

## Individual Funding Requests (IFR) Policy for NHS Leeds Clinical Commissioning Group

**Decision making with regard to services or treatments which are  
not routinely commissioned**

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Name & Title of originator/author:	Dr Sarah Forbes, Associate Medical Director NHS Leeds CCG Dr Fiona Day, Consultant in Public Health Medicine, Leeds City Council Elizabeth Micklethwaite, Business Manager IFR, NHS Leeds CCG
Name of responsible committee/individual:	Dr Simon Stockill, Medical Director
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Target audience:	Primary and secondary care clinicians, individual funding request panels, and the public

## **Executive Summary**

This policy applies to all Individual Funding Requests (IFR) for people registered with General Practitioners in NHS Leeds Clinical Commissioning Group (CCG), where the CCG is the responsible commissioner for this treatment or service.

This policy does not apply where the Leeds CCG is not the responsible commissioner.

The policy updates all previous policies and must (where appropriate) be read in association with the other relevant NHS Leeds Clinical Commissioning Group commissioning frameworks, which are to be applied across all the CCG, including but not limited to policies on cosmetic exceptions and other non-commissioned activity.

All IFR and associated policies will be published on the NHS Leeds CCG Website.

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## **1 Introduction**

Leeds CCG is the statutory body responsible for commissioning services for the patient for whom we are responsible in accordance with the National Health Service Act 2006. As part of these duties, there is a need to commission services which are evidence based, cost effective, improve health outcomes, reduce health inequalities and represent value for money for the taxpayer. The CCG is accountable to its constituent populations and Member Practices for funding decisions.

In relation to decisions on Individual Funding Requests (IFR's), the CCG in Leeds has a clear and transparent process and policy for decision making. It has a clear CCG specific appeals process to allow patients and their clinicians to be reassured that due process has been followed in IFR decisions made.

Due consideration must be given to IFRs for services or treatments which do not form part of core commissioning arrangements, or need to be assessed as exceptions to NHS Leeds CCG Commissioning Policies. This process must be equitably applied to all IFRs.

All IFR and associated policies will be publically available on the CCG website. Specialist services that are commissioned by NHS England, Leeds City Council, or Public Health England are not included in this policy.

## **2 Purpose**

Whilst the majority of service provision is commissioned through established service agreements with providers, there are occasions when services are excluded or not routinely available within the National Health Service (NHS). This may be due to advances in medicine or the introduction of new treatments and therapies or a new NHS Leeds CCG statement. The IFR process therefore provides a mechanism to allow drugs/treatments that are not routinely commissioned by the CCG to be considered for individuals in exceptional circumstances.

The purpose of the IFR policy is to enable officers of Leeds CCG to exercise their responsibilities properly and transparently in relation to IFRs, and to provide advice to General Practitioners, other clinicians, patients and members of the public about IFRs. Implementing the policy ensures that commissioning decisions in relation to IFRs are consistent and not taken in an ad-hoc manner without due regard to equitable access and good governance arrangements. Decisions are based on best evidence but made within the funding allocation of the CCG..

The policy is underpinned by the following key principles:

- The decisions of the IFR panels outlined in the policy are fair, reasonable and lawful, and are open to external scrutiny.
- Funding decisions are based on clinical evidence and not solely on the budgetary constraints.

- Compliance with standing financial instructions / and statutory instruments in the commissioning of healthcare in relation to contractual arrangements with providers.

### **3 Scope**

The CCG has established the processes outlined in this policy to consider and manage IFRs in relation to the following types of requests:

- Procedures requiring prior approval as identified in the CCG's Commissioning Policies
- Requests for approval for an exception to the CCG's Cosmetic Exclusions Policy (formerly NHS Leeds Cosmetic Exclusions)
- Procedures approved by the National Institute for Health and Care Excellence outside normal commissioning timeframes and commissioning intentions.
- Procedures not normally funded through existing Service Agreements e.g. alternative therapies.
- New treatments and drugs not widely available from the National Health Service.
- Exceptional requests for treatments (see section 12).
- Some requests may relate to policies agreed at a West Yorkshire level and adopted locally by NHS Leeds CCG.
- Access to treatment outside the NHS
- Access to services not normally commissioned by NHS Leeds CCG
- All requests from local primary care clinicians or hospital clinicians against the criteria for access to procedures defined by the evidence based NHS Leeds CCGs framework for Aesthetic (Cosmetic) procedures.
- Clinician initiated requests for funding of drugs for which there is no NICE guidance and which are not included in the current HRG Tariffs, and excluding drugs commissioned by NHS England. The process for commissioning medicines in Leeds. This panel will use the Non Nice Non Tariff Drugs underpinning Policy as the basis for decision making.

Applications need not request services, treatments and procedures covered in national or regional commissioning guidance or policies eg NICE, NHS England, Public Health England or Local Government Public Health services.

### **4 Definitions**

The CCG is not prescriptive in its definitions. Each Individual funding Request will be considered on its merits, applying this Policy.

### **5 Duties**

This policy applies to patients registered with General Practitioners within the NHS Leeds CCG or patients who are deemed to be resident under the NHS Health and Social Care Act 2012 where the CCG is the responsible

commissioner. This policy does not apply where the CCG is not the responsible commissioner.

Applications for consideration by the IFR panels must be submitted to the IFR Business Manager, NHS Leeds CCG.

The policy should also be read in conjunction with the NHS (Charges to Overseas Visitors) Regulations 2015 (as amended) <sup>1</sup>.

The procedures outlined in this policy for considering IFRs are consistent with the internal governance arrangements of NHS Leeds CCG, the NHS Constitution, and the Human Rights Act 1998.

## **5.1 Responsibilities and Duties**

### **5.1.1 Referring Clinician**

All IFR applications must be accompanied by written support and evidence provided by the clinical team treating the patient.

Applications should be made by the clinician responsible for the patient's care. If the patient is under multiple teams the recommendation should come from the most relevant clinician.

**It is the clinician's responsibility** to ensure that the appropriate information is provided to the CCG. If relevant information is not submitted or not submitted in a timely way, then the requesting clinician will bear responsibility for any delay that this causes.

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

Additional information may come from patients in addition to the clinician's request but this need to come via the requesting clinician due to cases being anonymised.

### **5.1.2 IFR Business Manager** – it is the role of the Business Manager to:

- Anonymise and collate all requests when they enter the CCG to check all relevant documents have been supplied:
  - Requests which do not contain all the relevant documents will be rejected at this point pending further information and the referrer will be informed.

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<sup>1</sup> <http://www.legislation.gov.uk/ukxi/2017/756/contents/made> (accessed 22.2.18)

- Use a logging and tracking system to ensure that IFRs are dealt with consistently and in a timely way.
- Forward the anonymised documents to the person with responsibility for making a recommendation on the case:
  - For service based requests this will be a commissioner.
  - For procedure or medication based requests this will be a clinician.
- Co-ordinate requests and recommendations and send to the final decision maker.
- Co-ordinate correspondence back to the referrer with regards to the outcome of the request.
- A written response is usually provided to the GP within seven working days of the panel meeting. This response includes details of the outcome of the panel and complaint procedure (if appropriate).
- For drug requests a written response is e-mailed to the Provider Trust clinician usually within 24 hours of panel.
- Ensure all relevant documents are available for the IFR panel.
- Record in writing the decision of the panel and the discussion behind it.
- Use standard letters to approve or reject IFR requests.
- Present any cases which go through the appeals process.

### **5.1.3 Persons with responsibility for making recommendations:**

Each case will be sent through to a person with relevant experience who will be asked to make a recommendation on the case.

- For cosmetic exception cases this will be a plastic surgeon
- For requests for service this will be the relevant commissioner
- For drug requests this will be a member of the medicines optimisation team
- For mental health advice this will be a psychiatrist

They will consider the facts of the case and then either make a recommendation to the designated decision maker (DDM) or send to the panel for further discussion.

### **5.1.4 Designated Decision Maker:**

- Evaluate cases and recommendations and make a decision to either
  - Accept case for funding

- Reject case for funding
- Ask for further information if they feel they do not have all the information required to make a decision
- Send to panel for a further discussion. This usually happens if a case is borderline against criteria or is being considered with regards to exceptionality.

The designated decision maker will be a senior clinician and member of the CCG Medical Directorate.

In exceptional circumstances a decision may be made by a non clinical member of the executive management team.

### **5.1.5 The IFR Advisory Panel**

The IFR panel will meet on a regular basis with appropriate representation. This will usually be monthly.

The Panel will meet in private. Patients, their representative or GP do not attend. The panel may require access to the patients' GP or Hospital records. Consent for this will be sought from the patient. It is important to note that the panel's decision will be based on the information submitted to them, so it is critical that this information is accurate and as detailed as possible.

The role of the IFR advisory panel is to discuss the case and make a recommendation to the DDM.

They will provide consistency and also advise on more complex cases.

The panel will consist of:

- The Chair (who will be the designated decision maker)
- At least one other member of the medical directorate
- The IFR Business Manager
- A lay member who has had appropriate training
- Consultant in public health medicine
- Specialist Advisors which may include: dermatologist; psychiatrist; plastic surgeon; pharmacist

### **5.1.6 Chair of the Panel:**

- This will be a member of the medical directorate.
- Ultimate decision maker for each case following discussion within the panel

## **5.2 Resubmission**



The CCG has established a mechanism to review the decisions of the IFR panels. Where the CCG has refused to support funding for a requested treatment, or has approved the treatment subject to conditions, the patient shall be entitled to ask for a review.

The screening process will look for evidence of new information or any changes in the policy that was initially applied. In the absence of either of these the request will be returned to the clinician.

The referring clinician or the patient will be entitled to request a review if they remain dissatisfied with the decision making process of any panel, but not the decision itself.

### **5.3 Appeals Panel**

To ensure that the appeals process is an internally independent review, the membership of this panel must not include anyone from the IFR panel who has assessed the case previously.

A decision taken by one of the IFR panels will not be reviewed on the grounds that the patient and/or clinician disagree with the decision. Appeals are not a re-hearing of the case or the decision itself and panel decisions will only be reviewed on one or more of the following grounds:

- Procedural impropriety (i.e. procedures as outlined within the IFR Policy were not applied correctly or consistently)
- Irrationality (i.e. relevant factors were not taken into account and irrelevant factors were not excluded. The decision was irrational, unreasonable and or unfair)
- Illegality (i.e the panel acted outside of its authority or the decision was taken contrary to a principle of law)

All requests for review must be supported by an explanation from the referring clinician and/or patient outlining their reasons for considering that the decision taken by the IFR panel was either procedurally improper, was a decision which no reasonable IFR panel could have reached, or was contrary to a principle of law.

It must be noted that the Appeals Panel is a reviewing panel and not a re-hearing panel.

Where a request for funding has been refused, reviewed and been subject to the CCG appeal process, the IFR Panel will not consider subsequent requests for funding, whether from the same or a different clinician, without demonstrably different evidence to support the new application being put forward. Persistent requests for funding for a patient from the same or different clinicians will be classified as vexatious and will not be processed.

#### **5.3.1 Membership of the Appeals Panel**

- Chief Officer and Lay Member of the Board
- In attendance (non-voting) IFR Business Manager (to act as Case Manager and present the case)

From time to time, when specific issues are discussed, other people with specialist knowledge may be requested to attend the meeting or provide information to support the case, including legal advisors.

If a patient's appeal is rejected, a clear explanation shall be provided to the patient, and to the referring clinician with the patient's consent, outlining the reasons for the panel's decision to reject the appeal.

If the patient's appeal against the original decision is accepted, the case will be returned to the relevant IFR panel for reconsideration. This includes situations where the Appeals Panel has agreed that the CCG would be prepared to consider evidence that was not put before the previous panel the first time round.

The Appeals Panel shall meet as required, with decisions being communicated as above, to the patient and where consent has been given, to the requesting clinician within seven working days from the date of the panel. The panel can be convened on exception when requested by the chair of the panel.

#### **5.4 Further Redress**

The decision of the Appeals Panel is final. Any patient or clinician wishing to further challenge a decision of the Appeals Panel is advised to seek their own advice.

**See Appendix D for the Appeals flowchart**

#### **5.5 Urgent Treatment Decisions**

NHS Leeds CCG recognises that there will be occasions when an urgent decision needs to be made to consider approving funding for treatment for an individual patient outside the CCGs' normal policies. In such circumstances, the CCG recognises that an urgent decision may have to be made before one of the IFR panels can be convened.

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

Urgency under this policy cannot arise as the result of a failure by the patient's clinical team to expeditiously seek funding through the

appropriate route and/or where the patient's legitimate expectation have been raised by a commitment being given by a provider trust to provide a specific treatment to the patient. In such circumstances, CCG expects the provider trust to proceed with treatment and for the provider to fund the treatment.

Provider trusts must take all reasonable steps to minimise the need for urgent requests to be made through the IFR process. If clinicians from any provider trust are considered by the CCG not to be taking all reasonable steps to minimise urgent requests to the IFR process, the CCG may refer the matter to the provider trust Chief Executive. In situations of clinical urgency, the decision will be made by the identified decision maker for the CCG or an exceptional IFR panel will be convened.

In making an urgent decision, the decision maker or the exceptional IFR panel will follow the procedures set out above. The decision maker shall consider the nature and severity of the patient's clinical condition and the time period within which the decision needs to be taken.

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

## **6 Main Body of Policy**

### **6.1 NHS England core Principles**

The principles listed below are the core principles for priority setting within NHS Leeds CCG. They are based on NHS England's Core Principles<sup>2</sup> as set out in the NHS England Publication Commissioning Policy: Ethical Framework for Priority Setting and Resource Allocation and are to be read in conjunction with the commissioning policies and position statements for Leeds CCG.:

#### **Principle 1**

The values and principles driving priority setting at all levels of decision-making must be consistent.

#### **Principle 2**

NHS Leeds CCG has a legal duty to commission healthcare within the area for which it has commissioning responsibility. This must be consistent with its legal duty to not overspend its allocated budget.

#### **Principle 3**

NHS Leeds CCG has a responsibility to make rational decisions in determining the way it allocates resources to the services it directly

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<sup>2</sup> <http://www.england.nhs.uk/wp-content/uploads/2013/04/cp-01.pdf> (accessed 9/9/13)(reviewed 22/2/18)

commissions. It must act fairly in balancing competing claims on resources between different patient groups and individuals.

#### **Principle 4**

Competing needs of patients and services within the CCGs areas of responsibility should have an equal chance of being considered, subject to the capacity of the CCG to conduct the necessary healthcare needs and services assessments. As far as is practicable, all potential calls on new and existing funds should be considered as part of a priority setting process. Services, clinicians and individual patients should not be allowed to bypass normal priority setting processes.

#### **Principle 5**

Access to services should be governed, as far as practicable, by the principle of equal access for equal clinical need. Individual patients or groups should not be unjustifiably advantaged or disadvantaged on the basis of age, gender, sexuality, race, religion, lifestyle, occupation, social position, financial status, family status (including responsibility for dependents), intellectual / cognitive function or physical functions.

There are proven links between social inequalities and inequalities in health, health needs and access to healthcare. In making commissioning decisions, priority may be given to health services targeting the needs of sub-groups of the population who currently have poorer than average health outcomes (including morbidity and mortality) or poorer access to services.

#### **Principle 6**

The CCG should only invest in treatments and services which are of proven cost-effectiveness unless it does so in the context of well-designed and properly conducted clinical trials that will enable the NHS to assess the effectiveness and/or value for money of a treatment or other healthcare intervention.

#### **Principle 7**

New treatments should be assessed for funding on a similar basis to decisions to continue to fund existing treatments, namely according to the principles of clinical effectiveness, safety, cost-effectiveness and then prioritised in a way which supports consistent and affordable decision-making.

#### **Principle 8**

The CCG must ensure that the decisions it takes demonstrate value for money and an appropriate use of NHS funding based on the needs of the population it serves.

#### **Principle 9**

No other body or individual other than those authorised to take decisions under the policies of the CCG, has a mandate to commit the CCG to fund any healthcare intervention unless directed to do so by the Secretary of State for Health.

### **Principle 10**

The CCG should strive, as far as is practical, to provide equal treatment to individuals in the same clinical circumstance where the healthcare intervention is clearly defined. The CCG should not, therefore, agree to fund treatment for one patient which cannot be afforded for, and openly offered to, all patients with similar clinical circumstances and needs.

### **Principle 11**

Interventions of proven effectiveness and cost-effectiveness should be prioritised above funding research and evaluation unless there are sound reasons for not doing so.

### **Principle 12**

Because the capacity of the NHS to fund research is limited, requests for funding to support research on matters relevant to the health service have to be subject to normal prioritisation processes.

### **Principle 13**

If a treatment is provided within the NHS which has not been commissioned in advance by the CCG save for those treatments approved by other NHS bodies and/or by sending organisations e.g. former CCGs, the responsibility for ensuring on-going access to that treatment lies with the organisation that initiated treatment.

### **Principle 14**

Patients participating in clinical trials are entitled to be informed about the outcome of the trial and to share any benefits resulting from having been in the trial. They should be fully informed of the arrangements for continuation of treatment after the trial has ended. The responsibility for this lies with the party initiating and funding the trial and not the CCG unless the CCG has either funded the trial itself or agreed in advance to fund aftercare for patients entering the trial.

### **Principle 15**

Unless the requested treatment is approved under existing policies of the CCG in general it will not, except in exceptional circumstances, commission a continuation of privately funded treatment even if that treatment has been shown to have clinical benefit for the individual patient.

## **6.2 Clinical exceptionality**

In order for an IFR to be approved, it must be demonstrated that the patient's case is clinically exceptional.

The CCG must coherently explain its decisions to clinicians, patients and the public. Its decision making is open to legal challenge and scrutiny by the court if necessary. This policy is designed to aid decision making but it is not possible to provide a comprehensive list of cases that are exceptional because, by definition, it is not possible to anticipate all instances of the unusual or the unexpected. The CCG must, however, be able to contemplate

what might amount to exceptionality in relation to each request received. A failure to do so could expose the CCG to criticism of a blanket refusal of any particular request for treatment.

However, as a general principle, in making a case for exceptionality, the patient or their requesting clinician must demonstrate that:

- the patient is significantly different to the general population of patients with the condition in question;  
**AND**
- the patient is likely to gain significantly more benefit from the intervention than might be normally expected for patients with that condition.

The fact that a treatment is likely to be effective for a patient is not, in itself, a basis for clinical exceptionality.

### **6.2.3 Factors that can be taken into account in deciding if a patient is clinically exceptional**

There are a number of factors that can be taken into account when judging whether or not a patient is 'significantly different to the general population of patients with the condition in question'.

Firstly, the IFR panels will consider whether there are any clinical features that make the patient unique or unusual compared to others with the same condition. If so, the IFR panels will go on to consider whether there are sufficient grounds for believing that this unusual clinical feature means that the patient would gain significantly more benefit than that would be expected for the general population of patients with the condition.

When considering exceptionality, the IFR panels are required to restrict themselves to consider only the patient's presenting medical condition and the likely benefits which have been demonstrated by the evidence to be likely to accrue to the patient from the proposed treatment. The IFR panels shall not make treatments available to individual patients, and no other clinically similar patients, on the basis of non-clinical factors.

Non clinical factors may be taken into account (including where defined by law eg military personnel). Psychological factors will not routinely be considered unless they relate to a diagnosed clinically recognised psychiatric disorder which has a significant or substantial bearing on the clinical case.

The IFR panels shall take care to avoid identification bias, often called the "rule of rescue". This can be described as the imperative people feel to rescue identifiable individuals facing avoidable death or a preference for identifiable over statistical lives. In general terms, this means; supporting intensive effort to prolong life when prognosis appears poor and death unavoidable, and when there is little research evidence to support the treatment options. The fact that a patient has exhausted all NHS treatment options available for a particular condition is unlikely, of itself, to be sufficient

to demonstrate exceptional circumstances. Equally, the fact that the patient is refractory to existing treatments where a recognised proportion of patients with the same presenting medical condition at this stage are, to a greater or lesser extent, refractory to existing treatments is unlikely, of itself, to be sufficient to demonstrate exceptional circumstances.

### **6.3 One-off decisions**

In some situations, the principle of exceptionality cannot readily be applied. For some IFRs, there may simply be no reference point as the patient does not come from a sizeable group of patients (often they may be unique), or if there is limited evidence about the treatment in question (and there may never be more). In these instances, the IFR panels have to assess only whether the patient is likely to benefit from the treatment and the priority to be given to the patient. This is treated as a 'service development for 1'. Under these circumstances, in addition to questions about priority and value for money, the following need to be asked:

- What is the nature of the condition?
- What is the nature of the treatment?
- What is the evidence that this treatment might work in this situation?

The majority of these can be dealt with through the IFR process alone. However, occasionally, the financial commitment is so large the decision needs to be referred to the CCG's Governing Body.

## **7 Equality Impact Assessment (EIA)**

This document has been assessed, using the EIA toolkit, to ensure consideration has been given to the actual or potential impacts on staff, certain communities or population groups, appropriate action has been taken to mitigate or eliminate the negative impacts and maximise the positive impacts and that the and that the implementation plans are appropriate and proportionate.

Include summary of key findings/actions identified as a result of carrying out the EIA. The full EIA is attached as Appendix A.

NHS Leeds CCG has a duty to have regard to the need to reduce health inequalities in access to health services and health outcomes achieved as enshrined in the Health and Social Care Act 2012. The CCG is committed to ensuring equality of access and non-discrimination, irrespective of age, gender, disability (including learning disability), gender reassignment, marriage and civil partnership, pregnancy and maternity, race, religion or belief, sex (gender) or sexual orientation. In carrying out its functions, the CCG will have due regard to the different needs of protected equality groups, in line with the Equality Act 2010. The Equality Impact Assessment screening tool is attached as Appendix H.

## **8 Implications and Associated Risks**

This policy and supporting frameworks set evidence based boundaries to interventions available on the NHS. It may conflict with expectations of individual patients and clinicians.

#### Education and Training Requirements

Members of the panels will undergo training at least every three years, particularly in relation to the legal precedents around IFRs.

All members will have completed the CCGS statutory mandatory training including equality and diversity training.

## **9 Monitoring Compliance and Effectiveness**

The IFR process is not a mechanism to introduce new treatments for a cohort of patients who are in the same or similar circumstances as the requesting patient, whose clinical condition means that they could make a like request, and who could reasonably be expected to benefit from the requested treatment to the same or a similar degree (a Service Development).

All IFRs submitted to NHS Leeds CCG will be subject to screening to determine whether or not the request represents a Service Development. The CCG expects that Service Developments will occur through annual commissioning cycles rather than IFRs. The CCG recognises however that occasionally, an IFR may alert them to the existence of a cohort of patients and in these instances, the CCG commissioning policies may need to be reviewed.

Interventions recommended in NICE technology appraisals will be implemented only when guidance is published unless previously prioritised. The CCG does not expect to introduce any healthcare intervention other than approved IFRs outside the annual commissioning round. To do so will take resources from identified priorities.

- An audit of the decisions made at triage and by the IFR panels will be reviewed on a six monthly basis to ensure consistency in decision-making and outcomes.
- Information governance standards will be maintained in relation to patient information and confidentiality, in line with Caldicott Guidelines, the Data Protection Act 1998, the GDPR, and the common law duty of confidentiality.
- Decisions of the IFR panels will be anonymised and a summary presented to NHS Leeds CCG Quality and performance Committee. It will also be published on the CCG website. This will allow the CCG Governing Body and members of the public to scrutinise the application of the IFR policy.
- The CCG's communications team will handle media requests.
- A support team will be available that can gather necessary supplementary information.



- Each IFR panel will maintain an accurate database of cases approved and rejected, to enable consideration of amendments to future commissioning intentions and to ensure consistency in the application of the CCG's Commissioning Policies.
- The financial impact of approvals outside of existing Service Level Agreements will be monitored to ensure the CCG identifies expenditure and ensures appropriate value for money. Member Practice clinicians need to be aware that all referrals will ultimately be a call on the CCG budget.
- A limit of £100,000 for an individual IFR will apply at which point the CCG Medical Director will discuss the case with the CCG Chief Officer and Chair who will in turn report the IFR to the CCG's Governing Body.

## 10 Associated Documentation

Other related policy procedural documents should be identified here.

## 11 References

- NHS Confederation. Priority setting: managing individual funding requests. <http://www.nhsconfed.org/resources/2008/12/priority-setting-an-overview> (accessed 22/2/18)
- NHS Confederation. Priority setting: legal considerations <http://www.nhsconfed.org/resources/2008/12/priority-setting-legal-considerations> (accessed 22/2/18)
- **NHS Clinical Commissioners. Making difficult decisions: Commissioning healthcare in changing times September 2016.** [http://445oon4dhpil7qjvs2jih81q.wpengine.netdna-cdn.com/wp-content/uploads/2016/09/Making-difficult-decisions\\_NHSCC.pdf](http://445oon4dhpil7qjvs2jih81q.wpengine.netdna-cdn.com/wp-content/uploads/2016/09/Making-difficult-decisions_NHSCC.pdf) (accessed 21.3.18)
- **Priority setting in the NHS, Faculty of Public Health (FPH), February 2014** <http://www.fph.org.uk/uploads/Position%20statement%20-%20Priority%20setting%20in%20the%20NHS.pdf> (accessed 21.3.18)
- **Setting priorities in health: The challenge of clinical commissioning. Nuffield Trust 2011.** <https://www.nuffieldtrust.org.uk/research/setting-priorities-in-health-the-challenge-of-clinical-commissioning> (accessed 21.3.18)
- NHS England Interim Ethical Framework 2013 <https://www.england.nhs.uk/commissioning/policies/gp/> (accessed 21.3.18)

## Appendices

### Appendix A: Equality Impact Assessment

#### Equality Impact Assessment

<b>Title of policy</b>	Individual Funding Requests	
<b>Names and roles of people completing the assessment</b>	Fiona Day Consultant in Public Health Medicine, Helen Lewis, Head of Acute Provider Commissioning	
<b>Date assessment started/completed</b>	03/09/2018	12/09/2018

1. Outline	
<b>Give a brief summary of the policy</b>	The purpose of the commissioning policy is to enable officers of NHS Leeds CCG to exercise their responsibilities properly and transparently in relation to commissioned treatments including individual funding requests, and to provide advice to general practitioners, clinicians, patients and members of the public about IFRs. Implementing the policy ensures that commissioning decisions are consistent and not taken in an ad-hoc manner without due regard to equitable access and good governance arrangements. Decisions are based on best evidence but made within the CCG's funding allocation This policy relates to Individual Funding Requests.
<b>What outcomes do you want to achieve</b>	We commission services equitably and only when medically necessary and in line with current evidence on cost effectiveness.

2. Evidence, data or research	
<b>Give details of evidence, data or research used to inform the analysis of impact</b>	See list of references

<b>3. Consultation, engagement</b>	
<p><b>Give details of all consultation and engagement activities used to inform the analysis of impact</b></p>	<p>Discussion with clinicians and patient representatives on the principles of decision making. Discussion with patient leaders relating to changes in the content of the policy and advice on proportionate engagement.</p> <p>The policy review was undertaken using any updated NICE or equivalent guidance, and input from clinicians was sought where possible. Engagement sessions with patient leaders were undertaken and all policies individually reviewed. Patient leaders were satisfied with the process by which the policy was developed, particularly in light of the robust process (including extensive patient engagement) by which NICE guidance are developed, and acknowledging their own local role in providing assurance. No concerns were raised with regard to the policy.</p> <p>Local clinical commissioning and clinical providers have had the opportunity to comment on the draft policies.</p>

<b>4. Analysis of impact</b>			
<p>This is the core of the assessment, using the information above detail the actual or likely impact on protected groups, with consideration of the general duty to;</p> <p>eliminate unlawful discrimination; advance equality of opportunity; foster good relations</p>			
	<p><b>Are there any likely impacts?</b></p> <p><b>Are any groups going to be affected differently?</b></p> <p><b>Please describe.</b></p>	<p><b>Are these negative or positive?</b></p>	<p><b>What action will be taken to address any negative impacts or enhance positive ones?</b></p>
<b>Age</b>	No		
<b>Carers</b>	No		
<b>Disability</b>	No		
<b>Sex</b>	No		
<b>Race</b>	No		

<b>Religion or belief</b>	No		
<b>Sexual orientation</b>	No		
<b>Gender reassignment</b>	No		
<b>Pregnancy and maternity</b>	No		
<b>Marriage and civil partnership</b>	No		
<b>Other relevant group</b>	No		
<b>5. Monitoring, Review and Publication</b>			
<b>If any negative/positive impacts were identified are they valid, legal and/or justifiable?</b>		The policy is designed to ensure equity of access to all patients within the CCG's responsibility based on clinical need.	
<b>Please detail.</b>			

<b>5. Monitoring, Review and Publication</b>			
<b>How will you review/monitor the impact and effectiveness of your actions</b>	Annual report of IFR activity reported through relevant committees to the CCG's Governing Body. A limited equity audit is undertaken as part of this. Complaints and appeals monitoring.		
<b>Lead Officer</b>	Simon Stockill	<b>Review date:</b>	

<b>6. Sign off</b>			
<b>Lead Officer</b>	Simon Stockill		
<b>Director</b>	Simon Stockill	<b>Date approved:</b>	

## Appendix B: Policy Consultation Process:

Title of document	Individual Funding Requests (IFR) Policy for NHS Leeds Clinical Commissioning Group
Author	Dr Sarah Forbes,
New / Revised document	Revised
Lists of persons involved in developing the policy. List of persons involved in the consultation process:	Dr Sarah Forbes, Dr Simon Stockill, Dr Fiona Day, Elizabeth Micklethwaite, Joanna Howard

### Policy development and review: consultation and engagement

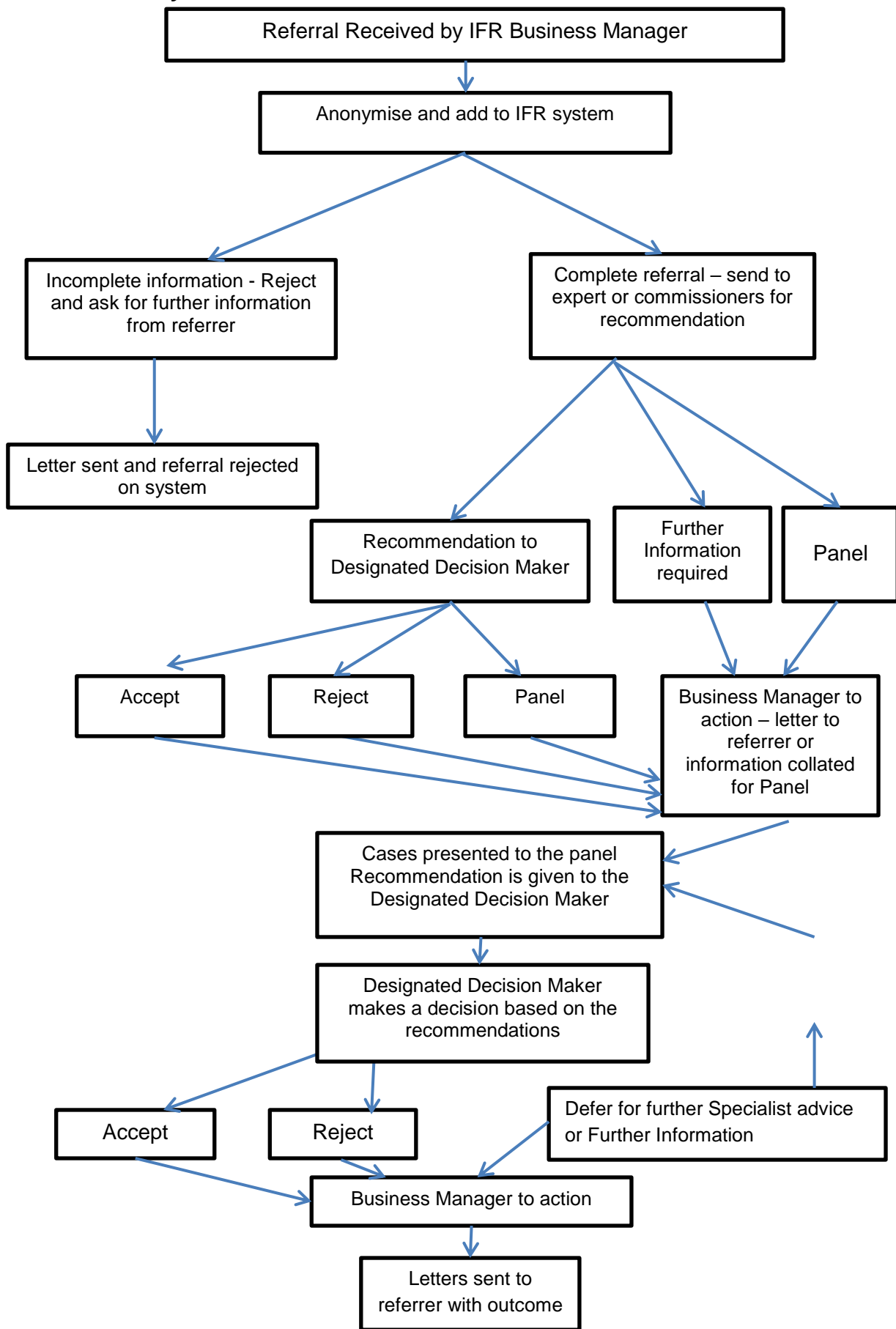
The policy was developed to:

- ensure a clear and transparent approach is in place for exceptional/individual funding request decision making; and
- provide reassurance to patients and clinicians that decisions are made in a fair, open, equitable and consistent manner.

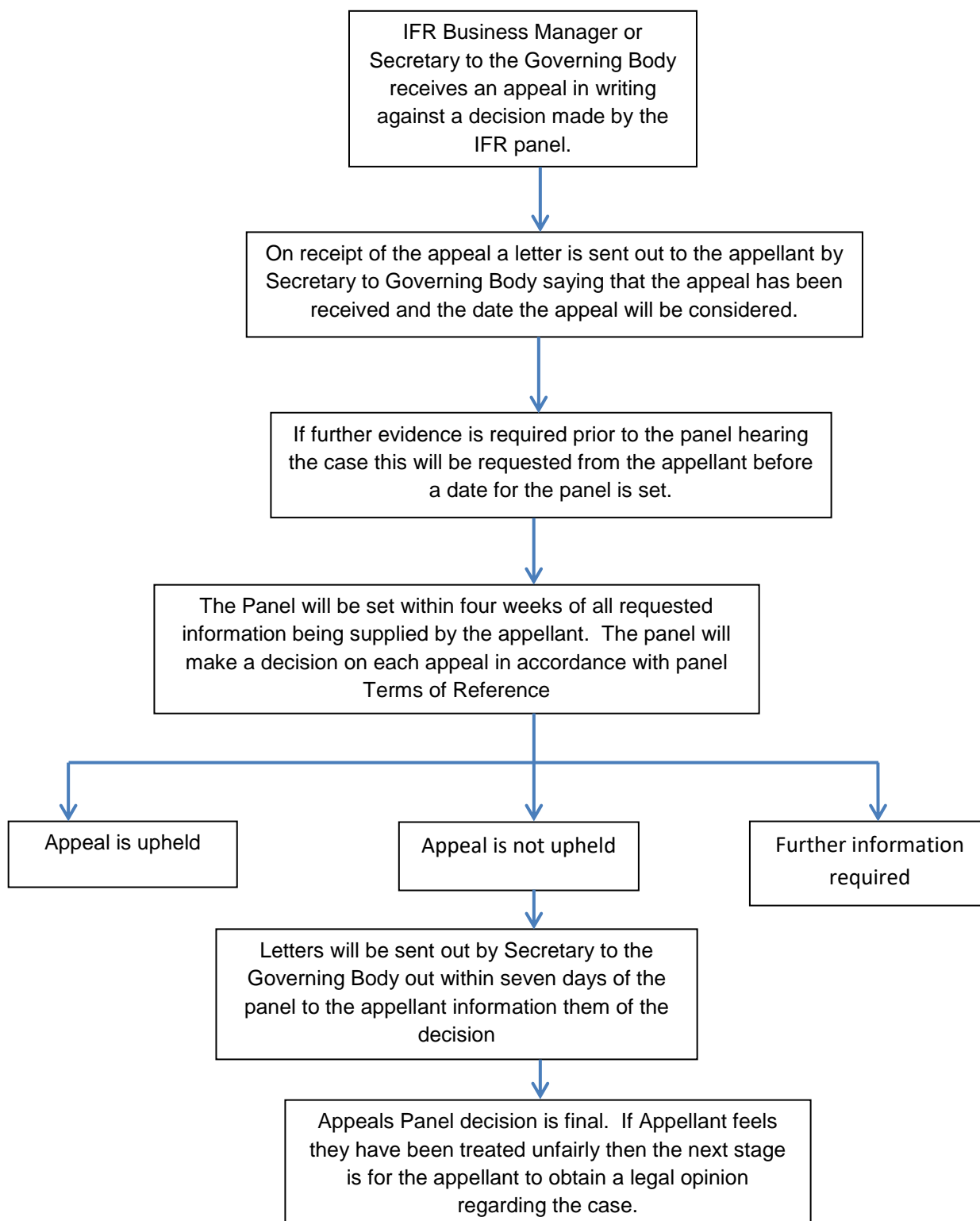
It was originally developed in line with NICE or equivalent guidance where this was available or based on a review of scientific literature. This included engagement with hospital clinicians, general practice, CCG patient advisory groups, and the general public cascaded through a range, mechanisms.

The policy review was undertaken using any updated NICE or equivalent guidance, and input from clinicians was sought where possible. Engagement sessions with patient leaders were undertaken and all policies individually reviewed. Patient leaders were satisfied with the process by which the policy was developed, particularly in light of the robust process (including extensive patient engagement) by which NICE guidance are developed, and acknowledging their own local role in providing assurance. No concerns were raised with regard to the policy

**Appendix C: Pathway**



## Appendix D: Appeals assessment pathway



**Appendix E: Version Control Sheet**

Version	Date	Author	Status	Comment
1.0	30.5.13	F Day	Initial draft	For multiple comments and amendments.
2.0	20.6.13	F Day	Draft 2.0	Comments received and amendments made.
3.0	26.6.13	F Day	Draft 3.0	Comments from medical directors
4.0	4.7.13	F Day	Draft 4.0	Comments from Medicines lead re HCD
5.0	23.7.13	F Day	Draft 5.0	Comments from legal team plus amended NNT flowchart
6.0	24.7.13	F Day	Draft 6.0	Acceptance of legal comments plus amends from medical
7.0	5.8.13	F Day	Draft 7.0	Clarification of terms from CCG Comms lead plus addition of lay observer to CEEP and NCA panels. Addition of
8.0	9.9.13	F Day	Draft 8.0	Formatting and rewording of section
9.0	10.9.13	F Day	Draft 9.0	Removal of high cost drugs commission pathway and moved this to NNNT
10.0	12.9.13	F Day	Draft 10.0	Addition of section 6 on core
11.0	11.11.13	F Day	Draft 11.0	Change social factors will not be taken into account TO non clinical factors 12.1.
12.0	18.11.13	F Day	Draft 12.0	Change review date to April 2016. Addition of comment from LNCCG 'Decisions are based on best evidence but made within the funding
13.0	29.11.13	F Day	Draft 13.0	Addition of dissemination plan
Amended final	22.5.14	F Day	Amended final	Clarification of when not responsible commissioner; role clarification for IFR business manager in Panels; minor typos; update of page



2016-2019	7/6/16	F Day/ Hempsons	Draft revised policy	Minor typos; updating of references; updating panel clinical advisory membership. Review by legal team and amends: -more clarity on exceptionality -clarity that patients can submit additional information but not a request in isolation from their clinician -amends to further redress in line with best practice
2016-19 amended	10.10.17	F Day/ Hempsons	Amended policy	Section 16.2 renamed 16.3: Addition of new 16.2 'Where a request for funding has been refused, reviewed and been subject to the CCG appeal process, the IFR Panel will not consider subsequent requests for funding, whether from the same or a different clinician, without demonstrably different evidence to support the new application being put forward. Persistent requests for funding for a patient from the same or different clinicians will be classified as vexatious and will not be processed.'
2018-21 draft v1	22.2.18	F Day	Policy updated to reflect 3 CCGs merging into one Leeds CCG	Addition of reference to west Yorkshire commissioning policies; addition of sentence relating to NHS (Charges to Overseas Visitors) Regulations 2015.

2018-21 draft v2	28.2.18	Carolyn Walker, Fiona Day, Elizabeth Micklethwaite, Simon Stockill, Helen Lewis, Laura Parsons, Jo Howard	Updated wording of draft v1	Wording relating to CCG merger clarified; addition of GDPR 2018; changes to appeal panel 'IFR business manager' from 'commissioning manager'; change of appeal panel 'lay member for governance' to 'lay member'; clarification of new arrangements for decision making for the new CCG.
2018-21 draft v3	21.3.18	Hempsons Lawyers	Updated wording to draft 2	Add list of changes
	09.05.18	S Forbes, S Stockill, E Micklethwaite, J Howard	Updated wording to draft 3	Add list of changes

