



# **Individual Funding Requests (IFR)**

**Commissioning Policy  
April 2020**

## **Commissioning Policy NHS Nottingham and Nottinghamshire Individual Funding Requests**

### **I. EQUALITY STATEMENT**

NHS Nottingham and Nottinghamshire Clinical Commissioning Group (NNCCG) aim to design and implement policy documents that meet the diverse needs of the services, population and workforce, ensuring that none are placed at a disadvantage over others. It takes into account current UK legislative requirements, including the Equality Act 2010 and the Human Rights Act 1998, and promotes equal opportunities for all. This document has been designed to ensure that no-one receives less favourable treatment due to their protected characteristics of age, disability, sex (gender), gender reassignment, sexual orientation, marriage and civil partnership, race, religion or belief, pregnancy and maternity. Appropriate consideration has also been given to gender identify, socio-economic status, immigration status and the principles of the Human Rights Act.

In carrying out their function, Nottingham and Nottinghamshire CCG must have due regard to the Public Sector Equality Duty (PSED). This applies to all activities for which Nottingham and Nottinghamshire CCG are responsible, including policy development, review and implementation.

### **ii. DUE REGARD**

This policy has been reviewed in relation to having due regard to the Public Sector Equality Duty (PSED) of the Equality Act 2010 to eliminate discrimination; harassment; victimisation; to advance equality of opportunity' and foster good relations between protected groups.

**Commissioning Policy NHS Nottingham and  
Nottinghamshire CCG (NNCCG) Individual Funding  
Requests:  
Contents**

<b>CONTENTS</b>	<b>PAGE</b>
Equality Statement	2
Due regard	2
1. Introduction	5
2. Purpose	7
3. CCG Commissioning Principles that Underpin IFR Decision making	7
4. Policy Guidance	8
4.1 Introduction to new drugs and technologies	8
4.2 Treatments covered by CCG Commissioning Policies	9
4.3 Treatments not covered by CCG Commissioning Policies	9
4.4 Requests to continue funding for patients coming off drugs trials	10
4.5 Requests to continue funding for treatments commenced “at risk” by providers or by others (including patients)	10
4.6 Requests to continue funding of care commenced privately e.g. reverting to NHS care	11
4.7 Decisions inherited from other CCGs e.g. patients who move	12
4.8 Second Opinions	12
4.9 Treatment in another country	13
5. Defining Exceptionality and An Individual Patient	13
5.1 Exceptionality	13
5.2 An Individual Patient	14
6. The Process for Managing Individual Funding Request (IFR)	16
6.1 Who can submit an IFR	16
6.2 Administration and Reporting	16
6.3 Timescale for Managing an IFR	16
6.4 Initial Handling of an IFR	17
6.5 Submission of a Treatment Request Form	17
6.6 Triage of a Treatment Request Form	18
6.7 Identifying urgent cases	19
6.8 Organisation of an IFR meeting	20
6.9 Membership of the IFR Panel	21
6.10 Conflict of Interest	22
6.11 Decision Making Framework of the IFR Panel	22
6.12 Demonstrating exceptional circumstances	23

6.13 The likely Clinical outcomes of the proposed treatment	24
6.14 The costs of proposed treatment	25
6.15 Similar Patients	25
6.16 Recording the decision	26
6.17 Outcome of the IFR Panel	26
6.18 Reconsideration	26
7. Review of IFR Panel decisions	28
7.1 Grounds for requesting a review of the IFR Panel Decision	28
7.2 Initial Consideration of a request for a review of the IFR Panel Decision	28
7.3 Membership of the Review Panel	28
7.4 Purpose of the Review Panel	29
7.5 Outcome of the Review Panel	30
8. Training	31
9. Monitoring	31
10. References	32

## 1. INTRODUCTION

The NHS exists to serve the needs of all of its patients but also has a statutory duty financially to break even (National Health Service Act 2012). Clinical Commissioning Groups (CCGs) have a responsibility to uphold the pledges of the NHS Constitution, to provide health benefit for the whole of their population, and to commission appropriate care to meet the clinical needs of individual patients. The CCGs receive a fixed budget from Central Government with which to commission the healthcare required by its population. Commissioned services include those provided through primary, secondary and tertiary care NHS providers, the independent sector, voluntary agencies and independent NHS contractors and in house service providers.

NNCCG do not expect to make significant decisions about funding outside the process that is routinely used and in particular do not expect to commit significant new resources in ear to the introduction of new healthcare technologies (including drugs, surgical procedures, public health programmes,), since to do so risks ad hoc decision making and can destabilise previously identified priorities.

The Commissioning process, by its very nature, focuses on cohorts of patients with the more common clinical conditions. It cannot meet every healthcare need of all patients in any one clinical group; or address the specific needs of patients with less common clinical conditions. The fact that the CCG is not meeting a healthcare need due to resource constraints is an inevitable fact of life in the NHS and not indicate that the CCG is breaching its statutory obligations.

The CCG is required to have a process for considering funding for individuals who seek NHS commissioned services outside established commissioning policies. There are in general two types of requests that come before an Individual Funding Request (IFR) Panel, namely:

Requests for funding treatments for medical conditions where the CCG has no established commissioning policy (as shown by CCG policy or the treatments which are approved for routine funding in service agreements).

Requests for funding treatments for medical conditions where the CCG does have an established commissioning policy for that condition but where the requested individual treatment is not in the CCG policy or does not meet the criteria set out in the policy.

This policy requires requests in the first category to be considered against the tests of clinical effectiveness, cost effectiveness and affordability provided the requesting clinician is able to demonstrate that the patient represents an Individual Patient (as defined in this policy who does not

have exceptional clinical circumstances). For patients in the second category the policy requires, as a threshold condition, the requesting clinician to demonstrate that the patient has exceptional clinical circumstances. If the clinician demonstrates that the patient has exceptional clinical circumstances (as defined in this policy) the request will be considered against the tests of clinical effectiveness, cost effectiveness and affordability.

This approach ensures that decisions relating to resource allocation are made transparently and consistently in relation to treatment for those patients with rare conditions, those patients for whom treatments of uncertain or unproven medical benefit are sought, or where treatment costs requested may be out of proportion with the benefit to the patient.

The CCG is responsible for the management of Individual Funding Requests. This policy must be used to consider:

- Requests for any form of medical treatment or care which is not included within existing service agreements;
- Requests for any form of medical treatment or care which, for this particular patient, are outside the parameters set by existing service agreements;
- Requests for any form of medical treatment or care where the treatment or care proposed could not be considered to be „mainstream“.

NHS Nottingham and Nottinghamshire CCG have established a single IFR process to consider such applications. This may include consideration by an Individual Funding Requests Panel. In considering an individual case the Panel will apply the CCG Commissioning Principles for decision making set out in Section 3 and the underpinning policies of the CCG.

## **2. PURPOSE**

The IFR process set out in this policy will be used to consider individual requests for funding where a service, intervention or treatment falls outside existing service agreements.

This process will ensure that each request for individual funding is considered in a fair and transparent way, with decisions based on the best available evidence and in accordance with the CCG commissioning principles.

### **3. CCG COMMISSIONING PRINCIPLES THAT UNDERPIN IFR DECISION MAKING**

It is important that a CCG ensures a consistent approach is used to guide the allocation of its resources in both population based and individual commissioning decisions.

A principle based decision making process supports the strategic planning and the effective use of resources within a CCG. All CCG decisions need to be made in accordance with these principles.

The Principles that the CCG seeks to support are:

- The CCG requires clear evidence of clinical effectiveness before NHS resources are invested in the treatment
- The CCG requires clear evidence of cost effectiveness before NHS resources are invested in the treatment
- The cost of the treatment for this patient and others within any anticipated cohort is a relevant factor.
- The CCG will consider the extent to which the individual or patient group will gain a benefit from the treatment
- The CCG will balance the needs of each individual against the benefit which could be gained by alternative investment possibilities to meet the needs of the community
- The CCG will consider all relevant national standards and take into account all proper and authoritative guidance
- Where a treatment is approved, the CCG will respect patient choice as to where a treatment is delivered.

When considering an IFR, a CCG will also ensure that decisions:

- Comply with relevant national policies or local policies and priorities that have been adopted by the CCG concerning specific conditions or treatments
- Are based on the available evidence concerning the clinical and cost effectiveness of the proposed treatment, including any NICE publications and;
- 1 principle: a basic truth or a general law or doctrine that is used as a basis of reasoning
- Or a guide to action or behaviour is taken without undue delay; a pragmatic approach may need to be taken when dealing with urgent requests i.e. where a delay in reaching a decision to fund adversely affects the clinical outcome.

The CCG considers all lives of all patients to be of equal value and in making decisions about funding treatments will seek not to discriminate on the grounds of age, sex, sexuality, race, religion, lifestyle, occupation, family and caring responsibilities, social position, financial status, family status (including responsibility for dependents), intellectual/cognitive functioning or physical functioning save where a difference in the treatment options made available to patients is directly related to the patient's clinical condition or is related to the anticipated clinical benefits for this individual to be derived from a proposed form of treatment.

#### **4. POLICY GUIDANCE**

In considering individual cases, the CCG will apply the Commissioning Principles, the underpinning policies of the CCG and the following guidance which expands upon them.

##### **4.1 Introduction of New Drugs and Technologies**

With the exception of NICE Technology Appraisals, the CCG will not introduce new drugs/technologies in an ad hoc basis through the mechanism of individual case funding. To do so risks inequity, since the treatment will not be offered openly and equally to all with equal need. There is also the risk that diversion of resources in this way will de-stabilise other areas of health care which have been identified as priorities by the CCG. The CCG expects consideration of new drugs/technologies to take place within the established planning frameworks of the NHS (for example the Local Operational Plan). This will enable clear prioritisation against other calls for funding and the development of implementation plans which will allow access for all patients with equal need.

##### **4.2 Treatments Covered by CCG Commissioning Policies**

The CCG policy is that treatments not currently included in established care pathways (as identified for example in the Schedules to the service agreements with acute care providers) or identified for funding through the commissioning process are not routinely funded. For a number of these interventions the CCG has published specific policy statements setting out restrictions on access based on evidence of effectiveness or relative priority for funding.

Policy development is an on-going process and future policy on further treatments, in response to NICE Guidance/Guidelines, health technology assessments etc will be produced and published.

### **4.3 Treatments Not Covered by CCG Commissioning Policies**

Specific groups of patients may not be covered by CCG Commissioning Policy including:

- Patients with conditions for which the CCG does not have an agreed policy, including patients with rare conditions and whose proposed treatment is outside agreed service agreements
- Patients with conditions for which the CCG does have an agreed policy but who may have exceptional clinical circumstances which lead to their clinician seeking a treatment that is not routinely available.

In such circumstances the CCG will not have given approval in advance to fund the treatment and approval will therefore be required under this policy. The treating clinician should consider, before making the application, whether the requested treatment is an appropriate request judged against the CCG Commissioning Principles.

The role of IFR Panel is to make decisions on individual cases. It cannot be used as a means of „creeping implementation“ for new technologies. Consideration therefore needs to be given as to the likelihood of other patients having the same clinical need who could also benefit from the proposed treatment. If there are or are likely to be other patients then, properly considered, the request is for a service development and not an individual application. Where a decision may affect other patients, the application should be considered as a service development and not through the IFR process.

Patients with rare conditions should neither be advantaged nor disadvantaged simply because their condition is uncommon. This means that the same approach will be taken in applying the principles of clinical effectiveness and cost effectiveness to patients with rare conditions as should be applied to all other patients.

### **4.4 Requests to Continue Funding for Patients Coming Off Drugs Trials**

The CCG does not expect to provide funding for patients to continue medication/treatment commenced as part of a clinical trial. In line with the Medicines for Human Use (Clinical Trials) Regulations 2004 and the Declaration of Helsinki, the responsibility lies with those conducting the trial to ensure a clear exit strategy from a trial AND that those benefiting from treatments provided within the trial setting will have on-going access to those treatments. The initiators of the trial (provider trusts and drug companies) have a moral obligation to continue funding patients benefiting from treatment until such time as the CCG agrees to fund through the commissioning process. Where the treatment is not prioritised through the commissioning process, the responsibility remains

with the trial initiators. The Research Ethics Committee should require this assurance as part of the approval for the trial.

#### **4.5 Requests to Continue Funding for Treatments Commenced ‘at risk’ by Providers or by others (Including Patients)**

On occasions, a request is received where a provider trust has commenced an unfunded treatment prior to asking for or receiving confirmation that the CCG will approve funding. Evidence that the patient is responding to the treatment is then presented as part of the case for CCG funding.

The provider trust’s decision to commence treatment in advance of any decision by the CCG to fund is a clear risk taken by the trust and/or patient. The CCG accepts no responsibility for the decision taken by the provider trust in these circumstances.

In considering a request for funding the CCG will apply the criteria set out in this policy as it would for any other request, and accords no special privileges because the unfunded drug was given by a provider trust.

The CCG policy is that, unless a decision has been taken to approve routine funding for a treatment, the treatment will only be commissioned for an individual patient if the clinician is able to demonstrate that the patient has exceptional clinical circumstances. The fact that a patient has responded to a drug or other treatment in a manner which was anticipated for a proportion of patients who are commenced on the treatment is unlikely to be sufficient to demonstrate exceptional clinical circumstances.

Where such an application is approved on the basis of the clinician demonstrating that the patient has exceptional clinical circumstances (as defined in this policy), the CCG will not accept responsibility for the costs of any treatment provided by the provider trust prior to authorisation being given by the CCG.

A similar approach will be adopted if a treatment has been funded initially by a pharmaceutical company or other third party.

There are occasions where the initial stages of an unfunded treatment have been funded privately by the patient. The CCG will consider any information submitted on behalf of a patient in support of their case that the patient has exceptional clinical circumstances.

This may include evidence derived from treatment that has been purchased privately and used by

the patient. However, this potentially opens the way for a limited group of patients who can afford to fund a treatment that the CCG does not usually fund to be able to demonstrate benefit by virtue of access to private care and then submit this as a reason to justify NHS funding for the treatment in their particular case.

This is a potentially inequitable approach and, in order to ensure that the CCG does not act in an inequitable manner, the issue of exceptional clinical circumstances will therefore continue to be the criteria applied by the IFR process. Accordingly, the CCG adopts no presumption in favour of continuing treatment which has been previously paid for privately by the patient. As stated above, evidence that a treatment works as anticipated for a proportion of patients in the patient's clinical circumstances is unlikely, in itself, to provide evidence of exceptionality.

#### **4.6 Requests to Continue Funding of Care Commenced privately e.g. reverting to NHS care**

Patients who are having private treatment have a right to revert to NHS funded treatment at any point during their care. However, if they wish to exercise this right, the CCG will expect their care to be transferred to local pathways. Funding for the individual to continue care in a private facility, or to transfer to an NHS provider with which a clinical consultant privately has a contract of employment will not routinely be authorised unless they form part of local pathways. Where personal clinical circumstances may make such funding appropriate the case will require consideration by the IFR process.

#### **4.7 Decisions Inherited from Other CCG's e.g. patients who move**

Occasionally patients move into the area and become the responsibility of the CCG (by registering with an NHS Nottingham and Nottinghamshire CCG GP) when a package of care or treatment option has already been approved by the CCG that was previously responsible for the patient's care. The CCG's policy is that, subject to resource constraints, it will normally agree to continue the treatment providing the care pathway has been initiated by a responsible NHS consultant and the requested treatment remains clinically appropriate.

#### **4.8 Second opinions**

A patient has no legal right to a second consultant opinion under current NHS guidance. However, they are entitled to request one and this should normally be approved if:

1. The request is supported by the patient's GP or consultant (the “first consultant opinion”)

**AND**

2. The second opinion is available from a clinical specialist who practices within a relevant mainstream NHS commissioned specialist service. This opinion needs to provide a balanced view of the benefits and risks and for care which is not routinely commissioned it should be from a specialist who is:
  - independent of the first “consultant opinion” provider
  - Independent of the specific service, service provider or provider of the intervention that is being requested (unless no other specialist is available who could provide that balanced opinion).

**AND**

3. The patient is seeking to establish access to care on the grounds of clinical ability to benefit and not social factors (that are not taken into account under Individual Funding Request processes).

Third or fourth opinions for the same clinical condition will not normally be supported unless there are extenuating circumstances.

#### **4.9 Treatment in another country**

Requests for NHS funded treatment abroad will be considered by NHS England in accordance with the current processes for accessing treatment in European Economic Area (EEA) countries via the S2 route and the Directive route.

### **5. DEFINING EXCEPTIONALITY AND AN INDIVIDUAL PATIENT**

#### **5.1 Exceptionality**

The words “exceptional”, “exceptionality” and “exceptional clinical circumstances” bear their natural meanings as defined in Oxford English Dictionary. In addition the NHS Confederation (2008) defined exceptionality as follows:

Exceptionality is essentially an equity issue that is best expressed by the question

“on what grounds can funding be justified for this patient when others from the same patient group are not being funded ?”

There is a difference between “individual” and “exceptional”. Every patient has features of his or her condition which are specific to that individual and are not likely to be repeated in other patients with the same clinical condition at the same stage of progression of the condition. Exceptionality is not the same as individuality.

In order to be able to consider whether a patient has exceptional clinical circumstances the IFR Panel may find it helpful to focus on the following issues:

- Are there any clinical features of the patient’s case which make the patient significantly different to the general population of patients with the condition in question at the same stage of progression of the condition?
- Would the patient be likely to gain significantly more clinical benefit from the requested intervention than might be normally expected for the general population of patients with the condition at the same stage of the progression of the condition?

The implications of this approach are that if a patient can be seen to be part of a group of patients for whom a treatment is not made available by the CCG under the CCG ’s existing policies then exceptionality for this individual patient is unlikely to be demonstrable. In this case the appropriate process for obtaining funding for the requested treatment will be for the CCG to change its policy. Such a change must happen through the normal commissioning process (which will require the development of a business case and for the treatment to be prioritised against other developments) or through the CCG agreeing to make a change to its policy outside the LOP process. Once the change is made it will apply to all similar patients. However the IFR Process is not the procedure for the CCG to make such policy changes.

The CCG is required to achieve financial balance each year and therefore has a default policy of not funding a treatment where no specific policy exists to approve funding for the treatment. If the CCG has not previously been asked to fund an intervention that has the potential to affect a number of patients, the application should be made by clinicians for the CCG to consider the intervention through its general commissioning policy and not by way of an IFR application.

The CCG policy is that the IFR committee should consider requests for treatments that are not routinely available based on the patient’s clinical circumstances. This means that social and

personal factors such as age, gender, education, caring responsibilities and family circumstances can only be taken into account where they are relevant to the patient's clinical outcome. Whilst a patient's professional, economic or social standing or their family responsibilities are important to individuals, the CCG policy is that they are not relevant in assessing whether a patient has exceptional clinical circumstances.

## **5.2 An Individual Patient**

For the purposes of this policy, an Individual Patient is determined by reviewing the incidence and prevalence of the requested intervention for a particular condition at the same stage of progression of that condition. If the CCG has no policy for the intervention being requested for a particular condition, then the IFR Panel can only consider the request if both the incidence and prevalence criteria that are set out below are met or the patient has exceptional clinical circumstances compared to the cohort of patients (however small) with the presenting condition. In some cases, CCG s may have adopted policies for small numbers of patients which have often been developed regionally. If the request is covered by such a policy then it should be viewed as a request to change the policy and therefore will not be considered by the IFR policy, even if the incidence and prevalence criteria are met.

An IFR request for an individual patient will be considered by the IFR Panel on its individual merits with the decision on whether to fund a requested intervention based on the evidence of clinical and cost effectiveness and affordability. If both the prevalence and incidence criteria are not met then the CCG will not consider that the request represents an individual patient. In these circumstances, funding can only be provided if a decision is made by the CCG to develop a policy for the requested intervention for a group of patients, including the requesting patient; unless the patient has exceptional clinical circumstances compared to the cohort of patients (however small) with the presenting condition. Such a change must happen through the LOP process (which will require the development of a business case and for the treatment to be prioritised against other developments) or through the CCG agreeing to develop a policy outside the LOP process. Once the policy is developed it will apply to all similar patients. However the IFR Process is not the procedure for the CCG to develop such policy.

**Incidence** e.g. the number of new cases of a disease in a defined population within a specified period of time the intervention for a particular condition at the same stage of progression of that condition is expected to be initiated for two or fewer patients per million population per year (10 patients across the East Midlands SHA CCG s population per year).

**Prevalence** e.g. the number of cases of a disease in a defined population at a point in time

The total number of patients on the intervention for a particular condition at the same stage of

progression of that condition is less than 10 patients per million population at any one time (40 patients across the East Midlands population)

## **6. THE PROCESS FOR MANAGING INDIVIDUAL FUNDING REQUEST (IFR)**

### **6.1 Who can submit an IFR**

This policy will apply to any patient for whom the CCG is the responsible commissioner. A doctor, or other health care professional directly involved in the care of a patient, can make a request for an intervention not routinely funded (as defined in Section 2.). It is the referring clinician's responsibility to ensure the treatment request form is completed as accurately and comprehensively as possible to avoid possible delays in considering the request. A patient, or a non-clinical representative, may not submit an IFR as a clinical sponsor is required. On receipt of a submission the following IFR process should be followed.

### **6.2 Administration and Reporting**

Requests will be date stamped, processed and logged onto the CCG IFR database (Blueteq) by the responsible IFR Officer (normally an IFR Manager). Acknowledgement will be sent to the referrer within 5 working days, with a copy to the patient/carer or guardian. It will be the responsibility of the IFR Officer to manage all requests received and correspondence with the referrer and patient/carer or guardian.

For each request received, a unique numbered case file will be generated with all paperwork pertinent to the case kept in chronological order. All decisions will be fully documented and all communication will be in writing whenever possible. When telephone conversations take place, a file note will be added as a record of the conversation. Both the evidence considered and the decision made will be recorded in writing. All national and local NHS policies regarding confidentiality, retention and destruction of records will be adhered to. The case files will be regularly reviewed by the IFR Panel and an annual report of cases considered by the IFR Panel and Review Panel will be submitted to the CCG Board.

### **6.3 Timescale for Managing an IFR**

Requests will be managed within a maximum period of 40 working days from the date of the receipt of a Treatment Request Form to the date of the letter from the CCG informing the requesting clinician of the decision of the IFR Panel. Within this time period, a number of recommended maximum time periods for stages of the IFR process are set out but these are advisory, rather than

mandatory, providing the overall process is completed within the 40 day period.

#### **6.4 Initial Handling of an IFR**

Cases are initially dealt with, and screened, by the IFR Officer who will advise the referrer whether the existing portfolio of contracts, SLAs or current commissioning policies would cover the request. If a policy exists, and where appropriate, the IFR Officer will check whether the criteria within the policy can be applied. Where clinical advice is required, the IFR Officer will seek advice from the screening pair. Clinically urgent requests will be determined by a senior Public Health professional, nominated by the screening pair, and will be managed under 6.7 „Identifying Urgent Cases“.

If an individual meets the criteria within a policy, and a decision to agree funding can be made at this point by the IFR Officer, then a response will normally be sent to the referrer within 10 working days of the date of acknowledgement of the initial request by the CCG. The IFR Officer is unable to authorise referrals outside existing contractual arrangements.

If the IFR Officer has reason to consider that simple application of SLAs and/or current commissioning policies would be inappropriate for a case, then the IFR Officer should advise the referrer, and the patient/guardian or carer, normally within 10 working days, that an Individual Funding Request must be submitted to the IFR Officer at the CCG using the IFR Treatment Request Form.

A copy of the Guidance Notes for submission of a Treatment Request Form should be included and the Patient Information Leaflet explaining the process (produced by the CCG). If a clinician wishes to discuss whether submission of a Treatment Request Form is appropriate, or would like help with completing the Treatment Request Form, then they should contact the IFR Officer who will then liaise with the screening pair if further advice is required.

#### **6.5 Submission of a Treatment Request Form (TRF)**

Only a clinician directly involved in the clinical care of the patient (usually their Consultant or GP) can submit a Treatment Request Form. On receipt of a Treatment Request Form, the CCG IFR Officer will acknowledge receipt within 5 working days using a standard letter outlining the CCG IFR process. The patient's GP will be sent a copy of all correspondence regarding the case if they are not the requesting clinician.

Each section of the IFR Form needs to be completed IN FULL in order for the request to progress. Any IFR form which is incomplete will be returned to the requester and the application will not progressed any further until completed and resubmitted as a new request.

## 6.6 Triage of a Treatment Request Form

The Treatment Request Form will be triaged by the screening pair, consisting of an IFR Manager and a public health consultant. (The Screening Pair).

The skills and expertise required of the screening pair are the ability to:

- Determine whether an existing policy or SLA adequately covers the treatment request
- Interpret the CCG definitions of exceptionality and an individual patient in the context of the clinical information that is presented

The pair will be able to consider four options;

- Approve the request if covered by an existing SLA/ commissioning policy
- Sign post clinicians to specialised commissioning services if applicable
- Refuse the request without reference to the IFR Panel
- Refer to the IFR Panel

The criteria that are used to triage a Treatment Request Form is whether there is an arguable case, based on the evidence presented in the application, that the IFR Panel could consider approving funding for the requested treatment under this policy.

The application will be refused at the triaging stage if:

- The requested treatment arises in relation to a medical condition where there is CCG policy and (a) the requested treatment is not a treatment that is approved under the policy, and (b) there is no arguable case on the evidence presented that the patient can show exceptional clinical circumstances.
- The requested treatment arises in relation to a medical condition where there is no CCG policy and (a) on the evidence presented the requested intervention for that particular condition may affect other patients in the CCG population as defined in this policy under 5.2 and (b) is no arguable case on the evidence presented that the patient can show exceptional clinical circumstances (which will normally be determined by comparing this patient to the cohort of patients (however small) with the presenting condition. so that the request should be properly treated as a request to change the CCG policy.

Where there is uncertainty, the case should be referred to the IFR Panel. All decisions made by the Screening Pair will be recorded and reported to the IFR Panel on a quarterly basis.

A routine request will normally be triaged within 10 working days of the date of receipt of the Treatment Request Form by the CCG unless additional information is required when an additional 10 working days will be granted. The requesting clinician will be contacted by letter and asked to comment on whether any additional information should be included in the Treatment Request Form.

If a request is refused a letter will be sent to the clinician and the patient explaining the reasons for the decision and outlining the options that are available, including using the NHS Complaints Procedure.

If a request is refused at the triaging stage this policy does not provide a right of appeal to the IFR Committee and does not provide a right to request that the decision should be reviewed by the Review Committee. However the patient has a right to make a complaint under the NHS Complaints Procedure. One outcome of such a complaint could be to require the triaging process to be reconsidered or for the case to be referred to the IFR Panel for consideration. However, if a requesting clinician believes they have significant new clinical evidence that they did not provide in their first submission which they feel may have made a difference to the decision made, then the clinician can submit a new IFR application with this new evidence.

If a request is referred for consideration by the IFR panel a meeting will normally be convened within 20 working days of the date of the triage meeting

## **6.7 Identifying Urgent Cases**

The screening pair can determine that a case is clinically urgent at any point in the IFR process after consultation with the patient's clinician. The timing of an urgent IFR Panel will be based on the individual clinical circumstances and the risks of an adverse clinical outcome if a funding decision on treatment is delayed. Urgent meetings of the IFR panel will be convened at the request of the Chair and will be formally recorded. Ideally all urgent cases will be considered by a face-to-face meeting, but where necessary, communication will be conducted virtually. Decisions that are made urgently outside of a formal IFR Panel meeting will be taken for information to the next meeting of the IFR Panel.

Where an urgent request is required to be considered, the IFR Panel shall continue to follow the procedure set out in this policy. In particular if a request, even if urgent, may affect other patients with the condition in question at the same stage of progression of the condition, and thus is

inappropriate for an IFR request, it shall be refused. Where, in order for the CCG to be able lawfully to commission the requested treatment, the CCG is required to change its commissioning policy, this can only happen if the clinician and/or the patient request the CCG to make an in-year change to its commissioning policy. Such an application must be made outside the IFR policy.

### **6.8 Organisation of an IFR Meeting**

The IFR Officer will arrange the date of the meeting and contact the requesting clinician to ask if they wish to submit any further information.

The IFR Officer will provide written correspondence to the patient/carer or guardian to inform them of the date set for consideration by the Panel, to list the items of information that will be presented to the Panel, and to ask them if they wish to provide written information to the Panel. However, the IFR Officer should remind the patient that decisions can only be made on the grounds of the patient's clinical circumstances and not on the basis of the patient's social or personal circumstances. If a patient wishes to provide written information, they should be directed to where they can seek assistance with this e.g. to the Patient Experience Team

The patient/carer or guardian, or their clinical or non-clinical representative, are not entitled to attend the panel in person.

The IFR Officer may also write to other health professionals with clinical involvement in the patient's care (for example consultant, therapist etc.), or to others with specialist knowledge with regard to the condition/intervention, for clarification of the patient's needs, evidence base etc, if appropriate.

A summary of the case will may be produces and considered by the IFR Panel. All documentation that has been received regarding the request will be made available to the panel at least 5 days before the meeting in an anonymised form to protect confidentiality or by way of "Diligent"

### **6.9 Membership of the IFR Panel**

NHS Nottingham and Nottinghamshire CCG will have an Individual Funding Request (IFR) Panel. The IFR Panel will consider all cases referred to it by the Screening Pair.

Members of the IFR panel should together have the skills and expertise necessary to make effective, fair and rational decisions by considering the evidence in the Decision Framework Document. The key competencies and experience required within a Panel are:

- Ability to understand and interpret the clinical information regarding the individual case and place it in the context of a wider clinical population
- Ability to understand and interpret clinical and cost effectiveness data (critical appraisal skills)
- A lay/societal perspective
- Ability to understand and advise on the broader commissioning policy implications for the CCG including consideration of the intervention in the LOP process.

The core panel will consist of:

- Independent Chair Non-Executive Director, Nottingham and Nottinghamshire CCG
- Chief Nurse or Deputy Chief Nurse, Nottingham and Nottinghamshire CCG
- 4 x General Practitioners, NHS Nottingham and Nottinghamshire
- Public Health Consultant
- Senior Finance Officer

In Attendance: Other individuals with specific expertise and skills may also be included on the panel e.g. pharmacist, commissioning manager in order to ensure effective and robust decision making.

The chair will be an independent lay representative appointed by the CCG. If the chair is unable to attend a meeting the CCG representatives will appoint a Deputy Chair from one of the CCG lay representatives to deputise in the Chairs absence. CCG Representatives must be director level officers of the CCG and will be appointed by the CCG.

The IFR Officer/Public Health will present the case to the members of the panel. Decisions will be reached by consensus where possible, but if a consensus cannot be achieved, will be decided by a vote of the panel members. If the panel is equally split then the chair will have a casting vote. Clinical members The chair will be an independent lay representative appointed by the CCG. If the chair is unable to attend a meeting the CCG representatives will appoint a Vice Chair from one of the CCG lay representatives to deputise in the Chairs absence. CCG Representatives must be director level officers of the CCG and will be appointed by the CCG.

### **6.10 Conflict of Interest**

If any of the members, or any observer, or attendee has a conflict of interest they must declare that conflict as soon as they become aware of it. Any such declaration will be recorded in the minutes together with a summary of the action taken. The Chair will be responsible for determining how any declarations will be dealt with.

## 6.11 Decision making framework of the IFR Panel

The IFR Panel will consist of members of the CCG with mandated authority to make decisions. It is not the role of the IFR Panel to make commissioning policy on behalf of the CCG. Consideration by the IFR Panel will always state from the overall policy position (whether or not the interventions has been prioritised) and will seek to determine exceptionality on that basis using the definition in section 5.

The IFR Panel shall only be entitled to approve requests for funding of treatment for individual funding requests where each of the following conditions are met:

Either (1) the clinician makes an individual request for funding for treatment in connection with a patient's presenting medical condition for which the CCG has no policy and where the clinician has demonstrated that the patient represents an Individual Patient (as defined in paragraph 5.2 above)

**or**

The clinician makes an exceptionality request for funding for treatment in connection with a patient's medical condition for which the CCG has a policy

**and** where the clinician has demonstrated that the patient has exceptional clinical circumstances (as defined in paragraph 5.1 above)

**or**

The clinician makes an exceptionality request for funding for treatment in connection with a medical condition for which the CCG has no policy and where the patient has demonstrated exceptional clinical circumstances (as defined in paragraph 5.1 above). This option would arise if the patient was not an Individual Patient (as defined in paragraph 5.2 above).

- There is sufficient evidence to show that, for the individual patient, the proposed treatment is likely to be clinically effective.
- Applying the approach that the CCG takes to the assessments of costs for other treatments outside this policy, the cost to the CCG of providing funding to support the requested treatment is justified in light of the benefits likely to be delivered for the individual patient by the requested treatment.

### **6.12 Demonstrating exceptional circumstances.**

The requesting clinician is required to present a full report to the IFR Panel using the Treatment Request Form which sets out a comprehensive and balanced clinical picture of the history and present state of the patient's medical condition, the nature of the treatment requested and the anticipated benefits of the treatment.

The IFR Panel shall determine, based upon the evidence provided to the panel, whether the patient has demonstrated exceptional clinical circumstances. The evidence to show that, for the individual patient, the proposed treatment is likely to be clinically effective may be part of the case that the patient's clinical circumstances are asserted to be exceptional.

In determining whether a clinician is able to demonstrate that a patient has exceptional circumstances the IFR Panel shall compare the patient to other patients with the same presenting medical condition at the same stage of progression.

The IFR Panel shall take care to avoid adopting the approach described in the "the rule of rescue". 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 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.

### **6.13 The likely clinical outcomes of the proposed treatment.**

The referring clinician shall:

- describe the anticipated clinical outcomes for the individual patient of the proposed treatment and the degree of confidence of the referring clinician that the outcomes will be delivered for this particular patient;
- refer to, and preferably include, copies of any clinical research material which supports, questions or undermines the case that is being made that the treatment is likely to be clinically effective in the case of the individual patient.

The IFR Panel shall be entitled but not obliged to commission its own reports from any duly qualified or experienced clinician, medical scientist or other person having relevant skills concerning the case that is being made that the treatment is likely to be clinically effective in the case of the individual patient.

The IFR Panel is not required to accept the views expressed by the referring clinician concerning the likely clinical outcomes for the individual patient of the proposed treatment but is entitled to reach its own views on:

- The likely clinical outcomes for the individual patient of the proposed treatment; and
- The quality of the evidence to support that decision and/or the degree of confidence that the IFR Panel has about the likelihood of the proposed treatment delivering the proposed clinical outcomes for the individual patient.

#### **6.14 The costs of the proposed treatment.**

The referring clinician shall set out the full attributable costs of and connected to the treatment. The IFR Panel shall be entitled but not obliged to commission its own reports from any duly qualified or experienced clinician or other duly qualified person concerning the full attributable costs of and connected to the treatment.

The IFR Panel shall, so far as it is able to do so, on the information before it, apply the principles set out in the CCG policy on cost effectiveness when reaching a view as to whether the requested treatment is likely to be cost effective.

In making the decision as to whether the costs of a requested treatment are justified, the IFR Panel shall refer itself to the approach concerning Quality Adjusted Life Years (QALYs) and Incremental Cost Effectiveness Ratio's (ICERs) that the CCG has adopted for other treatments and is required to bear in mind that the resources requested to support the individual patient will reduce the availability of resources for other investments. The IFR Panel shall have a broad discretion to determine whether the proposed treatment is a justifiable expenditure of the CCG 's resources.

#### **6.15 Similar Patients**

The IFR Panel shall consider whether the request is for a policy variation. If the IFR Panel determines that the case does not refer to an Individual Patient as defined in this policy, then it shall not be entitled to make a decision on the request (unless the patient demonstrates exceptional clinical circumstances in which case the matter shall be considered as an exceptionality request). In the event that the case does not refer to an Individual Patient the IFR Panel shall refer the request

to be considered by the CCG Service Development process.

This step is required because the IFR process is not designed to create precedents which may result in the CCG providing or being obliged to provide the same or similar treatment to other patients. Accordingly if the IFR Panel considers this is not a request about an individual patient then funding can only be provided for the requested treatment if a decision is made by the CCG to amend its policies to provide the treatment for a group of patients, including the requesting patient.

#### **6.16 Recording the decision**

The IFR Officer will record the decision of the IFR Panel against each of the above questions on the Decision Framework Document. The completed Decision Making Framework, together with the record of attendance, will form the minutes of the meeting. The minutes will be approved by the Chair of the Panel.

#### **6.17 Outcome of the IFR Panel**

The IFR Officer will provide written correspondence on behalf of the Chair of the IFR Panel to the referring clinician, and the patient/guardian or carer, within 5 working days to inform them of the outcome of the IFR Panel meeting with the reasons for the panel decision.

If funding was agreed, the IFR Officer will ensure that the clinician is able to deliver the treatment in a timely manner and that a mechanism is in place to monitor the clinical outcome in order to determine whether the treatment has resulted in benefit to the patient.

If funding was not agreed, the IFR Officer will inform the referring clinician, and the patient/guardian or carer, outlining the further options that are available - either reconsideration or review.

#### **6.18 Reconsideration**

If the referring clinician and/or the patient/guardian or carer believes that there is further relevant information that was not considered by the Panel they may ask the CCG to reconsider the case specifically in the light of this information. The additional information must be submitted to the IFR Officer within 10 working days of the date of the letter from the CCG setting out the panel decision. The CCG Screening Pair will determine, normally within 10 working days, whether the additional information significantly alters the nature and strength of the evidence that was submitted to the initial panel meeting.

If the new information is considered to be significant, a further panel meeting will be convened within

the timescales set out for the first panel. If the new information is not considered to be significant, the referring clinician and the patient/guardian or carer will be informed by letter with reasons for the decision not to refer the request back to the IFR Panel.

## **7. REVIEW OF IFR PANEL DECISIONS**

### **7.1 Grounds for requesting a review of the IFR Panel Decision**

The referring clinician and/or the patient/guardian or carer can make a request to the CCG for a review of the IFR panel decision. The request should be made in writing to the Chief Officer of the CCG and must be lodged within 20 working days of the date of the letter from the CCG setting out the IFR Panel decision. The Chief Officer may exercise discretion in accepting requests outside this time limit if there are good reasons for the delay.

The request for review must set the grounds on which the IFR panel decision is being challenged. A review can be requested on two grounds. It is believed that:

- The IFR Panel failed to follow due process and, as a result, the decision reached by the panel was different to the one that would be reached if due process had been followed.
- The IFR Panel did not take into account, or weigh appropriately, all relevant evidence when applying the CCG Decision Making Framework.

### **7.2 Initial Consideration of a Request for a Review of the IFR Panel Decision**

The request for a review will be initially considered by an officer designated by the CCG to consider these requests. This officer will not have been involved in the original IFR decision. If the officer considers that there is an arguable case to support the review, then a formal Review Panel meeting will normally be convened within 20 working days of the CCG accepting the need for Review. If the CCG does not accept the grounds put forward for a review, a letter will be sent on behalf of the Chief Officer of the CCG to the referring clinician and/or the patient/guardian or carer explaining the reasons for the decision not to review the IFR panel decision.

### **7.3 Membership of the Review Panel**

NHS Nottingham and Nottinghamshire CCG will have a Review Panel.

The Review Panel will consist of:

- Independent Chair Non-Executive Director, Nottingham and Nottinghamshire CCG
- Chief Officer or nominated Executive Director

- Senior Medicines Management Representative

None of these members should have been involved in the case prior to the Review Panel. The panel will only be quorate if all three members are in attendance and decisions will be reached by consensus.

#### **7.4 Purpose of the Review Panel**

The Review Panel will determine whether the original decision is valid in terms of process followed, the evidence/factors considered and the criteria applied. In deciding the outcome of a review, the Review Panel will consider whether:

- The process followed by the IFR Panel was consistent with that detailed in the IFR Policy
- The decision reached by the IFR Panel:
  - i. was consistent with the CCG Commissioning Principles
  - ii. had taken into account and weighed all the relevant evidence
  - iii. had not taken into account irrelevant factors
  - iv. indicates that members of the panel acted in good faith
  - v. was a decision which a reasonable IFR panel was entitled to reach.

The Review Panel will only consider the following written documentation:

- a) the original Treatment Request Form submitted to the CCG
- b) the IFR process records in handling the request
- c) the IFR Panel records, including the Decision Framework Document and any additional supporting information considered by the IFR Panel
- d) the grounds submitted by the referring clinician and/or the patient/guardian or carer in their request for review.

There will be no other representation at the Review Panel from the IFR Panel or the referring clinician and/or the patient/guardian or carer. The Review Panel will not consider new information or receive oral representations. If there is significant new information, not previously considered by the IFR panel, it will be considered as set out in 6.17 Reconsideration above.

The Review Panel will be able to reach one of two decisions:

- To uphold the decision reached by the IFR Panel.
- To refer the case back to the IFR panel with detailed points for reconsideration.

In the event that the Review Panel consider that either

- The decision may not have been consistent with the CCG Commissioning Principles; or
- The IFR Panel may not have taken into account and weighed all the relevant evidence; or
- The IFR Panel may have taken into account irrelevant factors; or
- The IFR Panel may have reached a decision which a reasonable IFR panel was not entitled to reach

Then the Review Panel shall refer the matter to the IFR Panel if they consider that there is an arguable case that the requested treatment will be approved by the IFR Panel when it reconsiders the case.

If the Review Panel considers that, notwithstanding their decision on the procedure adopted by the IFR Panel, there is no arguable case that the decision would have been different; the Review Panel shall uphold the decision of the IFR Panel.

## **7.5 Outcome from the Review Panel**

The outcome of the Review Panel will be either to uphold the decision of the IFR Panel or to refer the case back to the IFR Panel for reconsideration.

The Review Panel chair will write to the referring clinician, the patient/guardian or carer, and the IFR Panel Chair within 5 working days to inform them of the outcome of the Review Panel meeting with the reasons for the panel decision. Reasons given should only refer to the IFR policy as this is the basis on which the original decision is made.

If the original IFR Panel decision is upheld, the IFR Officer will inform the referring clinician, and the patient/guardian or carer, of their remaining options - either to pursue a complaint through the CCG Complaints Procedure or to take their case to the Healthcare Ombudsman. The CCG Complaints Policy may be used to review the decision making process for an individual case and may result in the matter being reconsidered by the IFR Panel.

If the Review Panel determines that the IFR panel needs to reconsider the case, the IFR Panel should reconvene within 10 working days of the date of decision letter from the Chair of the Review Panel. The IFR Panel will reconsider its decision and in doing so will formally address the detailed points raised by the Review Panel. The IFR panel is not bound to change its decision as a result of the case being referred for reconsideration, but if it confirms its original decision, then clear reasons must be given for not agreeing to fund the treatment request.

## **8. TRAINING**

Members of an IFR Panel (and Review Panel) should together have the skills and expertise necessary to enable them to make effective decisions. Members will need on-going training to undertake this role, in particular to enable them to comprehend and interpret complex data, and also in the legal and ethical aspects of the panels work. It is also important to establish a “core” group of individuals who are regularly involved in IFR decision making to gain the necessary breadth of experience from handling a wide range of clinical cases.

All members of an IFR Panel (and Review Panel) will undergo mandatory induction training organised by the Public Health Directorate of the CCG. This will cover both the legal and ethical framework for IFR decision making, the CCG commissioning processes and structures, and technical aspects of the interpretation of clinical evidence and research. This training will be regularly refreshed to ensure that all panel members maintain the appropriate skills and expertise to function effectively.

## **9. MONITORING**

The IFR process will be monitored and reviewed, both to ensure that decision- making is fair and consistent, and to make sure that the panel are considering the appropriate cases e.g. that both the triage of requests and the panel work effectively. The IFR panel will hold a quarterly meeting to review the IFR database with the IFR Officer to evaluate the process, including the consistency of decision making, and to consider any improvements that could be made.

The CCG will also put in place a mechanism to receive feedback by patients and requesting clinicians as part of the evaluation of the IFR policy and to contribute to on-going process improvement.

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