Isle of Man Government

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Individual Funding Requests Panel (IFRP)

Standard Operating Procedures

Department of Health & Social Care

25 November 2016

Contents

1. Introduction

This document sets out the procedures to be followed in respect of Individual Funding Requests (IFRs).

The document must be read in conjunction with the policy documents:

- Commissioning Policy: Individual Funding Requests dated August 2016,
- Commissioning Policy: Ethical framework for priority setting and resource allocation' dated August 2016

The term 'clinician(s)' used throughout this document refers to clinicians providing care to Isle of Man residents.

Patient and public consultation is NOT included in the process.

2. Process

Making the Request

IFRs are made by the patient's clinician and should be sent directly to the IFR Administrator of the IFR Panel (the Panel) at the Public Health Directorate.

IFR requests should be made by a clinician who has knowledge and expertise in the field in which the request is being made. For example, if the request is for an orthopaedic procedure that is not routinely funded, the request should come from an orthopaedic surgeon who has sufficient knowledge of the procedure requested to complete the IFR form.

Requests must be made using the Online IFR Request Form which can be found at www.gov.im/IFRP

Obtaining Consent

The requesting clinician is required to seek explicit consent from patients before their personal details are passed to the IFR Administrator of the Panel as part of the IFR process. The IFR Administrator will copy the patient into all correspondence regarding the processing of the request unless specifically requested not to do so by the requesting clinician. In this event, the requesting clinician is responsible for informing the patient about the process and the decision.

On receipt of the request, the IFR Administrator will send an email acknowledgment to the requesting clinician setting out the expected timescale for consideration.

Triage

The purpose of triage is to ensure that only appropriate requests go forward for Panel consideration. It is not a decision making process. Requests may be redirected if they are not appropriate IFR requests (or the conditions outlined in the IFR Panel Commissioning Policy are not met).

Preparation

All IFRs will be triaged (except urgent cases) after all patient identifiable information has been removed from the IFR by the IFR Administrator.

Procedure

The outcome for each request triaged will be one of the following:

i) That the request has been submitted using the correct form and with all the necessary information required for consideration by the Panel, and that the IFR Administrator can refer the request to the next meeting of the Panel

ii) That the request form has not been completed satisfactorily and should be returned to the requesting clinician by the IFR Administrator of the Panel with details of what is required if the request is to be progressed

iii) That the request does not fall within the scope of the IFR policy. This category includes, but is not limited to, requests which clearly apply to a cohort of patients and should be progressed as potential service developments. Where the request is deemed to be outside the scope of the IFR policy, the IFR Administrator will set out the reasons for this decision in their response to the requesting clinician.

The triage decision will be communicated to the requesting clinician by email. Where the decision is to progress the request to the Panel, the date of the Panel meeting will be confirmed.

IFR Panel Preparation

The agenda and paperwork for the Panel is prepared in advance, including all requests having successfully passed through triage, at least five working days before the date of the meeting.

Meeting Structure

The meeting is held monthly, on the second Thursday of each month and considers all requests that have completed triage by the date for sending out the papers to Panel members (i.e. 5 working days before the date of the Panel meeting). If no requests have completed triage at this date, the meeting will be cancelled. The Terms of Reference are set out at Appendix 1.

Procedure

Each case will be considered by the Panel on the basis of the information ..... submitted by the requesting clinician. Each case will be assessed against the ethical framework which is summarised in the document 'Applying the Ethical Framework through the Individual Funding Request (IFR) Panel: Aide Memoire for Decision Making and Recording' – see Appendix 3.

The outcome for each case will be one of the following:

i) *That the IFR be approved*

- The patient meets the test of exceptionality, or
- The patient satisfies the criteria for rarity

Treatment approved through the IFR process must be commenced within one year of the date of the approval letter. Should treatment not be commenced by that time, approval will lapse. Should the treatment still be required, a new application must be made.

ii) *That the IFR be declined*

- Patient does not meet the test of exceptionality, or
- Patient does not meet the criteria for rarity

iii) *Pended*

- It is the responsibility of the requesting clinician to provide all relevant information. Very occasionally the Panel may request additional information to support the request. In these circumstances, the decision will be pended until the additional information has been received and considered.
- The information requested must be received by the IFR Administrator within 30 working days. Where the information is not received within this timeframe, the case will be closed. Further consideration of the case will require a new application to be made.

The Panel decision, with reasons, will be communicated to the requesting clinician within 5 working days of the Panel meeting. Standard processes and template documents will be used to facilitate effective communication of outcomes to the requesting clinician and directly to the patient when appropriate.

Seeking Review of a Decision

Where a decision has been made by the Panel not to fund a healthcare intervention and the requesting clinician and/or patient consider that all the relevant information has been provided and considered but there has been a failure in the process by which the decision was reached, a request for review of the decision can be made. The request for review must be submitted by the requesting clinician using the electronic version of the standard decision review request form.

Further information on seeking a decision review is set out in the IFR Commissioning Policy document. Decision reviews will be undertaken by the IFR Review Panel, whose Terms of Reference are set out in Appendix 2.

3. Requests for Procedures requiring prior approval

There are a number of policies in place which are managed by the IFR Team on a prior approval basis. Requests for treatments which fall within the scope of one of these policies should be submitted via the IFR Safe Haven. It is the responsibility of the requesting clinician to demonstrate that the request meets the criteria set out in the relevant policy. Such requests will be considered by the IFR Team against the appropriate policy. The outcome for each case will be one of the following:

i) That the request is approved:

- The request meets the policy criteria and is therefore approved

ii) That the request is declined

- The request does not meet the policy criteria and is therefore declined

iii) Pended:

- The IFR Team requires additional information in order to make a decision.

Standard processes and template documents are in place to facilitate effective communication of outcomes to the requesting clinician.

4. Urgent Requests for Funding Treatment

Where the requesting clinician considers that treatment is required before the next IFR Panel date, urgent consideration through a 'virtual panel' can be requested. IFRs will not be handled as urgent on grounds that waiting until the next Panel is inconvenient or problematic for the patient or requesting clinician. A pre-booked appointment is also not an acceptable reason for clinical urgency. Before considering an IFR as urgent careful consideration will be given as to whether sufficient information is available for the Panel to make a decision without compromising any of the principles upon which decisions should be made.

The requesting clinician must demonstrate that there will be life-threatening consequences for the patient if the treatment is not commenced urgently. The decision to request a treatment not provided within the existing pathway must have been confirmed by the provider organisation (e.g. a hospital) through the most appropriate route (e.g. a multi-disciplinary team or by the clinical director).

The urgency of clinical need does not override the general principles of the ethical framework. Therefore, if a patient who is considered to have an urgent need for a treatment not currently funded within standard pathways belongs to a cohort of similar patients, none of whom would routinely be offered this treatment, then an IFR is not appropriate and will not be accepted simply on the basis of immediate clinical need.

5. General

Members of the Panel must declare interests that may be relevant and material to the consideration of any item of Panel business. In such an event, the member may not take part in discussions relating to any such item of business.

All discussions within the context of the Panel will be treated as strictly confidential amongst the Panel members.

6. Reporting Arrangements

Financial reporting

The IFR Team will provide an annual report to the Department of Health & Social Care (the Department) on the expenditure associated with the IFR approvals (based on the expected costs submitted within the IFR applications). This allows the monitoring of expenditure and budget forecasting.

Performance Reporting

The IFR Team will provide a report to the Department on an annual basis summarising activity and outcomes, identifying any emerging patterns of request and any areas requiring policy development.

7. Quality Assurance and Reporting to the Department

The IFR Team will put in place arrangements for the training of IFR Team and Panel members to ensure consistency across the Department and against the existing policies of the Department.

8. Sharing the Learning from IFRs

The IFR Team will take a proactive approach to sharing any learning from the cases received. Any learning, together with the commissioning policies and criteria will be disseminated to Department medical staff, local GP practices and other care providers. The aim is to manage the number of IFRs by supporting clinicians in discussing the availability of treatment options with patients.

Appendix 1

Individual Funding Request Panel

Terms of Reference

1. Purpose

The Panel will consider all requests for treatment falling within the scope of the IFR Commissioning Policy.

2. Membership

Medical Director (Chair)

Director of Commissioning (Vice-Chair)

Pharmaceutical Adviser

General Medical Practitioner

Director of Public Health

Medical Consultant (Acute)

Medical Consultant (Mental Health)

Lay Members (x2)

3. Terms of Office

Members will remain as members of the Panel for as long as they continue to be members of the Clinical Recommendations Committee.

4. Quoracy

The Panel must be quorate to make recommendations. The Chair (or in their absence the Vice-Chair), two medical members and two non-medical members must be present.

5. Deputies

No deputies are permitted.

6. Panel Decisions

The Panel will seek to make a majority decision in all instances. Where a majority cannot be reached the Chair's vote (or in their absence the Vice-Chair's vote) is casting.

7. Attendance at Meetings

Other members of staff either from the Department or one of its clinical providers may be requested to attend the Panel meetings in an advisory capacity as necessary to discuss particular issues or to offer advice to the Panel members.

8. Frequency of Meetings

The Panel will meet monthly and will consider all requests that successfully passed through triage at least 5 working days prior to the scheduled date of the meeting.

9. Duties and Operation

The duties of the Panel will be to consider, and either approve or decline, where appropriate, requests to fund treatment for individual patients.

It is the responsibility of the requesting clinician to provide all relevant information to support the application.

Patient identifiable information will be dealt with in confidence; all requests are received via Safe Haven and are anonymised prior to the Panel meeting. Patient identifiable information will not be used to consider the request.

The Panel will consider all relevant information received from the clinician involved in the patients care.

The Panel will apply the criteria in the IFR Commissioning Policy and Ethical Framework document.

10. General

Members of the Panel must declare interests that may be relevant and material to the consideration of any item of Panel business. In such an event, the Panel member may not take part in discussions relating to the case.

All discussions and paperwork within the context of the Panel will be treated as strictly confidential amongst the Panel members.

11. Review

These Terms of Reference should be reviewed annually.

Appendix 2

Individual Funding Request Review Panel

Terms of Reference

1. Purpose

The Purpose of the IFR Review Panel (the Review Panel) is to determine whether the IFR Panel has followed the Department's procedures, has properly considered the evidence presented to it and has come to a reasonable decision based upon the evidence. The Review Panel will follow the IFR Commissioning Policy.

2. Membership

Chief Executive Officer of the Department (Chair)

Finance Director

Lay Member

3. Quoracy

All members must be present

4. Deputies

No deputies are permitted.

5. Review Panel Decisions

The Review Panel will seek to make a majority decision in all instances. Where a majority cannot be reached the Chair's vote is casting.

6. Attendance at Meetings

Other members of staff either from the Department or one of its clinical providers may be requested to attend the Review Panel meetings in an advisory capacity as necessary to discuss particular issues or to offer advice to the Review Panel members.

7. Frequency of Meetings

The Review Panel will meet as and when required. The IFR Administrator will organise and administer the Review Panel.

8. Duties and Operation

The Review Panel shall consider whether:

i) The process followed by the IFR Panel was consistent with the operational policy of the Department.

ii) The decision reached by the IFR Panel:

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

A request for a review of an IFR Panel decision should be made within one calendar month of the date of the notification of the IFR Panel decision.

Requests from a patient or clinician for a review will be acknowledged within two working days of receipt.

The Review Panel will ensure that the appellant is notified of the Review Panel's decision within seven working days.

All proceedings of the Review Panel will be in private.

9. General

Members of the Review Panel must declare interests that may be relevant and material to the consideration of any item of Review Panel business. In such an event, the Review Panel member may not take part in discussions relating to the case.

All discussions and paperwork within the context of the Review Panel will be treated as strictly confidential amongst the Review Panel members.

10. Review

These Terms of Reference should be reviewed annually.

Appendix 3

a) APPLYING THE ETHICAL FRAMEWORK THROUGH THE CLINICAL RECOMMENDATIONS COMMITTEE (CRC): AIDE MEMOIRE FOR DECISION MAKING AND RECORDING

Each topic considered by the CRC should be evaluated against the following criteria from the Ethical Framework and the decision (with reasons) clearly recorded in the minutes and

ETHICAL FRAMEWORK CRITERION	ISSUES FOR CONSIDERATION
Clinical effectiveness	Is this intervention clinically effective? What is the evidence to support the clinical effectiveness of this intervention? How reliable are the conclusions that can be drawn from this evidence?
Cost effectiveness	Is this intervention cost effective? What is the evidence to support the cost effectiveness of this intervention? How reliable are the conclusions that can be drawn from this evidence?
Healthcare need and capacity to benefit	Are the outcomes of this intervention clinically significant and likely to be meaningful to patients and/or carers? How great an impact are these outcomes likely to have on individuals and/or carers receiving the intervention? How strong/reliable is the evidence for this?
Needs of the community	What are the likely impacts of this intervention at population level?
Cost of treatment and opportunity cost	What are the likely costs of this intervention per patient and modelled across our population?
Equity and protecting the vulnerable	Are there any issues related to equity or protecting vulnerable groups/individuals in our community? Would introducing this intervention risk widening health inequalities across the population? Would introducing this intervention be likely to reduce such inequalities? Are there any issues relating to equity/protecting the vulnerable that need particular consideration either in reaching a funding decision or in implementing the intervention?

ETHICAL FRAMEWORK CRITERION	ISSUES FOR CONSIDERATION
National strategic objectives	Would investing/disinvesting from this intervention further a national strategic objective (eg DHSC Health Strategy objectives)?
Service strategic objectives	Would investing/disinvesting from this intervention further a service strategic objective (eg acute care; cardiovascular disease; musculoskeletal; etc)?

b) APPLYING THE ETHICAL FRAMEWORK THROUGH THE INDIVIDUAL FUNDING REQUEST (IFR) PANEL: AIDE MEMOIRE FOR DECISION MAKING AND RECORDING

Each funding request should be evaluated against the following criteria from the Ethical Framework and the decision (with reasons) clearly recorded in the minutes and decision letters.

GROUNDS FOR REQUEST	ISSUES FOR CONSIDERATION	GUIDANCE
Exceptionality	Is this patient a member of a definable cohort?	Is there an identifiable group of patients with the same condition, at a similar stage of progression in line with the expected course of the condition and at a similar point in the care pathway? If yes, • agree and record the cohort to which the patient belongs • apply the tests for exceptionality as below. If no, consider whether the patient should be considered under 'rarity' as below.
	Does this patient have exceptional need compared to others in this cohort?	What has been put forward to demonstrate exceptional need for this patient? Does it distinguish them from the rest of the relevant cohort? Individual factors such as age, race, religion, gender or gender identity, sex or sexual orientation, lifestyle, employment status, social position, family or financial status, pregnancy, intelligence, disability, physical or cognitive functioning are not, per se, usually grounds for exceptional need.

GROUNDS FOR REQUEST	ISSUES FOR CONSIDERATION	GUIDANCE
Exceptionality	Does this patient have exceptional need compared to others in this cohort?	The fact that a patient, their family and/or their clinician has requested a particular treatment that is not routinely funded does not constitute exceptional need. The fact that there may be no other routinely funded treatments available at this point in the pathway does not constitute exceptional need. The fact that there may be a time component to treatment (the argument that the patient requires treatment now and cannot wait for a policy/service development decision) does not constitute exceptional need.
	Does the patient have exceptional capacity to benefit	What has been put forward to demonstrate exceptional capacity to benefit for this patient? Does it distinguish them from the rest of the relevant cohort? Is there sufficient evidence of clinical effectiveness to indicate both that the intervention is likely to be effective and the nature (clinical significance and impact on defined outcomes) of that effect? Is there sufficient evidence to indicate that this particular patient will derive greater benefit than other patients in the cohort who will not be offered the treatment under current policy? Note that, on occasion, social factors as listed above may have a bearing on capacity to benefit – this must be clearly assessed and recorded by the IFR panel as part of their decision making.

GROUNDS FOR REQUEST	ISSUES FOR CONSIDERATION	GUIDANCE
Rarity	Is this patient a member of a cohort of 4 or fewer patients with similar clinical condition likely to require treatment on Island per year (includes incident and prevalent cases)?	What evidence has been submitted to indicate that the relevant cohort is 4 or fewer patients for the Island per year? Can the Panel be assured that this is a robust and reliable estimate? Are there any other factors which should bring the 'rarity' argument into question? For example, if the patient has a condition which is common (e.g. rheumatoid arthritis) but has reached a point in the pathway that only a small proportion of patients reach (e.g. poor response to all biological drug options currently offered within policy), it may be appropriate to re-route the request to be worked up as part of pathway and service development for the full patient cohort. The 'rarity' category for individual funding is intended to protect the interests of those patients with rare conditions which are at risk of being overlooked in horizon scanning and the annual planning/commissioning round. Full pathway development for common conditions (including those stages of the pathway that may apply only to small numbers of patients on Island) should be undertaken as part of the annual planning/commissioning round as the needs even of small numbers at the end of such pathways can be expected to be foreseen and included in the usual funding/planning processes. If the Panel consider that the 'rarity' criterion has been met, the case should be considered further by application of the framework for CRC assessment. If the Panel considers the 'rarity' criterion has not been met, the Panel should reject the application and follow policy guidance re advising referrer on the appropriate service development consideration route (including CRC consideration).

GROUNDS FOR REQUEST	ISSUES FOR CONSIDERATION	GUIDANCE
	Will the total cost of treating all eligible patients (including incident and prevalent cases) be £150,000 or less per annum?	Is the Panel assured of the robustness of this estimate? If the criterion is satisfied, the Panel can make a decision for this patient and a policy recommendation to DHSC in respect of future patients. If the criterion is not satisfied, the Panel must reject the individual request and refer to CRC for a policy recommendation.

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

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Ref: IFRP02 Nov 2016