Isle of Man Government

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Individual Funding Request Panel (IFRP)

Commissioning Policy: Individual Funding Requests

Department of Health & Social Care

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Contents

Policy Statement 3

Equality Statement 4

1. **The Policy** 5

2. **Screening Individual Funding Requests** 6

Screening for service developments..... 6

What is a service development? 6

What is a "cohort of similar patients"? 7

What are the conditions which require consideration of a commissioning policy? 7

Screening for incomplete submissions..... 8

Screening to assess whether the request raises a case which ought to go to the IFR Panel 8

3. **Assessment of IFRs which have passed Screening** 9

Requests to provide funding to enable a patient to enter into a clinical trial.....10

Requests for funding based on rarity 11

Requests for second opinion 12

Identification bias 12

Information submitted to the IFR Panel 13

Approval of individual funding requests.....13

Review of the decision.....14

Co-operation of provider trusts.....15

Urgent treatment decisions.....15

Appendix A: Documents which have informed this policy 17

Policy Statement

The Department of Health and Social Care (DHSC) receives a fixed budget from the Treasury with which to fund all the health and social care required for the residents of the Isle of Man. Under the National Health Service Act 2001 (Section 1), the DHSC has a duty to *'continue to promote in the Island a comprehensive health service designed to secure improvement in (a) the physical and mental health of the people of the Island and (b) the prevention, diagnosis and treatment of illness.'*

It is not possible to fund all types of health and social care which may be requested within a fixed budget. The National Health Service Act 2001 reflects the reality of budget constraints by conferring a duty to 'promote a comprehensive health service', that is a target or aspirational duty which the DHSC must continually work towards, rather than a duty to fund a comprehensive service at any given point in time. The duty to promote a comprehensive service must be balanced against the concurrent duty to meet reasonable requirements for care within the allocated budget.

It follows, therefore, that decisions have to be made about which types of treatment and care are priorities for funding. The DHSC believes that the best and fairest way to fund and provide effective care for residents is through the development of clear care pathways and funding policies that allow equal access to all patients with similar clinical need.

However, the DHSC acknowledges that there will also be occasions when the specific circumstances of individual patients warrant consideration for an intervention which is outside existing pathways and policies. Requests for such interventions may be made by clinicians, on behalf of their patients, to the DHSC through the Individual Funding Request (IFR) process.

This policy outlines the circumstances in which such requests will be considered and the criteria which are used for decision-making. The processes for consideration of individual funding requests (IFRs) are outlined in the DHSC Document 'Individual Funding Requests Panel (IFRP): Standard Operating Procedures' dated November 2016.

This policy applies to any patient for whom the DHSC has responsibility for securing their NHS treatment (whether as the body responsible for delivery of care or as the body responsible for funding care from an external provider).

This policy will be implemented from November 2016 and kept under regular review.

Equality Statement

The DHSC recognises the Government's key priority to protect the vulnerable. This policy addresses that priority by seeking to reduce health inequalities in access to health services and health outcomes. The DHSC will seek to ensure equality of access and non-discrimination, irrespective of age, gender, disability (including learning disability), gender reassignment, marriage and civil partnership, pregnancy and maternity, race, religion or belief, sex (gender) or sexual orientation. This applies to all activities for which the DHSC is responsible, including policy development, review and implementation.

1. The Policy

a) This policy applies to any patient for whom the DHSC is responsible for securing their NHS treatment (whether as the body responsible for delivery of care or as the body responsible for funding care from an external provider).

b) Clinicians, on behalf of their patients, are entitled to make a request (an "individual funding request") to the DHSC for treatment that is not normally provided or funded by the DHSC, where the following conditions are met:

- The request does not constitute a request for a service development (i.e. the patient is not a member of a patient cohort with similar clinical needs);

AND

- The patient is suffering from a medical condition for which the DHSC is responsible for providing or funding care and the patient's particular clinical circumstances fall outside the circumstances in which this treatment would be routinely offered (whether through established custom and practice or as set out in a specific commissioning policy).

OR

- The patient is suitable to enter a clinical trial which requires individual explicit funding by the DHSC (for all or part of the costs associated with the trial) rather than being fully funded within the trial arrangements. The patient should not constitute a member of a larger group (cohort) all of whom could be eligible for the trial.

OR

- The cohort of patients likely to be eligible for this treatment in any one year can be robustly estimated to be fewer than five and therefore unrealistic to progress through the standard service development/business case route.

All correspondence will be copied to the patient, their carer or guardian (if appropriate) and General Practitioner (GP), unless there are specific reasons to suggest that this is not in the interest of the patient.

2. Screening Individual Funding Requests

Screening for service developments

All individual funding requests submitted to the DHSC will be screened by the Individual Funding Requests Panel in accordance with the procedures set out in the Standard Operational Procedures for Individual Funding Requests document to determine whether the request represents a service development.

Service developments include, but are not restricted to:

- New services.
- New treatments including medicines, surgical procedures and medical devices.
- New indications for or other developments to existing treatments including medicines, surgical procedures and medical devices (sometimes referred to as 'treatment repositioning').
- New diagnostic tests and investigations.
- Quality improvements.
- Requests to alter an existing policy (called a policy variation). The proposed change could involve adding in an indication for treatment, expanding access to a different patient sub-group or lowering the threshold for treatment.
- Requests to fund a number of patients to enter a clinical trial and the commissioning of a clinical trial are considered as service developments in this context as they represent a need for additional investment in a specific service area.

What is a service development?

A request for a treatment should be classified as a request for a service development if there is likely to be a cohort of similar patients who are:

In the same or similar clinical circumstances as the requesting patient:

- Whose clinical condition means that they could make a like request (regardless as to whether such a request has been made);

AND

- Who could reasonably be expected to benefit from the requested treatment to the same or a similar degree).

What is a "cohort of similar patients"?

A cohort of similar patients for the purposes of this policy has been defined as the number of requests received or likely to be received per year for a particular intervention for patients with a given condition who have reached a specified point on the treatment pathway. As set out below, where the expected number of requests per year is five or more, funding for the intervention should be considered through the clinical commissioning policy and annual commissioning round route, as a service development. In these circumstances, the IFR route to funding may only be considered if the patient is clinically exceptional to the cohort.

An example of a cohort would be:

Patients with chronic low back pain who have not responded to conservative treatment; or patients with rheumatoid arthritis who have not responded to disease modifying antirheumatic drugs.

What are the conditions which require consideration of a commissioning policy?

a) The DHSC will consider the development of a clinical commissioning policy where:

- The numbers of patients for whom the treatment will be requested per year is likely to be 5 or more patients on the Isle of Man.
- The cost of funding the requested treatment for an individual is likely to result in expenditure of more than £150,000 per year.

b) Where the number of patients eligible for the treatment is likely to be 5 or more, the DHSC will treat this as a service development requiring a commissioning policy.

c) If the number of patients presenting per year is fewer than 5, the DHSC will consider whether consideration through the IFR route is appropriate.

d) If the estimated cost for between 1 and 4 patients is <£150,000 per year, funding decisions can be made through the IFR Panel.

e) Where the numbers of patients and costs exceed these thresholds, the DHSC's Clinical Recommendations Committee will be notified.

f) The IFR Panel is not entitled to make policy decisions on behalf of the DHSC. It follows that where a request has been classified as a service development for a cohort of patients, the IFR Panel is not the correct body to make a decision about funding the request. In such circumstances the individual funding request should not and will not be presented to the IFR Panel but will be dealt with in the same way as other requests for a service development.

g) Where an IFR has been classified as a service development for a cohort of patients, the options open to the IFR Panel include the following steps:

- To refuse funding and request the provider prioritises the service development internally within the provider organisation that made the request and, if supported, to invite the provider to submit a business case as part of the annual commissioning round for the requested service development.
- To refuse funding and initiate an assessment of the clinical importance of the service development within the DHSC's Clinical Recommendations Committee with a view to developing a policy and determining its priority for funding in the next financial year.
- To refer the request for funding for immediate workup of the service development as a potential candidate for in year service development.

Screening for incomplete submissions

If a request is not categorised as a service development, it will be subject to screening by a medical member of the IFR Panel to determine whether the request has sufficient clinical and other information in order for the individual funding request to be considered fully by the IFR Panel. Where information is lacking the IFR will be declined and returned to the provider specifying the additional information which would be required in order to enable this request to proceed. The request can be resubmitted at any point.

Screening to assess whether the request raises a case which ought to go to the IFR Panel

If a request has been accepted as not constituting a service development and the paperwork is sufficiently complete to assess the case, then the request will be forwarded to the IFR Panel unless there is no reasonable prospect that the IFR Panel (applying the tests set out in this policy) will approve the request.

3. Assessment of IFRs which have passed Screening

Exceptionality requests which seek treatment for a patient whose clinical circumstances do not currently qualify them for funding under an existing commissioning policy and/or established treatment pathway

An exceptionality request can be made in relation to any medical condition/treatment which is not currently routinely provided or funded by the DHSC. Some, but not all, such treatments may be cases which do not meet the criteria in a specific DHSC commissioning policy. For other requests, there may be no specific policy. Requests in these groups should be completed by the clinician with reference to the relevant generic and/or treatment specific commissioning policy.

The IFR Panel shall be entitled to approve funding if the patient has exceptional clinical circumstances. In considering whether or not to fund a patient on grounds of exceptional clinical circumstances, in this situation, the IFR Panel will act as follows:

- the IFR Panel will use the information provided by the requester to compare the patient to other patients with the same presenting medical condition at the same stage of progression.

  The Panel will apply the following test of exceptionality:

  - o the patient is significantly different to the cohort of patients with the condition in question;

  AND

  - o the patient is likely to gain significantly more benefit from the intervention than might be normally expected for patients with that condition. The fact that a treatment is likely to be efficacious for a patient is not, in itself, a basis for exceptionality.

- When making their decision, the IFR Panel is required to restrict itself to considering only the patient's presenting medical condition and the likely benefits which have been demonstrated by the evidence to be likely to accrue to the patient from the proposed treatment.

- The DHSC and its delegated decision-making panels shall seek to make decisions in accordance with the DHSC's ethical framework, including the desire to reduce inequality and protect the vulnerable.

- The DHSC and its delegated decision-making panels shall not make treatments available to individual patients, which would not be offered equally to other clinically similar patients, on the basis of non-clinical factors
- The IFR Panel shall have a broad discretion to determine whether the proposed treatment is a justifiable expenditure for the DHSC. The IFR Panel is however required to bear in mind that the allocation of any resources to support any individual patient will necessarily reduce the resources available for investments in previously agreed priorities for care and treatments.

Requests to provide funding to enable a patient to enter into a clinical trial

The IFR Panel shall be entitled to approve funding for a patient to enter into a clinical trial (but see note under Section 1 above re trials with a potential cohort of patients). Many trials have funding (for example, from the Medical Research Council or a charitable organisation) which covers all or part of their cost. For major trials with full funding there may be no request to the DHSC for funding. In some cases, trials are part funded but have an element (often referred to as 'excess treatment costs') which would need to be met by the DHSC. Other trials may seek a greater degree of funding from DHSC.

In considering whether or not to provide funding to enable a patient to enter into a clinical trial the IFR Panel will consider the following:

- The potential strategic importance of the treatment to the patient group and to the health service generally. This requires a judgement to be made on whether the trial will address priorities for the programme area.
- The likelihood that other patients will be presented for funding during the trial duration and the possible numbers.
- The status of the clinical trial including whether or not the trial has been ratified by the National Institute for Health Research and/or other relevant clinical and research bodies.
- An assessment of the anticipated quality of the trial (based on the trial protocol) and whether or not it is likely to generate results 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.
- Ownership of the data. Trials which do not guarantee that the data will be made available in the public domain will not be considered for funding.

- Affordability and priority compared to other competing needs and unfunded developments.

All funding requests must be accompanied with the trial protocol and confirmation of research ethical committee approval.

Requests for funding based on rarity

The DHSC recognises that interventions for rare conditions present a challenge for commissioning since the very small numbers involved mean that they may be overlooked in the annual commissioning cycle and only be brought to the attention of the DHSC when an individual presents requiring care.

The DHSC wishes to ensure that patients with rare conditions are not, therefore, disadvantaged compared to patients with commoner conditions for which interventions are more easily identified and progressed through the policy and service development route.

To reflect this, the IFR Panel shall be entitled to consider requests for funding based on rarity where it can be robustly demonstrated that fewer than five patients per year are likely to require the treatment in question.

In these circumstances, the IFR Panel's assessment will be based on evidence of clinical and cost effectiveness rather than the test of exceptionality. As a result, the decision of the IFR Panel will effectively set policy for other members of the small cohort who may present subsequently.

In taking this approach, there is a risk that individuals in such circumstances (i.e. members of a cohort of one to four patients per year) will gain a benefit in terms of potential access to fast track, in year funding which would not be offered to members of a larger cohort for whom the service development route would be followed.

To mitigate this bias towards rarity, whilst the decision made by the IFR Panel in respect of the index case will be binding, the Panel will forward their assessment to the Clinical Recommendations Committee (CRC) for ratification or challenge.

Where the CRC supports the IFR Panel assessment and decision, and the CRC recommendation has been signed off by DHSC, policy will have been established for this small group of patients which can be applied to future similar requests without the need for IFR Panel consideration.

Where the CRC does not support the IFR Panel assessment and decision, a policy not to routinely fund the intervention in this small group of patients will result on sign off by DHSC. The test applied to any subsequent similar patients would then be that of 'exceptionality' rather than 'rarity'.

Requests for second opinion

The DHSC acknowledges the right of patients to seek a second opinion on their diagnosis and/or management. Wherever possible, the second opinion should be sought from a consultant on island within NHS health services. However, there will be occasions when a second consultant with relevant specialist expertise is not available on island. In such circumstances, the DHSC will fund the patient to have a consultant assessment (single appointment) for the purpose of providing a second opinion. The second opinion will be sourced within the established networks of providers in North West England with which the DHSC already holds service level agreements. The second opinion could be face-to-face through a standard out-patient clinic or via teleconference or other telemedicine approach if appropriate. Requests for second opinion in line with the above do not need to be considered by the IFR panel.

The patient's care will be expected to return on-island after the second opinion has been obtained. The patient's management plan should, if appropriate, be agreed by discussion between the two consultants and the patient.

Funding for a second opinion is not intended to provide a means for a patient to access a particular named consultant outside established care pathways, or to access a treatment/procedure offered by a particular consultant/provider but which is not routinely offered within current pathways for the Isle of Man.

Identification bias

The IFR Panel shall take care to avoid identification bias, often called the "rule of rescue". This can be described as the imperative people feel to rescue identifiable individuals facing avoidable death or a preference for identifiable over statistical lives. In plain terms this means: supporting intensive effort to prolong life (when prognosis appears poor and death unavoidable) and when there is little research evidence to support treatment options (e.g. in relapsed/refractory stages of disease). The fact that a patient has exhausted all NHS treatment options available for a particular condition is unlikely, of itself, to be sufficient to demonstrate exceptional circumstances. Equally, the fact that the patient is refractory to existing treatments where a recognised proportion of patients with same presenting medical condition at this stage are, to a greater or lesser extent, refractory to existing treatments is unlikely, of itself, to be sufficient to demonstrate exceptional circumstances.

McKie J, Richardson J. The rule of rescue. J Soc Sci Med. 2003 June;56(12):2407-19

Information submitted to the IFR Panel

All applications must be submitted using the standard application form for IFRs. It is the clinician's responsibility to ensure that the appropriate information is provided to the IFR Panel, according to the type of request being made, in a timely fashion consistent with the urgency of the request. If relevant information is not submitted, then the referring clinician will bear responsibility for any delay that this causes. In all instances the lead treating clinician must state whether or not they consider there are similar patients (in accordance with the definition set out above) and, if so, how many such patients there are.

All clinical teams submitting IFR requests must be aware that information that is immaterial to the decision will not be considered by the IFR Panel. This may include information about non-clinical factors relating to the patient or information which does not have a direct connection to the patient's clinical circumstances.

Approval of individual funding requests

The IFR Panel shall be entitled to approve requests for funding for treatment for individual patients where all the following conditions are met:

- Save in the case of funding requests under Section 2 (screening for service developments, the IFR Panel is satisfied that there is no cohort of similar patients. If there is a cohort of similar patients the IFR Panel shall decline to make a decision because the application is required to be treated as a request for a service development.
- One of the conditions set out in Section 1 above is met.
- Exceptional circumstances apply and there is sufficient evidence to show that, for the individual patient, the proposed treatment is likely to be clinically and cost-effective or that the clinical trial has sufficient merit to warrant NHS funding.
- The DHSC can afford the treatment.

The IFR Panel is not required to accept the views expressed by the patient or the clinical team concerning the likely clinical outcomes for the individual patient of the proposed treatment but is entitled to reach its own views on:

- The likely clinical outcomes for the individual patient of the proposed treatment;

AND

- The quality of the evidence presented to support the request and/or the degree of confidence that the IFR Panel has about the likelihood of the proposed treatment delivering the proposed clinical outcomes for the individual patient.

The IFR Panel shall be entitled but not obliged to commission its own reports from any duly qualified or experienced clinician, medical scientist or other person having relevant skills, concerning the case that is being made that the treatment is likely to be clinically effective in the case of the individual patient. Reference to nationally recognised evidence syntheses should be used where they address the specific issues under consideration.

The IFR Panel may make such approval contingent on the fulfilment of such conditions as it considers fit.

Very occasionally an IFR presents a new issue which needs a substantial piece of work before the DHSC can reach a conclusion upon its position. This may include wide consultation. Where this occurs the IFR Panel may adjourn a decision on an individual case until that work has been completed.

Review of the decision

Where the IFR Panel has refused to support funding for a requested treatment or has approved the treatment subject to conditions, the patient shall be entitled to ask that the decision of the IFR Panel be reviewed. All requests for review must be submitted by the senior treating clinician and must be based on the following grounds: the decision taken by the IFR Panel was procedurally improper; and/or misunderstood the medical evidence; and/or was in his or her opinion a decision which no reasonable IFR Panel could have reached. The clinician requesting review must provide evidence to support the grounds for the review. Any such review will be considered by the DHSC's IFR Review Panel.

The IFR Review Panel is part of the corporate governance process of the DHSC. The role of the IFR Review Panel is to determine whether the IFR Panel has followed the DHSC's procedures, has properly considered the evidence presented to it and has come to a reasonable decision based upon the evidence.

The IFR Review Panel shall consider whether:

- The process followed by the IFR Panel was consistent with the operational policy of the DHSC.
- The decision reached by the IFR Panel:
    - was taken following a process which was consistent with the policies of the DHSC
    - had taken into account and weighed all the relevant evidence
    - had not taken into account irrelevant factors
    - indicated that the members of the IFR panel acted in good faith
    - was a decision which a reasonable IFR Panel was entitled to reach.

In the event that the IFR Review Panel consider that there was any procedural error in the decision of the IFR Panel, the IFR Review Panel shall next consider whether there was any reasonable prospect that the IFR Panel may have come to a different decision if the IFR Panel had not made the procedural error identified by the IFR Review Panel.

If the IFR Review Panel considers that there was no reasonable prospect of the IFR Panel coming to a different decision, then the IFR Review Panel shall approve the decision notwithstanding the procedural error.

However, if the IFR Review Panel considers that there was a reasonable prospect that IFR Panel may have come to a different decision if the IFR Panel had not made the procedural error, the IFR Review Panel shall require the IFR Panel to reconsider the decision.

The IFR Review Panel shall not have power to authorise funding for the requested treatment but shall have the right to make recommendations to the IFR Panel and/or to request one of the Officers authorised to take urgent decisions to consider exercising that power.

Co-operation of provider trusts

The DHSC requires healthcare providers, including clinicians, to take the DHSC's commissioning policies into account in the advice and guidance given to patients prior to making the decision to treat a patient. The DHSC expects the management of its healthcare providers to have oversight of this process. The DHSC would expect every IFR to be reviewed and approved by the appropriate senior manager and reserves the right to return unapproved IFRs to the provider un-assessed. Repeated submission of inappropriate funding requests will be referred to the senior management of the relevant provider.

Urgent treatment decisions

The DHSC recognises that there will be occasions when an urgent decision needs to be made to consider approving funding for treatment for an individual patient outside the DHSC's normal policies. In such circumstances the DHSC recognises that an urgent decision may have to be made before a Panel can be convened. The following provisions apply to such a situation.

An urgent request is one which requires urgent consideration and a decision because the patient faces a substantial risk of death or significant harm if a decision is not made before the next scheduled meeting of the IFR Panel.

Urgency under this policy cannot arise as the result of a failure by the Clinical Team expeditiously to seek funding through the appropriate route and/or where the patient's legitimate expectations have been raised by a commitment being given by the provider trust to provide a specific treatment to the patient.

Provider Trusts must take all reasonable steps to minimise the need for urgent requests to be made through the IFR process. If clinicians from any provider are considered by the DHSC not to be taking all reasonable steps to minimise urgent requests to the IFR process, the DHSC may refer the matter to the provider senior management.

In situations of clinical urgency the decision will be made by a 'virtual panel' of the IFR Panel, as set out in the DHSC's 'Individual Funding Requests Panel (IFRP): Standard Operating Procedures' document.

The 'virtual panel' will as far as possible within the constraints of the urgent situation follow the policy set out above in making the decision. The 'virtual panel' shall consider the nature and severity of the patient's clinical condition and the time period within which the decision needs to be taken. As much information about both the patient's illness and the treatment should be provided as is feasible in the time available and this shall be considered for funding in accordance with relevant existing commissioning policies.

The 'virtual panel' shall be entitled to reach the view that the decision is not of sufficient urgency or of sufficient importance that a decision needs to be made outside of the usual process.

The 'virtual panel' shall be entitled to reach the view that the request is, properly analysed, a request for a service development and so should be refused and/or appropriately referred for policy consideration.

Appendix A: Documents which have informed this policy:

- The NHS CB Commissioning Policy: Ethical Framework for Priority Setting and Resource Allocation, April 2013, ref: NHSCB/CP/01.

- The NHS CB Interim Commissioning Policy: Individual Funding Requests, April 2013, ref: NHSCB/CP/03.

- Department of Health, The National Health Service Act 2006 (amended by the Health and Social Care Act 2012), The National Health Services (Wales) Act 2006 and The National Health Service (Consequential Provisions) Act 2006.

  http://www.dh.gov.uk/en/Publicationsandstatistics/Legislation/Actsandbills/DH 064103

- Department of Health, The NHS Constitution for England, July 2009

  http://www.dh.gov.uk.en.Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH 093419

- The National Prescribing Centre, Supporting rational local decision-making about medicines (and treatments), February 2009

  http://www.npc.co.uk.policy/resources/handbook complete.pdf

- NHS Confederation Priority Setting Series, 2008

  http://www.nhsconfed.ord/publications/prioritysetting/Pages/Prioritysetting.aspx

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This document can be provided in large print or in audio format on request

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