Midlands and Lancashire
Commissioning Support Unit
NHS Birmingham Cross City Clinical Commissioning Group
NHS Birmingham South Central Clinical Commissioning Group
NHS Solihull Clinical Commissioning Group
NHS Dudley Clinical Commissioning Group
NHS Sandwell and West Birmingham Clinical Commissioning Group
NHS Walsall Clinical Commissioning Group
NHS Wolverhampton Clinical Commissioning Group

Collaborative Commissioning Policy

Individual Funding Requests

Version 1.6 – March 2014

Contents

The Individual Funding Request Policy

1. Introduction

Clinical Commissioning Groups (CCGs) have been established under the National Health Service Act 2006 as the statutory bodies charged with the function of commissioning healthcare for patients for whom they are statutorily responsible.

The Clinical Commissioning Group receives a fixed budget from the NHS Commissioning Board to enable it to fulfil this duty. It has a statutory responsibility to maintain financial balance[1] and, as part of discharging this obligation, has to decide how and where finite local resources are allocated.

The need and demand for health care is always greater than the resources available to a society to meet it. It is evident, therefore, that it will not be possible for the CCG to commission all the health care that is needed by the population it serves and, as a result, it will need to prioritise its commissioning intentions, based on the needs of the local population.

In carrying out these functions, the CCG will act with a view to securing that health services are provided in a way which promotes the NHS Constitution and will promote awareness of the NHS Constitution among patients, staff and members of the public. Patients have a right to expect that the CCG will assess and prioritise the health requirements of the local community and commission the services to meet those needs as considered necessary. In discharging its obligations under this Policy, in particular, the CCG acknowledges that patients also have a right to expect that local decisions on the funding of treatments which have not been considered by the National Institute for Health and Care Excellence in its technology appraisal programme will be made rationally following a proper consideration of the evidence.

Those with responsibility for healthcare budgets have to take decisions about priorities at three levels: when developing strategic plans (the main priorities), when deciding year on year which investment and disinvestments to make, and at the individual patient level.

The individual funding request process is the means by which the CCG takes into account and prioritises requests for individuals with unusual clinical circumstances, which cannot be accommodated through its other commissioning processes. Being part of the CCG's priority setting processes, the decisions taken by the IFR Panel must be guided by the same principles as priority setting in the rest of the organisation. These are set out in the CCG's *Ethical framework for priority setting and resource allocation document*. These principles include taking affordability and relative priority vis-à-vis other needs into account.

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 (M&L CSU) to administer the IFR process. It is, nonetheless, for the CCG which is the responsible commissioner for the patient to decide whether or not an IFR application will be funded.

The M&L CSU is not a statutory body, although it is currently hosted by the National Health Commissioning Board. Each CCG, as a separate statutory organisation, remains individually responsible

[1] Section 223H National Health Service Act 2006: Financial duties of clinical commissioning groups: expenditure

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.

This policy sets out the decision making framework for individual funding requests and how they will be managed.

2. The policy

2.1 This policy applies to any patient for whom the CCG is the responsible commissioner.

2.2 In this policy a reference to "treatment" is a reference to any healthcare intervention provided or proposed to be provided by a clinician of any nature whatsoever.

2.3 Clinicians, on behalf of their patients, may make an individual funding request (IFR) to the M&L CSU for treatment that is not normally commissioned by the CCG, if it satisfies the following conditions (but not otherwise):

The request does not constitute a request for a service development, and either:

(a) the patient is suffering from a medical condition for which

- the CCG has commissioning responsibility; *and*
- a commissioning policy[2]; *and*
- the patient's particular clinical circumstances fall outside the criteria for funding set out in that commissioning policy or

(b) the patient's medical condition has rare clinical features, which render it impossible to carry out clinical trials for the intervention in question, and the clinician therefore wishes to use an *existing treatment* on an experimental basis; or

(c) the patient is suitable to enter a clinical trial which requires the CCG to fund the treatment costs of the trial or to give approval prior to the patient entering the trial to fund continuation of funding of treatment after the trial has been completed.[3,4]

Clinicians will be expected to use the M&L CSU IFR application form which can be found in Appendix 7.

[2] The CCG's Policy*: In-Year Service Developments and the Clinical Commissioning Group's approach to treatments not yet assessed and prioritised* sets out that the default commissioning policy for a treatment that the CCG has not yet had time to put through normal priority setting processes for service developments is a policy not to fund that particular treatment.

[3] Note that the CCG will not generally fund continuation of treatment without this prior approval.

[4] Consideration of requests to the CCG to support the treatment costs either during or after a clinical trial (which may be a trial sponsor's precondition for allowing a patient to enter a clinical trial) has been delegated to the those responsible for IFR decision-making because it is a decision to fund a treatment which is not normally funded at the patient level and it will commit additional, often substantial, resource of the CCG. The decision therefore has to be subject to normal priority setting processes at the level of the individual.

Screening Individual Funding Requests

Screening for Service Developments

2.4 All IFRs submitted to the M&L CSU will be subject to screening in accordance with the procedures set out in Appendix 6 of this document to determine whether the request represents a service development. Service developments include but are not restricted to:

- New services
- New treatments including medicines, surgical procedures and medical devices
- New diagnostic tests and investigations
- Quality improvements
- Requests to alter an existing policy ('a policy variation'). A request for a policy variation may include (without limitation) adding in an indication for treatment, expanding access to a different patient sub-group or lowering the threshold criteria for access to treatment
- Requests to fund the treatment costs for a number of patients to enter into a clinical trial
- The commissioning of a clinical trial

Requests for treatment will be classified as a request for a service development if there are likely to be a number of similar patients:

- 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.

A request will also be considered a service development if it will commit the CCG to regular and predictable expenditure because one or more patients can be reasonably expected to request similar funding in subsequent years.

2.5 The IFR Panel is the forum at which IFRs are considered and the evidence submitted with the application analysed. The CCG member or employee who sits on the Panel is authorised to make the decision as to whether or not the IFR will be funded

2.6 The IFR Panel is not entitled to consider policy for the CCG. Accordingly, if an IFR has been classified as a service development, the IFR Panel has no jurisdiction to hear the IFR. In those circumstances the IFR will not be submitted for consideration at the IFR panel but will be subject to the usual business planning and priority setting processes of the CCG.

2.7 Where an IFR has been classified as a service development, funding will be refused, and the M&L CSU will, as appropriate, then:

2.7.1 Refer the case back to the requesting Clinician and take no further action;

2.7.2 Refer the request to the responsible CCG for an assessment with a view to determining its priority for funding as a service development proposal in the next financial year;

2.7.3 Refer the request to the responsible CCG for an immediate workup of proposals as a potential candidate for funding as a service development in the current financial year.

Screening for Incomplete Submissions

2.8 If a request is not categorised as a service development, it will then be assessed to determine whether the request is accompanied by sufficient clinical, financial and other information to enable the IFR to be properly considered at the IFR Panel. Where information is incomplete or insufficient, the IFR will be refused and returned to the requesting Clinician specifying why the request has been rejected. An IFR rejected as being incomplete or insufficient can be resubmitted at any point.

It is the responsibility of the Clinician making the IFR to ensure that all relevant information on which they rely in support of the application is made available to the IFR Panel to enable the IFR Panel to properly evaluate and assess the IFR in accordance with the relevant policies and the CCG to reach a rational, evidence-based decision.

2.9 If screening demonstrates:

- that the IFR does not constitute a service development; and
- that the documentation is sufficient to assess the case,

then the request will be forwarded to the IFR Panel for the CCG to reach a decision unless:

(a) in the Screening Panel's reasonable opinion there is no realistic prospect that the CCG member/employee at the IFR Panel will approve the request applying the criteria contained in this policy; and

(b) the Screening Panel reasonably considers that there are no other special circumstances for the request to be forwarded to the IFR Panel.

Assessment of an IFR which has passed screening

2.10 In considering the case for funding the IFR Panel and the CCG member/employee will consider the following:

2.10.1 whether or not the patient has exceptional clinical features or circumstances compared to other apparently similar patients;

2.10.2 whether or not the benefit the patient is expected to derive from the intervention is likely to be significantly greater than that which other apparently similar patients would be likely to experience;

2.10.3 whether there is sufficient evidence to support the assertion that this patient is likely to gain additional benefit from treatment, as compared to apparently similar patients;

2.10.4 whether, on balance, there are justifiable grounds for funding this patient differently from those who will continued to be denied access to treatment.

2.10.5 In addition when a case engages a key principle in the Clinical Commissioning Group's *Ethical framework for priority setting and resource allocation* or in another policy [5] the IFR Panel and CCG member/employee must consider the risks associated with not acting in accordance with the principle. So, while the IFR Panel and the CCG member/employee will have regard to the patient's individual circumstances, these will need to be weighed against the risks of breaching a key principle. In each case, the relevant policy documents should be referred to and considered.

2.10.6 In all cases the CCG member/employee will consider whether or not the CCG can afford to fund the treatment vis-à-vis other competing demands.

2.11 Consideration of whether a IFR should be funded as an exception to the Clinical Commissioning Group's policy on *Experimental and unproven treatments* will vary from that set out above. This policy states that treatments that are experimental (i.e. where there is no evidence base) or unproven (i.e. where there is an insufficient evidence base to have demonstrated a positive benefit) will not normally be commissioned outside the context of a clinical trial. In considering whether to recommend funding of an experimental treatment outside of a clinical trial the IFR Panel will consider:

2.11.1 whether the evidence for assessing this treatment for this condition cannot be considered through a robust clinical trial;

2.11.2 whether the patient has a rare condition, complication or clinical feature/set of features;

2.11.3 whether there is sufficient evidence to support that argument that the patient will benefit from treatment;

2.11.4 whether the expected benefit represents a significant health gain; and

2.11.5 whether or not the CCG can afford to fund the treatment vis-à-vis other competing demands.

The *Experimental and unproven treatments* policy should be referred to the Panel and considered.

Rarity of itself is not a basis for agreeing an exception. In each case there should be evidence that supports the argument that the experimental treatment might work in the particular case.

Assessment of requests to provide treatment costs either during or after a clinical trial for an individual patient

2.12 These IFRs should be assessed in accordance with the CCG's Commissioning Policy on *Experimental and Unproven Treatments*. The IFR Panel shall consider:

- The potential strategic importance of the treatment to the patient group and to the health service generally. A judgment shall be made on whether the trial will address the agreed priorities for the relevant programme area.

[5] Examples of this would be pick-up funding from an Industry sponsored clinical trial which engages the principle that a third party, particularly an agent external to the NHS, cannot commit funding (and therefore affect the priorities) of the CCG without the CCG's consent.

- The status of the clinical trial including whether or not the trial has been ratified by the National Institute for Health Research and/or other relevant clinical and research bodies.

- The anticipated quality of the trial and whether or not it is likely to generate the information that is needed to enable those funding healthcare to reach a view on the clinical effectiveness and cost-effectiveness of the treatment. Specialist advice may be sought by the IFR Panel on the methodology to be adopted within any trial.

- The ownership of the data. Trials which do not guarantee that the data will be made available in the public domain will not be considered for funding.

- The affordability and priority of the requested trial, compared to the other competing needs and unfunded service developments.

All applications must be accompanied by the trial protocol.

Rule of rescue

2.13 The CCG will not adopt the approach described as "the rule of rescue". The fact that a patient has exhausted all treatment options available for a particular condition is unlikely, of itself, to be sufficient to demonstrate that there are exceptional circumstances. Equally, the fact that the patient is not responding to existing treatments where a recognised proportion of patients with the same presenting medical condition at a similar stage are, to a greater or lesser extent, refractory to existing treatments is unlikely, of itself, to be sufficient to demonstrate that there are exceptional circumstances.

Information submitted to the IFR Panel

2.14 All applications must be accompanied by:

- a statement of the written support of; and
- all evidence that is relied upon, and which is to be provided by the clinical team treating the patient, *appropriate to the category of IFR the patient falls into.*

Requesting Clinicians are reminded that is the sole responsibility of them and their clinical team to ensure that all the relevant information on which they rely in support of the application is made available to the Panel with the application, to enable them to properly evaluate and assess the request in accordance with the relevant policies applying to the IFR being made.

2.15 In all applications the Clinician must state whether or not he or she considers 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.

2.16 Any Clinician submitting an IFR request 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 Panel.

Approval of individual funding requests

2.17 The CCG shall be entitled to fund a treatment for an individual patient if all of the following conditions are met:

2.17.1 The CCG is satisfied that there is no cohort of similar patients. If there is a cohort of similar patients, the IFR application will be refused because the application is then to be treated as a request for a service development and clause 2.4 shall apply.

2.17.2 One of the conditions set out in 2.3 above is met.

2.17.3 There is sufficient evidence to show that, for the particular patient, either:

- the proposed treatment is likely to be clinically and cost-effective; or
- the clinical trial has sufficient merit to warrant public funding.

2.18 The CCG 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:

2.18.1 the likely clinical outcomes for the individual patient of the proposed treatment; and

2.18.2 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.

2.19 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.

2.20 The CCG is entitled to make approval subject to or contingent upon the fulfilment of, any conditions as it considers appropriate.

2.21 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, and the CCG reach its decision, once that investigation and research has been completed.

2.22 The decision to fund to fund rests with the CCG member/employee. The CCG will agree funding if the treatment can be afforded vis-à-vis other competing demands.

Appeal of the decision

2.23 Where an IFR has been considered at an IFR Panel and the CCG has:

- refused to support the request for funding; or
- has approved funding for the treatment, subject to conditions,

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

2.24 At the IFR Appeal 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 individual circumstances of the case.
- The IFR Panel took into account material factors relating to the application.
- The CCG came to a decision that fell within the range of responses which a reasonable CCG could have reached on the evidence.

2.25 In the event that it is considered that the decision taken did not comply with the requirements set out in clause 2.24, the IFR Appeal Panel shall next consider whether there was any reasonable prospect that the CCG would have come to a different decision if every aspect of clause 2.24 had been complied with.

2.26 If the IFR Appeal Panel considers that there was no reasonable prospect that the CCG 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.

2.27 If the IFR Appeal Panel considers that there was a reasonable prospect that the CCG may have reached a different decision, had the requirements of clause 2.24 been complied with, the IFR Appeal Panel shall refer the matter back to the IFR Panel for reconsideration.

3. Providers

3.1 Provider Trusts and clinicians are expected to take the commissioning policies of the CCG into account in providing advice and guidance to patients before making the decision to treat a patient. The CCG expects the management of Provider Trusts to have oversight of this process. The CCG expects every individual funding request to be sanctioned by the Provider Trust (by whatever mechanism it wishes to put in place) management and reserves the right to refer recurrent inappropriate funding requests to the Chief Executive of the relevant Provider Trust.

4. Urgent treatment decisions

4.1 The CCG recognises that there will be occasions when an urgent decision needs to be made to consider a request for funding for 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 a Panel can be convened. The following provisions apply to such a situation.

4.1.1 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.

4.1.2 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.

4.2 Provider Trust 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 M&L CSU not to be taking all reasonable steps to minimise urgent requests to the IFR process, the CCG or the M&L CSU acting on the CCG's behalf may refer the matter to the Chief Executive of the Provider.

4.3 Urgent requests can be made by telephone by the patient's clinician.

4.4 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 Authorised Officer procedures.

4.5 The Authorised Officer shall, as far as possible within the constraints of the urgent situation, follow the policy set out above in making the decision. The 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 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.

4.6 The 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.

4.7 The 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.

5. Operational Arrangements

The following operational arrangements are appended to this document:

Appendix 1 Terms of Reference for the IFR Team

Appendix 2 Terms of Reference for the IFR Screening Panel

Appendix 3 Terms of Reference for the IFR Panel

Appendix 4 Terms of Reference for an Authorised Officer

Appendix 5 Terms of Reference for the IFR Appeal Panel

Appendix 6 The Process for Managing IFRs

Appendix 7 Individual Funding Request (IFR) Application Form

Appendix 8 Funding Requests Screening Form

Appendix 9 IFR Panel Record

Appendix 10 Individual Funding Request (IFR) Appeal Form

6. Documents which have informed this policy

- The Clinical Commissioning Group's Commissioning Policy: Ethical Framework to underpin priority setting and resource allocation
- The Clinical Commissioning Group's Commissioning Policy: Experimental and Unproven treatments
- Department of Health, The National Health Service Act 2006, The National Health Service (Wales) Act 2006.
- Department of Health, The NHS Constitution for England, 2012, http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_132961
- The National Prescribing Centre, Supporting rational local decision-making about medicines (and treatments), February 2009, http://www.npc.nhs.uk/local_decision_making/resources/handbook_complete.pdf
- NHS Confederation Priority Setting Series, 2008

  Priority setting: an overview
  Priority setting: legal consideration
  Priority setting: strategic planning
  Priority setting: managing new treatments
  Priority setting: managing individual funding requests

Guidance note

Many policies which address general issues, such as the one which addresses experimental and unproven treatment, include guidance notes. A policy and its guidance note should be referred to when they are engaged by the particular IFR.

What is meant by exceptional clinical circumstances?

A CCG must have good reasons for granting funding on exceptional groups and therefore not adhering to approved commissioning policies or care pathways. There can be no exhaustive definition of the conditions which are likely to come within the definition of an exceptional case. The word 'exception' means 'a person, thing or case to which the general rule is not applicable'. However, it is easy for there to be a misunderstanding by the patient or the clinical team as to what is meant by this expression.

Requests under the IFR process often argue that an individual should be treated differently from other apparently similar patients and that their treatment should be funded when other patients will not be funded. The reasons put forward for this may be grounded in the moral or compassionate case for funding.

The IFR Panel should bear in mind that, whilst everyone's individual circumstances are, by definition, unique, and on compassionate grounds reasons can always be found for funding, very few patients have clinical circumstances which are exceptional, so as to justify funding for treatment for that patient which is not available to other patients. The following points constitute general guidance to assist the IFR Panel. However, the overriding question which the Panel needs to task itself remains: has it been demonstrated by the clinician that this patient's clinical circumstances are exceptional?

- If a patient has a condition for which there is an established care pathway, the IFR Panel may find it helpful to ask itself whether the clinical circumstances of the patient are such that they are exceptional as compared with the relevant subset of patients with that same medical condition at the same stage of progression.

- The fact that a patient failed to respond to, or is unable to be provided with, one or more treatments usually provided to a patient with his or her medical condition (either because of a co-morbidity or because the patient cannot tolerate the side effects of the usual treatment) may be a basis upon which an IFR Panel could find that a patient is exceptional.

  However, the IFR Panel would normally need to be satisfied that the patient's inability to respond to, or be provided with, the usual treatment was a genuinely exceptional circumstance. For example:

  - If the usual treatment is only effective for a proportion of patients (even if a high proportion), this leaves a proportion of patients for whom the usual treatment is not available or is not clinically effective. If there is likely to be a significant number of patients for whom the usual treatment is not clinically effective or not otherwise appropriate (for any reason), the fact that this particular patient falls into that group is unlikely to be a proper ground on which to base a claim that they are exceptional.

  - If the usual treatment cannot be given because of a pre-existing co-morbidity which could not itself be described as exceptional in this patient group, the fact that the co-morbidity is present in this patient and its impact on treatment options for this patient is unlikely to make the patient exceptional.

The most appropriate response in each of the above two situations, is to consider whether there is sufficient justification (including consideration of factors such as clinical effectiveness, value for money, priority and affordability) to make a change to the policy adopted by the CCG for funding that patient pathway so that a change can be made to that policy to benefit a subgroup of patients (of which the requesting patient is potentially just one such person). This change needs to be considered as a service development.

Non-clinical factors

It is common for an application for individual funding to be made on the grounds that a patient's personal circumstances are 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.

- Across the population of patients who make such applications, the IFR Panel is unable to make an objective assessment of material put before it relating to non-clinical factors. This makes it very difficult for the IFR Panel to be confident of dealing in a fair and even handed manner in comparable cases.

- 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.

- 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. 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 breaches a principle in the CCG's ethical framework. Such a decision would also set a precedent for the CCG to always favour those in work over those not currently in work. 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) is also discriminatory and would contribute to social inequality.

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.

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.

Accordingly, in reaching a decision as to whether a patient's circumstances are 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.

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.

Proving the case that the patient's circumstances are exceptional

The onus is on the Clinician making the request to set out the grounds clearly for the IFR Panel on which it is said that this patient is 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.

These grounds must be set out on the form provided by the NHS. The Clinician should clearly set out any factors which he or she invites the IFR Panel to consider as constituting exceptional clinical circumstances. 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 usual it is for the patient with this condition not to be able to be provided with the usual treatment.

If a clear case as to why the patient's clinical circumstances are said to be exceptional is not made out, the CCG is obliged to refuse the application. The CCG recognises that the requesting 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. The referring Clinician is advised to set out the evidence in detail because the Panel will contain a range of individuals with a variety of skills and experiences but may well not contain clinicians of that speciality. The CCG therefore requires the requesting clinician, as part of their duty of care to the patient, to explain why the patient's clinical circumstances are said as to be exceptional.

The policy of the CCG is that there is no requirement for the IFR Panel to carry out its own investigations about the patient's circumstances in order to try to find a ground upon which the patient may be considered to be 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 exceptionality is not made out by the paperwork placed before the IFR Panel, the IFR Panel would be entitled to turn down the application.

Multiple claimed grounds of exceptionality

There may be cases where Clinicians and/or patients seek to rely on multiple grounds to show that their case is exceptional. In such cases the IFR Panel should look at each ground individually to determine (a) whether the factor is capable, potentially, of making the case exceptional and (b) whether it does in fact make the patient's case exceptional. The IFR Panel may conclude, for example, that a factor is incapable of supporting a case of exceptionality (and should therefore be ignored) on one ground, but it might be relevant on another ground. That is a judgment within the discretion of the IFR Panel.

If the IFR Panel is of the view that none of the individual factors on their own make the patient's clinical circumstance exceptional, the IFR Panel should then look at the combined effect of those factors which are, in the IFR Panel's judgment, capable of supporting a possible finding of exceptionality. The IFR Panel should consider whether, in the round, these combined factors demonstrate that the patient's clinical circumstances are exceptional, reminding itself, of the difference between individual distinct circumstances and exceptional clinical circumstances.

Appendix 1: Terms of Reference for the Individual Funding Request Team

1. Purpose

The role of the Individual Funding Request Team is to support provide support to the IFR process to the Clinical Commissioning Groups. The IFR Team consist of:

- The Principal for Medicines and IFR Services
- The Head of IFR and Medicines Delivery
- The Senior IFR Development Manager
- IFR Case Managers
- IFR Support Officers
- IFR Administrators

The team will:

1. Provide oversight of the management and co-ordination of the IFR process.
2. Ensure that the IFRs are managed in line with the policies of the CCG.
3. Provide the administrative function for the Screening Panel, IFR Panel and IFR Appeals Panels.
4. Administer the paperwork, ensuring the efficient handling and documentation of submissions, from first receipt through to archiving.
5. Provide a single point of contact for patients and clinicians involved in the IFR and IFR Appeal processes.
6. Maintain an IFR database.
7. Maintain a register of Authorised Officers and liaise with them in urgent cases.
8. Maintain the website (or advise on publications on CCG websites)
9. Liaise with the CCG Boards, Committees and officers responsible for priority-setting and policy development as required.
10. Raise issues of policy with CCGs.
11. Bring new service developments to the attention of the CCGs.
12. Contribute to the recruitment and training of IFR Panel and IFR Appeal Panel members.
13. Attend meetings in an advisory capacity.
14. Liaise with the legal team.
15. Ensure the policies are regularly updated.
16. Provide a source of expertise including advising clinicians wishing to submit a funding request.
17. Monitor the quality of the IFR process and decision making including overseeing regular audits of the process.
18. Arrange training and ensure that members of the IFR Panels IFR Appeal Panels and Authorised Officers undergo training on a regular basis.

2. Corporate Governance and Risk Management

The IFR Team will adhere to all the corporate governance and risk management arrangements set out in the agreement between the Midlands and Lancashire Commissioning Support Unit and the 7 CCGs.

The IFR Team will provide a monthly report to the CCGs informing them of the number of IFRs that have been screened and the number considered at the IFR Panel, as well as the outcome and the financial commitment.

The IFR Team will provide an annual report to the CCG Boards.

The IFR Team will report any governance concerns or risks to the CCG when this comes to their attention.

All members of the IFR Team must undergo mandatory induction training organised by the M&L CSU. This will cover both the legal and ethical framework for IFR decision making, the CCG's commissioning processes and structures, the technical aspects of interpretation of clinical evidence and research, and guidance in respect of the policies relevant to their decision making. This training will be regularly refreshed to ensure that all IFR and IFR Appeal Panel members maintain the appropriate skills and expertise to function effectively.

Appendix 2: Terms of Reference for the IFR Screening Panel

1. Purpose

The role of the Individual Funding Request Screening Panel is to ensure that only those funding requests which can be considered under this policy go forward for consideration at the IFR Panel. In carrying out this function, IFR Screening Panel will:

- Ensure there is no existing NHS commissioned pathway for this patient which has not first been exhausted. It is expected that if a patient is clinically suitable for an existing pathway or treatment then this should have been exhausted before a request is submitted for the funding of an alternative service or pathway not normally commissioned by the responsible CCG.

- Apply the policies of the CCGs and identify individual funding requests which should be dealt with via another route, or clearly are not individual funding requests.

- Determine whether or not there is sufficient information to properly assess the case.

Should there be any element of doubt about the appropriateness of the request, the IFR Screening Panel should exercise caution and put the case before the IFR Panel.

2. Membership and Quoracy

The membership of the IFR Screening Panel will be:

- Head of the IFR Team (Chair) or the IFR Manager (Deputy Chair)
- A Public Health Consultant
- A Senior Pharmacist

Each member should declare any potential conflict of interest as soon as this comes to their attention.

A minimum of two members are required for the meeting to be quorate.

3. Corporate Governance and Risk Management

For each screened case the factors taken into account, the deliberations, the decisions and the reasons for the decision will be documented. (The IFR Screening Form can be found in Appendix 8).

Funding requests which have been returned to the Clinician at the screening stage will be referred to the patient's responsible CCG member/employee on the IFR Panel to provide assurance about the decisions taken. If the CCG member/employee considers the case should have been put before the IFR Panel then s/he can ask the M&L CSU to refer the IFR request to the IFR Panel. The IFR Team will keep a record of the CCG member's/employee's final decision on each referral.

An audit of the decisions taken by the IFR Screening Panel will be carried out every two years.

All members of the IFR Screening Panel must undergo mandatory training organised by the M&L CSU. This will cover both the legal and ethical framework for IFR decision making, the CCG's commissioning processes and structures, the technical aspects of interpretation of clinical evidence and research, and guidance in respect of the policies relevant to their decision making. This training will be regularly

refreshed to ensure that all IFR and IFR Appeal Panel members maintain the appropriate skills and expertise to function effectively.

4. Frequency of Meetings

The IFR Screening Panel will meet weekly.

Appendix 3: Terms of Reference for the IFR Panel

1. Purpose

The IFR Panel is a forum for discussion of the case and analysis of the evidence to assist the Clinical Commissioning Group member/employee to reach a decision in any particular case.

The role of the Individual Funding Request Panel (IFR Panel) is to:

- Review screened cases.
- Discuss and analyse each case put before the IFR Panel in which a decision will be reached by the responsible commissioner CCG.

The IFR Panel will consider all the written evidence which is provided to it, including the individual funding request form itself and any other documentary evidence which is provided to support it. In doing so, it will take into account the policies and procedures of the CCG.

The IFR Panel may at its discretion request the attendance of any clinician to provide clarification on any issue, or request independent expert clinical advice for consideration by the IFR Panel at a further date.

Only the member/employee from the patient's responsible Clinical Commissioning Group can take the final decision on funding.

2. Membership and Quoracy

The membership of the IFR Panel will be:

- One member or employee from each of the CCGs.
- A Consultant in Public Health
- Head of Individual Funding Requests
- Individual Funding Request Manager (Deputy Chair)

Not all CCG representatives are required at each meeting but a member/employee from the responsible commissioner CCG must be present when a case is put before the Panel.

There should be at least one medicine management representative and one general practitioner at each meeting of the Panel.

In instances where there is no CCG representative with a Medicines Management background, the CSU will provide a Senior Pharmacist.

Each member should declare any potential conflict of interest as soon as they become aware of it.

In order to be quorate there should be a minimum of a clinician, a medicines management team member and a public health consultant present and there must a member/employee of the responsible CCG for each IFR to be considered.

A general practitioner should not be involved in Panel discussions about their own patient or make a decision concerning their own patient. In these instances, another CCG member/employee should attend the Panel.

3. Decision making

The final decision for any given IFR will be taken by the responsible commissioner CCG member/employee.

4. Corporate Governance and Risk Management

For each case the factors taken into account, the deliberations, the decisions and the reasons for the decision will be documented. (The IFR Panel Record can be found in Appendix 9).

An audit of the decisions taken by the IFR Screening Panel will be carried out will be carried out every two years.

The IFR Team will provide monthly statistics and financial information to the CCG setting out the number of IFRs screened, the number presented to the IFR panel, the outcome and the financial commitment made.

All members of the IFR Panel must undergo mandatory training organised by the M&L CSU. This will cover both the legal and ethical framework for IFR decision making, the CCG's commissioning processes and structures, the technical aspects of interpretation of clinical evidence and research, and guidance in respect of the policies relevant to their decision making. This training will be regularly refreshed to ensure that all IFR and IFR Appeal Panel members maintain the appropriate skills and expertise to function effectively.

5. Frequency of Meetings

The IFR Panel will meet monthly.

Extraordinary meetings of the IFR Panel may be convened if needed.

Virtual meetings by telephone or web conferencing may be held as and when required.

The decisions made outside the regular meetings must be relayed to the next formal IFR Panel meeting for ratification by the CCG member/employee and incorporation into the minutes of the IFR Panel.

Appendix 4: Terms of Reference for an IFR Authorised Officer

1. Purpose

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

An Authorised Officer [6] must:

- have clinical training (be a doctor, pharmacist, nurse); and
- have substantial experience in dealing with individual funding requests

The Authorised Officer must follow the policies and procedures set out in this document to assess the case and must follow the same decision making process that would be expected of the IFR Panel.

In instances where the Authorised Officer, is a member or employee of the responsible CCG, then the individual has delegated authority to make the decision.

In instances where the Authorised Officer is not a member or employee of the responsible CCG, then the Officer much seek final authorisation from the responsible CCG.

2. Corporate Governance and Risk Management

The IFR Screening form will be used to document the assessment and the decision.

For each case assessed the factors taken into account, all communication, the decisions and the reasons for the decision will be documented. Copies of any email communication should be appended to the IFR Screening Form.

The IFR Screening Form should be returned to the IFR Team once the case is closed.

An audit of the urgent decisions will be carried out each year.

An Authorised Officer must undergo mandatory training organised by the M&L CSU. This will cover both the legal and ethical framework for IFR decision making, the CCG's commissioning processes and structures, the technical aspects of interpretation of clinical evidence and research, and guidance in respect of the policies relevant to their decision making. This training will be regularly refreshed to ensure that the Authorised Officer maintains the appropriate skills and expertise to function effectively.

[6] Authorised Officers are to be drawn from the M&L CSU pharmacists or from the Public Health teams contracted to support CCGs.

Appendix 5: Terms of Reference of the IFR Appeal Panel

1. Purpose

The role of the Individual Funding Request Appeal Panel (IFR Appeal Panel) is to consider appeals against decisions taken by the Clinical Commissioning Group to ensure that decisions have been taken in accordance with the policies and processes of the CCG and the specific processes and jurisdiction that are contained within this policy.

The IFR Appeal Panel will normally reach its decision on the basis of all the written evidence which is provided to it, although it may request the attendance of legal, clinical or public health expertise to clarify any points for consideration by the IFR Appeal Panel.

The IFR Appeal Panel will consider only the following written documentation:

(a) the original IFR submitted to the M&L CSU;

(b) the records documenting the process by which the request has been considered;

(c) the IFR Panel records, including the IFR Panel Record and any additional supporting information considered by the IFR Panel;

(d) the IFR Appeal Application Form (which can be found in Appendix 10) which sets out the grounds of the appeal by the requesting Clinician and/or the patient/guardian or carer in their request for review.

Neither the patient nor their representative will be invited to attend the IFR Appeal Panel.

The IFR Appeal Panel shall not consider any new information nor receive any oral representations. If there is substantive new evidence presented to the IFR Appeal Panel, the IFR Appeal Panel will remit the case to an IFR Panel and ask the CCG to review its original decision in light of the new evidence.

The IFR Appeal Panel will arrive at one of two decisions. The IFR Appeal Panel will either:

(a) uphold the decision reached by the IFR Panel and approved by the Clinical Commissioning Group; or

(b) refer the case back to the IFR Panel for reconsideration.

2. Membership and Quoracy

The membership of the IFR Appeal Panel will be constituted of 3 senior members or employees of the Clinical Commissioning Group such as:

- A Non-Executive Director / Chairman from the responsible CCG
- A Board Member GP from the responsible CCG
- The Director of Public Health from the Local Authority

The constitution of the IFR Appeals Panel will be at the discretion of the CCG.

To ensure that the review is independent of the original decision, the Appeal Panel members will be different from the IFR Panel members who originally considered the case and the CCG member/employee who made the original decision.

All members must be in attendance for the meeting to be considered quorate. In the event of one of the members not being able to attend, a nominated deputy should replace the member on that occasion.

The IFR Appeal Panel can request the attendance of other individuals in an advisory capacity.

A member of the IFR Team will provide administrative support, including taking minutes.

3. Corporate Governance and Risk Management

For each case considered the factors taken into account, the weighting given to those factors, the decisions and the reasons for the decision will be documented.

An audit of the decisions taken by the IFR Appeals Panel will be carried out will be carried out every two years.

All members of the IFR Appeals Panel must undergo mandatory training organised by the M&L CSU. This will cover the legal and ethical framework for IFR decision making, the CCG's commissioning processes and structures.

4. Frequency of Meetings

The IFR Appeal Panel will be convened within 30 days of an appeal being received.

Appendix 6: The Process for Managing IFRs

1. Submitting a request

1.1 Only a health care professional (usually expected to be the Clinician or General Practitioner directly involved in the care of a patient) may submit a funding request for a treatment that is not funded routinely.

1.2 The person making the application must be confident that their patient will benefit from the treatment sought.

1.3 It is the Clinician's responsibility to ensure the application form (Appendix 7) is completed, accurate and as comprehensive as possible in order to avoid possible delays in considering the request.

1.4 The information on the application form should have been discussed with the patient prior to submission, as part of the process of obtaining informed consent from the patient to make the application. In the event that the patient does not have the mental capacity to give informed consent, the application form should reflect compliance with the Mental Capacity Act 2005 and the accompanying Code of Practice.

1.5 In any event, the M&L CSU will assume that issues of consent have been dealt with by the Clinician before the application is sent.

1.6 All individual funding requests will need to be sanctioned by the Provider Trust.

1.7 **Individual Funding Request application forms should be fully completed, signed and submitted via one of the following:**

By email (for NHS Trusts) an nhs.net account to:
Referrals should be sent to the corresponding CCG email address that the patients GP belongs to

ifr.bcccg@nhs.net	for Birmingham Cross City CCG
ifr.dudley@nhs.net	for Dudley CCG
ifr.swb@nhs.net	for Sandwell and West Birmingham CCG
ifr.solihull@nhs.net	for Solihull CCG
ifr.bsc@nhs.net	for Birmingham South Central CCG
ifr.wolv@nhs.net	for Wolverhampton CCG
ifr.walsall@nhs.net	for Walsall CCG

A further email inbox exists for prior approvals
ifr.priorapproval@nhs.net

A generic email account also exists for general queries
cmcsu.ifr@nhs.net

Faxed to Safe Haven Fax: Funding Requests: (0121) 285 5990

Posted (marked confidential) to:
IFR Team
Midlands and Lancashire Commissioning Support Unit
Quality Directorate
Kingston House
438-450 High Street
West Bromwich
West Midlands
B70 9LD

1.8 Incomplete IFR forms will not be accepted and will be returned to the Clinician.

2. On receipt of a funding request

2.1 Requests will be date stamped and logged onto the M&L CSU IFR database.

2.2 The IFR Team will check the submitted IFR form to ensure it has been fully completed. The IFR Manager will return any partially completed application form to the Clinician.

2.3 If there is no response from the requesting Clinician, the IFR team will chase him or her after two weeks and notify them that the application for treatment will be closed after one month if no response is received. The patient's GP and the Clinician will be informed if the application is closed.

2.4 An acknowledgement will be sent to the Clinician within 5 working days of receiving an application that can proceed to IFR Screening Panel.

3. Identifying urgent cases

3.1 The IFR Team may determine that a case is clinically urgent at any point in time in the process after consultation with the patient's clinicians. The IFR Team will have the discretion to determine whether or not to convene an extraordinary IFR Panel based on the individual clinical circumstances and the risks of an adverse clinical outcome if a funding decision on treatment is delayed.

3.2 Where the request is assessed as of sufficient urgency that the decision should be made before the next IFR Panel meeting an 'extraordinary' IFR meeting may be convened.

3.3 Where an urgent request is required to be considered, the IFR Panel shall continue to follow the procedure set out in this policy.

3.4 Where a request is assessed to be very urgent (1-2 days) the request should be sent to an Authorised Officer.

3.5 Decisions that are made taken outside the IFR Panel meeting will be referred to the responsible CCG for ratification.

4. Tier 1 – Individual Funding Request (IFR) Screening Panel

4.1 The purpose of screening the IFR is to ascertain whether there is an arguable case, based on the evidence presented in the application, for the IFR Panel to consider the question of funding for the requested treatment under this policy.

Where there is uncertainty as to whether there is an arguable case, the case should be referred by the Screening Panel to the IFR Panel.

4.2 The IFR will be screened by the IFR Screening Panel.

4.3 A request will normally be screened within 7 working days of the date of receipt of the IFR.

4.4 The IFR Screening Panel may consider three options as set out in the main body of this policy:

4.4.1 to approve the request if covered by existing contracts or policies; or
4.4.2 to refuse the request without reference to the IFR Panel; or
4.4.3 to refer the request to the IFR Panel.

4.5 All deliberations and the decision made by an IFR Screening Panel will be recorded on the screening form (Appendix 8).

4.6 If a request is refused, a letter will be sent to the Clinician explaining the reasons for the decision and outlining the options that may be available.

4.7 If a request is refused at the IFR screening stage this policy does not provide a right of appeal to the IFR Panel.

4.8 The patient has a right to make a complaint under the responsible CCG's Complaints Procedure.

4.9 If the requesting clinician believes they have significant new clinical evidence that they did not provide in their first submission which they feel may have made a difference to the IFR screening decision made, then the clinician may submit a new IFR application with the new evidence.

4.10 The IFR Screening form for each patient will be sent to the IFR Panel for review. The responsible CCG's representative will then ratify the decision. In the event that the responsible CCG cannot send a representative then the form will be sent directly to the responsible CCG for ratification.

4.11 If there is concern over the decision the IFR Screening Panel they can request that the IFR is sent to the IFR Panel for consideration.

5 Tier 2 – The Individual Funding Request (IFR) Panel

5.1 Each referral to the IFR Panel will consist of the following anonymised documentation:

- The completed application form.
- Supporting documentation for the case.

- Copies of communication received relevant to the case.
- Evidence to support the case (e.g. peer reviewed research papers),summary of the evidence and background to the case.
- Copy of the IFR Screening Form.

5.2 Patients may, if they wish, submit a statement to the IFR Panel outlining their case for exceptionality. The treating Clinician is expected to advise the patient that they can submit written comments to the IFR Panel for consideration provided that they restrict their submissions to dealing with clinical factors. Any reference to social factors will not be considered at the IFR Panel. The patient's written comments should be forwarded with the completed application. No patient will be disadvantaged by not making a personal submission.

5.3 To ensure impartiality, all documentation will be anonymised. A document will be considered anonymised when the following fields are made illegible:

- All parts of the patient's name
- All information relating to the patient's address.

5.4 All papers for the IFR Panel should be submitted to the IFR Team 10 working days before the date of the IFR Panel to enable further analysis by the M&L CSU and for papers to be distributed to the IFR Panel in advance of the IFR Panel Meeting.

5.5 Patients and their representatives will not be invited to attend IFR Panels.

5.6 It is the responsibility of the Chair to ensure that each IFR Panel completes a signed attendance sheet and that a completed set of documents for each case is provided to all the Panel members prior to the scheduled meeting.

5.7 The decision may be deferred, pending the need to obtain more information and clarification i.e. specialist clinical advice. Decisions should usually be made within a total of 2 months.

5.8 All deliberations at Panel and the decision made by the CCG member/employee will be recorded on the IFR Panel Report (Appendix 9).

5.9 In addition to an IFR Panel Record that is completed for each IFR considered by the IFR Panel, minutes of the meeting will be taken.

5.10 All minutes will be written in such a way as to ensure the confidentiality of any information that could identify any individual whose case is considered at Panel.

5.11 A written decision and the reasons behind the decision will be sent to the requesting Clinician, the patient and the patient's General Practitioner within 5 working days.

6. Tier 3 - The Individual Funding Requests (IFR) Appeals Panel

6.1 Each referral to the IFR Appeal Panel will consist of:

- The same case summary, application form and supporting evidence that was considered by the IFR Panel.

- Background summary outlining how the process was followed and evidence considered.
- Minutes of the meeting, IFR Panel Record and all correspondence.
- A completed IFR Appeal Form detailing the basis on which the appeal is being made.

6.2 The grounds of the appeal should be clearly stated and outline how it is alleged that due process was not followed when the application was before the Individual Funding Requests panel.

6.3 Only written evidence may be submitted to the IFR Appeal Panel. The patient, their carer or guardian or clinician may submit written evidence to substantiate the appeal in terms of asserting that due process was not followed.

6.4 If new evidence regarding exceptionality or new clinical evidence is submitted then the case will need to be referred back for reconsideration at Panel.

6.5 To ensure impartiality, all documentation put before the IFR Appeal Panel will be anonymised. Documentation will be considered anonymised when the following fields are made illegible:

- All parts of the patient's name
- All information relating to the patient's address

6.6 The Chair of the IFR Appeal Panel is responsible for ensuring that this process happens as expeditiously as possible (normally within 30 working days of the appeal being received).

6.7 It is the responsibility of the Chair of the IFR Appeal Panel to ensure that each Panel completes a signed attendance sheet.

6.8 The IFR Appeal Panel will detail how the original decision did or did not accord with the CCG's policies and processes. All deliberations and the decision of the IFR Appeal Panel will be recorded.

6.9 All minutes will be written in such a way as to ensure the confidentiality of any information that could identify any individual whose case is considered by the IFR Appeal Panel.

6.10 The Chair of the IFR Appeal Panel will notify the patient (or their representative) and the clinician of the outcome of the appeal in writing, setting out the reasons for the decision made within 10 working days of the IFR Appeal Panel convening and reaching a decision.

6.11 Where the IFR Appeal Panel does not uphold the original decision, it is for the IFR Appeal Panel to:

- Make a statement outlining why the original decision was not upheld.
- Provide guidance on what factors and principles the IFR Panel and the CCG member/employee should take into consideration when reconsidering the case.
- Formally remit the application to the IFR Panel.

6.10 The Chair of the IFR Appeal Panel will be responsible for reporting the decision to the Board of the Clinical Commissioning Group.

6.12 If the IFR Appeal Panel upholds the decision, the patient may wish to pursue the matter through the NHS complaints procedure. Further information can be obtained from the CCG Complaints Manager.

7. Patient feedback

7.1 The M&L CSU will also put in place a mechanism to receive feedback from patients and requesting clinicians as part of the evaluation.

8. Monitoring

8.1 The IFR process will be monitored and reviewed, both to ensure that decision-making is fair and consistent, and to make sure that Panels are considering appropriate cases and in particular that both the screening of requests and the IFR Panel are working effectively.

8.2 Monthly finance and activity reports will be sent to the CCG.

8.3 A review of the IFR process and decision making will be undertaken by the CCG annually which will include audit carried out in any particular year.

8.4 The IFR Panel will submit an annual report to the Boards of the constituent CCGs.

Appendix 7: Individual Funding Request (IFR) Application Form

Midlands and Lancashire
Commissioning Support Unit

NHS Birmingham Cross City Clinical Commissioning Group
NHS Birmingham South Central Clinical Commissioning Group
NHS Solihull Clinical Commissioning Group
NHS Dudley Clinical Commissioning Group
NHS Sandwell and West Birmingham Clinical Commissioning Group
NHS Walsall Clinical Commissioning Group
NHS Wolverhampton Clinical Commissioning Group

APPLICATION FORM FOR INDIVIDUAL FUNDING REQUESTS

All sections of the form must be completed otherwise the case will not be considered

Important information

Before you begin to complete this form and make an application you MUST first consider the following question: ***Are there similar patients with similar clinical circumstances who could also benefit from the treatment you are requesting across the population of the CCGs?***

If the answer is YES then making an individual funding request is an inappropriate way to deal with funding for this patient. This is because the case represents a service development for a predictable population. You should discuss with your contract team how you submit a business case for consideration through the usual business planning process.

Mandatory field if proceeding with the IFR
Are there likely to be similar patients who will receive the same expected benefits from this intervention or clinical trial? **If YES, please indicate likely number of patients there are likely to be in a million population.**

If the answer is NO then please proceed by completing the application, providing the information and relevant evidence for the appropriate category of IFR into which this patient's case falls.

(M&L CSU use only)			
Case code:		**Date Received:**	
Date assessed by IFR Team:		**Decision:**	
IFR Screening Panel Date:		**Decision:**	
IFR Panel Date:		**Decision:**	

Mandatory field			
1. Patient Details			
Forename:		**NHS Number:**	
Surname:		**Hospital Number:**	
Date Of Birth:		**Sex: M/F:**	
Patient's Address & Postcode:		**Ethnic Origin:**	
(Please note that all necessary personal information will be removed from this form prior to being reviewed. This information is collected for monitoring purposes only)			

Mandatory field	
2. Patient consent	
Does the patient provide consent for all information regarding their case to be shared with the Individual Funding Request Panels?	**YES / NO**
If the patient does not have the mental capacity to give informed consent, then please confirm that you have complied with the Mental Capacity Act 2005 and the accompanying Code of Practice.	**YES / NO**

Mandatory field	
3. Registered GP Details	
Registered Practice:	
Registered GP Practice Address:	
Registered GP:	
Telephone no:	
Email Address:	

Mandatory field	
4. Requesting Clinician Details	
Name of Provider:	
Name & Designation of Requesting Clinician:	
Address:	
Telephone no:	
Email Address:	
Fax Number:	

Mandatory field	
5. Clinical Urgency	
Is the patient's application urgent?	
Processing requests takes on average one month. If the case is more urgent than this, please state why and how urgent the case is	

Mandatory field for all but requests to enter a patient in a clinical trial		
6. Treatment Requested		
Details of intervention / treatment for which funding is requested:	**Name of treatment/intervention:**	
	If a drug, dose and frequency:	
	Planned duration of intervention (including number of treatments):	
Cost of Treatment:	**Cost of the treatment:**	
	Detail of associated costs: (including VAT & Associated Inpatient / Outpatient Activity):	
	Anticipated total cost:	

Mandatory field for all but requests to enter a patient in a clinical trial	
7. Alternative Treatments	
What standard treatment does this request replace?	
Why is the standard treatment not appropriate?	
What would be the cost of the standard treatment?	
If this treatment request is not approved, what treatment will be given to the patient?	

Mandatory field for all but requests to enter a patient in a clinical trial
8. Drug status
If a drug treatment is requested, is the drug licensed for the requested indication in the United Kingdom? ***If not licensed is the request:*** ***a) Supported by the trust's drug and therapeutics committee or equivalent?*** ***b) Licensed in any other country?***

Mandatory field for all but requests to enter a patient in a clinical trial			
9. Treatment History			
Details of Diagnosis & Prognosis (for which the treatment is requested):			
Relevant medical history: (incl. dosage & frequency of all medications and co-morbidities)			
Previous treatments / interventions this patient has received for this condition:	**Date/s**	**Intervention (e.g. drug. surgery)**	**Reason for stopping / Response achieved**

Mandatory field for all but requests to enter a patient in a clinical trial
10. Request to treat this patient as an exception
Where known, please state which commissioning policy or policies this IFR relates to:
Please set out the case for this patient being considered an exception with reference to: • **The way in which the patient is clinical different to others.** • **The expected benefit expected in this patient.** • **On what evidence you base the assertion that this patient will benefit more than other patients <u>OR</u> Where a request is being made to use a treatment experimentally in an individual case please set out the evidence on which benefit has been inferred.** • **Any other material factors which have bearing on the case.** The case can be submitted either on this form or in a letter to be attached to this form. Please attach any evidence in support of the benefit of treatment *in this patient you consider is exceptional*

Mandatory for requests to enter a patient into a clinical trial	
11. Requests for treatment costs or pick-up costs to enter a single patient into a clinical trial	
The trial protocol (not the summary) must be submitted with the IFR request.	
Confirm that the patient meets the clinical entry criteria?	
Full name of the clinical trial:	
The trial registration number (state which register):	
Funding being sought: (please provide a breakdown of all costs)	

Mandatory – ALL	
12. Declaration	
To the best of my knowledge I have given the most accurate and up to date information regarding this patient's clinical condition.	
Name	
Position/Title	
Signature	
Provider Trust support for the application	
Name	
Position/Title	
Signature	
Date Completed	

On Completion

Email through the appropriate Clinical Commissioning Group via the nhs.net account to dedicated email:

Birmingham Cross City CCG	**ifr.bcccg@nhs.net**	**Harinder Kaur**	**0121 612 1653/612 1659**
Birmingham South Central CCG	**ifr.bsc@nhs.net**	**Terri-Ann Millington**	**0121 612 1645/612 1660**
Solihull CCG	**ifr.solihull@nhs.net**	**Terri-Ann Millington**	**0121 612 1645/612 1660**
Wolverhampton CCG	**ifr.wolv@nhs.net**	**Vicky Adams**	**0121 612 1661/612 2841**
Walsall CCG	**ifr.walsall@nhs.net**	**Denise Bell**	**0121 612 1636/612 2841**
Sandwell & West Birmingham CCG	**ifr.swb@nhs.net**	**Terri-Ann Millington**	**0121 612 1645/612 1660**
Dudley CCG	**ifr.dudley@nhs.net**	**Vicky Adams**	**0121 612 1661/612 2841**

For generic queries email: cmcsu.ifr@nhs.net or Fax to safe haven: 0121 285 5990
or Post (Marked Confidential) to:

IFR Team
Midlands and Lancashire CSU
Kingston House
438-450 High Street
West Bromwich
West Midlands B70 9LD

Appendix 8: Individual Funding Request (IFR) Screening Form

This document can also be used by the Authorised Officer to document the assessment and decision of an urgent case.

Case code:	
Responsible CCG:	
Date received :	
Screening Panel Date:	
Authorised officer (in urgent cases):	
Summary of the request:	Request for treatment X for a patient with Y at a cost of £
Which of the CCG's clinical commissioning policy/policies is/are relevant to the case?	• Experimental and unproven treatments • In-Year Service Developments and the Clinical Commissioning Group's approach to treatments not yet assessed and prioritised • Patients changing responsible commissioner • On-going access to treatment following the completion of a trial explicitly funded by the Clinical Commissioning Group • On-going access to treatment following the completion of industry sponsored clinical trials or funding • On-going access to treatment following the completion of non-commercially funded clinical trials covered by Department of Health Guidance HSG (97) 32 • On-going access to treatment following a 'trial of treatment' which has not been sanctioned by the Clinical Commissioning Group for a treatment which is not routinely funded or has not been formally assessed and prioritised • Defining the boundaries between NHS and Private Healthcare • Patients seeking treatment abroad • Treatment specific policy • Other

Date and Time	Record of assessment and communications
	Record details of any assessment and communications are made before the screening panel meet. Document attempts to clarify any details should be recorded. For example, if the clinician is contacted for further information before the screening panel meets, this should be recorded here along with date and response. All communications should be kept in the case file. In urgent cases the circumstances of the urgency should be recorded. The Authorised Officer will need to determine whether or not this is administratively urgent or a genuine clinical emergency. All communications should be recorded, and the date and time documented. Emails should be appended to the form. The reasons for a decision to fund or not fund in urgent

	cases must be fully documented either here or, if at all feasible, on an IFR Panel Decision Form.
Decision	
Outcome	☐ **Funding request returned to referring Clinician** ☐ **Funding request referred to the IFR Panel** Panel date booked: Assigned case officer: Letter sent to the referring clinician informing them of IFR Panel date and if needed requests for further information: ☐ **Funding agreed (urgent cases only)** Name of individual agreeing to funding: Title:
Reasons for the decision:	
This request falls within normally commissioned care: Reasons: Actions taken:	
This request represents a service development: Reasons: Actions taken:	
This request does not provide sufficient information for an assessment to be made: Reasons: Actions taken:	
Case is not exceptional Reasons: Actions taken:	
Request to fund a patient in a clinical trial denied.	

Reasons: Actions taken:	
Other: Reasons: Action taken:	
Signed:	Signed by the Chair of the IFR Screening Panel or the Authorising Officer
Date:	

Appendix 9: Individual Funding Request (IFR) Panel Record

Case code:		**Decision Outcome**	☐ Funding supported ☐ Funding supported but final decision referred to the CCG in order to fully assess affordability / opportunity cost ☐ Deferred decision pending further information/investigation ☐ Funding refused (exceptionality criteria have not been met) ☐ Funding refused (treatment low priority- represents poor value for money) ☐ Funding refused case represents a service development ☐ Funding refused treatment experimental and a clinical trial should be carried out in this ☐ Funding refused – other reason ☐ Funding refused trial not supported Additional action(s):
Decision date:		**Reasons for the decision**	The reasons set out here should be those that will be listed in the letter to the clinician and the patient. This section should also reference the arguments against the IFR and other relevant policies.

Decision Factor	Points to consider	Points considered
Is this a service development?	Are there any similar patients? Has a service development been missed by the screening process?	In these three sections the IFR Panel is trying to identify the relevant policies and questions that apply to the case and the key facts of the case. IFR requests tend to follow a restricted number of patterns and it is important to identify the question/s that the IFR panel has to answer during its deliberations. These might usefully be set out by an analysis of the case which is submitted along with the IFR submission. The IFR panel will not be bound by this analysis.
Is this case precedent setting in such a way as to require the CCG to first consider the ethical or policy issues raised?		
What issues and principles are engaged by this case?	1. The patient is different from the group of patients that fall outside an existing policy 2. The case is a rare clinical circumstance and the recommendation is for a treatment for which there is insufficient or no evidence in this type of case 3. The request is to enter the patient into a trial 4. Other Which policies are engaged?	
Exceptionality	What are the grounds for the case being an exception?	
Evidence of clinical effectiveness	What scientific evidence base is available relevant to the case? What is the quality of the evidence?	

	If the evidence is lacking are trials possible? What do NICE and other key organisations advise?	
The individual's health need and capacity to benefit-	What is the potential benefit to the patient? What alternative care is available?	
Costs	Consider: • Initial assessment • Treatment costs including drugs and service costs • Follow-up and after care • On-going care costs • Others	
Cost-effectiveness / value for money		
Equity	Is there a risk of the CCG discriminating against this patient or other unfunded patients on the basis of age, gender, sexual orientation, gender identity, race, nationality, religion, lifestyle, social position, family or financial status, intelligence, disability, physical or cognitive functioning? What is the balance between the needs of the wider community and the needs of this particular individual?	
Affordability	Does the CCG have the money to fund this? Does the health gain merit being treated as high priority vis-à-vis unfunded developments?	

Policy drivers		
Other considerations	Do the facts of the case have to be weighed against a key principle?	Some assessments will require the needs of the patient to be balanced against the risks of breaching a key principle. The most notable ones are: the risks associated with picking up Industry sponsored trial or other patients, picking up treatment funded privately but not normally commissioned and unsanctioned trial of treatments.
Additional comments		

Appendix 10: Individual Funding Request (IFR) Application Appeal Form

The remit of the Individual Funding Request Appeal Panel is to ascertain whether the decision taken by the CCG at the IFR Panel:

- was taken in accordance with the requirements of this policy;
- properly took into account and evaluated all the relevant evidence;
- did not take into account irrelevant factors;
- was taken in good faith; and
- was a decision that falls within the range of responses which the CCG was reasonably entitled to reach on the application and evidence submitted.

(M&L CSU use only)			
Case code:		**Date Received:**	
Date assessed by IFR Team:		**Decision:**	
IFR Screening Panel Date:		**Decision:**	
IFR Panel Date:		**Decision:**	
IFR Appeal Panel Date:		**Decision:**	

1. Patient Details			
Forename:		**NHS Number:**	
Surname:		**Hospital Number:**	
Date of Birth:		**Sex: M/F:**	
Patient's Address & Postcode:		**Ethnic Origin:**	

(Please note that all necessary personal information will be removed from this form prior to being reviewed. This information is collected for monitoring purposes only)

2. Appellant	
Name	
Position/Title	
Relationship to the patient	
Signature	
Date Completed	

3. Details of the appeal **(Please note that one of the sections below needs to be completed for an appeal to be considered)**
Please detail how the decision making process was not followed appropriately.
Please detail how the decision made by the Clinical Commissioning Group was unreasonable in light of the following factors: • **The evidence of exceptionality (which the IFR Panel deemed to not be demonstrated)** • **The clinical & cost effectiveness evidence** • **The patient's individual circumstances** • **Other material factors**
Please detail any other information that you consider to be relevant to the appeal
Please note that if new evidence regarding exceptionality or new clinical evidence is submitted then the case will need to be referred back to the Individual Funding Request Panel for reconsideration.

On Completion
Email through nhs.net account to dedicated email: cmcsu.ifr@nhs.net **or Fax to safe haven: 0121 285 5990** **or Post (Marked Confidential) to:** **IFR Team** **Midlands and Lancashire CSU** **Kingston House** **438-450 High Street** **West Bromwich** **West Midlands** **B70 9LD**

Glossary

TERM	DEFINITION
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	C*linical 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.
Cost effectiveness	*Cost effectiveness* is an assessment as to whether a healthcare intervention provides value for money. In this document it does not necessarily imply that this is measured using a specific methodology.
Cost effectiveness analysis	*Cost effectiveness analysis* is a method for assessing or measuring the reasonably anticipated benefits and clinical effectiveness of a particular expenditure. In the health setting this will be the cost of a particular healthcare intervention together with any other costs of delivering the healthcare intervention. Cost effectiveness analysis requires an examination of expenditure to determine whether the money spent could have been used more effectively (and ideally - whether the resulting benefits could have been attained through less financial outlay).
Effectiveness - general	*Effectiveness* means the degree to which pre-defined objectives are achieved and the extent to which targeted problems are resolved.
Effectiveness - clinical	C*linical 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.
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.
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.
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.
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. In the West Midlands 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.
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.
Value for money	*Value for money* in general terms is the utility derived from every purchase or every sum spent.