criteria will be treated regardless of: • the location of their treatment • their ability to pay • the cost of the treatment • how many other people have the same condition This will result in equity of access to treatments already funded by the NHS for patients in England. There is potential to re-focus some prescribing and formulary panel activity towards planning and implementation rather than the funding decision process.	Significant investment will be required in order to deal with the backlog of unfunded TAs. The estimated financial provision is for unfunded TAs published before 2019. It does not include provision for the 70+ TAs expected to be published during 2019. Some treatments are very high cost, and as an island population it is not possible to risk share the budget. 72 (45%) NICE TA-approved treatments are not cost effective within an ICER<£30,000 per QALY. New inequities will be introduced: Treatments not reviewed by NICE TAs are less likely to be able to secure funding. The opportunity costs will be borne by patients with



								treatments/conditions not covered by a NICE TA.
								Since the NICE TA programme is targeted at manufacturer sponsored drug therapies, this will exaggerate the inequity between priority for drugs and non-drug treatments. The process for making funding decisions about treatments will need to continue to consider requests for treatments that the NICE TA guidance will not cover. This could be using drugs for a different indication, devices, surgical interventions, new services,
								screening or prevention interventions etc.
								The health economy would lose the flexible approach to adopting NICE TA guidance. This might mean paying more for treatments when an alternative is available for a much lower cost e.g. intravitreal drug treatments for age related macular degeneration.
								This option values new treatments, particularly new drugs, recommended by NICE more highly than all other treatments.
Option 1a:	152	137	3,344	777	£6.9m	£4.5m	Except for HSTs:	HST approved treatments excluded
Fund NICE TA- approved							All patients who meet the NICE TA selection criteria will be treated	in this optionThe HST appraisal route is



treatments except Highly Specialised Technologies (HST) This option includes routine funding for all treatments approved by NICE TAs except for those appraised as a Highly Specialised Technology.		regardless of: • the location of their treatment • their ability to pay This will result in equity of access to treatments already funded by the NHS for patients in England. There is potential to re-focus some prescribing and formulary activity toward implementation rather than funding decision. Budget will not be reserved unnecessarily for rare conditions where there may be no uptake due to the absence of patients residing in Guernsey and Alderney.	reserved for treatments for orphan diseases only and consequently the cost of treatment is very high. There may be no patients on the islands for some of the treatments and associated indications recommended in the seven HSTs. • Even after discount, the gross cost of an HST treatment for one patient per annum ranges from over £100,000 to c.£500,000. • Patients with a very rare disease for which there is a high cost treatment recommended in a NICE TA will be denied funding on the basis of the:
			 cost of the treatment rarity of the condition This will create inequity between patients who receive care under the NHS in England and patients who rely on the States of Guernsey for their health care. The high cost of treatment, combined with the need to be taken by the patient for the rest of their life means that it is unlikely that any patient would be able to fund treatment



			privately.
			This option considers the merits of treatments and values cost effectiveness more highly. Patients whose condition is, by chance, rare are not favoured.
			Funding the TA-approved treatments included in this option:
			 Significant investment will be required in order to deal with the backlog of unfunded TAs.
			68 (44%) NICE TA-approved treatments are not cost effective within an ICER<£30,000 per QALY.
			 New inequities will be introduced:
			 treatments not reviewed by NICE TAs are less likely to be able to secure funding. The opportunity costs will be borne by patients with treatments/conditions not covered by a NICE TA.
			 since the NICE TA programme is targeted at manufacturer sponsored drug therapies, this will exaggerate the inequity between priority for drugs and non-drug treatments.
			The process for making funding



								decisions about treatments will need to continue to consider requests for treatments that the NICE TA guidance will not cover. This could be using drugs for a different indication, devices, surgical interventions, new services, screening or prevention interventions etc.
Option 2: Prioritise all NICE TA- approved treatments for Cancer over treatments for other conditions All new treatments for cancer	88	84	114	98	£3.2m	£3.2m	All patients with cancer who meet the NICE TA patient selection criteria will be treated regardless of: the location of their treatment their ability to pay the cost of the treatment how many other people have cancer Cancer treatments for the EoL or	Significant investment will be required in order to deal with the backlog of unfunded TAs for treatments for cancer. 59 (67%) NICE TA-approved treatments for cancer which would be funded within this option are not cost effective within an ICER<£30,000 per QALY. Prioritising funding for one category of disease only i.e. cancer may be
recommended in a NICE TA will be funded by the States for all patients who meet the patient selection criteria							approved as part of the CDF are included. This will result in equity of access to treatments for cancer already funded by the NHS for patients in England. There is potential to re-focus some prescribing and formulary panel activity toward planning and	considered irrational as it does not take into account the needs of that patients group, their prognosis, alternative treatment options, the extent to which their condition is lifechanging etc. Support from the stakeholders consulted during this Review was equivocal
							implementation rather than the funding decision process. Over half of the unfunded TA recommendations would be	44% of unfunded TAs are for treatments for conditions other than cancer. These treatments could be equally or more clinically and cost effective than the 88 cancer drugs



							funded [56% of the unfunded NICE TAs are for drugs for cancer (88/156)].	identified in this option. Patients who do not have cancer would not have funding for treatments recommended by NICE TA, solely on the basis of the category of disease. This option values one disease only, rather than the merits of the individual treatments. There is inequity solely on the basis of the type of disease.
Option 2a: Prioritise NICE TA-approved treatments for Cancer excluding those in the Cancer Drugs Fund (CDF) This option prioritises treatments for cancer which have been recommended by a NICE TA as being clinically and cost effective.	49	47	61	52	£1.2m	£1.2m	This option offers: equitable access for cancer treatments proven to meet the NICE criteria for clinical and cost effectiveness access to EoL cancer treatments which have a higher cost per QALY It excludes treatments approved in the CDF due to the uncertainty about the evidence and cost effectiveness. It will provide access to these cancer drugs regardless of: the location of treatment the patient's ability to pay the cost of the treatment how many other people have the same condition	treatments for cancer are not cost effective within an ICER<£30,000 per QALY. This option excludes TA-approved drugs likely to be part of the CDF for 24 months. This means that this option would delay access to treatment with these drugs for approximately 2 years whilst patients treated in England are routinely treated with these drugs. In addition, funding these drugs at the agreed discounted price during the CDF period, contributes to posthoc data collection and evidence. All other treatments are excluded including: NICE TA-approved treatment for other conditions



								44% of unfunded TAs are for treatments for other conditions. These treatments could be equally or more clinically and cost effective than the 88 cancer drugs identified in this option.
								Patients who do not have cancer would not have funding for treatments recommended by a NICE TA, solely on the basis of the category of disease.
								There was no consensus from the engagement feedback that EoL cancer treatment should be prioritised over other treatments.
								This option values one disease only, and selectively values the merits of individual treatments.
Option 2b: Prioritise NICE TA-approved treatments for Cancer only from the Cancer Drugs Fund	All CDF treatme nts only 39	38	53	46	£2.1m	£2.0m	Funding treatments in the CDF would contribute to improving the evidence base for these drugs. Patients would have early access to these treatments regardless of: the location of treatment the patient's ability to pay	Significant investment will be required in order to deal with the backlog of unfunded TAs for CDF cancer drugs. These treatments have insufficient evidence of clinical and cost effectiveness for NICE to approve them in a TA.
This option selects only those treatments for cancer which are part of the Cancer Drugs Fund.							 the cost of the treatment how many other people have the same condition 	30 (77%) NICE TA-approved treatments are not cost effective within an ICER<£30,000 per QALY. There are other treatments for cancer and other conditions which have been approved by NICE for which there is stronger evidence of



		clinical and cost effectiveness.
		It is not logical to fund research, but deny access to treatments already proven to be clinically and cost effective by NICE.
		New inequities will be introduced:
		 Patients who do not have cancer would not have funding for treatments recommended by a NICE TA, solely on the basis of the category of disease.
		 Treatments not reviewed by NICE TAs are less likely to be able to secure funding. The opportunity costs will be borne by patients with treatments/conditions not covered by a NICE TA.
		• Since the NICE TA programme is targeted at manufacturer sponsored drug therapies, this will exaggerate the inequity between priority for drugs and non-drug treatments.
		The process for making funding decisions about treatments will need to continue to consider requests for treatments that the NICE TA guidance will not cover. This could be using drugs for a different indication, devices, surgical interventions, new services, screening or prevention interventions etc.



								This option values one disease only, rather than the merits of individual treatments
Option 3: Prioritise NICE TA-approved life extending, at the end of life (EoL), treatments	51	49	74	62	£1.8m	£1.8m	Patients with cancer or other terminal illnesses who may benefit from life extending treatment near the end of their life will have access to the same treatments as patients in England regardless of: the location of treatment the patient's ability to pay the cost of the treatment	Significant investment will be required in order to fund the backlog and future requirement for unfunded life extending treatments for patients at the end of life. The estimated financial provision is for unfunded TAs published before 2019. It does not include provision for the 70+ TAs expected to be published during 2019.
						how many other people have the same condition	Prioritising treatments for the EoL was not identified as a priority for funding by stakeholders during engagement interviews and events.	
								EoL treatments usually have an ICER between £30,000 and £50,000 per QALY i.e. they are less cost effective than non EoL cancer drugs and treatments for other conditions.
								New inequities will be introduced:
								All unfunded EoL TA treatments currently approved by NICE are for cancer. Patients who do not have cancer would not have funding for treatments recommended by a NICE TA, solely on the basis of the category of disease.
								Treatments not reviewed by NICE TAs are less likely to be able



								to secure funding. The opportunity costs will be borne by patients with treatments/conditions not covered by a NICE TA. • Since the NICE TA programme is targeted at manufacturer sponsored drug therapies, this will exaggerate the inequity between priority for drugs and non-drug treatments. The process for making funding decisions about treatments will need to continue to consider requests for treatments that the NICE TA guidance will not cover. This could be using drugs for a
								different indication, devices, surgical interventions, new services, screening or prevention interventions etc.
								This option values the late stage of disease for one disease only, rather than the merits of the individual treatments.
Option 4:	44	40	3,221	679	£3.6m	£1.3m	There is no definition of 'common'. In this Review, a	Significant investment will be required in order to deal with the
Prioritise NICE TA-approved treatments for common diseases							common condition is one where there are 5 or more backlog patients across Guernsey and Alderney who meet the patient selection criteria for that	backlog of unfunded TAs. Although the ICER is low and well within the accepted range used by NICE, the cost impact is high due to the likely numbers of patients
This option attempts to maximise the							intervention. All patients who meet the NICE TA treatment criteria for a 'common' condition will be	expected to be eligible for treatment.



value of funding TA-approved treatments to the greatest number of people in Guernsey and Alderney. Option 5:		treated regardless of: • the location of their treatment • their ability to pay • the cost of the treatment This will result in equity of access to TA-approved treatments for common conditions already funded by the NHS for patients in England. For these patients (the majority), the ICER for treatments for common indications is usually below £30,000 per QALY indicating that the treatment is considered by NICE to be cost effective. There is potential to re-focus some prescribing and formulary panel activity towards planning, implementation and audit rather than the funding decision process. NICE already uses cost	 New inequities will be introduced: This option will discriminate against people who need treatment for rarer conditions or who need life-extending treatments at the end of their life. Treatments not reviewed by NICE TAs are less likely to be able to secure funding. The opportunity costs will be borne by patients with treatments or conditions not covered by a NICE TA. Since the NICE TA programme is targeted at manufacturer sponsored drug therapies, this will exaggerate the inequity between priority for drugs and non-drug treatments. The process for making funding decisions about treatments will need to continue to consider requests for treatments not covered by NICE TAs e.g. different indications, devices, surgical interventions, new services, screening or prevention interventions etc. This option values the number of patients with the disease, rather than the merits of the treatment itself.
Prioritise NICE		effectiveness of a treatment as a	£20k per QALY, significant

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cost effective treatments will priority for drugs and non-drug result in equity of access to treatments considered to provide the most value for manage. The process for making funding	TA-approved treatments on the basis of (clinical and) cost effectiveness <£20k per QALY <£30k per QALY <£40k per QALY <£50k per QALY <£100k per QALY	27 71 93 124 138	24 67 88 119 130	1,928 2,769 3,073 3,120 3,141	338 630 678 721 737	£1.3m £3.1m £4.7m £5.9m £6.7m	£0.5m £1.5m £2.5m £3.8m £4.4m	result in equity of access to treatments considered to provide	
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							There is potential to re-focus some prescribing and formulary panel activity towards planning, implementation and audit rather than the funding decision process.	need to continue to consider requests for treatments that the NICE TA guidance will not cover. This could be using drugs for a different indication, devices, surgical interventions, new services, screening or prevention interventions etc. This option values the merits of individual treatments for specific indications, rather than patient attributes or disease incidence or category of disease.
Option 6: Status quo - continue with the current system of individually reviewing the NICE evidence of clinical and cost effectiveness, if requested by a Consultant or GP	0	0	0	0	£0m	£0m	Existing process has resulted in funding for 320 out of 480 (66%) NICE TA recommendations published to the end of 2018. Process attempts to balance the needs of all patients regardless of whether the treatment that they need has been reviewed by NICE. Decisions are made by the States of Guernsey for the local population. Decisions should be based on maximising health within the allocated budget and be consistent with the health needs of the Guernsey population.	Patients can only access some NICE TA-approved treatments on the basis of their ability to pay. Lack of transparency about the fact that many treatments are not funded by the States, which is unwelcome news for individual patients at a time when they are vulnerable and planning for such an eventuality, is too late. Dissatisfaction with the apparent rigid application of cost effectiveness threshold: • apparent rejection of some treatments which appear to have ICER below £20k to £30k per QALY threshold Process is slow if there is a patient who needs the drug – it cannot be approved as an IFR because there



			may be more patients who need it but the service development route is too slow.
			Key operational issues would still need to be resolved in order to regain regard and confidence in the decision process and rules:
			 consistency between different decision making bodies e.g. Prescribing and Formulary (PAF) panel and Corporate Management Team (CMT)
			 consistency in funding being available following a PAF decision
			 variation between consultant applications – both content and enthusiasm
			 facilitation of applications from off island consultant
			 policy decisions and the rationale for them need to be easily retrievable and publically accessible
			This option values the merits of individual treatments for specific indications, rather than patient attributes or disease incidence or category of disease.



7.2 Recommendations arising from review of policy documentation and qualitative information from interviews, meetings and engagement events:

In Section 3.5 above, we reviewed policy documentation and qualitative information from interviews, meetings and engagement events, identifying a range of issues and themes. We developed a number of key recommendations to address some of these issues and themes. These are summarised as follows:

The reasons why some NICE TA-approved treatments are not funded is due in part to the current principles and processes adopted by CfHSC.

Dissatisfaction with the principles, rules and process described in G1033 and the decisions of the relevant committees (PAF Panel, Corporate Management Team) indicate that it is timely to review the principles and process which determine both policy and the framework against which individual funding request decisions are made.

- The policy development criteria and process described in G1033 would benefit from a diagrammatic description of the end-to-end process starting with a clinician (or other party) submitting a request for a new treatment to be funded, through to the treatment being approved and funded, or not approved.
- There is a need for clear and publicly available information about the appeals process for both decisions about IFR and service developments (drugs and non-drugs). This would improve transparency and regard for the policy development process. There is already a description of the appeals process for treatments turned down by the IFR panel (CfHSC 2017c) but the appeals process for treatments regarded as service developments is not published in the policy "G1033: Priority setting in Health and Social Care" (CfHSC 2017a), rather it is written into the Terms of Reference of the PAF. These are not published on the States of Guernsey website for clinicians to refer to if they believe that a policy development decision for a treatment or drug needs to be reviewed. There is no published appeals process for non-drug service development decisions made by CMT.
- A clear process needs to be developed and described for considering treatments that an off-island Consultant has recommended where that Consultant has not complied with the Guernsey request process. If no such process exists e.g. for the GP or an on-island Consultant to apply on their behalf, then the patient is left without a clinical advocate. They may resort to funding the treatment themselves or remaining untreated or inappropriately treated.
- The policy development process needs to ensure that the different policy committees apply the same principles and rules when making decisions. The online publication of minutes (both the decisions and decision rationale) of all policy development committees (PAF and CMT) would facilitate transparency and



confidence in the process adopted by CfHSC and the people responsible for delivering the process.

 A unified process for funding treatments approved by PAF Panel or CMT needs to be developed, in order to be able to be able to implement the decisions made using the principles described in G1033.

Together these improvements to the policy development process aim to improve the transparency and understanding of the process and decisions for patients and clinicians. They may also encourage clinicians from a wider range of clinical specialties who are unfamiliar with the process to engage with it and submit objective and competent proposals. In operating a restrictive policy development process, it is important to fund the approved treatments, in order to gain buy-in and due regard for decisions to not approve other treatments.

Communication & information

- Investment in communication and a single online source of policy decisions and rationale would alleviate the dissatisfaction and misunderstanding about which treatments are or are not funded regardless of whether they are drugs/non-drugs or NICE TA-approved or not.
- The omissions, and the lack of an explanation that the White List is not a definitive list of funded and unfunded drug treatments, appear to contribute to clinician and patient dissatisfaction about the transparency of funding for treatments. The A-Z list of funded and non-funded treatments is also difficult to comprehend. There are a large number of NICE TA-approved drug treatments which are not funded and not on the A-Z list. There are also treatments which are funded and not listed on the White List. We were only able to verify the funding arrangements for each of the individual 160 NICE TA-approved treatments and indications by liaising directly with individual professionals in Guernsey. This confirms that there is a lack of transparency about treatments which are funded and unfunded by the States of Guernsey.

The extent to which the States decide to fund NICE TA-approved treatments both now and in the future will be largely influenced by the adherence to existing financial constraints or deliberate additional financial provision. Regardless of the outcome of the Options Appraisal, addressing the process, communication and transparency issues discussed in this Review is just as important. Together with the funding for new treatments, the operation of the adopted principles, rules and process for policy development contributes to the delivery of key aims of 'A Partnership of Purpose', particularly:

- **User-centred care:** joined-up services, where people are valued, listened to, informed, respected and involved throughout their health and care journey;
- Fair access to care: ensuring that low income is not a barrier to health, through proportionate funding processes based on identified needs



- **Focus on quality:** measuring and monitoring the impact of interventions on health outcomes, patient safety and patient experience;
- A universal offering: giving islanders clarity about the range of services they can expect to receive, and the criteria for accessing them.



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9 Abbreviations and glossary of key terms

AGEM CSU - Arden and Greater East Midlands Commissioning Support Unit

BNF - British National Formulary

CAMHs - Child and Adolescent Mental Health Services

CDF - Cancer Drugs Fund

CHAT – Choosing Healthplans All Together

CfHSC - Committee for Health and Social Care

CMT – Corporate Management Team

CRC - Clinical Recommendations Committee (Isle of Man)

CVD - Cardio-Vascular Disease

DHSC - Department of Health and Social Care (Isle of Man)

DTC - Drugs and Therapeutic Committee

EoL - Treatments at the end of life

ESS - Employment and Social Security

GP - General Practitioner

HEAL - Health Equity for All

HST – Highly Specialised Technology

ICER - Incremental Cost Effectiveness Ratio

IFR - Individual Funding Request

LTC – Long Term Condition

LY – Life Years (gained/lost)

MDT - Multi-Disciplinary Team

MTEP – Medical Technologies Evaluation Programme

NDPB – Non Departmental Public Body

NHS - National Health Service

NICE - National Institute for Health and Care Excellence

PAF – Prescribing and Formulary (panel)

PBAC – Pharmaceutical Benefits Advisory Committee



QALY – Quality Adjusted Life Year

QoL - Quality of Life

SMC - Scottish Medicines Consortium

SPC – Summary of Product Characteristics

SPH – Solutions for Public Health

TA - Technology Appraisal

USA - United States of America

VAT - Value Added Taxation

Cost-effectiveness analysis

An analysis that assesses the cost of achieving a benefit by different means. The benefits are expressed in non-monetary terms related to health, such as symptom-free days, heart attacks avoided, deaths avoided or life years gained (that is, the number of years by which life is extended as a result of the intervention). Options are often compared on the cost incurred to achieve 1 outcome (for example, cost per death avoided).

End of life medicine

A medicine used to treat a condition at a stage that usually leads to death within two years with currently available treatments. NICE considers that treatments for patients with a short life expectancy, normally less than 24 months, which offer an extension to life, might be recommended, even if the cost per QALY is higher than the usual threshold of £30,000.

Incremental Cost Effectiveness Ratio

See under QALY

Intervention

This could be Drugs, medical devices (such as artificial hip joints), diagnostic techniques, surgical procedures and other treatments to improve health or prevent ill health Examples of public health interventions could include action to help someone to be physically active or to eat a more healthy diet.

NICE Guidance

Evidence-based recommendations produced by NICE. There are 6 types of guidance:

- guidelines covering clinical topics, medicines practice, public health and social care
- diagnostics guidance
- highly specialised technology guidance (HST)
- interventional procedures guidance
- medical technologies guidance
- technology appraisals guidance (TA)



All guidance is developed by independent committees and is consulted on. NICE may also publish a range of supporting documents for each piece of guidance, including advice on how to put the guidance into practice, and on its costs, and the evidence it is based on. Only NICE TAs and HSTs are subject to a statutory requirement for NHS organisations to make funding available for the treatments within 90 days of publication. Only NICE TAs and HSTs are within the scope of this review.

Patient Access Scheme / Commercial Access Agreement / Managed Access Agreement

A way for pharmaceutical companies to make high-cost drugs affordable for the NHS, particularly if there is uncertainty about the outcomes or value of the treatment or if the treatment has a higher cost per QALY than NICE usually accepts. Companies may submit a patient access scheme proposal for any technology going through the NICE single or multiple technology appraisal processes, and highly specialised medicines process. For example, the company might pay for the drugs for an introductory period for each patient, and then the NHS would take over the payments if the drug is shown to work for that person; or the NHS might pay for the first course of a drug and the company would take over the payments if the patient needs treatment for longer than average. Alternatively a simple discount to the list price may be applied.

QALY - Quality Adjusted Life Year

Nice defines a QALY as a measure of the state of health of a person or group in which the benefits, in terms of length of life, are adjusted to reflect the quality of life. QALYs are calculated by estimating the years of life remaining for a patient following a particular treatment or intervention and weighting each year with a quality-of-life score (on a 0 to 1 scale). It is often measured in terms of the person's ability to carry out the activities of daily life, and freedom from pain and mental disturbance.

QALY = years of life remaining x quality-of-life score:

1 QALY = 1 year of life in perfect health (1×1)

 $0.5 \text{ QALY} = \text{Half a year of life in perfect health } (0.5 \times 1)$

0.5 QALY = 1 year of life lived in a situation with quality of life score of 0.5 eg bedridden (1×0.5)

2 QALYs = 4 years of life lived in a situation with quality of life score of 0.5 eg bedridden (4×0.5)

For example, a person has a serious life-threatening condition and is currently receiving medicine A. If he continues to receive medicine A he will live for 10 years and his quality of life will be on average, 50% of normal (quality-of-life score 0.5). If he receives a new medicine, medicine B, for the same condition, he will live for 12 years and his quality of life will be, on average, 70% of normal (quality-of-life score 0.70).

The new medicine, medicine B, is compared with medicine A in terms of QALYs gained as follows:



- medicine A: QALY = 5 (10 years x 0.5)
- medicine B: QALY = 8.4 (12 years x 0.70)

Therefore, medicine B results in 3.4 additional QALYs when compared with medicine A.

Cost per QALY

Medicine A costs £10,000 and provides 5 QALYs. It has a cost per QALY of £2,000 (£10,000/5 QALYs).

Medicine B costs £20,000 and provides 8.4 QALYs. It has a cost per QALY of £2,380

ICER – incremental cost-effectiveness ratio

The ICER is the amount of money that needs to be spent to achieve 1 additional QALY with medicine B compared to medicine A and is calculated as the difference between the costs and the QALYs of two treatments:

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(Cost B – cost A) / (QALY B – QALY A)

(£20,000 - £10,000) / (8.4 - 5)

£10,000/3.4 = £2,941
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Treatment B has an ICER of £2,941 per additional QALY gained when compared with treatment A.

Technology appraisal (TA)

The Technical Appraisal Programme makes recommendations on the clinical and cost effectiveness of new and existing medicines and treatments within the NHS in England, such as:

- medicinal products
- medical devices
- diagnostic techniques
- surgical procedures
- therapeutic technologies other than medical products
- · systems of care
- screening tools

Some medicines and treatments may be covered by more than one technology appraisal.

Each technology appraisal may contain more than one recommendation. NICE classify their recommendations into four categories:

- Recommended the medicine or treatment is recommended for use:
 - In line with the marketing authorisation from the European Medicines Agency (EMA) or from the Medicines and Healthcare Products Regulatory Agency (MHRA) or
 - o In line with how it is used in clinical practice in the NHS
 - or both



- Optimised the recommendations have a material effect on the use of a medicine or treatment, and it is recommended for a smaller subset of patients than originally stated by the marketing authorisation. This test of materiality takes into account advice from clinical experts on the anticipated use of the technology in routine clinical practice. In some instances, an optimised recommendation is made because the committee considers that a medicine or technology is only a cost-effective treatment option for a specific group of people; for example in people who are resistant to or cannot tolerate other medicines.
- Only in research The medicine or treatment is recommended for use only in the context
 of a research study, for example, a clinical trial. Often, particularly in the case of
 promising new technologies, sufficient clinical evidence has not been collected at the
 time of the appraisal and so the Appraisal Committee is unable to recommend the
 technology for use in the NHS until further evidence on its effectiveness is available for
 re-appraisal.
- Not recommended the medicine or treatment is not recommended. In most instances, a
 technology will not be recommended if there is a lack of evidence for its clinical
 effectiveness or if the technology is not considered to be a cost-effective use of NHS
 resources, compared with current NHS practice.

The technologies included in an appraisal may not be the only treatment for the condition recommended in NICE guidance, or otherwise available in the NHS. Therefore, if a NICE technology appraisal recommends use of a technology, it is as an option for the treatment of a disease or condition. This means that the technology should be available for a patient who meets the clinical criteria set out in the guidance, subject to the clinical judgement of the treating clinician.

The NHS must provide funding and resources when the clinician concludes, and the patient agrees, that the recommended technology is the most appropriate to use, based on a discussion of all available treatments.

NICE technology appraisal guidance makes recommendations on the use of new and existing drugs and treatments in the NHS. If NICE recommends a drug or treatment for a particular condition, the NHS has to make it available for patients with that condition if it is suitable for them. Usually, this has to be done within 3 months of the guidance being issued.



Appendices

- Appendix 1: Stakeholder event agenda
- Appendix 2: Stakeholder event slides
- Appendix 3: Stakeholder event scenarios
- Appendix 4: Stakeholder event CHAT-boards
- Appendix 5: SPH understanding of the requirement / Terms of reference
- Appendix 6: Database data field list
- Appendix 7: Clinician proforma used for data collection
- Appendix 8: List of TAs for each option



Appendix 1: Stakeholder event agenda

Review of NICE drugs and treatments Agenda March-April 2019 **Agenda and Instructions** Timing 1. Welcome and introduction 17.30 2. Background and Purpose 17:30 - Current situation with NICE approved treatments - Drug and treatment review for CfHSC - How can you help? Outline for the event 3. Tasks for participants There are 6 scenarios based on treatments that the island does not currently fund. You will have 3 to consider for this task. a. Individually: 18.00 read the scenarios privately rank which you would prioritise and keep a record on a post-it note. 18:15 b. <u>In your groups:</u> discuss the characteristics of each scenario and whether you consider those features to be important in prioritising whether or not that treatment should be a higher priority for funding than some of the other treatments 18.45 record your own preferences on the board: o each person will have 13 dots, one for each 'principle' you may only put one dot in each segment you do not need to agree with your colleagues around the o we will photograph your completed boards at the end of the event 19.00 prepare feedback from your group to the whole audience 2 principles where there was general agreement 1 principle where the group was split – what were the issues?



4. Plenary feedback	19.15
Group feedback	
5. Straw poll of preferences	19:45
6. Closing remarks	19:55
7. Close	20.00



Appendix 2: Stakeholder event slides



Outline:

- 1. The Current Position
- The Review
- 3. Your Contribution
 - · Your preferences
 - · Your solutions





Current position: NICE

- Different publications: TA, Guidelines, IPGs, MedTech, QS...
- · TAs:
 - 875 treatments for specified indications
 - · 485 recommended
 - · 446 drugs, 39 non-drugs
 - SoS Directions to NHS organisations
 - No budget
 - Selection bias licensed drugs, manufacturer submission





Current position: Principles & Process

- · Transparency and fairness -
 - different types of treatments, different diseases, different time of year
- Reproducible
 - Same process, decision criteria and rules
- considers all potential and competing use of the funds in order to come to a view about the best option for investing limited funds.
- reallocate resources from existing low value / low priority care to care which is of higher value / higher priority.
- · Fit with CHSC/States of Guernsey key strategic aims







Current position: Maximise value

- · Within budget
- · Must not allow third parties to determine priorities or make funding decisions on its behalf.
- NICE TA=other investments
- Impact on other services
- Equity
 - targeting subgroups who are unable to access care
 - not fund one individual if others with the same need cannot be
- · Clinical trials not routinely funded



Current position: Principles

- Personal characteristics
 - age, gender, sexual orientation, gender identity, race, nationality, religion, lifestyle, social position, family or financial status, intelligence, disability, physical or cognitive functioning.
- Treatment
 - Cost effectiveness ceiling of £30,000 per QALY
 - Clinical effectiveness effect size, health outcome, % of pts who benefit, certainty
 - TA Drugs vs non TA drugs and non-drugs eg surgery, devices, prevention, screening
- - Emergency/acute vs lifelong/chronic condition
 - Terminal illness and end of life criteria
 - Orphan diseases vs more common diseases
 - CDF vs non CDF



Offisland care vs on island care



Current position: Requete

- · Guernsey residents who are treated off island get different care to people who live in England
- Inefficiency of reviewing NICE drugs again
- NICE TA-approved drugs: funding not available
 - Cancer Drugs Fund
 - End of Life criteria for treatments for terminal illness





The Review: Scope & Deliverables

- · Estimate of the impact of adopting ALL NICE TAs
 - Patients
 - Health gain
 - Cost impact
- Propose OPTIONS for prioritising NICE TA approved treatments
- · Identify the values and principles challenged when considering funding a healthcare intervention
- End of May 2019







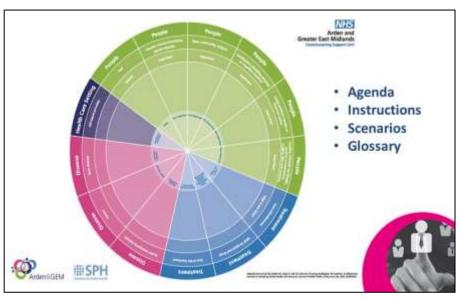


Your Contribution: Objectives

- · Elicit your preferences for the principles and values
- · Receive your suggestions for how to prioritise
- · How?
 - Considering and discussing fictitious scenarios
 - Individually and in groups
 - Boards: show agreement and disagreement
 - Postcard: straw poll/ suggestions
 - PH team/facilitators



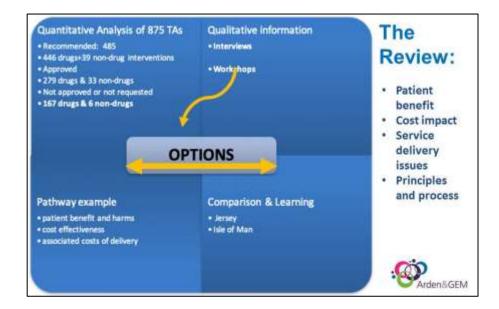






- Disclaimer
 - fictitious
- Assumptions
 - Clinical effectiveness is correct
 - NICE price/cost effectiveness is correct
- · Focus on recommended NICE TAs
 - OOS: Guidelines, IPGs, Medtech
 - OOS: Cystic Fibrosis drugs, IVF, other treatments or services









Appendix 3: Stakeholder event scenarios

Scenario 1

Liam is 41 years old and has lived in Guernsey for most of his life. During his teens and early twenties he did odd DIY jobs in the winter and every summer would work at a beach kiosk. In his late twenties he qualified as a bricklayer and has worked in the construction industry ever since. He now has a wife and two children and is the main bread winner in the household. His wife first noticed a mole on his shoulder that didn't look "quite right". After it had grown larger he visited his doctor and he was found to have advanced melanoma which had spread to his lymph nodes. Liam has a life expectancy of less than one year.

Ipilimumab
TA 319

Ipilimumab is recommended as a possible treatment for adults with advanced (unresectable or metastatic) melanoma that has not been treated before.

Advanced Melanoma

Melanoma is a form of skin cancer. Advanced melanoma is when the cancer can't be completely removed by surgery (unresectable) or has spread to other parts of the body (metastatic).

In advanced melanoma, the cancer cells have spread to one or more of the following areas of the body:

- lymph nodes far away from the original melanoma
- areas of skin distant from the original melanoma
- the lungs
- the liver
- the bones
- the brain
- the digestive system

Guernsey residents experience a higher rate of melanoma compared with England. The rate (age standardised) for combined years of 2009-2014 was 69 people per 100,000 in Guernsey, compared to around 31 people per 100,000 in England. Around 33 new cases of malignant melanoma are diagnosed each year in Guernsey, and it is one of the most common cancers in those aged under 40.

Ipilimumab is a life-extending drug for people near the end of their life. Compared to dacarbazine alone, the estimated increase in median overall survival is 2.1 months.

Ipilimumab is given by injection, and helps the body's immune system to recognise and destroy melanoma cells. It is a fully human antibody that binds to a molecule expressed on T cells that plays a critical role in regulating natural immune responses. Ipilimumab is designed to block the activity of an immune regulator that stops the immune response thereby sustaining the immune attack on cancer cells. It has a UK marketing authorisation 'for the treatment of advanced (unresectable or metastatic) melanoma in adults'.

It is administered intravenously over a 90-minute period every 3 weeks for a total of 4 doses.



Cost of treatment	Cost effectiveness	Cost impact for Guernsey (per year)
The recommended dose of ipilimumab is 3 mg per kilogram of body weight (mg/kg) administered	£47,900 per QALY gained for ipilimumab compared with dacarbazine alone.	Uncertain: from £5000 to £120,000 per annum for new two patients.
intravenously over a 90-minute period every 3 weeks for a total of 4 doses. Based on an average adult of 70 kilograms and a 10-ml vial costing £3750, cost of treatment £75,000 per patient.	£28,600 per QALY gained for ipilimumab compared with vemurafenib (based on 2014 prices).	NICE suggested in 2014 that the estimated additional cost per annum is £5000 to £10,000 for the drug costs alone. This is likely to be a gross underestimate, as the price of the comparators is now much lower than in 2014.
		Two patients per year will be suitable for treatment with ipilimumab for melanoma.



Stephanie is 26 years old. She works for Housing and visits a wide range of buildings. Three years ago Stephanie visited a domestic property after a neighbour complained about rubbish overflowing onto their property and that it was "in such a bad state of repair it was about to fall down". On this visit, Stephanie accidentally disturbed a wasp's nest and was stung by several wasps. She had a severe systemic reaction that required a hospital visit. She has been issued with an emergency kit, but is now anxious about being stung again in similar circumstances and worries that she may need to change her job to avoid it.

TA	NICE Recommendation	About moderate to severe bee or wasp allergy.	Intervention
TA 246 Pharmalgen	Pharmalgen is recommended as an option for the treatment for bee and wasp venom allergy in people who have had:	When a person is stung by a bee or wasp they typically have an intense, burning pain followed by redness and swelling at the site of the sting. This usually subsides within a few hours.	Pharmalgen is a venom immunotherapy. Immunotherapies are wellestablished treatments for certain severe allergies.
	 a severe systemic reaction to bee or wasp venom, or a moderate systemic reaction to bee or wasp venom and who have one or more of the following: a raised baseline serum tryptase, a high risk of future stings or anxiety about future stings Treatment with Pharmalgen should be initiated and monitored in a specialist centre experienced in venom immunotherapy. 	Moderate systemic reactions may include mild asthma, moderate facial or tongue swelling, abdominal pain, vomiting, diarrhoea and minor or transient hypotensive symptoms such as light-headedness and dizziness. Severe systemic reactions may include respiratory difficulty such as asthma or upper airway swelling, hypotension, collapse or loss of consciousness, as well as double incontinence, seizures, or loss of colour vision. Clinicians typically give an emergency kit to people with a venom allergy who are considered at risk of systemic reactions. The kit includes adrenaline (epinephrine; intramuscular injection) and can also include other emergency treatments such as a high-dose antihistamine (oral), a corticosteroid (inhaled),	Treatment involves the administration of increasing doses of allergen (the substance you are allergic to) over a prolonged period of time, to help teach your immune system to tolerate it and not 'fight' it. Wasp and bee venom immunotherapy has been shown to lower the risk of severe reactions to wasp and bee stings. It is given as a course of regular injections under the skin over years.
		and/or a bronchodilator (inhaled). Preventive measures include advice on how to avoid bee and/or wasp stings.	



Dosage and Administration	Cost of treatment	Cost effectiveness	Cost impact for Guernsey (per year)
Treatment with Pharmalgen is in two phases. There is an initial phase (about 12 weeks) and then a maintenance phase (at least 3 years). Before people receive Pharmalgen treatment, allergy to bee or wasp venom must be confirmed by case history and by in vivo and/or in vitro diagnosis. Pharmalgen is given by subcutaneous injection. During the initial phase, an increasing dose of Pharmalgen is given until the maximum tolerated dose is reached. The following types of dosing schedules can be used during the initial phase: 1. conventional (one injection every 3—7 days) 2. modified rush (clustered; two to four injections weekly given at intervals of 30 minutes) 3. rush (injections at 2-hour intervals with a maximum of four injections per day) During the maintenance phase, Pharmalgen is administered at a dose of 100 micrograms every 4—6 weeks for at least 3 years. The dosage may be adjusted depending on the person's history of allergic reactions and sensitivity to the specific allergen used.	Pharmalgen bee venom costs £54.81 for an initial treatment set and £63.76 for a maintenance treatment set of four infusions. Pharmalgen wasp venom costs £67.20 for an initial treatment set and £82.03 for a maintenance treatment set of four infusions.	Less than £20,000 per QALY gained. For people with a high risk of stings, treatment with Pharmalgen dominated the alternatives (that is, it was more effective and less costly). For people without a high risk of stings but reduced anxiety about re-stings after treatment with Pharmalgen, the most plausible ICER was less than £20,000 per QALY gained.	£10,000 in year 1 £24,000 in year 3 Assuming: 0.4% people are eligible for treatment c.20% patients (45) are treated each year



Nisha is 67 years old and of South Asian origin. She is a retired business executive and now spends a lot of her time caring for her three grandchildren, which allows her children to work. She has type 2 diabetes. Her GP found that her blood sugar level was not sufficiently controlled with metformin alone and so after 4 months introduced sulfonylurea. Unfortunately, sulfonylurea caused Nisha to gain weight (a common side effect) and she has been advised that Canaglifozin in addition to metformin may be a suitable alternative although another drug, Exenatide is available. This has shown weight loss in the trials and significant weight loss in the Guernsey patients being treated with it. Her doctor has also advised her to make lifestyle changes to lose weight as her current body mass index is 33kg/m² (obese).

TA	NICE Recommendation	About Type 2 Diabetes
TA 315 Canaglifozin	Canagliflozin in combination with metformin is recommended as an option for treating type 2	Type 2 diabetes is a common condition that causes the level of sugar (glucose) in the blood to become dangerously high.
	diabetes, only if:	It can cause symptoms like excessive thirst, needing to pee a lot and tiredness. It can also increase your risk of getting serious problems with your eyes, heart and nerves and fighting infections.
	a sulfonylurea is contraindicated	and fighting infections.
	 or not tolerated or the person is at significant risk of hypoglycaemia or its 	It's a lifelong condition that can affect your everyday life. You may need to change your diet, take medicines and have regular check-ups.
	consequences	It's caused by problems with a chemical in the body (hormone) called insulin. It's often linked to being overweight or inactive, or having a family history of type 2 diabetes.
	2. Canagliflozin in a triple therapy regimen is recommended as an option for treating type 2 diabetes in combination with:	People of South Asian, Chinese, African Caribbean or Black African origin are at higher risk.
	 metformin and a sulfonylurea or metformin and a thiazolidinedione 	Most people need medicine to control their type 2 diabetes. Medicine helps keep blood sugar level as normal as possible to prevent health problems and will need to be taken for the rest of the patient's life.
	Canagliflozin in combination with insulin with or without other antidiabetic drugs is	Diabetes usually gets worse over time, so your medicine or dose may need to change. Over time, patients may need a combination of medicines.
	recommended as an option for treating type 2 diabetes.	Insulin isn't often used for type 2 diabetes in the early years. It's only needed when other medicines no longer work.

The Review of Drugs and Treatments



Intervention	Cost of treatment	Cost effectiveness	Cost impact for Guernsey (per year)
Canagliflozin lowers blood glucose in people with type 2 diabetes by blocking the reabsorption of glucose in the kidneys and promoting excretion of excess glucose in the urine. It gives patients an additional option when other therapies are failing. It is orally administered so helpful for people who struggle with injections.	The expected annual cost of canagliflozin is £477.26 for the 100 mg daily dosage and £608.63 for the 300 mg daily dosage. Increase in daily dose from 100mg to 300mg occurs if the lower dose provides insufficient blood sugar control.	NICE considers that there are only very small differences in costs and QALYs between canagliflozin (100 mg and 300 mg) and its key comparators.	Cost per annum = £35,000 in year 1 rising to £175,000 by year 5. Based on a very conservative 65 people starting treatment per year.



John Smith is a 57 year old male. He was diagnosed with heart failure 2 1/2 years ago and despite being treated with other drugs his initial ejection fraction (how much blood the heart pumps out) which was 20% has not improved. A normal ejection fraction in a healthy individual would be between 50% and 70%. His job is in lawn care services and he needs to employ a helper to use the hedge trimmer as he does not have the energy or breath to do it himself. His cardiologist has suggested that he try a new drug, which is available for patients who live in England called sacubitril valsartan. He has been advised that he may experience side effects (low blood pressure, high potassium levels and kidney problems).

TA	NICE recommendation	About heart failure
TA 388 Sacubitril Valsartan	Sacubitril valsartan is recommended as an option for treating symptomatic chronic heart failure with	Heart failure means that the heart is unable to pump blood around the body properly. It usually occurs because the heart has become too weak or stiff. It can occur at any age, but is most common in older people.
	reduced ejection fraction, only in people:	The most common symptoms of heart failure are:
	with New York Heart	breathlessness – after activity or at rest; it may be worse lying down, and you may wake up at night needing to catch your breath
	Association (NYHA) class II to IV symptoms and	 fatigue – you may feel tired most of the time and find exercise exhausting swollen ankles and legs – this is caused by a build-up of fluid
	with a left ventricular ejection fraction of 35%	Heart failure is classed using four NYHA functional classes:
	 or less and who are already taking a stable dose of angiotensin-converting enzyme (ACE) 	 class 2 – you're comfortable at rest, but normal physical activity triggers symptoms class 3 – you're comfortable at rest, but minor physical activity triggers symptoms class 4 – you're unable to carry out any physical activity without discomfort and may have symptoms even when resting
	inhibitors or angiotensin II receptor-blockers (ARBs)	Most people with heart failure are treated with medication. Some of the main medicines for heart failure include:
	To store at about the	ACE inhibitors ACE inhibitors
	Treatment should be started by a heart failure	angiotensin receptor blockers (ARBs)beta blockers
	specialist with access to a multidisciplinary heart	mineralocorticoid receptor antagonistsdiuretics



failure team (MDT). Dose
titration and monitoring
should be performed by the
most appropriate team
member as defined in
NICE's Guideline.

- ivabradine
- sacubitril valsartan
- hydralazine with nitrate
- digoxin

Some people will need to have a procedure to implant a small device in their chest that can help control their heart's rhythm. The most commonly used devices are pacemaker, cardiac resynchronisation therapy (CRT) devices and implantable cardioverter defibrillators (ICDs).

Intervention	Cost of treatment	Cost effectiveness	Cost impact for Guernsey (per year)
Sacubitril valsartan is both a neprilysin inhibitor (sacubitril) and an angiotensin II receptor blocker (ARB; valsartan). Both sacubitril and valsartan lower blood pressure. Sacubitril valsartan is taken orally twice a day. It's suitable for people with more severe heart failure, whose heart is only able to pump a reduced amount of oxygenated blood around the body despite taking other medication. The most common side effects of sacubitril valsartan are low blood pressure, high potassium levels and kidney problems.	The annual cost per year for sacubitril valsartan 97mg/103mg twice daily is £1,190. Compared to standard therapies: Valsartan 160mg twice daily £58 Ramipril 5mg twice daily £32-£36 Candesartan 32mg daily £29 Enalapril 10mg to 20mg twice daily £22-£27 Lisinopril 35mg daily £41	Compared to a low dose of enalapril (10mg), the cost per QALY for sacubitril is £18,348. This based on an increased cost of £7,685 and a QALY gain of 0.42. Compared to angiotensin II receptor blockers, the cost per QALY for sacubitril is £16,621. This is based on an increased cost of £9,434 and a QALY gain of 0.57. The cost per QALY is highly dependent on: • reduced admissions to hospital observed in clinical trials in 47 countries. Reduced hospital admissions are unlikely to be realised in Guernsey • the type of previous drug treatment	If 375 patients are eligible, then this would cost £446,250 per annum in year 1, rising to £2.3 million in year 5 for heart failure only. Guernsey and Alderney does not have a HF MDT, so off-island health care costs may need to be factored in.



Rosa and Wilian have been resident in Guernsey for 15 years, having moved from Madeira to work in the hospitality industry on the island. Wilian has worked for the same hotel for ten years as the hotel's porter. His wife is a chef in the restaurant of the same hotel. They are devoutly Catholic. They have recently had their first baby - Francisco - who they took to Rome to be blessed by Pope Francis. Francisco is 18 months old and has recently been diagnosed with a rare hereditary genetic disorder called XLH. The Doctors at Great Ormond Street Hospital in London have recommended a treatment called Burosumab which is funded by NHS England for children who live in England. Francisco is not walking yet and cries often when he moves due to pain. Rosa and Wilian would like to have more children but are finding it difficult to look after Francisco, and are worried that another child might also inherit XLH.

TA	NICE recommendation	About X-linked Hypophosphataemia (XLH)
HST08 Burosumab	marketing authorisation, for treating X-linked hypophosphataemia (XLH) with radiographic evidence of bone disease in children aged 1 year and over, and in young people with growing bones. It is recommended only if the company provides burosumab according	

Intervention	Cost of treatment	Cost effectiveness	Cost impact for Guernsey (per year)
Clinical trial evidence suggests that burosumab provides short-term clinical benefits in children aged between 1	The full list price of burosumab in England	Unknown	There are no known children on Guernsey with XLH.
and 12 years. It is expected that there is some lifetime benefit for people having burosumab because it can	is £2,992 per 10 mg vial.		The incidence is 1 per 20,000 live
prevent irreversible bone damage, which could lead to less pain and a better quality of life as people get older.	Treatment for one year		births.
There are uncertainties in the clinical evidence (including a lack of evidence in young people aged between 13 and	for one patient with XLH (based on the full		There are c. 650 live births in Guernsey & Alderney per year. So
17 years, and on the long-term consequences of progressive bone disease and ongoing metabolic	list price) on the maximum dose (90mg)		statistically one birth every thirty years.
symptoms of XLH, which would not be affected by burosumab). However, burosumab is likely to provide	would be £700,128 per year.		The cost per child per year for the



important clinical benefits for people with XLH.		second year to 12 years of their life is
Burosumab is administered via subcutaneous injection	The details of the commercial access	c. £700,000.
once every 2 weeks. The recommended starting dose is 0.4 mg/kg, the normal maintenance dose is 0.8 mg/kg and the maximum dose is 2 mg/kg up to 90 mg. Doses	arrangement for the NHS in England are unknown.	Because XLH is a genetic condition, it often affects several members of a family.
should be rounded to the nearest 10 mg. Treatment can begin in children aged 1 year and can		
continue until the bones stop growing.		



Edward is 72 years old and was diagnosed with Chronic Lymphocytic Leukemia (CLL.) in 2013. He originally received 6 cycles of chemotherapy which put the cancer into remission. He had a second relapse and learned that he also had developed a chromosomal mutation (17p deletion) which was associated with a "poor prognosis". The 17p deletion is a mutation that not only makes traditional chemotherapy ineffective; it also negatively affects the P53 gene that controls the body's tumour suppression abilities.

Late in 2018 he experienced a third relapse. He was admitted to hospital for an extended stay. He has found out from a website where he meets other patients with the same cancer, that he meets the criteria for treatment with venetoclax, an oral drug that is recommended by NICE. Taking a pill at home is much easier than going into a clinic for an IV infusion. However, funding for this drug is not approved in Guernsey so he is paying for it himself.

Paying for treatment was not something he had anticipated when he was diagnosed and the energy and stress has been an unhelpful additional burden. He says that he and his wife are "spending our own money so I will survive. My cancer treatment choices should not depend on how much money I have to spend. The choices should be based on the best treatment options currently available".

TA	NICE Recommendation	About Chronic Lymphocytic Leukaemia (CLL)
TA 487 Venetoclax	Venetoclax is recommended for use within the Cancer Drugs Fund, within its marketing authorisation, as an option for treating chronic lymphocytic leukaemia, that is, in adults: • with a 17p deletion or TP53 mutation and when a B-cell receptor pathway inhibitor is unsuitable, or whose disease has progressed after a B-cell receptor pathway inhibitor or • without a 17p deletion or TP53 mutation, and whose disease has progressed after both chemo-immunotherapy and a B-cell receptor pathway inhibitor	CLL is an incurable cancer that affects the white blood cells and tends to progress slowly over many years. It mostly affects people over the age of 60 and is rare in people under 40. Children are almost never affected. In CLL, the spongy material found inside some bones (bone marrow) produces too many white blood cells called lymphocytes, which are not fully developed and do not work properly. Over time this can cause a range of problems, such as an increased risk of picking up infections, persistent tiredness, swollen glands in the neck, armpits or groin, and unusual bleeding or bruising. CLL does not usually cause any symptoms early on and may only be picked up during a blood test carried out for another reason. When symptoms develop, they may include: • getting infections often • anaemia – persistent tiredness, shortness of breath and pale skin • bleeding and bruising more easily than normal • a high temperature and night sweats

The Review of Drugs and Treatments

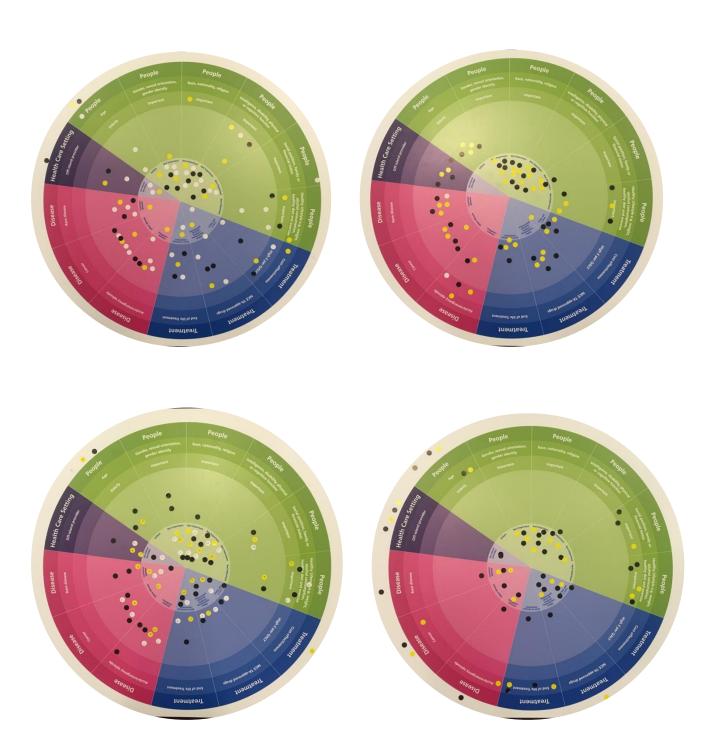


	 swollen glands in your neck, armpits or groin swelling and discomfort in your tummy unintentional weight loss
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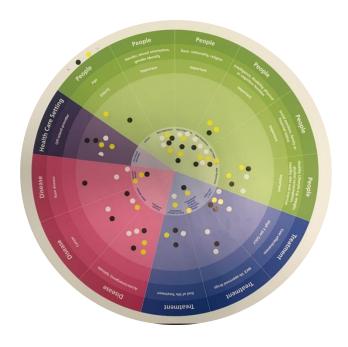
Intervention	Cost of treatment	Cost effectiveness	Cost impact for Guernsey (per year)
Venetoclax is a selective small molecule inhibitor of B-cell lymphoma 2, an anti-apoptotic protein overexpressed in around 95% of people with chronic lymphocytic leukaemia.	The commercial access agreement price for NHS England is unknown.	£50,000-60,000 per QALY before discount.	There are likely to be 5 new patients per annum on Guernsey.
Venetoclax has a conditional marketing authorisation for 'the treatment of chronic lymphocytic leukaemia (CLL) in the presence of 17p deletion or TP53 mutation in adult patients who are unsuitable for or have failed a B-cell receptor pathway inhibitor' and for 'the treatment of CLL in the absence of 17p deletion or TP53 mutation in adult patients who have failed both chemo-immunotherapy and a B-cell receptor pathway inhibitor'. It is associated with clinically meaningful overall response rates (77%), median progression free survival 27.2months and survival at 12 months of 87%. There is a risk of tumour lysis syndrome during the initial 5-week dose-titration phase of treatment because venetoclax can cause rapid tumour reduction. Grade 3 or 4 neutropenia has also been reported in patients treated with venetoclax. The starting dose is 20 mg once daily for 7 days. The dose must be gradually increased over 5 weeks up to the recommended daily dose of 400 mg.	28 days of 400 mg treatment costs £4,789 (excluding VAT). This equates to £62,263 per patient per annum.	Unknown (if cancer drugs fund price is available to Guernsey patients).	Without any discount, this would have cost impact of £311,000 per year in year 1, up to £622,000 in year 2, £933,000 in year 3 depending on survival.

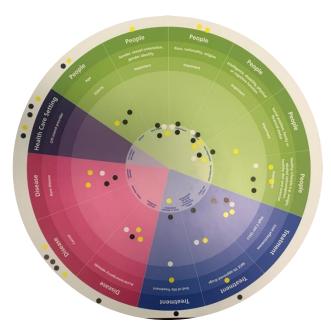


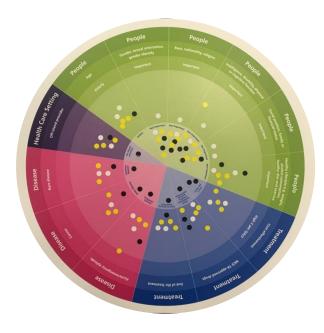
Appendix 4: Stakeholder event CHAT-boards

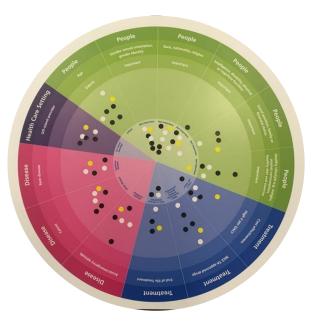




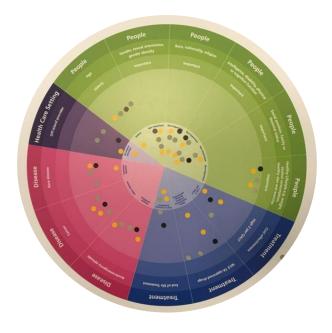


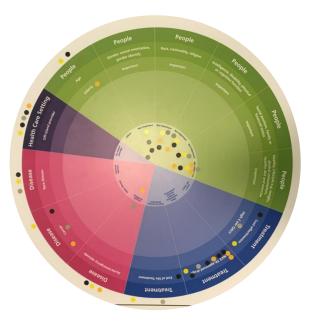




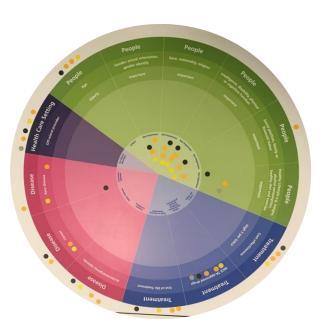






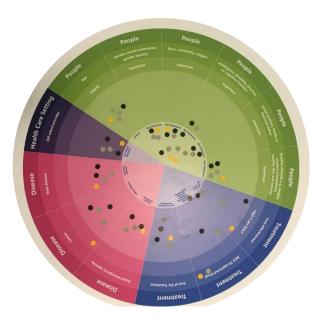


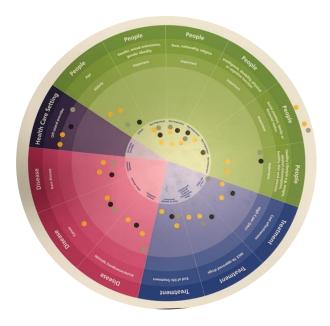


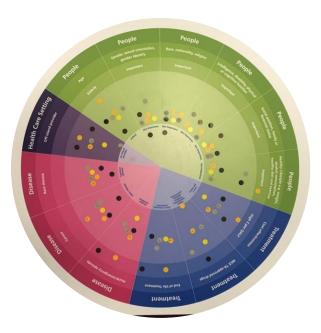




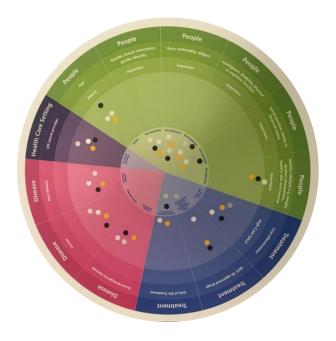


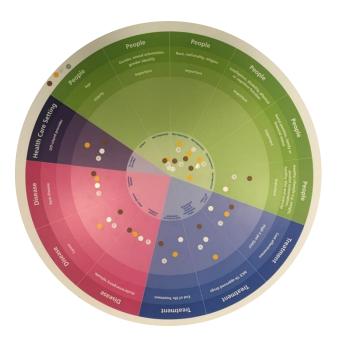


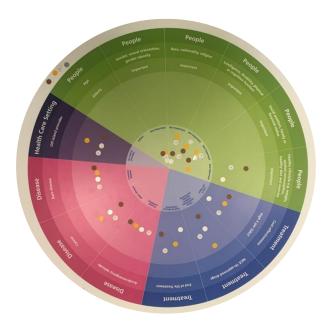












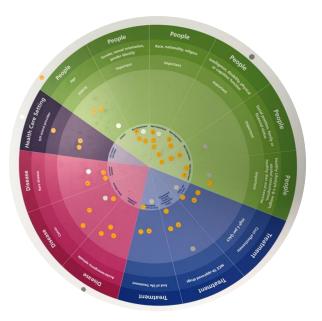
















Appendix 5: SPH understanding of the requirement / Terms of reference

SPH Proposal to The States of Guernsey for the provision of a Review of Drugs and Treatments V2 update

22nd January 2019





1 Background

NHS Solutions for Public Health (SPH) was approached in December by the Office of the Committee for Health and Social Care, States of Guernsey, to conduct a review of drugs and treatments.

The requirements for the work are driven by the need to review the costs and outcomes of moving from the current status quo, towards a position where NICE TA treatments approved for use in England are also funded by the States of Guernsey, and to review associated health access equity issues, especially in relation to tertiary care off-island.

Representatives of SPH visited the Guernsey DPH in December 2018 to gain a first-hand understanding of the background to the required work, and a number of clarification discussions have been held. This proposal sets out the understanding of SPH around the requirements and details the methodology to be adopted together with any assumptions, dependencies and limitations.

Reporting for the review is required in time to inform the next budgeting round for the States of Guernsey with reporting to be complete in late May/early June 2019.

2 Objectives and Methodology

The three key objectives of the review are to:

- To review the existing system of drug, treatment and device ("treatments") prioritisation and availability, and make recommendations on how this could be developed. Taking into account stakeholder feedback and healthcare decision processes in other jurisdictions, develop an equitable and effective process which is consistent with a move towards presumptive funding of all NICE TA approved treatments.
 - Review existing documentation (e.g. Partnership of Purpose, Priority Setting in Health and Social Care G1033) and identify existing underpinning equity and access principles.
 - Undertake desktop research and semi-structured interviews to develop an overview of the
 existing processes for treatment availability in the jurisdictions of Jersey, the Isle of Man and
 England. Compare these to the current situation in Guernsey and Alderney, highlighting key
 differences in approach, and finance, equity of access and health outcome consequences.
 - Consult with Bailiwick of Guernsey stakeholders e.g. Primary care, Secondary Care,
 CareWatch on principles and process which could impact access to NICE TA approved treatments.
 - Consider current equity of access issues to NICE TA approved treatments for Bailiwick of Guernsey patients treated in UK off-island centres.
 - Propose changes that may be necessary to the current principles and processes described in 'Priority Setting in Health and Social Care' and outline options for the move towards presumptive funding of NICE TA approved treatments.



2. Undertake cost and outcome analyses to inform future decision making:

- Identify which NICE TA-approved drugs, devices and treatments are not funded in Guernsey and Alderney.
- Subject to the limitations of available information, analyse and collate information in NICE
 TAs and other sources available to SPH to estimate the financial cost and health impact of
 extending funding to all NICE TA approved treatments, whilst taking account of information
 provided by DPH Guernsey.
- For one example, currently unfunded NICE TA-approved treatment, undertake a more detailed analysis of health and economic impact (e.g. taking account of required changes to the local treatment pathway)
- Estimate the cost and health impact of funding all not currently funded NICE TA approved
 End of Life (EoL) treatments where the NICE estimated benefit is above £30,000 per QALY.
- Develop costed subgroup analyses of groups of NICE TA approved recommendations e.g.
 CDF, rare diseases, conditions managed in primary care, prevention etc. This may inform possible implementation options for consideration.

3. Provide information around existing Cancer Drugs Funds to inform future decision making:

 Provide an overview of the operation of the Cancer Drug Fund in England since 2016 and the operation of the Cancer Drug Fund in the Isle of Man. Summarise any available information around cost and effectiveness.

3 Deliverables

Produce and present a report to the Committee for Health and Social Care which will include the following:

- 1. A proposal of options for consideration, consistent with a move towards presumptive funding of NICE TA approved treatments, based on comparison from other jurisdictions, stakeholder engagement and desktop research.
- 2. Findings of cost and outcome analyses to fund all NICE TA approved drugs, devices and treatments including a more detailed example of an example drug/treatment.
- 3. Findings of cost and health impact of funding all not currently funded NICE TA approved EoL treatments with a cost per QALY greater than £30,000.
- 4. Overview of Cancer Drug Fund operation in England and the Isle of Man, summarising any available information around cost and effectiveness.



4 Dependencies:

- 1. The Office of the Committee for Health and Social Care has kindly offered to provide administrative and logistical support with identifying local stakeholders, setting up interview schedules and local workshops, provision of venues and provision of a hot desk for SPH staff.
- The need to schedule interviews/workshops with key staff and stakeholders in 'batches' in order to maximise time spent on Guernsey and minimise travel time and travel and accommodation costs.
- 3. Timely support from colleagues in Guernsey to access documentation, pricing, activity, finance information and indications for which drugs on the whitelist are currently funded.
- 4. Availability of key stakeholders in Guernsey to participate and contribute to interviews and workshops.
- 5. The programme of work will be challenging to deliver within the limited timeframe available. Where SPH provides draft documentation for review by the Office of the Committee for Health and Social Care, return of documented comments within planned timescales will be important to ensure timely completion of final deliverables

5 Assumptions:

1. The level of information available within published NICE TAs is adequate to support the required analyses (with the exception of detailed drug costs which will be sought from other sources available to SPH).

6 Limitations:

- 1. The review will only consider currently unfunded NICE TAs published on or before 31st December 2018.
- 2. Cost analysis will be based on the latest available current Guernsey population estimates (likely to be December 2017)
- 3. Individual NICE TAs usually include an estimate of the numbers of patients in scope per 1000 population. These figures are based upon the estimated prevalence/incidence of disease in England. It will not be possible or appropriate to attempt to model the epidemiology of local States of Guernsey populations for each TA indication, due to the volume of work required and the fact that for many conditions the numbers of patients in scope would be small. The analysis approach will therefore be based on applying the NICE TA rates for affected patients directly to the States of Guernsey total adult or child populations.
- 4. We will undertake a high level analysis of health and economic impact, for one example currently unfunded NICE TA approved intervention. This will include, through document review and discussions with stakeholders, an estimate of the costs/savings associated with related changes to the local treatment pathway. This approach is intended to illustrate the wider funding complexities of adopting NICE TA treatments, beyond consideration of the cost of treatment alone. It will not include all steps necessary to formally plan a pathway change (e.g. public consultation).
- 5. With the exception of the example treatment outlined above (4), no analyses of *wider* cost impact (e.g. staffing, facilities, laboratory) associated with adoption and implementation of NICE TA-approved treatments will be undertaken.



- 6. The ability to realistically estimate the cost impact of adopting NICE TA approved drugs will be highly dependent on being able to access prices for the States of Guernsey. Cost analysis will be based upon information available within the NICE TA documentation plus costing information available within the NHS, for which permission to share with the States of Guernsey can be obtained. Where possible we will indicate the price that is available to the NHS in England. Where this is commercial in confidence (e.g. for cancer drugs approved by NICE but subject to an agreed discount), we will report the BNF price or Guernsey price, and aim to report a potential price for aggregated groups of drugs if the NICE discount was applied (where this adequately protects the commercially sensitive information).
- 7. The estimated cost impact of moving toward presumptive funding of NICE TA approved treatments will be based on the treatment initiated in year one and year two of policy implementation.
- 8. It will not be possible to model for subsequent or switching of treatments for the NICE TA approved treatments; for instance, if a patient with rheumatoid arthritis has started adalimumab and failed to achieve an adequate response, and is then switched to treatment with golimumab.

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REDACTED

8 Payment plan:

REDACTED

9 Other

This proposal is valid for 30 days from the date of receipt.

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Appendix 6: List of data fields included in the SPH NICE TA database

Rec no.
TA ID
Year of Publication
Process e.g. MTA or STA
Intervention
Technology type e.g. Drug or device
Manufacturer
Indication
Recommendation Category
Recommendation Comment
Full Recommendation Text
Guidance Status Detail
Guidance Status (current, withdrawn, replaced)
Guernsey Funding Status
Rare Diseases or Common Disease
Specialty Category e.g. cancer, T&O, respiratory
Specialty (Detailed breakdown for Cancer)
Population e.g. Children or Adults or both
Primary, Secondary, Tertiary initiated in England
Setting e.g. Primary, Secondary, Tertiary - ongoing treatment in England
On island or Off island prescribing
Pathway e.g. Prevention, Treatment, Emergency Treatment
Use e.g. Additional or Replacement Treatment
Monotherapy alternative TA-approved option (Are other TA-approved treatments available)
End of Life Treatment
Cancer Drugs Fund (CDF)
Is this a lifesaving intervention?



Link to Information from TA on Technology
Link to NICE Resource Impact Template
Price Per Patient Per Annum used in calculations
Price Per Patient Per Annum used in calculations for Year 2 (if different to Year 1) or where different dosages are cited
Biosimilar Available
Biosimilar Name
Biosimilar Price
Pharmacy Services Impact
Lab tests/Genomic testing required
NICE TA Dosage
NICE Treatment Duration
Patient Access Scheme
NICE TA Price
NHS England/Regional Price/PAS price
Price per patient per annum/treatment duration
NICE TA Price Per Patient Per Annum used in calculations
Updated (where available) TA cost per patient per annum
Discounted Price Per Patient Per Annum used in calculations
Combined Price per patient per annum (Discounted price or TA price (old)
Combined Price per patient per annum (Discounted price or TA price (current)
Percentage Discount Price
NICE TA Number of eligible patients (England)
Number of eligible patients in England
Link to NICE Resource Impact Report/Statement
England Population used in NICE Costing Template
Guernsey/Alderney Population
Estimated number of Guernsey eligible patients
Estimated number of eligible Guernsey patients from clinicians
Estimated number of patients switching to TA treatment from clinicians



Scottish Population Scotland Eligible Patients Scotland Uptake Year 1 Scotland Uptake Year 5 Guernsey number of Eligible Patients (pro rata from Scotland) Guernsey Year 1 Uptake number of patients (pro rata from Scotland) Guernsey Year 5 Uptake number of patients (pro rata from Scotland) Estimated number of NEW patients treated per annum from Guernsey clinicians Estimated number of NEW patients treated per 5 Years from Guernsey clinicians Estimated number of NEW patients treated per 5 Years from Guernsey clinicians divided by 5 Estimated number of current patients switching to TA treatment plus number of new patients per year provided by Guernsey clinicians Number of eligible patients initiated for treatment in Year 1 England uptake from TA Proportion of eligible patients initiated for treatment in Year 1 Guernsey number of eligible patients initiated for treatment in Year 1 (pro rata from England) Number of Eligible patients treated in Year 5 (England) Proportion of eligible patients initiated for treatment in Year 5 Guernsey number of eligible patients treated in Year 5 (pro rata from England) Guernsey Patients treated in Year 5 pro rata from England or Scotland combined Calculated Guernsey Patient Numbers Year 1 Calculated Guernsey New Patients Per Annum Cost Impact Year 1 (Guernsey patients switching to TA treatment or Year 1 uptake pro rata from England or Scotland based on NICE TA or SMC guidance) Cost Impact Year 1 (Guernsey patients switching to TA treatment plus New patients per annum or over 5 years, or Year 1 uptake based on NICE TA or SMC guidance) Cost Impact of estimated new patients per year provided by Guernsey clinicians Cost Impact Year 5 (based on pro-rata England patient numbers) Cost Impact Year 5 (based on pro-rata Scotland patient numbers) Cost Impact Year 5 (based on pro-rate England and pro-rata Scotland patient numbers combined)

Cost Impact Year 1: NICE TA Prices (Guernsey patients switching to TA treatment plus New patients per annum or over 5 years, or Year 1 uptake based on NICE TA

Cost Impact Year 1: NICE TA Prices (Guernsey patients switching to TA treatment or Year 1 uptake based on NICE TA or SMC guidance) NO DISCOUNT



or SMC guidance)

Cost Impact of estimated new patients per year provided by Guernsey clinicians: NICE TA Prices

Cost Impact Year 5: NICE TA Prices (based on pro-rata England patient numbers)

Cost Impact Year 5: NICE TA Prices (based on pro-rata Scotland patient numbers)

Cost Impact Year 5: NICE TA Prices (based on pro-rate England and pro-rata Scotland patient numbers combined)

Cost Impact Year 1 (current prevalent population) Adjusted Guernsey Prices

Cost Impact Year 1 (current prevalent population) Biosimilar Prices

Health Impact (Life Years Gained)

Health Impact (QALY Gain)

NICE Cost per additional QALY (ICER) before discount

NICE Cost per additional QALY (ICER) after discount

NICE TA ICER

NICE TA ICER Banding

Is TA treatment an oral drug?

ICER Text from NICE TA

Comparator Drug Name

Comparator drug annual cost per patient from TA/SMC (old price)

Comparator Drug annual cost per patient (current price either BNF or discounted)

Difference between old and current prices per patient per annum

Comparator drug administration method

Is Comparator Drug funded by the States of Guernsey?

Discounted price per patient per annum paid by Guernsey (if applicable)

Comparator Drug annual cost in Year 1: Old TA/SMC price (based on Guernsey patients switching to TA Treatment, or pro-rata England or Scotland)

Comparator Drug annual cost in Year 1: Current Price (based on Guernsey patients switching to TA Treatment) or pro-rata England or Scotland) using Guernsey discount where available

Comparator Drug annual cost: Old TA/SMC price (based on new patients per year)

Comparator Drug annual cost: Current Price (based on new patients per year) using Guernsey discount where available

Comparator Drug annual cost in Year 1: Old TA/SMC Price (based on Guernsey patients switching to TA drug plus new patients per year)

Comparator Drug annual cost in Year 1: Current Price (based on Guernsey patients switching to TA drug plus new patients per year)



Comparator Drug annual cost Year 5: Old TA/SMC Price (based on pro-rata England patients from NICE TA)

Comparator Drug annual cost Year 5: Current Price (based on pro-rata England patients from NICE TA)

Comparator Drug annual cost Year 5: Old TA/SMC Price (based on pro-rata Scotland patients from SMC Guidance)

Comparator Drug annual cost Year 5: Current Price (based on pro-rata Scotland patients from SMC Guidance)

Comparator Drug annual cost Year 5: Old TA/SMC price (based on pro-rate England and pro-rata Scotland patient numbers combined)

Comparator Drug annual cost Year 5: Current price (based on pro-rate England and pro-rata Scotland patient numbers combined)

Net Annual Cost in Year 1 (TA treatment minus comparator treatment) for Guernsey patients switching to TA treatment, or pro-rata patients from England or Scotland based on discounted or TA prices for TA treatment and current price of comparator treatment

Net Annual Cost (TA treatment minus comparator treatment) for new patients per annum provided by Guernsey clinicians based on discounted or TA prices for TA treatment and current price of comparator treatment

Net annual cost Year 5 (TA treatment minus comparator treatment) for estimated Guernsey patients from pro-rata England patients from NICE TA based on discounted or TA pricing for TA treatment and current pricing for comparator treatment

Net annual cost Year 5 (TA treatment minus comparator treatment) for estimated Guernsey patients from pro-rata Scotland patients from SMC guidance based on discounted or TA pricing for TA treatment and current pricing for comparator treatment

Net annual cost Year 5 (TA treatment minus comparator treatment) for estimated Guernsey patients from pro-rata England and Scotland patients from TA/SMC guidance based on discounted or TA pricing for TA treatment and current pricing for comparator treatment

Net costs where available (otherwise take gross)

Annual Cost in Year 1 (TA treatment minus comparator treatment) for Guernsey patients switching to TA treatment, or pro-rata patients from England or Scotland based on discounted or TA prices for TA treatment and current price of comparator treatment

Net costs where available (otherwise take gross)

Net Annual Cost (TA treatment minus comparator treatment) for new patients per annum provided by Guernsey clinicians based on discounted or TA prices for TA treatment and current price of comparator treatment

Option 1 All Unfunded TAs

Option 2 All Cancer TAs

Option 2a: Cancer Drugs Fund TAs

Option 2b: Non-Cancer Drugs Fund Cancer TAs

Option 3 End of Life TAs

Option 4 Common Disease TAs

Option 5 Cost Effective TAs

Option 6 Status Quo



Appendix 7: Proforma sent to Guernsey clinicians to obtain estimated patient numbers

Dear XX

I think you are aware that SPH have been commissioned by the States of Guernsey to provide a report on the consequences of routinely providing all treatments for the specific indications that are approved in the NICE Technology Appraisals.

As part of this work we are modelling how much the cost will be to the States of Guernsey if it were to approve all NICE TA-approved treatments. However, we are missing some key information about prevalence and incidence. We therefore need your clinical expertise to estimate how many patients might be eligible for and likely to take up these particular NICE TA-approved treatments should they become available to States residents in the future.

The attached spreadsheet lists the currently unfunded NICE TAs for a group of diseases. We have provided the name of the TA drug, the patient population for which it has been recommended by NICE and the relevant eligibility criteria set out in the TA recommendations.

What we would like from you is:

- 1. How many patients are you currently aware of on Guernsey and Alderney that would be eligible for treatment with this TA drug (i.e. meet the NICE TA indication and eligibility criteria)? Please enter a number into Column G.
- 2. Of these patients, how many do you think would be likely to switch or start treatment on the TA drug if it was to become available. Please enter a percentage into Column H.
- 3. Thinking ahead, how many new patients do you estimate would be likely to start treatment with the TA drug per annum? Please enter a number into either Column J (if one or more new patient per year) or Column K (if less than one new patient per year).

We don't expect that you will have precise and accurate figures. Your best guess is what we're looking for because at the moment we have very limited data to base our estimations on. The fact that estimations are based on clinical judgment will be made explicit in the report and no clinician will be named.

We would like this information returned to us no later than close of play on Thursday 18th April.

Thank you for your support with this important piece of work. If you have any queries please contact me via michael.griffin2@nhs.net or on +44 3300 555182.



TA ID	Intervention	Indication	Eligibility Criteria	Specialty Category e.g. cancer, T&O, respiratory	Cancer Grouping	Estimated number of Guernsey/Alderney PREVALENT patients i.e. the number currently untreated but eligible for treatment with this NICE TA approved drug	Proportion (%) of these (column G) who you would consider starting or switching to treatment with this NICE TA- approved drug	Estimated number of NEW patients treated per annum (If less than 1 please go to column K)	Estimated number of NEW patients treated per 5 years (Only complete if column I is less than 1)



Appendix 8: List of NICE TAs included in each potential policy option

TA ID	Intervention	Indication	Option 1: All Unfund ed TAs	Option 1a: All Unfund ed TAs exc. HSTs	Option 2: All unfund ed Cancer TAs	Option 2a: All unfund ed CDF TAs	Option 2b: All non- CDF TAs	Option 3: All end of life care TAs	Option 4: All commo n conditi on TAs	Option 5: ICER Under £20k per QALY	Option 5: ICER Under £30k per QALY	Option 5: ICER Under £40k per QALY	Option 5: ICER Under £50k per QALY	Option 5: ICER Under £100k per QALY
TA114	Methadone and buprenorphine for the management of opioid dependence	Drug misuse	Y	Y					Y		Y	Y	Y	Y
TA157	Dabigatran etexilate	Venous thromboembolism after hip or knee replacement surgery	Y	Y					Y		Y	Y	Y	Y
TA177	Alitretinoin	Severe chronic hand eczema	Υ	Υ							Υ	Υ	Υ	Υ
TA183	Topotecan in combination with cisplatin	Recurrent or stage IV cervical cancer	Y	Y	Y		Y					Y	Y	Y
TA184	Oral topotecan	Relapsed small-cell lung cancer	Y	Y	Y		Y	Υ				Y	Y	Y
TA185	Intravenous trabectedin	Advanced soft tissue sarcoma	Υ	Υ	Y		Υ	Υ				Y	Υ	Y
TA190	Pemetrexed (maintenance treatment)	Non-small-cell lung cancer	Y	Y	Y		Y	Y	Y				Y	Y
TA208	Trastuzumab, in combination with cisplatin and capecitabine or 5-fluorouracil,	Gastric cancer (HER2- positive, metastatic)	Υ	Y	Υ		Y	Y					Υ	Y
TA230	Bivalirudin in combination with	ST-segment-elevation myocardial infarction	Υ	Υ					Y	Υ	Υ	Y	Y	Y



	aspirin and clopidogrel												
TA235	Mifamurtide	Treatment of high-grade resectable non-metastatic osteosarcoma in children, adolescents and young adults	Y	Y	Y	Y					Y	Y	Y
TA246	Pharmalgen	Treatment of bee and wasp venom allergy	Y	Y					Y	Y	Y	Y	Y
TA249	Dabigatran etexilate	Prevention of stroke and systemic embolism in atrial fibrillation	Υ	Y				Y	Y	Y	Y	Y	Y
TA268	Ipilimumab	Previously treated advanced (unresectable or metastatic) melanoma	Y	Y	Y	Y	Y					Y	Y
TA279	Percutaneous vertebroplasty	Vertebral compression fractures	Υ	Υ					Y	Υ	Y	Y	Y
TA279	Percutaneous balloon kyphoplasty (without stenting)	Vertebral compression fractures	Y	Y					Y	Y	Y	Y	Y
TA288	Dapagliflozin in a dual therapy regimen in combination with metformin	Type 2 diabetes	Y	Y				Y	Y	Y	Y	Y	Y
TA288	Dapagliflozin in combination with insulin with or without other antidiabetic drugs	Type 2 diabetes	Y	Y				Y	Y	Y	Y	Y	Y
TA290	Mirabegron	Symptoms of overactive bladder	Υ	Y				Υ	Y	Y	Y	Y	Y
TA297	Ocriplasmin	Vitreomacular traction	Υ	Y				Υ		Υ	Y	Υ	Υ



	_, , ,	T = 1 1 1 1 1 1	.,	T 1/2		1		1		I			,	
TA301	Fluocinolone	Chronic diabetic macular	Υ	Υ					Υ		Υ	Υ	Υ	Y
	acetonide	oedema after an inadequate												
	intravitreal	response to prior therapy												
	implant													
TA303	Teriflunomide	Relapsing-remitting multiple	Υ	Υ						Υ	Υ	Υ	Υ	Υ
		sclerosis												
TA304	Resurfacing	End-stage arthritis of the hip	Υ	Υ										
	anthroplasty													
TA306	Pixantrone	Multiply relapsed or	Υ	Υ	Υ		Υ				Υ	Υ	Υ	Υ
	monotherapy	refractory aggressive non-												
		Hodgkin's B-cell lymphoma												
TA315	Canagliflozin in	Type 2 diabetes	Υ	Υ					Υ					
	combination with													
	metformin (dual													
	therapy)													
TA315	Canagliflozin in	Type 2 diabetes	Υ	Υ					Υ					
	combination with													
	metformin and a													
	sulfonylurea/thia													
	zolidinedione													
	(triple therapy)													
TA315	Canagliflozin in	Type 2 diabetes	Υ	Υ					Υ					
	combination with													
	insulin with or													
	without other													
	antidiabetic													
	drugs													
TA316	Enzalutamide	Metastatic hormone-	Υ	Υ	Υ		Υ	Υ			Υ	Υ	Υ	Υ
		relapsed prostate cancer												
TA319	Ipilimumab	Previously untreated	Υ	Υ	Υ		Υ	Υ					Υ	Υ
	·	advanced (unresectable or												
		metastatic) melanoma												
TA325	Nalmefene	Reducing alcohol	Υ	Υ					Υ	Υ	Υ	Υ	Υ	Υ
	· · ·	consumption in people with												
		alcohol dependence												
TA327	Dabigatran	treatment and secondary	Υ	Υ					Υ		Υ	Υ	Υ	Υ
			ı	1	1	1	1	II.	1	I	1	1		1



	etexilate	prevention of deep vein thrombosis and/or												
TA333	Axitinib	pulmonary embolism treating advanced renal cell carcinoma after failure of prior systemic treatment	Y	Y	Y		Y	Y					Y	Y
TA343	Obinutuzumab in combination with chlorambucil	Untreated chronic lymphocytic leukaemia	Υ	Y	Y		Y				Y	Y	Y	Y
TA345	Naloxegol	Opioid-induced constipation	Υ	Υ					Υ	Υ	Υ	Υ	Υ	Υ
TA347	Nintedanib in combination with docetaxel	Locally advanced, metastatic, or locally recurrent non-small-cell lung cancer	Y	Y	Y		Y	Y					Y	Y
TA357	Pembrolizumab	Treating advanced melanoma after disease progression with ipilimumab	Υ	Y	Y		Y	Y					Y	Y
TA358	Tolvaptan	Treating autosomal dominant polycystic kidney disease	Υ	Y									Y	Y
TA359	Idelalisib in combination with rituximab	Treating chronic lymphocytic leukaemia	Υ	Y	Y		Y	Y					Y	Υ
TA366	Pembrolizumab	Advanced melanoma not previously treated with ipilimumab	Υ	Y	Y	Y		Y					Y	Y
TA367	Vortioxetine	Major depressive episodes	Υ	Υ					Υ	Υ	Υ	Υ	Υ	Υ
TA377	Enzalutamide	Treating metastatic hormone-relapsed prostate cancer before chemotherapy is indicated	Y	Y	Y	Y					Y	Y	Y	Y
TA379	Nintedanib	Treating idiopathic pulmonary fibrosis	Y	Y					Y			Y	Y	Y
TA380	Panobinostat in combination with bortezomib and dexamethasone	Treating multiple myeloma after at least 2 previous treatments	Y	Y	Y	Y			Y		Y	Y	Y	Y



TA383	TNF-alpha inhibitors (Adalimumab, certolizumab	Ankylosing spondylitis and non-radiographic axial spondyloarthritis	Υ	Y						Y	Y	Y	Y
	pegol, etanercept, golimumab and infliximab)												
TA388	Sacubitril valsartan	Treating symptomatic chronic heart failure with reduced ejection fraction	Y	Y				Y		Y	Y	Y	Y
TA390	Canagliflozin monotherapy	Treating type 2 diabetes	Υ	Υ				Y	Υ	Y	Y	Y	Y
TA390	Dapagliflozin monotherapy	Treating type 2 diabetes	Υ	Y				Y	Y	Y	Y	Y	Y
TA391	Cabazitaxel in combination with prednisone or prednisolone	Treating hormone-relapsed metastatic prostate cancer treated with docetaxel	Y	Y	Y	Y	Y					Y	Y
TA393	Alirocumab	Treating primary hypercholesterolaemia and mixed dyslipidaemia	Y	Y				Y		Y	Y	Y	Y
TA394	Evolocumab	Treating primary hypercholesterolaemia and mixed dyslipidaemia	Y	Y				Y			Y	Y	Y
TA395	Ceritinib	Previously treated anaplastic lymphoma kinase positive non-small-cell lung cancer	Y	Y	Y	Y	Y					Y	Y
TA397	Belimumab	Treating active autoantibody-positive systemic lupus erythematosus	Y	Y									
TA400	Nivolumab in combination with ipilimumab	Treating advanced melanoma	Υ	Y	Y	Y				Y	Y	Y	Y
TA401	Bosutinib	Previously treated chronic	Υ	Y	Y	Y	Υ						Y



		myeloid leukaemia												
TA404	Degarelix	Advanced hormone-	Υ	Y	Υ		Y			Υ	Υ	Υ	Υ	Y
		dependent prostate cancer												
TA405	Trifluridine-	Previously treated metastatic	Υ	Y	Υ	Υ		Υ	Υ				Υ	Y
	tipiracil	colorectal cancer												
TA406	Crizotinib	Untreated anaplastic	Υ	Y	Υ	Y		Υ					Y	Y
		lymphoma kinase-positive												
		advanced non-small-cell lung												
		cancer		.,		.,							.,	.,
TA410	Talimogene	Treating unresectable	Υ	Y	Υ	Y					Υ	Υ	Y	Y
TA 442	laherparepvec	metastatic melanoma	Y	Y						Υ	Υ		Y	Y
TA413	Elbasvir–	Chronic hepatitis C	Y	Y						Y	Y	Y	Y	Y
TA415	grazoprevir Certolizumab	Rheumatoid arthritis after	Y	Y					Υ	Y	Υ	Υ		
1A415	pegol in	inadequate response to a	1	'					·	,	ī	,		
	combination with	TNF-alpha inhibitor												
	methotrexate	Tru dipila illinoitoi												
TA415	Certolizumab	Rheumatoid arthritis after	Υ	Υ									Υ	Υ
	pegol	inadequate response to a												
	monotherapy	TNF-alpha inhibitor												
TA416	Osimertinib	Locally advanced or	Υ	Y	Υ	Y								Υ
		metastatic EGFR T790M												
		mutation-positive non-small-												
		cell lung cancer												
TA417	Nivolumab	Previously treated advanced	Υ	Υ	Υ		Y	Υ					Υ	Y
		renal cell carcinoma							.,					.,
TA418	Dapagliflozin in	Treating type 2 diabetes	Υ	Y					Υ			Υ	Y	Y
	combinatin with metformin and a													
	sulfonylurea													
	(triple therapy)													
TA420	Ticagrelor in	Preventing atherothrombotic	Υ	Y					Υ		Υ	Υ	Υ	Υ
.,,,20	combination with	events after myocardial	-											
	aspirin	infarction												
TA422	Crizotinib	Previously treated anaplastic	Υ	Υ	Υ		Y	Υ					Υ	Υ
		lymphoma kinase-positive												



		advanced non-small-cell lung											
TA423	Eribulin	Treating locally advanced or metastatic breast cancer after 2 or more chemotherapy regimens	Y	Y	Y		Y	Y	Y			Y	Y
TA424	Pertuzumab, in combination with trastuzumab and chemotherapy	Neoadjuvant treatment of HER2-positive breast cancer	Y	Y	Y		Y				Y	Y	Y
TA425	Dasitinib	Treating imatinib-resistant or intolerant chronic myeloid leukaemia	Y	Y	Y		Y			Y	Y		
TA425	Nilotinib	Treating imatinib-resistant or intolerant chronic myeloid leukaemia	Y	Y	Y		Y					Y	Y
TA426	Nilotinib	Untreated chronic myeloid leukaemia	Y	Y	Y	Y					Y	Y	Y
TA427	Pomalidomide, in combination with low-dose dexamethasone	Multiple myeloma previously treated with lenalidomide and bortezomib	Y	Y	Y		Y	Y				Y	Y
TA428	Pembrolizumab	PD-L1-positive non-small-cell lung cancer after chemotherapy	Y	Y	Y		Y	Y					Y
TA431	Mepolizumab as an add-on to optimised standard therapy	Severe refractory eosinophilic asthma	Y	Y					Y	Y	Y	Y	Y
TA439	Panitumumab	Previously untreated metastatic colorectal cancer	Y	Y	Y	Y		Υ	Y			Y	Υ
TA442	Ixekizumab	Moderate to severe plaque psoriasis	Y	Y						Y	Y	Y	Y
TA443	Obeticholic acid	Primary biliary cholangitis	Υ	Y							Υ	Υ	Υ
TA445	Certolizumab pegol alone, or in	Psoriatic arthritis after inadequate response to	Y	Y						Y	Y	Y	Y



	combination with methotrexate	DMARDs												
TA448	Etelcalcetide	Secondary hyperparathyroidism	Υ	Y					Y		Y	Y	Y	Y
TA450	Blinatumomab	Previously treated Philadelphia-chromosome- negative acute lymphoblastic leukaemia	Y	Y	Y		Y	Y					Y	Y
TA451	Ponatinib	Chronic myeloid leukaemia and acute lymphoblastic leukaemia	Υ	Y	Y		Y	Y			Y	Y	Y	Y
TA457	Carfilzomib in combination with dexamethasone	Previously treated multiple myeloma	Υ	Y	Y		Y				Y	Y	Y	Y
TA461	Roflumilast as an add-on to bronchodilator therapy	Chronic obstructive pulmonary disease	Y	Y					Y		Y	Y	Y	Y
TA462	Nivolumab	Relapsed or refractory classical Hodgkin lymphoma	Y	Y	Y	Y		Y				Y	Y	Y
TA463	Cabozantinib	Previously treated advanced renal cell carcinoma	Υ	Y	Y		Y	Y					Y	Y
TA465	Olaratumab in combination with doxorubicin	Advanced soft tissue sarcoma	Υ	Y	Y	Y		Y						Y
TA467	Holoclar (ex vivo expanded autologous human corneal epithelial cells containing stem cells)	Limbal stem cell deficiency after eye burns	Y	Y							Y	Y	Y	Y
TA471	Eluxadoline	Irritable bowel syndrome with diarrhoea	Υ	Y					Υ	Y	Y	Y	Y	Y
TA472	Obinutuzumab with	Follicular lymphoma refractory to rituximab	Y	Y	Y	Y						Y	Y	Y



	bendamustine												
TA473	Cetuximab in combination with platinum-based chemotherapy	Recurrent or metastatic squamous cell cancer of the head and neck	Y	Y	Y	Y							
TA474	Sorafenib	Advanced hepatocellular carcinoma	Y	Y	Y	Y		Y				Y	Y
TA476	Paclitaxel as albumin-bound nanoparticles (nab-paclitaxel) with gemcitabine	Untreated metastatic pancreatic cancer	Y	Y	Y		Y					Y	Y
TA477	Autologous chondrocyte implantation	Symptomatic articular cartilage defects of the knee	Y	Y					Y	Y	Y	Y	Y
TA478	Brentuximab vedotin	Relapsed or refractory systemic anaplastic large cell lymphoma	Υ	Y	Y	Y				Y	Y	Y	Y
TA479	Reslizumab, as an add-on therapy	Severe eosinophilic asthma	Y	Y					Y	Y	Y	Y	Y
TA480	Tofacitinib with methotrexate	Moderate to severe rheumatoid arthritis	Υ	Y					Υ				
TA480	Tofacitinib with methotrexate	Moderate to severe rheumatoid arthritis	Υ	Y									
TA480	Tofacitinib monotherapy	Moderate to severe rheumatoid arthritis	Υ	Y									
TA483	Nivolumab	Previously treated squamous non-small-cell lung cancer	Υ	Y	Y	Υ		Υ					Υ
TA484	Nivolumab	Previously treated non- squamous non-small-cell lung cancer	Y	Y	Y	Y		Y				Y	Y
TA485	Sarilumab with methotrexate	Moderate to severe rheumatoid arthritis	Υ	Y							Υ		Υ
TA485	Sarilumab with methotrexate	Moderate to severe rheumatoid arthritis	Υ	Y									Υ
TA485	Sarilumab with	Moderate to severe	Υ	Y									Υ



	methotrexate	rheumatoid arthritis												
TA485	Sarilumab	Moderate to severe	Υ	Υ									Υ	
18463	monotherapy	rheumatoid arthritis	'	'									'	
TA487	Venetoclax	Chronic lymphocytic	Υ	Υ	Υ	Y		Y						Υ
17407	Verietociax	leukaemia		'	'	'		'						
TA490	Nivolumab	Squamous cell carcinoma of	Υ	Υ	Υ	Υ		Y						Υ
171430	Mivoranias	the head and neck after	·											
		platinum-based												
		chemotherapy												
TA491	Ibrutinib	Waldenstrom's	Υ	Υ	Υ	Υ								Υ
		macroglobulinaemia												
TA492	Atezolizumab	Untreated PD-L1-positive	Υ	Υ	Υ	Υ		Υ						Υ
		locally advanced or												
		metastatic urothelial cancer												
		when cisplatin is unsuitable												
TA493	Cladribine tablets	Relapsing-remitting multiple	Υ	Υ						Y	Υ	Υ	Υ	Υ
		sclerosis												
TA496	Ribociclib with an	Untreated, hormone	Υ	Υ	Υ		Υ		Υ		Υ	Υ	Υ	Υ
	aromatase	receptor-positive, HER2-												
	inhibitor	negative, locally advanced or												
		metastatic breast cancer												
TA498	Lenvatinib plus	Previously treated advanced	Υ	Υ	Y		Υ				Υ	Υ	Υ	Y
	everolimus	renal cell carcinoma												
TA500	Ceritinib	Untreated ALK-positive non-	Υ	Υ	Y		Υ				Υ	Υ	Υ	Y
		small-cell lung cancer												
TA504	Pirfenidone	Idiopathic pulmonary fibrosis	Y	Y					Υ		Υ	Υ	Y	Y
TA505	Ixazomib with	Relapsed or refractory	Υ	Y	Y	Y						Υ	Υ	Y
	lenalidomide and	multiple myeloma												
	dexamethasone													
TA507	Sofosbuvir–	Chronic hepatitis C	Υ	Y						Υ	Υ	Υ	Y	Υ
	velpatasvir–													
	voxilaprevir			.,								.,	.,	.,
TA508	Autologous	Symptomatic articular	Υ	Y					Υ	Y	Υ	Υ	Υ	Y
	chondrocyte	cartilage defects of the knee												
	implantation													
	using													



	chondrosphere												
TA509	Pertuzumab in combination with trastuzumab and docetaxel	HER2-positive breast cancer	Y	Y	Y	Y		Y			Y	Y	Y
TA510	Daratumumab monotherapy	Relapsed and refractory multiple myeloma	Y	Y	Υ	Υ							Y
TA511	Brodalumab	Moderate to severe plaque psoriasis	Y	Y						Y	Y	Y	Y
TA512	Tivozanib	Advanced renal cell carcinoma	Y	Y	Y		Y					Y	Y
TA513	Obinutuzumab	Untreated advanced follicular lymphoma	Y	Y	Y		Y			Y	Y	Y	Y
TA516	Cabozantinib	Progressive medullary thyroid cancer	Y	Y	Y	Y		Y		Y	Y	Y	Y
TA517	Avelumab (second-line and beyond treatment)	Metastatic Merkel cell carcinoma	Y	Y	Y	Y		Y			Y	Y	Y
TA517	Avelumab (first- line)	Metastatic Merkel cell carcinoma	Y	Y	Y	Y		Y					Y
TA519	Pembrolizumab	Locally advanced or metastatic urothelial carcinoma after platinum- containing chemotherapy	Y	Y	Y	Y		Y				Y	Y
TA520	Atezolizumab	Locally advanced or metastatic non-small-cell lung cancer after chemotherapy	Y	Y	Y		Y	Y				Y	Y
TA521	Guselkumab	Moderate to severe plaque psoriasis	Y	Y									
TA522	Pembrolizumab	Untreated locally advanced or metastatic urothelial cancer when cisplatin is unsuitable	Y	Y	Y	Y		Y					Y
TA523	Midostaurin	Untreated acute myeloid	Υ	Υ	Υ		Υ			Υ	Υ	Υ	Υ



		leukaemia												
TA524	Brentuximab	CD30-positive Hodgkin	Υ	Υ	Υ	Y					Y	Υ	Υ	Υ
	vedotin	lymphoma												
TA525	Atezolizumab	Locally advanced or	Υ	Υ	Y		Υ	Υ						
		metastatic urothelial												
		carcinoma after platinum-												
		containing chemotherapy												
TA526	Arsenic trioxide	Acute promyelocytic	Υ	Υ	Υ		Υ			Υ	Y	Υ	Υ	Υ
		leukaemia												
TA529	Crizotinib	ROS1-positive advanced non-	Υ	Y	Y	Υ		Υ					Υ	Y
		small-cell lung cancer												
TA531	Pembrolizumab	Untreated PD-L1-positive	Υ	Υ	Υ		Υ	Y	Y				Υ	Υ
		metastatic non-small-cell												
		lung cancer	.,	.,										
TA533	Ocrelizumab	Relapsing–remitting multiple	Υ	Υ								Υ	Υ	Υ
		sclerosis												
TA534	Dupilumab	Severe atopic dermatitis	Υ	Y					Υ		Y	Υ	Υ	Y
TA535	Lenvatinib	Thyroid cancer	Υ	Y	Y		Y	Y				Υ	Υ	Y
TA535	Sorafenib	Thyroid cancer	Υ	Y	Y	Y		Υ				Υ	Υ	Y
TA536	Alectinib	Untreated anaplastic	Υ	Y	Y		Υ				Y	Υ	Υ	Y
		lymphoma kinase (ALK)-												
		positive advanced non-small-												
		cell lung cancer (NSCLC)												
TA537	Ixekizumab	Psoriatic arthritis after	Υ	Υ						Υ	Y	Υ	Υ	Y
		inadequate response to												
		DMARDs												
TA538	Dinutuximab	Neuroblastoma	Υ	Υ	Y		Υ					Υ	Υ	Υ
	beta													
TA539	Lutetium (177Lu)	Unresectable or metastatic	Υ	Υ	Y		Υ	Υ			Y	Υ	Υ	Υ
	oxodotreotide	pancreatic neuroendocrine												
		tumours												
TA539	Lutetium (177Lu)	Unresectable or metastatic	Υ	Υ	Y		Υ				Y	Υ	Υ	Υ
	oxodotreotide	gastrointestinal												
		neuroendocrine tumours						ļ						
TA540	Pembrolizumab	Relapsed or refractory	Υ	Υ	Y	Y		Y					Υ	Υ
		classical Hodgkin lymphoma			1	1					1	1		1



TA541	Inotuzumab	Relapsed or refractory B-cell acute lymphoblastic leukaemia	Y	Y	Y	Y	Y				Y	Y	Y
TA542	Cabozantinib	Untreated advanced renal cell carcinoma	Υ	Y	Υ	Υ	Υ	Υ	Υ	Y	Y	Υ	Υ
TA543	Tofacitinib, with methotrexate	Psoriatic arthritis after inadequate response to DMARDs	Y	Y					Y	Y	Y	Y	Y
TA545	Gemtuzumab ozogamicin, with daunorubicin and cytarabine	De novo untreated acute myeloid leukaemia except acute promyelocytic leukaemia for patients age 15 years and above, in combination with daunorubicin and cytarabine	Y	Y	Y	Y				Y	Y	Y	Y
TA547	Tofacitinib (Xeljanz, Pfizer)	Treatment of adult patients with moderately to severely active ulcerative colitis who have had an inadequate response, lost response, or were intolerant to either conventional therapy or a biologic agent	Y	Y				Y	Y	Y	Y	Y	Y
TA551	Lenvatinib (Lenvima, Eisai)	Monotherapy for the treatment of adult patients with advanced or unresectable hepatocellular carcinoma (HCC) who have received no prior systemic therapy	Υ	Y	Y	Υ				Y	Y	Y	Y
TA552	Liposomal cytarabine— daunorubicin (Vyxeos, Jazz Pharmaceuticals)	The treatment of adults with newly diagnosed, therapy-related acute myeloid leukaemia (t?AML) or AML with myelodysplasia-related changes (AML?MRC)	Y	Y	Y	Y	Y					Y	Y



TA553	Pembrolizumab	Monotherapy for the	Υ	Υ	Υ	Υ		Υ	Υ	Υ	Υ	Υ
	(Keytruda, Merck	adjuvant treatment of adults										
	Sharp & Dohme)	with stage III melanoma and										
		lymph node involvement										
		who have undergone										
		complete resection										
TA554	Tisagenlecleucel	Paediatric and young adult	Υ	Υ	Υ	Υ				Υ	Υ	Υ
	(Kymriah,	patients up to 25 years of										
	Novartis)	age with B?cell acute										
		lymphoblastic leukaemia that										
		is refractory, in relapse post-										
		transplant or in second or										
		later relapse										
HST01	Eculizumab	Atypical Haemolytic Uraemic	Υ									
		Syndrome										
HST02	Elosulfase alfa	Mucopolysaccharidosis Type	Υ									
		IVa										
HST03	Ataluren	Duchenne Muscular	Υ									
		Dystrophy with a nonsense										
		mutation in the dystrophin										
		gene										
HST04	Migalastat	Fabry disease	Υ									
HST05	Eliglustat	Type 1 Gaucher disease	Υ									
HST06	Asfotase alfa	Paediatric-onset	Υ									
		Hypophosphatasia										
HST07	Strimvelis	Adenosine Deaminase	Υ									
		Deficiency										
HST08	Burosumab	X-linked Hypophosphataemia	Υ									

This report has been based on information and data publically available including that from NICE and the Scottish Medicines Consortium and provided by individuals and organisations consulted during the Review. Care was taken in the preparation of the information in this report and every effort has been made to ensure the information is accurate and up-to-date.

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The Review of Drugs and Treatments: Additional Costs for the Implementation of NICE TAS

A Report for the States of Guernsey Committee for Health & Social Care

www.sph.nhs.uk

July 2019

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1 Introduction and background

1.1 The Drug and Treatment Review

Solutions for Public Health (SPH) was commissioned in January 2019 to undertake a review of the policy implications and outline costs of adopting National Institute for Clinical Effectiveness (NICE) Technology Appraisal (TA) approved treatments and to provide the Committee *for* Health and Social Care with a range of commissioning options.

The scope of the review related to the direct cost of the drug or other treatment only. Any wider service delivery implications such as manpower, which may require funding when deciding on a policy of routine adoption of NICE TA-approved treatments, were out of scope.

1.2 Scope of this additional work

Drug and device acquisition costs are not the only consideration when adopting NICE TA-approved treatments. Other service delivery resources need to be taken into account when implementing new treatments and pathways.

Outpatient appointments, ward attendances and associated nurse time, pharmacy services required to make up and deliver treatments, diagnostics to monitor progression and manage side-effects and hospital admissions required to treat adverse events are all factors that should all be included in the decision making process.

To support the main review SPH were asked to assess the additional impact of implementing NICE TA approved treatments and to provide an indicative estimate of associated implementation costs for the TA recommendations unfunded as at 31st December 2018, with an ICER¹ of less than £40,000 per QALY during the first year of implementation.

The modelling required to predict year 2 and onwards activity (backlog patients still receiving treatment plus new patients entering the pathways) is not feasible within the time constraints of this review and without monitoring information from initial roll out and uptake.

¹ The primary outcome used by NICE is the quality-adjusted life year (QALY). A QALY is a single unit of health gain that combines both expected years of life gained and quality of life gained. The QALY is a 'common currency' which allows different interventions to be compared for different conditions. Where a new intervention appears to be more effective than the current comparator treatment, NICE usually compares the interventions by calculating the incremental cost- effectiveness ratio (ICER). The ICER is the ratio of the difference in the mean costs of an intervention compared with the next best alternative (which could be no action or treatment) to the differences in the mean health outcomes. ICERs are expressed as cost (in £) per QALY gained.



2 Methodology

The approach taken to identify the wider implications of adopting NICE TAs was to:

- identify the relevant TAs from the database produced as part of the main Drugs and Treatment Review
- prioritise those TAs which are most likely to substantially impact current service delivery capacity and capability
- review current and proposed treatment options with key professionals and service providers to identify key differences
- quantify and cost resources required over and above those in place currently

3 Relevant TAs

87 TAs containing a total of 92 TA recommendations with an ICER of <£40,000 per QALY, unfunded at 31st December 2019, were identified in the initial Drug and Treatment Review.

Table 1: Approved NICE TAs unfunded as at 31st December 2018 with an ICER of <£40,000 per QALY

Specialty	Number of TA recommendations ²	Estimated Guernsey patients Year 1	Estimated Guernsey New Patients Per Annum
Cancer	42	46.2	40.3
Cardiac Services	6	2030	240
Colorectal Services	2	110	23
Dermatology	5	12	10
Ear and Ophthalmology Services	3	21	15.2
Endocrinology	6	305	49
Hepatobiliary and Pancreas	1	2	1
Immunology and Allergy Services	1	4	1
Infectious Diseases	2	2	2
Mental Health	3	95	22
Neurosciences	3	5	3
Urology	1	150	40
Pain	1	100	100
Respiratory	5	100	49
Rheumatology	5	16	7
Trauma and Orthopaedics	5	60	60
Vascular Disease	1	15	15
Total	92	3073.2	677.5

Source: The Review of Drugs and Treatments, SPH 2019

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² A TA can include more than one recommendation



Table 1 shows that the 92 TA recommendations cover 17 specialties and an estimated 3,073 patients in year 1, plus 678 new patients per annum thereafter.

3.1 Prioritisation of NICE TAs for impact assessment

TA recommendations are not equal in terms of the number of patients that potentially meet the criteria for treatment, nor with regard to the potential impact on the care pathway and the infrastructure required to deliver the treatment.

Table 2 below shows that 42 (46%) of the TA recommendations are for anti-cancer treatments, but that they only cover 2% of the estimated year 1 patients. Conversely only 6 (7%) of the TA recommendations are for cardiac services, but these cover 66% of the estimated year 1 patients and there is only 1 TA recommendation for each of Urology and Pain treatments and they cover 5% and 3% of the estimated year 1 patients respectively.

Table 3 below shows the number of TA recommendations for each specialty by the type of treatment: drug – infusion, drug – injection, drug – oral, non-drug.



Table 2: Approved NICE TAs unfunded as at 31st December 2018 with an ICER of <£40,000 per QALY

Specialty	Total TA recommendations	% of total TA recommendations	Total estimated patients year 1	% of total estimated patients year 1	Total estimated new patients per annum	% of estimated new patients per annum
Cancer	42	46%	46.2	2%	40.3	6%
Cardiac Services	6	7%	2030	66%	240	35%
Colorectal Services	2	2%	110	4%	23	3%
Dermatology	5	5%	12	0%	10	1%
Ear and Ophthalmology Services	3	3%	21	1%	15.2	2%
Endocrinology	6	7%	305	10%	49	7%
Hepatobiliary and Pancreas	1	1%	2	0%	1	0%
Immunology and Allergy Services	1	1%	4	0%	1	0%
Infectious Diseases	2	2%	2	0%	2	0%
Mental Health	3	3%	95	3%	22	3%
Neurosciences	3	3%	5	0%	3	0%
Urology	1	1%	150	5%	40	6%
Pain	1	1%	100	3%	100	15%
Respiratory	5	5%	100	3%	49	7%
Rheumatology	5	5%	16	1%	7	1%
Trauma and Orthopaedics	5	5%	60	2%	60	9%
Vascular Disease	1	1%	15	0%	15	2%
TOTALS	92	100%	3073.2	100%	677.5	100%



Table 3: Approved NICE TAs unfunded as at 31st December 2018 with an ICER of <£40,000 per QALY by type of treatment

Drug -Infusion			Dr	rug -Injection Drug					None drug			
Specialty	TA recommendations	Estimated patients year 1	Estimated new patients per annum	TA recommendations	Estimated patients year 1	Estimated new patients per annum	TA recommendations	Estimated patients year 1	Estimated new patients per annum	TA recommendations	Estimated patients year 1	Estimated new patients per annum
Cancer	22	16.2	16.2	2	2	1.5	18	28	22.5	-	-	-
Cardiac Services	1	30	10	2	400	20	3	1600	210	-	-	-
Colorectal Services	-	-	-	-	-	-	2	110	23	-	-	-
Dermatology	-	-	-	4	10	8	1	2	2	-	-	-
Ear and Ophthalmology												
Services	-	-	-	1	10	5	-	-	-	2	11	10.2
Endocrinology	-	-	-	1	5	4	5	300	45	-	-	-
Hepatobiliary and Pancreas Immunology and Allergy	-	-	-				1	2	1	-	-	-
Services	_	_	_	1	4	1	-	_	_	-	_	_
Infectious Diseases	_	_	_	-	_	_	2	2	2	-	_	_
Mental Health	-	_	-	-	-	_	3	95	22	-	-	-
Neurosciences	1	2	1	-	-	_	2	3	2	-	-	_
Urology	-	_	-	-	-	-	1	150	40	-	-	-
Pain	-	_	-	-	-	-	1	100	100	-	-	_
Respiratory	1	10	2	1	10	2	3	80	45	-	-	-
Rheumatology	-	-	-	4	13	6	1	3	1	-	-	-
Trauma and Orthopaedics	-	-	-	-	-	-	1	50	50	4	10	10
Vascular Disease	-	-	-	-	-	-	1	15	15	-	-	-
Totals	25	58.2	29.2	16	454	47.5	45	2540	580.6	6	21	20.2



To reach a realistic assessment of resource impact, each potential new treatment should ideally be considered in detail alongside the current comparator treatment given in Guernsey.

The approach to assessing the resource implications of implementation is set out in Section 4.

To be able to complete the evaluation in the time available, it was necessary to prioritise the TA recommendations to focus effort on those treatments which are most likely to require service delivery planning, and possibly additional resource, beyond that of the incremental cost of the drug therapy or device alone in the first year following implementation.

The TA recommendations were categorised into 3 groups for assessment based on how the TA-recommended treatment is administered and the estimated number of patients involved:

• Group 1 - oral non-chemotherapy drugs

It is generally considered that the pathway and healthcare resources required to deliver the new treatment will not be dissimilar to the current comparator treatment. The main cost associated with these treatments will be putting the supply agreements in place and setting the drugs up on pharmacy systems.

The only cost allocated to implementation for the Group 1 TA recommendations was the time taken to set up the supplier contracts and delivery arrangements.

 Group 2a – oral chemotherapy drugs, drugs by infusion, drugs by injection and non-drug treatments with 1 or more patients estimated for year 1

These recommendations are highly likely to require increased healthcare resources over and above the resources in place to deliver current treatments.

Using the approach in Section 4, the resource implications for TA recommendations were considered in as much detail as possible, given the current knowledge of the proposed new treatments and subject to the limitations and assumptions described in Section 6.

Group 2b - oral chemotherapy drugs, drugs by infusion, drugs by injection and non-drug treatments with <1 patient estimated for year 1
 <p>These recommendations would also be likely to require increased healthcare resources over and above the resources in place to deliver current treatments but it was considered that the full resource impact would not be realised until after year 1.



The resource impact for the TA recommendations in Group 2b was also assessed using the approach in Section 4 but, due to time constraints, at a lower level of detail than for Group 2a.

Group 2a consisted of 40 TA recommendations across 10 specialties, 19 of which were in cancer services. Table 4 shows the split of the TA recommendations across the 3 groups.

Table 4: TA recommendations by assessment category

Group	Number of TA recommendations
1	24
2a	40
2b	24
Approved for funding since January 2019	4
Total	92

4 Assessment of resource requirements

4.1 The approach to evaluating the two treatments (current and proposed) and identifying where additional resources are required

A range of key clinical and operational staff were brought together to generate a common understanding of:

- the care pathway and delivery resources for the current treatment
- the potential care pathway and delivery resources for the new TArecommended treatment
- the differences in the resources required to deliver the two treatments
- the capability and capacity of the current services to absorb any increased requirements
- the type and extent of any additional resources required

For each TA recommendation, SPH provided information from The Review of Drugs and Treatments (SPH 2019) and from the NICE TA Guidance including:

- the intervention, indication and detailed patient criteria for which the drug or other treatment is approved by NICE.
- NICE recommended dose and schedule
- adverse events reported by NICE
- estimated numbers of patients for year one and new patients per annum



This information was reviewed by a group of clinical and operational specialists and compared to the current treatments given to the patient cohort.

Consideration was given to:

- specialty department staff availability
- · specialty department physical infrastructure, equipment and disposables
- pathology and other diagnostic services
- pharmacy services
- associated care eg treatment of adverse events and palliative care
- off island arrangements

For the TA recommendations which will introduce an increased workload the increase was quantified as far as possible for example:

- the number of additional infusions required per patient was estimated, and this estimate was applied to the number of Year 1 patients identified in the Drug and Treatment Review
- the increased number of clinic hours required in the Bulstrode Oncology Unit for new patients (currently not treated or current treatment not requiring hospital clinic attendance) was estimated along with any additional infusions per cycle and/or increased number of cycles associated with the new TArecommended treatment
- the number of additional pathology tests or scans required for diagnostics and/or monitoring of disease progression and management of side effects was also estimated

Where the current service area would not be able to deliver the increased workload without additional resources, the type and amount of resources were estimated. These estimates included:

- numbers/type of staff
- increased clinic appointment slots/theatre time
- higher volume of requests for pathology tests
- pharmacy infusion preparation etc.

4.2 Findings

The discussions and analyses around current workload and future workload based on the proposed TA recommendations were informative and constructive. Although there are currently a number of unknowns, the key areas identified for additional resource were:

the volume of infusions to be prepared in the pharmacy department



- the available nurse and clinic time in the Bulstrode Oncology Unit to deliver the increased volume of infusions and management of the care pathways (monitoring for disease progression, side effects etc)
- the palliative and community care needed to support increased longevity of treatments and increased survival times/life expectancy
- the volume of requests for pathology tests for diagnostics, disease progression and side effect management
- the addition of new treatment administration methods to specialties such as Respiratory
- the requirement for off-island commissioning where treatments cannot be provided in Guernsey

4.2.1 Bulstrode Unit

The area most impacted by the implementation of NICE approved TAs is the Bulstrode Oncology Unit. Although the number of cancer patients likely to be eligible for the TA-approved treatments is relatively small, the TA recommendations are predominantly for drugs administered by infusion and many of the new regimes have more infusions per cycle and more cycles than current treatments. In addition to this, the new regimes are often continued until disease progression, unlike current drugs where the number of treatment cycles is generally limited. As a result of these differences an additional 300/400 infusions per annum are expected to be required for the new anti-cancer TA approved treatments. An increase of approximately one third in clinic hours is required to accommodate the increased number of infusions and associated consultations.

We have been informed that current operational and staffing patterns do not have the capacity to deliver this increased number of infusions. To do so the Bulstrode Unit would be looking to implement specialist oncology scheduling software, to maximise utilisation, and to increase their opening hours to 8 am – 6 pm, Monday to Friday. An approximate software cost has been obtained from a supplier and included in Section 5 below. Also in Section 5 below, 33% of current pay costs has been used as an estimate of costs for extended opening hours

Specialist oncology scheduling software

Currently appointment scheduling is done via a manual task of checking lists and inputting in to Microsoft Outlook calendars. This requires nurse time to ensure that the patients are allocated the times appropriate to their specific treatment, for example the length of transfusion, whether the infusion has a short expiry time following manufacture or can be kept in a fridge overnight.

Applications are available specifically for oncology clinic scheduling which enable much more effective appointment scheduling. For example, using the BookWise software would:

- maximise efficiency and increase capacity by clearly showing space available
- streamline care pathways



- allow the setup of timings and rules within the system, making scheduling an administration role (not a nurse/clinician)
- identify appointment options taking into account the nursing and chair time required and regimen timings
- support the planning of capacity based on staff availability
- allow the pharmacy to view real-time activity on the unit and plan their workload appropriately
- identify all completed treatments where costs can be recouped (PAS rebates)
- help plan and follow a patient's treatment pathway to ensure patients are on track with their prescribed plan
- enable the production of reports such as drug usage, unit utilisation
- provide automated text service for appointment reminders

Adoption of a specialist booking system is an integral part of the Bulstrode Unit being able to implement new TA recommendations.

4.2.2 Pharmacy

An approximate increase of 600 infusions (anti-cancer infusions plus infusions for treatments in other specialties) and 300 oral items could be experienced if all the previously identified NICE TA recommendations with an ICER of <£40,000 per QALY are implemented.

Currently the pharmacy team has the capacity to manufacture 19 items a day. It is not possible at this stage to estimate when the current capacity limit will be reached as this is dependent on the uptake pattern for the new treatments and the resultant timing of the increased infusion preparation workload.

However, it is highly likely that the pharmacy service will need to be extended early in year 1 implementation of TA recommendations. Estimated costs shown in Section 5 below are based on an additional 0.7 WTE band 8A pharmacist, 1 WTE band 5 pharmacy technician and 1 WTE band 4 pharmacy assistant with an element for increased disposables/consumables.

There is also an opportunity to consider pharmacy led oral medication clinics for appropriate patients and regimes. This has not been explored or costed in this report.

4.2.3 Diagnostics

It is anticipated that increased infusion cycles, increased monitoring of disease progression and management of side effects will increase the amount of diagnostics requested from the specialties implementing NICE TA-approved treatments

Pharmacy

An estimate of an additional 350 requests for each of the 3 key oncology pathology tests has been used to reflect increases to workload. A unit cost has been allocated against each additional test in the estimated costs shown in Section 5 below.



A change to pathology opening hours to support the Bulstrode Unit extended hours is currently not envisaged.

There is, however, an opportunity to consider pharmacy led oral medication clinics for appropriate patients and regimes. In which case patients could have bloods done in pathology for any regimes where this is thought to be an option. This has not been explored or costed in this report.

It has not been possible to estimate additional pathology tests required from other specialties. Further increases in demand, over and above the oncology estimates included in this report, and the service capacity to deliver them will need to be monitored as implementation progresses.

Other diagnostics

IT has not been possible to estimate the increase in requests for other diagnostic tests (eg radiology and cardiology). Additional demand for these and the service capacity to deliver them will need to be monitored as implementation progresses

4.2.4 Palliative and community care

The life extending outcomes of many of the new TA recommended treatments will result in more patients needing supportive care for longer. Currently palliative care is resourced by a part time visiting consultant. This is unlikely to be sufficient to provide adequate, appropriate care to all patients as the new TA recommendations are implemented.

Primary costs for year one, included in Section 5 below, have been calculated on the basis of employing a full time nurse (possibly split between palliative care and community nursing). As the implementation of NICE TA-approved treatments progresses and impact of longevity of treatment and extension of life on palliative care demand increases additional consultant hours may be required.

4.2.5 Respiratory Services

The TA-approved recommendations for respiratory treatment include drug therapy by infusion. This service could be undertaken in a respiratory outpatient clinic. However, there is insufficient respiratory nurse time to be able to do this (part time nurse currently). An increase of 0.6 WTE band 7 nurse is required. An increase in respiratory nurse hours has already been included in the prioritisation process and the requirements of implemented TA treatments will be a core part of the job role.

4.2.6 Off-island commissioning

There are a number of TA-recommended treatments which will be provided by commissioning the treatment off-island. The reasons for this include:

- the service is not currently available on-island for example, paediatric oncology, inpatient oncology
- the medicines require specialist facilities to manufacture which are not currently available on-island for example, freezing at -90C



 very low patient numbers mean that demand is insufficient to develop a local service

The majority of off-island treatment requirements from the TA recommendations in scope for this exercise are for anti-cancer treatment (70%).

A proportionate increase to current off-island chemotherapy drug costs and flights for patient transfer have been used as a basis for the impact on off-island commissioning.

4.2.7 Treatment set up

All new treatments, regardless of administration method, other than those to be commissioned off-island will need to be set up and available for prescribing. This includes contacting manufacturers and suppliers, agreeing prices and contracts, and populating local systems with treatment information and protocols.

To do this for a large number of new treatments is time consuming and additional pharmacist resources will be required at the hospital and in the community. This must be taken into consideration in future workforce planning.

5 Estimation of costs

SPH worked with the individual departments and the States of Guernsey Finance Team to put a provisional cost against the additional resources identified.

Table 5 gives a summary of the indicative costs by area for implementation of NICE TAs with an ICER of <£40,000 per QALY in the first year following implementation.



Table 5: Indicative cost estimates for year 1 implementation of NICE TA by ICER banding

	Bulstro	ode Unit	Pharm	acy and pathol	ogy		Other de	partments			
	Specialist oncology scheduling software ¹	Additional oncology clinic and infusion costs ²	Additional pharmacy costs for drug supply set up and management 3	Additional pharmacy infusion and		Additional off-island costs 6	Additional respiratory nurse costs ⁷	Additional palliative care and community nurse costs 8	Additional palliative care consultant costs 8		
Set up/one off costs	£30,000										
Cumulative costs for additional implementation resources											
Year 1 costs ICER under £10k per QALY		£6,081	£8,825*	£2,671	£1,578	£0		£5,809	£27,928		
Year 1 costs ICER under £20k per QALY		£46,823	£47,737*	£2,671	£12,151	£1,357		£31,422	£151,065		
Year 1 costs ICER under £30k per QALY		£187,292	£71,588*	£75,076	£48,603	£17,647	£23,034*	£47,121	£226,544		
Year 1 costs ICER under £40k per QALY		£263,000	£79,000*	£105,492	£68,250	£47,510	£31,200*	£52,000	£250,000		

approximate software licence costs

assuming an increase of approximately one third in clinic hours required to accommodate the increased number of infusions and associated consultation - extended opening of the unit from 8am to 6pm five days per week - 33% of current pay costs

an additional 1 WTE at SO3 level is required – this is already factored in to future workforce planning with the aim to repurpose an existing post. If this is not approved through workforce planning then the funding will need to be provided from the NICE TA Implementation Programme



- based on a unit cost for each additional infusion and oral treatment over and above current treatment level calculated from the individual TA treatment schedule and estimated year 1 patient numbers (patient numbers from The Drugs and Treatment Review (SPH 2019))
- based on additional pathology tests required by oncology (approximately 350 additional requests for 3 tests). Note: additional pathology tests required from other specialties are not included and neither is the increase in requests for other diagnostic tests (eg radiology and cardiology). Additional demand for these and the service capacity to deliver them will need to be monitored as implementation progresses
- based on an increase of one third to the current off-island chemotherapy drugs budget plus return transfer for estimated patient numbers
- an additional 0.6 WTE Band 7 nurse is required this has already been included in Prioritisation plans. If this resource is not approved through the Prioritisation process then the funding will need to be provided from the NICE TA implementation programme
- based on a 1.0 WTE band 7 nurse. Primary costs for year 1 have been calculated on the basis of employing a full time nurse (possibly split between palliative care and community nursing). As the implementation of NICE TA-approved treatments progresses, and impact of longevity of treatment and extension of life on palliative care demand increases, additional consultant hours may be required. The cost of a full time on-island consultant is £250,000 which will be offset by the cost of the current part time visiting consultant

Table 6: Indicative total cost estimates for year 1 implementation of NICE TA by ICER banding

	Total cumulative budget	- excluding full time palliative care consultant if assessed as not needed	 excluding full time palliative care consultant if assessed as not needed excluding items funded through Prioritisation or workforce planning
Set up/one off costs	30,000	£30,000	£30,000
Year 1 costs ICER under £10k per QALY	£52,892	£24,964	£16,139
Year 1 costs ICER under £20k per QALY	£293,225	£142,161	£94,424
Year 1 costs ICER under £30k per QALY	£696,905	£470,361	£375,740
Year 1 costs ICER under £40k per QALY	£896,452	£646,452	£536,252



6 Summary of findings and conclusions

It is not feasible to implement NICE TA-approved recommendations with an ICER<£40,000 per QALY without investment in service delivery areas. A high level estimation of costs for the current backlog of TAs is approximately £900,000.

This is an indicative estimate only as a basis for initial decision making. Estimates for areas already considered will need to be refined and areas excluded from consideration so far (see Section 7) will need to be investigated.

This exercise has increased understanding of the potential impact of implementing NICE TAs, the need for further detailed planning prior to implementation and the opportunities to achieve increases in efficiency and effectiveness presented.

7 Exclusions and limitations

The approach described above and the subsequent findings reflect the time constraints and are subject to a number of exclusions and limitations.

Exclusions from this review include:

- the additional treatment acquisition costs over and above existing treatments (as these were included in the Drug and Treatment Review)
- consideration of the impact of NICE TA recommendations published since 1st
 January 2019 (24 new TAs as of 1st May 2019) and ongoing
- consideration of the impact of NICE TA recommendations with ICER values greater than £40,000 per additional QALY
- the potential change in private patient income arising from adoption of a greater proportion of NICE TA guidance
- training requirements for pharmacists, clinical consultants, nurses, etc in relation to the adoption of new TA-recommended treatments
- monitoring and audit for compliance with NICE TA eligibility criteria
- processes and systems for communicating policy/funding decisions and treatment approvals and for managing compliance with patient eligibility criteria, for example, BlueTeq
- e-prescribing which is being considered by a States of Guernsey Digital Improvement Programme
- other types of NICE guidance: There are 6 types of Evidence-based recommendations produced by NICE:
 - technology appraisals guidance (TA)



- highly specialised technology guidance (HST)
- guidelines covering clinical topics, medicines practice, public health and social care
- o diagnostics guidance
- o interventional procedures guidance
- o medical technologies guidance

Only NICE TAs and HSTs are within the scope of this report.

· clinical effectiveness and outcomes

Limitations of this review include:

- patient numbers: as part of the Drugs and Treatment Review (SPH 2019)
 Guernsey clinicians provided estimates of the number of people who might be
 eligible for each TA-approved treatment and indication. The initial approach to
 apply a crude pro-rata of England patient numbers (published by NICE) was
 abandoned due to the lack of complete NICE costing templates for the TAs
- in calculating implementation costs we have used the Year 1 patient numbers from the Drug and Treatment review. These numbers reflect the backlog of eligible patients likely to present for treatment in the first year. It has not been possible to estimate what proportion of the patients treated in Year 1 are likely to continue treatment in subsequent years, so these implementation costs relate only to the first 12 months following implementation
- with a small population, demand will fluctuate for some treatments (particularly those for rarer indications) year on year to such an extent that a budget is difficult to set and manage on a year on year basis
- NICE TA information can date quite quickly, in particular in relation to the cost of the intervention and comparator, and this may result in changes to the estimated ICER value
- there will be a number of cases where the comparator drug used by NICE in calculating the ICER value compared with the TA recommended treatment, is not the treatment currently provided in Guernsey. In these cases, we cannot say what is the true ICER value



This report has been based on information and data publically available including that from NICE and the Scottish Medicines Consortium and provided by individuals and organisations consulted during the Review. Care was taken in the preparation of the information in this report and every effort has been made to ensure the information is accurate and up-to-date.

Acknowledgements

With acknowledgment and thanks to all those who provided information or material.

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Deputy Heidi Soulsby President Committee of Health & Social Care Le Vauquiedor Office Rue Mignot St Andrew GY6 8TW

Parth & Social Care
Office

3rd September 2019

Dear Deputy Soulsby

Marin Santa



Re Review of Drugs, Treatments and Devices

Thank you for your letter of 14th August on the above matter. It has been shared with all IslandHealth Partners and was discussed at our most recent Practice Meeting. IslandHealth is fully supportive of the Committee's aspirations to implement National Institute for Health and Care Excellence (NICE) drugs and treatments with technological appraisals. Reducing any disparity between the availability of drugs for Guernsey and Alderney patients and those available in the UK is laudable. IslandHealth was reassured to learn that any programme of introduction should be incremental and regularly reviewed.

Some concerns were expressed about the impact on other parts of HSC's budget by this additional cost burden so we would wish to support and underline the view expressed in your letter that 'additional funding required should not be at the expense of existing services within HSC.'

We are comfortable with you including this letter in your Policy Letter.

I hope this is helpful.

Yours sincerely

Mr Andrew Carey Practice Manager

Ref:jae/HSC (formerly HSSD)/Review of Drugs, Treatments and Devices/Letter to Deputy Heidi Soulsby 030919

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THE STATES OF DELIBERATION Of the ISLAND OF GUERNSEY

COMMITTEE FOR HOME AFFAIRS

POLICE SUPPORT FOR ALDERNEY AND SARK

The States are asked to decide: -

Whether, after consideration of the Policy Letter dated 28th October 2019, of the Committee *for* Home Affairs, they are of the opinion:

- i. to agree that the Police Force (Guernsey) Law, 1986 should be amended to enable visiting police officers from the United Kingdom and the Bailiwick of Jersey to operate in Alderney and Sark on the same basis, including being subject to the same requirement for authorisation by the Bailiff, as that Law provides for such officers to operate in Guernsey;
- ii to direct the preparation of such legislation as is necessary to give effect to their above decision.

The above Propositions have been submitted to Her Majesty's Procureur for advice on any legal or constitutional implications in accordance with Rule 4(1) of the Rules of Procedure of the States of Deliberation and their Committees.

THE STATES OF DELIBERATION Of the ISLAND OF GUERNSEY

COMMITTEE FOR HOME AFFAIRS

POLICE SUPPORT FOR ALDERNEY AND SARK

The Presiding Officer States of Guernsey Royal Court House St Peter Port

28th October, 2019

Dear Sir

1 Executive Summary

- 1.1 This policy letter proposes an extension to the law that permits police officers from the United Kingdom and the Bailiwick of Jersey, to temporarily undertake duties in the island of Guernsey, to also cover the islands of Alderney and Sark.
- 1.2 The additional policing assistance, arranged through mutual aid agreements, is required from time-to-time to meet special demands on the resources of the Island Police Force, particularly during critical incidents, major investigations and Royal/VIP visits.
- 1.3 Legal advice has recently highlighted that an amendment to legislation is required to ensure that the authority for such officers to perform their duties in those islands, is beyond doubt.

2. Background

- 2.1 The Police Force (Guernsey) Law, 1986 allows for visiting officers to temporarily possess the same powers and privileges, and be subject to the same duties, as local police officers, following an application by the Committee *for* Home Affairs to the Bailiff.
- 2.2 Once authorised, these mutual aid officers come under the direct command of the Chief Officer of the Island Police Force, and are subject to the authority and jurisdiction of the Guernsey courts.
- 2.3 However, this Law only applies to the island of Guernsey, not Alderney or Sark, and there is no equivalent legislation in those jurisdictions. It would appear that the Alderney (Application of Legislation) Law, 1948 and the Reform (Sark) Law, 2008 may not be relied upon to provide the certainty required.

3. Conclusion

- 3.1 There is a serious risk to policing operations in support of Alderney and Sark if these additional officers are unable to be authorised. For example, the advanced plans for Royal visits to the Bailiwick include UK personal protection officers, however these plans cannot currently be extended to the other islands.
- 3.2 It is far more efficient to seek the assistance of specialist officers from other jurisdictions as and when needed, than to permanently maintain all the potential skills locally.
- 3.3 The proposal would not lead to any increase in public expenditure.
- 3.4 Without such an amendment the communities of Alderney and Sark will not have access to the same level of protection as that of the citizens of Guernsey.

4 Compliance with Rule 4

- 4.1 Rule 4 of the Rules of Procedure of the States of Deliberation and their Committees sets out the information which must be included in, or appended to, motions laid before the States.
- 4.2 In accordance with Rule 4(1), the Propositions have been submitted to Her Majesty's Procureur for advice on any legal or constitutional implications. She is content that there is no reason in law why the Propositions should not to be put into effect.
- 4.3 In accordance with Rule 4(4) of the Rules of Procedure of the States of Deliberation and their Committees, it is confirmed that the propositions above have the unanimous support of the Committee however Deputy Oliver and Deputy Smithies were not present when the Policy Letter was considered.
- 4.4 In accordance with Rule 4(5), the Propositions relate to the duties of the Committee on crime prevention and law enforcement including policing.
- 4.5 Also in accordance with Rule 4(5), the Committee has consulted with the authorities in Alderney and Sark. On the 22nd August 2019, the Chairman of the States of Alderney Policy and Finance Committee, confirmed in writing that the Committee resolved to support an amendment to the Police Force (Guernsey) Law, 1986, to cover Alderney. On the 2nd October 2019, at the Michaelmas meeting of the Island of Sark Chief Pleas, there was also approval for an amendment to this Law to cover Sark.

Yours faithfully

M M Lowe President M P Leadbeater Vice-President

V S Oliver P R Le Pelley J C S F Smithies