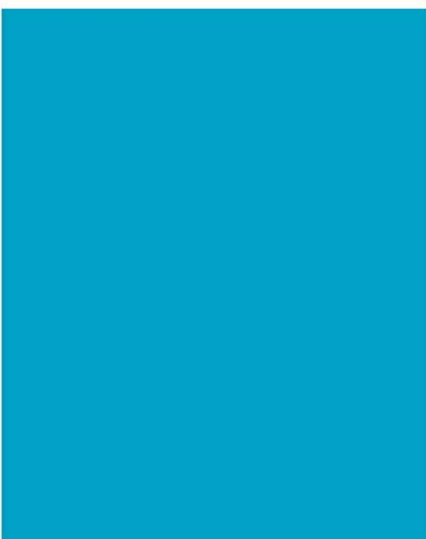
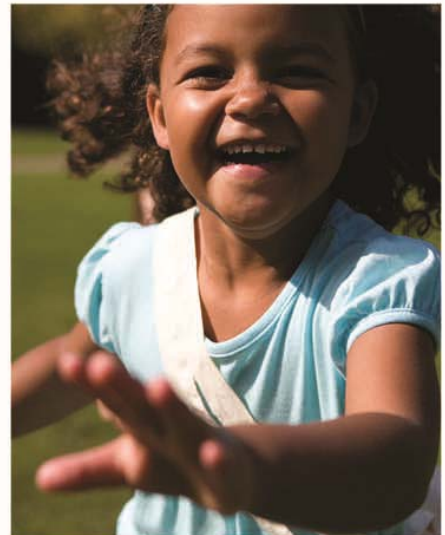


**Interim Commissioning
Policy: Individual funding
requests**

April 2013

Reference : NHSCB/CP/03



NHS Commissioning Board

Interim Commissioning Policy: Individual funding requests

First published: April 2013

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First published April 2013

Published by the NHS Commissioning Board, in electronic format only.

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INTERIM

Interim Policy Statement

Clinicians, on behalf of their patients, are entitled to make a request (an Individual Funding Request or IFR) to the NHS CB for treatment that is not normally commissioned by the NHS CB under defined conditions.

This policy outlines these conditions and the criteria which are used for decision-making. The processes for consideration of individual funding requests (IFRs) are outlined in the Standard Operating Procedures document NHSCB/SOP/02.

This policy applies to any patient who is in circumstances where the NHS Commissioning Board (NHS CB) is the responsible commissioner for NHS care for that person or needs medical treatment where the NHS CB is the responsible commissioner for the provision of that medical treatment as part of NHS care to that person.

This policy will apply to patients eligible for NHS services in England only.

This interim policy will be implemented from 1 April 2013 and subject to further review in 2013/2014

Equality Statement

The NHS CB has a duty to have regard to the need to reduce health inequalities in access to health services and health outcomes achieved as enshrined in the Health and Social Care Act 2012. The NHS CB is committed to ensuring equality of access and non-discrimination, irrespective of age, gender, disability (including learning disability), gender reassignment, marriage and civil partnership, pregnancy and maternity, race, religion or belief, sex (gender) or sexual orientation. In carrying out its functions, the NHS CB will have due regard to the different needs of protected equality groups, in line with the Equality Act 2010. This document is compliant with the NHS Constitution and the Human Rights Act 1998. This applies to all activities for which they are responsible, including policy development, review and implementation.

1. The policy

1.1. This policy applies to any patient who is in circumstances where the NHS CB is the responsible commissioner for NHS care for that person or needs medical treatment where the NHS CB is the responsible commissioner for the provision of that medical treatment as part of NHS care to that person.

1.2. Clinicians, on behalf of their patients, are entitled to make a request (an “individual funding request”) to the NHS CB for treatment that is not normally commissioned by the NHS CB under defined conditions:

- The request does not constitute a request for a service development;

AND

- The patient is suffering from a medical condition for which the NHS CB has commissioning responsibility and a commissioning position and the patient’s particular clinical circumstances falls outside the criteria set out in an existing commissioning policy for funding the requested treatment

OR

- The patient is suitable to enter a clinical trial which requires individual explicit funding by the NHS CB as opposed to being part of a group of such trial patients

OR

- The patient has a rare clinical circumstance, thus rendering it impossible to carry out clinical trials, and for whom the clinician wishes to use an existing treatment on an experimental basis.

All correspondence will be copied to the patient, their carer or guardian (if appropriate) and General Practitioner (GP), unless there are specific reasons to suggest that this is not in the interest of the patient.

SCREENING INDIVIDUAL FUNDING REQUESTS

Screening for service developments

1.3 All individual funding requests submitted to the NHS CB will be subject to screening in accordance with the procedures set out in the NHS CB Operational Policy for Individual funding requests 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
- Developments to existing treatments including medicines, surgical procedures and medical devices
- New diagnostic tests and investigations
- Quality improvements
- Requests to alter an existing policy (called a policy variation). The proposed change could involve adding in an indication for treatment, expanding access to a different patient sub-group or lowering the threshold for treatment
- Requests to fund a number of patients to enter a clinical trial and the commissioning of a clinical trial are considered as service developments in this context as they represent a need for additional investment in a specific service area

What is a Service Development?

A request for a treatment should be classified as a request for a service development if there are likely to be a cohort of similar patients who are:

- In the same or similar clinical circumstances as the requesting patient
- Whose clinical condition means that they could make a like request (regardless as to 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).

What is a “cohort of similar patients”?

A cohort of similar patients for the purposes of this policy has been defined as the number of requests received or likely to be received per year which will require consideration of a commissioning policy. In these circumstances, the IFR route to funding may only be considered if the patient is clinically exceptional to the cohort.

What are the conditions which require consideration of a commissioning policy?

The NHS CB will consider the development of a clinical commissioning policy where:

- the numbers of patients for whom the treatment will be requested per year is likely to 5 or more patients in the population served by any of the NHS CB regions

OR

- The cost of funding the requested treatment for an individual is likely to result in expenditure of more that £150,000 per year.

If the numbers of patients for whom the treatment is requested per year reaches 5 or more, the NHS CB Area Team will treat this as a service development requiring a commissioning policy.

If the number of patients presenting per year is less than 5, the NHS CB Area Team will consider whether an IFR is appropriate.

If the estimated cost for between 1 and 4 patients is < £150,000 per year, funding decisions can be made through the IFR Panel.

Where the numbers of patients and costs exceed these thresholds, the NHS CB Medical Directorate Clinical Effectiveness Team will be notified.

1.4 The IFR Panel are not entitled to make policy decisions for the NHS CB. It follows that where a request has been classified as a service development for a cohort of patients, the IFR Panel is not the correct body to make a decision about funding the request. In such circumstances the individual funding request should not and will not be presented to the IFR panel but will be dealt with in the same way as other requests for a service development.

1.5 Where an IFR has been classified as a service development for a cohort of patients, the options open to the NHS CB Area Team IFR Panel include taking the following steps:

- To refuse funding and request the provider prioritises the service development internally within the provider organisation that made the request and, if supported, to invite the provider to submit a business case as part of the annual commissioning round for the requested service development
- To refuse funding and initiate an assessment of the clinical importance of the service development within the NHS CB with a view to developing a policy and determining its priority for funding in the next financial year
- To refer the request for funding for immediate workup of the service development as a potential candidate for in year service development

Screening for incomplete submissions

1.6 If a request is not categorised as a service development, it will be subject to screening by the IFR Screening Panel to determine whether the request has sufficient clinical and other information in order for the individual funding request to be considered fully by the IFR Panel. Where information is lacking the individual funding request will be declined and returned to the provider specifying the additional information which would be required in order enable this request to proceed. The request can be resubmitted at any point.

Screening to assess whether the request raises a case which ought to go to the IFR Panel.

- 1.7 If a request has been accepted as not constituting a service development and the paperwork is sufficiently complete to assess the case, then the request will be forwarded to the IFR Panel unless there is no reasonable prospect that the IFR Panel (applying the tests set out in this policy) will approve the request

ASSESSMENT OF IFRS WHICH HAVE PASSED SCREENING

Exceptionality requests which seek to secure treatment for a patient whose clinical circumstances does not currently qualify them for funding under an existing commissioning policy

- 1.8 An exceptionality request can be made in relation to a medical condition where the NHS CB has a Commissioning Policy or has a positive NICE TAG recommendation but the patient's clinical circumstances or the requested treatment falls outside the NHS CB Policy. These exceptionality requests should be completed by the clinician *with reference to the relevant generic and/or treatment specific commissioning policy.*
- 1.9 The IFR Panel shall be entitled to approve funding if the patient has exceptional clinical circumstances. In considering whether or not to fund a patient on grounds of exceptional clinical circumstances, in this situation, the IFR Panel will act as follows:
- The IFR Panel will use the information provided by the requester to compare the patient to other patients with the same presenting medical condition at the same stage of progression. Specifically, the panel may consider, based upon the evidence provided to it, whether or not the patient has demonstrated exceptional clinical circumstances which lead the panel to believe that the patient would benefit significantly more from the treatment than the other patients not meeting funding criteria.
 - When making their decision, the IFR Panel is required to restrict itself to considering only the patient's presenting medical condition and the likely benefits which have been demonstrated by the evidence to be likely to accrue to the patient from the proposed treatment.

- The NHS CB and its delegated decision-making panels shall seek to make decisions in accordance with the NHS CB ethical framework, including the requirement to have due regard to the obligations of the Equality Act 2010 save where a difference in treatment is based on objectively justifiable factors and is a justified and proportionate response to the needs of different groups of patients.
- The NHS CB and its delegated decision-making panels shall seek to make decisions in accordance with the 1998 Human Rights Act.¹
- The NHS CB and its delegated decision-making panels shall not make treatments available to individual patients, and not other clinically similar patients, on the basis of non-clinical factors.
- The IFR Panel shall have a broad discretion to determine whether the proposed treatment is a justifiable expenditure for the National Commissioning Board. The IFR panel is however required to bear in mind that the allocation of any resources to support any individual patient will reduce the availability of resources for investments in previously agreed care and treatments.

Exceptionality requests which seek to fund an existing treatment experimentally for one or more patients with a rare clinical condition or rare clinical circumstances.

- 1.10 This patient group represents a distinct group of exceptions and so are assessed in line with the NHS CB commissioning policy on experimental and unproven treatments.
- 1.11 The IFR Panel shall be entitled to approve funding an experimental treatment for patients with rare clinical conditions or clinical circumstances.
- 1.12 The IFR Panel will assess, in the first instance, whether or not the treatment for this condition could be readily subjected to a robust clinical trial. If so the funding request will, save in exceptional circumstances, be rejected. The fact that the research community has not prioritised the clinical trial is not grounds for funding the treatment outside of a clinical trial.

¹ The Human Rights Act 1998. Available from: <http://www.legislation.gov.uk/ukpga/1998/42/contents>. Accessed 14/12/12

1.13 In considering whether or not to agree to fund the treatment the IFR Panel's consideration shall include the following factors:

- The potential benefit and risks of the treatment
- The biological plausibility of anticipated benefit for the patient based on evidence of this treatment in other similar disease states
- Value for money
- Affordability and priority compared to other competing needs and unfunded developments
- Where the request is in respect of more than one patient or it is clear from the nature of the request that there is likely to be more than one patient, then the IFR panel should consider whether or not the request is a service development or trial

Requests to provide funding to enable a patient to enter into a clinical trial

1.14 Reference should be made to the NHS CB commissioning policy on experimental and unproven treatments (NHSCB/CP/05).

It should be noted however that it is likely that with a single commissioner covering England, most requests to fund patients in clinical trials will represent service developments because the NHS CB will be the sole source of NHS funding for a treatment related to specialised services. The likely exceptions to this are international trials of rare conditions.

1.15 The IFR Panel shall be entitled to approve funding for a patient to enter into a clinical trial. In considering whether or not to provide funding to enable a patient to enter into a clinical trial the IFR Panel will consider the following:

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

- The likelihood that other patients will be presented for funding during the trial duration and the possible numbers
- 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.
- An assessment of the anticipated quality of the trial (based on the trial protocol) and whether or not it is likely to generate the sort of information needed to enable those funding healthcare to reach a view on the clinical effectiveness and cost effectiveness of the treatment. Specialist advice may need to be sought on the methodology to be adopted within any trial.
- 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.
- Affordability and priority compared to other competing needs and unfunded developments.

1.16 All funding requests must be accompanied with the trial protocol.

Identification bias

1.17 The IFR Panel shall take care to avoid identification bias, often called the “rule of rescue”. This can be described as the imperative people feel to rescue identifiable individuals facing avoidable death or a preference for identifiable over statistical lives.² In plain terms this means; supporting intensive effort to prolong life (when prognosis appears poor and death unavoidable) and when there is little research evidence to support treatment options (e.g. in relapsed/refractory stages of disease). The fact that a patient has exhausted all NHS treatment options available for a particular condition is unlikely, of itself, to be sufficient to demonstrate exceptional circumstances. Equally, the fact that the patient is refractory to existing treatments where a recognised proportion of patients with same presenting medical condition at this stage are, to a greater or lesser extent, refractory to existing treatments is unlikely, of itself, to be sufficient to demonstrate exceptional circumstances.

[McKie J, Richardson J.](#) The rule of rescue. [Soc Sci Med.](#) 2003 Jun;56(12):2407-19.

INFORMATION SUBMITTED TO THE IFR PANEL

- 1.18 All applications must be accompanied by written support and evidence provided by the clinical team treating the patient in line with the NHS CB Operational Policy for the Management of Individual Funding Requests.

It is the clinician's responsibility to ensure that the appropriate information is provided to the NHS CB according to the type of request being made, in a timely fashion consistent with the urgency of the request. If relevant information is not submitted, then the referring clinician will bear responsibility for any delay that this causes. In all instances the lead treating clinician must state whether or not they consider there are similar patients (in accordance with the definition set out above) and, if so, how many such patients there are.

- 1.19 All clinical teams submitting IFR requests must be aware that information that is immaterial to the decision will not be considered by the IFR Panel. This may include information about non-clinical factors relating to the patient or information which does not have a direct connection to the patient's clinical circumstances.

APPROVAL OF INDIVIDUAL FUNDING REQUESTS

- 1.20 The IFR Panel shall be entitled to approve requests for funding for treatment for individual patients where all the following conditions are met:

- Save in the case of funding requests under paragraph 1.3, the IFR Panel is satisfied that there is no cohort of similar patients. If there is a cohort of similar patients the IFR Panel shall decline to make a decision because the application is required to be treated as a request for a service development.
- One of the conditions set out in 1.2 above is met.
- Exceptional circumstances apply and There is sufficient evidence to show that, for the individual patient, the proposed treatment is likely to be clinically and cost-effective or that the clinical trial has sufficient merit to warrant NHS funding.
- The NHS CB can afford the treatment.

- 1.21 The IFR Panel is not required to accept the 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:
- The likely clinical outcomes for the individual patient of the proposed treatment;
- AND
- The quality of the evidence presented to support the request and/or the degree of confidence that the IFR Panel has about the likelihood of the proposed treatment delivering the proposed clinical outcomes for the individual patient.
- 1.22 The IFR Panel shall be entitled but not obliged to commission its own reports from any duly qualified or experienced clinician, medical scientist or other person having relevant skills, concerning the case that is being made that the treatment is likely to be clinically effective in the case of the individual patient. Reference to nationally recognised evidence syntheses should be used where they address the specific issues under consideration.
- 1.23 The IFR Panel may make such approval contingent on the fulfilment of such conditions as it considers fit.
- 1.24 Very occasionally an individual funding request presents a new issue which needs a substantial piece of work before the NHS CB can reach a conclusion upon its position. This may include wide consultation. Where this occurs the IFR Panel may adjourn a decision on an individual case until that work has been completed.

REVIEW OF THE DECISION

- 1.25 Where the IFR Panel has refused to support funding for a requested treatment or has approved the treatment subject to conditions, the patient shall be entitled to ask that the decision of the IFR Panel be reviewed. All requests for a review must be supported by the senior treating clinician who must explain his or her reasons for considering that the decision taken by the IFR panel was either procedurally improper and/or misunderstood the medical evidence and/or was in his or her opinion a decision which no reasonable IFR panel could have reached. Any such review will be considered by the NHS CB IFR Review Panel.

1.26 The IFR Review Panel is part of the corporate governance process of the NHS CB. The role of the IFR Review Panel is to determine whether the IFR Panel has followed the NHS CB procedures, has properly considered the evidence presented to it and has come to a reasonable decision upon the evidence.

1.27 The IFR Review Panel shall consider whether:

- The process followed by the IFR Panel was consistent with the operational policy of the NHS CB.
- The decision reached by the IFR Panel:
 - was taken following a process which was consistent with the policies of the NHS CB
 - had taken into account and weighed all the relevant evidence
 - had not taken into account irrelevant factors
 - indicated that the members of the panel acted in good faith
 - was a decision which a reasonable IFR panel was entitled to reach.

1.28 In the event that the IFR Review Panel consider that there was any procedural error in the decision of the IFR Panel, the IFR Review Panel shall next consider whether there was any reasonable prospect that the IFR Panel may have come to a different decision if the IFR Panel had not made the procedural error identified by the IFR Review Panel.

If the IFR Review Panel considers that there was no reasonable prospect of the IFR Panel coming to a different decision, then the IFR Review Panel shall approve the decision notwithstanding the procedural error.

However if the IFR Review Panel considers that there was a reasonable prospect that IFR Panel may have come to a different decision if the IFR Panel had not made the procedural error, the IFR Review Panel shall require the IFR Panel to reconsider the decision.

The IFR Review Panel shall not have power to authorise funding for the requested treatment but shall have the right to make recommendations to the IFR Panel and/or to request one of the Officers authorised to take urgent decisions to consider exercising that power.

CO-OPERATION OF PROVIDER TRUSTS

1.29 The NHS CB requires provider trusts and clinicians to take the NHS CB commissioning policies into account in the advice and guidance given to patients prior to making the decision to treat a patient. The NHS CB expects the management of its provider trusts to have oversight of this process. The NHS CB would expect every individual funding request to be sanctioned by provider trust management and reserves the right to return unsanctioned individual funding requests to the provider trust un-assessed and refer recurrent inappropriate funding requests to the Chief Executive of the relevant provider trust.

URGENT TREATMENT DECISIONS

1.30 The NHS CB recognises that there will be occasions when an urgent decision needs to be made to consider approving funding for treatment for an individual patient outside the Board's normal policies. In such circumstances the NHS CB recognises that an urgent decision may have to be made before a panel can be convened. The following provisions apply to such a situation.

- An urgent request is one which requires urgent consideration and a decision because the patient faces a substantial risk of death or significant harm if a decision is not made before the next scheduled meeting of the IFR Panel.
- Urgency under this policy cannot arise as the result of a failure by the Clinical Team expeditiously to seek funding through the appropriate route and/or where the patient's legitimate expectations have been raised by a commitment being given by the provider trust to provide a specific treatment to the patient. In such circumstances the NHS CB expects the provider trust to proceed with treatment and for the provider to fund the treatment.
- Provider trusts must take all reasonable steps to minimise the need for urgent requests to be made through the IFR process. If clinicians from any provider trust are considered by the NHS CB not to be taking all reasonable steps to minimise urgent requests to the IFR process, the NHS CB may refer the matter to the provider Trust Chief Executive.

- In situations of clinical urgency the decision will be made by staff authorised to make an urgent decision as set out set out in the NHS CB Standard Operational Procedures (SOP) for the Management of Individual Funding Requests.
- The authorised senior health professional or the extraordinary IFR Panel (as described in the Board's SOP for the Management of Individual Funding Requests) will as far as possible within the constraints of the urgent situation, follow the policy set out above in making the decision. The authorised personnel shall consider the nature and severity of the patient's clinical condition and the time period within which the decision needs to be taken. As much information about both the patient's illness and the treatment should be provided as is feasible in the time available and this shall be considered for funding in accordance with relevant existing commissioning policies.
- The authorised senior health professional and the exceptional IFR Panel shall be entitled to reach the view that the decision is not of sufficient urgency or of sufficient importance that a decision needs to be made outside of the usual process.
- The authorised senior health professional and the exceptional IFR Panel 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.

Appendix A: Guidance notes

The UK Faculty of Public Health has published a statement describing the concept of exceptionality³:

“It is important to distinguish between an exceptional case and an individual funding request. In an exceptional case, a patient seeks to show that he or she is an ‘exception to the rule’ or policy and so may have access to an intervention that is not routinely commissioned for that condition. In contrast, an individual funding request arises when a treatment is requested for which the [commissioning organisation] has no policy. This may be because:

- it is a treatment for a very rare condition for which the [commissioners] have not previously needed to make provision *or*
- there is only limited evidence for the use of the treatment in the requested application *or*
- the treatment has not been considered by the [commissioners] before because it is a new way of treating a more common condition. This should prompt the development of a policy on the treatment rather than considering the individual request unless there is grave clinical urgency.”

In practice, all requests for funding for an individual patient have been called Individual Funding Requests (IFRs) but these sub-categories of request should be recognised. IFRs also need to be understood in the context of routinely funded services. Most established treatments and services are subject to routine commissioning arrangements: a portfolio of contracts and service level agreements, clinical commissioning policies, mandatory National Institute of Health and Clinical Excellence (NICE) technology appraisal guidance.

This guidance note is intended to distinguish the broad types of request that may be received. These are where the request:

1. represents a service development for a cohort of patients
2. is on grounds of clinical exceptionality where there are commissioning arrangements in place
3. is on grounds of rarity and no commissioning arrangements exist

³ Faculty of Public Health. FPH Position Statement. Describing exceptionality for funding panels. 2012. Available from: http://www.fph.org.uk/policy_reports. Accessed 11/12/12.

4. is for a new intervention or for use of an intervention for a new indication, where no commissioning arrangements exist

1. SERVICE DEVELOPMENTS AND COHORTS OF SIMILAR PATIENTS

A service development is any aspect of healthcare which the NHS CB has not historically agreed to fund and which will require additional and predictable recurrent funding.

The term refers to all decisions which have the consequence of committing the NHS CB to new expenditure for a cohort of patients including:

- New services
- New treatment including medicines, surgical procedures and medical devices
- Developments to existing treatments including medicines, surgical procedures and medical devices
- New diagnostic tests and investigations
- Quality improvements
- Requests to alter an existing policy (called a policy variation). This change could involve adding in an indication for treatment, expanding access to a different patient sub-group or lowering the threshold for treatment.
- Support for establishing new models of care
- Requests to fund a number of patients to enter a clinical trial.
- Commissioning a clinical trial.

It is normal to consider funding new developments during the annual commissioning prioritisation round.

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 NHS CB agrees to fund outside of the annual prioritisation and commissioning round.

When a commissioning organisation considers funding a service development outside the normal prioritisation and commissioning process it is particularly important that those taking the decision pay particular attention to the need to take account of the opportunity cost for the NHS CB to fund other areas of competing health needs.

Unplanned investment decisions should only be made where they have been

approved in accordance with the terms of this policy, which will usually be 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.

It is common for clinicians to request an individual funding request for a patient where the request is, properly analysed, the first patient of a group of patients wanting a particular treatment. For example, a new drug has been licensed for a particular type of cancer and for patients with particular clinical characteristics. Any individual funding request which is representative of this group, represents a service development. As such it is difficult to envisage circumstances in which the patient can properly be classified to have exceptional clinical circumstances. Accordingly the individual funding request route is usually an inappropriate route to seek funding for such treatments as they constitute service developments. These funding requests are highly likely to be returned to the provider trust, with a request being made for the clinicians to follow the normal processes to submit a bid for a service development.

The concept of a cohort of similar patients.

The policy recognises that there needs to be a distinction between cases where the clinical circumstances are genuinely exceptional and those where the presenting clinical circumstances are representative of a small group of other patients.

Where the presenting clinical circumstances are representative of a small group of other patients the position of the NHS CB is that a decision to fund or not is a policy decision and not a funding decision for an individual patient i.e. it has wider funding implications. Treating this as a policy decision, to be made in the wider context of NHS CB commissioning and priority setting ensures that the outcome of the decision is applied equally to all the other patients who have the same presenting clinical circumstances and the principle of prioritisation is upheld.

The NHS CB has set the level at which cases will require consideration of a commissioning policy. Once this number of requests is met, the IFR route to funding may only be considered if the patient is clinically exceptional to the cohort.

The NHS CB will consider the development of a clinical commissioning policy where:

- the numbers of patients for whom the treatment will be requested per year is likely to 5 or more patients in the population served by any of the NHS CB

Regions

OR

- The cost of funding the requested treatment for an individual is likely to result in expenditure of more than £150,000 per year.

If the numbers of patients for whom the treatment is requested per year reaches 5 or more⁴, the NHS CB Area Team will treat this as a service development requiring a commissioning policy.

If the number of patients presenting per year is less than 5, the NHS CB Area Team will consider whether an IFR is appropriate.

If the estimated cost for an individual patient is < £150,000 per year, funding decisions can be made through the IFR Panel.

Where the numbers of patients and costs exceed these thresholds, the NHS CB Medical Directorate Clinical Effectiveness Team will be notified.

2. EXCEPTIONALITY

What is meant by exceptional circumstances?

There can be no exhaustive definition of the conditions which are likely to come within the definition of an exceptional individual case. The word 'exception' means 'a person, thing or case to which the general rule is not applicable'.

The IFR Panel should bear in mind that, whilst everyone's individual circumstances are, by definition, unique, 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 panel. However, the overriding question which the panel needs to ask itself remains: has it been demonstrated that this patient's clinical circumstances are exceptional?

⁴ This means an incidence of a new variant of the patient subgroup of about 1 per 2.5 million i.e. a rare manifestation of probably an already rare disease.

- It may be possible to demonstrate exceptionality where the patient has a medical condition or circumstance which is so rare that the result of the NHS CB prioritisation process provides no established treatment care pathway for that treatment (see 'Assessment of requests to fund existing treatments experimentally for patients with rare clinical circumstances'.)
- If a patient has a condition for which there is an established care pathway, the 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 medical condition.
- 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 another medical condition or because the patient cannot tolerate the side effects of the usual treatment) may be a basis upon which a Panel could find that a patient is exceptional.
- However, the Panel would normally need to be satisfied that the patient's inability to respond to, or be provided with, the usual treatment was genuinely an 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 the requesting patient falls into that group is unlikely to be a proper ground on which to base a claim that the requesting patient is 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 the requesting patient is unlikely to make the patient exceptional.

The most appropriate response in each of the above 2 situations, is to consider whether there is sufficient justification (including consideration of factors such as clinical effectiveness, cost-effectiveness, priority and affordability) to make a change to the policy adopted by the NHS CB 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 one such person). This change needs

to be considered as a service development)

To meet the definition of 'exceptional clinical circumstances' there must be an NHS CB policy in place that describes the availability of the requested intervention and your patient must demonstrate that they are both:

- Significantly different clinically to the group of patients with the condition in question and at the same stage of progression of the condition

AND

- Likely to gain significantly more clinical benefit than others in the group of patients with the condition in question and at the same stage of progression of the condition

Non-clinical factors

It is common for an application for individual funding to be 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 NHS CB understand that everyone's life is different and that such factors may seem to be of vital importance to patients in justifying investment for them in their individual case. However, including non-clinical factors in any decision-making raises at least three significant problems for the NHS CB.

- Across the population of patients who make such applications, the Board is unable to make an objective assessment of material put before it relating to non-clinical factors. This makes it very difficult for the 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 Board is making funding available on a one-off basis to a patient where other patients with similar conditions would not get such funding. If non-clinical factors are included in the decision making process, the Board does not know whether it is being fair to other patients who are denied such treatment and whose non-clinical factors are entirely unknown.
- The Board is committed to a policy of non-discrimination in the provision of medical treatment. If for example, treatment was to be provided on the grounds that would enable an individual to stay in paid work then this would potentially discriminate in favour of those working compared to 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 on which the NHS was founded and still currently operates. The NHS

CB has not, therefore, been mandated to distribute resources based on these divisions within society, Such a decision would also set a precedent for the NHS CB to always favour those in work over those not currently in work. The same can be said of many other non-clinical factors such as having children / not having children, being a carer / not being a carer and so on.

Generally, the NHS does not take into account non-clinical 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. It does not seek to deny treatment to smokers on the grounds that they have caused or contributed to their own illnesses through smoking, nor does it deny treatment to those injured participating in sports in which they were voluntary participants.

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

In reaching a decision as to whether a patient's circumstances are exceptional, the Panel is required to follow the principles that non-clinical factors including social value judgements about the underlying medical condition or the patient's circumstances are not relevant.

Clinicians are asked to bear this policy in mind and not refer to 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 clinical applicant to set out the grounds clearly for the 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 which the patient has.

These grounds must be set out on the form provided by the NHS CB and should clearly set out any factors which the clinician invites the panel to consider as constituting a case of 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, the referring clinician must explain how common it is for the

patient with this condition not to be able to be provided with the usual treatment.

If a clear case as to why the patient's clinical circumstances are said to be exceptional is not made out, then the Panel can do no other than refuse the application. The Panel recognises that the patient's referring 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 NHS CB therefore requires the referring clinician, as part of their duty of care to the patient, to explain why the patient's clinical circumstances are said to be exceptional.

The policy of the NHS CB is that there is no requirement for the 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 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 their case is exceptional. In such cases the panel should look at each factor individually to determine (a) whether the factor was capable of making the case exceptional and (b) whether it did in fact make the patient's case exceptional. The panel may conclude, for example, that a factor was incapable of supporting a case of exceptionality and should therefore be ignored. That is a judgment within the discretion of the panel.

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

It may be possible to demonstrate exceptionality where the patient has a medical condition or clinical circumstance which is so infrequent/unpredictable that the result of the NHS CB prioritisation process provides no established treatment care

pathway for that patient.

3. RARITY

Assessment of requests to fund existing treatments experimentally for patients with rare clinical circumstances

The assessment of these funding requests should be distinguished from requests on the grounds of exceptionality.

A set of criteria need to be applied when a patient's medical condition is so rare or their condition is so unusual that the clinician wishes to use an existing treatment in an experimental way. This exception does not routinely apply to rare disorders or small subgroups of patients within a more common disorder because here it would be normal to have a trial involving sufficient patients formally to evaluate the proposed treatment in a trial.

In assessing these cases the panel should consider the following

- Can this treatment be studied properly using any other established method? If so then funding should be refused.
- Is the treatment likely to be clinically effective?
- In addition the usual considerations are included. Whether the treatment is cost-effective, and what is this patient's priority compared to patients whose care has not been funded.

In the case of a rare indication, and where the incidence and prevalence is below the threshold figure indicated on p.7, the case can be considered by the NHS CB Area Team IFR Panel. If the threshold test is not met, the request will be declined on the grounds that funding an individual case would be inequitable for the defined cohort.

4. REQUEST FOR USE OF A NEW INTERVENTION OR FOR USE OF AN INTERVENTION FOR A NEW INDICATION, WHERE NO COMMISSIONING ARRANGEMENTS EXIST

If the request is for an intervention that is new, or is a new application of an existing intervention, and the number of likely patients exceeds the threshold test (i.e. the patient represents a cohort) the IFR process is not appropriate and the requester will be directed to the process for requesting a service development.

Giving Reasons

The NHS Constitution⁵ requires NHS organisations to make decisions 'rationally following a proper consideration of the evidence' and be clear about the reasons for their decisions. The NHS CB will give reasons for its decisions.

What is the purpose of the duty to give reasons?

The purpose of a duty to give reasons is to tell the patient in general terms why a public body reached the decision it did and the factors that it took into account in reaching the decision. The Court of Appeal has said as follows about a duty to give reasons⁶:

“(1) The duty is a function of due process, and therefore of justice. Its rationale has two principal aspects. The first is that fairness surely requires that the parties—especially the losing party—should be left in no doubt why they have won or lost. This is especially so since without reasons the losing party will not know (as was said in *Ex p Dave*) whether the court has misdirected itself, and thus whether he may have an available appeal on the substance of the case. The second is that a requirement to give reasons concentrates the mind; if it is fulfilled, the resulting decision is much more likely to be soundly based on the evidence than if it is not.

(2) The first of these aspects implies that want of reasons may be a good self-standing ground of appeal. Where because no reasons are given it is impossible to tell whether the judge has gone wrong on the law or the facts, the losing party would be altogether deprived of his chance of an appeal unless the court entertains an appeal based on the lack of reasons itself.

⁵ Department of Health. The NHS Constitution. Available from: <http://www.dh.gov.uk/health/category/policy-areas/nhs/constitution> Accessed 08/003/2013

⁶ See *Flannery v Halifax Estate Agents* [2000] 1 WLR 377 at 381.

Where a public body is required to give reasons for its decision, it is required to give reasons which are proper, adequate, and intelligible and enable the person affected to know why they have won or lost. These can be expressed in a few sentences but they need to go into sufficient detail so that the patient knows that the main aspects of his case have been properly considered.

What are adequate reasons?

The best statement of the adequacy of reasons is probably set out in *South Bucks District Council v Porter*⁷ where Lord Brown said in the context of a planning appeal:

“The reasons for a decision must be intelligible and they must be adequate. They must enable the reader to understand why the matter was decided as it was and what conclusions were reached on the “principal important controversial issues”, disclosing how any issue of law or fact was resolved. Reasons can be briefly stated, the degree of particularity required depending entirely on the nature of the issues falling for decision. The reasoning must not give rise to a substantial doubt as to whether the decision-maker erred in law, for example by misunderstanding some relevant policy or some other important matter or by failing to reach a rational decision on relevant grounds. But such adverse inference will not readily be drawn. The reasons need refer only to the main issues in the dispute, not to every material consideration. They should enable disappointed developers to assess their prospects of obtaining some alternative development permission, or, as the case may be, their unsuccessful opponents to understand how the policy or approach underlying the grant of permission may impact upon future such applications. Decision letters must be read in a straightforward manner, recognising that they are addressed to parties well aware of the issues involved and the arguments advanced. A reasons challenge will only succeed if the party aggrieved can satisfy the court that he has genuinely been substantially prejudiced by the failure to provide an adequately reasoned decision.

In order to ensure that reasons given for an IFR decision are lawful, the IFR Panel ought to ensure that the decision document (which will usually be the letter to the patient or their GP) goes through the tests under this policy, and explains both the decisions that the IFR panel reached on each element and states a précis as to why the panel reached that decision.

General advice on discharging the duty to give reasons.

Whether the NHS CB IFR Panel has or has not discharged the duty to give reasons

⁷ [2004] 1 WLR 1953

will all depend on the individual circumstances. There will be simple cases where a single sentence is sufficient and there will be more complex cases where a full paragraph or two is needed to explain the thinking of the IFR panel.

The duty will usually mean that the decision letter should explain:

- Whether the panel reached the view that the patient did or did not demonstrate exceptional clinical circumstances, and the basis for that decision. If the panel felt that the patient's clinical circumstances were broadly in line with the clinical circumstances of those in the cohort of other patients in the same clinical condition then this should be stated.
- If the patient put forward specific factors which were said to support his or her claim to be in exceptional clinical circumstances, the letter should explain (by reference to the main factors) why the panel did not consider that these amounted to exceptional clinical circumstances.
- The letter should say whether the panel considered if the requested treatment was likely to be clinically effective for this individual patient. If it was then this should be stated. If the panel reached the view that the requested treatment was not likely to be clinically effective for this individual patient, then the letter should explain why this decision was reached.
- The letter should say whether the panel considered whether the requested treatment will be a cost effective use of NHS resources. If the panel reached the view that the requested treatment was not likely to be cost effective for this individual patient, then the letter should explain why this decision was reached.

What happens if the reasons given are not adequate?

If the original letter giving reasons is not adequate then, where there is a duty to give reasons there are limited circumstances in which the court allows the public body to expand on the reasons given in the decision letter. The best course is often to hold the panel again and then, after a reconsideration, to provide a letter with proper reasons explaining the decision that this panel came to.

Adding to the original reasons is occasionally permitted by the Court but it is far better for public bodies to take time to get the statement of reasons original letter right rather than seeking to expand the explanations on a later occasion.

Appendix B: Documents which have informed this policy

- The NHS CB Commissioning Policy (reference): Ethical Framework to underpin priority setting and resource allocation
- Department of Health, The National Health Service Act 2006 (amended by the Health and Social Care Act 2012), The National Health Service (Wales) Act 2006 and The National Health Service (Consequential Provisions) Act 2006.
http://www.dh.gov.uk/en/Publicationsandstatistics/Legislation/Actsandbills/DH_064103
- Department of Health, The NHS Constitution for England, July 2009,
http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_093419
- The National Prescribing Centre, Supporting rational local decision-making about medicines (and treatments), February 2009,
http://www.npc.co.uk/policy/resources/handbook_complete.pdf
- NHS Confederation Priority Setting Series, 2008,
<http://www.nhsconfed.org/publications/prioritysetting/Pages/Prioritysetting.aspx>