Midlands and Lancashire
Commissioning Support Unit

Individual Funding Requests Management Policy

A Cheshire and Merseyside Collaborative Document

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Contents

1. Introduction

1.1 The Clinical Commissioning Group (CCG) recognises that there are a number of general circumstances when it is appropriate to consider funding at the level of the individual i.e. via an Individual Funding Request (IFR).

1.2 The NHS Confederation defines an IFR as a request to fund treatment that does not have services already agreed through existing commissioning arrangements and is within the commissioning responsibility of CCGs. However for the purposes of this document and suite of policies, a wider definition is used, i.e. an individual funding request is a request to fund treatment that is within the commissioning responsibility of the CCG and which either does not have services already agreed through existing commissioning arrangements, or requires prior approval on an individual patient basis.

1.3 Reasons for not having a commissioned service include:

- the medical condition in question is rare;
- the treatment is new or unproven in effectiveness;
- the treatment is a high cost intervention;
- the treatment is of value and clinical benefit but funding is not available from the prioritisation process.

1.4 An individual funding request is not a request to:

- fund a service development;
- fund an existing commissioned service where the CCG has not commissioned the whole pathway of care; or
- fund treatment from a provider of the individual's choosing where that is not the usual provider of that service for the CCG;

1.5 Some requests for healthcare may more appropriately be considered as service developments than as individual funding requests. This is particularly likely when a significant number of similar requests are anticipated. A service development is a change to the CCG's portfolio of service agreements such that a particular new healthcare intervention shall be routinely commissioned for a defined group of patients. Service developments are likely to result from a prioritisation process.

1.6 This document is part of the governance framework adopted by the CCG to inform the commissioning of IFRs. The framework consists of:

- Individual Funding Requests Standard Operating Procedure;
- Individual Funding Requests Management Policy; (This Policy)
- Individual Funding Requests Decision Making Policy;
- Clinical Commissioning Policies (also known as: Procedures of Limited Clinical Priority (PLCP)).

1.7 Each policy in the framework is a separate public document in its own right, but may be applied with reference to other policies in that suite.

2. Purpose

2.1 This policy describes the way the following CCGs will make provision for the management of IFRs:

- NHS Eastern Cheshire Clinical Commissioning Group;
- NHS Halton Clinical Commissioning Group;
- NHS Knowsley Clinical Commissioning Group;
- NHS Liverpool Clinical Commissioning Group;
- NHS South Cheshire Clinical Commissioning Group;
- NHS South Sefton Clinical Commissioning Group;
- NHS Southport & Formby Clinical Commissioning Group;
- NHS St Helens Clinical Commissioning Group;
- NHS Vale Royal Clinical Commissioning Group;
- NHS Warrington Clinical Commissioning Group;
- NHS Western Cheshire Clinical Commissioning Group;
- NHS Wirral Clinical Commissioning Group.

2.2 This policy does not cover IFRs for treatments and services which are the commissioning responsibility of NHS England. If a request for treatment that is not the commissioning responsibility of the CCG is received, the requester will be advised accordingly and the case record closed.

3. Responsible Commissioner

3.1 The following criteria will be used to assess whether a treatment/service and its indication for use are the commissioning responsibility of the CCG.

a. Is the treatment for which funding is requested associated with a service, treatment of a patient group described as the commissioning responsibility of a CCG in the published Manual for Prescribed Specialised Services, the associated Identification Rules, a published CCG Clinical Commissioning Policy or Service Specification?
b. Is the patient for whom the treatment/service is requested one of the groups of patients for whom the CCG directly commissions services?

3.2 If any of the above applies, the CCG is the responsible commissioner. Services are commissioned by the CCG for the population where the patient is eligible for NHS treatment.

4. Delegated Authority

4.1 In order to carry out its functions, the CCG has entered into an arrangement with the other CCGs listed at the beginning of this document and sought support from the Midlands and Lancashire Commissioning Support Unit (MLCSU) to administer the IFR process.

4.2 MLCSU is not a statutory body, although it is currently hosted by NHS England. As such, each CCG, as a separate statutory organisation, remains individually responsible for the fulfilment of its legal obligations and its duties and responsibilities to its own patient population, as set out in the National Health Service Act 2006.

4.3 It is for the CCG, as responsible commissioner for the patient, to decide whether or not an IFR application will be funded; however, the CCGs listed have delegated authority to MLCSU to operate an end to end IFR service.

4.4 Each CCG has delegated the decision to fund a treatment for any individual funding request meeting this policy, to MLCSU IFR Service up to an agreed delegated limit of £5k (cost of total package of care being approved). The decision for a package of care that exceeds this limit will be escalated to the CCGs senior management team for agreement, all ongoing communications with the applicant will be undertaken by the IFR team.

4.5 The need to obtain CCG sign-off excludes any approvals made for procedures/interventions identified within the CCG's Clinical Commissioning Policy (PLCP) or NICE TA which will be routinely commissioned should the patient meet the clinical criteria specified. The costs for such procedures/interventions are already recognised by the CCG and therefore have been agreed with their contracted providers.

5. Roles and Responsibilities

5.1 The responsibilities for implementation of this policy are set out in this section.

A. IFR Team

5.2 It will be the responsibility of the MLCSU IFR Team, on behalf of the CCG, to:

Screen

a. Receive, acknowledge and process IFR requests submitted to the CCG within agreed timescales;
b. Screen all applications according to the provisions in this policy and procedure and aligned IFR operating procedures;
c. Re-direct applications as appropriate;
d. Coordinate the timely review of applications by screening panel members in accordance with this policy and procedure and the aligned IFR standard operating procedures;

IFR Panels

e. Appoint Panel members to act/make recommendation on behalf of the CCG;
f. Schedule regular IFR Panels to ensure that delay to decision making is minimised. Increase frequency if necessary to accommodate unexpected peaks;
g. Ensure that sufficient Panel members are available for Panels to be quorate;
h. Coordinate the thorough preparation of an IFR application to take to the Panel;
i. Coordinate the provision of additional information or seek clarification through contact with the clinical applicant or associate clinicians, to allow the case to be considered by the Panel;
j. Report precedence of any previous funding decisions for similar cases to support effective Panel assessment;
k. Coordinate the administration of the Panel papers and their timely distribution to Panel members, maintaining patient confidentiality and timeliness;
l. Ensure high-quality minutes from the IFR Panel through established quality assurance measures;
m. Securely archive and catalogue individual case documentation so that they can be made available when considering new applications;

Notification of outcomes

n. Communicate the outcome of the screening, IFR Panel or Process Review Panel to the applicant, the patient or their representative as appropriate and to other associated clinicians where necessary;

Sign-posting

o. Sign-post requests/the applicant to alternative clinical pathways or funding routes as relevant, supporting the patient's journey as much as possible;

Service developments

p. Identify and communicate potential service developments by keeping accurate records of treatments requested for same or similar conditions, noting where patterns appear to be emerging;

q. Proactively support the CCGs process for evaluating the clinical and cost-effectiveness of provider business-cases with the same rigour as an IFR to enable CCGs to make commissioning decisions for a wider population;

Training

r. Deliver appropriate training to all members of the IFR Panel and Process Review Panel and those within MLCSU responsible for the administration of the process; as well as Public Health colleagues within local authorities contributing to the process. The training will include the ethical and legal aspects of resource allocation (see Appendix 1).

B. IFR Senior Manager

5.3 It will be the responsibility of the MLCSU IFR Senior Manager to:

a. Support IFR Panels as a non-voting member to:
   - Ensure consistency in the decision making processes, ensuring the maintenance of a record of prior decisions to enable reference to precedent where relevant;
   - Share experience gained in dealing with requests for individual patients within and across CCGs;
   - Ensure IFR teams and Panels operate according to best practice with regard to this policy;

b. Arrange for the provision of regular reports (Monthly, Quarterly and Annually as agreed) to CCG commissioners on the decisions made under the schedule of delegation, including activity patterns and trends in requests for individual funding;

c. Agree interim arrangements with the CCG to manage subsequent requests received for identified/agreed service developments;

C. Clinical Applicant

5.4 It will be the responsibility of the clinical applicant to:

a. Use the agreed MLCSU IFR application form which can be found online on the CCG's web page.

b. Take the commissioning policies of the CCG into account in providing advice and guidance to patients before raising expectation, referring the patient for treatment or making the decision to treat a patient.

c. Fully demonstrate that the patient meets eligibility criteria according to local access policies, or detail why the patient differs from others with the same clinical condition such that the treatment should be considered for them when it is not available to others with a similar clinical condition, according to the definition of exceptionality outlined in this policy;

d. Ensure consent to share information has been sought from the patient and highlighted in the application;

e. Attempt to ensure that all information that is likely to be immaterial to the decision, including non-clinical information, or information which does not have a direct connection to the patient's clinical circumstances, shall not be included in the application;

f. Ensure that requests from the IFR team for additional information are responded to in a timely manner according to the deadlines communicated, to avoid delay to the patient;

g. Inform the patient and any other relevant healthcare professionals of the decision; this is to ensure effective on-going arrangements for the patient's care. The clinician making the request is also responsible for notifying the patient of the process review process (including the time frame for the review).

D. Provider Organisations

5.5 The responsibility of provider organisations includes:

a. Taking the commissioning policies of the CCG into account in providing advice and guidance to patients before raising expectation, referring the patient for treatment or making the decision to treat a patient.
b. The sanctioning of IFR requests (by whatever mechanism it wishes to put in place) to ensure funding requests are appropriate. The IFR Team reserves the right to refer recurrent inappropriate funding requests to the Chief Executive of the relevant Provider Trust.

E. Clinical Commissioning Group

5.6 The responsibility of the CCG includes:

a. Identifying a member or manager with delegated responsibility to make decisions based on the recommendations made by the MLCSU through the IFR process, including urgent cases needing accelerated consideration;
b. Determining the financial limits to which the IFR team can make funding decisions;
c. Defining the process for application outside of financial limits in line with the local Standing Financial Instructions (SFIs) ensuring that the CCG can act quickly to confirm authorised expenditure over the agreed delegated limit;
d. Agree, sign-off and communicate clinical policies against which applications for some procedures are considered e.g. Procedures of Limited Clinical Priority (PLCP);
e. Identify a process to enable consideration of service development requirements where identified by the IFR team, including determining and communicating interim arrangements as necessary;
f. Communicate established and new clinical pathways to support appropriate consideration of requests and sign-posting of requests/applicants as relevant.

F. IFR Panel and Process Review Panel

5.7 The responsibility of the IFR Panel and Process Review Panel includes:

a. Upholding and working within the legal context to decision making, as set out in Appendix 1.
b. Considering and determining eligible IFRs where the CCG is the responsible commissioner of NHS care, according to the principles set out in the IFR Decision Making Framework;
c. Referring to the relevant CCG adopted clinical policies to determine whether a patient who does not meet the criteria in the policy can be considered to be exceptional taking the information provided within the application into account;
d. The Process Review Panel will review applications where the applicant appeals the decision making process of the IFR Panel and does not provide any new information for consideration.

G. IFR Panel and Process Review Panel Chair

5.8 The Chair will be responsible for ensuring that:

a. Reasonable effort has been made to acquire adequate data and intelligence to inform the discussion and decision;
b. All material factors have been taken into account and that immaterial factors have been appropriately handled;

c. The rationale for the decision has been explicitly recorded, against the terms of this policy, and that the conflicting arguments have been managed;
d. They are available to approve the minutes and letter(s) within the specified time frame following IFR Panel or Process Review Panel meetings and to ensure that decisions made are correctly reflected;
e. The IFR Panel and Process Review Panel meetings are quorate in line with the Terms of Reference;
f. The Chair of the IFR Panel will be accountable to the MLCSU for the delivery of this role;
g. The Chair of the IFR Process Review Panel will be accountable to the CCG Governing Body for the delivery of this role;

H. IFR Authorised Officer

5.9 The Authorised Officer role is to assess IFRs outside the usual IFR process when there is a clinical imperative to make the decision urgently (usually within 1 or 2 days).

5.10 The Authorised Officer has delegated authority to make the decision up to a delegated limit specified by the CCG. However where packages of care exceed agreed limits the final decision to fund will be escalated to the CCG (IFR Lead) for urgent agreement as relevant.

5.11 An Authorised Officer [1] must:
a. have clinical training (be a doctor, pharmacist, nurse); and
b. have substantial experience in dealing with IFRs; and
c. have been appointed by the IFR Team as a Clinical Advisor;
d. follow the policies and procedures set out in this document to assess the case; and
e. must follow the same decision making process that would be expected of the IFR Panel;

I. General responsibilities – safeguarding adults and children

5.12 All partners involved in the IFR process must follow local protocols regarding the safeguarding of vulnerable adults and children.

5.13 If any potential abuse and neglect to an adult and or child is identified through an IFR application then a safeguarding referral should be made to the local authority where the individual is resident, in accordance with the local CCG safeguarding policies for adults and children.

5.14 The person identifying the concern should contact the CCG safeguarding lead for further advice if necessary.

6. Communication

Patient Communication

6.1 MLCSU is under obligation to copy the patient or their representative into correspondence relating to their IFR application and the outcome, only where this is indicated as clinically appropriate.

6.2 MLCSU will not automatically copy correspondence to the patient or their representative unless it is indicated, by the applying clinician, that it is clinically appropriate on the IFR application form.

[1] Authorised Officers are to be drawn from the MLCSU pharmacists, IFR Team appointed GPs and/or from the Public Health team.

6.3 If **not indicated** or indicated otherwise on the application form, the patient, carer or guardian will not routinely be copied into correspondence.

6.4 If **indicated** as clinically appropriate, the patient, carer or guardian will be copied into all correspondence from MLCSU relating to the IFR application, including the outcome.

6.5 As the main point of access for the patient, the patient's General Practitioner (GP) will always be copied into correspondence to ensure they are advised of progress and can therefore communicate with the patient as relevant and appropriate.

Information

6.6 Information for patients outlining the process and method for making an IFR, and reviewing a decision of an IFR panel, will be made available on the CCGs' respective websites.

6.7 To ensure that patients and clinicians have access to the policies within which the IFR process operates; this policy, and those clinical policies/frameworks which support the IFR process, will also be available to members of the public and referring clinicians via the CCGs' respective website.

Feedback

6.8 The CSU on behalf of the CCGs will put in place mechanisms to gain feedback from applying clinicians and where appropriate the patient, as part of the process.

7. Submitting a request

7.1 It is the clinician's responsibility to ensure that the MLCSU provided IFR application form is fully completed and that it contains all the relevant clinical and financial information which will be required for the CCG to properly evaluate and assess the IFR in accordance with the relevant policies and reach an appropriate decision.

7.2 It will be the sole responsibility of the clinician and their clinical team to ensure all the relevant information on which they rely in support of the application is made available to the IFR team with the application. This enables a thorough evaluation and assessment of the request.

7.3 In all applications received claiming grounds for clinical exceptionality, the clinician must state whether or not he or she considers that there are similar patients. If there are other similar patients then it is likely that the case represents a service development and the IFR route is not the appropriate route for prioritising the patient's clinical need.

7.4 Any clinician submitting an IFR application must attempt to ensure that no immaterial information, including information about the social or personal circumstances of the patient; or information which does not have a direct connection to the patient's clinical circumstances; is included in the application. Any information which is not relevant will be disregarded by the IFR decision making process.

7.5 General Practitioners who request treatments provided by secondary care will be advised to make a referral for opinion only to an appropriate clinician with specialist knowledge of the treatment and therefore the ability to ensure the technical clinical detail is included and any case for clinical exceptionality is robust and evidenced.

8. Consent

8.1 The requesting clinician should complete the consent section of the form to confirm that the patient is aware of the application and has agreed to their personal clinical information being shared.

8.2 If the requesting clinician considers that the patient does not have capacity to give informed consent this should be indicated and explained in the IFR form. In these circumstances the submission should also confirm whether consent has been obtained instead from a patient representative and, if not, the basis on which the IFR is nevertheless being made by the clinician.

8.3 Submissions which do not include either confirmation of appropriate informed consent by the patient or a patient representative, or a satisfactory clinical explanation as to why the application is being made without consent cannot be processed and must be returned for amendment.

9. Photographic evidence

9.1 Photographic evidence will not be accepted for consideration unless it is impossible to make the case in any other way. The decision to submit photographic evidence remains with the patient and responsible clinician.

9.2 Costs incurred as a result of producing photographic evidence will be the responsibility of the patient or referring clinician. A request will not be at a disadvantage if photographs are not provided.

9.3 Photographs can be misleading, embarrassing or discriminatory and ultimately it is the responsibility of the applicant to decide whether photographs are necessary, and submitted photographs may be taken into account if all of the following apply:

- A statement of what the photographs show and why they are submitted is included in the text of the application;
- Photographs should be professionally taken, preferably by a medical illustration department;
- Photographs are submitted with the patient's consent, including consent for the photographs to be examined, stored and destroyed in accordance with information governance requirements;
- Submission of photographs should be made by secure NHS email with the IFR application detailing the identity of the patient, the date of the photograph and clinical opinion that it represents a true likeness of the affected body part;
- As far as possible subject to the body part in question, the photographs should be of the clothed appearance with the patient not being identifiable. Applicants should note that in many cases Clinical Commissioning Policies take account of the social (i.e. clothed) appearance rather than the intimate (unclothed) appearance.
- Photographs will be submitted only to support or clarify a case made in writing. There should be no expectation that the photographs themselves will amount to a case for funding, or will lead to a decision that the case is stronger than is described in writing.
- If, after consideration has been given to the written case, there is doubt about whether the CCG should offer funding and that doubt can be resolved only by examination photographs.

9.4 If photographs are accepted for consideration in accordance with the above criteria, they will be examined by clinical members of the IFR team. In the course of the work for the case the applicant should be aware that other members of the IFR Panel, IFR Process Reviews Panel or IFR team who prepare the papers may need to handle or see the photographs during their work on the case.

10. Screening

10.1 The screening process required as part of the IFR Process is intended to be fair to all parties, including the other patients funded by the CCG and the IFR Panel, by only sending cases to a panel meeting if there is some reasonable prospect that the IFR Panel will accept that the criteria under the IFR governance framework are met in the individual cases. This means the IFR Panel can then apply all of its time to those cases which have a prospect of success.

10.2 Any IFR request will first be screened by the IFR Team in accordance with the procedures set out in the IFR Standard Operating Procedure to establish whether the request falls within the commissioning responsibility of the CCG, and has sufficient clinical or other necessary information for it to be properly considered. Where the IFR Team conclude that there is insufficient information, it will be returned to the referring clinician specifying the additional information required.

10.3 The IFR Panel can only approve funding if all of the criteria in the policies are stratified. It follows that the IFR Team should not allow an application to go forward to the IFR Panel unless there is information to support the contention that each of the essential criteria is met. A strong application on one part of the criteria cannot make up for an absence of proper evidence to support another of the tests that the IFR Panel must apply in order to make a decision that funding should be approved.

10.4 If, in the opinion of the IFR Team considering a submitted IFR in relation to a patient, there is likely to be a defined group of patients in similar clinical circumstances to that patient, the application will be classified as a request for development of a new policy or service specification which needs to be considered by the CCG to determine whether it will be routinely commissioned. The requesting clinician will then be redirected to the relevant contact point to start the process in that policy. The request will not be progressed through the IFR route from that point.

10.5 All IFRs submitted to the CCG will be screened by the IFR Team to determine whether the request appears to present an arguable case for clinical exceptionality. The IFR screening process included clinical members of the IFR panels and their understanding of the information required by an IFR Panel enables them to make these decisions. If the screening process considers that there is not an arguable case for clinical exceptionality, the IFR will not proceed further through the process and will be declined.

10.6 An IFR will be considered as indicating an “arguable case” for clinical exceptionality if the IFR Team consider that there is some realistic prospect that the IFR Panel would conclude that the patient is clinically exceptional. A case would be turned down only where the IFR Team are confident that, based on the available information, the IFR Panel would come to a conclusion that the patient is not clinically exceptional. If the IFR Team have any reasonable doubt about whether a case satisfies the criterion of exceptionality, it should be forwarded to the IFR Panel.

10.7 If a case is returned to the applicant from the screening stage, the explanation provided may enable the requesting clinician to submit new clinical information to augment the original argument for clinical exceptionality. The IFR Team will reconsider a case if new and relevant clinical information is provided.

11. IFR Panel

11.1 The IFR Panel is a standalone multi-disciplinary professional group responsible for recommending a decision on IFRs.

11.2 The IFR Panel works on behalf of the CCG and makes recommendations/decisions in respect of funding for individual cases. The IFR Panel will work to the published IFR Policies and each request will be processed by following the CCG's IFR Standard Operating Procedure. This will ensure that all requests are considered in a consistent, fair and transparent way, with decisions based on the available evidence presented by the treating clinician and the CCG commissioning principles.

11.3 The referring clinician is advised to set out as clearly as possible and in detail, the clinical evidence and the basis on which they consider that the patient's clinical circumstances are exceptional.

11.4 The clinician should not assume particular knowledge of the Panel for the condition from which their patient is suffering or the relevant area of medical practice. This is because the Panel will contain a range of individuals with a variety of skills and experiences. The Panel will not necessarily include a clinical with expertise in the condition for which treatment is being sought. This is appropriate because not only is the question one of demonstrable clinical exceptionality (resting on the difference between this patient and other with the condition) but the Panel must consider whether it is appropriate to divert resources away from other services in order to fund the requested treatment.

11.5 Applications are forwarded to the IFR Panel following screening review. The IFR team will schedule the application for discussion at the next available IFR Panel.

11.6 The IFR Panel will consider, but not be limited to, the following factors:

- Relevant CCG clinical commissioning policies;
- All of the clinical information provided with the application;
- The planned treatment/intervention and the expected benefits and risks of the treatment;
- The clinical evidence base of the treatment/intervention;
- The value for money to the NHS of the treatment/intervention;
- Whether the treatment/intervention being requested is experimental for a rare clinical circumstance;
- Whether the treatment/intervention being requested constitutes a service development for a cohort of patients;
- The implications of its decision on other patients and on the health of the population;

11.7 For cases referred to the IFR Panel for consideration, an evidence based evaluation of the requested treatment will be prepared by pharmacists or public health representatives for presentation. This case preparation will include an assessment of the evidence of clinical and cost effectiveness, and refer to any precedent set through previous funding decisions.

11.8 The IFR Panel will operate within the limits of delegated authority as determined by the CCG's scheme of delegation.

11.9 The IFR Panel will be held when required in order to ensure that there is a timely response to all requests for funding. Four meetings will be scheduled per month although whether or not a Panel meets will be based on there being cases to review.

11.10 The IFR Panel will make its decision based on the IFR policies and processes within this governance framework and other CCG published clinical commissioning policies or NICE mandated guidance relevant to the application or interpretation of the criteria.

11.11 In reaching its decision, the IFR Panel will consider whether there are justifiable grounds for funding the requested treatment and if so what those grounds are.

11.12 The IFR Panel in all circumstances will take into account published evidence of clinical effectiveness and likely value for money relating to the proposed treatment.

11.13 It is also open to the IFR Panel to conclude, notwithstanding the screening decisions taken by the IFR Team, that:

- The request should be properly classified as a service development. In this case the request will be refused.
- Further information or evidence is required before the IFR Panel can take a decision on whether funding should be given, in which case further information will be requested through the IFR Team. This can be sought from the clinician, from within the CCG or from other clinical advisers as considered appropriate.

11.14 In considering individual cases, the IFR Panel will take care to avoid identification bias. This term describes the effect on decision makers of being presented with the detail of an individual's life. In these circumstances, it is hard to separate from the emotion behind a decision. Decision makers are more likely to decide in favour of that individual, even when this is at the expense of others who cannot be identified as clearly.

11.15 The IFR Panel will also take care to avoid "rule of rescue". This is the imperitive people feel to 'rescue' individuals facing avoidable death or ill health. For example, supporting the effort of prolong life where there is little prospect of improvement, or death is unavoidable or there is little published evidence to support the requested treatment option in relapsed/refractory stages of the individual's disease/condition. Where the IFR Panel consider that application of the rule of rescue would form the basis for treatment, funding will be declined.

11.16 The IFR Panel will take account of the evidence submitted with the application form before making a recommendation.

11.17 The IFR Panel shall be entitled to recommend approval of funding if the patient has exceptional clinical circumstances. In considering whether or not to fund a patient on grounds of exceptional clinical circumstances, the IFR Panel will act as follows:

a. The IFR Panel will use the information provided by the applicant to compare the patient to other patients with the same presenting medical condition at the same stage of progression. Specifically, the panel may consider, based upon the evidence provided to it, whether or not the clinician has demonstrated exceptional clinical circumstances which lead the panel to believe that the patient would benefit significantly more from the treatment than other patients not meeting funding criteria.
b. When making their decision, the IFR Panel is required to restrict itself to considering only the patient's presenting medical condition and the likely benefits which have been demonstrated by the evidence to be likely to accrue from the proposed treatment.
c. The IFR Panel shall seek to make decisions in accordance with the CCG priority setting processes, guided by the same principles as priority setting for the rest of the organisation. This includes the requirement to have due regard to the obligations of the Equality Act 2010 except 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 patients.

d. The IFR Panel shall seek to make decisions in accordance with the 1998 Human Rights Act.
e. The IFR Panel shall not apply non-clinical factors to decision making to differentiate between applications.
f. The IFR Panel shall have a broad discretion to determine whether the proposed treatment is a justifiable expenditure for the CCG within its delegated financial limit. The IFR Panel is required to consider that the allocation of any resources to support any individual patient will reduce the availability of resources for investments in previously agreed care and treatments.

11.18 The IFR Panel is not required to accept views expressed by the patient or the clinical team concerning the likely clinical outcomes for the individual patient of the proposed treatment but is entitled to reach its own views on:
a. the likely clinical outcomes for the individual patient of the proposed treatment; and
b. the quality of the evidence to support that decision and/or the degree of confidence that it has about the likelihood of the proposed treatment delivering the proposed clinical outcomes for the individual patient;

11.19 The IFR Panel may commission its own reports from any duly qualified or experienced clinician, medical scientist or other person having relevant skills in relation to any assertion within the application that the treatment is likely to be clinically effective in the case of the individual patient.

11.20 The IFR Panel is entitled to recommend approval subject to or contingent upon the fulfilment of, any conditions as it considers appropriate.

11.21 The IFR Panel may adjourn consideration of an individual case where the funding request presents a new issue which needs a substantial investigation and research to be conducted before a conclusion can be reached. This may include the need to consult widely on the issue or on any implications of funding the treatment. The Panel will reconvene to reach its decision, once that investigation and research has been completed.

11.22 The IFR Panel may adjourn consideration of an individual case where the Panel feels more information is required to support an informed decision. The Panel will reconvene to reach its decision, once the required information has been provided.

11.23 Throughout the process described above, the IFR Team may, at any time, be asked to request additional information from the referring clinician.

11.24 A funding request will not be resubmitted to the IFR Panel once it has been considered unless there is new evidence or policy to support a new assessment of the case. Resubmissions are recorded as a new IFR application and the IFR team will only consider these where there is new information relevant to the case to be considered.

11.25 The outcome of each individual IFR will be communicated to the referring clinician within 10 working days of the decision. This timescale is required to ensure that the documentation from the Panel has been authorised by the membership.

12. Clinical Exceptionality

12.1 Details of the application of Clinical Exceptionality, is described in more detail in the IFR Decision Making Policy.

12.2 The onus will be on the clinician making the request to clearly set out the grounds on which it is said that their patient is clinically exceptional. The grounds will usually arise out of exceptional clinical manifestations of the medical condition, as compared to the general population of patients with the medical condition from which the patient is suffering.

12.3 The IFR process only considers clinical information. The NHS does not make judgements about the worth of different individuals and seeks to treat everyone fairly and equitably. It is a core value that NHS care is available – or unavailable – equally to all.

12.4 These grounds must be set out on the form provided by the MLCSU on behalf of the CCG. The clinician should clearly set out any factors which he or she invites consideration as constituting exceptional clinical circumstances.

12.5 If, for example, it is said that the patient cannot tolerate the usual treatment because of the side effects of another treatment they are receiving, the referring clinician must explain how common it is for the patient with this condition, not to be able to be provided with the usual treatment.

12.6 If a clear case as to why the patient's clinical circumstances are said to be clinically exceptional is not made, the CCG, via the MLCSU IFR process, will be obliged to refuse the application. The CCG recognises that the applying clinician and the patient together, are usually in the best position to provide information about the patient's clinical condition, as compared to a subset of patients with that condition.

12.7 Evidence must be set out in detail by the applying clinician. Whilst a range of individuals with a variety of skills and experiences are involved in the IFR decision making process, they may not be clinicians of that particular speciality. The CCG requires the applying clinician, as part of their duty of care to the patient, to explain why the patient's clinical circumstances are said as to be clinically exceptional.

12.8 The policy of the CCG is that there is no requirement for the IFR processes to include an investigation of a patient's circumstances in order to try to find a ground upon which the patient may be considered to be clinically exceptional; nor to make assumptions in favour of the patient if one or more matters are not made clear within the application. Therefore, if a clear case of clinical exceptionality is not made by the paperwork placed before the IFR decision making team, the IFR team would be entitled to turn down the application.

13. Clinical Effectiveness

13.1 Clinical effectiveness is a measure of the extent to which a treatment achieves pre-defined clinical outcomes in a specific group of patients.

13.2 Clinical evidence that considers the efficacy of a particular treatment will be carefully considered by the IFR screening groups and IFR Panel. It is the sole responsibility of the referring clinician to provide this information and the IFR Teams will not be responsible for undertaking any evidence searches. Inevitably, the evidence base put forward in support of an IFR is unlikely to be as robust as in more common presentations of the condition or the more usual use of the treatment. However it is important that the referring clinician makes explicit linkages between the grounds under which exceptionality is clamed and the sections of the submitted research literature that are considered to support the clinician's view regarding the differences between the patient's clinical position and that of other patients in the group, and regarding the patient's anticipated response to the requested treatment.

13.3 When considering clinical effectiveness, the IFR Panel will consider:

a. How closely the patient matches the patient population from whom the results are derived in any study relied on by the clinician;
b. The plausibility of the argument that the patient will achieve the anticipated outcomes from treatment, based on the evidence supplied;
c. The impact of existing co-morbidities on both the claim for exceptionality and treatment outcome;
d. Any complications and adverse events of the treatment including toxicity and rates of relapse. The panel will take account of side effects when considering the benefits of the treatment;
e. The likely impact of the treatment on quality of life using information as available;
f. Reported treatment outcomes and their durability over the short, medium and longer term, as relevant to the nature of the condition. The requesting clinician must demonstrate why they consider that the proposed treatment will be effective for the whole period for which it will be given.

13.4 When considering the clinical effectiveness of the proposed treatment, the following hierarchy of evidence[2] will be taken into consideration:

a. Well-conducted meta-analysis of several, similar, large, well-designed Randomised Controlled Trials (RCTs);
b. Large well-designed RCTs;
c. Meta-analysis of smaller RCTs;
d. Case-control and cohort studies;
e. Case reports;

13.5 Evidence to support clinical effectiveness should be provided by the applicant in the form of full copies of all the papers cited.

13.6 Evidence reviews will be supported by Public Health Specialists and/or Senior Medicines Management representatives as required.

14. Good Use of NHS Resources

14.1 The requesting clinician will be expected to explain why they consider the treatment for which funding has been applied for will be a good use of NHS resources.

14.2 This criterion is only applied where the Panel has already concluded that the criteria of clinical exceptionality and clinical effectiveness have been met. Against this criterion the Panel balances the degree of benefit likely to be obtained for the patient from funding the treatment against cost. Having regard to the evidence submitted and the analysis they have carried out when considering clinical exceptionality and clinical effectiveness, Panel members will consider the nature and extent of the benefit the patient is likely to gain from the treatment, the certainty or otherwise of the anticipated outcome from the treatment and the opportunity costs for funding the treatment. This means considering, for example, how significant a benefit is likely to be gained for the patient, and for how long that benefit will last. These factors need to be balanced against the cost of the treatment and the impact on other patients of withdrawing funding from other areas in order to fulfil the IFR. This reflects the fact that the only way to provide the funding for treatment under IFRs, i.e. outside commissioned clinical policies which are developed through the structured prioritisation process, is to divert resources away from current services.

[2] *Hierarchy of Evidence* (Taken from NPC 'Supporting rational local decision-making about medicines (and treatments) First Edition Feb 2009)

14.3 When determining whether a treatment would be a good use of NHS resources it is very important to consider the length of time for which funding of a treatment is being requested, in relation to the duration of the evidenced efficacy of the treatment i.e. whether the clinical evidence indicates short, medium or long term effectiveness of a particular treatment.

14.4 Due to the very nature of the cases considered by the IFR Panel, the degree to which effectiveness can be considered certain is likely to be limited, and this will be a relevant factor when considering whether funding would be a good use of NHS resources.

14.5 However the Panel should also take into account its ability to impose conditions on any funding it agrees, for example to monitor the impact of the funded treatment.

14.6 In applying this criterion Panel members will draw upon their professional and analytical skills and knowledge of the NHS system and how it works.

15. Non-clinical and social factors

15.1 It is common for an application for individual funding to be made on the grounds that a patient's personal circumstances are clinically exceptional. This assertion can include details about the extent to which other persons rely on the patient, or the degree to which the patient has contributed or is continuing to contribute to society. The CCG understand that everyone's life is highly individual. However, including non-clinical, social factors in any decision-making raises at least three significant problems.

15.2 **One:** across the population of patients who make such applications, the IFR decision making team is unable to make an objective assessment of material put before it relating to non-clinical factors. This makes it very difficult, upon consideration, to be confident of dealing in a fair and even handed manner in comparable cases.

15.3 **Two:** The essence of an individual funding application is that the CCG is making funding available on a one-off basis to one patient, where other patients with similar conditions would not get such funding. If non-clinical factors are included in the decision making process, the CCG does not know whether it is being fair to other patients who are denied such treatment and whose social factors are entirely unknown.

15.4 **Three:** The CCG is committed to a policy of non-discrimination in the provision of medical treatment. If, for example, treatment were to be provided on the grounds that this would enable an individual to stay in paid work; then this would potentially discriminate in favour of those working compared to those not working. A decision to offer a treatment to one patient and not another on the basis that the funded patient was working and the patient denied funding was out of work, would be considered a breach of ethical principles, setting a precedent for the CCG to always favour those in work over those not currently in work.

15.5 The same can be said of many other social factors such as having children / not having children, being a carer / not being a carer and so on. Requests to fund treatment for adolescents on the grounds that they wish to go to University (thereby deploying the argument that not funding treatment would inhibit the individual from fulfilling their true potential) or because of a person's role in society (e.g. professional) are also discriminatory and would contribute to social inequality.

15.6 Generally, the CCG does not take into account social factors in deciding what treatment to provide, unless a service is specifically designed to address health inequality or a prevailing inequity of access to normally provided care or treatment.

15.7 In general, the NHS treats the presenting medical condition and does not inquire into the background factors which led to that condition as the basis on which to decide whether to make treatment available or not. The policy of the CCG is that it should continue to apply this general principle in individual applications for funding approval. The CCG will therefore seek to invest in treatment based on the presenting clinical condition of the patient and not based on the patient's non-clinical circumstances.

15.8 Accordingly, in reaching a decision as to whether a patient's circumstances are clinically exceptional, the CCG is required to follow the principle that non-clinical or social factors, including social value judgments about the underlying medical condition or the patient's circumstances, are not relevant.

15.9 Clinicians are asked to bear this policy in mind and not to refer to social or non-clinical factors to seek to support the application for individual funding.

16. Cohorts of patients

16.1 This policy recognises that there needs to be a distinction between cases where the clinical circumstances of a patient are genuinely exceptional and cases where the presenting clinical circumstances are representative of a small group (cohort) of similar patients.

16.2 Where the presenting clinical circumstances are realised as a representative of a small group (cohort) of similar patients, the decision to fund or not is a commissioning policy decision, not a funding decision for an individual patient (i.e. it has wider funding implications).

16.3 A cohort will be considered if there are likely to be 5 per 100,000 population or more similar patients in the population served by the CCG:

- who are in the same or similar clinical circumstances as the patient who is the subject of the request; and

- whose clinical condition means that they could make a similar request (regardless of whether such a request has been made); and
- who could reasonably be expected to benefit from the requested treatment to the same or a similar degree as the patient on whose behalf the request is made;

16.4 A cohort will be established when:

- A prevalence review confirms there is likely to be 5 per 100,000 population or more similar patients in the population served by the CCG; and/or
- the number of treatment requests received by the IFR team on behalf of a CCG, has exceeded 5 per 100,000 population or more similar patients in the population served by the CCG;

16.5 This is the level at which requests will require a service development/commissioning policy decision from the CCG.

16.6 Treating it as a service development/commissioning policy decision, within the wider context of the commissioning and priority setting will ensure that the outcome of the decision is applied equally to all other patients who have the same or similar presenting clinical circumstances.

16.7 The IFR team will routinely screen all requests and where a request meets the criteria to be considered a service development rather than an IFR, the IFR team will refuse funding through the IFR process and:

- Request that the provider submitting the application prioritise a service development and, if supported internally, invite the provider to submit a business case either as part of the annual commissioning round, or as an in year service development proposal, for the requested service development;
- Escalate the issue to commissioners within the CCG to initiate an assessment of the clinical importance of the service development with a view to developing a policy and determining its priority for funding either in year or as part of the next annual commissioning round.
- Agree an interim process with the CCG on how this and subsequent requests will be processed. This would be an interim CCG commissioning policy decision at the developmental stages to allow funding to be approved for patients that meet the proposed criteria.

16.8 As a general rule the first approach will be applied to requests that originate from within a secondary care provider organisation.

17. Service developments (or Commissioning Policy Decisions)

17.1 A service development is any aspect of healthcare which a CCG has not historically agreed to fund and which will require additional and predicable recurrent funding because one or more similar patients (a cohort) can be reasonably expected to request similar funding in subsequent years.

17.2 The term refers to all decisions which have the consequence of committing CCG to new expenditure for a cohort of similar patients, including:

- New services;
- New treatments including medicines, surgical procedures, and medical devices;
- Licensed treatments not considered by NICE;
- Developments to existing treatments including medicines, surgical procedures, and medical devices;
- New diagnostic tests and investigations;
- Quality improvements;
- Requests to alter existing policy, such as adding an indication for treatment, expanding access to a different patient sub-group or lowering the threshold for treatment;
- Support for establishing new models of care;
- Requests to fund a number of patients to enter a clinical trial;
- Commissioning a clinical trial;

17.3 It is not unusual for clinicians to request funding via the IFR process for a patient who actually represents the first of a group of patients wanting a particular treatment. Any IFR application that is representative of such a group also represents a service development need, as it is difficult to envisage circumstances in which the patient can properly be classified to have exceptional circumstances.

17.4 A CCG will normally consider funding new developments during the annual commissioning round, however in-year service developments (i.e. developments presented outside the annual commissioning round) will also be considered by the CCG.

17.5 MLCSU will escalate the need for a commissioning policy decision to the CCG as a request for a service development, via established routine reporting and communication arrangements. This will include a report to support the business case based on the application reviewed for the proposed treatment.

17.6 The CCG will be required to use its discretion to determine the most appropriate action in each case and may consider issuing an interim protocol to support the patient journey whilst a service development is being considered. This should include explicit criteria to be applied by the IFR Team in considering subsequent requests as part of the screening process (see Appendix 2).

18. Personal Health Budgets

18.1 People with complex health care needs have the right to ask for a personal health budget (PHB), subject to certain conditions. A PHB is an amount of money to support the planned and agreed healthcare and wellbeing needs of an individual. PHBs, therefore, give people more independence over how their healthcare money is spent. For more on the operation of PHBs see: http://www.personalhealthbudgets.england.nhs.uk/.

18.2 IFRs relate to cases where money is identified to fund healthcare based on exceptionality of the individual, following a referral from an NHS clinician. Having a PHB would not therefore exclude the patient from making an IFR to meet assessed needs beyond those included in the PHB.

19. Private Service Providers

19.1 Independent sector service providers, if requested **must** hold an NHS contract albeit perhaps with a different CCG. This provides assurance that the expected standards of healthcare are met and are continually monitored for quality.

19.2 However, such requests will not be approved where it is identified that there is equivalent NHS services available.

19.3 The IFR Team will undertake the necessary checks with the proposed provide in this regard before a decision to approve a request is made. The IFR Team will liaise with the CCG Contracts Team if it is found that an NHS contract is not in place and no equivalent NHS services are identified to provide the treatment required.

19.4 The decision to approve a request for private service provision will ultimately rest with the CCG, regardless of cost and may involve the consideration of a commissioning contract with the independent sector provider or an existing NHS commissioned provider if appropriate.

20. Urgent treatment decisions

20.1 The CCG recognises that there will be occasions when an urgent decision needs to be made to consider a request to fund treatment for an individual patient outside the CCG's normal policies. In such circumstances the CCG recognises that an urgent decision may have to be made before an IFR Panel can be convened or the decision making process concluded. The following provisions apply to such a situation:

a. An urgent request is one which requires urgent consideration and a decision because the patient faces a substantial risk of significant harm if a decision is not made before the next scheduled meeting of the IFR Panel.
b. A matter will not be treated as an urgent request where the apparent urgency arises solely as a result of:
    - a failure by the clinical team to apply for funding through the appropriate route in a timely manner; or

- the patient's expectations being improperly raised by a commitment being given by the clinician to provide a specific treatment to the patient.

In such circumstances the CCG will expect the treatment to be provided and funded by the Provider.

20.2 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 MLCSU not to be taking all reasonable steps to minimise urgent requests to the IFR process, the CCG or the MLCSU acting on the CCG's behalf may refer the matter to the Chief Executive of the provider.

20.3 Where an urgent decision needs to be made to authorise treatment for an individual patient outside the CCG's normal policies, the CCG will be assisted by the IFR Authorised Officer (see roles and responsibilities above).

20.4 The IFR Authorised Officer shall, as far as possible within the constraints of the urgent situation, follow this policy in making the decision. The IFR Authorised Officer 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 IFR Authorised Officer shall collect as much information about both the patient's illness and the treatment as is feasible in the time available and shall consider the request for funding in accordance with relevant existing commissioning policies.

20.5 The IFR Authorised Officer 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.

20.6 The IFR Authorised Officer shall be entitled to reach the view that the request is, properly analysed, a request for a service development and so should be refused and/or appropriately referred for policy consideration.

21. Retrospective funding

21.1 This policy excludes requests for funding approval made after an episode of care has commenced. Retrospective funding requests for any care or treatment which has not been given prior approval will not be funded. Unless it can be demonstrated that the treatment was needed urgently to avoid a life threatening situation or significant harm to a patient who is subsequently found, by the IFR decision making process, to meet the clinical exceptionality test.

22. Funding decisions

22.1 The decision to fund up to the delegated limit specified by the CCG (£5k total package of care) rests with the IFR team having followed the decision making process. However, where packages of care exceed agreed limits the decision to fund will be escalated to the CCG for agreement.

22.2 The CCG will be required to fund a treatment for an individual patient if all of the following conditions are met:

a. The IFR decision making process has determined that there is no cohort of similar patients;
b. Conditions set out in this policy have been met;
c. There is sufficient evidence to show that, for the particular patient, the proposed treatment is likely to be clinically and cost-effective;

22.3 A letter will be sent to the referring clinician, by the IFR team on behalf of the Chair of the IFR Panel, or the decision maker for the CCG, advising on the outcomes of the IFR Panel. The letter will be copied to the patient or their representative where this has been indicated as clinically appropriate by the applying clinician.

23. Decision expiry

23.1 If the CCG makes a decision to fund an IFR, this decision will be valid for a period of six months from the date that the decision was communicated to the applicant.

24. Reconsideration of decisions

24.1 Where an application for a requested treatment has been refused or has been approved subject to conditions, the patient or their representative clinician will be entitled to ask that the decision be reconsidered.

24.2 All requests for reconsideration must be supported by the senior treatment clinician who must provide information that has not previously been submitted for consideration and/or explain his or her reasons why the IFR decision making process may have misunderstood the clinical evidence previously provided.

24.3 Where the senior treating clinician believes the decision made by the IFR Panel was either procedurally improper and/or was in his or her opinion a decision which no reasonable IFR panel could have reached they should request a process review of the decision.

25. Process Review of the decision

25.1 Previously referred to as an Appeal a Process Review of the decision is where an IFR has been considered following the IFR decision making process outlined in this policy and funding has been:

- refused; or
- approved subject to conditions;

the clinician acting on the patient's behalf, shall be entitled to ask that the decision be reviewed.

25.2 In most circumstances it is anticipated that the original applying clinician would initiate a process review. In rare circumstances it may be initiated by the patient, although they would still need to have the written support of the clinician who made the original application.

25.3 Process Review Requests must be made in writing via the Process Review Application Form and should be submitted to the relevant email address or postal address given on the application form.

25.4 Upon receipt of a Process Review Request application the IFR team, taking advice from clinical members, will undertake a review of the process review application to ensure that no new evidence has been submitted in relation to the case. If new information has been submitted then the applicant and clinician will be advised that a resubmission of the IFR application is required.

25.5 The IFR team will consider the basis for the process review and make a recommendation to the CCG Process Review Panel Chair. If the Chair determines that these are not reasonable (for example, the applicant merely disagrees with the decision without putting up a reasonable argument as to why procedure was not followed) then a process review panel will not be convened and the applicant will be informed why and of their right to make a complaint under the CCG Complaints procedure.

25.6 In all other circumstances the IFR Team will convene a process review panel meeting as promptly as possible (within 20 working days from receipt of the process review request application). The applicant or the patient may submit supporting information relevant to the grounds for process review.

25.7 If the applicant considers that there is greater clinical urgency for the Process Review Panel this should be specified in the process review application form and a telephone call made by the applying clinician to the IFR Team to alert them to the urgent request.

25.8 At the IFR Process Review Panel, consideration shall be given to whether:

- The decision making process was followed and the required standards set out in this Policy adhered to.
- The decision not to fund was reasonable in light of the available evidence and the individual circumstances of the case.
- The IFR decision making process took into account material factors relating to the application.
- The IFR decision making process and therefore the CCG came to a decision that fell within the range of responses which could have been reasonably reached based on the evidence provided.

25.9 In the event that it is considered that the decision taken did not comply with the requirements set out above, the IFR Process Review Panel shall next consider whether there was any reasonable prospect that the IFR decision making process would have come to a different decision if every aspect had been complied with.

25.10 If the IFR Process Review Panel considers that there was no reasonable prospect that the IFR decision making process would have come to a different decision, the decision not to fund or only to fund subject to certain conditions shall be approved, notwithstanding the non-compliance.

25.11 If the IFR Process Review Panel considers that there was a reasonable prospect that the IFR Panel may have reached a different decision, had the requirements outlined above been complied with, the IFR Process Review Panel shall refer the matter back to the IFR team or IFR Panel for reconsideration.

25.12 The process and timescales for notification of a decision will be the same as with the IFR Panel. The letter will detail the grounds for this decision and the circumstances under which the complaints procedure of the responsible CCG may be relevant.

26. Information Governance and Confidentiality

26.1 MLCSU will hold patient level information on behalf of the CCGs to support the IFR process. All patient information will be handled in confidence and stored in accordance with the Information Governance Framework relating to person identifiable information.

26.2 IFR Panel members will take into account the need for confidentiality and operate under the Caldicott guidelines. All patient specific electronic communication will be via a secure method in line with the Information Governance framework.

26.3 MLCSU IFR processes will comply at all times with information privacy, confidentiality and security legal and regulatory requirements and best practice. MLCSU will fully respect patient confidentiality and ensure that patient information is not collected, processed or shared without valid patient consent or other legal basis.

27. Equality Statement

27.1 The CCG has a duty to have regard to the need to reduce health inequalities in access to health services and health outcomes achieved as enshrined in the Health and Social Care Act 2012.

27.2 The CCG is committed to ensuring equality of access and non-discrimination, irrespective of age, gender, disability, gender reassignment, marriage and civil partnership, pregnancy and maternity, race, religion or belief, sex (gender) or sexual orientation.

27.3 In carrying out its functions, the CCG will have due regard to the different needs of protected equality groups, in line with the Equality Act 2010.

27.4 This document is compliant with the NHS Constitution and the Human Rights Act 1998. This applies to all activities for which they are responsible, including policy development, review and implementation.

27.5 Throughout the development of this policy statement, the CCG has:

(a) Given due regard to the need to eliminate discrimination, harassment and victimisation, to advance equality of opportunity, and to foster good relations between people who share a relevant protected characteristic (as cited under the Equality Act 2010) and those who do not share it; and

(b) Given regard to the need to reduce inequalities between patients in access to and outcomes from healthcare services and to ensure services are provided in an integrated way where this might reduce health inequalities.

28. Review and Monitoring of this policy and procedure

28.1 This policy will be subject to further review to ensure it continues to meet local, legislative and national objectives. Addenda to the policy will be added subsequent to any review and a decision on the need to re-issue the policy will be based on the significance of the amendments required.

29. Documents which have informed this policy

a) Department of Health, The National Health Service Act 2006, The National Health Service (Wales) Act 2006.

b) NHS Confederation Priority Setting Series, 2008
   a. Priority setting: an overview
   b. Priority setting: legal consideration
   c. Priority setting: strategic planning
   d. Priority setting: managing new treatments
   e. Priority setting: managing individual funding requests

c) Improving Access to medicines for NHS patients. A report for the Secretary of State for Health by Professor Mike Richards CBE. (November 2008).

d) Department of Health. National Prescribing Centre. Defining DH guiding principles for processes supporting local decision-making about medicines (January 2009).

e) National Prescribing Centre and Department of Health. Supporting rational local decision- making about medicines (and treatments) (February 2009).

f) Department of Health, The NHS Constitution for England, 2012.

g) National Prescribing Centre. Local decision-making Competency framework: For groups involved in making local decisions about the funding of medicines and treatments in the NHS. 2012.

h) NHS England – Interim Commissioning Policy: Individual Funding Requests – April 2013

i) Midlands and Lancashire Commissioning Support Unit – General Policy for Individual Funding Request Decision Making for Lancashire Clinical Commissioning Groups – January 2016

j) NHS England - Interim Standard Operating Procedure: The Management of Individual funding Requests – February 2016

k) Midlands and Lancashire Commissioning Support Unit - A collaborative Individual Funding Request process for Lancashire Clinical Commissioning Groups – June 2016

l) NHS England – Specialised Commissioning – Service Development Policy – September 2017

m) NHS England – Commissioning Policies: Funding of Treatment outside of Clinical Commissioning Policy or Mandated NICE Guidance – October 2016

n) NHS England – Commissioning Policy – Individual Funding Requests – November 2017

o) NHS England - Standard Operating Procedure: The Management of Individual funding Requests – November 2017

p) NHS England – Specialised Commissioning – Application form to make an Individual Funding Request – November 2017

A glossary of Terms used in the application of the IFR policy and process is provided in Appendix 3.

Appendix 1 – Legal context to decision making

This document sets out the legal and ethical considerations relevant to the IFR process.

CCG Responsibilities and Regulations

1 The foremost amongst these considerations are the following patient rights, specified under the NHS Constitution[3] and underpinned by law:

- "You [the patient] have the right to access NHS services. You will not be refused access on unreasonable grounds."

- "You [the patient] have the right to expect local decisions on funding of other drugs and treatments 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 feel would be right for you, they will explain that decision to you."

2 Part 7 of the National Health Service Commissioning Board and Clinical Commissioning Groups (Responsibilities and Standing Rules) Regulations 2012[4] make specific provision in relation to the funding and commissioning of drugs and other treatments by CCGs, including providing for a duty to give reasons for funding decisions.

Legal and financial duties and the duty to provide services

3 Under the NHS Act 2006[5] (as amended by the Health and Social Care Act 2012 ("HSCA)) the CCGs; NHS England and the Secretary of State have a concurrent duty to provide a comprehensive health service. For CCGs, the following applies[6]:

4 "A clinical commissioning group must arrange for the provision of the following to such extent as it considers necessary to meet the reasonable requirements of the persons for whom it has responsibility:
…
(c) medical, dental, ophthalmic, nursing and ambulance services,
…
(e) such other services or facilities for the prevention of illness, the care of persons suffering from illness and the after-care of persons who have suffered from illness as he considers are appropriate as part of the health service,
(f) such other services or facilities as are required for the diagnosis and treatment of illness."

5 In addition to this duty to meet the above requirements, CCGs have a statutory obligation to maintain financial balance. When considering whether or not to commission specific treatments for groups of people with the same medical condition, CCGs will assess the clinical and cost effectiveness of the treatment, the benefits to patients in terms of quality of life and the priority of this treatment or service in relation to others already commissioned or proposed for commissioning.

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[3] The NHS Constitution March 2010 http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/@dh/@en/@ps/documents/digitalasset/dh_113645.pdf

[4] National Health Service Commissioning Board and Clinical Commissioning Groups (Responsibilities and Standing Rules) Regulations 2012/2996 February 2012

[5] The NHS Act 2006 3http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/@dh/@en/documents/digitalasset/dh_063171.pdf

[6] Section 3 of the NHS Act 2006 (as amended)

6 So a treatment of very little benefit is unlikely to be commissioned simply because it is the only treatment available, this ensures that limited resources are used to provide the greatest health benefit.

7 At an individual or patient group level, treatment will not generally be funded solely because a patient requests it. CCGs will not normally fund treatment for one patient, which is not available to all other patients with the same clinical need, except in the context of this policy.

8 CCGs will not discriminate on grounds of personal characteristics, such as age, gender, sexual orientation, race, religion, lifestyle, social position, family or financial status, intelligence or cognitive functioning and will act in compliance with duties under the Equality Act 2010. However, funding decisions will be made on the basis that the patient is more likely to benefit significantly more than other patients with the same clinical condition.

Administrative Law

9 Decisions made by public bodies including CCGs can be challenged in the Administrative Court by way of judicial review. The traditional grounds for judicial review are that the public body:

- acted beyond its lawful powers;
- came to a decision which no other reasonable CCG could have reached;
- acted unfairly, because it did not follow proper procedures;
- breached the patient's human rights;
- breached the Equality Act 2010.

10 These grounds are the basis for the Process Reviews Process set out in this document.

Equality Duties

11 The main impact of the Equality Act 2010[7] has been the duty on health bodies to monitor their compliance – extending the race equality monitoring to gender, religious belief and sexual orientation where this is relevant – and to give due regard to the public sector equality duty. This policy complies with the Equality Act 2010.

12 The CCG has a duty to comply with public sector equality duty, part of the Equality Act 2010, and must, in the exercise of their functions, have due regard to the need to:

- Eliminate unlawful discrimination, harassment and victimisation and other conduct prohibited under the Act
- Advance equality of opportunity between persons who share a relevant protected characteristic and persons who do not share it
- Foster good relations between persons who share a relevant protected characteristic and persons who do not share it.

The Human Rights Act 1998

13 The Human Rights Act 1998[8], Article 6 requires a fair hearing for determining civil rights and proportionality of decision-making which the courts consider a fair balance between protection for individual rights and the interests of the community. The proportionality test involves balancing different interests – such as those of the individual applicant for treatment funding with those who

[7] http://www.legislation.gov.uk/ukpga/2010/15/contents

[8] http://www.opsi.gov.uk/acts/acts1998/ukpga_19980042_en_3#sch1

await service improvements that depend on the availability of new funding. Other key considerations are Articles: 2 (the right to life); 3 (the right not to be subjected to inhumane or degrading treatment); 8 (the right to respect for privacy and family life); 12 (the right to marry); and 14 (the requirement for non-discrimination against groups because of their sex, race, religion, disability, disease).

Statutory duty of quality

14 CCGs need to demonstrate compliance with a statutory duty of quality, in accordance with the NHS Act 2006 (as amended by the HSCA) with specific consideration of the following points in section 14:

- s14P (Duty to promote NHS Constitution);
- s14Q (Duty as to effectiveness, efficiency and economic value);
- s14R (Duty as to improvement in quality of services);
- s14T (Duties as to reducing inequalities);
- s14U (Duty to promote involvement of each patient) and
- s14V (Duty as to patient choice).

15 As part of the statutory duty of quality the CCG will ensure that the process for assessing and making decisions about individual funding requests should be timely and flexible enough to respond rapidly where the health of an applicant mandates a more urgent decision.

Ethical Considerations

16 The four principles widely used in medical ethics are:

- Autonomy: respecting the decision-making capacities of individual people to make their own reasoned informed choices
- beneficence: considering the balance between the benefits of an intervention against its risks and costs and choosing the one with greater benefit to the individual patient
- non maleficence: avoiding the causation of harm and ensuring any is proportionate to the benefits of treatment
- distributive justice: sharing benefits equitably, and risks and costs fairly; so that patients in similar positions should be treated in a similar manner irrespective of age, sex, race, disability and employment.

Patient's Right to Choice

17 CCGs have a statutory duty as to patient choice under section 14V of the NHS Act, which sets out that each CCG must, whilst carrying out its functions, act with a view to enabling patients to make choices in respect of aspects of health services provided to them.

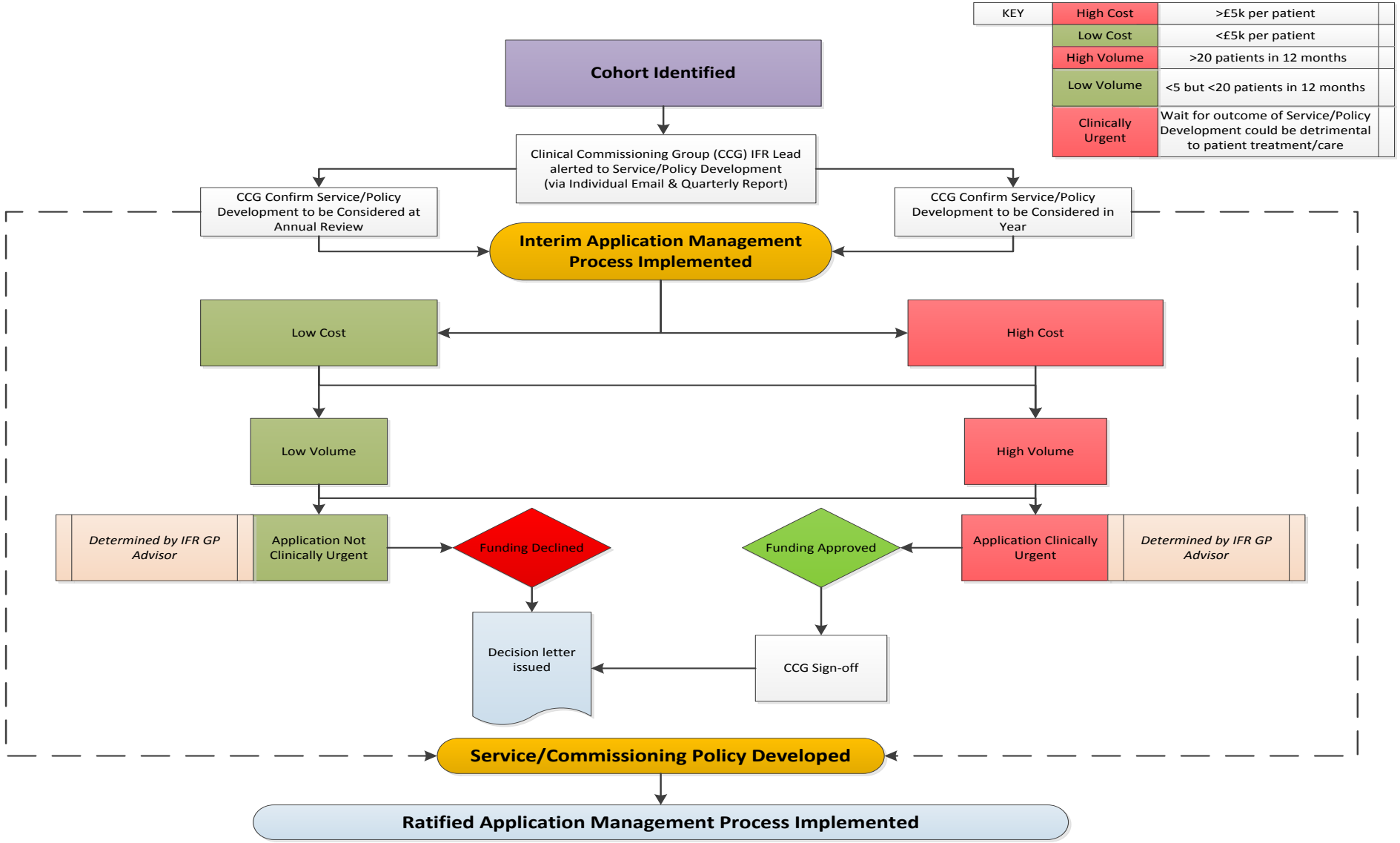
18 The NHS Constitution sets out certain rights that patients have in relation to choice. In addition, the Department of Health (2014/15) Choice Framework outlines the services where patients have a right to choice.[9]

19 CCGs must also consider Part 8 of the NHS CB and CCGs (Responsibilities and Standing Rules) Regulations 2012, which provides a specific duty of choice in relation to elective referrals, and the NHS (Procurement, Patient Choice and Competition) (No. 2) Regulations 2013/500 in relation to choice of alternative provider.

[9] https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/299609/2014- 15_Choice_Framework.pdf

20 The right to choice excludes referrals for persons needing urgent or emergency treatment; persons detained under the Mental Health Act 1983, serving members of the Armed Forces and prisoners (including those on temporary release), those needing urgent or emergency care, maternity services, high secure psychiatric services or drug and alcohol misuse services commissioned or provided by local authorities.

Appendix 2 – Pending Service Development – Example Interim Protocol Flow



Appendix 3 – Glossary/Definitions

TERM	DEFINITION
Appropriate IFRs	An appropriate IFR is where: • A patient's treatment falls outside generic or treatment specific policies where an unusual ('exceptional') clinical circumstance applies to the individual; • A particular treatment or intervention could benefit a patient with a very rare clinical condition;
Case by case decision making	Case by case decision making in the context of priority setting is when the decision maker opts to allocate resources for a specified treatment and for specified patients in the absence of policy or as a substitute to policy making. A fundamental principle of the NHS is that if a treatment is made available to one patient by an NHS commissioner, it should be made available to all other patients for whom the commissioner is responsible and who have an equal need for that treatment. If a treatment from which 100 patients could benefit then the Clinical Commissioning Group would either have to offer it to all patients or to none. It would be unacceptable to offer it to 30 unless it was possible to divide the relevant patients into different clinical subgroups. However case by case decision making means that the Clinical Commissioning Group only considers one patient from the 100 patients at a time.
Clinical effectiveness	Clinical effectiveness is a measure of how well a healthcare intervention achieves the pre-defined clinical outcomes of interest in a real life population under real life conditions.
Clinical trial	A clinical trial is a research study in human volunteers to answer specific health questions. Clinical trials are conducted according to a plan called a protocol. The protocol describes what types of patients may enter the study, schedules of tests and procedures, drugs, dosages, and length of study, as well as the outcomes that will be measured. Each person participating in the study must agree to the rules set out by the protocol. The ethical framework for conducting trials is set out in the Medicines for Human Use (Clinical Trials) Regulations 2004 (as amended). It includes, but does not refer exclusively to, randomised control trials.
Cohorts of patients	A cohort of patients is an identifiable group of patients with a similar condition, for which approval to fund treatment for one patient would result in a commitment to fund an identifiable group of future patients with the same clinical circumstances. Examples of a cohort might include: • When it is likely that the CCG could expect to receive more than one application per year on an ongoing basis for the same treatment and clinical indication as determined by prevalence indications or other research evidence; • When a group of similar requests have already been made to a CCG or its neighbouring CCGs.
Cost effectiveness	Cost effectiveness is an assessment as to whether a healthcare intervention is clinically effective and provides value for money. In this document it does not necessarily imply that this is measured using a specific methodology.
Effectiveness - general	Effectiveness means the degree to which pre-defined objectives are achieved and the extent to which targeted problems are resolved.
Effectiveness - clinical	Clinical effectiveness is a measure of the extent to which a treatment achieves pre-defined clinical outcomes in a target patient population.
Efficacious	A treatment is efficacious where it has been shown to have an effect in a carefully controlled and optimal environment. However, it is not always possible to have confidence that data from trials which suggest that treatments will be efficacious will translate into clinically meaningful health gain and more specifically the health gain of interest. This is the difference between disease oriented outcomes and patient oriented outcomes. For example a treatment might have demonstrated a change in some physiological factor which is used as a proxy measure for increased life expectancy but this relationship might not be borne out in reality.

TERM	DEFINITION
Exceptional	Exceptional means out of the ordinary, unusual or special.
Exceptional clinical circumstances	Exceptional clinical circumstances are clinical circumstances pertaining to a particular patient which can properly be described as exceptional. This will usually involve a comparison with other patients with the same clinical condition and at the same stage of development of that clinical condition and refer to features of the particular patient which make that patient out of the ordinary, unusual or special compared to other patients in that cohort. It can also refer to a clinical condition which is so rare that the clinical condition can, in itself, be considered exceptional. That will only usually be the case if the NHS commissioning body has no policy which provides for the treatment to be provided to patients with that rare medical condition.
Experimental and unproven treatments	Experimental and unproven treatments are medical treatments or proposed treatments where there is no established body of evidence to show that the treatments are clinically effective. The reasons may include the following: • The treatment is still undergoing clinical trials for the indication in question. • The evidence is not available for public scrutiny. • The treatment does not have approval from the relevant government body. • The treatment does not conform to an established clinical practice in the view of the majority of medical practitioners in the relevant field. • The treatment is being used in a way other than that previously studied or for which it has been granted approval by the relevant government body. • The treatment is rarely used, novel, or unknown and there is a lack of evidence of safety and efficacy. • There is some evidence to support a case for clinical effectiveness but the overall quantity and quality of that evidence is such that the commissioner does not have confidence in the evidence base and/or there is too great a measure of uncertainty over whether the claims made for a treatment can be justified.
Healthcare intervention	A healthcare intervention means any form of healthcare treatment which is applied to meet a healthcare need.
Inadequate Individual Funding Requests	Examples of Inadequate IFR includes: • A request where no information is submitted in support of the individual's exceptionality; • A request where no information is submitted to demonstrate the clinical effectiveness of the treatment;
Inappropriate Individual Funding Requests	An inappropriate IFR is where: • The request represents a service development and therefore needs to be triaged into the appropriate population decision making group; • The treatment requested is covered by another CCG policy or process; • The request is for a service or procedure that is commissioned by another organisation where funding is not the responsibility of the CCG; • A Patient is referred for physical treatment (for example, cosmetic surgery) on the grounds of psychological problems, which should in the first instance be treated through the mental health route.
Individual Funding Requests (IFR)	An IFR is a request to fund, for an individual patient, a treatment that falls outside existing contracts and commissioning arrangements.
In-year service development	An in-year service development is any aspect of healthcare, other than one which is the subject of a successful individual funding request, which the Clinical Commissioning Group agrees to fund outside of the annual commissioning round. Unplanned investment decisions should only be made in exceptional circumstances because, unless they can be funded through disinvestment, they will have to be funded as a result of either delaying or aborting other planned developments.
NHS commissioned care	NHS commissioned care is healthcare which is routinely funded by the patient's responsible commissioner. The Clinical Commissioning Group has policies which define the elements of healthcare it is and is not prepared to commission for defined groups of patients.

TERM	DEFINITION
Opportunity cost	Opportunity cost is the loss of the ability for the NHS to fund other healthcare interventions when a decision is made to apply NHS resources to a particular healthcare intervention. If for example a commissioner can only afford to fund one of the following: a cancer treatment, a screening programme, or 6 more palliative care beds then the opportunity cost of choosing the cancer treatment is the loss of the opportunity to fund a screening programme and/or palliative care beds.
Outlier	An outlier is a clinical observation of a patient or group of patients that lies outside the normal clinical picture. The outlier may be different from the patient group of interest in one of two ways. Their response to treatment may be very different to the rest of the group or their clinical presentation / natural history might be very different to the rest of the group. In order for an outlier to be identified it is necessary to characterize the patient subgroup of interest.
Policy variation	A policy variation occurs when an existing policy is changed. When there is a proposal which would result in increased access to a treatment (for example by lowering the threshold for treatment or adding a new indication for treatment) the policy variation is a service development and will be treated as such.
Priority setting	Priority setting is the task of determining the priority to be assigned to a service, a service development, a policy variation or an individual patient at a given point in time. Prioritisation is needed because the need and demands for healthcare are greater than the resources available.
Prioritisation	Prioritisation is decision making which requires the decision maker to choose between competing options.
Retrospective funding requests	A Retrospective funding request is an IFR application which is received after the requested treatment has already commenced i.e. without funding approval;
Rule of rescue	Rule of rescue is the observation that human beings, in situations where an individual's life is at risk, have the proclivity to take action to rescue the individual regardless of the cost and the chances of success. Action taken, therefore, is in part about meeting the emotional needs of the decision maker. In the healthcare setting the term has been used in a number of ways. The term refers to agreeing funding for treatments for patients whose prognosis is grave on the basis that their prognosis is grave and without regard to cost or ability to benefit.
Service Development	A Service Development is an application to the Clinical Commissioning Group to amend the commissioning policy of the Clinical Commissioning Group to provide that a particular healthcare intervention should be routinely funded by the Group for a defined group of patients. The term refers to all new developments including new services, new treatments (including medicines), changes to treatment thresholds, and quality improvements. It also encompasses other types of investment that existing services might need, such as pump-priming to establish new models of care, training to meet anticipated manpower shortages and implementing legal reforms. Equitable priority setting dictates that potential service developments should be assessed and prioritised against each other within the annual commissioning round. However, where investment is made outside of the annual commissioning round, such investment is referred to as an in-year service development.
Similar patient(s)	A Similar Patient refers to the existence of a patient within the patient population who is likely to be in the same or similar clinical circumstances as the requesting patient and who could reasonably be expected to benefit from the requested treatment to the same or a similar degree. When the treatment meets the regional criteria for supra-CCG policy making, then the similar patient may be in another CCG with which the Clinical Commissioning Group collaborates. The existence of one or more similar patients indicates that a policy position is required of the Clinical Commissioning Group.
Singular decision making	Singular decision making, in the context of priority setting, occurs when a decision maker assesses a treatment in isolation from the budget and does not compare that proposal with other competing needs.

TERM	DEFINITION
Treatment	Treatment means any form of healthcare intervention which has been proposed by a clinician and is proposed to be administered as part of NHS commissioned and funded healthcare.
Urgent request	An urgent request is a request which requires an urgent 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 a result of a failure by the clinical team expeditiously to seek funding through the appropriate route and/or where the patient's legitimate expectations have been raised by commitment being given by the provider trust to provide a specific treatment to the patient. In such circumstances the CCG expect the provider trust to proceed with treatment and for the provider to fund the treatment.
Value for money	Value for money in general terms is the utility derived from every purchase or every sum spent.