NHS
Bradford District and Craven
Clinical Commissioning Group

Policy and Procedures for Individual Funding Requests

Key information

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Contents

SECTION A: POLICY FOR INDIVIDUAL FUNDING REQUESTS

1. Introduction

1.1 This document describes how NHS Bradford District and Craven CCG (the commissioner) deals with requests for an individual to receive a health care intervention that is not routinely funded by the commissioner.

1.2 For the purpose of this policy, the term 'health care intervention' includes use of a medicine or medical device, diagnostic technique, surgical procedure, and other therapeutic intervention. Commonly, these are themed individual funding requests (IFRs).

1.3 This document has been agreed by the commissioner's Senior Leadership Team (SLT) and will be considered extant from 1 April 2021. The commissioner is clear that it actively owns this policy and is responsible for implementing it.

2. Scope of the policy

2.1 The implementation of this policy and associated procedures, applies to all employees of the commissioner, any staff who are seconded to the commissioner, contract and agency staff and any other individual working on the commissioner's behalf.

2.2 The policy aims to provide a framework for individual funding request decisions, and it should be read in conjunction with other relevant procedures and policies adopted by the commissioner.

3. Accountability and responsibilities

3.1 Decision making within the policy and procedures set out here is the legal responsibility of the commissioner.

4. Summary

4.1 The overall process for dealing with individual funding requests has three key stages:

1. Triage
2. Individual Funding Request (IFR) Panel
3. Appeal Panel

4.2 All these stages are of significance and require appropriate resourcing in terms of workforce and skills. An easy reference summary of the key features of the process is attached at Appendix I (see page 34).

5. Background

5.1 This policy has been developed in response to the legal duties set out in the secretary of state for health and social care's directions to CCGs and trusts, the NHS constitution and a range of guidance as set out below. Specific direction or advice that informs this policy include, but are not limited to:

5.2 The NHS Constitution for England (January 2021); two rights relate specifically to the availability of medicines and other treatments:

5.2.1 You have the right to drugs and treatments that have been recommended by the National Institute for Health and Care Excellence (NICE) for use in the NHS, if your doctor says they are clinically appropriate for you; and

5.2.2 You have the right to expect local decisions on funding and other drugs and treatments to be made rationally following a proper consideration of the evidence. If the local NHS decides not to fund a drug or treatment you and your doctor feel would be right for you, they will explain that decision to you.

6. Development of general policies for interventions

6.1 The commissioner has a statutory responsibility to commission care, including medicines and other treatments, for its population within available resources. Each year, the commissioner plans investment in health care interventions and services as part of its operating plan development process to meet the needs of its local population. Decisions on funding are usually made in collaboration with partners and other stakeholders and are taken in the context of the commissioner's available resources to ensure that care is fairly allocated to all patients and, where appropriate, measured against the commissioner's other service development priorities, the NHS mandate, NICE guidance and national priorities.

6.2 When planning its investments, the commissioner works with partners to identify, as far as possible, those new interventions that are likely to have a significant clinical impact and require funding in the coming years. This is often referred to as horizon scanning.

6.3 Most health care interventions are commissioned as part of the NHS standard contract or contracts with provider partners. However, it is likely that during the year, there will be requests for interventions not covered by the commissioner's policies. The commissioner, therefore, needs to be able to make decisions about these requests that are fair and consistent.

6.4 The commissioner will use a standard individual funding request (IFR) submission form to receive such requests and will triage all such requests to identify whether a funding request submitted on behalf of an individual would apply to a population of patients. Where that is the case, the request will trigger the development of a new policy for that intervention and indication (called a general commissioning policy) or modification of an existing policy.

6.5 The commissioner will make general policies available on request or on its website.

7. Individual Funding Requests

7.1 An individual funding request (IFR) is appropriate where either of the following applies:

7.1.1 The commissioner has a general policy not to fund a health care intervention for the specified indication or health care interventions that are only funded under certain circumstances, but a doctor or dentist considers his/her patient to be 'exceptional' to that policy, or

7.1.2 The commissioner has no policy in place for the requested health care intervention and indication and the clinical circumstance is so rare that it is unlikely that any other patients will require the intervention.

7.2 In responding to an IFR, the commissioner accepts no clinical responsibility for the health care intervention or its use, or for the consequences of not using the intervention.

7.3 Decisions about which health care interventions are to be requested are the responsibility of the referring clinician and the provider organisation. In instances where there is disagreement between clinicians, or between the patient and their clinicians, as to which intervention is to be requested or the manner in which it is to be administered, the commissioner will take no part in these discussions other than to provide current commissioning policies. It is the duty of the referring provider organisation to obtain appropriate arbitration in instances of disagreement between clinicians or between patients and clinicians.

What is 'exceptional'?

7.4 Exceptionality should be considered in the context of the commissioner's general policy for a health care intervention and specified indication.

7.5 In general, the commissioner must justify the grounds upon which it chooses to fund a health care intervention for a patient when that intervention is unavailable to others with the condition.

7.6 A patient may be considered exceptional to the general policy if both the following apply:

7.6.1 The patient is significantly different clinically to the group of patients with the condition in question and at the same stage or progression of the condition; and

7.6.2 There are good grounds to believe the patient is likely to gain significantly more clinical benefit than others in the group of patients with the condition in question and at the same stage of progression of the condition.

7.7 When considering IFRs, the commissioner will use the same ethical framework and guidelines for decision-making that underpin its general policies for health care interventions. Where social, demographic or employment circumstances are not

considered relevant to population-based decisions, these factors will not be considered for IFRs.

7.8 In respect of the IFR processes, social or other non-clinical circumstances will not normally be considered. However, the IFR Panel has the option to include these if it is felt they are sufficiently important – this will be decided on a case-by-case basis, at the discretion of the IFR Panel chair. The rationale for considering a non-clinical factor will be clearly documented in the minute of the meeting, as will the weight that was given to that factor.

7.9 Where a patient has already been established on a health care intervention, for example as part of a clinical trial or following payment for additional private care, this will be considered to neither advantage nor disadvantage the patient. However, response to an intervention will not be an exceptional factor.

8. Triage of requests for individual funding

8.1 Individual funding requests will be accepted from a GP, hospital consultant or dentist where the individual or employing organisation holds a signed NHS standard contract.

8.2 The referring clinician should complete the standard IFR form and submit it to the commissioner within the normal provider governance arrangements. This requires responses to a common set of questions that will assist the commissioner in determining if the patient is exceptional to the general policy.

8.3 The completed form should be sent to the commissioner. The commissioner has an officer that can help with the process if this is required.

8.4 The commissioner will triage the request to see if the requested health care intervention is funded as part of a general policy.

9. Consideration of urgent requests

9.1 The need to make urgent funding decisions should be minimised by horizon scanning and the proactive development of general policies in collaboration with provider partners. However, occasionally, clinical circumstances may require urgent use of a health care intervention that requires an individual funding decision.

9.2 While the commissioner will endeavour to respond to such urgent requests as quickly as possible, this should not compromise the quality and validity of the decision-making process.

9.3 At all times, the provider partner can fund a health care intervention pending a decision from the commissioner. The commissioner accepts no responsibility for the clinical consequences of any delay in responding to an individual funding request.

10. The Individual Funding Request Panel

10.1 The commissioner has a panel called the Individual Funding Request (IFR) Panel, the membership of which includes members who have specific training in the assessment of individual funding requests. The IFR Panel has been established as a sub-committee of the commissioner's SLT.

10.2 The membership of the panel is made up of clinical and lay inputs from commissioning managers, consultants in public health, senior pharmacists, general practitioners (GPs) and is chaired by a lay representative.

10.3 The IFR Panel will receive the request from the referring clinician together with advice from the commissioner's clinical advisors and any other relevant information.

10.4 The referring clinician may submit additional information to the IFR Panel that they consider to be relevant and appropriate.

10.5 Where possible, the commissioner will ensure separation between those who review the clinical evidence for a request and those who make the funding decision.

10.6 The referring clinician, on behalf of the patient, can request copies of the clinical information submitted to the IFR Panel, but may not attend meetings of the IFR Panel.

10.7 Timescales for the process are set out in the policy and procedure document and can be found on page 17.

10.8 The referring clinician will receive a response to the funding request within the agreed timescale. In most cases, and providing all the requested information was submitted, this will be with a decision on funding. However, if further information or clarification is needed, the commissioner will advise the referring clinician of the revised timescale for the decision.

10.9 The decisions made by the IFR Panel are documented.

10.10 The panel's decision may be to fund the individual request or not to fund the request. If a decision cannot be made, the reasons will be made clear to the referring clinician.

10.11 If the commissioner decides to refuse a request to fund a health care intervention for an individual, where the commissioner's general policy is not to fund that treatment, a designated officer of the commissioner (a person responsible for offering advice and guidance) will provide the patient's referring clinician with a written statement of the reasons for the decision.

10.12 The chair of the panel, or designated officer, will inform the patient's referring clinician of the decision.

Principles of decision making

10.13 In making its decision, the panel will, as a minimum, consider the following:

- patient safety

- clinical and cost effectiveness and strength of evidence
- place in therapy relative to available health care interventions
- national guidance and priorities
- local priorities

10.14 An evidence review framework will be used to inform decisions.

10.15 The IFR Panel will work within the standing financial instructions of the commissioner.

11. Appeal

11.1 Where a decision has been made by an IFR Panel not to fund a health care intervention and the referring clinician feels that all relevant clinical information has been provided and considered, but that due process was not followed, the referring clinician may appeal on behalf of the patient. Information on how to do this is contained within the patient information leaflet (see appendix II page 36).

11.2 The purpose of the Appeal Panel is not to review the decision on approval of a request or otherwise, but to review the process through which the decision was reached.

11.3 Appeals are referred to the IFR Appeal Panel. An appeal against the IFR process should be made within three months of the date of the decision letter. The terms of reference of the IFR Appeal Panel can be found on page 32.

11.4 Membership of the IFR Appeal Panel is different to the IFR Panel and will usually include a lay member of the governing body. The IFR Appeal Panel can access expert evidence as required, including from independent clinicians.

11.5 The IFR Appeal Panel provides a procedural review of the IFR Panel process. The IFR Appeal Panel has access to all the relevant documentation about the request, but does not, in general, consider new evidence.

11.5.1 Such review will include:

- Was due process followed? Did the IFR Panel follow is own policies and procedures?;
- Did the IFR Panel consider all the relevant information available at that time?; and
- Was the decision reasonable and in line with the available evidence?

11.6 The patient's referring clinician will be notified of the date of the appeal hearing and be invited to submit statements to the Appeal Panel to support the appeal that the IFR process was not followed.

11.7 Typically, the entire case will be received by the Appeal Panel on paper / PDF without either the appellant or representatives of the IFR Panel being present. However, if, in extraordinary circumstances the Appeal Panel believes that it would benefit the panel to have one 'side' present at the hearing, the other side will also be invited to attend.

11.8 The patient's referring clinician will be sent the set of papers submitted to the IFR Appeal Panel by the IFR Panel.

11.9 The IFR Appeal Panel may decide that the IFR process was followed and to uphold the original decision or it may request the IFR Panel reconsider its decision.

11.10 The chair of the IFR Appeal Panel, or a designated officer, will inform the patient's referring clinician of the decision of the Appeal Panel.

11.11 The decision of the IFR Appeal Panel is final, and no more than one appeal will be heard in respect of one IFR Panel decision.

11.12 If the IFR Appeal Panel decides the IFR Panel process was followed, the IFR Panel will uphold the original decision not to fund an intervention; the patient may choose to complain about the decision within the NHS complaints procedure.

SECTION B: PROCEDURES AND TIMESCALES

1. Summary of overall IFR process

The overall process for dealing with individual funding requests has three key stages:

1.1 Triage – clinical and administrative process:

- The IFR manager receives individual funding requests from referring clinicians
- The associate clinical director for IFR assesses requests against existing policies and for completeness
- Requests for interventions where there is a policy to not fund are returned to the referrer unless explicit evidence of exceptionality is provided
- Further information is requested from the referrer, if necessary, for requests to be submitted to the IFR Panel
- The referrer is informed of timescales for commissioner's decision-making process

1.2 Individual Funding Request Panel process:

- Receives individual funding requests following the triage process
- Receives appraisal of the requested intervention from the associate clinical director for IFR
- Makes a funding decision made and communicates this to the referrer

1.3 IFR Appeal Panel process:

- The IFR manager receives the case with a request for appeal
- A judgement is made, most often by the IFR manager and associate clinical director for IFR, whether additional clinical evidence is offered that had not been previously seen by the IFR Panel and thus the case would need to be reconsidered or whether the appeal is in fact a true appeal
- IFR Appeal Panel provides a procedural review of the appeal
- The decision of the IFR Appeal Panel is communicated to patient's referring clinician

2. Triage process

2.1 All funding requests relating to individual patients are received and processed by the IFR manager, who classifies them as one of:

- Requests for drugs or devices
- Requests for interventional procedures
- Other, including (but not limited to) diagnostic technologies or out of area treatment requests

2.2 These are then processed on a weekly basis by the IFR manager and the associate clinical director for IFR as follows:

a. Requests for drugs or devices are considered against existing policies where they exist or forwarded to the IFR Panel.

b. Requests for interventional procedures are screened against existing policies where they exist.

c. Out of area treatment requests are forwarded to the IFR Panel.

2.3 The screening process can perform only seven actions, these being:

a. Drug requests are forwarded to the IFR process as above.

b. A funding request for an interventional procedure is approved on the basis that the intervention requested is routinely funded under an existing commissioning policy for the clinical condition in question and that the patient satisfies any requirements therein, negating the need for an IFR or any other further action.

c. A funding request for an interventional procedure is approved under prior approval on the basis that the intervention requested is funded under an existing prior approval policy for the clinical condition in question and that the patient satisfies the requirements for prior approval, negating the need for an IFR or any other further action.

d. A funding request for an interventional procedure is declined on the basis that the intervention requested is not routinely funded under an existing commissioning policy for the clinical condition in question.

e. A funding request for an interventional procedure is declined under prior approval on the basis that the intervention requested is funded under an existing prior approval policy for the clinical condition in question and that the patient does not satisfy the requirements for prior approval.

f. If funding for an interventional procedure is declined as set out in (d) and (e) above and the referring clinician has identified appropriate reasons why the patient may be exceptional to the policy, the triage process will pass the request on to the IFR process for consideration, subject to appropriate timescales determined by the urgency of the request. However, if no claim of ‘exceptionality’ is made, the referring clinician will be advised of the funding decision and the general policy and no further action will be taken.

g. When triage process identifies the need for further information, the associate clinical director for IFR or the IFR manager will contact the patient’s referring clinician directly to request it.

3. Individual funding request procedure

3.1 Decisions made by IFR Panel:

a. A decision to fund may be accompanied by conditions or restrictions as may be deemed appropriate by the IFR Panel. This may include a requirement to monitor outcomes to build up an evidence base, or a time limit to funding to assess whether there has been a response. Recommendations made by the IFR Panel to fund a treatment exceptionally will not constitute a precedent.

b. In circumstances where the IFR Panel consider there is disagreement or uncertainty within the evidence submitted about the best way to clinically manage a patient, the panel will make clear that it can take no role in advising on the clinical management of a patient. The role of the IFR Panel is to make decisions on whether to fund an intervention. If the IFR Panel, following advice from clinical advisors, considers that it is not certain exactly what it is being asked to fund; or that there is disagreement on the best course of action within the background to the request, the panel will ask for this to be clarified.

c. The factors considered within each decision made by the IFR Panel will be clearly recorded in the minute of each case. A decision form (see section C page 25) will be used to ensure a standardised approach to recording these factors and the rationale for the decision.

d. If the IFR Panel does not approve a request to fund a health care intervention for an individual, where the commissioner's general policy is not to fund that treatment, a designated officer of the commissioner will provide the referring clinician with the decision and a written statement of the reasons for the decision. If requested, a copy of this information will be sent to the patient's GP/consultant.

e. It is the responsibility of the referring clinician to explain the outcome of the referral request to the patient. The clinician is the advocate of the patient throughout the process. It is expected that, as the advocate of the patient, the referring clinician will provide this information to the patient. In such circumstances that the clinician has explicitly informed the commissioner that they refuse to do so, the commissioner will produce a written statement explaining to the patient the rationale for the decision; this will be copied to the referring clinician. This statement will be an extract from the minutes of the meeting or a file note of the decision made outside of IFR panel.

f. Referring clinicians may make a fresh referral where circumstances change and/or additional information becomes available.

g. Following approval, referrals must be made without delay and within 14 calendar days.

3.2 Cases where there is insufficient time to consider the request in full:

a. There may be rare occasions where treatment needs to be given before funding can be agreed.

For example, if a request is received by the commissioner on the day that treatment is to be commenced and a funding decision cannot be completed in such a short timescale (for example if a new treatment is being requested and the evidence has not yet been reviewed).

b. Under these circumstances it is the sole responsibility of the provider to decide whether the treatment will be given before funding can be approved. The commissioner accepts no responsibility for this decision.

c. Funding requests made after a treatment has been commenced will rarely be funded, other than in cases where there is overriding and urgent clinical need, or where delay would be life threatening. Referrals deemed by the IFR Panel to be outside of this will not be funded.

d. In all circumstances, it is the sole responsibility of the provider and/or the treating clinician to decide whether to proceed with treatment before approval for funding has been obtained from the commissioner. The commissioner accepts no clinical risk.

4. Procedure for appeal panel

4.1 Patients may request their GP or consultant to notify the commissioner of their wish to appeal against the decision-making process of the IFR Panel. Appeals should be sent to the commissioner's IFR manager. Appeals require the support of the patient's referring clinician.

4.2 On receipt of an appeal, the IFR manager and associate clinical director for IFR will review the submitted documentation to determine whether the request to appeal is, in fact, a 'true' appeal or whether additional clinical evidence is offered that had not been previously seen by the IFR Panel and thus the case would need to be reconsidered by the IFR Panel. If there is clinical information that has not been considered by the IFR Panel, the IFR manager will bring this to the attention of the IFR Panel at its next meeting and the case will be reconsidered.

4.3 If there is no new clinical information and a judgement is made that the request is a true appeal against IFR process, the IFR manager will convene the IFR Appeal Panel.

4.4 Any appeal must be received by the IFR Appeal Panel within three months of the date of the decision letter. The Appeal Panel will meet as necessary and will consider all appeals within 20 working days of the appeal letter having been received.

4.5 The Appeal Panel may access expert evidence as required, including that from independent clinicians, but will not as a rule, consider new evidence. That is a matter for the IFR Panel.

4.6 The role of the Appeal Panel is to review the process of decision making and determine whether it was robust and duly considered all relevant evidence.

If the Appeal Panel finds that a failure in process has occurred, the IFR Panel will be instructed to reconsider the case. The purpose of the Appeal Panel is not to review the decision on approval of a request or otherwise, but to review the process through which the decision was reached.

4.7 Such a review by the IFR Appeal Panel will typically include:

- Was due process followed? Did the panel follow its own policies and procedures?
- Did the IFR Panel consider all of the relevant information available at the time?
- Was the decision rational and in line with existing policy and evidence?

4.8 Appeals, and any subsequent rehearing of a case that is instructed by the Appeal Panel, will be heard in accordance with the policy and procedures that were in place at the time of the original review of the case by the IFR Panel. Where a decision relates to a specific treatment, appeals and subsequent re-hearings will be held in accordance with the commissioning policy pertaining to that treatment at the time of the appeal and any re-hearing.

4.9 The patient's referring clinician will be notified of the date of the appeal hearing.

4.10 If the referring clinician/patient believes that important evidence was not submitted in the original process, the referring clinician may submit this evidence no later than five working days before the date of the Appeal Panel. The associate clinical director for IFR may provide advice to the IFR Panel chair and IFR Appeal Panel chair on whether the new evidence should be considered by the IFR Panel in a re-hearing of the case, as opposed to the IFR Appeal Panel.

4.11 Typically, the entire case will be received by the Appeal Panel on paper without either side (namely, the appellant or a representative of the IFR Panel) being present. However, if, in extraordinary circumstances, the Appeal Panel believes that it would benefit the panel to have one side present at the hearing, the other side will also be invited to attend. A member of the IFR Panel may also be available to attend the Appeal Panel to answer any queries regarding process/procedures.

4.12 The Appeal Panel may decide to uphold the original decision or to ask the IFR Panel to reconsider the case.

4.13 Where the Appeal Panel decide that the proper process has not been followed, they will communicate this to the chair of the IFR Panel. In these circumstances, the IFR Panel will be instructed to put right the process within a further 30 working days.

4.14 The chair of the Appeal Panel, or a designated officer, will inform the patient's referring clinician of the decision of the Appeal Panel within 10 working days of the Appeal Panel meeting.

4.15 Patients or referring clinicians who remain dissatisfied following the outcome of the process may take up the matter through the commissioner's complaints procedures, and/or legal processes.

5. Timescales

5.1 Triage: IFR requests will normally be triaged within five working days.

5.2 Urgent requests

5.2.1 The referring clinician must make it clear that 'urgent requests' are based on clinical need, for example a missed therapeutic window or a rapid or marked deterioration of the patient's condition if the decision is delayed.

5.2.2 While the commissioner will endeavour to respond to such urgent requests as quickly as possible – assuming the commissioner has all the information required to decide, this should not compromise the quality or validity of the decision-making process. The length of time required to adequately research information and evidence to make an urgent funding decision is at the discretion of the members of the IFR Panel involved in the process. The IFR Panel members involved will make efforts to reach a decision as quickly as possible; however, the commissioner reserves the right to stipulate a minimum of five days to complete the decision-making process. At all times the provider can fund a health care intervention pending a decision from the commissioner and the commissioner accepts no responsibility for the clinical consequences of any delay in responding to the request.

5.2.3 If the request does not specify urgency, but the associate clinical director for IFR considers that the request may have some clinical urgency, the IFR manager will contact the referring clinician within two working days of triage. The following question will be asked of the referrer – 'is there a clinical urgency in this case that requires a decision prior to the date of the IFR Panel meeting? If so, please outline the nature of the urgency and the date by which a decision is required'.

5.3 Decisions made outside of panel: requests notified as urgent will be considered within five working days of the request.

5.4 IFR Panel meeting: all IFR requests will be heard by the IFR Panel or the associate clinical director for IFR with appropriate wider input within 30 working days of the request and all relevant information being received. The IFR Panel meets once a month.

5.5 Request for further information: if no response is received within 6 weeks of the date of the letter requesting further information, then the IFR process will assume no further action is required/the patient no longer wishes to pursue treatment and the IFR manager/associate clinical director for IFR will close the file

5.6 Decision letters from IFR Panel: decision letters will be sent to the patient's referring clinician within 10 working days of the decision having been made.

5.7 Appeal

5.7.1 An appeal must be received by the IFR manager within three calendar months of the date of the decision letter to the referring clinician.

5.7.2 The Appeal Panel will be convened within 20 working days of the appeal letter being received by the IFR manager.

5.7.3 A decision letter following the appeal hearing will be sent to the referring clinician within 10 working days of the hearing.

5.7.4 When a decision is referred back to the IFR Panel following an appeal hearing, the request must be reconsidered within 30 working days of the Appeal Panel hearing.

5.7.5 In general, in circumstances where a case is reheard (following the recommendation of the Appeal Panel for example), the policy that is extant at the time of the rehearing will be used to guide the rehearing.

SECTION C: IFR DOCUMENTATION

1. Guidance on the completion of forms

1.1 General guidelines for completion of IFR form:

1.1.1 Requests for funding will only be considered if submitted on the IFR form. Requests not complying with this requirement will be returned to the referring clinician with advice to resubmit on the relevant documentation.

1.1.2 If an urgent (ie before the next IFR Panel meeting) response is required, the clinical justification for this should be made clear.

1.1.3 Any deadline will commence on receipt of the request form by the IFR manager.

1.1.4 In order to preserve anonymity in dealing with the referral request, the only patient details which should be included are NHS number, date of birth and gender.

1.1.5 The request should provide as much detail as possible about the assessment or treatment to which referral is requested. As a minimum this should include information on clinical effectiveness evidence, clinical context for the patient, rationale for why the funding request should be considered exceptional, assurance that a procedure or drug is approved for use in the requested indication by a drug and therapeutic committee or committee of equal standing, or by chairman's action.

1.1.6 Responsibility for demonstration of exceptionality lies with the referring clinician. Referrers are responsible for providing information explaining why the funding request should be considered exceptional to the commissioner's policy not to fund the requested intervention.

1.1.7 Referrers must provide specific information to justify that the patient meets both requirements of the exceptionality criteria:

a. explain how the patient is different clinically to the group of patients with the condition in question and at the same stage of progression of the condition; and

b. explain the grounds for believing that the patient is likely to gain significantly more clinical benefit than others in the group of patients with the condition in question and at the same stage of progression of the condition.

1.1.8 Referrers are reminded that:

a. referral requests will not be granted <u>after</u> referral to a provider for assessment or treatment has already been made;

b. funding requests with insufficient information to make a robust decision may be returned to the referring clinician for further details to be supplied;

c. at all times the patient's referring clinician remains clinically responsible until a referral request, having been granted, is accepted by the chosen provider; and

d. it is the referring clinician's responsibility to inform the patient of the IFR Panel decision promptly.

1.1.9 Referral request and appeals should be made in writing and/or emailed to the IFR manager.

Individual Funding Request Form

PART A: For all cases

PART B: Cosmetic procedures (complete pages 1 – 2)

PART C: Drug requests (complete pages 1, 3 and 4)

PART A: for all cases	
PATIENT DETAILS AND CLINICAL CONTEXT: to be completed by referring clinician	
Name and contact details of referring clinician	
Name and address of GP	
Patient's NHS Number	
Patient's Date of Birth	
Details of treatment / procedure referral	
Has this referral been matched against a commissioning policy?	YES / NO
Have further details of relevant clinical treatment been attached?	YES / NO
EXCEPTIONALITY	
How is the patient significantly different clinically to the group of patients with the condition in question and at the same stage of progression of the condition?	
What are the grounds for believing that this patient is likely to gain significantly more clinical benefit than others in the group of patients with the condition in question at the same stage of progression of the condition?	

Signed	**Date signed**

PART B: cosmetic procedures	
Weight: **BMI:** (please specify for drug request also)	**Breast size (breast surgery only)**

Categorisation

1	**Reconstructive**	☐		
	a		Trauma and surgery; acute repair and acute reconstruction	☐
	b		Cancer surgery and reconstruction	☐
	c		Burns; acute care and reconstruction	☐
2	**Functional**	☐		
	a		Surgery is requested to manage pain	☐
	b		Surgery is requested to manage a skin condition	☐
	c		Surgery is requested to manage restriction of movement	☐
	d		Surgery is requested to manage a diagnosed psychiatric condition associated with unhappiness with body image	☐
	e		Other (please specify):	☐
3	**Aesthetic**	☐		
	a		Surgery is requested due to unhappiness with body image unrelated to a diagnosed psychiatric illness	☐
	b		Surgery is requested for a child or adolescent in order to mitigate against developmental problems e.g. bullying	☐
	c		An anatomical defect has resulted in noticeable asymmetry	☐
	d		A congenital or developmental malformation has resulted in unhappiness with body image	☐
	e		Other (please specify):	☐
4	**Opportunistic**	☐		
			Surgery is requested to augment another procedure in order to maximise outcome	☐
5	**Other (please specify)**	☐		

PART C: Drug requests	
Drug treatment	
Indication for use	
Is the drug licensed for the intended use?	
When was treatment approved for this indication by the DTC/Chairman's action	
State patient selection criteria agreed by DTC	
Is the treatment part of a current or planned clinical trial or audit?	

EVIDENCE BASE AND CLINICAL CONTEXT	
Is there a NICE or another approved treatment pathway for this condition?	
If yes, explain why it is unsuitable for this patient	
Anticipated start date?	
CLINICAL BACKGROUND	
Outline the clinical situation, including: • previous and current therapies and treatment tried, intolerance and response • current symptoms • anticipated prognosis if treatment requested *IS NOT* funded (include what treatment will be given to the patient) • anticipated clinical benefits if the treatment request *IS* funded in this patient	
How frequently has your unit undertaken this treatment and what were the results?	
Is this a single treatment or part of a course?	

If part of a treatment course, what is the number of doses that will be given and at what intervals?	
What is the total length of time of the proposed course of treatment?	
What clinical outcomes will be used to assess response and how will they be used to determine when the treatment is ineffective?	
BROADER CONTEXT & SERVICE / PATHWAY IMPLICATIONS	
How often would you expect to request this treatment for this condition at this stage of progression of the condition for a given size of population?	
What is the cost of the treatment/procedure and how does this compare with the cost of the standard therapy it replaces?	
ADDITIONAL COMMENTS/ CONSIDERATIONS FOR THE IFR PANEL TO CONSIDER	
Clinicians are required to provide all relevant correspondence with this request	

Decision made in panel form

Reference code:
Date:

Approved / not approved (delete as applicable) on the basis of:

1. Complies with NICE TAG **Specify:**	**Yes** ☐ **No** ☐
2. Complies with local commissioning policy **Specify:**	**Yes** ☐ **No** ☐
3. Prior approval **Specify:**	**Yes** ☐ **No** ☐
4. Exceptionality **Specify criteria 1:** **Specify criteria 2:** **Specify reference population:**	**Yes** ☐ **No** ☐
5. Other **Specify:**	☐

Literature referenced:

-

Patient factors:

-

Other factors:

-

Date of IFR Panel meeting

SECTION D: TERMS OF REFERENCE

Individual Funding Request (IFR) Panel Terms of Reference

1. Accountability arrangements and authority

The Individual Funding Request (IFR) Panel has been established as a sub-committee of the NHS Bradford District and Craven CCG Senior Leadership Team (SLT).

The remit, responsibilities, membership and reporting arrangements of the IFR Panel are set out in these terms of reference. The IFR Panel has no executive powers other than those specifically delegated in these terms of reference.

The IFR Panel is accountable to SLT and will provide SLT with assurance on the discharge of its duties.

2. Relationships and reporting

The IFR Panel is accountable to the SLT.

The GP representatives and / or lay chair of the IFR Panel shall draw to the attention of the SLT any significant issues or risks.

Draft minutes of IFR Panel meetings will be circulated to members and be subject to ratification by the next meeting.

The IFR Panel will present an annual report to the SLT covering the following aspects:

- data on requests received and the outcomes of these;
- themes and trends arising from requests received and any implications relating to commissioning policies or intentions;
- a summary of the key issues arising during the year; and
- whether and how the committee has met and performed its function, in compliance with its terms of reference.

3. Role and function

The role of the IFR Panel is:

- To make decisions on those individual funding requests referred to the panel in line with the CCG's IFR policy and procedures; and
- To advise on the development and / or amendment of commissioning policies arising from the work of the panel.

4. Responsibilities

4.1 IFR triage and decisions

- To review the triaging of requests by the associate clinical director for IFR to ensure these have been appropriately applied in line with the CCG IFR policy and procedures
- To make decisions on those individual funding requests referred to the panel in line with the CCG's IFR policy and procedures

*[*The panel makes decisions on whether requests can be funded in line with IFR policy and procedures. The decision as to whether a treatment (for which funding has been approved) should be recommended to a patient, lies with the referring clinician.]*

4.2 Commissioning policies

- Where there is a possibility that the approval of an IFR would, in fact, constitute the development of a service, the IFR Panel will provide expert advice in developing commissioning policies that are not covered by existing contracts with providers. Where a new commissioning policy is required, the evidence review will be undertaken by public health colleagues who will, in turn, inform the development of the policy by the CCG. Such commissioning policies will be submitted for approval to the SLT.

5. Membership and attendees

The voting members of the IFR panel are:

Voting Member	Role on IFR panel
Lay chair (who has a standing invitation to attend and contribute to governing body meetings, but who is not a member of the governing body)	Ensure the efficient and effective operation of IFR Panel meetings. Input to IFR Panel discussions and decisions from a lay perspective.
Strategic clinical director	To provide additional clinical input to discussions and decision-making consistent with CCG strategy. To provide clinical oversight and assurance to SLT and governing body on the functioning of the IFR process. To identify clinical and non-clinical risk to the CCG from panel decisions.

Voting Member	Role on IFR panel
Strategic director organisation effectiveness (chief of staff)	Ensures the reputation of the CCG is protected throughout decision-making, representing the SLT on corporate governance, risk and assurance.
GP member	Provide GP clinical input to IFR Panel discussions and decisions.
Senior medicines management representative	Provide input on medicines related matters, including relevant NICE guidance. Provide clinical input (prescriber) to IFR Panel discussion and decisions.
Senior commissioning representative	Provides input on existing CCG policies to inform IFR Panel discussion and decisions. Oversee the development of new commissioning policies where necessary in light of IFRs received.

Members may send deputies to represent them. Deputies will count towards quorum and will have voting rights. Members are normally expected to attend at least 75% of meetings during the year.

The following individuals are expected to attend IFR Panel meetings in an advisory, non- voting capacity:

Attendee (non-voting)	Role on IFR PANEL
Associate clinical director for IFR	Identifies IFRs that require consideration at IFR Panel meetings. Presents cases to panel with all relevant information and in a manner to ensure equity. Provides expert advice to support the IFR Panel in its discussion and decisions.
Senior public health representative	Undertakes evidence reviews to inform the IFR Panel discussions and decisions.
IFR manager	Minute-taking and input relating to the administration of IFRs.

Other CCG staff may be requested to attend in an advisory capacity. Any member of SLT is entitled to attend this committee with observer status.

6. Chair

The chair of the IFR Panel shall be a lay representative, appointed by the clinical chair.

Where the IFR Panel chair cannot attend, or is conflicted, committee members present will elect one of their number to act as the chair on that occasion.

7. Decision-making & voting

Generally, it is expected that panels decisions (including recommendations on the approval or otherwise of IFRs) will be reached by consensus.

Should this not be possible, each voting member of the IFR Panel will have one vote. Decisions will be by majority vote.

In the event of a tied vote, the chair of the IFR Panel will have the second and casting vote.

Should a vote be taken, the outcome of the vote and any dissenting views will be recorded in the minutes of the meeting.

8. Quorum

The committee will be quorate when four voting members are present, including two clinical* members. At least one of the minimum of two clinical members entitled to vote will be a currently active clinician who practices with patients in Bradford district and Craven.

*[*In this context, clinician is defined as someone of good standing with a recognised regulatory body in the field of healthcare.]*

Any voting member who is also a clinician (even if that is not their primary reason for attendance) can count towards quoracy of four voting members, two of whom will be clinicians.

9. Frequency of meetings

The IFR Panel will normally meet monthly, with a minimum of 10 meetings per annum.

10. Conduct

The IFR Panel will have due regard to, and operate within, the constitution, standing orders, the scheme of delegation, the prime financial policies and other policies and procedures of the CCG.

The IFR Panel will conduct its business in accordance with relevant national guidance, including codes of practice such as the Nolan principles, which are included in the CCG constitution.

11. Management of conflicts of interest

The IFR Panel will adhere to the CCG's business conduct and conflicts of interest policy.

If any member of the IFR Panel has an actual or potential conflict of interest in any matter on the agenda and is present at the meeting at which the matter is under discussion, they will declare that interest at the start of the meeting and again at the relevant agenda item.

This shall be recorded in the minutes (note: this includes where an IFR is being considered for a patient at a practice where a GP member of the panel is employed or is a partner).

The chair of the meeting will determine how any interests declared will be managed in accordance with the CCG's business conduct and conflicts of interest policy.

The minutes must specify how the chair decided to manage the declared interest, i.e. did the individual(s) concerned:

- take part in the discussion but not in the decision-taking
- not take part in either the discussion or decision-taking
- take part in the discussion and left the meeting for the decision or
- left the meeting for the whole of the item

In making this decision the chair will need to consider the following points:

- the nature and materiality of the decision
- the nature and materiality of the declared interest(s)
- the availability of relevant expertise and
- as a general rule (and subject to the judgement of the chair), if an interest involves a financial interest or a significant non-financial interest, the individual should be asked to leave the meeting for the whole item

12. Administration and support

The IFR manager will provide administrative support to the IFR Panel and will ensure that papers are issued at least five working days before a meeting and that draft minutes are circulated within 10 working days after a meeting.

The associate clinical director for IFR and all members of the IFR Panel are responsible for supporting the chair in the management of the IFR Panel's business and for drawing the panel's attention to best practice, national guidance and other relevant documents as appropriate.

13. Urgent matters arising between meetings

It is important that urgent funding decisions are not delayed due to the timing of IFR Panel meetings. The IFR Panel may meet on a virtual basis (i.e. undertake panel business by videoconference, teleconference or email) when necessary to do so. Videoconferences and/or teleconferences shall be minuted and a full audit trail retained of any decision-making undertaken via email.

14. Monitoring of performance and compliance

The IFR Panel will review its own effectiveness, its compliance with its terms of reference and the terms of reference document itself at least annually and a report of the outcomes of this review will be produced and reported to the SLT. The panel will consider external review of effectiveness every two years.

15. Terms of reference review date and approving body

Annually (during quarter one of the year), or as and when legislation or best practice guidance is updated.

Any amended terms of reference will be proposed by the IFR Panel for approval by a subsequent meeting of the CCG's SLT.

Enquiries: batpct.clinicalpriorities@nhs.net

Version Control

V.	Detail	Approval
V1.0	First version for BDC CCG	Approved by Chair's action 01.04.20 and subsequently reported to SLT.
V2.0	Amendments to role titles, membership and quorum	Approved by SLT 12.08.20 Adopted by the IFRP from 22.09.20

IFR Appeal Panel Terms of Reference

1. Chair

The Chair will be nominated by the commissioner's accountable officer.

2. Principal purpose

The role of the Appeal Panel is to review the process and rationality of decision making. If the Appeal Panel finds that a failure in process has occurred, the IFR Panel will be instructed to put right the process and reconsider the case. The purpose of the Appeal Panel is not to review the decision itself, but to review the process through which the decision was reached.

The IFR Panel should work within the IFR policy and procedures agreed by the SLT.

3. Principal duties

The principal function of the Appeal Panel is to determine that due process has been followed in reaching a reasonable decision. The panel will consider appeals made by referring clinicians (on behalf of their patients) that the IFR Panel have not properly followed the approved IFR policy and procedures. It is not to review the individual details of a case.

Potential outcomes of Appeal Panel meetings include:

Finding:	The decision of the IFR Panel was reasonable and due process was followed
Outcome:	Decision upheld
Finding:	Due process was not followed by the IFR Panel
Remedy:	The IFR Panel will be instructed to put right the process and reconsider the case within 30 working days following the appeal panel hearing
Finding:	The decision did not take into account all the relevant information available to the IFR Panel
Remedy:	Refer the decision back to the next IFR Panel meeting with an instruction to consider all the relevant information. The timescale for this is 30 working days from the Appeal Panel hearing
Finding:	The IFR Panel did not take into account significant new evidence as it was not available to the panel. The new evidence or information may or may not affect the original decision of the panel
Remedy:	Refer the decision back to the next IFR Panel meeting with an instruction to consider all the new information. The timescale for this is 30 working days from the Appeal Panel hearing

A summary report on the work of the Appeal Panel will be provided to the SLT on a frequency set by the SLT or when requested by the SLT.

Remuneration for panel members will be agreed within the relevant commissioner policies.

4. Membership

The Appeal Panel will be chaired by a lay member and will include an SLT clinician and a lay governing body member. All members of the Appeal Panel should not have been involved in the original IFR Panel decision.

Proposed members of the panel will declare any interest in a particular case and will then take no part in an Appeal Panel concerning that patient.

5. Attendance and quorum

All three members are required for the Appeal Panel to be quorate.

6. Frequency of meetings

The panel will meet as necessary to meet the timescales laid down within the policy and procedures.

7. Accountability

The Appeal Panel is accountable to the Senior Leadership Team.

APPENDIX I: DECISION-MAKING FRAMEWORKS FOR IFRs

Factors that may be considered in informing decisions on IFRs

For each disease and proposed treatment/intervention, a funding request will be considered against a range of factors to ensure that an informed decision can be made. These will include:

1. The disease

- symptoms
- impact on quality of life
- course of disease
- prognosis
- treatment options

2. Impact on quality of life

- criteria for initiating treatment
- criteria relating to duration of treatment or pre-determined response requirements for continuation of treatment
- how the treatment will be delivered

3. Scientific evidence

- clinical effectiveness and outcomes
- economic evaluation – cost-effectiveness ratio falls above the commonly used NICE threshold per additional quality-adjusted life year (QUALY), the following factors will be considered:
    - the degree of uncertainty surrounding the calculation of the QUALY
    - the innovative nature of the technology
    - the features of the condition and the population receiving the technology
    - instances where there are wider societal costs and benefits
- quality and nature of evidence
- safety and adverse effects

4. Guidelines and best practice

- international
- national
- regional
- local
- specialist professional bodies

5. Cost

Considering cost in IFRs is a difficult issue. It is one of many considerations and may occasionally be a factor in the decision-making process. Where the policy is to not routinely fund a treatment but where exceptional clinical circumstances are cited, cost of the intervention will very rarely be considered in the decision-making process – which should be entirely driven by considerations of exceptionality.

Where there is no commissioning policy for a treatment – i.e. a "true IFR" the IFR Panel is, in effect, making a commissioning decision – cost is a factor. Cost information should be available to the IFR Panel, but should only be a part of the decision making process. If cost of the intervention is considered, it should be carefully documented what role cost played in the decision making process.

There are circumstances where the level of funding requested is beyond the standing financial instructions of the members of the IFR Panel. In such circumstances the chair of the IFR Panel will take a recommendation of the panel to the commissioner's accountable officer or the chief finance officer, cost will (by definition) be considered in these circumstances. The type of cost information that may be considered is:

- cost of the treatment, absolute affordability
- associated treatment and diagnostic costs
- opportunity cost
- scope for efficiency savings

6. Others

- alternative treatments and why they are not being used
- identification of new ethical or policy issues
- precedent
- impact on existing services
- exceptional circumstances
- legislation, national and local priorities

APPENDIX II: PATIENT INFORMATION LEAFLET

Will the NHS in Bradford district and Craven pay for my treatment?

Information for patients

This leaflet aims to give you a brief summary of the process to request funding for treatments and procedures which are not routinely commissioned in Bradford district and Craven.

Funding health services

The Clinical Commissioning Group (CCG) in Bradford district and Craven is responsible for planning and buying the health services that local people need. This includes hospital services, community services, mental health and learning disability services and emergency and urgent healthcare.

The demand for healthcare services is increasing and new and often expensive treatments are regularly becoming available. We only have a set amount of money to spend, so we need to make sure that we make the best use of our budget (with the use of clinical evidence) so that people living in Bradford district and Craven can achieve the best outcome and access the healthcare services they need. Each year we identify our priorities and agree a plan for the following year. The CCG has to make difficult decisions about whether to fund treatments for people outside that plan.

What if a treatment is not normally available?

We have a policy called an Individual Funding Request (IFR) policy that sets out how we should assess a request for funding to provide a treatment or service for an individual patient.

Underpinning this IFR policy is a range of other policies about the treatments and services that are not routinely available.

Your GP or NHS consultant can approach the CCG to ask on your behalf for funding that is not routinely available for one of two reasons:

1. You have a medical condition that is rare or is not covered by general policies for treatment
2. He or she feels that there are exceptional clinical circumstances in your case and would need to show that your circumstances differ greatly from that of the majority of patients with the same medical condition. They would also need to show that you are likely to gain more benefit than they would normally expect to see

If your doctor can show that both of these apply in your case, then they can contact us on your behalf with an individual funding request to pay for a treatment that we would not normally provide.

Clinical commissioning groups are not responsible for buying all health services; NHS England is also responsible for some services. Your doctor will know who to make the request to. More information at www.england.nhs.uk

Making an IFR

If you would like to request a treatment that we don't normally provide, please discuss this with your GP or hospital consultant. They will complete an application form on your behalf and send it to us, along with any supporting information. They will need to demonstrate why they feel that your request has exceptional clinical circumstances. Each request is considered individually and so we encourage your GP or hospital consultant to provide us with supporting evidence, for example how your condition affects your daily life.

Any contact or additional information that may need to be supplied to the panel should be done via your GP or consultant.

How do we decide what treatments to fund?

We know that this can sometimes be difficult to define for each patient, and so the overarching individual funding request policy and procedure document sets out how we assess each application and how we make our decisions. We aim to make these difficult decisions in a way that is fair and consistent by using the underpinning policies.

How will a decision be made?

We have a panel of specially trained people that meet once a month which considers each individual request.

Who sits on the panel?

The panel is made up of a mix of clinically qualified people (general practitioners and pharmacists, consultants in public health, and commissioning managers). They will consider each application, and they have the expertise to assess all the evidence that your doctor has provided. Sometimes we may go back to your doctor or consultant for additional information to support your request.

A trained lay representative will also attend the panels to make sure that the proper process is followed and consistent decisions are made.

What is the decision making process?

Your GP or hospital consultant will make a referral to the Individual Funding Request Panel which meets monthly. Your doctor will be sent the decision made by the panel within ten working days of the meeting.

Can I contact the panel?

No. If you want to make the panel aware of any additional information, you should do this via your GP or consultant as they act as your advocate throughout the entire process. You would also not be able to attend the panel meeting.

How will I know what the decision is?

Your doctor will contact you to let you know what the decision is. In some cases, where approval has been given, there may be conditions or restrictions on your treatment.

Making an appeal

To make an appeal against the outcome of an individual funding request, your GP or consultant must put an appeal in writing to the IFR Manager. The Appeals Panel is different to the IFR Panel and will include a lay member of the governing body. An appeal will not be heard just on the grounds that you disagree with the original decision.

Appeals can only be made if you think that

- The panel didn't follow the agreed process
- The panel did not consider all of the relevant information that was available to them
- The panel acted outside of its authority or a decision was made that was contrary to a principle of law

The appeals process includes situations where the Appeals Panel identifies that there was additional evidence that was not made available. If the appeal is rejected, a clear explanation will be given to your GP / consultant. If the appeal is accepted, it will be returned to the IFR Panel to be considered again.

Making a complaint

If you remain unhappy with the response you received following your appeal, you have the right to make a formal complaint. To do this you can:

Write to:

Patient support team, NHS Bradford District and Craven CCG,

Scorex House (West), 1 Bolton Road, Bradford BD1 4AS

Telephone:

07583 102430 / 07866 015382

E-mail:

bdc.complaints@nhs.net

If you remain unhappy after speaking to our patient support line, you have the right to refer your request to the Parliamentary and Health Service Ombudsman

Write to:

The Parliamentary and Health Service Ombudsman

Millbank Tower, Millbank, London, SW1P 4QP

E-mail:

phso.enquiries@ombudsman.org.uk

APPENDIX III: EQUALITY STATEMENT

Promoting equality and addressing health inequalities are at the heart of Bradford District and Craven CCG's values. Throughout the development of this policy statement, we have:

- given due regard to the need to eliminate discrimination, harassment and victimisation, to advance equality of opportunity, and to foster good relations between people who share a relevant protected characteristic (as cited under the Equality Act 2010) and those who do not share it

  and

- given regard to the need to reduce inequalities between patients in access to, and outcomes from healthcare services and to ensure services are provided in an integrated way where this might reduce health inequalities

APPENDIX IV: RETENTION PERIOD

All national and local NHS policies regarding confidentiality, retention and destruction of records will be adhered to in line with the law and national guidance:

www.nhsx.nhs.uk/media/documents/NHSX_Records_Management_Code_of_Practice_2020_3.pdf