The Office *of the*
Committee *for*
Health & Social Care

Priority setting in Health and Social Care

This document sets out the guiding principles and contains policy statements to support the Committee *for* Health & Social Care (CHSC) decision making on how best to allocate limited resources. It also sets out the processes by which resources will be allocated.

Linked policy documents: *G1002: Individual Funding Requests*.

Lead Professional/Author	Corporate Commissioning Policy
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Committee *for* Health & Social Care Policy

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This is a controlled document. As a controlled document, the correct version of the document is the current version published on CHSC intranet and the States of Guernsey website.

Version History

Version Number	Date	Person responsible	Prepared by	Status	Reason for Issue
4.2	Jan 2023	Medical Director	Head of Client Team	Approved	Amended to add text about private testing and screening so that 'Funding the consequences of private funding of tests' (G1059) can be decommissioned. Wide consultation followed by approval at QGC, CfHSC, and CMT.
4.1	Aug 2022	Medical Director	Head of Client Team	Approved	Updated to reflect the correct QALI figure as at the current status of the agreed NICE TA changes. Otherwise extended to allow further analysis of the impact of the transfer of the Health Benefits function and to allow for a wider review of the HSC prioritisation process.
4.0	Aug 2017	Chief Secretary	Public Health Advisor	Approved	Operational aspects of priority setting processes have been added. Title of policy changed to reflect this incorporation.
3.0	Feb 2017	Director of Public Health	Public Health Advisor	Approved	This is the first step in a two-stage process to bring all the policies relating to priority setting and resource allocation into one document. The final stage is expected to occur during 2017. The first has been a comprehensive review of all the policies related to priority setting currently in operation and with all but the policy dealing with individual funding requests brought together into a single policy. (*A list of

Version Number	Date	Person responsible	Prepared by	Status	Reason for Issue
					the existing policies can be found at the bottom of this table). The ethical framework has been expanded to include some key rules for decision making. The policy now also covers priority setting in social care. Key additions have been a new assessment framework for medical devices, a section dealing with patients moving between the private and public sector, a section dealing with patient requested second opinions, requests by patients to have appointments specifically to consider clinical trials. The explanatory note which previously was available to clinicians and the public on why treatments are prioritised as low priority has also been incorporated into this document.
2.0	April 2013	Director of Public Health	Public Health Advisor	Superseded	Minor revisions made and put into new policy format.
1.0	2011	Director of Public Health	Solutions for Public Health	Superseded	Title: The Ethical Framework for prioritising health care for the States of Guernsey New policy

* List of existing policies and documents that have been incorporated into this Policy:

G1001: Ethical framework prioritising health care for the States of Guernsey;

G1004: Choice of provider and treatment outside the United Kingdom and Jersey;

G1005: In-year service developments and the Health and Social Services Department's approach to treatments not yet assessed and prioritised;

G1007: Guidance produced by the National Institute for Health and Care Excellence and cost-effectiveness thresholds;

G1008: End of life treatments;

G1009: The English cancer drugs fund;

G1010: Experimental and unproven treatments;

G1011: On-going access to treatment following a trial of treatment which has not been sanctioned by the Health and Social Services Department for a treatment which is not routinely funded or has not been formally assessed and prioritised;

G1012: On-going access to treatment following the completion of a trial explicitly funded by the Health and Social Care Department;

G1013: On-going access to treatment following the completion of industry sponsored clinical trials or funding;

G1014: On-going access to treatment following the completion of non-commercially funded clinical trials;

G1015: Treatments for orphan diseases;

G1018: Funding care for patients moving to Guernsey and therefore changing national jurisdictions;

G1019: On-going access to self-funded treatment not normally provided by the health and social services department

G1030: Consultant to consultant referrals in the UK;

G1059: Funding the consequences of private funding of tests

Explanatory note for patients and clinicians on why some treatments and services are considered low priority

Contents

Part 1: Guiding principles, rules and policy statements to underpin resource allocation in health and social care

1. Introduction

The Committee *for* Health & Social Care (CHSC) is responsible to the States of Guernsey for the health and social wellbeing of the people of Guernsey and Alderney. The Committee has a mandate to advise the States on matters relating to the mental, physical and social wellbeing of the people of Guernsey and Alderney and to be responsible for:

- Promoting, protecting and improving personal, environmental and public health;
- Preventing or diagnosing and treating illness, disease and disability;
- Caring for the sick, old, infirm and those with disabilities;
- Providing a range of social services to all age groups including ensuring the welfare and protection of children, young people and their families and ensuring that the best interests of the child shall be a primary consideration.

CHSC is required not to exceed its annual budget. Given the prevailing financial environment the capacity for real growth in public funding to provide health and social care is extremely limited. By reason of resource constraints CHSC cannot meet all the health and social care needs of individuals within its areas of responsibility. CHSC therefore must continue to make difficult choices between competing needs. The fact that CHSC will need to take decisions not to commission or restrict access to specific services or interventions (even when they are cost-effective) does not mean that CHSC is breaching its mandated obligations.

The States of Guernsey is not unique in facing these issues. They are challenges faced by all health care systems.

The challenge of managing within a defined budget is not a new problem but the nature of the pressure is changing. In particular, there is an increase in very high cost technologies and an increase in the number of individuals with complex

needs, particularly in the elderly.

Historically health care services have applied a number of approaches to manage costs: the prevention of disease and disability, the provision of only evidence based interventions and minimising costs by increased productivity and the improvement of the quality and safety of services. All these approaches remain important. However, taken alone these actions will be insufficient to deliver the best health care that can be delivered within any given resource and they do not guarantee that services reflect the priority needs of the population or the values of patients or society generally.

In deciding how to how to allocate finite resources CHSC must consider:

- The services that are to be made publicly available;
- The level to which those services will be made available (with the application of access criteria);
- The design of those services (as different models of care have different cost implications);
- The quality of those services;
- The organisation that will provide the service (when costs are very different).

Fundamental to all decisions which commit resources is that value must be derived for the population. CHSC will strive to improve all aspects of value [1] both in healthcare and social care provision. Value in health care includes:

1. **Allocative value** by determining how best to distribute resources across different services for different patient and care groups.

2. **Technical value** by determining how best to use resources for a particular group of patients or clients so that what is provided represents value for money and provides the most impact to those affected.

3. **Personal value** by delivering decisions in a way which matters to patients:

[1] Sir Muir Gray, Better Value Healthcare, February 2016

- making clinical and care decisions which focus on the problem that is of most concern to the individual, not their diagnosis; and
- taking into consideration the value the individual places on the benefits and risks of the options for intervention available to them.

As of 1 January 2022, functions previously funded from the Health Service Fund and the Social Insurance Fund (patient travel only) have been transferred to the Committee *for* Health & Social Services. At this stage, a full integration of the policies has not yet taken place and the previous policies will continue to apply. Until that reconciliation has taken place, if the previous policy is in conflict with G1033, then the previous policy will have precedence.

2. An ethical system for decision making

In order to determine which services should be funded CHSC has to undertake a complex series of decision making at different levels; *strategic*, *service*, *disease or condition* and /or the *individual* level.

This policy sets out the principles that will underpin the decision making of CHSC and its Committees in relation to resource allocation.

This policy is ethically based. An ethical system for decision-making includes:

- Setting down key principles, decision rules, criteria and considerations which ensure that CHSC operates within an appropriate legal, ethical and financial framework;

- clear processes for decision-making; and

- a governance process which ensures that decision making is compliant with the policies of CHSC (including this policy).

CHSC will continue to establish and evolve mechanisms to make priority setting more open, transparent and clear with aim of:

- ensuring public funding is used to best effect to improve the overall health and well-being of the population;

- ensuring that investments are aligned to pre-agreed strategies, priorities and policies;

- ensuring competing needs and demands to have a fair chance of being considered for funding, which will mean mitigating against those with the resources and ability to lobby obtaining greater access to healthcare than those vulnerable groups who may not have the ability or resources to lobby in the same way;

- making decisions according to good practice guidance and the demands of good governance; and

- gaining public confidence so that decisions that have been taken by CHSC are viewed as fair and legitimate by the public and that service users, professionals and the public are able to understand how a decision was made.

3. Key principles that will be applied to all CHSC resource allocation

See Appendix 1 for a guidance note

CHSC will apply a number of principles whenever allocating resource to ensure that it does not breach the duties placed on it by the States; or the provisions of this Policy. These are:

3.1 CHSC 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, CHSC will adopt prioritisation as the primary methodology for all its decisions making around resources. This means:

3.2.1 When making an investment decision, CHSC 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. CHSC will not, save in the exceptional circumstances set out in this policy, make isolated decisions about investments.

3.2.2 CHSC may reallocate resources from existing low value / low priority care to care which is of higher value / higher priority.

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 CHSC costs unless this has been sanctioned by CHSC. 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 Stakeholders participating directly in priority setting as part of the formal CHSC decision making processes, whilst bringing their particular perspective, expertise and experience of health or social care to that decision making are expected to consider the needs of

the whole population when participating in CHSC priority setting.

3.3 CHSC will only invest in interventions that are cost-effective.

3.4 CHSC 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 CHSC policy *G1002: Individual funding requests*.

3.5 CHSC will live within the budget allocated to it by the States of Guernsey.

3.5.1 CHSC must not knowingly commit resources it does not have.

3.5.2 When CHSC predicts there is a risk that it will overspend its budget it must take those actions necessary to prevent this, including stopping or delaying agreed investments, making disinvestments in services or facilities or delaying aspects of the delivery of health care services.

3.5.3 Where an adopted policy turns out to exceed the budget allocated for it, CHSC will review the future access criteria.

3.6 CHSC will not fund one individual if others with the same need cannot be funded

3.6.1 When making investment decisions at an individual level, CHSC will not fund an individual's health or social care simply because they have come to the attention of CHSC when there are other similar patients or clients for whom funding provision has not been made.

3.6.2 CHSC will not make arbitrary policy decisions which knowingly under-commits resources to fund treatments, care or services for group of similar patients or clients. If a treatment or service cannot be afforded to the whole group of patients or clients, then either it must not be offered in an individual case or the access criteria must be modified in order to be affordable to meet all

those who are expected to meet the access criteria.

3.7 CHSC must not allow third parties to determine priorities or make funding decisions on its behalf.

3.7.1 CHSC 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 CHSC 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, and this might be determined at assessment on a case by case basis.

4. Option appraisal used to decide between competing service developments and potential disinvestment in services

4.1 When deciding which service developments are the next priority for investment or when taking the decision to disinvestment in services, care or treatments CHSC has to make complex assessments and trade-offs between competing needs.

4.2 The following factors may be included when making choices between competing needs:

4.2.1 Whether there is a legal requirement which mandates CHSC to fund a particular proposed service development or an element of it.

4.2.2 Whether or not there is a major negative impact in not proceeding with the proposal.

4.2.3 Whether or not the proposed service development and/or the benefits anticipated to be derived from the proposed service development have been identified as a priority within the strategic plan for that service. This includes the extent to which the proposed service development supports the delivery of CHSC's commissioning intentions.

4.2.4 The degree to which the proposed service development meet the aims of CHSC's and/or States of Guernsey's key strategic aims including the Transformation of Health and Social Care Services.

4.2.5 *Social care:* The anticipated benefits of the service development.

Health care: The anticipated clinical effectiveness of the proposed service development both in terms of the nature of the health outcome, the size of effect and the proportion of patients of those treated that will benefit from treatment.

4.2.6 The number of patients potentially benefiting from the introduction of the proposed service development per year.

4.2.7 Whether an evaluation of all the options has been carried out using valid assumptions and the validity of the conclusion reached that the proposed option(s) are the best for delivering the proposal's aims.

4.2.8 The potential impact of the proposed service development on one or more other services funded or provided by CHSC or the States (for example the potential for increased pressure on other parts of health and social care services or the reduced demand for another service).

4.2.9 The level of CHSC's confidence in the evidence underpinning the case for the proposed service development.

4.2.10 The level of CHSC's confidence in the assumptions made in the business case for the proposed service development (including activity, cost, the impact on other services having been fully identified, risks and the ability to mitigate identified risks and similar factors).

4.2.11 The level of CHSC's confidence that the proposed service development can be delivered within the specified timescale.

4.2.12 The value of the services to be delivered by the proposed service development (including cost-effectiveness, availability and appropriateness of the service, and whether the proposed business model represents good value for money).

4.2.13 The anticipated budgetary impact of the proposed service development including:

- An assessment of the total budgetary impact of funding the proposed service development; and

- Whether the proposed service development is overall reducing

costs or cash releasing in the short, medium or long term.

4.2.14 The anticipated risks related to the proposed service development including harm to patients or clients.

4.2.15 Whether the proposed service development will improve access to care to subgroups of individuals thereby improving equity of access.

4.2.16 The effect of the proposed service development on patient or client choice.

4.3 CHSC may adopt decision aids in different settings to help decision-making. These may be standard tools / aids or ones particularly created for a particular decision / set of decisions.

5. Experimental and unproven treatments

See Appendix 3 for a guidance note

5.1 Except for those circumstances set out below, treatments which are judged to be experimental or not of proven effectiveness will not be routinely funded.

Commercial clinical studies

5.2 It is expected that all treatment and additional service costs (including but not limited to additional blood tests, scans, outpatient visits which are needed to monitor a clinical trial) will be funded by the commercial sponsor.

Ongoing access to a treatment following the completion of Industry-sponsored clinical studies

5.3 CHSC will not pick up the funding of a patient's treatment at the end of a clinical trial that has been sponsored by Industry without the prior written agreement of CHSC. Provider organisations seeking funding from CHSC for the continuation of treatment for a patient leaving a clinical trial must provide clear evidence that any such agreement has been given.

5.4 It is the responsibility of both the organisation conducting the trial (usually the Provider organisation) and the patient's clinician to ensure that patients are fully informed, as part of their consent to enter a trial, that their treatment may not continue to be funded by the public sector after the trial has finished. CHSC will only provide funding when this has been agreed in advance and in writing by CHSC.

5.5 CHSC observes that the usual arrangement, in accordance with the *UK Medicines for Human Use (Clinical Trials) Regulations 2004* and the *Declaration of Helsinki* adopted by the World Medical Assembly is that at the conclusion of the study, patients entered into the study are entitled to be informed about the outcome of the study and those conducting the trial will share any benefits that result from it, for example, access to interventions identified as beneficial in the study or to other appropriate care or benefits. CHSC expects the relevant Research Ethics Committees to

require that a clinical trial will not be approved unless funding has been identified by those conducting the trial and explicitly approved by the proposed funder to ensure that any patients benefitting from the treatment administered in the trial are able to continue with the treatment.

5.6 In the event that CHSC makes an exception to the policy by providing funding to continue a treatment to a patient, this decision does not represent a policy decision by CHSC to fund that treatment for other patients who were not part of the clinical trial. Any application for a service development to support funding for the treatment in question will be assessed and prioritised under CHSC's service development policy in the normal way.

Non-commercial clinical studies

5.7 The Concordat [2] between the UK Department of Health and non-commercial bodies such as the Medical Research Council establishes the principle that the NHS (UK) will provide funding for additional service costs related to research activities of key non-commercial research bodies. This does not apply in the Bailiwick of Guernsey. As such, any clinician wishing to enter a patient into a clinical trial must seek prior written permission from CHSC.

5.8 All requests to CHSC to fund the treatment costs of a clinical trial or to pick-up the cost of continuing treatment following a clinical trial must be sought in advance of entering a patient into a clinical trial.

5.9 A funding request that seeks funding for a single patient to enter into a clinical trial will be managed through the individual funding request policy and process.

5.10 A funding request that seeks funding for a cohort or potential cohort of patients to be entered into a single clinical trial will be treated as a proposed service development (see Section 7 concerning in-year service

[2] Department of Health (UK) HSG(97)32: Responsibilities for meeting Patient Care Costs
associated with Research and Development in the
NHS

developments).

5.11 In assessing requests to fund the treatments costs of one or more patients to enter a clinical trial, or to fund the continued treatment for a patient following completion of a trial, CHSC will consider the following:

5.11.1 the potential strategic importance of the treatment. This requires a judgment to be made as to whether the trial will address key Bailiwick priorities for the particular patient group or programme area (e.g. cancer, cardiovascular disease);

5.11.2 the status of the clinical trial including whether or not the trial has been ratified by the National Institute for Health Research in the UK and / or other relevant professional and research bodies;

5.11.3 the quality of the trial and whether or not it is expected to generate the sort of information needed to enable those funding healthcare to reach a view on the clinical effectiveness and cost effectiveness of the treatment. Specialist advice may need to be sought on the methodology to be adopted within any trial;

5.11.4 the ownership of the data. Trials which do not guarantee that the data will be made freely and unconditionally available (other than subject to any reasonable condition preserving confidentiality) to public authorities and research communities for independent evaluation will not be considered for funding; and

5.11.5 the affordability of the treatment and its relative priority when compared with competing unmet needs.

5.12 When an application is made, the clinician must provide as much information about the trial as possible including patient numbers (where relevant), costs, potential on-going costs, the treatment and the trial objectives. A copy of the trial protocol, or a detailed summary, must also be included with the application. CHSC may also request assurance and any relevant evidence that the trial complies with this Policy.

5.13 In all circumstances where funding is granted, the Provider organisation

must keep a record of acceptance to ensure pick-up funding is available for an individual patient .

On-going access to treatment following the completion of a non-commercially funded clinical study

5.14 If CHSC has explicitly agreed to fund one or more patients' treatment in the context of a clinical trial, then on-going care will be funded as outlined in paragraph 5.3. The final decision as to whether the patient has received a benefit rests with CHSC and not the provider organisation.

5.15 In the event that CHSC agrees to fund treatment, this decision does not represent a policy decision by CHSC to fund that treatment for other patients who were not part of the clinical trial. Any application for a service development to support funding for the treatment in question will be assessed and prioritised in the normal way.

Requests for referrals to the UK specifically to discuss clinical trials

5.16 CHSC expects the discussion of clinical trial entry to be part of routine care provided by the existing clinical team managing a patient.

5.17 The treating clinician is expected to identify possible studies on request of the patient by checking the following clinical trials registers and if needed discussing with the lead investigator if a patient is suitable:

- https://clinicaltrials.gov/
- https://www.ukctg.nihr.ac.uk/
- http://www.isrctn.com/

However, where public funding is required clinicians must not raise patient expectations that clinical trial funding will be available and patients should be advised that financial constraints make the threshold for being granted public funding for clinical trials high.

5.18 The treating clinician should make every effort to establish that a patient is a suitable candidate before seeking permission to refer a patient for an assessment for trial entry (where the trial is fully funded by other sources) or to make an application for funding to support the patient going into a

clinical trial.

5.19 CHSC will not fund requests by patients or a doctor on their behalf for an outpatient referral to a different team specifically to determine which trials may be available or to register interest with a specialist centre to be considered a future trial participant.

Pharmaceutical company sponsorship 3

5.20 CHSC will not fund a patient's ongoing treatment when company sponsored funding is withdrawn unless there has been prior written agreement with CHSC. Provider organisations seeking funding from CHSC for the continuation of treatment after sponsorship from Industry has been withdrawn must provide clear evidence that any such agreement has been given.

5.21 It is the responsibility of the Provider organisation and the patient's clinician to ensure that patients are fully informed under what circumstances pharmaceutical company funding is being provided, how long this funding will be provided and what will happen when it is withdrawn and that such arrangements have been explicitly approved by the relevant governance body of the Provider organisation (for example the Drugs and Therapeutics Committee). The patient must agree to their management plan on the discontinuation of treatment. This responsibility includes making patients expressly aware of this Policy. The patient's consent under this paragraph 5.21 should be documented.

5.22 The continued provision of a treatment is the responsibility of those individuals or parties that have initiated and sponsored either the clinical trial or drug company sponsored treatment (including where the treatment has been paid for with private funding).

5.23 In the event that CHSC makes an exception to the policy under paragraph 5.22 above by providing funding to continue a treatment to a patient, this decision does not represent a policy decision by CHSC to fund that

[3] Pharmaceutical companies frequently provide free treatment to patients in hospital in the period between the end of a clinical trial and licensing. This is also known by the term 'compassionate funding'.

treatment for other patients. Any application for a service development to support funding for the treatment in question will be assessed and prioritised under CHSC's service development policy in the normal way.

Use of an existing treatment experimentally for rare clinical circumstances outside the context of a clinical trial

5.24 This type of request will be considered under the CHSC's policy *G1002: Individual funding requests.*

5.25 CHSC will give consideration to supporting an existing treatment in an experimental context for rare clinical situations provided that the clinician making the application is able to demonstrate that running a good quality clinical trial for the treatment in the clinical situation in question is not possible.

5.26 In assessing these cases CHSC will make a decision having regard to the following factors:

5.26.1 evidence of the effect or assessment of biological plausibility based on other evidence; and

5.27.2 the potential benefit and risks of the treatment; and

5.28.3 an estimate of cost of the treatment and the anticipated value for money; and

5.29.4 the priority of the patient's needs compared to other competing needs and unfunded developments.

5.27 The clinician will be expected to provide as much information as possible about the treatment, the relevant research upon which the claim for benefit is based, the costs, as well as clinically relevant information on the patient. In addition, the clinician will identify the clinical markers and clinical outcomes that will be monitored to assess the treatment response.

5.28 The options for consideration by CHSC in these instances are:

5.28.1 Not to fund the treatment;

5.28.2 Fund on the condition that the patient enters a properly conducted *'n of 1'* trial (if and when this option is available in the UK);

5.28.3 Fund a trial of treatment but make on-going treatment subject to the demonstration of clinical benefit for the individual patient using criteria agreed in advance with the clinical team;

5.28.4 Fund with no evaluation requirements, although an outcomes report may be requested;

5.29 CHSC may additionally impose conditions for funding as considered appropriate.

5.30 In all instances, the contribution to any relevant clinical database or population registry that is already in operation will be an additional condition before CHSC gives approval of funding for the treatment.

Novel treatments not previously studied at all

5.31 Primary research into novel treatments will not be funded by CHSC.

5.32 Patients wishing to access novel treatments will need to fund them privately.

5.33 CHSC will not, in general, support the use of novel treatments outside the context of clinical trials on its premises. Patients wishing to access such treatments will need to seek treatment in the UK.[4]

[4] The Access to Medical Treatments (Innovation) Bill 2015-16 is at the date of this Policy currently going through the UK Parliamentary process. The Bill aim to allow patient wishes to access highly experimental treatments outside of clinical trials. It has two main provisions:

to enable the creation of a database of innovative medical treatments; and

to set out steps which doctors can take in advance of carrying out an innovative treatment, to show that they are acting responsibly (and therefore reduce the risk that they may be judged to have acted negligently for departing from established treatments).

6. Guidance produced by the National Institute of Health and Care Excellence and cost-effectiveness thresholds

See Appendix 3 for a guidance note

NICE Guidance

6.1 All guidance produced by the National Institute for Health and Care Excellence 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 £40,000 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 £40,000 per quality adjusted life years will be further assessed to determine whether or not they should be forwarded for prioritisation.

End of life treatments 5

6.3 CHSC 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

http://services.parliament.uk/bills/2015-16/accesstomedicaltreatmentsinnovation.html

[5] The National Institute for Health and Clinical Excellence, Appraising life0extending, end of life treatments https://www.nice.org.uk/guidance/gid-tag387/resources/appraising-life-extending-end-of-life-treatments-paper2

6.4 CHSC 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]

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 CHSC.

6.6 An equivalent of the English Cancer Drugs Fund will not be operated in Guernsey.

[6] Details can be found at the NHS England Website https://www.england.nhs.uk/cancer/cdf/

7. Consideration of funding service developments outside of the annual commissioning round (In-year service developments)

See Appendix 4 for a guidance note

7.1 Potential investments will generally only be considered and prioritised during CHSC's annual planning process.

7.2 Investments in any given financial year will only be provided in accordance with CHSC's commissioning intentions or under its policy dealing with its policies *G1002: Individual funding requests* for health care treatments

7.3 No decision will be made to provide a new treatment or service that is not contained within CHSC's commissioning intentions until the proposed service development has been assessed, prioritised and a policy decision has been taken as to whether CHSC's existing commissioning intentions should be amended to include the proposed service development.

7.4 Any application to amend CHSC's commissioning intentions to include an in-year service development must be set out in an approved business case, which describes the proposed policy change, the evidence base to support the service development and details the cost and implications of both making the policy change and not making the policy change. CHSC will require considerable and compelling evidence of both the clinical and cost effectiveness of the proposed service development before agreeing to a change in a current financial year.

The default commissioning policy

7.5 A consequence of this approach is that CHSC's will operate a default commissioning position. That position is that a treatment or service will not normally be funded for any patient until the service development has been assessed and been subject to consideration through the annual commissioning process.

7.6 In-year service developments will only be agreed on an exceptional basis. In order to be treated as exceptional the investment should fall into one of

the following categories:

7.6.1 To manage a critical incident. This might include, for example, a major epidemic or the sudden loss of a service.

7.6.2 To introduce very high value treatments, care or services which in the view of CHSC should not be delayed. These occurrences are expected to be few and far between.

7.6.3 To address high risks in a service where it is concluded that the investment will result in significant risk reduction.

7.6.4 To pump prime a service redesign which is guaranteed to release the equivalent investment within the same year.

7.6.5 To implement a planned high priority investment early because of the release of other funding through disinvestment in low value healthcare or cost-efficiencies.

7.6.6 To substitute one treatment or service with another where these are cost-neutral.

7.6.7 To fund the support of an important clinical study for which there is a short window of opportunity.

7.6.8 To fund a care and support plan where there is high level of complex need and risks and which cannot be managed within the existing service provision and without which individuals will suffer significant harm

7.7 An in-year service development will not be approved unless CHSC can reach a clear conclusion that the following tests are satisfied:

7.7.1 that the proposed service development would have been highly likely to have been supported by CHSC in the last annual funding round, in priority to those service developments which could not be afforded by CHSC at that time;

7.7.2 that the proposed service development is a high value intervention because it provides very significant beneficial outcomes for patients or clients;

7.7.3 that the proposed service development is affordable in the current financial year and in following years.

8. The boundaries between healthcare funded by CHSC and privately funded healthcare

See Appendix 5 for a guidance note

Entitlement to HSC funded care

8.1 Care funded by CHSC is made available to patients in accordance with CHSC mandate given by the States of Guernsey and the policies adopted by CHSC in the discharge of that mandate. However, individual patients are entitled to choose to access publicly funded care and to pay for their own healthcare through a private arrangement with doctors and other healthcare professionals.

8.2 Except as set out in this policy, a patient's entitlement to access CHSC funded healthcare is not affected by that patient's decision to fund part or all of their healthcare needs privately.

Privately funded healthcare

8.3 Any privately funded arrangement that is agreed between a patient and a healthcare provider is a commercial matter between those parties. Except in instances where CHSC is the provider (in whole or part) of private healthcare, CHSC is not a party to those arrangements and cannot take any responsibility for the terms of the agreement, its performance or the consequences for the patient of the treatment including any subsequent treatment that becomes necessary or desirable by reason of the patient having received that private treatment.

8.4 Private patients are expected to pay for all costs associated with private treatment.

In instances where the treatment being accessed is something not normally funded by CHSC, then the patient is also expected to fund all care related to complications which are not defined as a medical emergency.

8.5 The patient's agreement to the likely costs and to the risk of incurring potential additional costs must be sought by the provider in advance of any

private care being provided, preferably in writing. Those providing private health care to an individual patient should ensure that the patient can cover the predictable and potential costs of all their treatment including possible short and long term complications, follow up, ancillary services and monitoring.

8.6 Patients are entitled to pay for additional healthcare while receiving healthcare funded by CHSC but a patient cannot, in general, be both a private and a public patient at the same time for a single episode of care except those set out under paragraph 8.26.

8.7 Providers of health care to Guernsey patients should ensure that for each episode of care the status of the patient is documented in their records. For care provided on Island the patients status should be recorded on the Trak system and in all relevant medical records and on any system related to patient billing.

8.8 Private patients may move back into the public sector for the treatment of complications that arise as a medical emergency either during an inpatient stay or subsequently, even if the complication is attributable to their private treatment.

A medical emergency are complications which are organ, limb or life threatening or which are likely to lead to significant functional impairment.

Illustrations

Patient A has funded a breast implant for breast augmentation as a cosmetic procedure. While an inpatient she has problems arising with her wound. This is a direct and non-emergency complication. The patient will pay all associated costs both while she is an inpatient and also for any on-going costs after discharge including post-operative complications.

Patient B has elected to go privately for his hip replacement. While an inpatient he develops a deep vein thrombosis. Although potentially serious this is a direct and non-emergency complication and so the patient will need to pay for all associated costs while he is an inpatient including the complications. However once discharged from hospital the patient may enter the public system for on-going

management of the thrombosis.

Patient C has elected to go privately for his hip replacement. While an inpatient he develops a deep vein thrombosis and a life-threatening pulmonary embolus and has to be admitted to intensive care. Although a direct complication, this requires emergency management and the patient can move into the public sector for the remainder of his inpatient stay.

8.9 In those cases where a patient needs the same tests for both the private and public element of their care, those tests should not be done twice, and the patient may ask for the tests to be funded by CHSC. Tests that are only required for the private element of care must be paid for by the patient.

Private testing and screening

8.10 If private testing or privately funded screening identifies a condition for which States of Guernsey would normally fund treatment, then the patient may choose to be referred for States-funded treatment as a separate episode of care in the normal way (through their GP or another referral pathway accepted by HSC).

8.11 Treatment of patients referred as a result of a private screening programme will be accepted into contract care subject to the programme having been previously endorsed by the Clinical Reference Group and Public Health.

8.12 Pre- and post-genetic test counselling is an essential and integral part of any genetic test. To undertake testing without appropriate counselling is poor practice. As a result the CHSC considers that counselling before testing and counselling to advise on the interpretation of the test results should form part of any genetic testing done privately.

Patients wishing to move back into the public sector following commencing private treatment

8.13 An individual who has accessed private health care may request a move back into publicly funded care at the next episode of care along the patient pathway. An individual cannot elect to transfer into the public sector during an inpatient stay except in the circumstances permitted under paragraph 8.8.

8.14 In the event that a patient moves back into the public system the patient will be provided with the same treatment as they would otherwise have received had they been publicly funded throughout.

8.15 At the time that the patient seeks a transfer back into care funded by CHSC:

8.15.1 CHSC is entitled to seek further information or apply additional requirements for patients wishing to move back into the public sector. This may include reassessment of the care needs; to ensure that there is equity of access to publicly funded care.

8.15.2 The patient will not be given any preferential or priority treatment by virtue of having accessed part of their care privately.

8.15.3 The patient will be subject to standard CHSC waiting times, or if treatment is to be given in the UK, standard NHS waiting times.

8.15.4 8.12.4 For patients who have been seen at a Provider Organisation from whom CHSC does not normally commission *that particular care pathway* the patient will be required to transfer to the CHSC's usual provider for that pathway.

8.16 An individual whose private consultant has recommended treatment with a medication can ask their GP or Medical Specialist Consultant to provide this medication as long as:

8.16.1 the medication is normally funded by CHSC or the Committee *for* Employment & Social Security (CESS) for that indication; and

8.16.2 the doctor considers it to be medically appropriate in the exercise of his or her clinical discretion; and

8.16.3 the doctor is willing to accept clinical responsibility for prescribing the medication.

8.17 In cases where a patient's private consultant has recommended treatment with a medication which is specialised in nature and the patient's GP is not

prepared to accept clinical responsibility for the recommended prescribing decision the GP should consider whether to make a referral to the [Medical Specialist Group] to consider whether the patient meets the criteria to be prescribed the medication as part of treatment funded by CHSC or CESS. In all cases there should be clear and appropriate communication between the consultant and the GP.

8.18 A medication recommended by a private consultant may be more expensive than the medication options prescribed as part of care funded by CHSC or CESS. Under these circumstances the prescribing doctor should prescribe the cheaper medication. If in doubt advice should be sought from CHSC or CESS (as the case may be). The patient has the option of purchasing the more expensive medication through his private consultant but must pay the whole of the cost and will not be able to reclaim any part of the cost by way of contribution from CHSC or CESS.

8.19 Clinicians and health care professionals working in or funded by the public sector are entitled to refuse to accept a private patient back into public care if they are unwilling to accept on-going clinical responsibility for the patient for any reason. It is expected that such instances will be very rare. Any instance where this situation arises should be reported to CHSC Director responsible for Clinical Governance.

Retrospective funding of privately funded healthcare following a move back into the public sector

8.20 CHSC will not make any contribution to privately funded care to cover the cost of treatment that the patient could have accessed through publicly funded healthcare.

Treatment not normally funded by CHSC

8.21 When a patient opts to pay privately for treatment that is not usually funded by CHSC, the patient will be required to pay all costs associated with the privately funded episode and subsequent care pathway. The costs of all medical interventions and care associated with the treatment include the costs of preparation and delivery, assessments, inpatient and outpatient attendances, monitoring, rehabilitation and follow-up. This obligation includes the costs of dealing with direct and non-emergency complications.

8.22 CHSC will not pick up the costs of on-going treatment. This includes direct non-emergency complications of treatment.

8.23 In instances where the clinician considered there to be exceptional reasons to justify ongoing public funding an application can be made through the CHSC's individual funding request process for funding. However, where CHSC has decided not to fund a treatment routinely, the fact that the patient has demonstrated a benefit from the private treatment to date (in the absence of any evidence of exceptionality as defined by CHSC policy) would not itself be a proper basis for CHSC to agree to support the application, since to do so would result in CHSC approving differential funding criteria for persons who could afford to fund part of their own treatment.

8.24 If funding is granted, following an approved individual funding request, CHSC will not reimburse the patient for any treatment received as a private patient before that funding request was approved.

Co-funding — Patients being treated by NHS Providers in the UK

8.25 Co-funding is not allowed in the NHS as set out in the March 2009 Department of Health Document 'Guidance on NHS patients who wish to pay for additional private care'. [7]

8.26 Where the private and the public activity cannot be separated, the patient must pay privately for all costs relating to the episode of care if they wish to have the specific treatment of choice.

8.27 The principle of separation may be overridden when there are concerns over safety or where patients are put at unacceptable additional risk. All requests to allow co-funding must be sanctioned by CHSC and also be sanctioned by, and in accordance with, the Providers local policy on co-funding and their internal processes.

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[7] https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/404424/patients-add-priv-care.pdf (Accessed 6th September 2016)

Co-funding — Patients being treated under contract in the Princess Elizabeth Hospital in Guernsey

8.28 CHSC will allow co-funding within the local publicly health care system.

8.29 The CHSC will operate a list of standard procedures and the costs incurred by the patient. The list may be added to over time.

8.30 Requests for co-funding outside of this list will need to be sanctioned by the Finance Business Partner and the Medical Director and the costs falling to the patient decided in advance the patient is consented to treatment.

8.31 Individual health care professionals or CHSC staff cannot individually sanction and consent patients for co-funding for treatments that are not on the pre-agreed list, or without agreement and the provision of costings from the Finance Business Partner.

Private referrals to the UK

8.32 All private referrals to the UK are expected to be accompanied by the Office of CHSC covering letter entitled: 'Private patients from Guernsey - information for clinicians and providers in United Kingdom & Jersey'. This makes clear:

- That the patient is a private patient.
- That the treating consultant and provider in the UK are not authorised to transfer the patient into States funded care or enter the patient into a clinical trial.
- If the consultant wishes to transfer the patient into States funded care (either for treatment or as part of a clinical trial) they must formally apply to CHSC for prior authorisation.
- That authorisation is not at all guaranteed.

Authorisation of patients moving back into the public sector having been seen as a private patient in the UK

8.33 No consultant, general practitioner or other health care professional has the authority to give permission for a patient being treated privately in the UK to be transferred into publicly funded care whether at the same facility

or another facility in the UK.

Authorisation of patients to enter clinical trials requiring CHSC funding

8.34 No consultant, general practitioner or other health care professional has the authority to give permission for a patient being treated in the UK either as a private patient or as a CHSC funded patient to enter a clinical trial which requires public funding.

Commissioning care from private providers

8.34 CHSC will on occasions need to commission health care for publicly funded patients from private providers where this is not otherwise available as part of normal commissioned care.

8.35 CHSC may commission care from private providers as part of the normal care pathway.

Clinical governance

8.35 Transferring patients between private and publicly funded care must be carried out in a way that avoids putting patients at any unnecessary risk. Both public and private providers must work collaboratively to ensure effective risk management, the timely sharing of information, continuity of care and coordination between public and private care at all times.

Treatment initiated in another country while travelling abroad

8.36 Individuals travelling in another country may be initiated on treatment under their travel insurance which is not normally funded by CHSC. CHSC will not fund ongoing care. Patients will be offered normally commissioned care only.

In situations where the funding position is unclear

8.37 All health care professionals, administrative and operational managers are expected to be familiar with this policy.

8.38 When the funding position is unclear, health care professionals,

administrative and operational managers should refer the decision to a member of the Corporate Management Team.

9. Funding care for patients moving to Guernsey and therefore changing national jurisdictions

See Appendix 6 for a guidance note

9.1 Where responsibility for providing healthcare has been transferred from another country's jurisdiction to the States of Guernsey, the on-going funding of existing treatments and care cannot be guaranteed by CHSC. In general patients will be offered access to those treatments, care and services on the same basis as those available to existing residents.

If the clinician believes there are good reasons to continue with existing treatment an application should be made under the CHSC individual funding request policy and process.

10. Choice of provider and treatment outside the United Kingdom and Jersey

10.1 All patients accessing health care are expected to follow agreed care pathways. This includes care provided by specified providers from whom CHSC normally commissions health care.

10.2 When treatment is available on Island, CHSC will not fund off-island treatment unless there are exceptional circumstances.

10.3 CHSC will not routinely fund treatments or services outside the United Kingdom or Jersey.

10.4 In exceptional circumstances funding may be considered for the provision of care beyond the UK. In order to be considered for funding, a request must meet all of the following conditions:

10.4.1 The application must be made by an appropriate clinician, normally a UK recognised expert in the clinical field in question.

10.4.2 The treatment and provider in question must form part of a well-recognised care pathway within the NHS.

10.4.3 The treatment must be cost-effective.

10.4.4 The treatment must be affordable.

10.5 CHSC will not pick up the funding for a patient who has been referred to a non-designated provider as a private patient and who subsequently wishes to continue their care at that provider as a patient funded by CHSC. A new referral to a designated provider will be required.

10.6 It is the responsibility of the referring doctor to ensure that the patient is aware of this policy and in particular paragraph 8.31 prior to referring patients privately to non-designated providers.

11. On-going access to treatment following a trial of treatment which has not been sanctioned by CHSC for a treatment and which is not routinely funded or has not been formally assessed and prioritised

See Appendix 7 for a guidance note

11.1 CHSC will not pick up the funding of a patient's treatment at the end of a 'trial of treatment' for treatments that are not normally commissioned by CHSC, without the prior written agreement of CHSC. Provider organisations seeking funding will need to provide evidence of that agreement.

11.2 It is the responsibility of the Provider organisation providing the care to the patient and the patient's clinicians to ensure that patients are fully informed and consent before they agree to a trial of treatment. As part of that process patients must be informed, if it is the case, that no written agreement has been secured from CHSC to provide for future funding for the treatment. In these circumstances the patient must be made aware of this policy including the section relating to experimental and not proven treatments.

11.3 In the event that funding is not sanctioned, responsibility for providing on-going access to a treatment is the responsibility of the Provider organisation that initiated treatment.

11.4 In the event that CHSC exceptionally agrees to provide funding to continue a treatment to a patient that has been commenced on a trial basis, this decision does not represent a policy decision by CHSC to fund that treatment for other patients who are in the same or similar clinical circumstances. Any application for a service development to support funding for the treatment in question will be assessed and prioritised under CHSC's service development policy in the normal way.

12. Consultant to consultant within the United Kingdom

12.1 CHSC will not fund consultant-to-consultant referrals without having given prior approval. This includes:

12.1.1 between consultants of the same specialty for a different indication, or consideration of a surgical procedure within the same hospital or healthcare provider;

12.1.2 between consultants of different specialties within the same hospital or healthcare provider;

12.1.3 between consultants of the same specialty between different hospitals or healthcare provider;

12.1.4 between consultants of different specialties between different hospitals or healthcare provider.

12.2 Following a request for funding CHSC may:

- Approve the referral.
- Decline the approval and ask for the patient to be discharged back into the care of a local consultant for review.
- Seek further information and advice.

Exceptions

12.3 No prior approval is required:

12.3.1 Where a consultant anaesthetist considers that a patient is not fit for surgery and refers that patient directly to another consultant, for example, a cardiologist or chest physician, if they think the patient has a condition that is severe and needs urgent referral.

12.3.2 Where a short delay might be life threatening or is likely to impact on the long-term prognosis for a patient.

12.3.3 Where the treating consultant makes a referral that is needed for a

tertiary opinion on an inpatient.

12.3.4 Where the onward referral of a patient will reduce the public health risk from one of the notifiable communicable diseases.

12.3.5 Where a patient has been admitted with multiple medical needs (for example major trauma) which requires management by different medical teams.

If a clinician is in doubt they should discuss the case with CHSC's Off Island Team.

12.4 CHSC will not fund attendances resulting from a consultant-to-consultant referral if it identifies non-compliance with this policy.

13. Patient requested second opinions

13.1 A patient requested second opinion is defined as a visit to a doctor other than the one the patient has previously seen in order to get a further opinion.

13.2 If a patient wishes to seek a second opinion funded by CHSC the patient's general practitioner will have discretion to refer to a different consultant on island providing there is a second consultant on island with sufficient expertise to provide that second opinion.

13.3 If the second opinion is being sought off island, (regardless of whether the first treating clinician is on or off island), an application must be made by the patient's GP or consultant in the form of a clinical letter to CHSC Off Island Team. The application will need to state:

- The reason(s) for the second opinion, why the patient does not accept the first opinion and why it needs to be off-island.

- To whom the referral will be made.

- A brief summary of the patient's history including those clinicians (or other healthcare professionals) the patient has already seen for this condition and identifying whether funded by CHSC or privately.

Any proposed referral must be to another consultant following normally funding care pathways funded by CHSC.

If the referral falls outside the normal care pathway, those reasons must be provided and the referral may need to be made by way of an individual funding request.

13.4 Referrers should be made aware of the restrictions over choice of provider under this policy.

Where a visiting clinician has been involved and CHSC has approved taking a second opinion it will normally be to see the relevant specialist team at the visiting clinician's hospital and not a different hospital.

13.5 CHSC will have discretion to take into account any privately funded opinions that have already been obtained.

13.6 If agreed CHSC will direct the most appropriate person to make the referral.

13.7 An agreement to fund a second opinion does not commit CHSC in any way to funding treatment at that centre and it is important for patients to be made aware, and must understand, that the referral is only for a second opinion.

13.8 Patient requested third opinions will not normally be funded.

14. Funding requests for individual patients

Funding request which required the commitment of additional resource to normally funded care and which can only be dealt with at the level of the individual are currently covered by separate policy documents.

Funding requests for health care treatments or services for individual patients that are not normally or currently commissioned can only be funded in exceptional circumstances. These are dealt with through the Individual Funding Request Process of CHSC the details of which can be found in CHSC policy *G1002: Individual Funding Requests*

Part 2: Operational processes to support priority setting

15. Commissioning intentions

15.1 Each year CHSC will produce its programme of work and investment plan for the following year in its Commissioning Intentions.

With respect to priority setting; this document will include the CHSC plans for:

- The development of strategy.
- The CHSC service improvement plan for health and social care (including prevention services).
- Changes to the funding of services; including new investments (including capital investments) and decommissioning of services.

15.2 The commissioning intentions document will be the document which determines the funding commitments of the CHSC for the coming year.

15.3 Only the CHSC has the mandate to make changes to the Commissioning Intentions.

16. Strategic planning

16.1 In order to determine funding priorities, the CHSC will operate a programme of strategic planning and pathway redesign across the care pathway (primary, secondary and tertiary care, rehabilitation, and palliative care and community services, including social care).

17. Pathway for agreeing service developments

17.1 *Triaging stage* (not all potential service developments)

17.1.1 Potential new treatments may initially be assessed by a number of individuals most notably the Screening Officers of the Individual Funding Request Process, the Chief Pharmacist, the Medical Director, the Director of Public Health and the Chief Nurse.

17.1.2 These officers are authorised to make a rapid assessment of proposed new treatments to determine if they are either an experimental or unproven treatment (as defined in Section 5 of this Policy) or are deemed not cost effective (as defined in Section 6 of this Policy).

17.1.3 A screening form will be completed for all triaged treatments (see Appendix 9).

17.1.4 For treatments which are declined at this stage, the screening officer should have their decision considered by the appropriate committee (so for example a medicine will be referred to the Drugs and Therapeutic Committee).

17.2 Detailed assessment of service developments involving technologies

17.2.1 Proposals which involve technologies which have passed the triage stage will be further assessed for cost-effectiveness, costs and service delivery issues, regardless of whether they are to be delivered on or off island by the relevant technical committee or when appropriate the Corporate Management Team.

17.2.2 The relevant Committees are as follows:

Intervention	Committee
Medicines and radio isotope treatments	Drugs and Therapeutics Committee
Surgical procedures, medical devices, nursing interventions, radiotherapy and interventional radiology	New and Novel Procedures Committee
Diagnostic and screening programmes for individual patients with genetic disorders	Diagnostic Committee
Public health intervention include	Public Health Committee

population screening	
Vaccines and immunisations	The Vaccines and Immunisation Committee

17.3 Initial prioritisation of service developments

17.3.1 A standard summary of each proposal will be provided by the proposing individual or committee (see Appendix 10).

17.3.2 The proposals will be reviewed by the Corporate Management Team and given the following ratings:

17.3.2.1 The proposal is a low priority and as such will move onto the not routinely funded list, with a defined review date set.

17.3.2.2 The proposal will be registered as a potential service development for consideration.

17.3.3.3 The proposal is a high priority and a detailed business case is required for consideration in the coming annual commissioning round.

17.3.2.4 The proposal is a potential in year service development and a detailed business case is required for consideration.

17.3.3 All service developments which go forward for further business case development or consideration for funding in the annual commissioning process will be logged onto the HSC's register of investments and disinvestments.

17.4 *Assessment of business cases*

17.4.1 Before final prioritisation, a business case will be required.

17.4.2 Business cases will be assessed to consider all aspects of service delivery and to ensure that the specific proposal represents value for

money and is feasible within the timeframe stated.

17.4.3 The relevant Committees to undertake assessment of business cases are:

Intervention	Committee
Clinical service developments	The Clinical Reference Group
Population health interventions	The Public Health Committee
Social care service developments	The Social Care Priority Committee
Capital investments	The Capital Investment Committee

17.4.4 Committee's may seek advice on the business case from others within the organisation or an external review.

17.5 *Annual commissioning round*

17.5.1 The Corporate Management Team will review and rank service developments on a regular basis.

17.5.2 The States of Guernsey scorecard *may* be used to support decision making (see Appendix 11).

17.5.3 In order to do this, the Corporate Management Team may co-opt individuals to help with this task, as required.

17.5.4 Annually the Corporate Management Team will put forward those service developments which will be funded in the coming year. These will form part of the commissioning intentions for the following year.

18. Disinvestments

18.1 Proposals for disinvestment will be managed in the same as for investment:

18.1.1 A summary of the proposal will be put forward to the Corporate

Management Team.

18.1.2 For those considered potential disinvestments, CMT will ask for a more detailed plan of action for disinvestment.

19. Investment and disinvestment register

19.1 CHSC will maintain a register of all potential investments and disinvestments.

19.2 Investments and disinvestments can only be put on the register once initially assessed by the Corporate Management Team.

19.2 The responsible officer for the maintenance of the register will be the Office for HSC Business Manager.

20. In-year service developments

20.1 In-year service developments will be kept to a minimum in line with the policy set out in Section 7 of this document.

20.2 Only the Corporate Management Team can authorise in-year service developments.

21. In-year service developments for one individual

HSC's policy *G1002: Individual funding requests* sets out how funding requests for treatments not normally funded are dealt with when they concern only one individual.

22. Accountability

The Accountable Officer for the IFR process is the Chief Secretary to the CHSC.

23. Compliance monitoring

Compliance monitoring is the responsibility of the Corporate Management Team.

24. Distribution

- Health and Social Care intranet
- Health and Social Care's Off Island Team
- Medical Specialist Group
- General practitioners (through Chair of the Primary Care Committee)
- States of Guernsey website

25. Review

This policy will be reviewed and updated in January 2020.

The responsible officer is the Chief Secretary to CHSC.

26. Policy removal

The policy will be retained until such time as its replacement is ratified or it is assessed and deemed no longer relevant.

27. Effective date

16th November 2017.

Appendix 1: Guidance note on the principles underpinning CHSC's priority setting

Priority setting is the task of determining the priority to be given to particular health or social care needs of a group of individuals with the same or similar condition/need or a particular individual with exceptional need at a given point in time. Priority setting is needed because the need and demands for care are always greater than the resources available.

Prioritisation is decision making which requires the decision maker to choose between competing needs. If prioritisation is to be fair then competing needs have to be considered at the same time, compared and a choice made from amongst them. Prioritisation gives rise to the important concept of *opportunity cost*. Opportunity cost is the loss of benefits forgone when resources are allocated. If, for example, those funding health care can only afford to fund one of the following: a new cancer treatment, a new screening programme, or 6 more palliative care beds, then the opportunity cost of choosing the cancer treatment is the loss of the benefit that would have been delivered by either the screening programme or the palliative care beds.

The opposite of prioritisation is *singular decision making.* In the context of priority setting, this occurs when a decision maker assesses a treatment in isolation from the budget and does not compare that proposal with other competing needs. This generally is considered unethical decision-making by those responsible for the health and social wellbeing of a population because it precludes the opportunity cost being considered. Patients with unmet need which may be greater are not given the chance of their needs being met.

The fact that CHSC's budget has been raised through general taxation means that CHSC has to act as proxy decision maker for Society. This puts the decision maker into the role of citizen.

Each individual participating in resource allocation will bring with them a unique perspective (for example in health care: clinical understanding and experience, patient understanding and experience, public health, finance etc.) but ultimately all must act as proxy for all citizens and as such set aside their personal interests.

The fact that health care is funded through taxation also means that CHSC is bound to live within the resources allocated to it.

All public bodies have a duty to spend money in the wisest way possible. The fact that CHSC has a mandate to look after a wide range of patient and client groups within a restricted budget means that it is necessary to balance the competing needs.

When considering resources, CHSC is answering a different question to that facing clinicians and their patients as indicated below.

Different perspectives when a new treatment becomes available

When faced with a new treatment CHSC is answering the question: *What is the next best investment for the people we serve?*	Clinicians, patients or the public wanting access to a new treatment is answering the question: *Is this treatment something that is good thing for my patient / for me?*
This requires priority setting as the basis for the decision-making. The decision maker is required to give all competing needs a fair hearing and consider all the current potential investments against each other and exercise a judgment.	*This is a singular decision making where only one option for investment is considered at a time. The question does not consider whether or not there might be other patients who could benefit more for the same investment, or a better use of those resources.*

Exercises which have involved clinicians, patients and the public in making choices between competing needs (i.e. engage them in the actual decisions facing those funding healthcare) demonstrate that there is often concordance in the choices made between these groups and those funding healthcare.

Legal requirements

Any public body has to act within its powers and duties. The branch of law dealing with all decisions taken by public bodies is administrative law and challenges to decision making are made through judicial review in which the decision-making of the body is subject to judicial scrutiny. When assessing and reviewing how a particular decision has been taken a judge will consider whether the decision taken was lawful, reasonable, and proportionate and has been taken assiduously and consistently in accordance with the CHSC own policies.

The law therefore shapes how CHSC will make decisions.

Accountability for reasonableness

The principle of '*accountability for reasonableness'* [8] directs public organisations to focus on fairness, transparency and rational decision making and very much overlaps with the legal requirements. It also requires legitimacy, a mechanism for appeal and a commitment that the organisation is willing to change its decisions in the light of new evidence. Legitimacy and transparency are critical to the concept of accountability for reasonableness.

Guiding principles to underpin decision-making

In order to ensure that CHSC does not breach its duties and responsibility legally or ethically when committing its resources, it is necessary to adopt rules which ensure consistent decision making The principles are applied when making decisions about services for both groups of patients and individual patients. .

Of these the requirement to consider opportunity cost is the most important. This means parallel systems that allow individual treatments or individuals to bypass prioritisation should not be allowed. CHSC must not, therefore, allow itself to be unduly influenced by those lobbying for single treatments or issues.

Within health care CHSC considers that if funding for a treatment cannot be justified as an investment for all patients in a particular cohort, the treatment should not be offered to only some from within the patient group **unless it is possible to discriminate on a rational basis between different sub-groups of patients on clinical grounds.** A treatment policy approved by CHSC should therefore not be approved unless CHSC has made funds available to allow all patients within the clinical group identified in the policy to access that treatment. Within social care, individuals with the exact same circumstances should also be given equitable access to care. It is however the case that defining difference objectively is frequently easier within healthcare than within social care.

Since it is not possible to meet all need it is rational to target resources on interventions that have been shown to provide value for money. CHSC will not

[8] N Daniels, Accountability for Reasonableness, British Medical Journal, 2000 Nov 25; 321(7272): 1300–1301.

therefore invest in treatments which are experimental or services whose benefits are uncertain, even when there is good quality evidence available.

The need to demonstrate that a treatment is clinically effective or that a service development represents value for money is only the first stage in assessing priority. These are minimum requirements that can then lead to the service development being subject to more scrutiny and compared with other competing potential investments. Being effective and cost-effective are therefore not the sole criteria on which CHSC will commit resources. This is because being cost-effective does not necessarily mean that a new treatment or service represents the best use of available resources at any given point in time. Being cost effective (with a threshold set at £40,000 costs per quality adjusted life years) also does not mean a treatment or service can be afforded.

CHSC is sometimes asked to take on funding commitments made by another statutory body or other type of organisation and on occasions to carry on the funding of treatment for an individual who has paid for a treatment that would not normally be available. While there might be instances when CHSC may choose to take on these commitments in exceptional individual circumstances it will not do so automatically. CHSC will not assume responsibility for a funding decision in which it has played no part unless there is a legal requirement to do so.

Only CHSC as budget holder can understand the needs and priorities of its population. To delegate funding decisions to outside parties, or allow undue pressure from third parties to dictate its resource would mean that CHSC is now carrying out its mandate properly.

Appendix 2: Guidance note on experimental and unproven treatments

Introduction

There are a number of organisations shaping and funding medical research, each of which has its own goals, interests and perspectives. The potential relationship between the different organisations responsible for planning and funding healthcare and research is complex.

In the UK the NHS has been an active player in research & development since its beginning. Historically, those funding healthcare services have also funded research in specific instances. This position was strongly supported in the Peckham Report (circa 1990) that recommended that NHS organisations (both providers and 'purchasers') should spend about 1-2% of their budget on research and development. In July 2009 a letter from the Department of Health in the UK to health bodies set out the framework for entering more patients into clinical trials. The notion that those funding health care should fund research is therefore not unusual.

In an environment where the demand and need for healthcare is greater than the ability of healthcare systems to provide services, experimental treatments and the evaluation of experimental treatment have to be undertaken judiciously, responsibly and for clearly defined purposes. That activity also has to be prioritised.

Despite the importance that is placed on ensuring that clinical practice and public policy are based on sound evidence, public bodies are under increasing pressure from a number of sources to introduce treatments early and with less evidence. It is important that CHSC does not promote poor practice by agreeing to fund treatments which have inadequate evidence concerning benefits and risks to patients.

Another difficulty is the use and abuse of 'research' and 'evaluation' to avoid prioritisation decisions. CHSC therefore will seek to ensure that new healthcare interventions are not implemented through the guise of a short-term study, but without commitment to cease provision once the study ends. (These clinical trials have been termed 'seeding trials'.) The funding of new treatments under the guise of research can lead to an intervention becoming established without having gone

through the organisation's normal prioritisation processes.

Clinical researcher time is a scarce resource, as are the funds to support trials. As a result it is highly likely that important and desirable trials cannot be carried out because of resource constraints. CHSC will not accept that the failure to prioritise a treatment for study becomes an express or implied justification for CHSC to fund the experimental treatment.

Efficacy and Effectiveness

Those funding healthcare have always differentiated between efficacy and clinical effectiveness.

Effectiveness means the degree to which those objectives that have been identified in advance are achieved. **Clinical effectiveness** is a measure of the extent to which a treatment achieves pre-defined clinical outcomes in a target patient population.

A treatment that is **efficacious** is one that has been shown to have a beneficial effect in a carefully controlled and optimal environment. It is not always possible to have confidence that data from clinical trials will translate in the clinical setting to bringing the anticipated benefits or that any meaningful health gain for the target patient population of interest will be achieved. This is the difference between disease-orientated outcomes and patient orientated outcomes. For example a treatment might have demonstrated a change in some physiological factor that is used as a surrogate measure for increased life expectancy but this relationship might not be borne out in reality.

There are four main reasons why a treatment might be considered efficacious but not clinically effective:

1. The trial is poorly designed so that it cannot answer the question of interest. It is of particular concern to those funding healthcare that there is generally a lack of studies which compare the new treatment with standard current treatment.

2. Use of invalid surrogate outcome measures. A surrogate outcome measure is a measure used as an alternative to the clinical outcome of interest.

3. Adoption of inappropriate short follow-up periods for the study, which makes it impossible to establish whether the long term clinical outcomes claimed are actually realised and whether other effects, that had not been predicted, do occur. This is particularly important in the context of patient safety.

4. It is a known fact that treatments often perform less well in practice than under trial conditions. The reasons for this include: clinical expertise, patient

selection, variable clinical practice, and loss of the Hawthorne effect (a placebo effect specific to trials). While it is not always possible to anticipate the likelihood of a discrepancy between trials and a routine setting such as the NHS in advance, it is sometimes possible to anticipate the circumstances in which this might be a problem.

Licensing processes (including those in drug licensing, the Medicines and Healthcare Products Regulatory Agency approval for medical devices, and the National Institute for Health and Clinical Excellence's interventional procedures programme for invasive procedures) are designed to assess safety and efficacy. They do not address either the effectiveness or cost-effectiveness of the product being licensed.

It is also possible for the benefits of a treatment that were demonstrated in a clinical trial do not show the same benefit when they come into general use. This is because the studies used small samples of highly selected patients or were conducted in particular types of units and the findings cannot be replicated by other clinical teams.

For many treatments only time and experience in the context of long terms studies can establish the optimum use of the treatment.

Experimental treatments

What is an experimental treatment?

Those funding health services seek to provide as comprehensive a health service as possible across all patient groups and across the entire patient pathway, within an obligation to stay within the financial budget allocated to them. Given that demand for healthcare will always exceed the resources available to fund treatment, it is justifiable to give the funding of experimental treatments, a lower priority than the funding of core services and those treatments of proven benefit.

Suggested criteria for considering a treatment as experimental include:

- The treatment is still undergoing clinical trials for the indication in question.
- There are no relevant articles published in the peer-reviewed journals available on the treatment for the indication in question.
- The treatment does not have approval from the relevant government body.

- The treatment does not conform to usual clinical practice in the view of the majority of medical practitioners practising in the relevant field.
- The treatment is being used in a way other than that previously studied or that for which it has been granted approval by the relevant government body.
- The treatment is rarely used, novel, or unknown and there is a lack of authoritative evidence of safety and efficacy.

From the position of those funding healthcare two other criteria can be added:

- The evidence is not yet available for public scrutiny.
- The decision maker does not have confidence in the evidence base that has been presented (which refers to the interpretation of the evidence).

Treatment in this latter group will often be described as unproven because the place of that treatment in the care pathway, its benefits and value for money are poorly understood.

Primary policy position of CHSC on experimental treatments

CHSC will not fund treatments which are still considered experimental outside the context of a properly conducted clinical study; irrespective of the potential health benefit for either individuals or groups of patients.

Possible exceptions to the general rule

On occasions, however, when CHSC may choose to fund an experimental treatment. Before doing so it needs to reassure itself of two things:

- That the decision to agree to an exception to the general rule is made for very clear and explicit reasons which are consistent with the organisation's priority setting principles.

- Whenever possible the funding of experimental treatment is undertaken in a way that will contribute to the knowledge base.

There are a number of regular occurring circumstances in which the funding of an experimental treatment may be considered by CHSC.

Scenario 1: An experimental treatment for rare clinical situations and the commissioner judges that trials will be impossible to carry out

It is common to receive funding requests for individual patients for experimental treatments supported by an argument that trials are impossible. It is recognised that there are circumstances where the potential for trials is restricted because of the nature of the treatment and/or the epidemiology of the disease. It is however easy for those requesting the funding to overstate the case, even for rare disorders. Robust multicentre international trials, whilst a major challenge, are possible. Rarity is therefore not always a sufficient ground for accepting a lack of evidence.

It is important to distinguish between those instances where trials are either impossible or improbable and those where the research community and industry have not prioritised a trial.

Having ruled out those treatments where trials are possible, CHSC is then left to justify a funding request in which there is either:

- no evidence, or;
- anecdotal evidence, or;
- case reports or small case series, or;
- evidence of effectiveness in a similar condition to the clinical circumstance under consideration.

In these circumstances decision-makers have to approach the decision as though it were any other service development (albeit a service development for 1 patient). This is by:

- assessing the evidence of benefit
- judging the potential benefit and risks;
- estimating value for money; and
- prioritising the patient's need against other competing demands.

It is often identified that direct evidence of benefit in such cases is sparse and judgments may rest on the biological plausibility of benefit by seeking a view on the biological mechanism and/or extrapolating information from unrelated cases.

If, after having considered the issue, CHSC is minded to fund and can afford to do

so – then there are three options available:

1. Agree to fund on the condition that the patient enters a properly conducted *'n of 1'* trial (including the adequate blinding of recipients, providers and assessment and having objective and relevant outcome measures).[9] The UK does not currently have such a trial unit and so this option is not currently a realistic option in most instances.

2. Fund the treatment for a period of time and make any on-going treatment subject to identifying demonstrable benefit for an individual patient using locally agreed criteria. Under these circumstances there should be agreement about the timescales of the trial and the measurable outcomes against which to determine on-going treatment. Such an approach is often **erroneously** referred to as an n of 1 trial. It is more appropriately called a **trial of treatment**. This is only an option where there is a course of treatment or long-term treatment. It is not suitable, for example, for a surgical intervention.

3. Fund with no additional conditions. A report providing an update on the patient's progress should be requested from the clinician.

In all instances where a clinical database or a population registry operates, data should be submitted to this database or registry as a condition of the funding.

Scenario 2: Experimental treatments that are currently being studied but require CHSC to sponsor the treatment costs for one or more individual patients to enter into a trial or to continue funding the patient's treatment after the trial ends.

Most research is Industry-sponsored and so this situation does not commonly arise. However, those funding healthcare in the UK do regularly fund excess service costs of non-Industry trials such as those conducted by the Medical Research Council. This funding arises out of the Concordat that exists between the UK Department of Health and research bodies. It is a memorandum of understanding and as such it is guidance rather than a direction to the NHS to

[9] N of 1 trials are a particular trial design in which the subject acts as their own control. They are therefore best used for drugs for chronic disorders. These trials are conducted in the same way as other studies; to strict trial protocol, double blind etc. Few of these trials have been carried out in the UK to date and currently there is no infrastructure to support running this type of trial.

support such research. In reality UK commissioners are rarely aware of the fact that they are supporting a trial because additional hospital activity related to the trial is logged under routine contract activity such as a diagnostic or chemotherapy episode. There are some areas of clinical practice – most notably in the treatment of haematological and childhood cancers – where routine treatment is commonly delivered within the context of trials.

Trials which come under the auspice of this arrangement are listed on the National Institute for Health Research Clinical Trials Register (http://public.ukcrn.org.uk/search/Portfolio.aspx).

It is important to establish what the status of a trial is, who has sponsored it and which bodies contribute to funding the trial.

The Concordat does not apply in the Bailiwick of Guernsey. However it is likely that there will be requests to support the treatment costs for a patient to enter into a clinical trial. It is expected that CHSC will be asked to explicitly fund trials in two ways:

1. By funding a number of patients or a qualifying patient to enter the trial. In these instances, the request should be treated as a service development. If it is a very large trial with considerable budgetary consequence it is more appropriate that prioritisation should be undertaken through the annual commissioning process. If the trial is strategically important it may be that the funding of clinical trials is considered as an in-year service development (see Section 7).

2. By a request to support a single patient to enter a trial. This request should be managed under CHSCs individual funding request policy (see Section 14)

In both these instances the following should be considered:

1. The potential strategic importance of the treatment. This is essentially a judgment as to whether the trial will address the key goals and priorities of the programme area. The collective experience of commissioners suggests that opportunities of this kind are rare, as most funding requests for experimental treatments are for second, third and fourth line treatments for the seriously ill, as a last resort. Equally uncommon are requests to fund patients in trials that address specific questions for an existing and established

treatment.

2. The quality of the trial and whether or not it is going to generate the sort of information needed to come to a view on the treatment.

3. Ownership of the data. Public funds should not be used to support trials where there is no guarantee that the results will be put into the public domain and the data subject to external scrutiny.

4. Whether the trial can be afforded and whether it should be prioritised over competing needs.

Scenario 3: Potentially important treatments which can only be progressed through public funding.

Very rarely, those funding healthcare services may consider an experimental treatment so important that they wish to see a publicly funded trial established. Given the lack of research & development and Industry support for certain types of trials (such as surgical procedures) it may be necessary for commissioners to initiate and fund the whole trial themselves. This will become more important if health systems are to gain information about treatments other than medicines. It is unlikely that such trials will be initiated and solely conducted in Guernsey. NHS England has established a 'Commissioning through Evaluation Programme' which aims to address some of these issues although it is early days for this programme. [10]

Unproven treatments

It is not uncommon to have a situation where a treatment is supported by reasonably good trials but important questions still remain about the treatment. In these instances the requirement for on-going evaluation is legitimate.

A definition of unproven treatment which has been commonly used in the United States is: [11]

[10] https://www.england.nhs.uk/commissioning/spec-services/npc-crg/comm-eval/

[11] United Health Care: Experimental Investigational and Unproven Services, Guideline number: CDG-A-010, 2012.

2007- 2011 Generic Certificate of Coverage Definition: - services, including medications, that are determined not to be effective for treatment of the medical condition and/or not to have a beneficial effect on health outcomes due to insufficient and inadequate clinical evidence from well-conducted randomized controlled trials or cohort studies in the prevailing published peer-reviewed medical literature.

- *Well-conducted randomized controlled trials. (Two or more treatments are compared to each other, and the patient is not allowed to choose which treatment is received.)*

- *Well-conducted cohort studies. (Patients who receive study treatment are compared to a group of patients who receive standard therapy. The comparison group must be nearly identical to the study treatment group.)*

Unfortunately, treatments, associated with high risks (for example high budgetary impact, potential for use beyond the available evidence, uncertainties about risks and true benefits that might be achieved) are all too often released into clinical practice without a robust plan for the review of the treatment some years ahead.

Non-drug interventions often have a sparse evidence base and present a particular challenge to commissioners.

Issues that might result in CHSC taking a view that a treatment should only be made available if there is on-going evaluation include but are not limited to:

- Where there are concerns about the true nature of the benefit and/or risks.

- Where a treatment's true place in the management of that condition has yet to be established.

- Where there is potential for significant variation in clinical practice (which might otherwise be difficult to control).

- Where it is not known how best to deliver the treatment (e.g. dose, frequency, sequencing, concurrent treatment, duration of treatment).

- Where there is a good chance that real-life effects and/or costs may differ

from those seen in clinical trials because of difference in context, patient mix, treatment delivery, service provision and similar factors.

CHSC must, therefore, be able to apply conditions when funding treatments in this category.

Existing treatments

Because most healthcare systems do not have adequately built in the evaluation of treatments as they are introduced there are a number of treatments which are in current practice and routinely funded but whose benefits, and sometimes risks, are not sufficiently understood and quantified. This is also true for treatments whose use has expanded without any underpinning evidence.

There are times, therefore, when those funding healthcare services may wish to review an existing treatment with a view to no longer funding that treatment.

Using research to address value for money and affordability issues

There are treatments that present a different set of problems. These are:

- Effective treatments which provide significant health benefits and which fall above the accepted cost-effectiveness threshold. [12]

- Effective treatments which fall below the threshold but whose budgetary impact is considered too high to be affordable (i.e. the opportunity costs are too great).

The question, in both the above instances, is how does CHSC approach potentially useful treatments that are not cost-effective or not affordable although they are clinically-effective?

[12] Note there are three categories of treatments which fall above the threshold: those that are not cost-effective because they are poor treatments (such treatments need no further attention and should not be funded), those that are not-cost effective because of pricing but which provide valued health benefits in the opinion of the commissioner and whose costs might be brought down to acceptable levels, and finally treatments which provide valued health benefits but which will always stay above the threshold (biological ultra-orphans being a case in point). Each has its own decision path and it is the second group which is referred to here.

Price negotiation is one option but is unlikely given the purchasing power of the States.

Another option is to explore ways of obtaining a similar outcome at much lower cost. This is particularly pertinent to the new biological drugs that are often licensed at a dose higher than that which is needed to deliver a clinical effect. In this context research to explore more cost effective solutions for patients has a legitimate role.

These instances illustrate circumstances where those funding health care could fund research directly. A public body could justify the funding of such research, as the return on the investment will accrue to society generally rather than the licence or patent holders of the technology under investigation.

The greatest challenge for commissioners in funding certain types of clinical trials is to secure the mandate for undertaking them. Until there is wider support for public value research, options will always be limited and controversial.

The process for developing new treatments

For medicines there is an internationally recognised basis for generating systematic evidence for medicines and licensing organisations have, until recently, required medicines to go through this process. This practice is changing with licenses being given subject to further evaluation. In addition, there are many instances where medicines are being used for indications other than their licensed use, not based on any notable body of evidence.

For treatments that are not medicines the position is even more problematic. Frameworks similar to those developed for medicines are now available for surgical procedures and medical devices. These frameworks will guide CHSC in its classification of treatments as experimental, unproven or with an adequate evidence base to determine a policy position on a treatment.

Drugs [13]

The process for generating evidence for drugs has long been established and is as

[13] Modified from: http://www.cancerresearchuk.org/cancer-help/trials/types-of-trials/phase-1-2-3-and-4-trials

follows:

Phase 0 trials (Equivalent of proof of concept studies)

Phase 0 trials are usually the earliest trials of drugs in people. These studies aim to find out if a drug behaves in the way researchers expect it to from their laboratory studies. Phase 0 studies usually only involve a small number of people and they only have a very small dose of a drug to ascertain how the drug works in the human body. The main aim of these studies is to speed up the development of promising new drugs.

Phase 1 trials (In part proof of concept studies / in part safety)

They are usually small trials, recruiting only a few patients, in order to assess:

- The safe dose range
- What the side effects are
- How the body copes with the drug
- If the treatment appears to have a positive effect

Phase 2 trials

Phase 2 trials aim to assess:

- If the new treatment works well enough to test in a larger phase 3 trial
- Which types of cancer the treatment works for
- More about side effects and how to manage them
- More about the best dose to use

Phase 2 trials are often larger than phase 1. There may be up to 100 patients taking part. Sometimes in a phase 2 trial a new treatment is compared with another treatment already in use, or with a dummy drug (placebo). If the results of phase 2 trials show that a new treatment may be as good as existing treatment, or better, it then moves into phase 3.

Phase 3 trials

These trials compare new treatments with the best currently available treatment (the standard treatment). These trials may compare:

- A completely new treatment with the standard treatment

- Different doses or ways of giving a standard treatment
- A new way of giving radiotherapy with the standard way

Phase 3 trials should involve enough people to have sufficient power to identify real differences in risks and benefits.

Phase 4 trials

Phase 4 trials are done after a drug has been shown to work and has been granted a license. The main reasons for running phase 4 trials are to assess:

- Long term side effects and the safety of the drug
- Long term benefits
- Monitoring the benefit when using the drug in normal practice rather than under trial situations (as patients often do better when in a trial, even if they receive standard treatment or a placebo)

Surgical treatments and medical devices

The IDEAL framework is the equivalent framework for incrementally developing the level of evidence required to assess the risks and benefits of surgical procedures. [14]

Treatments that are at stage 2a, 2b and 3 of development will not be routinely commissioned outside of the context of robust on-going evaluation. Most of the clinical evaluation at stage 2a and 2b will not be in the form of a randomised controlled trial, but all the same, the process of evaluation should meet robust epidemiological methods, with a written protocol and clarity over reporting mechanisms. Patients should also be consented in the same way as for any other experimental or unproven treatment.

The pathway for the generation of systematic evidence is different for medical devices although the stages are similar. [15]

[14] P McCulloch et al , No surgical innovation without evaluation: the IDEAL recommendations, Lancet, 2009, 374:1089-96

[15] IDEAL-D: a rational framework for evaluating and regulating the use of medical devices BMJ 2016; 353 :i2372

IDEAL - Surgery

	1 Idea	2a Development	2b Exploration	3 Assessment	4 Long-term study
Purpose	**Proof of concept**	**Development**	**Learning**	**Assessment**	**Surveillance**
Numbers and types of patients	Single digit, highly selective	Few, selected	Many, may expand to mixed, broadening indication	Many, expanded indications (well defined)	All eligible
Numbers and types of surgeon	Very few, innovators	Few, innovators and some early adopters	Many, innovators, early adaptors and early majority	Many, early majority	All eligible
Output	Description	Description	Measurement, comparison	Comparison, complete information for non-RCT participants	Descriptions, audit regional variation, quality assurance, risk adjustment
Intervention	Evolving, procedure inception	Evolving, procedure development	Evolving procedure refinement, community learning	Stable	Stable
Method	Structured case reports	Prospective development studies	Research database, explanatory or feasibility RCT, disease based (diagnostic)	RCT with or without additions, modifications; alternative designs	Registry, routine database, rare case reports.
Outcomes	Proof of concept, technical achievement, disasters, dramatic successes	Mainly safety; technical and procedural success	Safety, clinical outcomes (specific and graded), short term outcomes, patient centred outcomes, feasibility outcomes	Clinical outcomes (specific and graded), middle-term and long-term outcomes, cost-effectiveness	Rare events, long-term outcomes, quality assurance
Ethical approval	Sometimes	Yes	Yes	Yes	No

Appendix 3: Guidance note concerning guidance from the National Institute for Health and Care Excellence and CHSC's approach to cost-effectiveness

The National Institute for Health and Care Excellence (NICE) guidance

The Institute of Health and Care Excellence produces the following types of guidance documents:

- Cancer service guidance
  http://guidance.nice.org.uk/CSG/Published
- Clinical guidelines
  http://guidance.nice.org.uk/CG/Published
- Diagnostic guidance
  http://guidance.nice.org.uk/DT/Published
- Highly specialised technologies guidance
  https://www.nice.org.uk/guidance/published?type=hst
- Interventional procedures guidance
  http://guidance.nice.org.uk/IP/Published
- Medical technologies guidance
  http://guidance.nice.org.uk/MT/Published
- Medicines practice guidelines
  https://www.nice.org.uk/guidance/published?type=mpg
- Public health guidance
  http://guidance.nice.org.uk/PHG/Published
- Technology appraisals guidance
  http://guidance.nice.org.uk/TA/Published
- Quality standards
  http://guidance.nice.org.uk/qualitystandards/qualitystandards.jsp
- Safe staffing guidance
  https://www.nice.org.uk/guidance/published?type=sg
- Social care guidance
  https://www.nice.org.uk/guidance/published?type=sc

All have the status of guidance in Guernsey.

In the UK all but technology appraisals are guidance. The NHS, by law, has to implement technology appraisals within 3 months of them being issued by NICE.

Automatic adoption of NICE technology appraisals by CHSC presents some ethical problems:

- CHSC has sole responsibility for funding aspects of health and social care and operates in a completely different jurisdiction to NICE. To take a position of automatically adopting NICE guidance would result in delegating decision making over its budget to an organisation which operates in a different country and which is unable to take into account local needs.

- Different commissioners have different financial circumstances, populations and historical patterns of services. Compared to the UK, for example, Guernsey has additional costs to maintain necessary local health services and high transport costs associated with patients travelling for specialist care.

- NICE's technology appraisal programme only covers a minority of healthcare interventions and has a bias towards drugs. Many of the treatments recommended under this programme are less cost-effective than other interventions recommended under its other programmes. So it is the case that the NHS has to invest in a treatment which is judged to have a cost-effectiveness in the region of £40,000 per Quality-Adjusted Life Years but interventions which are judged to have a cost-effectiveness below £10,000 per QALY and therefore are a much better investment, are not funded.

- NICE technology appraisals do not and cannot indicate to the NHS what the *next best* investment for any given population because NICE is not a budget holder and has no knowledge of actual opportunity costs.

- Many of the other NICE guidance reports set out standards of care or patient pathways which frequently represent an ideal service. This guidance does not take into account funding and therefore whether full implementation is affordable or not. Generally, within any piece of guidance, a core element can be provided, below which a service would be considered substandard or unacceptable. Above this, all other elements are development or aspirational.

Commentary on measures of cost-effectiveness

When comparing the needs of different patients and patient groups a number of factors are taken into account. The main factors used by CHSC are set out in this

document. One of those factors is a treatment's cost effectiveness and how this compares with other competing treatments.

Efficacy and clinical effectiveness have already been defined in Appendix 2
Cost effectiveness is a particular term used in healthcare but it essentially means value for money in which the benefit derived is determined for every sum spent. In healthcare terms, the benefit is the *clinical effectiveness*.

Cost Effectiveness Analysis assesses the cost effectiveness. It is not the only method of doing so. Cost effectiveness analysis particularly aims to compare very different types of healthcare interventions using a ratio of an intervention cost versus its clinical effectiveness.

Cost-utility analysis, which is the type of health economic analysis carried out by NICE, was designed to compare very different healthcare interventions. It was originally designed to help the decision maker prioritise treatments and services by providing some measure of value for money. It was never designed to become the basis on which a treatment is funded or not. Politically, however, it becomes useful for many Governments to move priority setting into a 'technical' arena and away from the political arena.

There are many reasons why it is problematic to use cost-effectiveness as the sole consideration when making a funding decision. First, health technology assessment requires many subjective judgements and assumptions to be made; it is therefore not as objective as it may sometimes be portrayed.

Second, the methodology is designed to place equal value on 365 individuals getting one day of extra life to one patient gaining an extra year of life. Commissioners of health care and the public would not place the same value on these different health benefits. This is increasingly being recognised as a problem amongst those undertaking health technology assessments.

Another difficulty is the cost-effectiveness threshold. Health economic theory requires that the threshold be set at the 'affordable level' at which a healthcare economy can afford everything that falls below this threshold. This means that if a treatment has a threshold below this limit there is low risk of it displacing something of higher value. Clearly the threshold will vary according to the level of funding available, the level of need and the number of healthcare interventions available. So in England, for example, a commissioner that receives 15% more

funding than allocated will have a higher threshold than one of the commissioners that is well below its target. The threshold will also vary with changes in the economic fortune of a country. However NICE has not, to date, varied the threshold in this way. Precise calculation of this threshold is not possible but it is estimated to be in the order of £18,000. [16]

NICE frequently recommends treatments that fall above this level, which means that these treatments displace treatments and services that provide more health gain or represents better value healthcare.

Given all the problems it is unwise to the cost-effectiveness of an intervention as the sole basis for agreeing to fund it.

Increasingly there is recognition with those undertaking HTA that the factors to be taken into account when priority setting are much wider than just the cost-effectiveness of a treatment.

Another estimate of value for money often used is much quicker to calculate though not without its problems either. This is the investment needed for one patient to gain the benefit. For example the clinical trials indicated that, cancer drug A prevents death from the cancer and that the 'Number Needed to Treat' is 50. This means that 50 patients will be treated for one patient's to not die from this cancer. The other 49 will not benefit (either they will survive as they would have done without treatment or they will die as they would have done without treatment). If a course of treatment costs £40,000 then the healthcare system is investing £2 million to prevent one death from the cancer. Because this measure does not drive but informs decision-making no threshold or absolute value has been considered.

End of life premiums

In 2009, the National Institute of Health and Care Excellence issued *Supplementary Advice to its Technology Appraisal Committees* which set out the circumstances in which one of its Technology Appraisal Committees can

[16] K Claxton et al, Methods for the Estimation of the NICE Cost Effectiveness Threshold, SCHARR, 2013, http://www.york.ac.uk/media/che/documents/papers/researchpapers/CHERP81_Methods_estimation_NICE_costeffectiveness_threshold.pdf (last accessed 23.09.13)

recommend a treatment even though it is not cost-effective (as considered in the NHS in England) in relation to end of life care.

The criteria that NICE has set out to its committees are as follows:

- The treatment is indicated for patients with a short life expectancy, normally less than 24 months and;
- There is sufficient evidence to indicate that the treatment offers an extension to life, normally of at least an additional 3 months, compared to current NHS treatment, and;
- The treatment is licensed or otherwise indicated, for small patient populations.
- When the conditions described [above] are met, the Appraisal Committee will consider:
- The impact of giving greater weight to Quality of Life Adjusted Years achieved in the later stages of terminal diseases, using the assumption that the extended survival period is experienced at the full quality of life anticipated for a healthy individual of the same age, and;
- The magnitude of the additional weight that would need to be assigned to the Quality of Life Adjusted Years benefits in this patient group for the cost-effectiveness of the technology to fall within the current threshold range.

The Supplementary Advice has the effect that NICE can recommend treatments above the £40,000 threshold for treatments which have small health outcomes or are very expensive for terminally ill patients. Often these treatments are used after a number of other treatments have been given.

The effect of this policy is that NICE has given preferential treatment to those interventions which provide palliation at the end of life, the result of which is that other treatments which offer more health benefit are displaced.

Orphan treatments

The European Union (EU) legislation defines an orphan drug as one that could treat a disease with a prevalence of less than five per 10,000 of the population.

A drug can be designated as an Orphan Drug by the European Medicines Evaluation Authority (EMEA) and in due course may be given marketing authorisation by the EMEA. This will give the Pharmaceutical Company additional benefits such as a longer patent, and market exclusivity (namely another drug company cannot produce a similar drug).

The EMEA does not differentiate between orphan and ultra-orphan drug status. Ultra-orphan drugs are treatments for very rare disorders, and frequently cost more than £100,000 per patient for a year of treatment.

Most care that is provided to patients with rare disorders is similar to that provided to other patient groups and at the same or similar cost. This includes treatment and drug costs.

Not all orphan drugs are expensive.

Not all orphan drugs are designed to treat rare conditions. Many are first licensed to treat a subgroup of patients who have a relatively common disorder.

The challenges of dealing with orphan and ultra-orphan drugs in priority setting are similar. The critical questions are:

- Should a premium be applied to rarity? (i.e., should Society be willing to pay more for treatments for patients with rare conditions?)
- Should that premium apply regardless of the nature of the health gain?
- And if so, what is the limit? (For instance one of the most expensive treatments in 2017 is £345,000 per patient per year)
- And at what point is the opportunity cost too much to bear? (e.g. should a service be cut to pay for a treatment?)

This is a controversial area of pricing and policy-making. To date it has been difficult to come up with a fair and sustainable set of principles to deal with this issue.

The States of Guernsey has limited funds available to meet the healthcare needs of the residents for which it is responsible. It cannot therefore meet all needs and demands of the population it serves.

CHSC has carefully considered the ethical issues around the funding of high cost drugs and other treatments for small numbers of patients but is satisfied that it would not be right to depart from its established principles and procedures for the assessment and prioritisation of treatments for treatments specifically used to treat patients with rare disorders.

The English Cancer Drugs Fund

The Cancer Drugs Fund is an initiative of the UK Government that has the aim of increasing access to cancer drugs. In particular it is designed to provide treatments in instances where a treatment has either not yet been assessed by NICE or has been rejected by NICE and other bodies. It only operates in England. In 2016 the Fund was reviewed and some changes have been made to it, and some further changes might be expected. [17]

In the UK there is no equivalent fund for patients with other conditions or a fund covering treatments for cancer which are not medicines.

The role of the CDR has changed and from 2016 will fund:

1. Cancer drugs which have been given interim positive recommendation by NICE under its rapid assessment programme for cancer drugs (namely this is a means to use the fund to create early access to patients before the drug is given a licence and NICE final appraisal recommendation has been delivered after which the drug will be funded out of the normal NHS budget).

2. Drugs which NICE considers there to be plausible potential for the drug/indication to satisfy the criteria for routine commissioning, but where there is significant remaining clinical uncertainty (namely it a means of commissioning through evaluation).

Patients in Guernsey do not have access to the English Cancer Drugs Fund.

A cancer drug which has been granted a license and which clinicians treating

[17] Appraisal and Funding of Cancer Drugs from July 2016 (including the new Cancer Drugs Fund) - A new deal for patients, taxpayers and industry
https://www.england.nhs.uk/wp-content/uploads/2013/04/cdf-sop.pdf

Guernsey patients want access to will be assessed, in the usual way, to CHSC's Drugs and Therapeutics Committee. This Committee is not authorised to give any additional weight to treatments by virtue of them having been funded by the English Cancer Drugs Fund.

Commentary on NICE's Interventional Procedures Programme

This type of guidance is particularly open to being misunderstood.

The Interventional Procedures Programme (IP) aims to assess the safety of a particular type of procedure to define the governance framework within which clinicians should use the procedure. The remit of the programme, as defined by NICE, is:

"The IP Programme assesses the efficacy and safety of interventional procedures, with the aim of protecting patients and helping clinicians, healthcare organisations and the NHS to introduce procedures appropriately. By reviewing evidence, consulting widely, facilitating data collection and analysis, and providing guidance on the efficacy and safety of interventions, the Programme enables clinical innovation to be conducted responsibly. No interventional procedure is entirely free from risk; the Programme gauges the extent of risks and benefits and makes recommendations in terms of their implications.

To fall within the remit of the IP Programme, a notified interventional procedure must:

- involve an incision or a puncture or entry into a body cavity, or the use of ionising, electromagnetic or acoustic energy, and
- be available within the NHS or be about to be used for the first time in the NHS, outside formal research, and
- be either not yet generally considered standard clinical practice, or a standard clinical procedure, the safety or efficacy of which has been called into question by new information."

The programme's main focus is safety. It considers efficacy but not cost-effectiveness. The recommendations are largely focused on how a treatment should be delivered within the NHS. There are 4 categories of recommendation as to use of the procedure:

Standard arrangements: NICE has concluded that the evidence for the efficacy and safety of the procedure is deemed adequate and has recommended that clinicians should observe normal arrangements for governance, consent and audit.

Special arrangements: NICE has concluded that the procedure needs further evaluation and/or is an emerging technology. Clinicians wishing to use such a procedure are advised to inform their clinical governance lead, make special arrangements for consent and make special arrangements to audit and review their results.

Procedures which are recommended only to be carried out in the context of formal research studies approved by a research ethics committee: These are procedures that are still considered experimental.

Procedures which should not be used in the NHS: NICE has concluded that the evidence suggests that the procedure has no efficacy and/or poses unacceptable safety risks.

The classification of procedures into categories 1 and 2 above is not to be interpreted as a recommendation for a procedure being made available and funded by the NHS. Many of the procedures falling into these two categories would still be considered to be of unproven clinical effectiveness and/or unproven cost-effectiveness by many funding bodies.

Where NICE has deemed standard arrangements apply commissioners should assess the recommended treatment as it would any potential service development.

Where NICE has deemed special arrangements apply (i.e. treatments are still considered experimental or whose safety is not certain) CHSC will consider the treatment as experimental or unproven.

Where consideration is given to a treatment whose safety is still of concern then funding should only be considered in the context of on-going national surveillance programmes.

Where NICE has deemed that the treatment should only be made available in the context of a clinical trial (research only) then funding the treatment should not be

considered. If the treatment is of strategic importance an option would be to support a clinical study.

Where NICE has taken a view that the treatment should not be used, funding should not be sanctioned save in the most exceptional circumstances.

Appendix 4: Guidance note on service developments and similar patients particularly in relation to individual funding requests

With the exception of public health emergencies or service loss emergencies any aspect of health care that CHSC has not historically agreed to fund and which will require an additional and predictable commitment of recurrent funding is a potential Service Development.

Any potential service development will have to demonstrate that it is clinically effective and cost-effective before being forwarded for prioritisation against competing service developments. Experimental and unproven treatments, by definition therefore cannot be considered potential service developments unless it is to fund a clinical trial.

The term service development encompasses anything which has the potential to commit CHSC to new expenditure including:

- New services
- New treatments including medicines, surgical procedures and medical devices
- New diagnostic tests and investigations
- Quality improvements
- Requests to alter an existing policy (called a policy variation). This change could involve adding in an indication for treatment, expanding access to a different patient sub-group or lowering the threshold for treatment.
- Pump priming to establish new models of care
- Requests to fund a number of patients to enter a clinical trial.
- Commissioning a clinical trial.

A common error is made by clinicians who make an Individual Funding Request for a patient who is the first of a group of patients they wish to treat with a particular treatment or who they may wish to access a particular service. The patient is therefore one of a number of similar patients. Accordingly, the individual funding request is usually an inappropriate route to seek funding for such treatments. These funding requests will therefore usually be returned to the requesting Clinician, with a request that they follow the normal processes to submit a bid for a service development.

Commissioning for small populations

Although the term 'similar patients' is a useful concept, problems arise in the use of the term when those funding health care for small populations. This is because many diseases and conditions will be relatively uncommon or rare in the local population served. The fact that it might be rare for an individual to have a disease in a small population cannot determine how that treatment is approached.

As a result categorising treatments into treatments that are experimental or which need to be considered through the service development route is determined by the evidence and not the number of patients that have the relevant condition in the population served.

Identifying service developments within the individual funding request process

The Individual Funding Request process for CHSC is designed to deal with two common situations.

The first is are requests for funding a treatment which is not normally commissioned on the grounds they are exceptional and that they are likely to respond or benefit from treatment more than those patients who are being denied access to the treatment in question.

The second are requests to consider funding an experimental treatment outside a clinical trial for an individual patient on the basis that it is not possible to establish the benefit of treatment through the usual mechanisms because of the rarity of the condition or clinical presentation.

In both these circumstances it is common to have to make an assessment in the absence of normal levels of evidence.

In the second group it is important to consider the clinical circumstances that make studying a treatment impossible or difficult using normal epidemiological methods.

The argument that a treatment cannot be subject to a proper clinical trial on the basis of the rarity of the target patient group is often overstated. A rare disorder (called an orphan disease) is defined by the European Union in its orphan drug

legislation as having prevalence of fewer than 5 in 10,000 people.

In the UK an ultra-orphan disease (even rarer still) is considered to have a prevalence of fewer than 1 in 60,000 people. For example Gaucher's disease is an ultra-orphan disease with a prevalence of 1 in 100,000 although in one ethnic community the prevalence increases to 1 in 450. There are therefore thousands of patients with the disease. The World Registry for this condition has 4,000 patients listed. In this instance at least, new treatments targeted at the condition, can still be studied through robust and formal evaluation. This will not necessarily be the case for all very rare diseases, or subgroups of patients with rare conditions where they may only be a matter of a few hundred patients Worldwide.

Rarity is of itself not sufficient grounds for exceptionality.

If one or more well designed trials have been completed for a treatment then the clinical effectiveness of the treatment can generally be assessed regarding its clinical effectiveness On this basis the decision to fund the treatment must be taken through the service development route.

Appendix 5: Low priority health care

CHSC is embarking on a programme of developing more explicit statements concerning what services and treatments will be funded and which will not. This will take time.

The factors taken into consideration when deciding between competing needs are set out in in the main body of this policy (See Section 4).

The term low value when applied to treatments or care in the context of resource allocation has very specific meaning. The perspective come from the value provided to the whole Society when considering not all care can be provided.

1. The treatment might not have good enough evidence based for CHSC to know whether or not the treatment works as well as it is claimed.

Historically clinical practice was developed based on clinicians' personal experiences. This has been shown to be a relatively unreliable assessment of both the risks and benefits of a treatment. Over the years healthcare professionals, academics, ethicists, healthcare funders and patient interest groups have demanded better evidence on which to base the decision to treat a patient and to justify the use of public resources.

If the evidence is not adequate to have any confidence about a treatment's benefit then the treatment is considered to be experimental or unproven. Decision-making around this group of treatments is set out in Section 5.

Treatments that have been shown to be cost-effective for one condition may be used in other clinical situations that are not supported by sufficient evidence. This is referred to as *clinical creep* as practice extends beyond the evidence base.

CHSC will only support treatments where there is a sound evidence base.

There is always the possibility of funding an experimental treatment when it is provided in the context of a clinical trial. However, it is likely that CHSC will not have the necessary resources available to fund all the clinical trials it would wish to support.

2. The treatment has been shown not to work

Clearly if the evidence has shown that a treatment does not work, it should not be funded. This would be a waste of money.

Generally, CHSC will not produce a healthcare policy for this group because in most cases it is accepted by the wider health service community when treatments do not work. However, there will be times when a policy is considered necessary.

The National Institute for Health and Care Excellence has a growing list of 'do not do' statements taken from their published clinical guidelines. These can be found at: http://www.nice.org.uk/usingguidance/donotdorecommendations/index.jsp

In reality however very few treatments do not work at all. Most provide some benefit to some patients although this is not of itself sufficient to fund a treatment.

3. There is evidence of significant harm to the treatment

All treatments carry risks. There are some treatments for which the risks of treatment outweigh their benefits, and so it is decided that the treatment should not be provided.

Such treatments sometimes have their regulatory support withdrawn. In others the situation is more complex, in that the balance between risk and benefit varies in different patient groups. In some where the benefit is small the risk high then the treatment offers little value.

Sometimes it takes time for the risks to become apparent.

4. The treatment only works for some groups

Often treatments work best for subgroups and a common challenge of both clinicians and those funding health care is to determine which groups should be targeted for treatment. Even when this is known the treatment is not always targeted properly. This gives rise to unwarranted variation.

Unwarranted variation [18] in health care service delivery refers to differences that

[18] J Wennberg and P Thomson Time to tackle unwarranted variations in practice, BMJ 2011,

cannot be explained by the local population's burden of disease or the dictates of evidence-based medicine. (See the NHS Atlas of Variation series[19])

5. The treatment is not cost-effective

The treatment provided is not value for money because the cost of delivery of the health gain is too high.

The investment priority of the treatment or service

All low value health care interventions are considered low priority in terms of investment decisions in that they are unlikely to ever be funded by a public body.

However not all service developments considered low priority are necessarily low value treatment. Some services and health care are considered low priority because of the relative priority to other service.

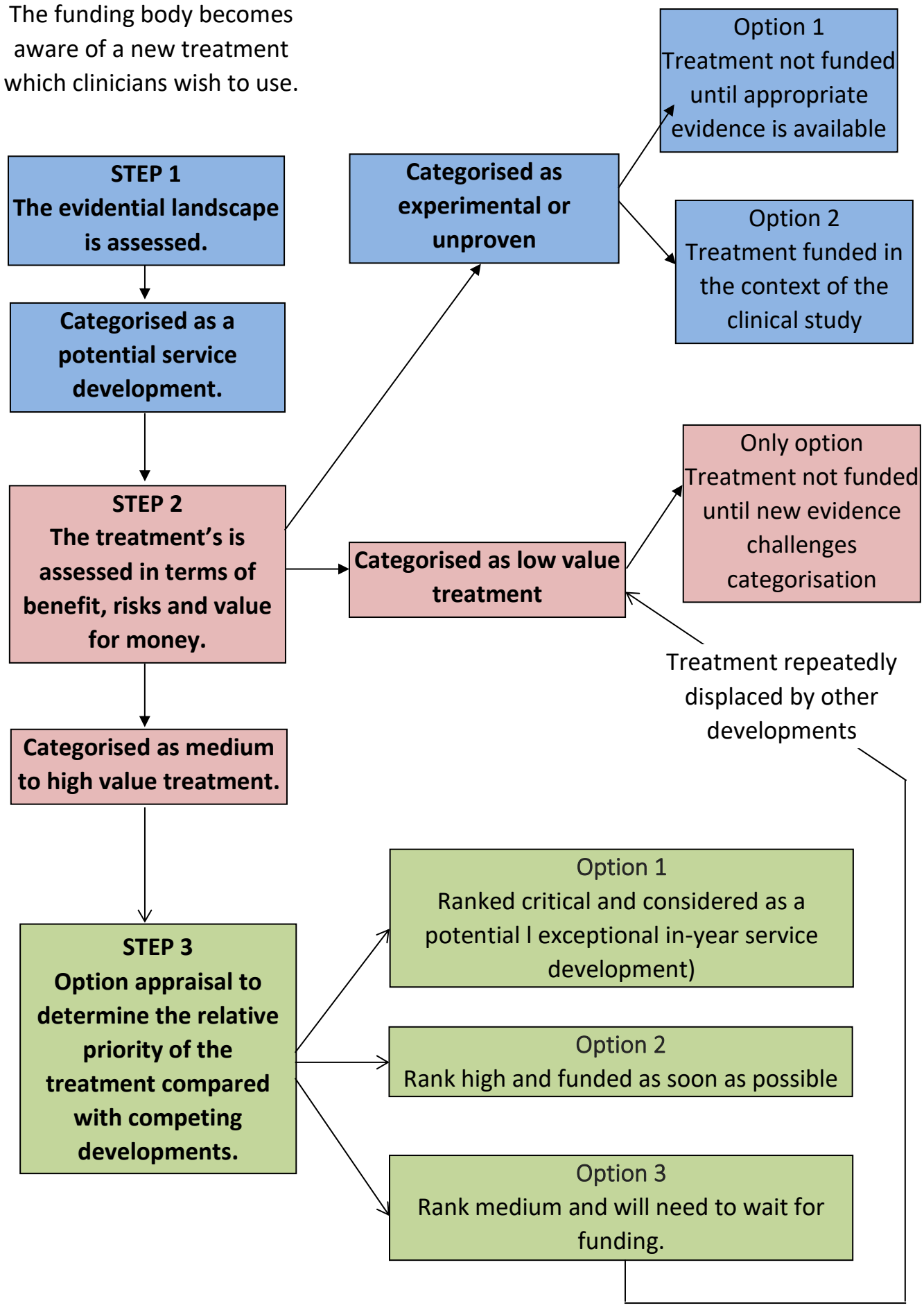
The following diagram provides a simple overview of some of the key steps in priority setting.

Step 3 aims to rank all potential new investments in order of priority. In some instances it might be possible, when comparing service developments against each other, whether or not a service development is likely to be ranked low priority. At other times, it may be the case that a service development constantly fails to reach sufficient priority (within the funding available) to be funded and so there comes a point in time when it is taken of the list of potential services for development. It may then get classified as a low priority service. It is important to understand that these ranking are priorities relative to competing calls on funding, and that the percentage of treatments or services which might be considered low priority will depend on the funding available.

342,d1513

[19] https://www.england.nhs.uk/rightcare/intel/cfv/atlas/

Diagram 1: Essential steps in priority setting



In addition to making investment decisions about new treatments, it is necessary for funding bodies to also consider whether it should cease to provide existing treatments or services. This sometimes will be necessary either in order for organisations to stay within budget, or find resources or to release funding so that it is possible to invest in treatments or services which are judged to be higher priority. Needless to say, CHSC will aim to keep disinvestment to a minimum and will seek to release funding resources through improved efficiency in services it directly provides, or price negotiation for services and goods it contracts for or buys. The reality is that releasing resources through disinvestment will be essential going forward. Again, this is no different to other healthcare systems.

Unfunded service developments

Treatments and services that are considered medium and high priority make them candidates for funding. It is still necessary for these to be prioritised to the point where funding is secured. Treatments needing additional funding to be provided will have to wait some time before they can be funded. These are generally referred to as unfunded service developments. These are developments that CHSC would like to provide but cannot afford. These service developments remain on the list for consideration.

As already indicated sometimes a new treatment remains unfunded for so long that it is clear that it is unlikely to compete with other service developments. It will then be moved into the low priority category and may be assigned an earlier review date.

Appendix 6: Guidance note on the interface between privately and publicly funded health care

Definitions

Normally funded health care is care which is funded by CHSC.

Private patients are patients who receive private healthcare, funded either directly by the patients themselves or via a medical insurance policy (which includes travel health insurance). On Guernsey private patients are also referred to as non-contract patients.

Private healthcare means any care that has not been funded by the States of Guernsey regardless of whether or not a particular treatment or service is normally commissioned by CHSC.

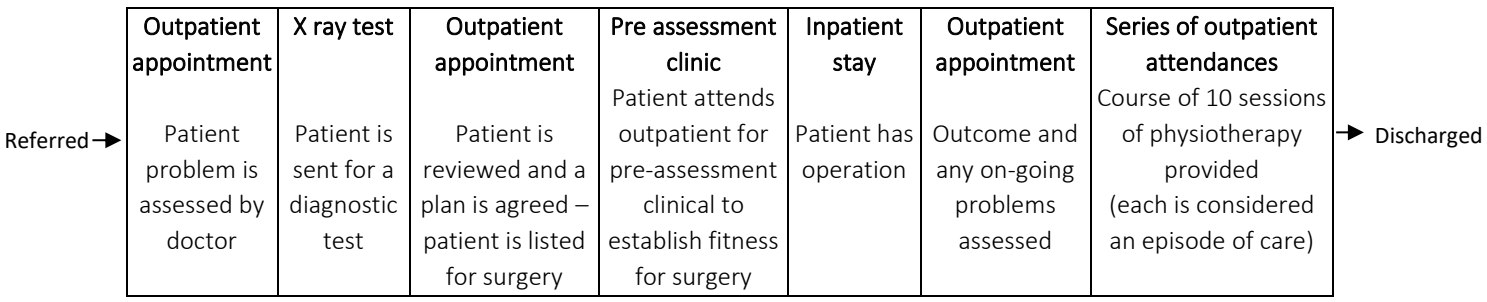
Private healthcare may be delivered by the Princess Elizabeth Hospital on Guernsey, the Medical Specialist Group, a NHS Hospital or by a private hospital in the independent healthcare sector.

Private healthcare may be purchased by a patient instead of having care funded by CHSC (for all or part of the care pathway) or in order to access care not currently funded by HSC.

An episode of care means a discrete element of care along a care pathway. For example:

- A single outpatient attendance
- A single diagnostic attendance
- An inpatient episode

A care pathway is made up of a series of episodes of care.



Co-funding means joint funding between the public sector and another party for an episode of care.

Top-up payments means those payments made where the public sector allows a publicly funded patient to upgrade or supplement the clinical health care paid for by CHSC by the patient paying a contribution.[20]

Co-payments are Government mandated patient contributions to their care such as prescription charges.

Attributable costs of private health care refer to all costs which would not have been incurred by CHSC had the patient not sought private treatment. They include both the immediate costs and those that may be incurred over time – for example the costs of on-going monitoring of the effect of a treatment.

Key principles underpinning this policy

- An individual's right to access public funded health care does not change because they have chosen to fund part of their care privately. Private patients should therefore be able to access publicly funded health care on the same basis as any other patient.
- Publicly funded health care should be provided equitably on the basis of

[20] In the NHS in England any individual is at liberty to seek private health care. Where that provision occurs in a private facility no issues are likely to arise. However if both the private and public health care are both delivered in the same facility it is important to be clear when an individual is a private patient and when they are a public patient. This is to ensure that the NHS is not delivering a two tier service to public patients, the NHS does not subsidise private patients and all attributable costs of delivering the private healthcare are recovered. The *principle of separation* has been adopted and co-funding is not allowed in the NHS except under specific clinical circumstances.
'Top up payments' as defined by the Department of Health (*Improving access to medicines for NHS patients: a report for the Secretary of State for Health by Professor Mike Richards, 2008)* are also not allowed currently in England. Top up funding (payments) differ from co-funding in that with top-up funding the patient remains an NHS patient at all times. Currently charging NHS patients is illegal under the NHS Act except for a small number of defined situations (such as making a co-payment for each drug on a prescription). The difference between co-funding and top-up funding is a subtle but important difference in the UK
Unfortunately many institutions have not adopted the definitions adopted by Professor Richards and erroneously refer to patients paying for private care in addition to public funded care as 'top up funding'.

clinical need and not social factors such as the ability to pay. Private patients should not therefore have different access to public health care by virtue of having the means to pay for some of their care privately.

- The patient should bear the full costs of any private services. Public resources should never be used to subsidise the use of private care.
- It should be clear at any point in time, to both the Provider Organisation and to the patient, whether an episode of care is privately funded or publicly funded.

The principle of separation

In the UK to ensure delivery of the above private and publicly funded care is generally separated in that:

- Private care is carried out in a different time to the public funded care that a patient is receiving.
- Private care is carried out in a different place to publicly funded care, whenever possible. A different place includes the facilities of a private healthcare provider, or part of a public facility that has been permanently or temporarily designated for private care, such a private wing, amenity beds or a private room. Putting in place arrangements for separation does not necessarily mean running a separate clinic or ward. As is the case now, specialist equipment such as scanners may be temporarily designated for private use as long as there is no detrimental effect to publicly funded patients.

In funding care in the UK, CHSC will adhere to these principles. Requests to co-funding will not routinely be funded.

On Guernsey the principle of separation is more difficult to logistically achieve. In addition, the provision of private health care is critical to the sustainability of a secondary care service on island. Co-funding will therefore be allowed within defined situations. This will be on the basis of an agreed list of procedures for which co-funding has been allowed. This list will be added to only through agreement of CHSC to ensure fair pricing and avoidance of onerous administration.

Requests for pick-up funding based on a patient's response to a treatment not normally funded by CHSC.

A request for the CHSC to pick up funding initiated privately is not uncommon.

Critical to assessing individual funding requests that engage this policy is understanding of some key aspects of priority setting and healthcare policy development.

A hypothetical cancer Drug X will be used to illustrate key principles.

In deciding whether or not to fund Drug X the funding body will aim to consider the range of clinical presentations, natural histories and responses to treatment that might be exhibited by the patient group of interest (the "target group").

Clinical trials suggest that, on average, Drug X extends life by 2 - 3 months, although there is naturally a range of responses amongst the target group.

The evidence from trials suggests that, out of every 100 patients that receive treatment, most will not get any benefit from Drug X. Some will get a few weeks' benefit and 3 patients are observed to live 12 months longer than expected and with reasonable quality of life.

In this instance, the normal range of response of the target group is from no benefit to one year's extension to life at a reasonable quality.

The funder must take a policy decision on the basis of this evidence.

Having assessed the cost-effectiveness of treating all patients in the target group, the funder reaches the decision that Drug X is not cost-effective and should not be funded. However, the funder undertakes a sub-group analysis on the three patients who get the most benefit and decides that for this group the treatment is cost-effective and does present good value for money and therefore ideally should be considered for funding during the annual prioritisation process.

The final funding position will depend on whether or not this sub-group of 3 out of 100 patients can be identified in advance of treatment.

If it is possible to clinically distinguish this subgroup *before* starting treatment, the

treatment is likely to be prioritised for this subgroup and the treatment funded as a service development.

If the patients in this subgroup cannot be identified in advance, then it would be necessary to treat 100 patients for 3 people to derive the desired health benefit. This would not represent good value for money and so Drug X would not be funded for any patient. This position could be reviewed if new evidence came to light.

An alternative option that may be open to the funding body is to fund all patients to a point where the 3 can be clearly identified. However this option could only be considered for interventions that involved a series of treatments (e.g. a course of chemotherapy) or on-going treatment. Furthermore, this approach could only be justified if this approach delivered value for money. Whether it was value for money would be influenced by:

- The cost of each dose or course of treatment.
- The speed with which responders could be identified.
- The availability of a valid measure that reliably linked response to outcome. A particular problem relating to outcome is the fact that proxy measures are frequently used in clinical trials and also clinical practice. In the case of cancer treatments, disease-free progression is frequently used as a marker of long-term survival, but the correlation between these two measures has been seriously questioned by Bowater, Bridge and Lilford [21].

Funding bodies frequently get requests to fund patients who have either received third party funding or who have funded themselves privately for treatments not normally commissioned by the funder on the basis that they have responded exceptionally well to the treatment.

Let us say that a patient seeks funding for Drug X because the drug has proved to be clinically effective in his or her particular case, and that they are likely to be one of the 3 patients who benefit the most.

At first glance, the decision maker may be tempted to vary its policy to permit

[21] J Bowater, L Bridge and R Lilford: The relationship between progression-free and post-progression survival in treating four types of metastatic cancer, Elsevier, *Cancer Letters*, Volume 262, Issue 1, Pages 48-53

Drug X to be funded in those instances where response has been demonstrated. However, such a policy would mean only allowing the funding to be made available to patients who can either afford to fund the early stages of the treatment themselves or who have access to a drug company supported initial treatment. It would thus involve making CHSC's willingness to provide treatment contingent on a prior private investment by the individual patient or a commercial investment by an interested party.

A funding body would therefore be acting entirely rationally (and thus lawfully) in refusing to make either a policy variation to provide Drug X to patients who had, by virtue of funding treatment outside of the public health service, been identified as the 3 patients who benefit more from treatment or to fund them as an individual patient on grounds of exceptionality.

Appendix 7: Guidance note on pick up funding for an unauthorised trial of treatment

Where a provider of healthcare has started a patient on a treatment which is either not routinely commissioned or which is experimental, without the knowledge and consent of CHSC, the Provider Organisation can neither commit nor require CHSC to fund on-going treatment of that patient.

This is the case whether or not the Provider Organisation has a contract for the provision of health care with CHSC.

To pick-up funding in this situation would not only put CHSC at considerable financial risk, it would also leave CHSC vulnerable to having its funding priorities, identified by reference to the needs of its population in accordance with its mandated obligations, destabilised by a third party.

In considering any individual funding request for pick up following a trial of treatment, CHSC would obviously need to have regard to the individual circumstances of the particular case. However, even where a patient has been shown to benefit from the trial of treatment, CHSC must weigh this against the important principle of not allowing third parties to drive the priorities of CHSC.

Appendix 8: Guidance note on patient choice

The States of Guernsey have limited funds available to meet the healthcare needs of the residents for which it is responsible. It cannot meet all needs. It is therefore essential that CHSC makes the most efficient use of its resources.

By establishing relationships with a restricted number of providers CHSC can provide overall more health care because of lower costs. CHSC has considered the benefits and costs of providing patients choice over where to have their treatment versus offering more health care to more people, and on balance have come to the view that restricting choice can be justified in the context of a publicly funded healthcare.

Appendix 9: Scorecard for screening proposed investment or disinvestment for treatments

This tool is to be used for rapid triaging of potential investments or disinvestment and to identify treatments which should not be funded

Intervention	
Total cost	
Description	
Claimed benefit	
Risks	
Service impact / feasibility	
Other commentary	

Health benefit x numbers benefiting per £100,000	~ 30%	Score =	/150
Evidence base	~ 20%	Score =	/100
Cost effectiveness	~ 20%	Score =	/100
Opportunity cost (total cost of development)	~ 20%	Score =	/100
Local priority - additional points awarded	~ 10%	Score =	/60
TOTAL			/510

OR

Low priority treatment (intervention)	

Health Benefit x numbers benefiting per £100,000	Score =	/150

			1 or less	Up to 4	Up to 10	Up to 100	Greater than 100
			1	2	5	10	15
Negligible	0	Marginal improvement in health (for example extension of life of 3 months, small quality of life improvement, marginal impact on activities of daily living)	Low priority treatment	Low priority treatment	Low priority treatment	Low priority treatment	Low priority treatment
Moderate	3	Some improvement in quality of life (most mainstream health care interventions, includes improved survival at one year)	1	6	15	30	45
Significant	7	Significant extension to life (improved survival after 3 year) or improvement in quality of life	7	14	35	70	105
Lifesaving / Life transforming	10	Transforms prognosis (improves 5-year survival / increased life saved / prevents major disability)	10	20	50	100	150

Evidence base	Score =	100/100

High	Several high-quality studies with consistent results. In special cases one large, high quality multi-centre trial. Further research unlikely to change our confidence in the evidence.	100
Moderate	One high-quality study / Several studies with some limitation. Further research likely to have an important impact on our confidence of in the estimate of effect and may change the estimate.	60
Low	One or more studies with severe limitations (e.g. case series). Further research likely to have an important impact on our confidence of in the estimate of effect and it is likely to change the estimate.	10
Very low	Expert opinion / No direct research evidence / one or more studies with very severe limitations.	Experimental or unproven treatment Low priority treatment

Cost effectiveness	Score =	/100

QALY <£10,000		100
QALY between £10,000 & £15,000		60
QALY between £15,000 & £20,000		20
QALY between £20,000 & £25,000	Some discretion to determine value offered	10
QALY between £25,000 & £30,000	Some discretion to determine value offered	5
QALY between £30,000 & £40,000	Some discretion to determine value offered	1
QALY >£40,000		Not cost-effective Low priority treatment
Cost effectiveness cannot be calculated because evidence too poor		Low priority treatment

Alternative Number needed to treat (NNT) x Cost per treatment (sliding scale estimate)

Note NNT of less than 3 considered good but many interventions have NNT 10-50. Value will depend on benefit and cost.

Estimate somewhere between 100 and Zero

High NNT High Cost		High NNT Low Cost	
Herceptin for HER2 positive breast cancer (adjuvant primary therapy) NNT = 50 to reduce death by 1 at 2 years Cost = £21,000 per course One saved life = £1.05 million	Low value	Aspirin in acute MI NNT = 42 to avoid one death at 1 month Cost = less than 10p per tablet One life saved = £4.20	High value
Low NNT High Cost		**Low NNT Low Cost**	
Renal replacement therapy (dialysis). NNT = 1 to avoid death Cost = £27,500 (UK average tariff)	High value	Glucocorticoids (Steroids) for Croup NNT = 8 to improve respiratory symptoms Cost =	Moderate value

Opportunity cost (total cost of development)	Score =	/100

Cash releasing pump priming will need discretion to give priority

Pump priming to cash release	100
<£10,000	60
Between £10,000 & £50,000	50
Between £50,000 & £100,000	40
Between £100,000 & £200,000	30
Between £200,000 & £300,000	20
Greater than £300,000	1

Local priority - additional points awarded	Score =	/60

States priority (only to be applied if evidence of benefit is good and cost – effective (QALY below £20,000) Addresses inequality or inequity Enables people to lead independent life Primary or secondary prevention	Extra 20 points for each
Worsens inequality	Low priority

Appendix 10: Summary sheet for initial prioritisation by the Corporate Management Team

Service development	
Description	
Costs • Pump priming • Capital • Annual • Additional related costs (for example treating high cost complications)	
Does this service development release cash or it is substation – if so give details	
Is there a legal requirement to implement?	
What are the expected benefits of the service development?	
What are the expected risks to the patient/client of delivering this service?	
The number of individuals benefit from the service in any year?	
What is the nature of the evidence for the treatment or service?	
Is this a priority arising from a progamme specific priority?	
What priority ranking does this have the programme area?	
Which strategic priorities of the CHSC does this meet? (2020 or Policy and Resources Plan 2017)?	
Is the cost-effectiveness of service development known?	
What are the implications for the existing services?	
Is there a potential major negative impact in not proceeding with the proposal?	
In what timeframe can the service be realistically delivered once funding has been agreed?	
What impact does the service have on patient choice?	

Appendix 11:The States of Guernsey Scorecard

Service development	
Description	
Costs • Pump priming • Capital • Annual • Additional related costs (for example treating high-cost complications)	

Criteria	**Description**	**Score**	**Score given**
Fit with States' objectives	The degree to which the proposal will **directly advance** individual States' objectives.	*0-25*	
Overall impact of not proceeding	Whether there is legal, reputational, health or other major impacts of not proceeding with the proposal.	*0-10*	
Breadth of beneficiaries	The number of people proposed to benefit from this proposal.	*0-10*	
Depth of benefits	The impact the proposal will have on individual beneficiaries.	*0-10*	
Option(s) proposed has been evaluated as best solution	The evaluation of options has been carried out using valid assumptions and the proposed option(s) are the best for delivering the proposal's aims.	*Absolute 0 or 5*	
Proposal will deliver value for money	Proposed solution will deliver value money for the aims and benefits indicated in the proposal. Whether the proposal will have a net ongoing cost to the States, net income or be cost neutral.	*0-15*	
Achievability of the proposal	Whether the project management arrangements (or strategy to put in place such arrangements) will be sufficient to deliver the proposal on time and on budget.	*0-10*	
Risk to successful delivery	Overall assessment of impact and likelihood of major risks affecting successful delivery of proposal.	*0-10*	