



Individual Funding Requests (IFR) Policy for the Clinical Commissioning Groups in Leeds

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

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| Version: | 2016-19 Updated October 2017 |
| Ratified by: | NHS Leeds Clinical Commissioning Groups Partnership Quality and Performance Committee – 9 November 2017 |
| Name & Title of originator/author(s): | Dr Simon Stockill & Dr Manjit Purewal, Joint Medical Directors Leeds Clinical Commissioning Groups Partnership Dr Fiona Day, Consultant in Public Health Medicine, Leeds City Council |
| Name of responsible committee/individual: | Dr Simon Stockill & Dr Manjit Purewal, Joint Medical Directors Leeds Clinical Commissioning Groups Partnership |
| Date issued: | 13 November 2017 |
| Review date: | December 2019 |
| Target audience: | Primary and secondary care clinicians, individual funding request panels, and the public |
| Document History: | Leeds CCGs policy Feb 2014 |

Produced on behalf of NHS Leeds Clinical Commissioning Groups Partnership

Summary

This policy applies to all Individual Funding Requests (IFR) for people registered with General Practitioners in the following three Clinical Commissioning Groups (CCGs), where the CCG is the responsible commissioner for this treatment or service:

- NHS Leeds West CCG
- NHS Leeds North CCG
- NHS Leeds South and East CCG

This policy does not apply where any one of the Leeds CCGs is not the responsible commissioner.

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

All IFR and associated policies will be publically available on the internet for each CCG.

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1 Introduction

The Clinical Commissioning Groups (CCGs) (NHS Leeds West CCG, NHS Leeds North CCG and NHS Leeds South and East CCG) were established on 1 April 2013 under the Health and Social Care Act 2012 as the statutory bodies responsible for commissioning services for the patients for whom they are responsible in accordance with s3 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 CCGs in Leeds are accountable to their constituent populations and Member Practices for funding decisions.

In relation to decisions on Individual Funding Requests (IFR), the CCGs in Leeds have a clear and transparent process and policy for decision making. They have 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 by the Non Commissioned Activity Panel, Cosmetic Exclusions and Exceptions Panel, or Non NICE Non Tariff Drug Panel (the IFR panels).

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 Leeds CCGs Commissioning Policies. This process must be equitably applied to all IFRs.

All IFR and associated policies will be publically available on the internet for each CCG. Specialist services that are commissioned by NHS England or Public Health England are not included in this policy.

2 Purpose

The purpose of the IFR policy is to enable officers of the Leeds CCGs to exercise their responsibilities properly and transparently in relation to IFRs, and to provide advice to general practitioners, 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 CCGs.

The policy outlines the process for decision making with regard to services/treatments which are not normally commissioned by the CCGs in Leeds, and is designed to ensure consistency in this decision making process.

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.

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 cross-Leeds Clinical Commissioning Group statement. The IFR process therefore provides a mechanism to allow drugs/treatments that are not routinely commissioned by the Leeds CCGs to be considered for individuals in exceptional circumstances.

3 Service Developments

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

Interventions recommended in NICE technology appraisals will be implemented only when guidance is published unless previously prioritised. The Leeds CCGs do 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.

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 of 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

4 Scope

The CCGs in Leeds have 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 CCGs in Leeds Commissioning Policies

- Requests for approval for an exception to the CCGS in Leeds 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).

5 Definitions

The CCGs in Leeds are not prescriptive in their definitions. Each IFR will be considered on its merits, applying this Policy.

6 Core Principles for Managing Individual Funding Requests in Leeds

The principles listed below are the core principles for priority setting within Leeds CCGs. They are based on NHS England's Core Principles¹ 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 decision making frameworks for Leeds CCGs, including:

- Decision Support Framework for ongoing access to treatment requests following an industry sponsored trial or sponsorship, privately funded treatment, an N of 1 trial of treatment, treatment initiated/ approved by another CCG (or PCT) or a not for profit trial funded by a national recognised body eg MRC
- Decision support framework for defining the boundaries between privately funded treatment and entitlement to NHS funding under a range of circumstances
- Commissioning Framework for Experimental Treatments
- Framework for clinical interventions that are targeted to deliver maximum health benefit

Principle 1

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

Principle 2

The three Leeds Clinical Commissioning Groups have a legal duty to commission healthcare within the areas for which they have commissioning responsibility. This must be consistent with its legal duty to not overspend their allocated budget.

Principle 3

The three Leeds Clinical Commissioning Groups have a responsibility to make rational decisions in determining the way they allocate resources to the services they directly commission. Each organisation 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 areas of responsibility of the

¹ <http://www.england.nhs.uk/wp-content/uploads/2013/04/cp-01.pdf> (accessed 9/9/13)(reviewed 19/05/16)

three Leeds Clinical Commissioning Groups should have an equal chance of being considered, subject to the capacity of the three Leeds Clinical Commissioning Groups 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 dependants), 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 three Leeds Clinical Commissioning Groups 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 three Leeds Clinical Commissioning Groups must ensure that the decisions they take demonstrate value for money and an appropriate use of NHS funding based on the needs of the population they serve.

Principle 9

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

Principle 10

The three Leeds Clinical Commissioning Groups 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 three Leeds Clinical Commissioning Groups 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 three Leeds Clinical Commissioning Groups save for those treatments approved by other NHS bodies and/or by sending organisations eg former PCTs, 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 three Leeds Clinical Commissioning Groups unless the relevant Leeds Clinical Commissioning Group 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 three Leeds Clinical Commissioning Groups, in general they 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.

7 Eligibility

This policy applies to patients registered with General Practitioners within the Leeds Clinical Commissioning Groups (NHS Leeds West CCG, NHS Leeds North CCG and NHS Leeds South and East), or patients who are deemed to be resident under the NHS Health and Social Care Act 2012 where one of the three Leeds CCGs is the responsible commissioner. This policy does not apply where any one of the Leeds CCGs is not the responsible commissioner.

Applications for consideration by the IFR panels must be submitted to the Business Manager, NHS Leeds West CCG, on behalf of all CCGs in the city.

8 Information for Patients

It is fundamental that decisions are based on the principles of equality of access and are based on the health needs of the patient.

Information for patients which outlines the process and method for making an IFR, and appealing a decision of an IFR panel, are available on the Leeds CCGs respective websites. This is to ensure that patients and clinicians have access to the policies within which the IFR panels operate.

This policy, and those clinical policies/frameworks which support the IFR process,

are available to members of the public and referring clinicians via the Leeds Clinical Commissioning Group's respective website.

9 Responsibilities & Duties

Whilst this policy and associated decision making policies will be applied on a cross-Leeds basis for patients from all three CCGs in Leeds, each individual CCG will retain responsibility for the decision making for its own patients. To this end, each CCG will delegate its decision making in relation to IFRs to a CCG specific decision maker for patients from that specific CCG, in accordance with its own Constitution.

This decision maker will attend the relevant IFR panel and will also have responsibility for approving the triage process for patients from their own CCG population. The triage process is the process of screening requests to see whether the request meets the policy criteria and which referrals need to be considered by an IFR panel; see sections on IFR panels for more information. The decision maker for each CCG is responsible for decision making solely for patients within their own CCG registered population. This will normally be the Medical Director or their designate. This will be detailed in the CCG Constitution as an Appendix.

In exceptional circumstances, when a CCG is unable to send a delegated decision maker to the IFR panel, the panel may discuss the case in their absence and may make a recommendation. However, the decision maker for the specific CCG must make the final decision whether or not to approve the IFR.

10 Evidence Based Commissioning/Clinical Effectiveness

Each of the panels identified in the policy will ensure that the decisions they reach are reasonable and lawful, and are based on assessment that the proposed clinical intervention will provide the intended health benefit and improved health for the patient. Priority will be given to clinical interventions which achieve maximum health benefit.

To support each of the panels in assessing the potential for health benefit, access to appropriate specialist or professional opinion will be sought where required. The CCGs in Leeds have a budget to facilitate the attendance of an expert clinician or professional to give their advice.

11 Equality Statement

The Leeds CCGs have 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 Leeds CCGs are 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 their functions, the Leeds CCGs 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.

12 IFR Framework, Governance & Procedure

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

The process for considering an IFR encompasses the following:

- Notes of IFR panels' decision making processes and outcomes will be retained.
- IFR panels' decisions will be externally reviewed on a periodic basis to ensure consistency in decision-making and outcomes. An annual report will be presented to the Governing Body of each CCG and the IFR process will be subject to Internal Audit.
- Information governance standards will be maintained in relation to patient information and confidentiality, in line with Caldicott Guidelines, the Data Protection Act 1998, and the common law duty of confidentiality.
- Decisions of the IFR panels will be anonymised and a summary presented to the relevant Leeds CCG Governing Bodies. This will allow the CCGs Governing Body and members of the public to scrutinise the application of the IFR policy.
- The relevant Leeds CCG communications team will handle media requests.
- Ongoing audits of patient outcomes will be undertaken for patients who receive exceptional funding in order to inform future decision making.
- A logging and tracking system will be used to ensure that IFRs are dealt with consistently and in a timely way.
- A documented screening (triage) system will be used to identify IFRs:
 - that represent service developments.
 - for which there clearly is no clinical case.
 - that raise a major policy issue and need more detailed work.
 - that can be funded because they meet pre-agreed exceptions.
 - that can be dealt with under another existing contract.
 - for which an alternative satisfactory solution can be found.
- Standard letters will be used for screened cases.
- If an IFR passes the screening (triage) system, consideration will be given to whether the request has sufficient clinical and other information in order for the IFR to be considered fully by the IFR panels. Where information is lacking, the IFR will be declined and returned to the clinician specifying the additional information required to enable the request to proceed.
- A standard pro-forma will be used that clearly indicates the information that the IFR Panel needs.
- Leaflets will be available that explain the IFR process and exceptionality for clinicians and for patients in plain English.
- The Leeds CCGs will ensure that all individuals involved in decision making, at whatever level, are familiar with the CCGs approach to priority setting, as well as all legal and ethical issues. This includes the requirement to have due regard to the obligations of the Equality Act 2010 save where a difference in treatment is based on objectively justifiable factors and is a justified and proportionate response to the needs of different groups of people.
- A support team will be available that can gather necessary supplementary information.
- A system will be used that allows for the possibility of gathering more clinical information or receiving information from the patient.
- The IFR panels will not make policy decisions for the Leeds CCGs.

Clinical policy questions should always be referred for consideration by the relevant delegated committee of each CCG and agreed on a cross-Leeds basis.

- There is a process by which an IFR decision can be appealed. Each CCG will have its own separate appeals process (see below). All correspondence will be copied to the patient, their carer or guardian (if appropriate) and General Practitioner, unless there are specific reasons to suggest that this is not in the best interests of the patient.

13 Exceptionality

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

The Leeds CCGs must coherently explain their decisions to clinicians, patients and the public. Their 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 CCGs 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 CCGs 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;
- 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 exceptionality.

13.1 Factors that can be taken into account in deciding if a patient is 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 will not be taken into account (except where defined by law eg military personnel), neither will psychological factors 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 have a broad discretion to determine whether the proposed treatment is a justifiable expenditure for the CCG. The IFR panels are however required to bear in mind that allocating any resources to support any individual patient will reduce the availability of resources for investments in previously agreed care and treatments.

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.

13.2 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 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 relevant CCG Governing Body.

14 Information submitted to the IFR Panel

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

It is the clinician’s responsibility to ensure that the appropriate information is provided to the Leeds CCGs. 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 that₁ is₂

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 directly from patients in addition to the clinician's request.

15 The IFR Panels

The Cosmetic Exceptions and Exclusions Panel (CEEP), the Non Commissioned Activity Panel, and the Non-NICE, non-Tariff Drugs Panel will consider all IFRs received by the Leeds CCGs. A limit of £100,000 for an individual IFR will apply at which point the relevant CCG Medical Director will discuss the case with relevant CCG Chief Officer and Chair who will in turn report the IFR to the CCGs Governing Body.

15.1 Cosmetic Exceptions and Exclusions Panel (CEEP)

This panel will consider all requests from local primary care clinicians or hospital clinicians against the criteria for access to procedures defined by the evidence based Leeds CCGs framework for Aesthetic (Cosmetic) procedures.

Referrals to this panel can be forwarded by the patient's general practitioner or hospital clinicians to the Business Manager at NHS Leeds West CCG, on behalf of all CCGs in the city.

Membership of the Group:

- Decision maker delegated from the Medical Director from each of the three Leeds CCGs normally a General Practitioner (also double up as Panel Chair on a rotating basis).
- City Wide IFR Business Manager from NHS Leeds West CCG (administrative role).
- Consultant in Public Health/ Public Health Medicine, Leeds City Council (advisory role).
- Specialist Advisors which may include dermatologist; psychiatrist; plastic surgeon; psychiatric nurse specialist (advisory roles).
- Trained lay observer (Observation role only)

The panel will appoint co-opted clinical professionals if cases received for consideration by the panel require expert clinical opinion. The panel must have an administrator/ minute taker.

The panel will meet on a monthly basis, with decisions being communicated to the requesting clinician within seven working days of the date from the date of the panel.

See Appendix A for the Terms of Reference and referral process for the CEEP panel.

15.2 Non Commissioned Activity Panel (NCA)

This panel will consider applications for:

- Access to treatment outside the NHS
- Access to services not normally commissioned by Leeds CCGs

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.

Referrals to this panel can be forwarded by the patient's general practitioner or hospital clinician to the Business Manager, NHS Leeds West CCG, on behalf of all CCGs in the city.

Membership of the Group:

- Decision maker delegated from the Medical Director from each of the three Leeds CCGs normally a General Practitioner (also double up as Panel Chair on a rotating basis)
- City Wide IFR Business Manager from NHS Leeds West CCG (administrative role)
- Consultant in Public Health/ Public Health Medicine, Leeds City Council (advisory role)

- Specialist Advisors which may include dermatologist; psychiatrist; plastic surgeon; psychiatric nurse specialist (advisory roles).
- Trained lay observer (Observation role only)

The Panel will appoint co-opted clinical professionals if cases received for consideration by the panel require expert clinical opinion. It must have an administrator/ minute taker.

The panel will meet on a monthly basis, with decisions being communicated 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.

See appendix B for Terms of Reference and Pathways of the NCA Panel.

15.3 Non-NICE, Non-Tariff Drugs Panel (NNNT)

This panel will consider 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 of medicines in Leeds is included as appendix C. This panel will use the Non Nice Non Tariff Drugs underpinning Policy as the basis for decision making.

Referrals to the panel can be forwarded by the patient's general practitioner, usual clinician, or via the request service at Leeds Teaching Hospitals NHS Trust, using the Leeds CCGs' request form.

Membership of the Group:

- Decision maker delegated from the Medical Director from each of the three CCGs in Leeds normally a General Practitioner (also double up as Panel Chair on a rotating basis)
- Consultant in Public Health Medicine (advisory role)
- Citywide IFR Business Manager from NHS Leeds West CCG (administrative role)
- Leeds Collaborative Plus Medicines Effectiveness Pharmacist (advisory role)
- Other specialist advisors as needed. The panel will appoint co-opted clinical professionals if cases received for consideration by the panel require expert clinical opinion. It must have an administrator/ minute taker.

The panel will meet on a monthly basis, with decisions being communicated to the requesting clinician within seven working days of the date from the date of the panel. The panel can be convened on exception when requested by the chair of the panel.

See Appendix C for Terms of Reference and Pathway for the NNNT Panel.

16 Review Process

Each CCG has established a mechanism to review the decisions of the three IFR panels with regard to its own population. Where an IFR panel has refused to support funding for a requested treatment, or has approved the treatment subject to conditions, the patient shall be entitled to ask for a review.

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.

16.1 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 disagrees 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.

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.

16.3 Membership of the Appeals Panel

NHS Leeds West CCG

- Chief Officer and Lay Member for Governance
- In attendance (non-voting) Commissioning Manager (to act as Case Manager and present the case)

NHS Leeds North CCG

- Chief Officer, Executive Director and non-executive Director
- In attendance (non-voting) Commissioning Manager (to act as Case Manager and present the case)

NHS Leeds South and East CCG

- Chief Clinical Officer (or designate) and one other member of the Governing Body
- In attendance (non-voting) Commissioning 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 relevant Leeds 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.

See Appendix D for the Appeals flowchart.

17 Urgent Treatment Decisions

The Leeds CCGs recognise 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 Leeds CCGs' normal policies. In such circumstances, the Leeds CCGs recognise 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, the Leeds CCGs expect 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 Leeds CCGs not to be taking all reasonable steps to minimise urgent requests to the IFR process, the Leeds CCGs 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 in each 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.

18 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.

19 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.

20 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.

21 Monitoring compliance and effectiveness

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 CCGs in Leeds Commissioning Policies.

The financial impact of approvals outside of existing Service Level Agreements will be monitored to ensure the Leeds CCGs identify expenditure and ensure appropriate value for money. Member Practice clinicians need to be aware that all referrals will ultimately be a call on their own CCG budgets.

22 Associated Documentation

This policy must be read in conjunction with the underpinning Leeds CCGs decision making frameworks.

23 References

- NHS Confederation. Priority setting: managing individual funding requests. <http://www.nhsconfed.org/resources/2008/12/priority-setting-an-overview> (accessed 7/6/16)
- NHS Confederation. Priority setting: legal considerations <http://www.nhsconfed.org/resources/2008/12/priority-setting-legal-considerations> (accessed

7/6/16)

Appendix A: Cosmetic Exclusions and Exceptions Pathway and Terms of Reference

NB referrals sent directly to a hospital consultant without prior approval from CEEP will be returned to the GP

Patient Consults GP/clinician (or representative) asking for cosmetic surgery

Advise patient cosmetic surgery unlikely to be available on NHS. Is the case an exception? Does it meet the prior approval criteria? Are the grounds for exception clear (consult current Cosmetic Exceptions Framework).

YES

GP/clinician (or representative) requests exception from the Leeds CCGs Cosmetic Exceptions panel, explaining the reasons why the patient should be treated **(L)**

Referrals to a provider without Cosmetic panel approval will be returned to the GP

Cosmetic Exclusions and Exceptions Panel Public Health Advisor triages request.

Request additional information ←

1. Is there enough evidence to support the exception application?
2. IFRs which clearly meet or fail to meet requirements of policy can be actioned at this stage but need to be authorised by CCG decision maker.
3. Otherwise forward to monthly exceptions panel

Panel decides if patient qualifies for treatment based on detail within the exception application **(P)** The Panel meets to discuss each case on an anonymous basis where the decision is uncertain to determine outcome of the request. CCG decision maker authorises triage decisions for their own CCG.

GP informed of the decision and is asked to inform the patient of the decision

YES **NO**

Refer to appropriate consultant

1. Provide further information if available
2. Relevant CCG appeal panel if it is felt due process has not been followed
3. Patient seeks legal advice if wishes to take further

(L) The letter must include as much background information as possible on the reasons for exception and any relevant medical history. The current Leeds CCGs' Cosmetic Exceptions Framework must be consulted. The patient must be advised that it is unlikely that cosmetic surgery will be available on the NHS. The letter must be sent to the Business Manager, NHS Leeds West CCG on behalf of all CCGs in the city.

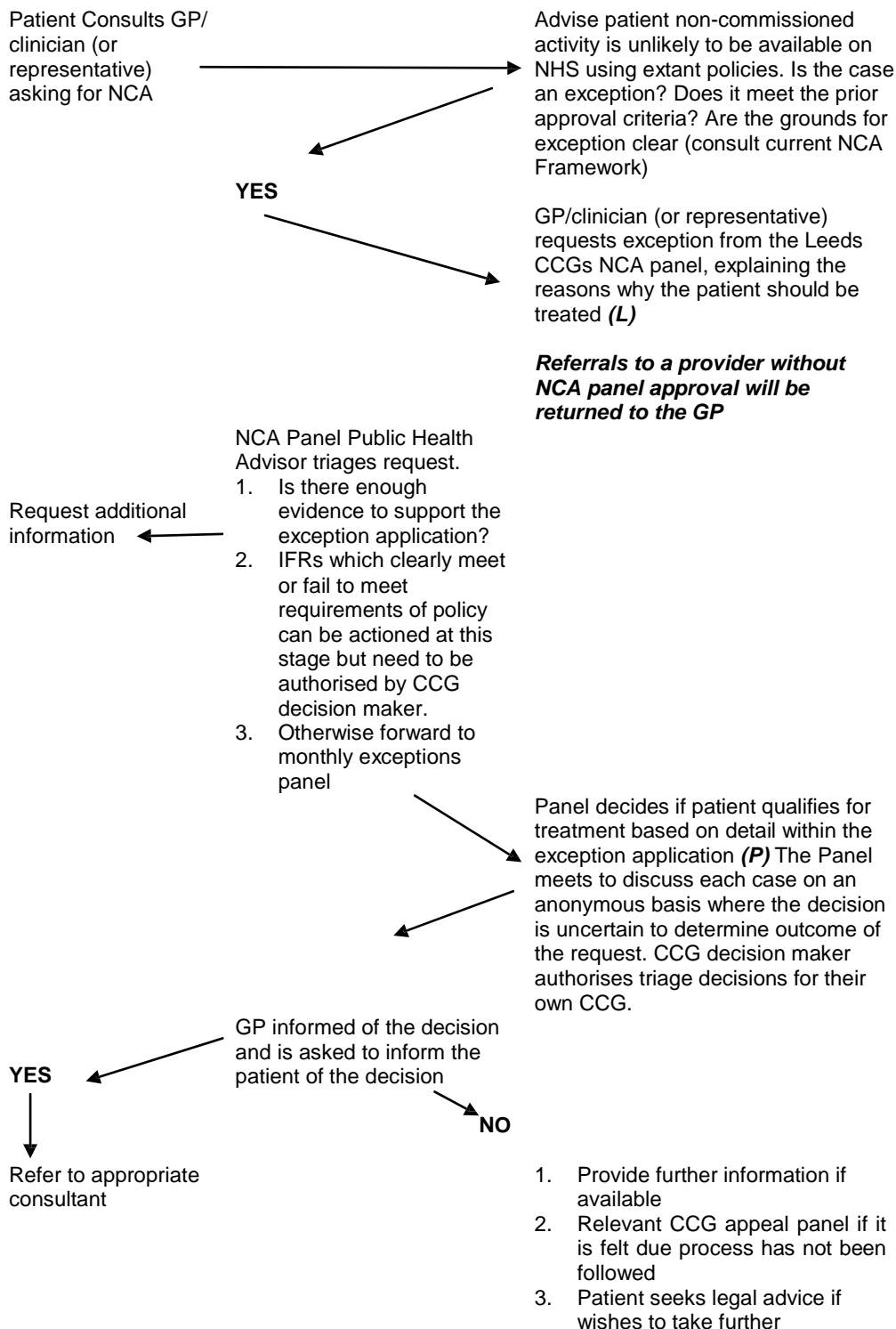
(P) The Exceptions Panel will meet in private. Patients, their representative or GP do not attend. The panel may require access to the patients' GP or Hospital records. Consent for this will be sought from the patient. It is important to note that the panel's decision will be based on the information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

Cosmetic Exclusions and Exceptions Panel Terms of Reference

- IFRs for exception to the Aesthetic (Cosmetic) Surgery policy will be considered by the Cosmetic Exclusions and Exceptions Panel (CEEP).
- The role of the Panel is to seek clarification of the nature of exceptionality.
- The panel is multidisciplinary and inter-organisational with clinical leadership. Each member of the team brings their own expertise to the panel.
- The panel meets on a monthly basis and deals with all requests within eight weeks of receipt. This will normally be at the next scheduled meeting of the panel, subject to the availability of the appropriate supporting information.
- A written response is 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).
- The panel is quorate if attended by at least two members plus the Chair. No decision can be authorised for any CCG that does not have a CCG decision maker attend the panel, and all triage decisions can only be authorised by the relevant CCG decision maker.
- Panel decisions together with supporting evidence are recorded in writing and the appropriate correspondence communicating the outcome and the reasons behind it are sent to the GP/clinician or patient.
- The decision of the panel is final. The panel will consider additional information if the clinical picture has changed. In this circumstance a decision maker from the relevant CCG must make the final decision.

Appendix B: Non Commissioned Activity Referral Pathway and Terms of Reference

NB referrals sent directly to a hospital Consultant without prior approval from the NCA Panel will be returned to the GP



(L) The letter must include as much background information as possible on the reasons for exception and any relevant medical history. The Leeds CCGs' current non Commissioned Activity Framework must be consulted. The patient must be advised that it is unlikely that

non-commissioned activity will be available on the NHS. The letter must be sent to the Business Manager, NHS Leeds West CCG on behalf of all CCGs in the city.

(P) The Exceptions 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.

Non Commissioned Activity Panel Terms of Reference

- A request by a referring GP to consider an intervention outside agreed SLAs and contracts will be considered by the Non Commissioned Activities Panel (NCA). The role of the panel is to seek clarification of the likely effectiveness of the proposed intervention, and assure themselves that the interventions cannot be provided through existing contracting arrangements.
- The panel is multidisciplinary with clinical leadership. Each member of the team brings their own expertise to the panel.
- The panel meets on a monthly basis and deals with all requests within four weeks of receipt. This will normally be at the next scheduled meeting of the panel, subject to the availability of the appropriate supporting information. The chair of the panel will make decisions where the clinical situation dictates a more rapid response
- A written response is provided to the GP/clinician within seven working days of the panel meeting. This response includes details of the outcome of the Panel and complaint procedure (if appropriate).
- The panel is quorate if attended by at least two members plus the chair. No decision can be authorised for any CCG who does not have a CCG decision maker attend the panel, and all triage decisions can only be authorised by the relevant CCG decision maker.
- Panel decisions together with supporting evidence are recorded in writing and the appropriate correspondence communicating the outcome and the reasons behind it are sent to the GP/clinician or patient.
- The decision of the panel is final. The panel will consider additional information if the clinical picture has changed. In this circumstance a decision maker from the relevant CCG must make the final decision.

Appendix C: Non NICE Non Tariff Drug Panel Pathway and Terms of Reference (NNNT)

Non NICE Non Tariff Drug Pathway

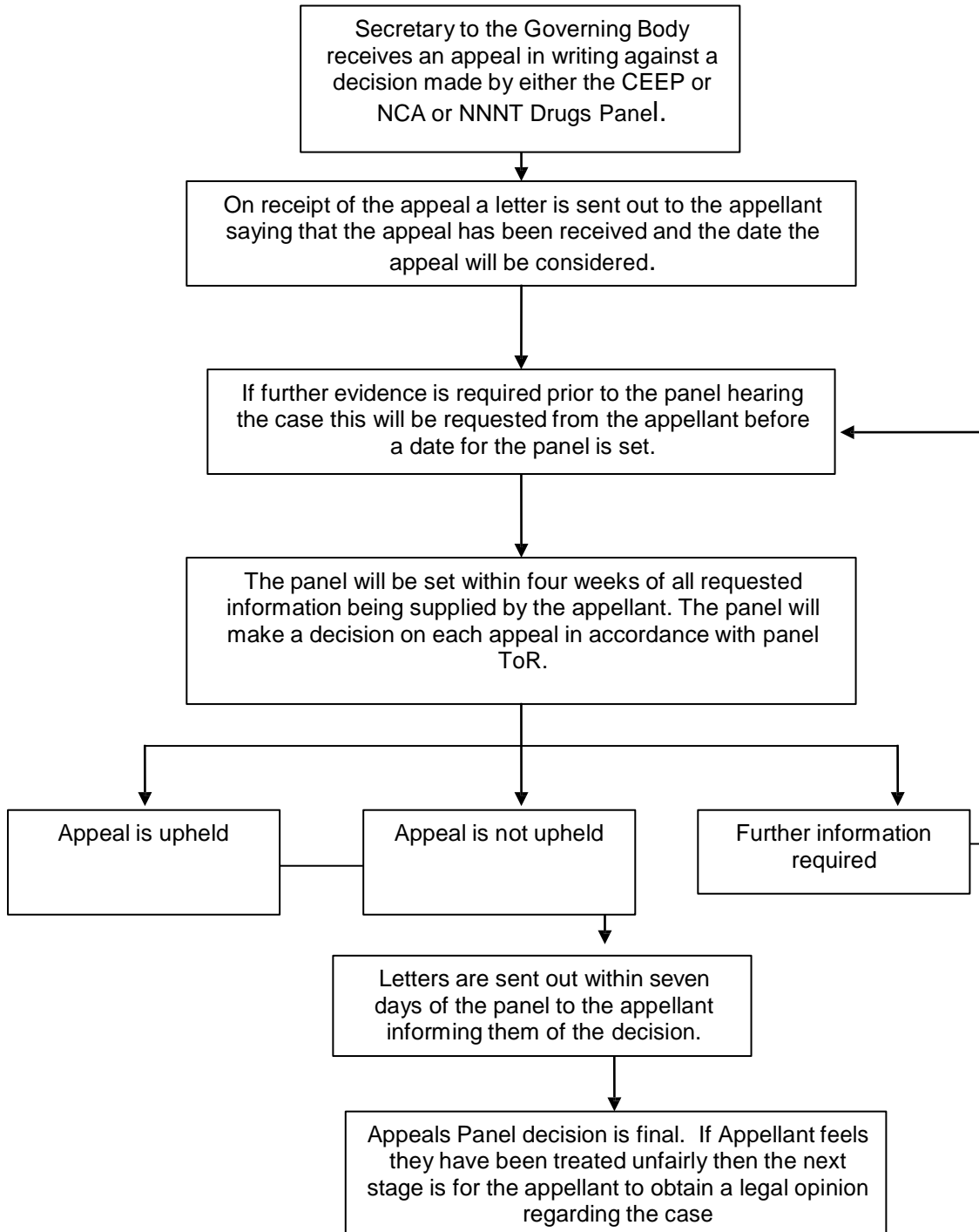
Referrals from secondary care providers can be e-mailed via the agreed request process, other clinicians and GPs should write to the Business Manager, NHS Leeds West CCG.

Non NICE Non Tariff Drug Panel Terms of Reference

- A request by a referring GP or Clinician to consider a NNNT drug will be considered by the Non NICE Non Tariff Drug panel.
- The role of the panel is to seek clarification of the likely cost effectiveness of the proposed intervention.
- The panel is multidisciplinary with clinical leadership. Each member of the team brings their own expertise to the panel, however the decision making is delegated solely to the delegated decision maker for the relevant CCG.
- The panel meets on a fortnightly basis and deals with all requests within two weeks of receipt. This will normally be at the next scheduled meeting of the panel, subject to the availability of the appropriate supporting information. The named decision maker for each CCG will make decisions where the clinical situation dictates an urgent response if there is not sufficient time to convene the panel.
- A written response is e-mailed to LTHT within 24 hours or sent to the clinician or GP initially within 24 hours by fax and then in writing within seven working days of the panel meeting. This response includes details of the outcome of the panel. Where a request is turned down the panel will automatically ask the clinician if there is any additional information that they want to be considered, but the decision of the panel will not be changed unless additional relevant information becomes available.
- The panel is quorate if attended by at least two members plus the chair. No decision can be authorised for any CCG who does not have a CCG decision maker attend the panel, and all triage decisions can only be authorised by the relevant CCG decision maker.
- Panel decisions together with supporting evidence are recorded in writing and the appropriate correspondence communicating the outcome and the reasons behind it are sent to the clinician, GP or patient.
- The decision of the panel is final. The panel will consider additional information if the clinical picture has changed or if it requests further clarification. In this circumstance a decision maker from the relevant CCG must make the final decision.

Appendix D: Appeals Assessment Pathway

Appeals Assessment Pathway



Appendix E: Equality Impact Assessment

| | | |
|--|---|---------|
| Title of policy | Individual Funding Requests | |
| Names and roles of people completing the assessment | Fiona Day Consultant in Public Health Medicine, Helen Lewis, Head of Acute Provider Commissioning | |
| Date assessment started/completed | 26.6.16 | 25.7.16 |

| 1. Outline | |
|---|--|
| Give a brief summary of the policy | The purpose of the commissioning policy is to enable officers of the Leeds CCGs 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 funding allocation of the CCGs. This policy relates to Individual Funding Requests. |
| What outcomes do you want to achieve | We commission services equitably and only when medically necessary and in line with current evidence on cost effectiveness. |

| 2. Evidence, data or research | |
|---|------------------------|
| Give details of evidence, data or research used to inform the analysis of impact | See list of references |

| 3. Consultation, engagement | |
|---|--|
| Give details of all consultation and engagement activities used to inform the analysis | 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. The policy review was undertaken using any updated NICE |

| | |
|------------------|--|
| of impact | <p>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> |
|------------------|--|

4. Analysis of impact

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; eliminate unlawful discrimination; advance equality of opportunity; foster good relations

| | Are there any likely impacts? Are any groups going to be affected differently? Please describe. | Are these negative or positive? | What action will be taken to address any negative impacts or enhance positive ones? |
|--------------------------------|--|--|--|
| Age | No | | |
| Carers | No | | |
| Disability | No | | |
| Sex | No | | |
| Race | No | | |
| Religion or belief | No | | |
| Sexual orientation | No | | |
| Gender reassignment | No | | |
| Pregnancy and maternity | No | | |
| Marriage and civil | No | | |

| | | | |
|--|----|--|--|
| partnership | | | |
| Other relevant group | No | | |
| 5. Monitoring, Review and Publication | | | |
| If any negative/positive impacts were identified are they valid, legal and/or justifiable? Please detail. | | | |

| | | | |
|---|--|---------------------|----------|
| 5. Monitoring, Review and Publication | | | |
| How will you review/monitor the impact and effectiveness of your actions | Annual report of IFR activity reported through relevant committees to Governing Bodies of the 3 CCGs. A limited equity audit is undertaken as part of this. Complaints and appeals monitoring. | | |
| Lead Officer | Simon Stockill | Review date: | Dec 2019 |

| | | | |
|--|---|-----------------------|---------|
| 6. Sign off | | | |
| Lead Officer | | | |
| Director on behalf of the 3 Leeds CCG Medical Directors | Dr Simon Stockill, Medical Director, Leeds West CCG | Date approved: | 24.8.16 |

Appendix F Policy Consultation Process:

| | |
|---|---|
| Title of document | Individual Funding Requests (IFR) Policy for the Clinical Commissioning Groups in Leeds |
| Author | F Day |
| New / Revised document | Revised |
| Lists of persons involved in developing the policy | F Day Consultant in Public Health Medicine, Leeds City Council; Hempsons Lawyers |
| List of persons involved in the consultation process: | See appendix A |

Appendix G: 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 | FDay | 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.' |

