The Review of Drugs and Treatments: Options Appraisal

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

Final report

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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 (C*f*HSC) 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:

1. 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
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

All the options, apart from option 6 (status quo), if adopted may conflict with a number of principles and rules in the C*f*HSC 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 C*f*HSC 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 C*f*HSC 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, C*f*HSC 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. C*f*HSC will not, save in the exceptional circumstances set out in this policy, make isolated decisions about investments	●	●	●	●	●	●	●	●
3.3 C*f*HSC will only invest in interventions that are cost-effective	●	●	●	●	●	●	●	●
3.4 C*f*HSC will not fund treatments of unproven clinical effectiveness unless it is in the context of a well-designed clinical study					●			
3.5 C*f*HSC 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, C*f*HSC will review the future access criteria	●	●	●	●	●	●	●	●
3.7 C*f*HSC 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 C*f*HSC 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 C*f*HSC 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 C*f*HSC. 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 recommendations / TAs		Number of patients		Net cost 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 recommendations / TAs		Number of patients		Net cost 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
    - 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 recommendations / TAs		**Number of patients**		**Net cost 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 life-changing 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 excluding those in 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
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 only 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

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

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 of patients		Net cost 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

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

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 of patients		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' (C*f*HSC 2017b). It required health and social care providers and organisations to partner with the Committee *for* Health & Social Care (C*f*HSC) 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)'*
>
> (C*f*HSC 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 C*f*HSC 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.'*
>
> (C*f*HSC 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)*'

(C*f*HSC 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.

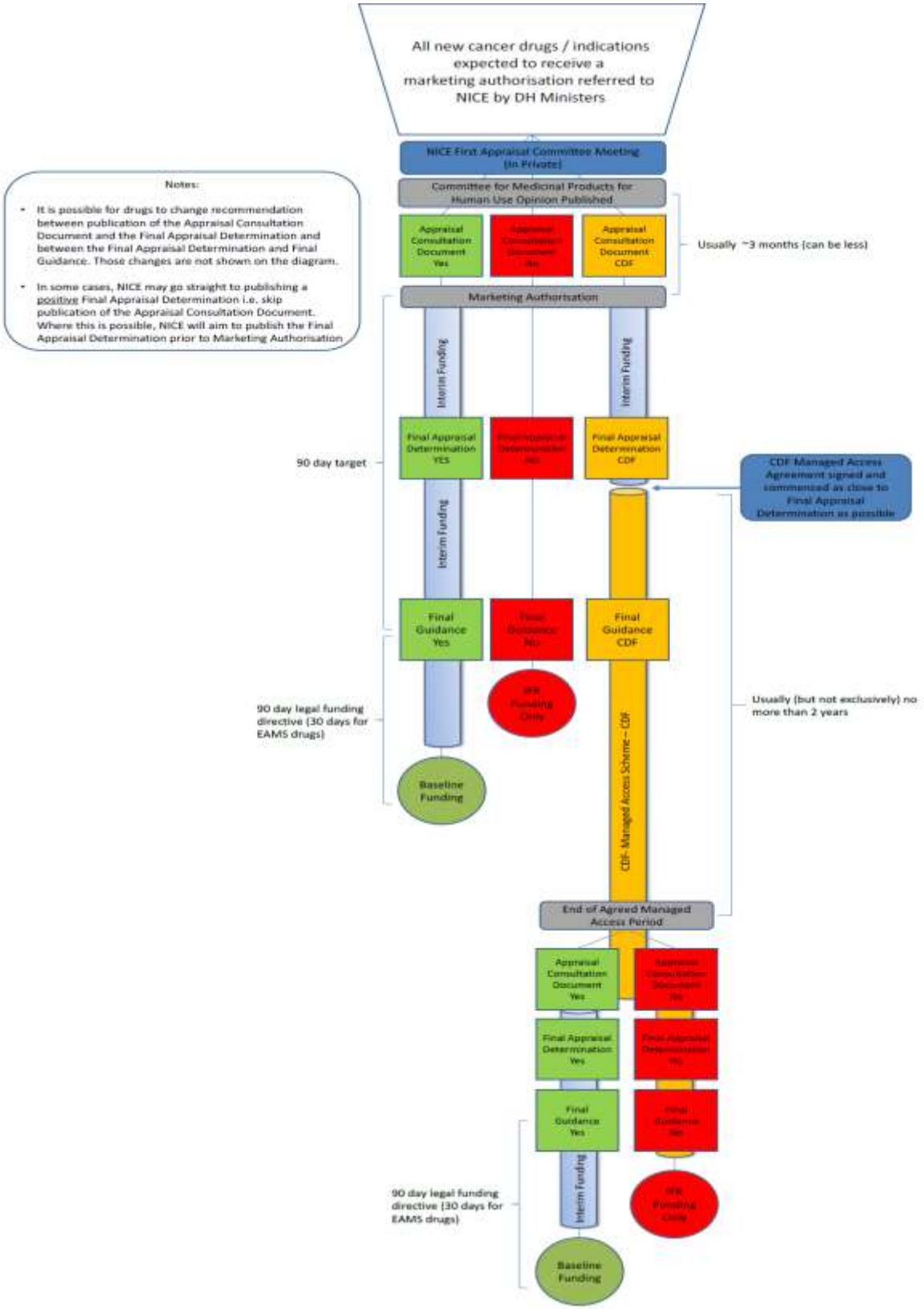
The CDF budget is a fixed funding envelope set annually by NHS England Board. For 2018/19, the CDF budget was set at £340 million as it has been since 2015/16 (NHS England CDF Team 2019). The budget covers the cost of the drugs and the administration of the CDF. Individual clinicians or a nominated trust 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 (C*f*HSC 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

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 TA-approved 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 TA-approved 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 TA-approved 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 multi-disciplinary 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 TA-approved 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" (C*f*HSC 2017a) and "Individual Funding Requests" (C*f*HSC 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 (C*f*HSC)

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
18th March	Les Cotils Conference Centre, Guernsey	Health and social care professionals	48
20th March		Public and Patients	46
21st March		Deputies of the States of Guernsey	16
3rd April	Island Hall, Alderney	Members of the State of Alderney	12
3rd April		Public and Patients	4
4th 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:

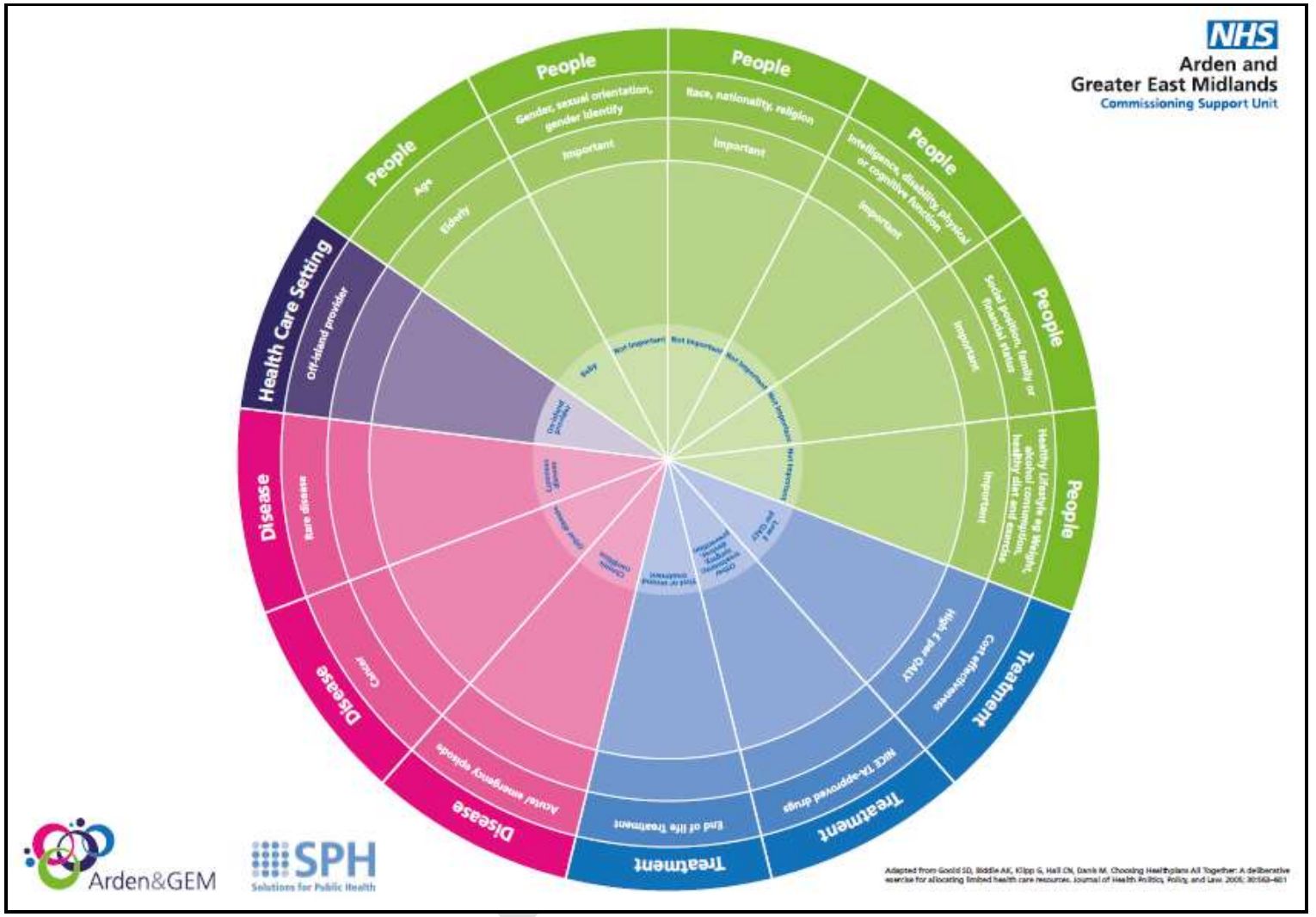
- age
- family
- wealth, and employment circumstances
- a story about their diagnosed disease
- the NICE TA-approved treatment that is currently not funded by the States
- the expected benefit of the treatment and the cost

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

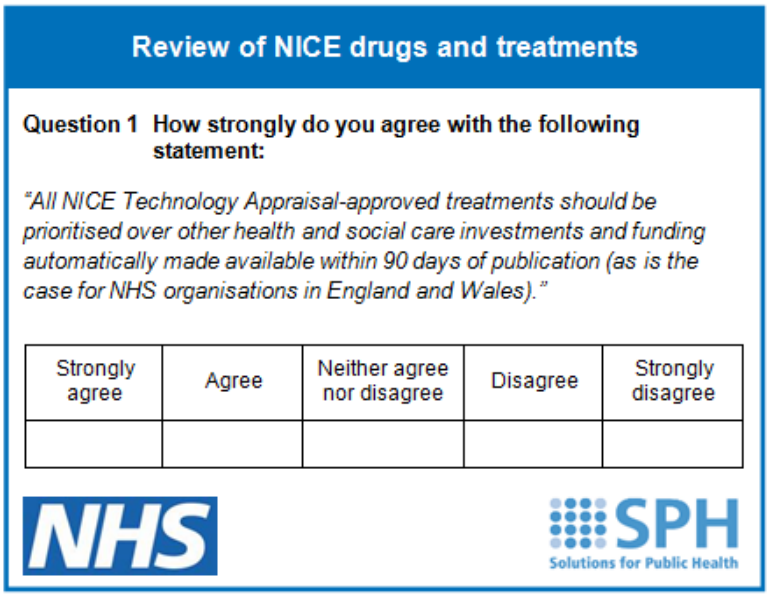
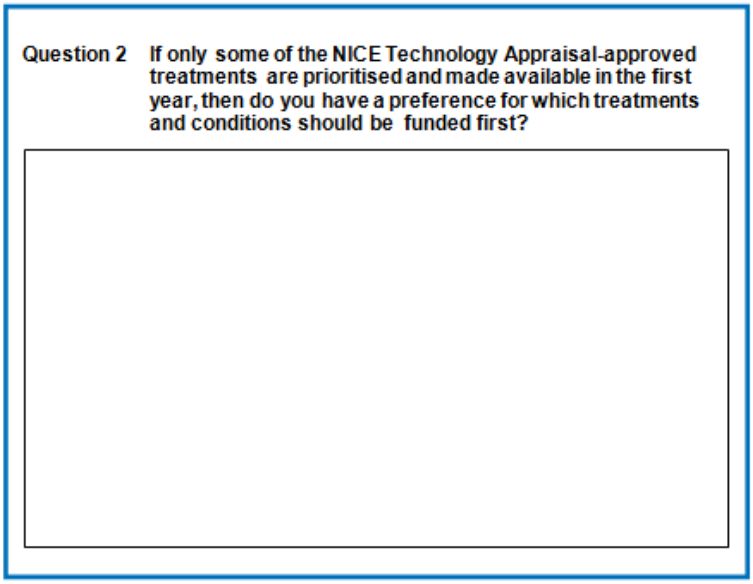


Figure 5: Opinion postcard question 2



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 (C*f*HSC) abides by a set of principles and processes published in ‘G1033: Priority Setting in Health and Social Care’ (C*f*HSC 2017a) and ‘G1002: Individual Funding Requests’ (C*f*HSC 2017c).

These principles, rules and policy statements explain the decision making framework that the C*f*HSC 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(C*f*HSC 2017b). This cost pressure does not take into account major service development such as adopting all NICE TA-approved treatments. As C*f*HSC 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 C*f*HSC resource allocation decisions are:

"3.1 C*f*HSC 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, C*f*HSC 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 C*f*HSC costs unless this has been sanctioned by C*f*HSC. 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 C*f*HSC will only invest in interventions that are cost-effective.

3.4 C*f*HSC 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 C*f*HSC policy G1002: Individual funding requests.

3.5 C*f*HSC will live within the budget allocated to it by the States of Guernsey.

3.5.1 …

3.5.2 …

3.5.3 …

3.6 C*f*HSC will not fund one individual if others with the same need cannot be funded

3.6.1 …

3.6.2 …

3.7 C*f*HSC must not allow third parties to determine priorities or make funding decisions on its behalf.

3.7.1 C*f*HSC 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 C*f*HSC 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."

(C*f*HSC 2017a)

In addition to the principles above G1033 also gives more detailed rules about how C*f*HSC 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 orphan[4] 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 C*f*HSC
- 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 (C*f*HSC 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 …"

(C*f*HSC 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 C*f*HSC."

"3.9 C*f*HSC 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 C*f*HSC) 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 C*f*HSC, 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 C*f*HSC 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 C*f*HSC for an immediate workup of proposals as a potential candidate for funding as a service development in the current financial year."

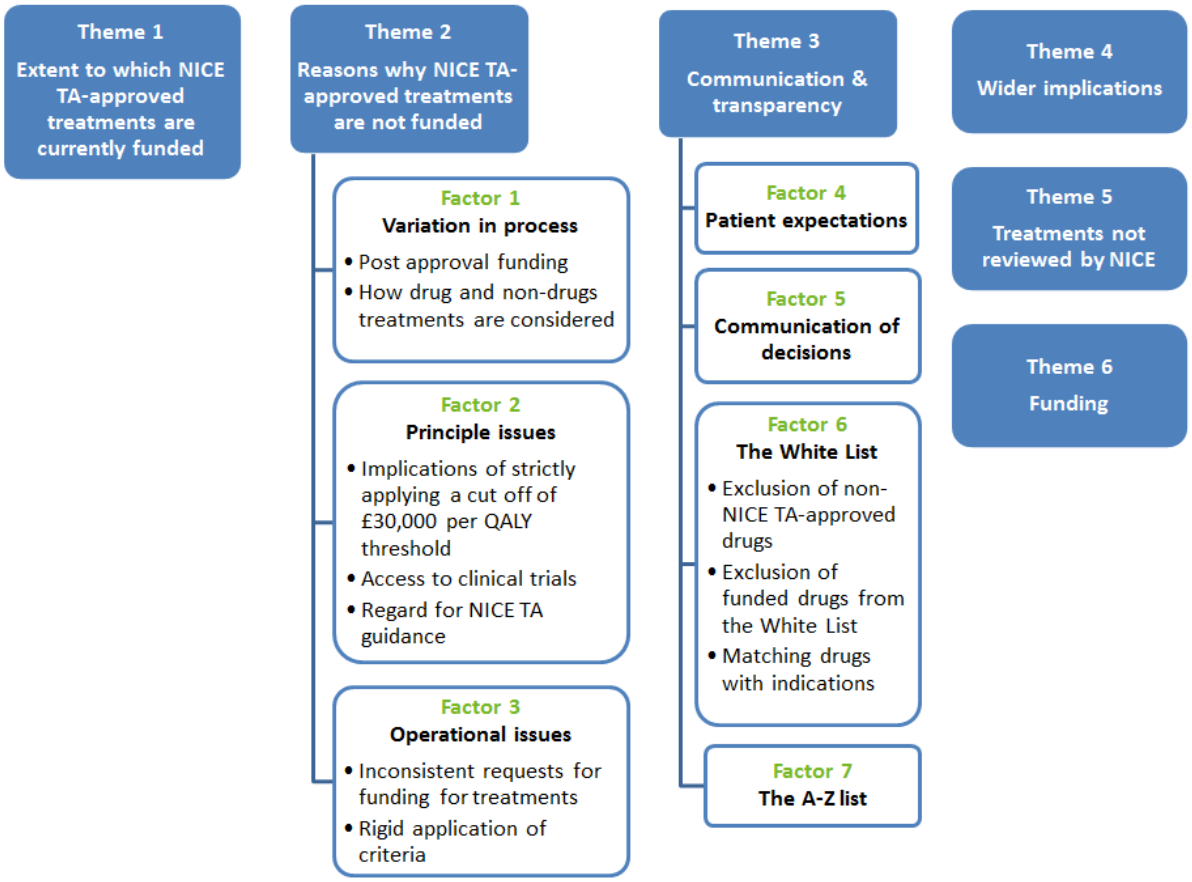
(C*f*HSC 2017c)

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.

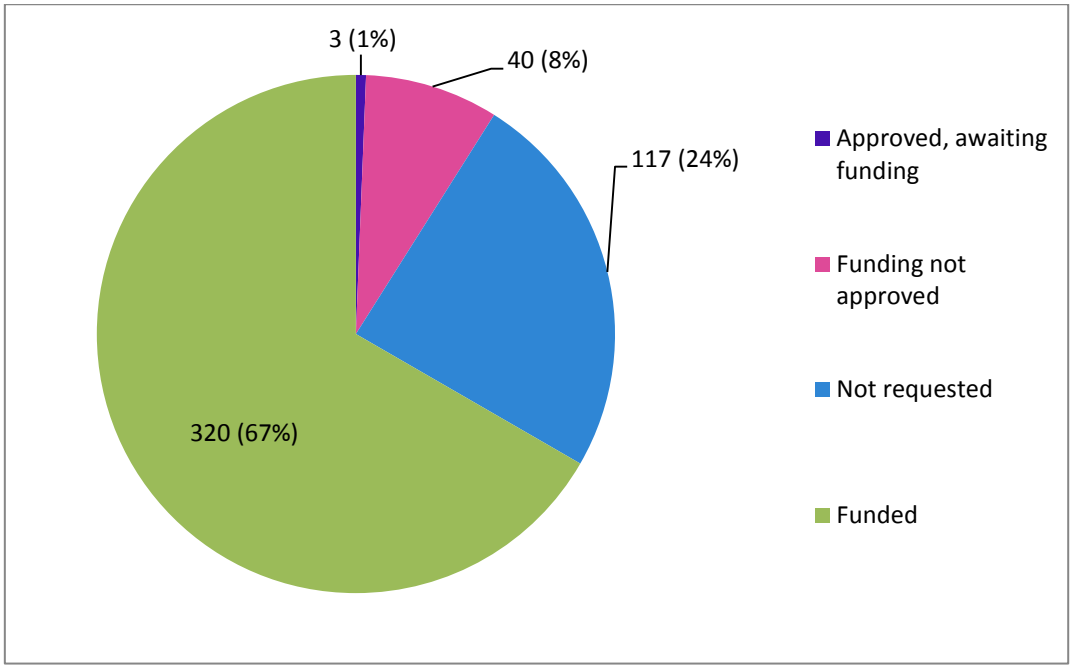
Figure 6: Themes from document review, meetings and interviews



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 C*f*HSC (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.

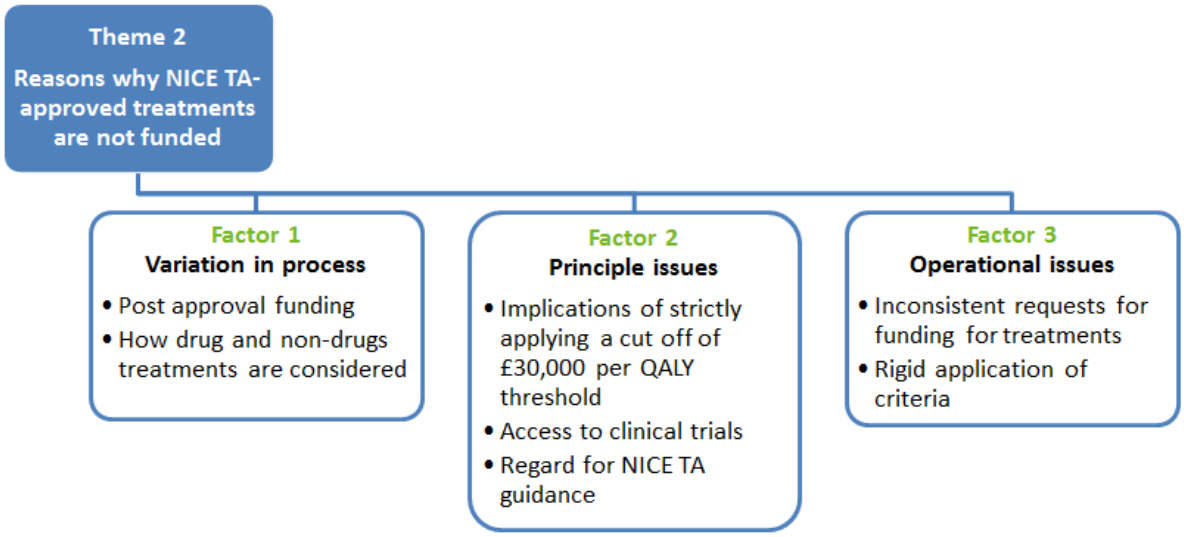
Figure 7: The proportion of NICE TA-approved treatments for specific indications which are funded and not funded



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"*** (C*f*HSC 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."
>
> (C*f*HSC 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 off-island 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 document[5] 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 C*f*HSC *"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:

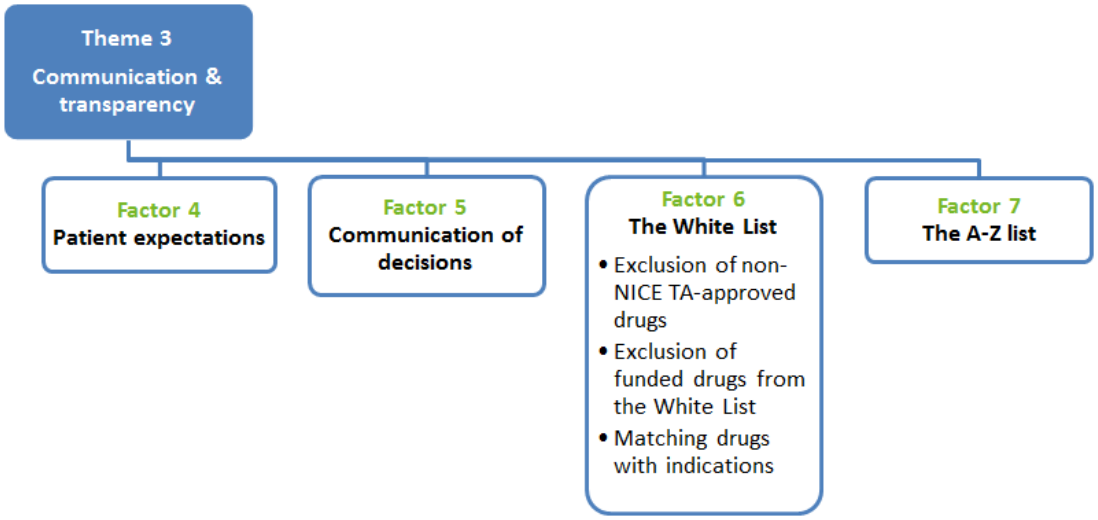
> "6.2.1 Treatments whose cost-effectiveness is estimated to be above £30,000 per quality adjusted life years will not be funded, unless exceptional circumstances apply.
> 6.2.2 Treatments whose cost-effectiveness is estimated to be below £30,000 per quality adjusted life years will be further assessed to determine whether or not they should be forwarded for prioritisation."
>
> (C*f*HSC 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 (C*f*HSC 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 C*f*HSC 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 C*f*HSC costs unless this has been sanctioned by C*f*HSC. 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"
>
> (C*f*HSC 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 patients[6] 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 C*f*HSC 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 TA-approved 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 C*f*HSC.

Dissatisfaction with the principles, rules and process described in G1033 (C*f*HSC 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 (C*f*HSC 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 C*f*HSC 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 – Total 134	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 completely disregarded that this might lead to: • over-treatment or treatment for people who have other co-morbidities which affect their ability to benefit from the treatment e.g. cancer treatment

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 – Important 4 – Not important 110 – Neither 18 – Total 132	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. The criterion about financial status was raised by participants who wished to explore: • 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 – Total 135	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: • *"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*

Principle for decision-making and sticker count	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.
Treatment principles		
Cost effectiveness – Low 70 – mid 46 – High 15 – Total 131	Over 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 C*f*HSC increasing the current cost per QALY ceiling above £30,000 per QALY.
NICE TA-approved drugs vs other interventions – Drugs 31 – Neither 67 – Devices/surgery 43 – Total 141	Range 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. There was a particular concern that existing services should not be cut in order

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 – Equal 96 – Rare 4 – Total 140	Range of opinion	There was range of opinion about whether treatments for rare conditions should be prioritised for funding over treatments for common conditions. The majority of participants favoured treating all conditions equally regardless of how many other people are also affected. 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.

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 – On island 16 – Neither 115 – Off island 6 – Total 137	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 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

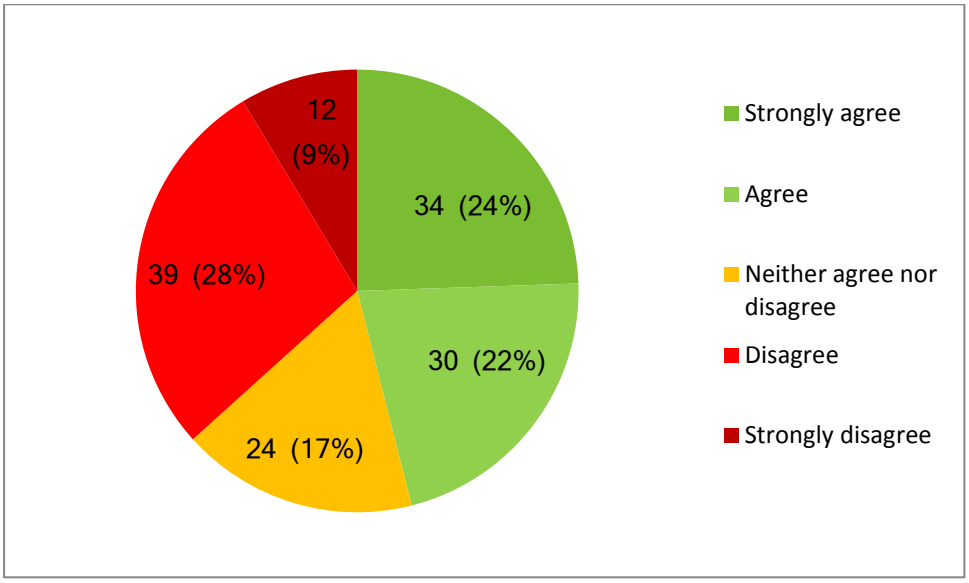
Q2: If only some of the NICE Technology Appraisal-approved treatments are prioritised and made available in the first year, then do you have a preference for which treatments and conditions should be funded first?			
Principle	**CHAT-board Summary**	**Number of responses**	**Rank**
Cost effectiveness	Strong consensus that the most cost effective treatments should be prioritised.	37 [plus 25 for 'strength of evidence of effectiveness']	1 [2]
Cancer	Strong consensus that treatments for cancer should not be prioritised over treatments for other diseases.	25	2
Common diseases / largest number of people benefit	Majority of participants favoured treating all conditions equally regardless of how many other people are also affected. Strong consensus that rare conditions should not be prioritised for funding over treatments for common conditions.	22	3 Chronic disease including CVD, diabetes, LTC: count 19, rank 4
Life-extending, end of life treatments	Strong consensus that treatments classed by NICE as life-extending, end of life treatments (for which NICE gives a greater weight to QALYs) should not be considered a higher priority for funding than other NICE TA-approved treatments	5 against 1 in favour	rank 9 rank 12
Fund all NICE TA-approved treatments	Range of opinion about the priority of NICE TA-approved drugs over other treatments including other drugs therapies not considered by the NICE TA programme, surgery or devices.	9	7
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 TA-approved 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 health, Acute/emergencies, Fit people, High profile cases,	1 (per suggestion)	12
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
2. 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
   - 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 (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
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

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 TA-approved 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 TA-approved treatment
  - the expected number of new patients per year who would receive this TA-approved 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
6. **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/m^2
- 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 TA-approved 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

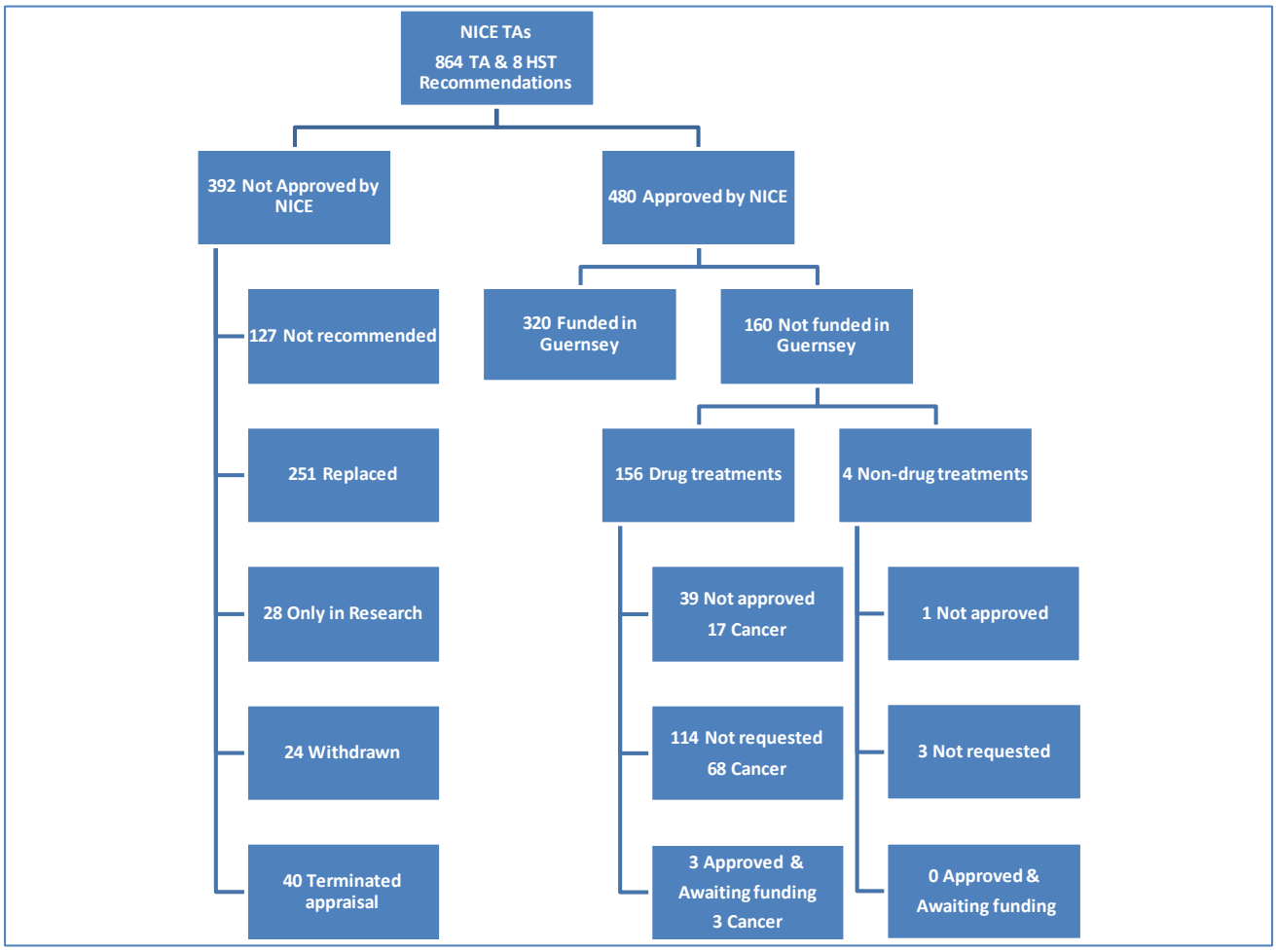


Figure 11 shows that of the 480 TA recommendations approved by NICE, 320 are funded by the States of Guernsey and 160 are not funded. The majority of the TA recommendations not funded by the States of Guernsey have not yet been requested for routine funding. This reflects local arrangements in Guernsey 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	27	24	1,928	338	£1,253,455	£456,718
<30k	71	67	2,769	630	£3,132,167	£1,523,265
<40k	93	88	3,073	678	£4,726,920	£2,522,646
<50k	124	119	3,120	721	£5,871,939	£3,764,477
>100k	138	130	3,141	737	£6,703,689	£4,416,348
6. Status quo	0	0	0	0	£0	£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	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	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			
Total	**88**	**114**	**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.

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 sub-set 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 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**
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 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	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 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)	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 Recommendations	Estimated Number of Patients Treated in Year 1	Estimated Number of New 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 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	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 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	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			
Total	**124**	**3,120**	**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.

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.

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 Recommendations	Estimated Number of Patients Treated in Year 1	Estimated Number of New 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 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	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			
Total	**138**	**3,141**	**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.

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 Recommendations	Estimated Number of Patients Treated in Year 1	Estimated Number of New 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 policy[8] 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 off-island 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.

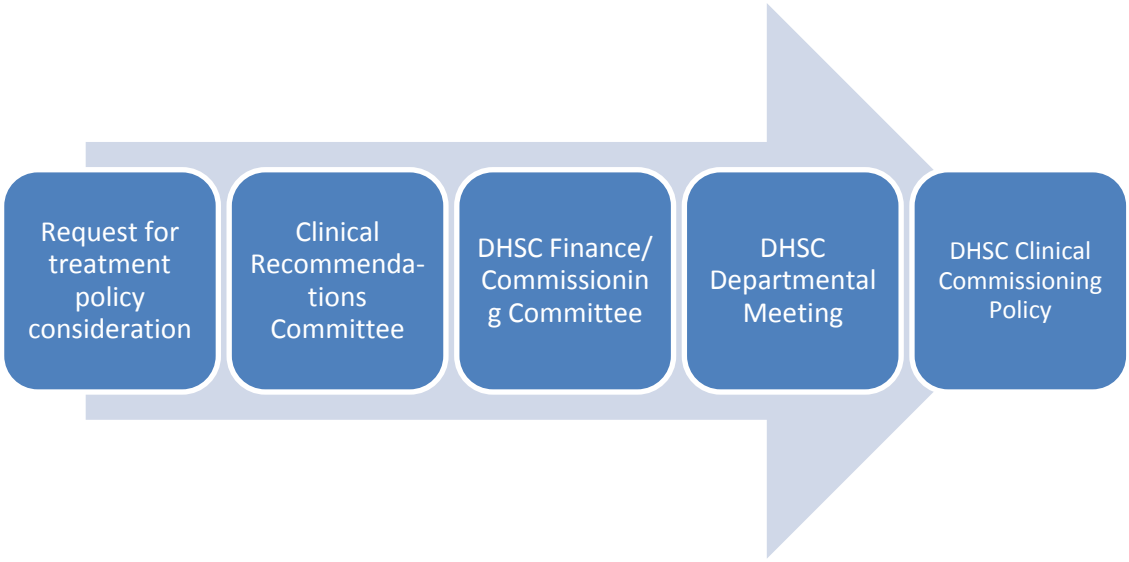
5.3 Isle of Man

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 ring-fenced budget either for cancer drugs generally or for drugs covered by the CDF in

[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*							
	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 /m^2 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 Indication: *locally advanced or metastatic PD-L1-positive non-small-cell lung cancer in adults who have had at least one chemotherapy*						
	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 Indication: untreated PD-L1-positive metastatic non-small-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: untreated PD-L1-positive metastatic non-small-cell lung cancer						
	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	3 hours nurse time for each cycle.	14.2 months (Median Overall Survival)	3-4 months (GEMCarbo) 10 months Pemetrexed	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: Pembrolizumab with pemetrexed and platinum chemotherapy for untreated, metastatic, non-squamous non-small-cell lung cancer (TA557).

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 managed access agreement.

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.

Option	Number of TA Recommendations/ TAs		Number of Patients		Net Cost Impact		Strengths	Weaknesses
	Number of TA Recommendations	Number of TAs	Backlog	New patients per annum	Backlog patients	New patients per annum		
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: **Fund NICE TA-approved**	152	137	3,344	777	£6.9m	£4.5m	**Except** for HSTs: All patients who meet the NICE TA selection criteria will be treated	HST approved treatments excluded in this option • The 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: o 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. • 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: o 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. o 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** recommended in a NICE TA will be funded by the States for all patients who meet the patient selection criteria	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 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 implementation rather than the funding decision process. Over half of the unfunded TA recommendations would be	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 that patients group, their prognosis, alternative treatment options, the extent to which their condition is life-changing etc. Support 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

							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	32 (65%) NICE TA-approved 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 post-hoc data collection and evidence. All other treatments are excluded including: • NICE TA-approved treatment for other conditions • All treatments for non-cancer

								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** This option selects only those treatments for cancer which are part of the Cancer Drugs Fund.	All CDF treatments 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 • the cost of the treatment • how many other people have the same condition	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
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 • how many other people have the same condition	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.
Option 4: **Prioritise NICE TA-approved treatments for common diseases** This option attempts to maximise the	44	40	3,221	679	£3.6m	£1.3m	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	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.

value of funding TA-approved treatments to the greatest number of people in Guernsey and Alderney.							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.	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.
Option 5: **Prioritise NICE**							NICE already uses cost effectiveness of a treatment as a	For treatments with an ICER above £20k per QALY, significant

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	decision criterion since it was established in 2001.. This has been proven to be a rational and defensible decision support criterion in England. It 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.	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. 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

							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 C*f*HSC.

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 (C*f*HSC 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 C*f*HSC 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

C*f*HSC – 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 x 1)
>
> 0.5 QALY = Half a year of life in perfect health (0.5 x 1)
>
> 0.5 QALY = 1 year of life lived in a situation with quality of life score of 0.5 eg bedridden (1 x 0.5)
>
> 2 QALYs = 4 years of life lived in a situation with quality of life score of 0.5 eg bedridden (4 x 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:

(Cost B – cost A) / (QALY B – QALY A)
(£20,000 - £10,000) / (8.4 – 5)
£10,000/3.4 = £2,941

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

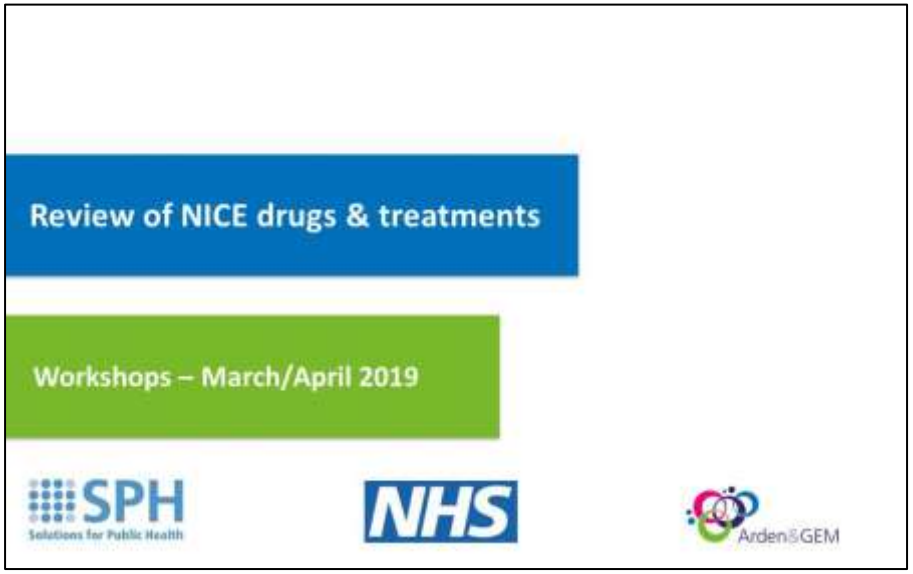
Appendix 1: Stakeholder event agenda
Appendix 2: Stakeholder event slides
Appendix 3: Stakeholder event scenarios
Appendix 4: Stakeholder event CHAT-boards
Appendix 5: SPH understanding of the requirement / Terms of reference
Appendix 6: Database data field list
Appendix 7: Clinician proforma used for data collection
Appendix 8: List of TAs for each option

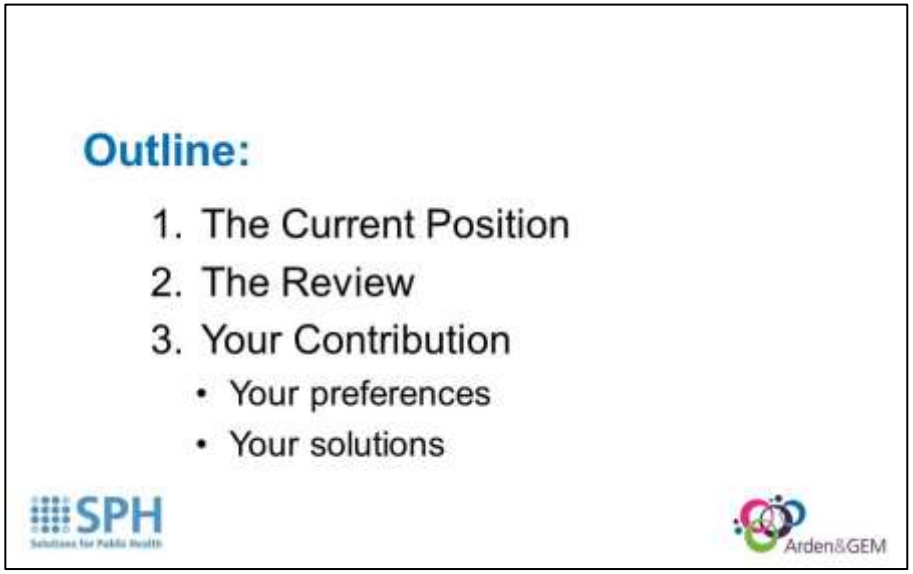
Appendix 1: Stakeholder event agenda

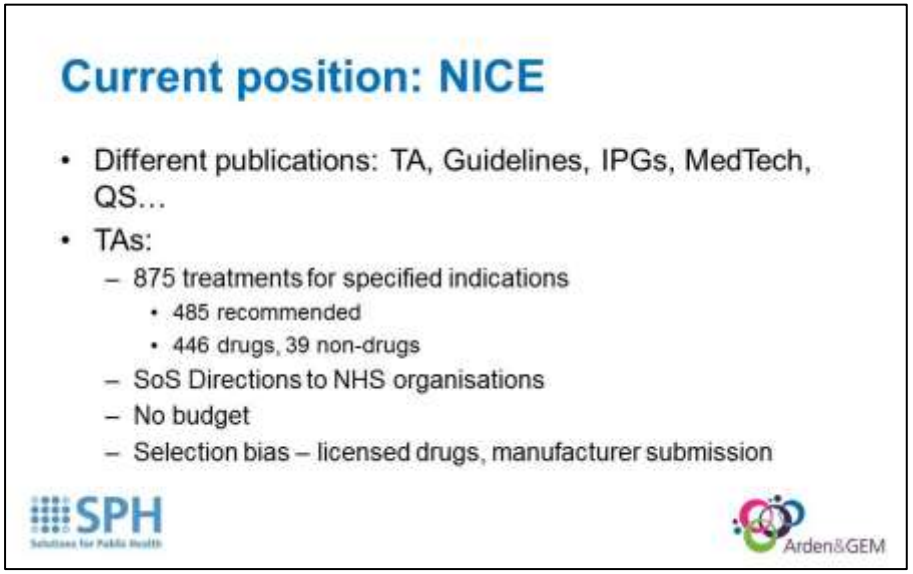
Review of NICE drugs and treatments Agenda March-April 2019	
Agenda and Instructions	**Timing**
1. Welcome and introduction	**17.30**
2. Background and Purpose – Current situation with NICE approved treatments – Drug and treatment review for C*f*HSC – How can you help? – Outline for the event	**17:30**
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. <u>Individually:</u>** • read the scenarios • privately rank which you would prioritise and keep a record on a post-it note. **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 • record your own preferences on the board: o each person will have 13 dots, one for each 'principle' o you may only put one dot in each segment o you do not need to agree with your colleagues around the table o we will photograph your completed boards at the end of the event • 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?	**18.00** **18:15** **18.45** **19.00**

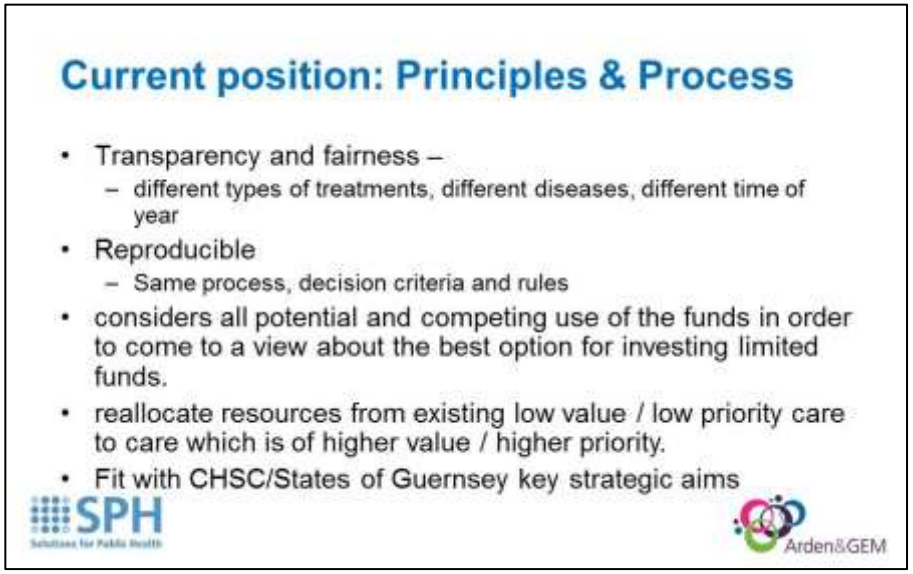
4. Plenary feedback Group feedback	**19.15**
5. Straw poll of preferences	**19:45**
6. Closing remarks	**19:55**
7. Close	**20.00**

Appendix 2: Stakeholder event slides









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 funded
- Clinical trials – not routinely funded

SPH Arden&GEM

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
- **Disease**
  - Emergency/acute vs lifelong/chronic condition
  - Terminal illness and end of life criteria
  - Orphan diseases vs more common diseases
  - CDF vs non CDF
- **Healthcare setting**
  - Off island care vs on island care

SPH Arden&GEM

Current position: Requete

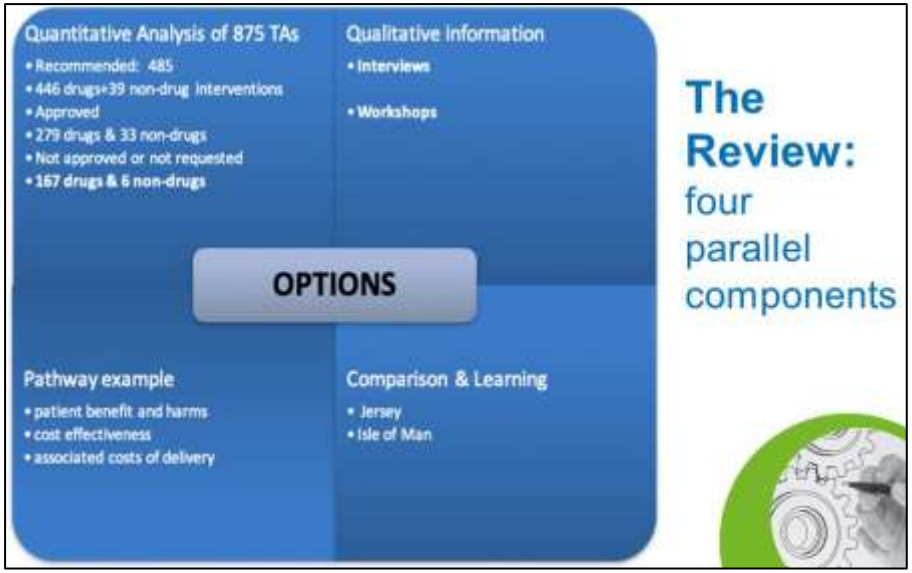
- Guernsey residents who are treated off island get different care to people who live in England
- Inefficiency of reviewing NICE drugs again
- NICE TA-approved drugs: funding not available
  - Cancer Drugs Fund
  - End of Life criteria for treatments for terminal illness

SPH Arden&GEM

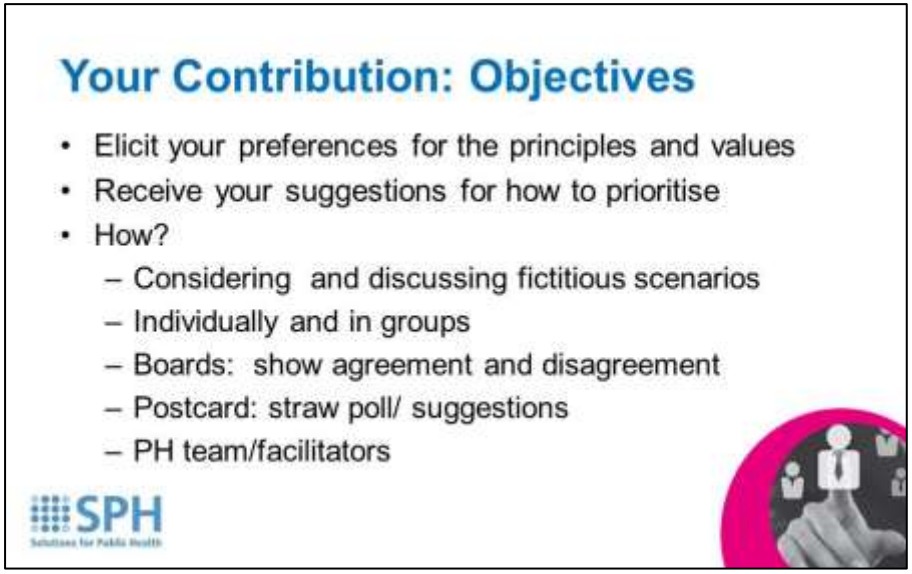
The Review: Scope & Deliverables

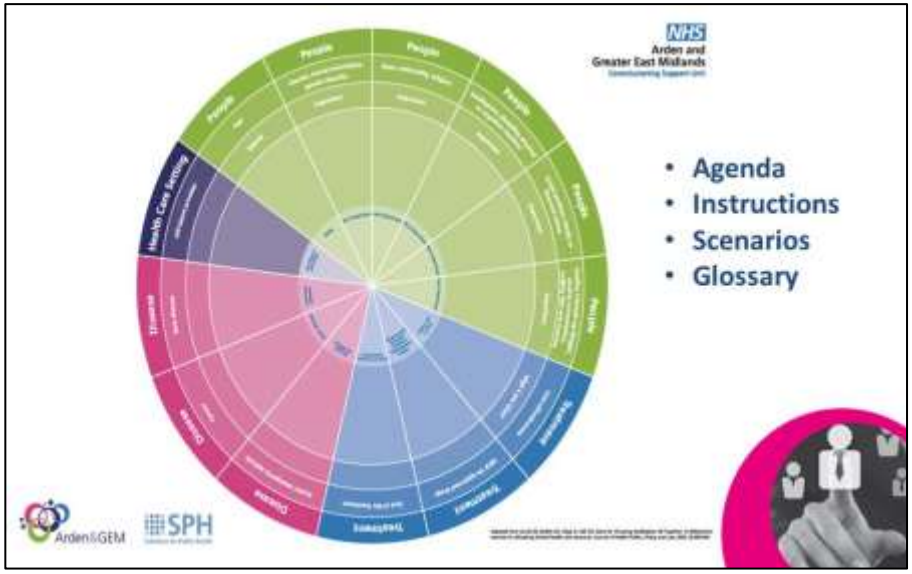
- Estimate of the impact of adopting **ALL** NICE TAs
  - Patients
  - Health gain
  - Cost impact
- Propose **OPTIONS** for prioritising NICE TA approved treatments
- Identify the **values and principles** challenged when considering funding a healthcare intervention
- End of May 2019

SPH


Quantitative Analysis of 875 TAs
• Recommended: 485
• 446 drugs+39 non-drug interventions
• Approved
• 279 drugs & 33 non-drugs
• Not approved or not requested
• 167 drugs & 6 non-drugs
Qualitative information
• Interviews
• Workshops
OPTIONS
Pathway example
• patient benefit and harms
• cost effectiveness
• associated costs of delivery
Comparison & Learning
• Jersey
• Isle of Man
The Review: four parallel components


The Review: Interviews
What outcome(s) would you like to see from the review ?
Are there any particular disease areas or types of treatment you are concerned about?
Are there any specific concerns you have about the review e.g. our credentials, impartiality ?
Areas of inequality off island care and private patients vs publically funded patients
If you had to prioritise, how would you go about it?
SPH

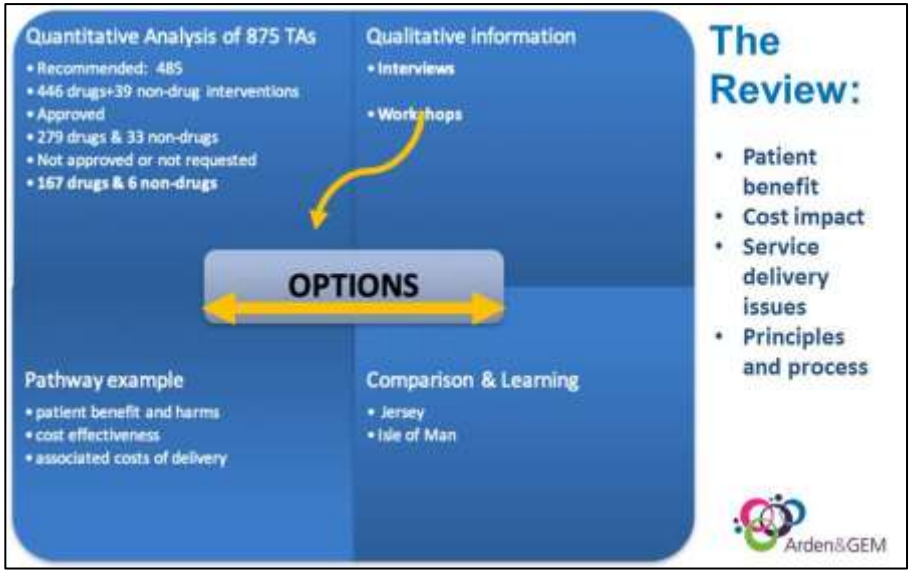

Your Contribution: Objectives
• Elicit your preferences for the principles and values
• Receive your suggestions for how to prioritise
• How?
– Considering and discussing fictitious scenarios
– Individually and in groups
– Boards: show agreement and disagreement
– Postcard: straw poll/ suggestions
– PH team/facilitators
SPH


NHS
Arden and Greater East Midlands
• Agenda
• Instructions
• Scenarios
• Glossary
ArdenSGEM
SPH

Scenarios

- 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

SPH



Thank you for taking part
Any questions?

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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 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.	£47,900 per QALY gained for ipilimumab compared with dacarbazine alone. £28,600 per QALY gained for ipilimumab compared with vemurafenib (based on 2014 prices).	Uncertain: from £5000 to £120,000 per annum for new two patients. 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.

Scenario 2			
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	1. Pharmalgen is recommended as an option for the treatment for bee and wasp venom allergy in people who have had: • 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 2. Treatment with Pharmalgen should be initiated and monitored in a specialist centre experienced in venom immunotherapy.	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. 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), and/or a bronchodilator (inhaled). Preventive measures include advice on how to avoid bee and/or wasp stings.	Pharmalgen is a venom immunotherapy. Immunotherapies are well-established treatments for certain severe allergies. 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.

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 2 £34,000 in year 3 Assuming: 0.4% people are eligible for treatment c.20% patients (45) are treated each year

Scenario 3		
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/m^2 (obese).		
TA	**NICE Recommendation**	**About Type 2 Diabetes**
TA 315 Canaglifozin	1. Canagliflozin in combination with metformin is recommended as an option for treating type 2 diabetes, only if: • a sulfonylurea is contraindicated or not tolerated **or** • the person is at significant risk of hypoglycaemia or its consequences 2. Canagliflozin in a triple therapy regimen is recommended as an option for treating type 2 diabetes in combination with: • metformin and a sulfonylurea **or** • metformin and a thiazolidinedione 3. Canagliflozin in combination with insulin with or without other antidiabetic drugs is recommended as an option for treating type 2 diabetes.	Type 2 diabetes is a common condition that causes the level of sugar (glucose) in the blood to become dangerously high. 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. 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. 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. People of of South Asian, Chinese, African Caribbean or Black African origin are at higher risk. 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. Diabetes usually gets worse over time, so your medicine or dose may need to change. Over time, patients may need a combination of medicines. Insulin isn't often used for type 2 diabetes in the early years. It's only needed when other medicines no longer work.

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.

Scenario 4		
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 reduced ejection fraction, only in people:
	
	• with New York Heart Association (NYHA) class II to IV symptoms and
	• with a left ventricular ejection fraction of 35% or less and
	• who are already taking a stable dose of angiotensin-converting enzyme (ACE) inhibitors or angiotensin II receptor-blockers (ARBs)
	
	Treatment should be started by a heart failure specialist with access to a multidisciplinary heart
		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.
		
		The most common symptoms of heart failure are:
		
		• breathlessness – after activity or at rest; it may be worse lying down, and you may wake up at night needing to catch your breath
		• 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
		
		Heart failure is classed using four NYHA functional classes:
		
		•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
		
		Most people with heart failure are treated with medication. Some of the main medicines for heart failure include:
		
		• ACE inhibitors
		• angiotensin receptor blockers (ARBs)
		  • beta blockers
		  • mineralocorticoid receptor antagonists
		  • diuretics

	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.

Scenario 5
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	Burosumab is recommended, within its 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 to the commercial arrangement.	XLH is a rare genetic condition that causes significant skeletal deformities in children from a young age, and lifelong disability and pain. Conventional therapy consists of managing symptoms and disability, and supplements of oral phosphate and active vitamin D (such as alfacalcidol). Oral phosphate has a complex dosing regimen, disagreeable taste and unpleasant side effects.

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 and 12 years. It is expected that there is some lifetime benefit for people having burosumab because it can prevent irreversible bone damage, which could lead to less pain and a better quality of life as people get older. There are uncertainties in the clinical evidence (including a lack of evidence in young people aged between 13 and 17 years, and on the long-term consequences of progressive bone disease and ongoing metabolic symptoms of XLH, which would not be affected by burosumab). However, burosumab is likely to provide	The full list price of burosumab in England is £2,992 per 10 mg vial. Treatment for one year for one patient with XLH (based on the full list price) on the maximum dose (90mg) would be £700,128 per year.	Unknown	There are no known children on Guernsey with XLH. The incidence is 1 per 20,000 live births. There are c. 650 live births in Guernsey & Alderney per year. So statistically one birth every thirty years. The cost per child per year for the

important clinical benefits for people with XLH. Burosumab is administered via subcutaneous injection 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 should be rounded to the nearest 10 mg. Treatment can begin in children aged 1 year and can continue until the bones stop growing.	The details of the commercial access arrangement for the NHS in England are unknown.		second year to 12 years of their life is c. £700,000. Because XLH is a genetic condition, it often affects several members of a family.

Scenario 6

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.

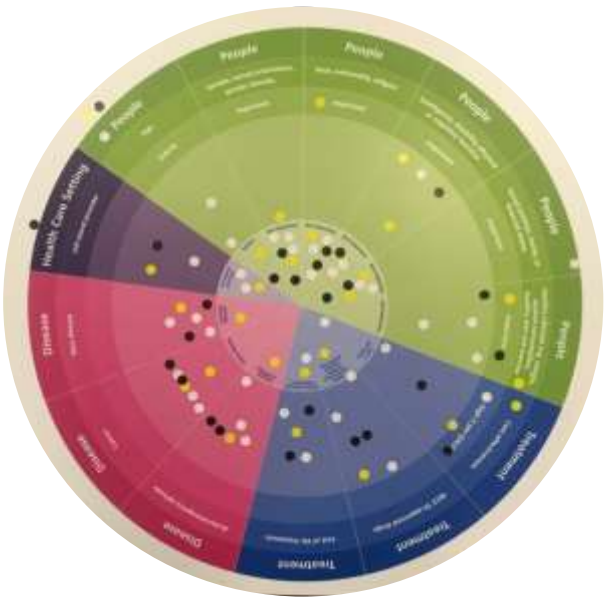
Paying for treatment was not something he had anticipated when he was diagnosed and the energy and stress has been an unhelpful additional burden. He says that he and his wife are "spending our own money so I will survive. My cancer treatment choices should not depend on how much money I have to spend. The choices should be based on the best treatment options currently available".

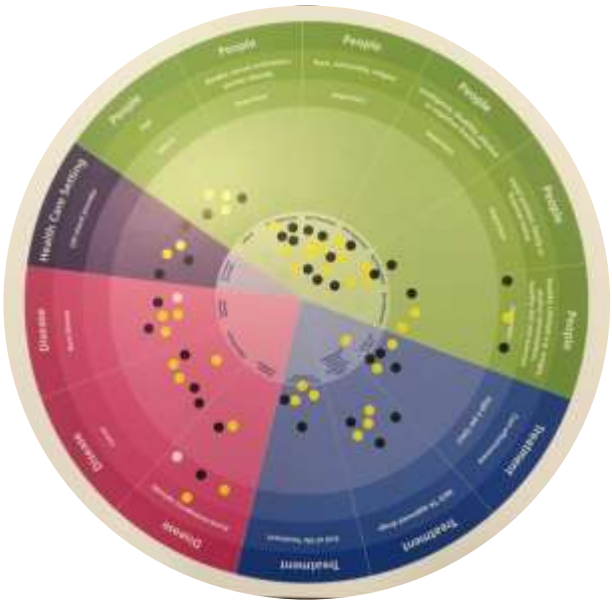
TA	NICE Recommendation	About Chronic Lymphocytic Leukaemia (CLL)
TA 487 Venetoclax	Venetoclax is recommended for use within the Cancer Drugs Fund, within its marketing authorisation, as an option for treating chronic lymphocytic leukaemia, that is, in adults: • with a 17p deletion or TP53 mutation and 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

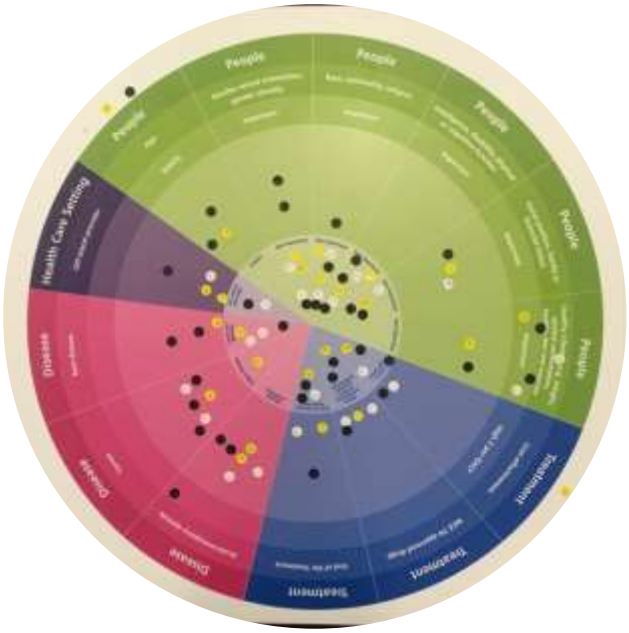
		• swollen glands in your neck, armpits or groin • swelling and discomfort in your tummy • unintentional weight loss

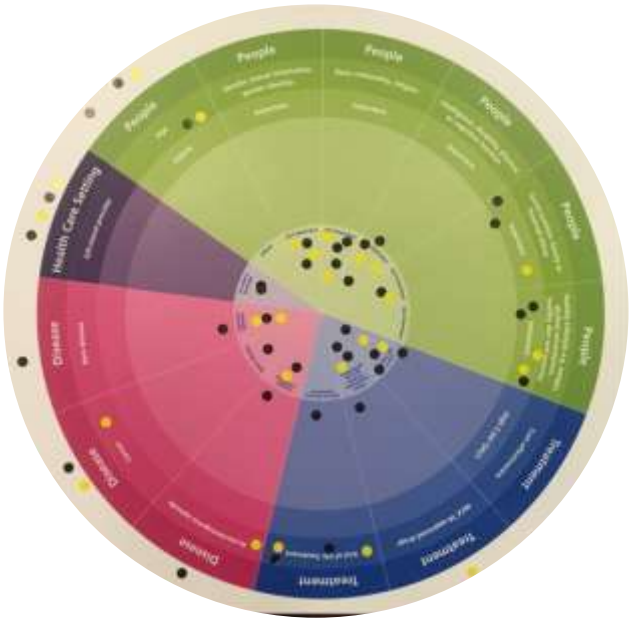
Intervention	**Cost of treatment**	**Cost effectiveness**	**Cost impact for Guernsey (per year)**
Venetoclax is a selective small molecule inhibitor of B-cell lymphoma 2, an anti-apoptotic protein overexpressed in around 95% of people with chronic lymphocytic leukaemia. Venetoclax has a conditional marketing 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.	The commercial access agreement price for NHS England is unknown. 28 days of 400 mg treatment costs £4,789 (excluding VAT). This equates to £62,263 per patient per annum.	£50,000-60,000 per QALY before discount. Unknown (if cancer drugs fund price is available to Guernsey patients).	There are likely to be 5 new patients per annum on Guernsey. 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.

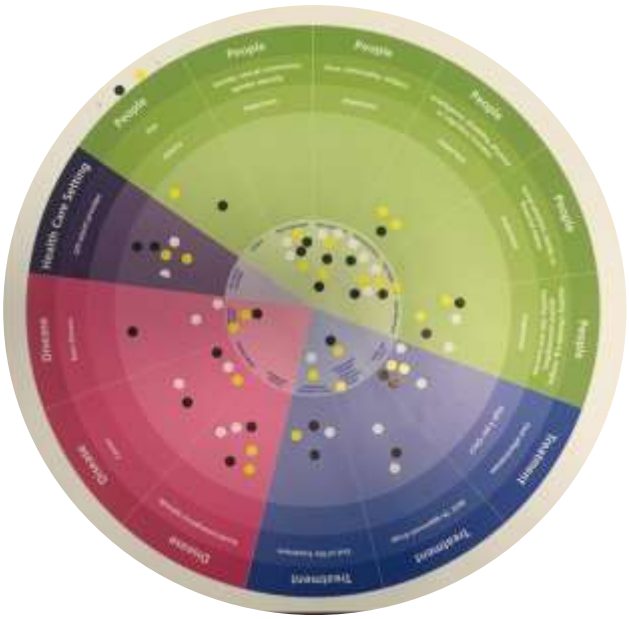
Appendix 4: Stakeholder event CHAT-boards







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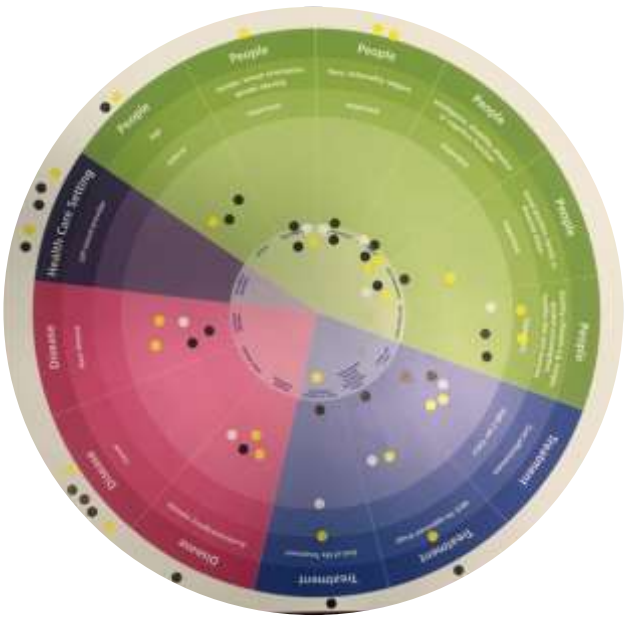
Health Care Setting
Disease
Treatment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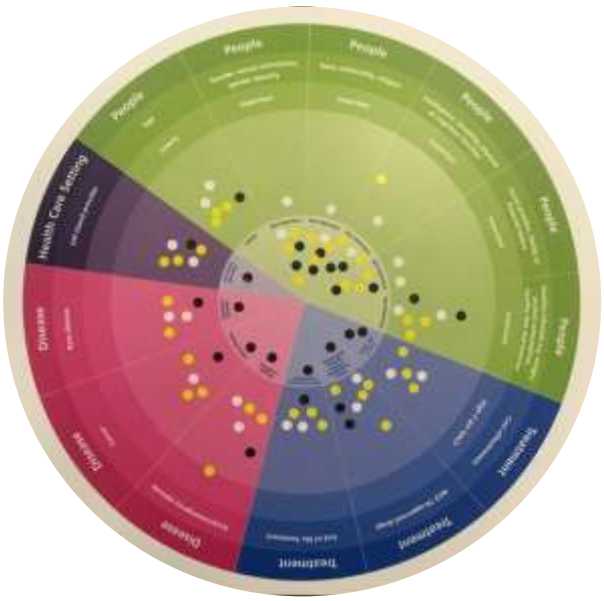
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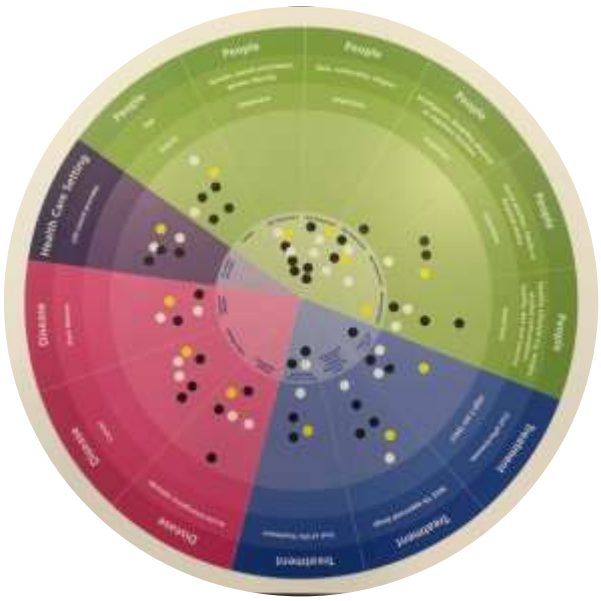
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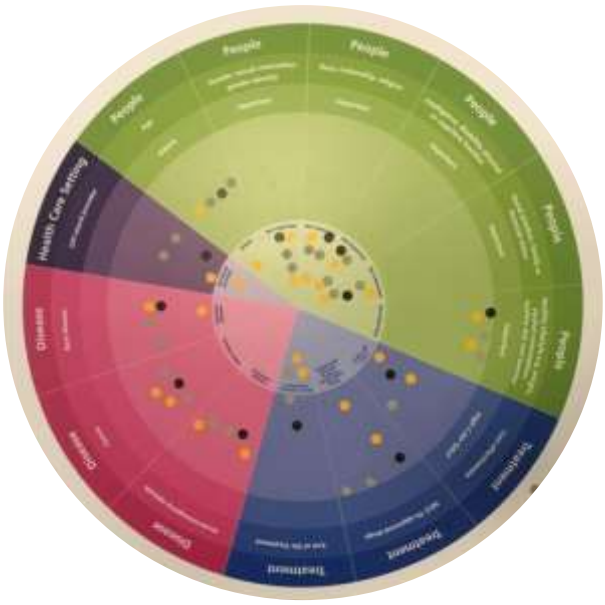
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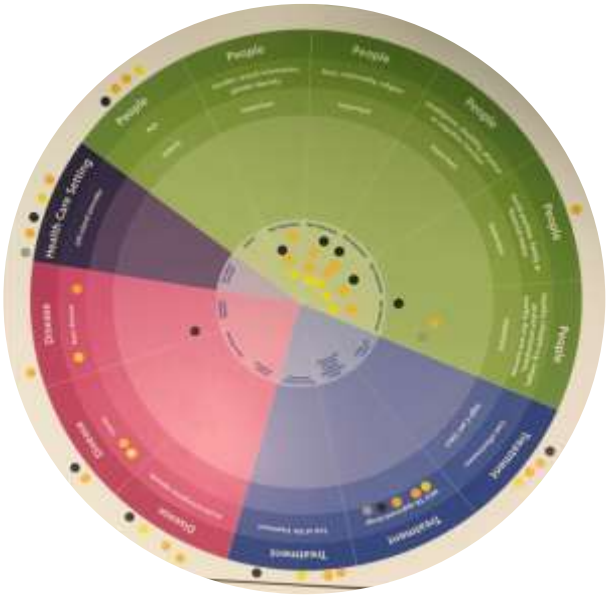
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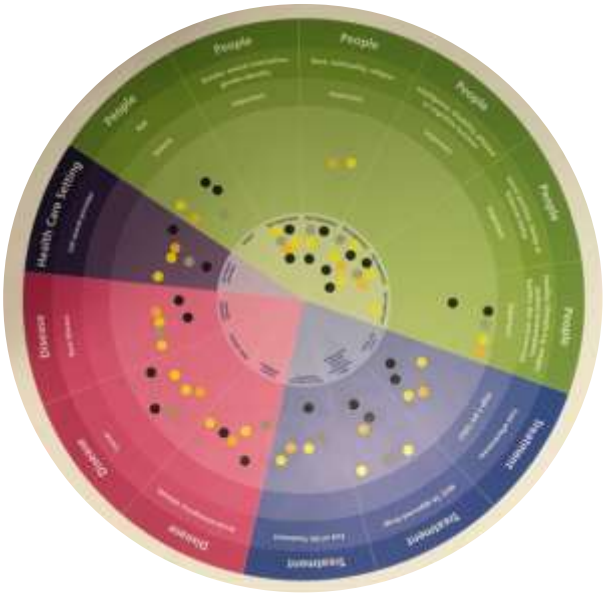
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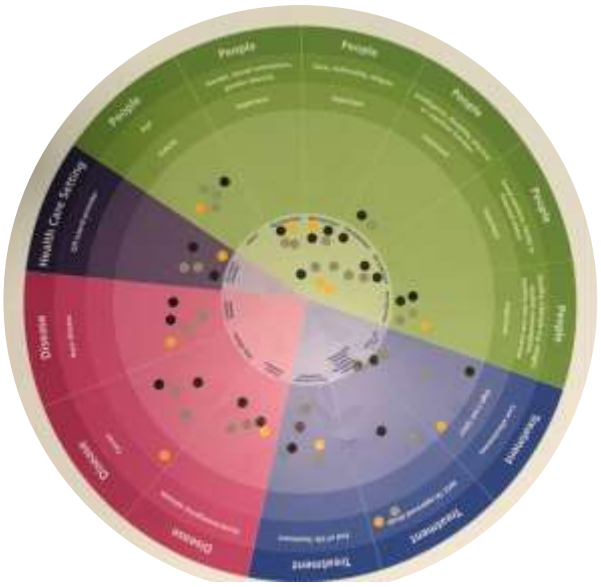
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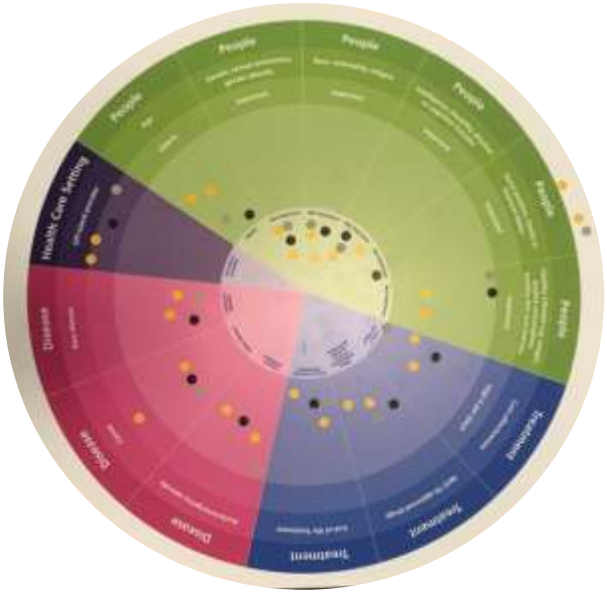
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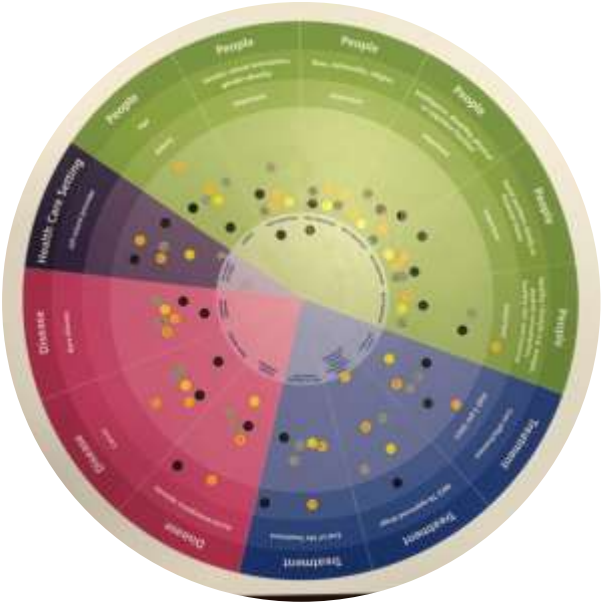
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Health Care Setting
Disease
Treatment


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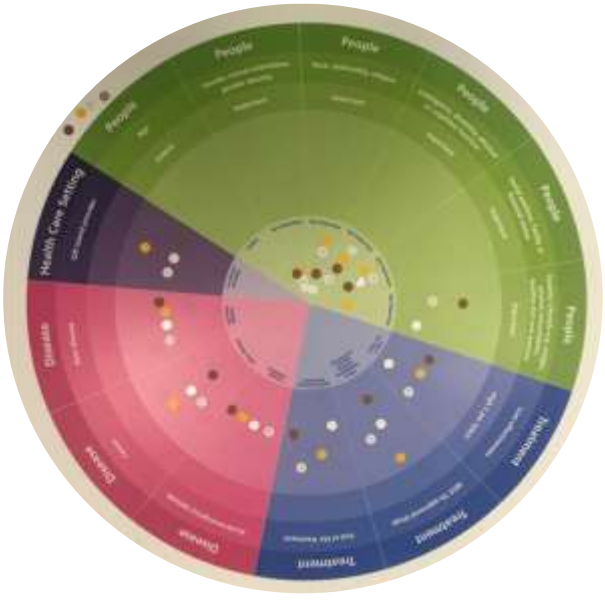
Disease
Treatment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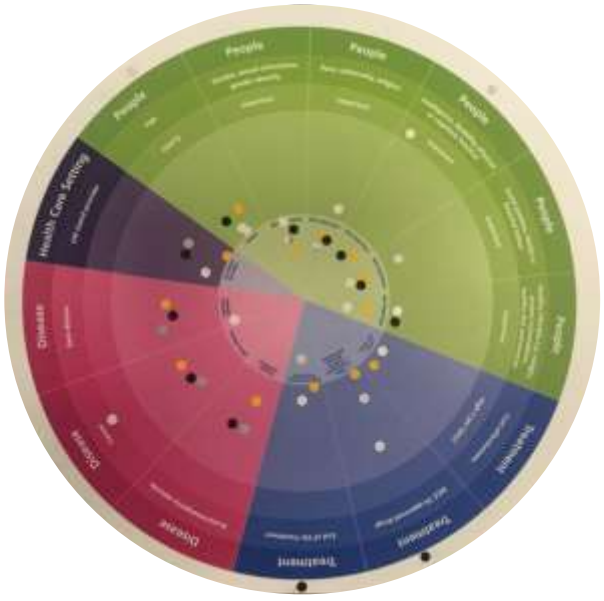
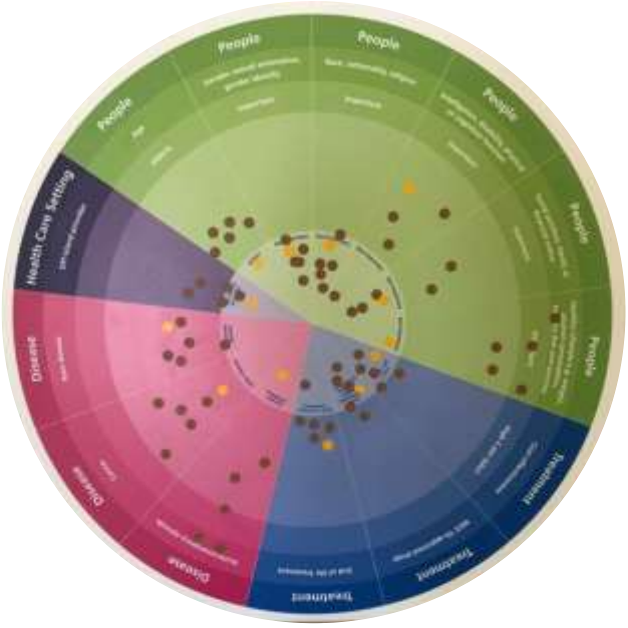
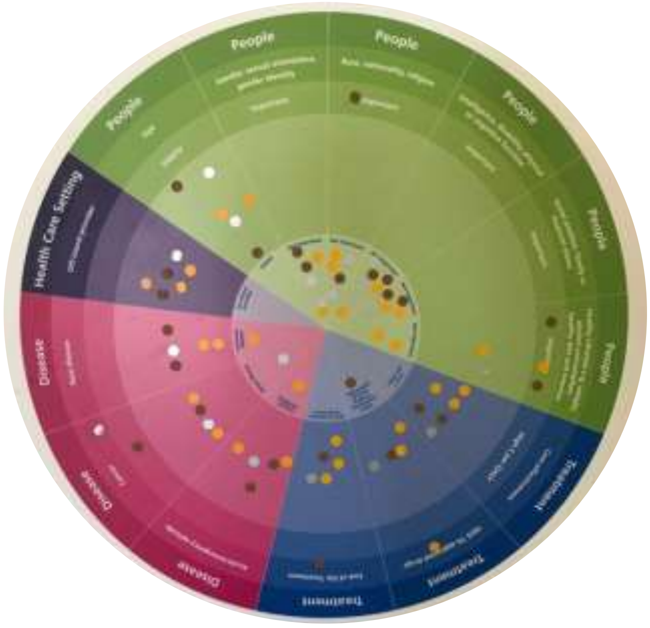
Health Care Setting
Disease
Treatment


People
Health Care Setting
Disease
Treatment


People
People
People
People
People
People
Health Care Setting
Disease
Disease
Disease
Treatment
Treatment
Treatment


People
People
People
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People
People
Health Care Setting
Disease
Disease
Disease
Treatment
Treatment
Treatment


People
People
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Health Care Setting
Disease
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Treatment
Treatment


People
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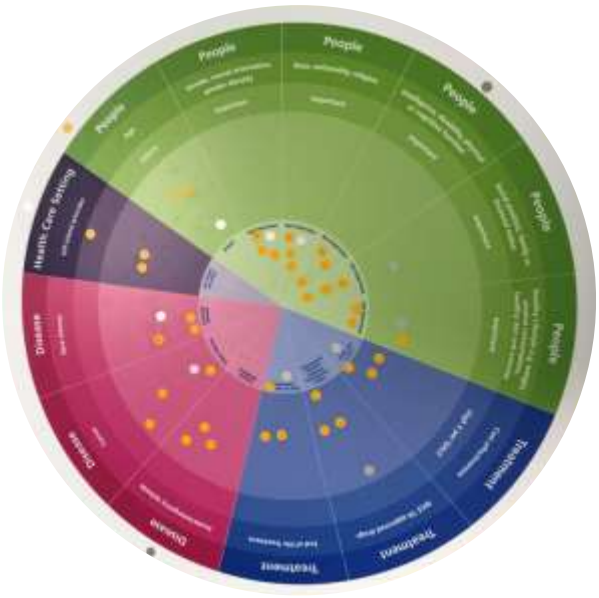
Treatment
Treatment
Treatment


People
People
People
People
People
Health Care Setting
Disease
Disease
Disease
Treatment
Treatment
Treatment


People
People
People
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People
Health Care Setting
Disease
Disease
Disease
Treatment
Treatment
Treatment

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:

1. **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.
2. 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.

7 Pricing:

REDACTED

8 Payment plan:

REDACTED

9 Other

This proposal is valid for 30 days from the date of receipt.

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 or Year 1 uptake based on NICE TA or SMC guidance) NO DISCOUNT
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

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	Calculated number of treated patients 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 Unfunded TAs	Option 1a: All Unfunded TAs exc. HSTs	Option 2: All unfunded Cancer TAs	Option 2a: All unfunded CDF TAs	Option 2b: All non-CDF TAs	Option 3: All end of life care TAs	Option 4: All common condition 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	Y	Y							Y	Y	Y	Y
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	Y				Y	Y	Y
TA185	Intravenous trabectedin	Advanced soft tissue sarcoma	Y	Y	Y		Y	Y				Y	Y	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)	Y	Y	Y		Y	Y					Y	Y
TA230	Bivalirudin in combination with	ST-segment-elevation myocardial infarction	Y	Y					Y	Y	Y	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	Y	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	Y	Y						Y	Y	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	Y	Y					Y	Y	Y	Y	Y	Y
TA297	Ocriplasmin	Vitreomacular traction	Y	Y					Y		Y	Y	Y	Y

TA301	Fluocinolone acetonide intravitreal implant	Chronic diabetic macular oedema after an inadequate response to prior therapy	Y	Y					Y		Y	Y	Y	Y
TA303	Teriflunomide	Relapsing-remitting multiple sclerosis	Y	Y						Y	Y	Y	Y	Y
TA304	Resurfacing anthroplasty	End-stage arthritis of the hip	Y	Y										
TA306	Pixantrone monotherapy	Multiply relapsed or refractory aggressive non-Hodgkin's B-cell lymphoma	Y	Y	Y		Y				Y	Y	Y	Y
TA315	Canagliflozin in combination with metformin (dual therapy)	Type 2 diabetes	Y	Y					Y					
TA315	Canagliflozin in combination with metformin and a sulfonylurea/thiazolidinedione (triple therapy)	Type 2 diabetes	Y	Y					Y					
TA315	Canagliflozin in combination with insulin with or without other antidiabetic drugs	Type 2 diabetes	Y	Y					Y					
TA316	Enzalutamide	Metastatic hormone-relapsed prostate cancer	Y	Y	Y		Y	Y			Y	Y	Y	Y
TA319	Ipilimumab	Previously untreated advanced (unresectable or metastatic) melanoma	Y	Y	Y		Y	Y					Y	Y
TA325	Nalmefene	Reducing alcohol consumption in people with alcohol dependence	Y	Y					Y	Y	Y	Y	Y	Y
TA327	Dabigatran	treatment and secondary	Y	Y					Y		Y	Y	Y	Y

	etexilate	prevention of deep vein thrombosis and/or pulmonary embolism												
TA333	Axitinib	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	Y	Y	Y		Y				Y	Y	Y	Y
TA345	Naloxegol	Opioid-induced constipation	Y	Y					Y	Y	Y	Y	Y	Y
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	Y	Y	Y		Y	Y					Y	Y
TA358	Tolvaptan	Treating autosomal dominant polycystic kidney disease	Y	Y									Y	Y
TA359	Idelalisib in combination with rituximab	Treating chronic lymphocytic leukaemia	Y	Y	Y		Y	Y					Y	Y
TA366	Pembrolizumab	Advanced melanoma not previously treated with ipilimumab	Y	Y	Y	Y		Y					Y	Y
TA367	Vortioxetine	Major depressive episodes	Y	Y					Y	Y	Y	Y	Y	Y
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 pegol, etanercept, golimumab and infliximab)	Ankylosing spondylitis and non-radiographic axial spondyloarthritis	Y	Y							Y	Y	Y	Y
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	Y	Y					Y	Y	Y	Y	Y	Y
TA390	Dapagliflozin monotherapy	Treating type 2 diabetes	Y	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	Y	Y	Y	Y					Y	Y	Y	Y
TA401	Bosutinib	Previously treated chronic	Y	Y	Y	Y		Y						Y

		myeloid leukaemia												
TA404	Degarelix	Advanced hormone-dependent prostate cancer	Y	Y	Y		Y			Y	Y	Y	Y	Y
TA405	Trifluridine–tipiracil	Previously treated metastatic colorectal cancer	Y	Y	Y	Y		Y	Y				Y	Y
TA406	Crizotinib	Untreated anaplastic lymphoma kinase-positive advanced non-small-cell lung cancer	Y	Y	Y	Y		Y					Y	Y
TA410	Talimogene laherparepvec	Treating unresectable metastatic melanoma	Y	Y	Y	Y					Y	Y	Y	Y
TA413	Elbasvir–grazoprevir	Chronic hepatitis C	Y	Y						Y	Y	Y	Y	Y
TA415	Certolizumab pegol in combination with methotrexate	Rheumatoid arthritis after inadequate response to a TNF-alpha inhibitor	Y	Y					Y	Y	Y	Y		
TA415	Certolizumab pegol monotherapy	Rheumatoid arthritis after inadequate response to a TNF-alpha inhibitor	Y	Y									Y	Y
TA416	Osimertinib	Locally advanced or metastatic EGFR T790M mutation-positive non-small-cell lung cancer	Y	Y	Y	Y								Y
TA417	Nivolumab	Previously treated advanced renal cell carcinoma	Y	Y	Y		Y	Y					Y	Y
TA418	Dapagliflozin in combinatin with metformin and a sulfonylurea (triple therapy)	Treating type 2 diabetes	Y	Y					Y			Y	Y	Y
TA420	Ticagrelor in combination with aspirin	Preventing atherothrombotic events after myocardial infarction	Y	Y					Y		Y	Y	Y	Y
TA422	Crizotinib	Previously treated anaplastic lymphoma kinase-positive	Y	Y	Y		Y	Y					Y	Y

		advanced non-small-cell lung cancer												
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		Y	Y				Y	Y
TA442	Ixekizumab	Moderate to severe plaque psoriasis	Y	Y							Y	Y	Y	Y
TA443	Obeticholic acid	Primary biliary cholangitis	Y	Y								Y	Y	Y
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	Y	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	Y	Y	Y		Y	Y			Y	Y	Y	Y
TA457	Carfilzomib in combination with dexamethasone	Previously treated multiple myeloma	Y	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	Y	Y	Y		Y	Y					Y	Y
TA465	Olaratumab in combination with doxorubicin	Advanced soft tissue sarcoma	Y	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	Y	Y					Y	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	Y	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	Y	Y					Y					
TA480	Tofacitinib with methotrexate	Moderate to severe rheumatoid arthritis	Y	Y										
TA480	Tofacitinib monotherapy	Moderate to severe rheumatoid arthritis	Y	Y										
TA483	Nivolumab	Previously treated squamous non-small-cell lung cancer	Y	Y	Y	Y		Y						Y
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	Y	Y								Y		Y
TA485	Sarilumab with methotrexate	Moderate to severe rheumatoid arthritis	Y	Y										Y
TA485	Sarilumab with	Moderate to severe	Y	Y										Y

	methotrexate	rheumatoid arthritis												
TA485	Sarilumab monotherapy	Moderate to severe rheumatoid arthritis	Y	Y									Y	
TA487	Venetoclax	Chronic lymphocytic leukaemia	Y	Y	Y	Y		Y						Y
TA490	Nivolumab	Squamous cell carcinoma of the head and neck after platinum-based chemotherapy	Y	Y	Y	Y		Y						Y
TA491	Ibrutinib	Waldenstrom's macroglobulinaemia	Y	Y	Y	Y								Y
TA492	Atezolizumab	Untreated PD-L1-positive locally advanced or metastatic urothelial cancer when cisplatin is unsuitable	Y	Y	Y	Y		Y						Y
TA493	Cladribine tablets	Relapsing–remitting multiple sclerosis	Y	Y						Y	Y	Y	Y	Y
TA496	Ribociclib with an aromatase inhibitor	Untreated, hormone receptor-positive, HER2-negative, locally advanced or metastatic breast cancer	Y	Y	Y		Y		Y		Y	Y	Y	Y
TA498	Lenvatinib plus everolimus	Previously treated advanced renal cell carcinoma	Y	Y	Y		Y				Y	Y	Y	Y
TA500	Ceritinib	Untreated ALK-positive non-small-cell lung cancer	Y	Y	Y		Y				Y	Y	Y	Y
TA504	Pirfenidone	Idiopathic pulmonary fibrosis	Y	Y					Y		Y	Y	Y	Y
TA505	Ixazomib with lenalidomide and dexamethasone	Relapsed or refractory multiple myeloma	Y	Y	Y	Y						Y	Y	Y
TA507	Sofosbuvir–velpatasvir–voxilaprevir	Chronic hepatitis C	Y	Y						Y	Y	Y	Y	Y
TA508	Autologous chondrocyte implantation using	Symptomatic articular cartilage defects of the knee	Y	Y					Y	Y	Y	Y	Y	Y

	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	Y	Y								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	Y	Y	Y		Y				Y	Y	Y	Y

		leukaemia												
TA524	Brentuximab vedotin	CD30-positive Hodgkin lymphoma	Y	Y	Y	Y					Y	Y	Y	Y
TA525	Atezolizumab	Locally advanced or metastatic urothelial carcinoma after platinum-containing chemotherapy	Y	Y	Y		Y	Y						
TA526	Arsenic trioxide	Acute promyelocytic leukaemia	Y	Y	Y		Y			Y	Y	Y	Y	Y
TA529	Crizotinib	ROS1-positive advanced non-small-cell lung cancer	Y	Y	Y	Y		Y					Y	Y
TA531	Pembrolizumab	Untreated PD-L1-positive metastatic non-small-cell lung cancer	Y	Y	Y		Y	Y	Y				Y	Y
TA533	Ocrelizumab	Relapsing–remitting multiple sclerosis	Y	Y								Y	Y	Y
TA534	Dupilumab	Severe atopic dermatitis	Y	Y					Y		Y	Y	Y	Y
TA535	Lenvatinib	Thyroid cancer	Y	Y	Y		Y	Y				Y	Y	Y
TA535	Sorafenib	Thyroid cancer	Y	Y	Y	Y		Y				Y	Y	Y
TA536	Alectinib	Untreated anaplastic lymphoma kinase (ALK)-positive advanced non-small-cell lung cancer (NSCLC)	Y	Y	Y		Y				Y	Y	Y	Y
TA537	Ixekizumab	Psoriatic arthritis after inadequate response to DMARDs	Y	Y						Y	Y	Y	Y	Y
TA538	Dinutuximab beta	Neuroblastoma	Y	Y	Y		Y					Y	Y	Y
TA539	Lutetium (177Lu) oxodotreotide	Unresectable or metastatic pancreatic neuroendocrine tumours	Y	Y	Y		Y	Y			Y	Y	Y	Y
TA539	Lutetium (177Lu) oxodotreotide	Unresectable or metastatic gastrointestinal neuroendocrine tumours	Y	Y	Y		Y				Y	Y	Y	Y
TA540	Pembrolizumab	Relapsed or refractory classical Hodgkin lymphoma	Y	Y	Y	Y		Y					Y	Y

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	Y	Y	Y		Y	Y	Y	Y	Y	Y	Y	Y
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	Y	Y	Y		Y				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 (Keytruda, Merck Sharp & Dohme)	Monotherapy for the adjuvant treatment of adults with stage III melanoma and lymph node involvement who have undergone complete resection	Y	Y	Y	Y				Y	Y	Y	Y	Y
TA554	Tisagenlecleucel (Kymriah, Novartis)	Paediatric and young adult patients up to 25 years of age with B?cell acute lymphoblastic leukaemia that is refractory, in relapse post-transplant or in second or later relapse	Y	Y	Y	Y						Y	Y	Y
HST01	Eculizumab	Atypical Haemolytic Uraemic Syndrome	Y											
HST02	Elosulfase alfa	Mucopolysaccharidosis Type IVa	Y											
HST03	Ataluren	Duchenne Muscular Dystrophy with a nonsense mutation in the dystrophin gene	Y											
HST04	Migalastat	Fabry disease	Y											
HST05	Eliglustat	Type 1 Gaucher disease	Y											
HST06	Asfotase alfa	Paediatric-onset Hypophosphatasia	Y											
HST07	Strimvelis	Adenosine Deaminase Deficiency	Y											
HST08	Burosumab	X-linked Hypophosphataemia	Y											

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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