LOCAL DECISION MAKING ABOUT INDIVIDUAL FUNDING REQUESTS (IFRs) FOR MEDICINES AND OTHER INTERVENTIONS

An Individual Funding Request (IFR) is a request to fund a healthcare intervention for an individual that falls out of the range of services and treatments that the local Clinical Commissioning Group has agreed to commission.
1. Introduction

This Policy describes the guiding principles and framework by which the IFR process operates, the processes by which NHS Clinicians make funding requests on behalf of their patients, and refers to the commissioning policies which guide the IFR Panel through their decision making. It sets out a framework which is designed to ensure consistently fair and equitable consideration of requests for funding or treatment outside routine contractual agreements.

This Policy applies to all employees of the Doncaster CCG contract and agency staff and any other individual working on behalf of Doncaster CCG.

2. Overview

NHS Doncaster CCG make decisions about the funding of medicines and other interventions on a population basis for the majority of interventions. Contracts for these routinely commissioned interventions are then put in place. Where a clinical need is identified for interventions that sit outside routine commissioning, these requests are subject to a process called Individual Funding Requests (IFR). The NHS Constitution (January 2009) states:

- You have the right to drugs and treatments that have been recommended by NICE for use in the NHS, if your doctor/registered health practitioner says they are clinically appropriate to you.

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

An Individual Funding Request is therefore normally regarded as being appropriate for a treatment, intervention or drug not routinely commissioned by Doncaster CCG.

These requests, for exceptional funding, are considered by the Individual Funding Request (IFR) Panel. The Panel meets on a weekly basis to decide upon funding requests for medical and general health interventions that sit outside that which is routinely commissioned.

The IFR Panel business centres around requests which are either where:

- There is a commissioning standard operating procedure not to fund a health care intervention for the specified indication but a referring clinician considers their
patient to be exceptional to that standard Policy, those requests will be considered for funding by the IFR Panel. In addition the IFR Panel will consider a request where the clinical circumstances are so unique that it is unlikely that other patients will require this intervention.

- There is no standard operating procedure in place for the requested health care intervention or indication and the clinical circumstance is so rare that it is unlikely that other patients will routinely require this intervention. Usually these requests are for a new intervention which has become available and which has not previously been considered. The IFR Panel will identify whether this request is likely to apply to a population of patients. The overall aim is to reduce the number of requests to the IFR Panel and to concentrate on developing policies for new and existing interventions and treatments.

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

- The triage process during which requests are filtered to ensure they are appropriate IFR requests (this process is not a decision making process).
- The IFR Panel during which funding decisions are made on behalf of the CCG.
- The Appeals Panel which is convened when a request has been declined and the referring clinician or their patient believes that there has been a failure to follow due process or to interpret the standard Policy.

3. Exceptionality

Exceptionality should be considered in the context of the CCGs policies for a health care indication. In general, the IFR Panel must justify the grounds upon which it chooses to recommend funding a healthcare intervention for a patient when that intervention is unavailable to others with the condition.

A patient may be considered exceptional to the general standard Policy if both the following apply:

- He/she is different to the general population of patients who would normally be refused the healthcare intervention, and
- There are good grounds to believe that the patient is likely to gain significantly more benefit from the intervention than might be expected for the average patient with that particular condition.

In assessing exceptionality, the IFR Panel will not consider social, demographic or employment circumstances.
Where a patient has already been established on a health care intervention, for example as part of a clinical trial or following payment for additional private care, this will be considered to neither advantage nor disadvantage the patient. However, response to an intervention will not be considered to be an exceptional factor.

4. Principles and Values

NHS Doncaster CCG have a statutory duty to maximise the health of the local population by ensuring the provision of accessible, quality health care services within available resources. However, demand for services for patients may exceed the capacity and resources available. There is, therefore, a constant need to prioritise spending on clinical and cost effective interventions and with due consideration to equity of access. The IFR Panel therefore applies a fundamental set of principles to all such decision making and these are reflected in the work of the IFR department as outlined below:

- The IFR department must ensure that all processes potentially involving patient identifiable information are managed confidentially and comply with data protection standards.

- The IFR Panel must ensure that the intervention requested is likely to be provided where the patient may gain easy access, will be affordable, and have sound evidence of clinical and cost effectiveness.

- The IFR Panel should promote the use of more effective services over less effective (giving due consideration to equity and accessibility) and utilise existing proven pathways of care over new or experimental technologies.

- The IFR Panel will seek to identify interventions producing the greatest health outcomes, and will consider all national and local guidance and local funding priorities.

The IFR Panel is committed to ensuring that decision making is transparent, fair, equitable and open to scrutiny. Application of this standard Policy in practice should ensure that the IFR process stands up to external scrutiny. The standard Policy is available on the CCG website and accessible to all.

At all times decisions to fund treatments will be based upon both national guidance and locally adopted policies. Interventions recommended in NICE technology appraisals will be implemented on publication of guidance unless previously prioritised. Patients have the right to have funding made available where the drug or treatment requested through the IFR is recommended in NICE Technology Appraisal Guidance. Where NICE has yet to issue guidance, or where NICE will not be appraising a drug, the IFR Panel should make decisions based upon rational and proper consideration of all evidence available.
5. **Consideration of Individual Funding Requests**

5.1 **Pre-requisites**

The following criteria need to be met prior to the consideration of an IFR request:

- The patient must be registered with a South Yorkshire and Bassetlaw General Practitioner.
- The request for funding must be made by an NHS clinician, or a medical consultant within the independent or private sector with whom one of the South Yorkshire and Bassetlaw CCGs hold a contract.

5.2 **Process**

5.2.1 **Triage**

The purpose of triage is to ensure that only appropriate requests go forward for Panel consideration and is not a decision making process. Requests may be redirected if they are not appropriate IFR requests (for example requests for removal of benign skin lesions that should follow the dermatology pathway) or the pre-requisites above are not met. Occasionally requests are received for healthcare interventions that are part of the contracted activity between a specific provider and CCG. These will be triaged out of the process and the clinician making the request will be informed that no prior approval is required.

5.2.2 **Panel**

*Preparation*

The agenda and paperwork for the panel is prepared in advance.

*Meeting structure*

The meeting is held weekly and considers all requests that are received on (up to and including) the Thursday lunch time of the previous week. The Terms of Reference can be found at Appendix 1.

*Membership*

- At least one GP Medical Advisor (clinical advice, research, clinical liaison and decision-making). Medical Advisors may be virtual and may submit their comments to the IFR team prior to a meeting.
- 1 IFR Lead Manager or deputy (compliance with IFR and commissioning standard Policy and communication of further commissioning actions)
- Other clinicians as required, including Complex Neurology and Rehabilitation Advisor, Pharmacist.
• IFR Assurance Officer or deputy (to record decisions and actions and aid compliance with standard Policy)

Procedure
Each case is considered in turn, with reference to all the available information, and with participation of additional clinical advisors as required. The outcome for each case will be one of the following:

• Approved
  o Patient meets standard Policy criteria
  o Patient does not meet standard Policy criteria but evidence of exceptionality has been provided

• Declined
  o Patient does not meet standard Policy criteria
  o Patient does not meet standard Policy criteria and evidence of exceptionality has not been provided

• Pended
  o The Panel have considered the information provided and have requested additional information to support the request

Actions are agreed appropriate to the outcome. Standard processes and template documents are in place to facilitate effective communication of outcomes to the requesting clinician and directly to the patient when appropriate. Cases that are pended in order to receive additional information are reconsidered or closed within a specified timeframe (30 days).

Cases will always be reconsidered if new information is presented, even outside the specified timeframe.

5.3 Appealing Against a Decision

Where a decision has been made by the IFR Panel not to fund a healthcare intervention and the clinician that made the request feels that all the relevant information has been provided and considered but is concerned that there has been a failure to follow due process or to interpret the standard Policy correctly, the patient or the clinician can appeal against the IFR Panel decision within 90 working days.
6. OTHER PROCESSES MANAGED BY THE IFR DEPARTMENT

6.1 Requests for Complex rehabilitation

The IFR Panel apply the same standard of robust decision-making to other requests made by NHS clinicians for placements for adults outside of routinely commissioned services, primarily for those with complex rehabilitation needs, such as neuro-rehabilitation. This process has been put in place to ensure placements (which may be provided within the independent sector) are of the correct standard, are closely monitored as to achievement of anticipated benefits, are concluded at the clinically appropriate time and wherever possible ensuring that patients remain linked to local service provision or are reconnected as soon as possible.

6.2 Procedures subject to threshold and prior approval

South Yorkshire and Bassetlaw CCGs from time to time will identify the need to manage referrals for specific indications, in line with achieving evidence-based balanced use of resources. This requires a process of peer assessment of referral or treatment requests against a set of predefined criteria. This process is serviced by the IFR team and requires the same level of GP clinical support as the IFR process.

Where a treatment requested requires commissioner prior approval an appropriate decision on whether to approve funding will be made by the IFR Panel. This is not the same as an IFR request but will follow the same robust decision making process.

6.3 Equipment

The IFR Panel also consider requests for bespoke and standard equipment for adults and children which cannot be provided via equipment loan services.

7. SPECIFIC EXCLUSIONS

IFRs in the following circumstances will normally be refused:

- Where an IFR results from a patient who has paid for treatment who then wishes to have their treatment continued by the same provider but funded by the NHS for whatever reason (e.g. an insurance company refuses to pay the treatment costs or a patient can no longer afford treatment). The provider and/or the GP will be asked to refer the patient to NHS funded services for an assessment of whether the requested care is clinically required and available within existing service agreements held by South Yorkshire and Bassetlaw CCGs.

- Where the IFR requested is also available elsewhere within a Trust with which South Yorkshire and Bassetlaw CCGs have a contract, this will be handled within normal contractual processes. Where the IFR is made retrospectively unless it can be demonstrated that treatment was needed as an emergency.
• Where the patient does not take up treatment within one year of approval being given, then the case will be closed and a new application for funding must be made.

• Where an IFR is made by a non NHS clinician based in a private provider with whom South Yorkshire and Bassetlaw CCGs do not hold a contract.

• Where an IFR is made for a treatment within a private provider, when equivalent NHS services are available.

• Where the IFR is made retrospectively unless it can be demonstrated that treatment was needed as an emergency.

8. REFERRALS TO PROVIDERS IN THE INDEPENDENT SECTOR

IFRs to providers in the independent sector must meet the criteria specified above. The independent sector includes private providers with whom South Yorkshire and Bassetlaw CCGs already hold a contract or where clinical evidence states that this is the only provider which is suitable for the treatment requested.

9. LOW PRIORITY PROCEDURES

Low Priority Procedures (LPPs) are managed by the IFR Team and are submitted via the IFR Safe Haven. They are considered on a weekly basis by an IFR GP Medical Advisor and the outcome for each case will be one of the following:

• Approved – the request meets the standard Policy criteria and is therefore approved

• Declined – the request does not meet the standard Policy criteria and is therefore declined

• Pended – the GP Medical Advisor requires additional information in order to make a decision

Standard processes and template documents are in place to facilitate effective communication of outcomes to the requesting clinical and directly to the patient when appropriate.

10. URGENT REQUESTS FOR FUNDING TREATMENT

The processes outlined below relate to the clinical urgency with which a funding decision must be made by the IFR Panel.

The urgency of the request will be determined by a member of the IFR team, i.e. that the request must be processed quickly in order to avert, alleviate or avoid any perceived
significant harm to the patient, which may arise unless a decision is taken in a shorter timescale than might otherwise be expected within the IFR Process.

The CCG will not retrospectively fund any care or treatment which has not been given prior approval, unless it can be demonstrated that the treatment was needed as an emergency or to avoid a life threatening situation and that unsuccessful efforts were made to contact the IFR Team.

All applications for treatment or funding deemed urgent will be acknowledged by telephone, fax or email on the day of receipt.

Contact will be made with the applicant by telephone to agree a timescale within which a response must be provided in order to meet the patient’s clinical need, this will be a maximum of two working days. In such cases one IFR Medical Advisor and the IFR Lead Manager will be required to make the decision to be ratified by a second medical advisor. The IFR Assurance Officer is notified of the outcome of the consideration of the request and will aim to seek approval from the CCG.

The IFR Assurance Officer will immediately notify the referring clinician of the decision, followed by written confirmation.

The IFR Assurance Officer will notify the panel for ratification at the next panel meeting.

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

11. GENERAL

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

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

12. APPROVAL AND REPORTING ARRANGEMENTS

All recommendations made by the IFR Panel must be signed off by a nominated person with delegated authority from the CCG prior to the clinician who made the request being informed of the outcome.

Where urgent recommendations are made outside the usual IFR Panel meeting, the IFR Assurance Officer will aim to get CCG sign off. If sign off by the CCG cannot be achieved for any reason the referring clinician will be notified of the decision prior to sign off in order to meet the patient’s clinical need.
The IFR panel will operate at all times in accordance with the Standing Orders and the Standing Financial Instructions of CCG. The expenditure of the Panel will be reviewed and reconciled monthly with finance managers.

13. **CONTRACTS**

Subject to the conditions set out in this document, patients may be referred to NHS organisations with which the South Yorkshire and Bassetlaw CCGs hold a contract without the need for prior approval.

For NHS organisations with which South Yorkshire and Bassetlaw CCGs do not hold a contract, different arrangements apply.

If the referral is not to one of the ‘specialised services’ defined by the Department of Health, and it is covered by mandatory tariff, then there is no need for prior approval.
1. **Purpose**

The IFR Panel will consider all requests for treatment that are not routinely commissioned including exceptions to the existing standard Policy and requests made in the absence of any standard Policy.

2. **Membership**

- 2 GP Medical Advisors (clinical advice, research, clinical liaison and decision-making). Medical Advisors may be virtual and may submit their comments to the IFR team prior to a meeting. If only one Medical Advisor is available to consider cases prior to the Panel meeting, all decisions should be signed off by the second Medical Advisor following the meeting.

- 1 IFR Lead Manager or deputy (compliance with IFR and commissioning policies and communication of further commissioning actions)

- Other clinicians as required, including Complex Neurology and Rehabilitation Advisor, Pharmacist etc.

- IFR Assurance Officer or deputy (to present cases and record decisions and actions and aid compliance with policies)

3. **Quoracy**

- The Panel must be quorate to make decisions. At least one GP Medical Advisor and 1 IFR Lead Manager or deputy must be present.

- If only one Medical Advisor is available to consider cases prior to the Panel meeting, all decisions should be signed off by the second Medical Advisor following the meeting.

4. **Panel Decisions**

The Panel will seek to make a majority decision. Where there is a difference of opinion the IFR Assurance Officer will seek further advice from another GP Advisor and the case will be discussed at the next available Panel meeting until a unanimous decision can be made.
5. **Attendance at Meetings**

Other members of staff may be requested to attend the Panel meetings in an advisory capacity as necessary to discuss particular issues or to offer advice to the Panel members.

6. **Frequency of Meetings**

The Panel will meet weekly and will consider all requests received up to Thursday lunch time prior to the meeting.

7. **Duties and Operation**

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

7.2 The IFR Panel may seek additional or supporting information to further inform the request.

7.3 Patient identifiable information will be dealt with in confidence, and will not be used unless essential to the consideration of the request.

7.4 The IFR Panel will consider all the necessary information received from the clinicians involved in the patient’s care.

7.5 The IFR Panel will assess and evaluate the evidence base for the clinical and cost-effectiveness of each intervention under discussion, and will consider the views of relevant stakeholders where appropriate.

7.6 The Panel will produce clear reasons for their decisions, using the checklist which will be based on current guidance, the overall resources available to the CCG decision making values including evidence of effectiveness, equity and accessibility.

7.7 The IFR Panel will always consider national guidance when making decisions on individual cases.

8. **General**

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

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

9. **Review**

These Terms of Reference should be reviewed one year from date of operation.