

Policy for the Management of Individual Funding Requests

Ref:	LSCICB_Clin04
Version:	2.1
Purpose	This document is part of a governance framework adopted by the Integrated Care Board (ICB) to inform the commissioning of Individual Funding Requests (IFRs)
Supersedes:	2
Author (inc Job Title):	Under Review
Ratified by: (Name of responsible Committee)	ICB Board (adopted 1 July 2022)
Cross reference to other Policies/Guidance	<ul style="list-style-type: none"> • A Statement of Principles • Policy for Individual Funding Request Decision Making • Policy for the Consideration of Applications for Exceptionality to Commissioning of Healthcare Policies • Policies for the Commissioning of Healthcare
Date Ratified:	1 July 2022 (date adopted)
Date Published and where (Intranet or Website):	July 2022 (Website)
Review date:	19 June 2022 (under review)
Target audience:	All LSC ICB Staff

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Document control:		
Date:	Version Number:	Section and Description of Change
June 2020	V2	Ratified by Lancashire and South Cumbria Clinical Commissioning Groups (CCGs)
July 2022	V2.1	Policy adopted by Lancashire and South Cumbria ICB – references to CCG replaced by ICB where relevant

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1. Introduction

- 1.1 The NHS belongs to us all. It is there to improve our health and well-being, support us to keep mentally and physically well, to get better when we are ill and, when we cannot fully recover, to stay as well as we can to the end of our lives.
- 1.2 To make sure that we can provide the best care for the maximum number of people it is vital that we make every penny count. This means funding procedures and treatments that have been demonstrated to work and where there is a high likelihood of benefit and a low likelihood of harm. Carrying out procedures such as operations that are not of great health benefit uses up resources that could be spent on really making a difference elsewhere. As happens in other parts of the country, we may decide that a treatment or procedure should not be routinely funded because:
- There is only limited or no evidence of its effectiveness (whether it works or not)
 - It is considered a low priority for funding, (for example, cosmetic surgery) compared to other treatments (for example, dementia or stroke care)
- 1.3 This document outlines the process by which the Integrated Care Board (ICB) manages and administers applications for funding for treatments for individuals in accordance with the *General Policy for Individual Funding Request Decision Making*, the *Statement of Principles* and the *Policy for Considering Applications for Exceptionality to Commissioning Policies*.
- 1.4 Lancashire and South Cumbria ICB is responsible for making the decisions to fulfil its legal obligations, duties and responsibilities for its own patient population. Therefore, it is for the ICB to ultimately decide whether an IFR should be funded.
- 1.5 ICBs may commission business support services to help with the administration and process of IFR's. Lancashire and South Cumbria ICB currently purchases these services from NHS Midlands and Lancashire Commissioning Support Unit (MLCSU).
- 1.6 It is important to remember that, while the NHS does not want to carry out procedures or treatments which have little health benefit in general, there may be overwhelming health benefits for an individual patient. In these cases, a doctor, on behalf of a patient, will explain the exceptional circumstances and request that these are considered through the IFR process. A decision will be made on an individual case basis whether the NHS will fund the procedure. The process for requesting funding on an individual patient basis is detailed in this document below. This process is applied consistently.
- 1.7 The IFR process identifies whether:
- the request is for a commissioned service in accordance with a clinical commissioning policy, or
 - whether the request is for a commissioned service as an exception to a clinical commissioning policy, or
 - whether the request is a service development that is not currently commissioned, or
 - whether the request should be assessed empirically as a rare case for which the ICB would not expect to commission a service for a cohort of patients
- 1.8 A *Service Development* can be defined as a change to the ICB's portfolio of service

agreements such that a particular new healthcare intervention shall be routinely commissioned for a defined group of patients. Service developments are likely to result from a prioritisation process. Some requests for healthcare will more appropriately be considered as service developments than as individual funding requests.

- 1.9 This document forms part of the governance framework in relation to IFRs and should be read in conjunction with the *General Policy for Individual Funding Request Decision Making, Policies for the Commissioning of Healthcare, Statement of Principles* and the *Policy for Considering Applications for Exceptionality to Commissioning Policies*.

2. Information Governance and Confidentiality

- 2.1 To support consistency and enable effective governance of all requests received, MLCSU will hold patient level information on behalf of the ICBs to support the IFR process. All patient information will be handled in confidence and stored in accordance with the Information Governance Framework relating to person identifiable information.
- 2.2 IFR Panel members will consider the need for confidentiality and operate under the Caldicott guidelines. All patient specific electronic communication will be via a secure method in line with the Information Governance framework.
- 2.3 MLCSU will, on behalf of the ICB, keep a full set of information electronically.
- 2.4 Electronic records and IFR panel minutes will be saved securely and access will be available to authorised staff only.
- 2.5 MLCSU IFR processes will always comply with information privacy, confidentiality and security, legal and regulatory requirements and best practice. MLCSU will fully respect patient confidentiality and ensure that patient information is not collected, processed or shared without valid patient consent or another legal basis.

3. Submitting an Individual Funding Request (IFR)

- 3.1 Funding applications can be made in either Primary or Secondary Care. Applications for funding should ideally be made by the clinician who has the most knowledge of the condition and intervention the request relates to.
- 3.2 All applications, except for applications on behalf of patients registered with a Morecambe Bay GP Practice, must be submitted by a clinician using the IFR Application Form (Appendix 4) which can be obtained from the IFR Team or ICB web site. For Morecambe Bay GP registered patients please complete the online application form via the following link <https://www.morecambebayccg.nhs.uk/about-us/policies-and-procedures>
- 3.3 The Terms of Reference for the Individual Funding Request Team is shown in Appendix 1:
- 3.4 It is the responsibility of the applicant to ensure that the IFR form is fully completed and that it contains all relevant clinical and financial information required to enable the request to be considered. This includes information and evidence in support of the efficacy of a treatment and the benefit of the treatment for the patient. For clinical exceptionality to be considered, Section 13 of the IFR form must be fully completed clearly explaining the grounds for clinical exceptionality.
- 3.5 It is the sole responsibility of the referring clinician to provide this information and the IFR team will not be responsible for undertaking any evidence searches. The onus is on the

clinician making the request to clearly set out the grounds for clinical exceptionality. Where references are cited within the application, these should be provided in full as an attachment to the application together with a clear indication of the relevance of each reference given and the relevant sections that support the application. Evidence should be submitted as Adobe.pdf or Microsoft Word document (electronically or hard copy). The IFR Team are unable to accept abstracts or web links.

- 3.6 It is important that the referring clinician makes explicit linkages between the grounds under which exceptionality is claimed and the sections of the submitted research literature that are considered to support the clinician's view regarding the differences between the patient's clinical position and that of other patients in the group, and regarding the patient's anticipated response to the requested treatment.
- 3.7 A senior IFR clinical reviewer will undertake an assessment to ensure that the evidence presented is a reasonable representation of the published evidence base.
- 3.8 Applications should be submitted via an approved secure email (e.g. nhs.net) to the IFR Team. The email addresses are provided on the application form (Appendix 4).
- 3.9 Postal applications are not recommended to prevent loss of patient identifiable information and minimise unnecessary delays for patients.
- 3.10 For any queries the IFR Team can be contacted by email; funding.requests@nhs.net (for general enquiries) or by phone **01772 214054**.
- 3.11 The clinician submitting the IFR application is responsible for informing the patient and/or their carer of progress.
- 3.12 The clinician is responsible for ensuring that the patient or their authorised representative has consented to the IFR application and to their medical details being shared with the commissioner and relevant stakeholders defined in this policy for the purposes of considering the IFR application.
- 3.13 A flow diagram for funding decision making is shown in Section 16.

4. Urgent Applications

- 4.1 It is unusual for the ICB to be asked to consider an urgent request for funding. It is expected that clinicians take reasonable steps to minimise the need for urgent requests to be made through the IFR process.
- 4.2 In rare circumstances, the ICB recognises that an urgent decision may have to be made before an IFR Panel can be convened. This section defines how the ICB will administer these cases to an urgent timescale.
- 4.3 An urgent request is one which requires urgent consideration and a prompt decision because the patient faces a substantial risk of significant harm if a decision is not made before the next IFR Panel. It will be for the requesting clinician to clearly demonstrate the likelihood of this event occurring and the severity of its impact.
- 4.4 A request will not be treated as urgent where the apparent urgency arises solely as a result of:

- i. A failure by the clinical team to apply for funding through the appropriate

- route in a timely manner or,
- ii. the patient's expectations being improperly raised by a commitment being given by the clinician, or their GP to provide a specific treatment to the patient.

- 4.5 In cases where the urgent request is inappropriate, the ICB will request an investigation is carried out by the referring organisation to prevent similar cases. The IFR Team will provide advice or training to the referring organisation on appropriate IFR referrals where required.
- 4.6 Urgent requests should be sent to the IFR Team as per the process described in Section 3 above.
- 4.7 **To ensure that a case is prioritised as urgent, the IFR Team must be contacted by phone to advise that the application is urgent.** This is to ensure the application is identified as urgent as soon as possible in the process. The clinician must outline in the application the level of urgency defined by the nature and severity of the patient's condition and the reasons why the request is defined as urgent. This information enables the IFR Team to ensure that the request is genuinely urgent and provides clarity for the administration team on timescales and rationale for communication with the ICB in the process.
- 4.8 Where an urgent funding decision is required, the IFR Team will contact an Authorised Officer designated by the ICB. The Authorised Officer should be trained or experienced in IFRs.
- 4.9 The Authorised Officer has authority to make decisions on behalf of the ICB and will follow the ICB's policies and procedures when making a decision. The Authorised Officer will consider the nature and severity of the patient's clinical condition, and the time period within which the decision needs to be taken. The Authorised Officer will be supported by advice from expert reviewers, e.g. medicines management, public health or an IFR nurse adviser.
- 4.10 The Authorised Officer shall be entitled to reach a view that the decision is not of sufficient urgency that a decision needs to be taken outside of the usual process.
- 4.11 The Authorised Officer is also entitled to reach a decision that the request is for a service development and therefore, refer the request to the relevant ICB process.
- 4.12 If the urgent application does not contain sufficient information to enable a decision to be made the Authorised Officer may request that further information is sought from the applicant. This information will be requested by the IFR Team on behalf of the Authorised Officer. The clinician will share the information with the IFR Team who will ensure that the case remains anonymous, and that the process is recorded fully.
- 4.13 The case, decision, evidence and rationale will be recorded, and the record will be maintained by the IFR Team on behalf of the ICB.

5. Photographic evidence

- 5.1 The ICB advises that photographic evidence will not be accepted for consideration unless it is impossible to make the case in any other way. The decision to submit photographic evidence remains with the patient and responsible clinician. The ICB is concerned that

photographs could be misleading, embarrassing or discriminatory. Ultimately however it is the responsibility of the applicant to decide whether photographs are necessary, and submitted photographs may be considered if all of the following apply:

- A statement of what the photographs show and why they are submitted is included in the text of the application.
- The photographs are professionally taken by a medical illustration department.
- They are submitted with the patient's consent, including consent for the photographs to be examined, stored and destroyed in accordance with information governance requirements,
- The submission should be made by secure NHS email with the IFR application detailing the identity of the patient, the date of the photograph and clinical opinion that it represents a true likeness of the affected body part.
- The photographs will be submitted only to support or clarify a case made in writing. There should be no expectation that the photographs themselves will amount to a case for funding or will lead to a decision that the case is stronger than is described in writing.

5.2 After consideration has been given to the written case, if there is doubt about whether the ICB should offer funding and that doubt can be resolved only by examination of the photographs then a request will be made to the applicant.

5.3 If photographs are accepted for consideration in accordance with the above criteria, the applicant should be made aware that members of the IFR Panel, IFR Appeals Panel and the IFR Team may see the photographs during their work on the case.

6. Pre-screening stage

6.1 On receipt of the funding request, the IFR Team will review the IFR application form to ensure that it is fully complete. Any incomplete, partially completed or unsigned IFR application forms will not be processed and the referring clinician will be notified. The IFR team will email the referring clinician advising of the need to complete the application fully and to resubmit the application for consideration.

6.2 As part of the pre-screening process, the IFR Team will perform the necessary checks to identify the responsible commissioner.

6.3 All completed IFR application forms will be logged on the IFR database. A case reference number will be assigned to the application

6.4 Within five working days an acknowledgement will be sent by the IFR Team to the referring clinician advising that the application will be progressed through to screening stage.

6.5 At any point during this or subsequent stages, the IFR Team may request further information from the referring clinician. On occasion it may also be necessary to seek additional clinical information or request independent expert clinical advice from a clinician not directly involved in the patient's care. Where this is necessary, the request will be made in writing, a response timeframe will be given, and the applicant will be informed. Where the information is not forthcoming within the timescale given (which would usually be no longer than 4 weeks), the application will be progressed to a decision based on the information

received to date.

- 6.6 The IFR team will not request additional information by telephone, nor accept information given verbally.
- 6.7 The IFR team will not chase missing information on more than one occasion unless directed to do so by the IFR Panel.
- 6.8 All cases will be treated as routine unless otherwise specified by the referring clinician. It is the aim of the ICB to review all applications and provide a decision within 40 working days. However, this is largely dependent upon the complexity of the application, whether or not all of the relevant information is contained within the initial application and whether there is a requirement to seek additional or supplementary information. Therefore, the 40 working day target is exclusive of any delays incurred whilst any additional information is obtained.

7. Screening stage

- 7.1 The screening stage is administered by the IFR Team who may seek support from expert reviewers to screen the application.
- 7.2 The function of the screening stage is to ensure that the *General Policy for Individual Funding Request Decision Making*, the *Statement of Principles* the *Policy for Considering Applications for Exceptionality to Commissioning Policies* are applied.
- 7.3 The screening review identifies if the application can be funded by an existing commissioned service or has grounds for exceptionality.
- 7.4 The screening review will determine whether or not there is sufficient information such as clinical, financial and other information to enable the IFR Panel to properly assess the case.
- 7.5 The following individuals may be involved in screening applications:
 - Members of the IFR Team
 - IFR Nurse Adviser
 - Medicines Management Lead
 - Public Health Lead
 - General Practitioner
- 7.6 All applications will be screened by at least two individuals. Where necessary, the most appropriate expert reviewer will be requested to review the case; for example, medicines requests are shared with the Medicines Management Lead.
- 7.7 Reviews will be recorded on the secure IFR database in a systematic way.
- 7.8 The outcome of the screening stage will determine whether the application:
 - Is for a treatment that fulfils an existing clinical commissioning policy/contract.
 - Is for a treatment excluded by an existing clinical commissioning policy/contract and there is no basis for clinical exceptionality. The application is therefore not approved
 - Is for a treatment excluded by an existing clinical commissioning policy/contract but there is a basis for clinical exceptionality that a reasonable panel might accept in accordance with the exceptionality policy, and therefore the application will be submitted for consideration by the IFR Panel

- Is for a treatment where no policy /contract exist, and the patient is described as a rare case for which the ICB would not expect to be required to commission a service for a cohort of patients. The application will be submitted for consideration by the IFR Panel
- Is for a treatment commissioned by NHS England (or any other commissioner) and is not a matter for the ICB to determine. The applicant will be advised to contact the appropriate commissioner and complete their application process.
- Is for a treatment that may be relevant to one of a group of patients in similar circumstances. Such a case should be regarded as a potential service development and considered in accordance with whatever agreement exists at the time for the management of such cases. In the absence of a specific agreement the individual case will be submitted for consideration by the IFR panel, and the ICB will be notified of the issue.

- 7.9 If there is uncertainty during the screening stage about the application of a clinical commissioning policy, or whether there is exceptionality, the case is progressed to the IFR Panel.
- 7.10 If the expert reviewer requests further information, then the IFR team will seek that information from the applicant. The target 40 working day time frame in which applications are considered will be stopped whilst further information is sought. Any delay incurred whilst additional evidence is supplied will not form part of the time taken to consider the request.
- 7.11 If the further information is not supplied within a reasonable period of time for the particular case (which would usually be no longer than 4 weeks) then the expert reviewer and the IFR Team will consider whether a decision can be taken on the available evidence or whether the case should be closed.
- 7.12 If a decision has been made the IFR Team will write to the applicant and the patient's GP to outline the outcome of the screening stage and the rationale for the decision. Correspondence will be circulated by secure electronic means (e.g. nhs.net mail) in accordance with relevant data protection legislation. In the absence of a secure electronic method of communication applicants will be notified of the outcome via formal letter.
- 7.13 Where applicable the patient/patient's representative will receive a copy of this letter. The responsibility for contacting the patient and explaining the decision and answering any questions which the patient may have lies with the requesting clinician. This is because the clinician is best placed to discuss the next steps, or alternative treatment options with the patient, depending on the outcome.

8. Individual Funding Request (IFR) Panel

- 8.1 The IFR Panel is a multi-disciplinary professional group responsible for assisting ICB representatives to make decisions on IFRs.
- 8.2 The clinician should not assume particular knowledge within the Panel for the condition from which their patient is suffering or that a clinician from the relevant area of medical practice is in attendance. This is because the Panel will contain a range of individuals with expertise in assessing IFRs as well as a variety of skills and experiences, including general medical, clinical, public health, medicines and commissioning skills. The Panel will not necessarily include a clinician with expertise in the condition for which treatment is being sought. This is

appropriate because it is the referring clinician's responsibility to set out in sufficient detail the case for clinical exceptionality. The purpose of the Panel deliberation is to consider not only the question of demonstrable exceptionality (resting on the differences between this patient and others with the condition) but the Panel must also decide whether it is appropriate to divert resources away from other services in order to fund the requested treatment.

- 8.3 Applications may be forwarded to the IFR Panel following screening review. The IFR Team will schedule the application for discussion at the next available IFR Panel. All personal identifiable information will be redacted from the application to ensure anonymity during the process of decision making
- 8.4 The IFR Panel will operate within the limits of delegated authority as determined by the ICB's detailed scheme of delegation.
- 8.5 The membership of the Panel is defined in the Terms of Reference, which can be found at Appendix 2.
- 8.6 The IFR Panels will be held when required in order to ensure that there is a timely response to all individual funding requests. Meetings are usually held 4-6 weekly.
- 8.7 The IFR Panel will take account of the evidence submitted with the application form before making a decision on an IFR.
- 8.8 The outcome of each IFR will be communicated to the referring clinician within two weeks of the decision. This timescale is required to ensure that the documentation from the Panel has been authorised.
- 8.9 The IFR Panel will consider factors that may include, but will not be limited to the following:
 - The ICB's overarching commissioning principles
 - The clinical information provided with the application
 - Relevant ICB clinical commissioning policies
 - The planned treatment/intervention, and the expected benefits and risks of the treatment
 - The clinical evidence base of the treatment/intervention
 - The value for money to the NHS of the treatment/intervention
 - Whether the treatment/intervention being requested is experimental for a rare clinical circumstance
 - Whether the treatment/intervention being requested constitutes a service development for a cohort of patients
 - The evidence cited as grounds for clinical exceptionality
 - The implications of its decision on other patients and on the health of the population
- 8.10 A letter will be sent to the referring clinician by the IFR Team on behalf of the Chair of the IFR Panel, or the decision maker for the ICB, advising on the outcomes of the IFR Panel. Where applicable the patient/patient's representative will receive a copy of this letter.
- 8.11 Throughout the process described above, the IFR Team may, at any time, be asked to request additional information from the referring clinician.
- 8.12 A funding request cannot be resubmitted to the IFR Panel once it has been considered unless there is new evidence, a new policy to support a new assessment of the case or at

the request of the IFR Appeals Panel.

9. Reconsideration

- 9.1 If a requesting clinician believes there is significant new clinical information that was not previously submitted, which may alter the decision then they may submit the information and request reconsideration of their decision.
- 9.2 A request for a reconsideration of a decision will only be processed where there is new information relevant to the case to be considered. All reconsiderations must be submitted to the IFR Team, using the designated form (Appendix 5), within 12 weeks of the decision.
- 9.3 The application and the new information will then be reconsidered in line with the process outlined in this document.

10. Decision Notification

- 10.1 The applicant and the patient's GP will be notified of the outcome of the application via a letter outlining the decision in detail.
- 10.2 All communications between the IFR Team and the applicant will be via secure nhs.net email accounts wherever possible. Where this is not possible, communication will be made via formal letter or another secure method available.
- 10.3 The patient/patient's representative will receive a copy of this letter where it is considered appropriate. The responsibility for contacting the patient and explaining the decision and answering any questions which the patient may have is with the requesting clinician. This is because the clinician is best placed to discuss the next steps, or alternative treatment options with the patient, depending on the outcome.

11. Committed Funding Period

- 11.1 If the ICB makes a decision to fund an individual patient request, the decision is valid for a period of six months from the date that the decision was communicated to the applicant. Treatment must be commenced within that period.
- 11.2 Any requests to extend this period must be submitted formally, in writing, to the IFR Team, providing:
 - details of the extenuating circumstances that have resulted in the intervention/procedure not being undertaken within the agreed six-month period
 - the period of extension being sought
 - if applicable, confirmation that the patient continues to fulfil the relevant intervention specific criteria
 - if applicable, confirmation that the circumstances by which the patient was deemed exceptional are still valid

12. Appeals Process

- 12.1 There is no statutory requirement for the ICB to hold appeals. However, in line with best practice, the ICB does allow an Appeal to be made against **the process** that was followed to arrive at the decision.

- 12.2 All appeals must be made in writing using the designated form (Appendix 6) and submitted to the IFR Team within 12 weeks of the decision. An Appeal can be made by a clinician requesting the treatment, or a patient. Where an Appeal is submitted by a patient, this must have the full support of their clinician.
- 12.3 It must be noted that an Appeal Panel cannot overturn a decision which has been taken by the IFR Panel. However, it can request the decision is reconsidered by the IFR Panel, in line with section 12.14 below.
- 12.4 On receipt of a request for an Appeal, the IFR Team will identify whether any new clinical information has been submitted which was not available at the time the decision was made. Where new information is available the appeal will not be considered further. The Appellant will be notified and will be informed that it will be necessary for a completed Reconsideration Form to be submitted should they wish the new information to be reviewed and considered.
- 12.5 The person submitting the appeal must clearly evidence where and how due process was not followed or where a policy was incorrectly applied and must confirm the basis for the appeal, that is:
- | | |
|-------------------------|--|
| Illegality: | The refusal of the application was not an option that could lawfully have been taken. |
| Procedural Impropriety: | There were substantial and/or serious procedural errors in the way in which the IFR process was conducted. |
| Irrationality: | The decision of the ICB to refuse funding for the requested treatment/intervention was one which could not reasonably have been reached on the evidence available. |
- 12.6 Where an Appeal application does not confirm the basis for the appeal using one of the above three scenarios, the Appeal application will not be considered further, and the Appellant will be advised accordingly.
- 12.7 Appendix 3 defines the membership and terms of reference for the Appeal Panel.
- 12.8 No Appeals Panel member will have had involvement in the original IFR application or Panel decision or should know the patient. A member of the IFR Team will be in attendance to provide administrative support, including minute taking.
- 12.9 The IFR Team will submit all Appeals, in which no new information has emerged since the IFR Panel's decision, to the Chair of the Appeals Panel within two weeks of receipt of the request for Appeal. Prior to convening a formal Appeals Panel meeting, the Chair of the Appeals Panel will read and consider all of the documentation relating to the original IFR Panel decision along with the Appeals submission. The Chair of the Appeals Panel will then decide within 2 weeks whether or not there is a case to answer. If there is no case to answer, the Chair of the Appeals Panel will communicate this decision in writing to the appellant and the case will be closed. If the Chair of the Appeals Panel decides to convene an Appeals Panel, the IFR Team will inform the appellant in writing.
- 12.10 The IFR Team on behalf of the Chair of the Appeals Panel will convene the meeting, inviting appropriate representation. The Chair will ensure that the Appeal Panel is quorate in accordance with the Terms of Reference and consider if additional attendance or advice is required to ensure that a robust consideration of the Appeal can be made. The clinician and the patient (or representative) will be given the opportunity to attend and will be given a minimum of 7 days' notice of the date and time of the Appeal. The patient (or

representative) may bring up to two additional people to the panel and must advise the Chair in advance if they wish to do so.

12.11 At the Appeal Panel meeting, the patient's clinician, or the patient (or their representative) will be given the opportunity to set out orally the basis for the appeal. If preferred, information can be submitted in writing to the Chair via the IFR Team to be considered at the Appeal Panel. The Appeal Panel will review this alongside the Appeal application (Appendix 6).

12.12 A ICB member of the IFR Panel will also be asked to explain the process that was followed and the rationale for the original decision. The ICB member can request any other expert member of the IFR Panel to join the Appeal Panel to support this part of the process.

12.13 The Appeals Panel will:

- i. Consider whether the decision-making process was followed in accordance with the ICB's IFR Policy.
- ii. Consider whether the correct clinical commissioning policy/policies was/were applied for the decision.
- iii. Consider whether the IFR Panel took account of all of the relevant information provided at the time of its decision and consider whether or not the IFR Panel took account of any irrelevant information at the time of its decision that may have affected the outcome.
- iv. Consider whether the IFR Panel came to a decision that fell within the range of decisions which a reasonable IFR Panel could have reached with the same evidence available to them.

12.14 If the Appeals Panel concludes that:

- new information has emerged since IFR Panel's decision or,
- that the IFR Panel did not consider all the available information or,
- that the IFR Panel had considered irrelevant information that could have affected the outcome or,
- the wrong clinical commissioning policy was considered when the decision was made, or
- the decision did not fall within a range of decisions which a reasonable ICB could have reached based on the evidence before them or,
- that there had been misinterpretation of evidence submitted or,
- that the IFR Panel had not followed due process or documented the decision making clearly to explain the rationale for the decision making.

then, the Chair of the Appeals Panel will refer the case back to the IFR Panel for reconsideration.

12.15 The application will be scheduled for discussion at the next available IFR Panel to reconsider all the information previously received including any new information and the recommendations of the IFR Appeal Panel. The decision and rationale for the new decision of the IFR Panel will be sent to the Chair of the Appeals Panel. The Chair of the Appeals Panel is required to satisfy him/herself that the IFR Panel has addressed the recommendations and documented this before a decision is shared with the patient by the IFR Panel. If the Chair cannot satisfy him/herself, then he/she will meet with the Appeal panel decision maker(s). If that fails to resolve the issue, the matter will be referred to the Chair of the ICB, whose decision is final.

12.16 If the Appeals Panel concludes that due process was followed when the original decision was taken, and it wishes to uphold the original decision taken by the IFR Panel to decline

funding, then the Chair of the Appeals Panel will communicate this to the clinician and the patient (or their representative) if appropriate, within four weeks of the Appeals Panel meeting. The Chair of the Appeals Panel will also advise the Chair of the IFR Panel, in writing, of the Appeal Panel's conclusions.

12.17 The Chair will not have meetings with the patient (and or representative) or any member of the IFR Panel prior to the Appeal Panel.

13. IFR Complaints/Member of Parliament (MP) Enquiry Management

13.1 Complaints can be submitted at any point in the IFR process. Details of the complaint process and contact details can be found at the relevant ICB web site.

13.2 The IFR Team will support the complaint investigation process as required.

14. Patient and clinician feedback

14.1 The CSU on behalf of the ICB will put in place mechanisms to gain feedback from patients and requesting clinicians as part of the process.

15. Monitoring

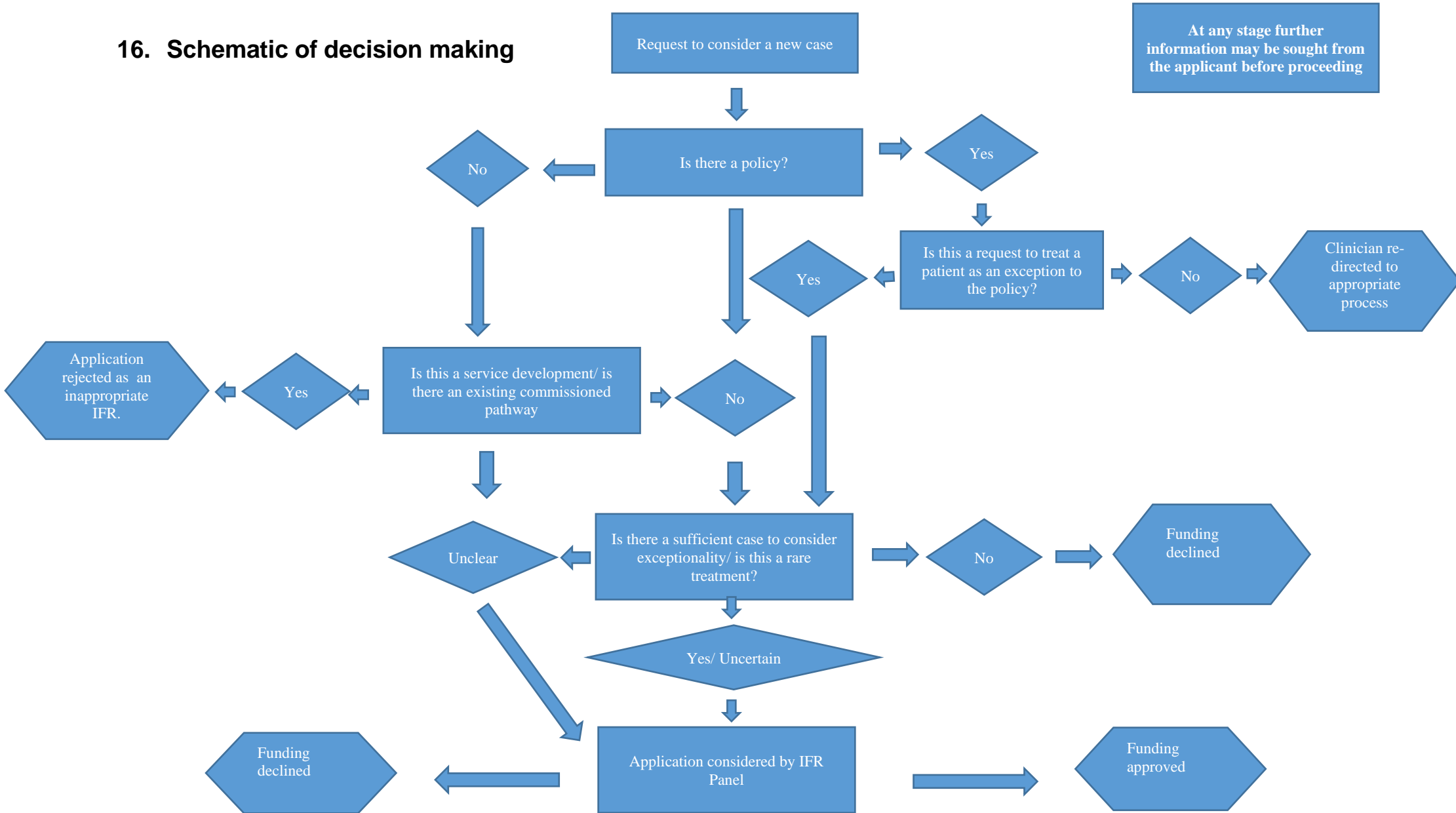
15.1 The IFR process will be monitored and reviewed to ensure that the decision making is fair and consistent and to make sure that screening stages and IFR Panels are following the processes appropriately and effectively.

15.2 Regular activity reports will be provided to the ICB.

15.3 The Management of IFRs document for Lancashire and South Cumbria ICB will be reviewed every two years by the ICB supported by the CSU.

15.4 An annual report will be submitted on behalf of the IFR Panel to the ICB.

16. Schematic of decision making



Appendix 1: Terms of Reference for the Individual Funding Request Team

(NB: this is for reference only. The current version is available upon request from the IFR Team and may vary slightly to accommodate dynamic improvements/changes)

1. Purpose

- 1.1 The role of the Individual Funding Request Team is to support the IFR process for the Integrated Care Board. The team will:
- a. Provide oversight of the management and co-ordination of the IFR process.
 - b. Ensure that the IFRs are managed in line with the policies of the ICB.
 - c. Provide the administrative function for screening, IFR Panels and IFR Appeals Panels.
 - d. Provide administrative oversight and ratification on IFR functions supported with clinical expertise where required
 - e. Administer the paperwork, ensuring the efficient handling and documentation of submissions, from first receipt through to archiving.
 - f. Provide a single point of contact for clinicians involved in the IFR and IFR Appeal processes.
 - g. Maintain an IFR database.
 - h. Maintain a register of Authorised Officers and liaise with them in urgent cases.
 - i. Advise on publications on ICB websites
 - j. Liaise with the ICB Boards, Committees and officers responsible for priority-setting and policy development as required.
 - k. Raise issues of policy with ICB.
 - l. Bring new service developments identified during the IFR process to the attention of the ICB.
 - m. Contribute to the recruitment and training of IFR Panel and IFR Appeal Panel members.
 - n. Attend meetings in an advisory capacity.
 - o. Liaise with the legal team to support the ICB.
 - p. Support update of the IFR policies
 - q. Provide a source of expertise including advising clinicians wishing to submit a funding request.
 - r. Monitor the quality of the IFR process and decision making including overseeing regular audits of the process.
 - s. Arrange training if required to do so and ensure that members of the IFR Panels, IFR Appeal Panels and Authorised Officers undergo training on a regular basis.
 - t. Liaise with Local Authority and other teams in the CSU supporting the IFR process.

2. Corporate Governance and Risk Management

- 2.1 The IFR Team will adhere to all the corporate governance and risk management arrangements set out in the agreement between the Midlands and Lancashire Commissioning Support Unit and the ICB.
- 2.3 The IFR Team will provide regular reports to the ICB informing them of the number of IFRs that have been screened and the number considered at the IFR Panel, as well as the outcome and the financial commitment.
- 2.4 The IFR Team will provide an annual report to the ICB.

- 2.5 The IFR Team will report any governance concerns or risks to the ICB when this comes to their attention.
- 2.6 All members of the IFR Team and IFR Panel members will undergo training to cover both the legal and ethical framework for IFR decision making, the ICB's commissioning processes and structures, the technical aspects of interpretation of clinical evidence and research, and guidance in respect of the policies relevant to their advice. This training will be regularly refreshed to ensure that all IFR and IFR Appeal Panel members maintain the appropriate skills and expertise to function effectively.

Appendix 2: Individual Funding Request (IFR) Panel Terms of Reference

(NB: this is for reference only. The current version is available upon request from the IFR Team and may vary slightly to accommodate dynamic improvements/changes)

1. Purpose

- 1.1 The IFR Panel is a forum for discussion of the case and analysis of the evidence to assist the ICB member/employee to reach a decision in any particular case. This panel may be delivered as part of a wider commissioning committee within an ICB depending on organisational approaches. For example, a Commissioning Request Panel which might include cases for Continuing Health Care and IFRs.
- 1.2 The role of the IFR Panel is to:
 - Review screened cases
 - Discuss and analyse each case put before the IFR Panel in which a decision will be reached by the responsible commissioner.
- 1.3 The IFR Panel will consider all the written evidence which is provided to it, including the individual funding request form itself and any other documentary evidence. In doing so, it will take into account the policies and procedures of the ICB.
- 1.4 The IFR Panel may at its discretion request the attendance of any clinician to provide clarification on any issue or request independent expert clinical advice for consideration by the IFR Panel at a further date.
- 1.5 Only the member/employee from the patient's responsible Integrated Care Board can take the final decision on funding.

2. Membership and Quoracy

- 2.1 The membership of the IFR Panel will be:
 - A Chair, who shall be a senior manager of the IFR team from the CSU
 - A case manager from the IFR Team from the CSU
 - A General Practitioner from the ICB
 - A senior authorising manager from the ICB
 - A medicines management representative from the ICB/CSU
 - An additional health professional member who may have a medical and/or dental and/or nursing and/or public health (MFPH or equivalent) background.
- 2.2 A member of the IFR team will be in attendance to support administration and minute taking. Other members of the IFR team and ICB staff may also be in attendance if they have been involved in preparing cases for the agenda or are recording the discussion.
- 2.3 The role of the panel will be to provide formal collective advice to the ICB decision makers. To be quorate at least the following three members must be present:
 - Chair
 - Senior authorising manager from the ICB
 - A General Practitioner from the ICB

- 2.4 The final decision will be taken by the ICB decision makers.
- 2.5 Each member should declare any potential conflict of interest as soon as they become aware of it. A general practitioner should not be involved in Panel discussions about their own patient or patients from their practice or make a decision concerning their own patient or patients from their practice. In these instances, another ICB member/employee should attend the Panel.

3. Decision making

- 3.1 The final decision for any given IFR will be taken by the responsible commissioner ICB member/employee.
- 3.2 The role of the remaining panel members is therefore to advise the ICB's decision maker.

4. Corporate Governance and Risk Management

- 4.1 For each case the factors taken into account, the deliberations, the decisions and the reasons for the decision will be documented.
- 4.2 Members of the IFR Panel must undergo IFR training to cover legal and ethical frameworks for IFR decision making, the ICB's commissioning processes and structures, the technical aspects of interpretation of clinical evidence and research, and guidance in respect of the policies relevant to their advice. This training will be regularly refreshed to ensure that all IFR and IFR Appeal Panel members maintain the appropriate skills and expertise to function effectively.

5. Frequency of Meetings

- 5.1 The IFR Panel will meet regularly to ensure cases can be considered in a timely manner. Panels will normally be scheduled to meet every 4-6 weeks, but meetings may be cancelled or additional meetings arranged depending on the nature and amount of requests.
- 5.2 Virtual meetings by telephone or web conferencing may be held, as and when required.
- 5.3 The decisions made outside the regular meetings must be relayed to the next formal IFR Panel meeting for ratification by the ICB member/employee and incorporated into the minutes of the next IFR Panel.

Appendix 3: Terms of Reference of the IFR Appeal Panel

(NB: this is for reference only. The current version is available upon request from the IFR Team and may vary slightly to accommodate dynamic improvements/changes)

1. Purpose

- 1.1 The role of the Individual Funding Request Appeal Panel (IFR Appeal Panel) is to consider appeals against the process taken to reach decisions made by the Integrated Care Board to ensure that decisions have been taken in accordance with the policies and processes of the ICB and the specific processes and jurisdiction that are contained within the policy.
- 1.2 The IFR Appeal Panel will normally reach its decision on the basis of all the written evidence which is provided to it, although it may request the attendance of legal, clinical or public health expertise to clarify any points for consideration by the IFR Appeal Panel.
- 1.3 The IFR Appeal Panel will consider only the following documentation:
 - (a) the original IFR application submitted to the CSU
 - (b) the records documenting the process by which the request has been considered
 - (c) the IFR Panel records, including the IFR Panel minutes and any additional supporting information considered by the IFR Panel
 - (d) the IFR Appeal application form (which can be found in Appendix 6) which sets out the grounds of the appeal by the requesting clinician and/or the patient/guardian or carer in their request for review
 - (e) Any supporting written evidence if an oral presentation at the Panel is not made by the patient (or their clinician or representative).
- 1.4 If there is substantive new evidence presented to the IFR Appeal Panel, the IFR Appeal Panel will request that the application is submitted to an IFR Panel for further consideration and for the ICB to review its original decision in light of the new evidence.
- 1.5 The IFR Appeal Panel will arrive at one of two decisions. The IFR Appeal Panel will either:
 - (a) uphold the decision reached by the IFR Panel and approved by the Integrated Care Board; or
 - (b) refer the case back to the IFR Panel for reconsideration.

2. Membership and Quoracy

- 2.1 The Appeal Panel will comprise one lay Governing Body member, who will chair the panel, one General Practitioner, and one ICB senior manager. No member of the appeal panel shall have been involved in the case previously. The appeal panel will be supported by the IFR Team.
- 2.2 To ensure that the review is independent of the original decision, the Appeal Panel members will be different from the IFR Panel members who originally considered the case and the ICB member/employee who made the original decision.

- 2.3 All members must be in attendance for the meeting to be considered quorate.
- 2.4 The Chair of the IFR Appeal Panel can request the attendance of other individuals in an advisory capacity.
- 2.5 A member of the IFR Team will provide administrative support. This may include staff who have been involved in administering the case for the IFR Panel.

3. Corporate Governance and Risk Management

- 3.1 For each case considered, the factors taken into account, the weighting given to those factors, the decisions and the reasons for the decision will be documented.
- 3.2 All members of the IFR Appeals Panel must undergo training.

4. Frequency of Meetings

- 3.3 The IFR Appeal Panel will be convened within 5 weeks of an appeal being received.

Appendix 4: IFR Application Form

(NB: this application form is for reference only. The current version is available to download from the commissioner's web site or upon request from the IFR Team and may vary slightly to accommodate dynamic improvements/changes)

For Morecambe Bay patients an online application form should be submitted. This can be accessed via the following link: <https://www.morecambabayccg.nhs.uk/about-us/policies-and-procedures>

Important information

All sections of the form must be completed otherwise the case will not be considered. Do not include patient or Trust/requesting clinician identifiable data in any free text sections. Where there are large amounts of identifiable data included in the free text sections, the application will be returned to you for redaction and resubmission.

This form is an appendix to *The Management of IFRs*. The full document must be considered before making an application on behalf of a patient to ensure that it is appropriate.

Before you begin to complete this form to make an application you MUST first consider the following question: *Are there similar patients with similar clinical circumstances who could also benefit from the treatment you are requesting across the population of the ICB?*

If the answer is YES then making an individual funding request is an inappropriate way to deal with funding for this patient. This is because the case represents a service development for a predictable population. You should discuss with your contract team (or commissioning leads at the ICB) to understand how you submit a business case for consideration through the usual business planning process.

If the answer is NO then please proceed by completing the application, providing the information and relevant evidence for the appropriate category of IFR into which this patient's case falls.

SECTION 1- REQUEST URGENCY	
Indicate the level of clinical urgency for this request.	<input type="checkbox"/> Not urgent <input type="checkbox"/> Urgent - state reasons: State reasons:
PLEASE NOTE: If a request is considered urgent the IFR team must be contacted by telephone, in line with Section 4 of The Management of IFR's.	

SECTION 2 – PATIENT PERSONAL DETAILS			
Patient Surname:		NHS Number:	
Patient Forename:		Patient Date of Birth:	
Patient Middle Name(s):		Patient Sex (M/F):	
1i. Patient Address: (Including Postcode)			
Please note that all unnecessary personal information will be removed from this form prior to consideration by the IFR Panel. This information is collected for monitoring purposes only.			

SECTION 3 – REGISTERED GP DETAILS	
GP Name:	

GP Practice Name:	
GP Practice Address:	
GP Practice Postcode:	
GP Telephone Number:	
GP Email Address:	

SECTION 4 – CONSENT

I confirm:

This Individual Funding Request (IFR) has been discussed in full with the patient and/or patient representative¹. They are aware that they are consenting for the IFR Team to receive and review confidential clinical information about their health to enable full consideration of this funding request.

- Yes
 No

Responsibility lies with the requesting clinician to present a full submission which sets out a comprehensive and balanced picture of the history and present state of the patient’s clinical condition, the nature of the treatment requested and the anticipated benefits of treatment.

SECTION 5 – DETAILS OF REQUESTER (if different to the patient’s GP)

Name:	
Job role:	
Organisation:	
Contact telephone number:	
Secure NHS.net email or postal address:	

SECTION 6 – DETAILS OF PROVIDER (if different to the requester or patient’s GP)

Provider organisation:	
Clinical department / specialty:	
Contact telephone number:	
Secure NHS.net email or postal address:	

SECTION 7 – PATIENT DIAGNOSIS AND CLINICAL BACKGROUND

Primary diagnosis related to this request:
Outline of the patient’s condition including the timeline, current presentation and symptoms. Please give validated clinical measures, named in full.
Relevant medical history: (Including co-morbidities)

SECTION 8 –REQUESTED TREATMENT

Name of requested treatment: (Include any alternative terms)	
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¹ This means a person with legal authority to take decisions about medical care and treatment on behalf of the patient, on the basis that they lack capacity to take these decisions themselves. The source of that legal authority should be clearly identified LSCICB_Clin04 Policy for the Management of Individual Funding Requests
Version 2.1, July 2022

Is the treatment part of a course?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A If yes, please give details of the proposed treatment frequency and duration and the total number of proposed treatments/doses:
Anticipated start date, if known/appropriate:	

SECTION 9 – CURRENT TREATMENT
Please give details of the patient’s relevant current treatment/medications including regimen, response (including any intolerance or adverse events) and start date.

SECTION 10 – PREVIOUS TREATMENTS
Please give details of relevant previous treatment/medication including the treatment, regimen, response (including any intolerance or adverse events), start date, stop date, reason for stopping.

SECTION 11 – STANDARD TREATMENT
What is the natural history of the condition this patient has and what would be the expected course of the condition and prognosis?
What is the standard treatment for this condition at this stage in the pathway and why is this not appropriate for this patient?
If this treatment request is not approved, what treatment will be given to the patient?

SECTION 12 – ANTICIPATED OUTCOMES
What are the anticipated outcomes of the treatment requested for this patient?
How will the outcomes of the treatment requested be measured? Use validated measures.
When will these outcomes be expected?
What stopping criteria will be in place (if appropriate)?

SECTION 13 – CLINICAL EXCEPTIONALITY
It is recommended that you read the policy on clinical exceptionality that is in force at the time of your application prior to completing this section. This will be available to view on the ICB’s website.
In summary, the application must demonstrate:
<ul style="list-style-type: none"> • Why the patient in question is materially different to the usual population of patients to whom the Standard Policy applies in terms of the principle or principles on which the Standard Policy is based; AND • Why that material difference means the Standard Policy should not apply.

Please explain why the patient is materially different to the usual population of patients to whom the Standard Policy applies in terms of the principle or principles on which the Standard Policy is based
Please explain why that material difference means the Standard Policy should not apply.

SECTION 14 – SUPPORTING EVIDENCE

PLEASE NOTE:
 Where references are cited within the application, these should be provided in full as an attachment to the application together with a clear indication of the relevance of each reference given and the sections that support the application. Evidence should be submitted as pdf or word document (electronically or hard copy). The IFR Team are unable to accept abstracts or web links.
 For further information please see section 3 of The Management of Individual Funding Requests for Lancashire and South Cumbria ICB

Please provide a summary of the evidence base for the clinical and cost effectiveness and safety of the requested procedure / treatment in support of the application for clinical exceptionality.

Is the treatment licensed in the UK for the intended use?	<input type="checkbox"/> Yes <input type="checkbox"/> No
If Yes, please give details:	
Has it been subjected to NICE appraisal or other scrutiny?	<input type="checkbox"/> Yes <input type="checkbox"/> No
If Yes, please give details:	
Is the procedure/treatment part of a current or planned national or international clinical trial or audit?	<input type="checkbox"/> Yes <input type="checkbox"/> No
If Yes, please give details:	
Does the proposed procedure/treatment have any exclusion criteria in place for occasions when the procedure/treatment could be ineffective?	<input type="checkbox"/> Yes <input type="checkbox"/> No
If Yes, please give details:	

SECTION 15 – TREATMENT/PROCEDURE COSTS

Ensure you include all costs that are connected to providing the treatment or procedure.

What is the cost of the treatment / procedure? <i>Please include any associated costs such as drug / attendance costs / device / administration / staff / follow up / diagnostics costs / consumables etc</i> <i>Please give a breakdown of this cost per annum, per cycle etc. as appropriate</i>	£
What is the total estimated cost for the package of treatment/care?	£
What is the cost of the standard therapy it replaces including any drug / attendance costs / staff / follow up / diagnostics costs etc.? Please give a breakdown of this cost per annum, per cycle etc. as appropriate:	£

SECTION 16 – DECLARATION OF INTERESTS

Clinicians are required to disclose all material facts as part of this process. Are there any relevant declarations of interest that are appropriate to bring to the attention of the IFR Team?

SECTION 17 – SIGNATURE OF REQUESTING CLINICIAN

Signature:

Date

ON COMPLETION

Please email the completed form and enclosures via secure email to the email address:
funding.requests@nhs.net

Appendix 5: IFR Reconsideration Form

(NB: this application form is for reference only. The current version is available to download from the commissioner's web site or upon request from the IFR Team and may vary slightly to accommodate dynamic improvements/changes)

Important Information:

This form is to be used where there is new clinical information that was not available for consideration at the time of the original funding decision, that is relevant to the treatment or intervention requested.

Do not include patient or Trust/requesting clinician identifiable data in any free text sections. Where there are large amounts of identifiable data included in the application, it will be returned to you for redaction and resubmission.

SECTION 1 – REQUEST URGENCY

Indicate the level of clinical urgency for this request.

- Not urgent
 Urgent - state reasons:
State reasons:

Proposed start date or date treatment commenced:

PLEASE NOTE: If a request is considered urgent, the IFR Team must be contacted by telephone, in line with Section 4 of The Management of IFRs.

SECTION 2 – EXISTING CASE ID NUMBER

Case ID number:

SECTION 3 – PATIENT PERSONAL DETAILS

Patient Surname:

NHS Number:

Patient Forename:

Patient Date of Birth:

Patient Middle Name(s):

Patient Sex (M/F):

Patient Address:
(Including Postcode)

Please note that all unnecessary personal information will be removed from this form prior consideration by the IFR Panel. This information is collected for monitoring purposes only.

SECTION 4 – CLINICAL CONTACT DETAILS

Are you the clinician who submitted the original application?

- Yes
 No

If the answer is no please provide your contact details below:

SECTION 5 – NEWLY AVAILABLE SUPPORTING CLINICAL INFORMATION:

Please Note: Only new information, which was not submitted for consideration with the original application should be provided here.

For the application to be considered at least one of the boxes below must contain new clinical information.

Requested treatment.	<p>Is there new information available? <input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p>If yes, please provide further details:</p>
Clinical presentation and background.	<p>Is there new information available? <input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p>If yes, please provide further details:</p>
Information to support the evidence base for the requested intervention.	<p>Is there new information available? <input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p>If yes, please provide further details:</p>
Clinical exceptionality	<p>Is there new information available? <input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p>If yes, please provide further details:</p>
Other	<p>Please provide any further information you believe is relevant to the application that was not considered at the time of the original application.</p>

SECTION 6 – SIGNATURE OF REQUESTING CLINICIAN

Signature	
Date	

ON COMPLETION

Please email the completed form and enclosures via secure email to the email address listed below funding.requests@nhs.net

Appendix 6: IFR Appeal Form

(NB: this application form is available to download from the commissioners web site or upon request from the IFR Team and may vary slightly to accommodate timely improvements/changes)

Important information:

The remit of the IFR Appeal Panel is to ascertain whether the process followed in reaching the decision taken in relation to a funding request:

- was taken in accordance with the requirements of this policy
- properly took into account and evaluated all the relevant evidence
- did not take into account irrelevant factors
- was taken in good faith; and
- was a decision that falls within the range of responses which the ICB was reasonably entitled to reach on the application and evidence submitted.

The IFR Appeal Panel is not able to consider new information that was not available at the time of the original decision. If further information exists to support an application for funding this should be submitted using the IFR Reconsideration Form, which can be found at Appendix 5.

SECTION 1 – PATIENT PERSONAL DETAILS			
Patient Surname:		NHS Number:	
Patient Forename:		Patient Date of Birth:	
Patient Middle Name(s):		Patient Sex (M/F):	
Patient Address: (Including Postcode)			

SECTION 2 – APPELLANT DETAILS	
Name:	
Position/Title:	
Relationship to the patient:	
Signature	
Date Completed:	

SECTION 3 – DETAILS OF THE APPEAL	
Please confirm which of the following three reasons is the basis for the appeal:	<p>a) Illegality <input type="checkbox"/></p> <p>b) Procedural impropriety <input type="checkbox"/></p> <p>c) Irrationality <input type="checkbox"/></p>
Please provide an explanation of the reason for the appeal in the relevant section below. Please note, at least one of the sections must be completed for an appeal to be considered.	

Illegality: Please detail how the decision made was not a lawful option that could be taken.	
Procedural impropriety: Please identify any serious or substantial procedural errors that occurred during the IFR	
Irrationality: Please detail how the decision to refuse funding was one which could not reasonably have been reached on the evidence available.	

SECTION 4- OTHER RELEVANT INFORMATION

Please detail any other information that you consider to be relevant to the appeal	
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SECTION 5 – SIGNATURE OF REQUESTING CLINICIAN

Signature	
Date	

ON COMPLETION

Please email the completed form and enclosures via secure email to the email address below:
funding.requests@nhs.net