



Department of  
**Health**

An Roinn Sláinte

Máinnystrie O Poustie

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# **INDIVIDUAL FUNDING REQUEST DRAFT POLICY DOCUMENT**

**January 2017**

## **Policy Statement**

This policy document outlines the conditions and criteria under which hospital consultants, on behalf of their patients, can make an application to the Individual Funding Request (IFR) Regional Scrutiny Committee (RSC) for treatment which is not normally commissioned by the Health and Social Care Board (HSCB) under defined conditions. This policy applies to any patient who is in circumstances where the HSCB is the responsible commissioner for health and social care for that person.

This policy will apply to patients eligible for health and social care (HSC) services only.

This policy will apply from xx xxx xxxx and will be subject to review one year hence.

## **Equality statement**

Section 75 of the NI Act 1998 requires all public bodies in carrying out their functions to have due regard to the need to promote equality of opportunity between:

- Persons of different religious belief, political opinion, racial group, age, marital status or sexual orientation;
- Men and women generally;
- Persons with a disability and persons without; and
- Persons with dependants and persons without.

In addition, without prejudice to the above, public bodies must also in carrying out their functions have regard to the desirability to promote good relations between persons of a different religious belief, political opinion or racial group.

This policy will apply regionally and should not present any specific rural impact.

## 1. The policy

- 1.1. This policy applies to any patient where the Health and Social Care Board (HSCB) is the responsible commissioner for the provision of health and social care (HSC) for that person
- 1.2. Hospital consultants, on behalf of their patients, are entitled to make an “*individual funding request*” (IFR) to the HSCB for treatment that is not normally commissioned by the HSCB under the following defined conditions:

- The request does not apply to a cohort of patients (see sections 1.3 - 1.5);

AND

- The patient is suffering from a medical condition for which the patient’s particular clinical circumstances fall outside the criteria set out in an existing commissioning policy for funding the requested treatment (see sections 1.8 - 1.9);

OR

- The request is for a new intervention or, for an intervention for a new indication outwith its licensed indication, where no commissioning arrangements exist (see appendix A section 5);

OR

- The patient has a rare clinical circumstance for whom the hospital consultant wishes to use an existing treatment outwith it’s licensed clinical indication, with the explicit consent of the patient (see sections 1.10 – 1.13);

All correspondence will be copied to the referring consultant, Medical Director and Service Manager. It is expected that referring hospital consultants will discuss the referral with the patient, document the discussion and advise on likely timescales for consideration of the request. Normally a patient should be offered a copy of the referral form.

## SCREENING INDIVIDUAL FUNDING REQUESTS

### *Screening for service developments*

1.3 All individual funding requests submitted will be subject to screening for service development<sup>1</sup>.

A request for a treatment should be classified as a request for a service development if there is likely to be a cohort (see section 1.3.1) of similar patients:

- With the same or similar clinical circumstances as the patient who is the subject of the request;
- Whose clinical condition means that their consultant 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.

If the number of patients presenting per year is less than 3, the Regional Scrutiny Committee (RSC) will consider whether an IFR is appropriate.

#### **1.3.1 What is a “cohort of similar patients”?**

For the purpose of this policy a cohort is defined as a group of clinically similar patients.

If the numbers of clinically similar patients for whom the treatment is requested per year reaches 3 or more, the HSCB will treat this as a service development requiring a commissioning policy and the Specialist Services Commissioning Team (SSCT) will be notified.

1.4 The RSC is not entitled to make policy decisions for the HSCB. It follows that where a request has been classified as arising from a cohort of clinically similar patients, the RSC is not the correct body to make a decision about funding the request.

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<sup>1</sup> Further guidance on service development is provided in Appendix A, Section ‘Service development and cohorts of similar patients’.

- 1.5 Where an IFR has identified a cohort of patients the RSC will refer to the relevant commissioner who will make a timely decision on commissioning. While the commissioning position is being considered, the RSC will continue to provide that treatment under the IFR process within a reasonable time frame.

### ***Screening for incomplete submissions***

- 1.6 If a request is not categorised as arising from a cohort of clinically similar patients, it will be subject to screening by the IFR Screening Panel to determine whether the request has sufficient clinical and other information for the IFR to be fully considered by the RSC. Where information is lacking the IFR will be returned to the requester specifying the additional information required to enable the request to proceed. The request can be resubmitted at any point.
- 1.7 If a request has been accepted as not applying to a cohort and the paperwork is sufficiently complete to assess the case, then the request will be forwarded to the RSC.

## **ASSESSMENT OF IFRS WHICH HAVE PASSED SCREENING**

### ***Requests for a patient whose clinical circumstances do not currently qualify them for funding under an existing commissioning policy***

- 1.8 Where there is an existing policy on the management of a disease a hospital consultant may request a treatment not covered by this policy where the individual's circumstances differ from the ordinary (i.e. a non commissioned treatment) through the IFR process. This application must make reference to the existing commissioning position.
- 1.9 The RSC shall be entitled to approve funding if the patient has exceptional clinical circumstances<sup>2</sup>. In considering whether or not to fund a patient on grounds of exceptional clinical circumstances the RSC will act as follows:
- The RSC 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 application has demonstrated exceptional clinical circumstances which leads the panel to believe that the patient would benefit significantly more from the treatment than other patients with the same condition at the same stage.

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<sup>2</sup> Further guidance on exceptionality is provided in Appendix A, Section 2 'Exceptionality'.

- When making their decision the RSC is required to restrict itself to considering only the patient's presenting medical condition and the likely benefits (demonstrated by the evidence) from the proposed treatment.
- The RSC shall not fund treatments on the basis of non-clinical factors. Non-clinical factors include age, marital status or employment, or any such information which does not have a direct clinical connection to the patient's clinical circumstances.
- The RSC shall consider the relative cost of treatment and the likely benefit to the individual patient, taking into account that allocation of resources to support any individual patient will reduce the availability of resources for investment in previously agreed care and treatments.

***Requests to fund an existing treatment outwith licensed clinical indications 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 expert views as to the patient's clinical suitability<sup>3</sup>.
- 1.11 The RSC shall be entitled to approve funding the use of a licensed medicine for 'off label' use in the treatment of patients with rare clinical conditions or rare clinical circumstances.
- 1.12 The RSC will assess, in the first instance, whether or not it is possible for the patient to access the treatment through a clinical trial. If so the IFR will, save in exceptional circumstances, be rejected.
- 1.13 In considering whether or not to agree to fund the treatment the RSC'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.
  - Capacity, deliverability and opportunity costs 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 RSC should consider whether or not the request is applicable to a cohort of clinically similar patients.

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<sup>3</sup> Further guidance is provided in Appendix A Section 3 'Rarity'

## URGENT TREATMENT DECISIONS

1.14 The HSCB 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 HSCB's normal policies and processes. In such circumstances the HSCB recognises that an urgent decision by an authorised senior health professional or an extraordinary RSC may have to be made before the next routine RSC 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 RSC.
- Every effort should be made by the hospital consultant to seek funding through the appropriate route. Urgency under this policy cannot arise as the result of a failure by the hospital consultant to expeditiously seek funding through the appropriate route and/or where the patient's legitimate expectations have been raised by a commitment being given by the hospital consultant to provide a specific treatment to the patient. In such circumstances the HSCB expects the hospital consultant's provider Trust to proceed with treatment and for the provider Trust 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 hospital consultants from any provider Trust are considered by the HSCB not to be taking all reasonable steps to minimise urgent requests to the IFR process, the HSCB may refer the matter to the provider Trust's Chief Executive.
- In situations of clinical urgency the decision will be made by those authorised to make an urgent decision<sup>4</sup>.
- The authorised senior health professional or the extraordinary RSC, as far as possible within the constraints of the urgent situation, consider the nature and severity of the patient's clinical condition and the time period within which the decision needs to be taken – preferably within 48 hours. 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 extraordinary RSC shall be entitled to reach the view that the decision is not of sufficient urgency or of

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<sup>4</sup> Further guidance is provided in Appendix A, Section 4 '*Clinically Critically Urgent Treatment Outside Established Policy*'

sufficient importance that a decision needs to be made outside of the usual process.

- The authorised senior health professional and the extraordinary RSC shall be entitled to reach the view that the request is, properly analysed, a request applicable to a cohort of similar patients and so should be refused and/or appropriately referred for policy consideration.

### ***Identification bias***

1.15 The RSC shall take care to avoid identification bias, often called the “rule of rescue”<sup>5,6</sup>. This can be described as the imperative people feel to rescue identifiable individuals facing avoidable death or a preference for identifiable over statistical lives. 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 HSC treatment options available for a particular condition is unlikely, of itself, to be sufficient to demonstrate exceptional clinical 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 clinical circumstances.

### **INFORMATION SUBMITTED TO THE RSC**

1.16 It is the hospital consultant’s responsibility to ensure that the appropriate information is provided to the RSC 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 hospital consultant will bear responsibility for any delay that this causes. In all instances the lead treating hospital consultant must state whether or not they consider there are similar patients, and if so, how many such patients there are.

1.17 All clinical teams submitting IFR requests must be aware that information that is immaterial to the decision will not be considered by the RSC. This may include

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<sup>5</sup> McKie J, Richardson J. The rule of rescue. Soc Sci Med. 2003 Jun; 56(12):2407-19.

<sup>6</sup><https://www.nice.org.uk/news/feature/what-social-values-should-nice-consider-when-balancing-fairness-with-efficiency>



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**

1.18 The RSC may approve requests for funding treatment for individual patients where all the following conditions are met:

- One of the conditions set out in section 1.2 is met.
- Exceptional clinical circumstances apply and there is sufficient evidence to show that, for the individual patient, the proposed treatment is likely to be clinically effective.
- The HSC can afford the treatment where the costs of that treatment are justifiable.
- Where the cost of the drug therapy is less than the threshold of £150,000.<sup>7</sup> Should the request exceed the threshold, the RSC must clarify the funding position with the commissioner before a decision is made.

1.19 The RSC is not required to accept the views expressed on the IFR application form 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 RSC has about the likelihood of the proposed treatment delivering the proposed clinical outcomes for the individual patient.

1.20 Where time permits the RSC shall be entitled, but not obliged, to commission further information from any duly qualified or experienced hospital consultant, medical scientist or other person having relevant skills. Reference to nationally recognised evidence syntheses should be used where they address the specific issues under consideration.

1.21 The RSC may make such approval contingent on the fulfilment of such conditions as it considers fit.

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<sup>7</sup> Further guidance is provided in Appendix A, Section 1 '*The concept of a cohort of similar patients.*'

1.22 Very occasionally an IFR presents a new issue which needs a substantial piece of work before the RSC can reach a conclusion upon its position. This may include wide consultation. Where this occurs the RSC may adjourn a decision on an individual case until that work has been completed.

## **APPEALING A DECISION**

1.23 Where the RSC has declined to recommend a requested treatment, or has approved the treatment subject to conditions, the referring hospital consultant shall be entitled to ask that the decision of the RSC be reviewed as part of an appeal process. The hospital consultant must explain his or her reasons for considering that the decision taken by the RSC was either:

- procedurally improper;

AND/OR

- in his/her opinion a decision which no reasonable RSC could have reached.

Any such review will be considered by the IFR Appeals Panel.

1.24 The IFR Appeals Panel is part of the HSCB's corporate governance process. The role of the IFR Appeals Panel is to determine whether the RSC has followed the procedures, has properly considered the evidence presented to it and has come to a reasonable decision upon the evidence.

1.25 The IFR Appeals Panel shall consider whether:

- The process followed by the RSC was consistent with the operational policy.
- The decision reached by the RSC:
  - i. was taken following a process which was consistent with the policy;
  - ii. had taken into account and weighed all the relevant evidence;
  - iii. had not taken into account irrelevant factors outwith the policy;
  - iv. indicated that the panel acted impartially and within their competence;<sup>8</sup>
  - v. was a decision which a reasonable RSC was entitled to reach.

1.26 In the event that the IFR Appeals Panel consider that there was any procedural error in the decision of the RSC, the IFR Appeals Panel shall next consider whether there was any reasonable prospect that the RSC may have come to a

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<sup>8</sup> 'Acting impartially', in this instance, means that RSC panel members had either no conflict of interest, or had declared any conflict of interest prior to the decision being made.

different decision if the RSC had not made the procedural error identified by the IFR Appeals Panel.

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

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

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

## Appendix A: Guidance notes

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 made on grounds of exceptional clinical circumstance where there are commissioning arrangements in place;
3. Is made on grounds of rarity and no commissioning arrangements exist;
4. Is made for a new intervention or for use of an intervention for a new indication, where no commissioning arrangements exist

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 and/or mandatory National Institute of Health and Clinical Excellence (NICE) technology appraisal guidance.

The UK Faculty of Public Health has published a statement describing the concept of exceptionality<sup>9</sup>:

*“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.”*

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<sup>9</sup> Faculty of Public Health. FPH Position Statement. Describing exceptionality for funding panels. 2012. Available from: [http://www.fph.org.uk/policy\\_reports](http://www.fph.org.uk/policy_reports). Accessed 11/12/12.

## 1. SERVICE DEVELOPMENTS AND COHORTS OF SIMILAR PATIENTS

A service development is any aspect of healthcare which the HSCB 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 HSCB 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 service. 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;

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 HSCB 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 HSCB 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 clinical circumstances, because, unless they can be funded through disinvestment, they will have to be funded as a result of either delaying or standing down other planned developments.

It is common for hospital consultants to request an individual funding request for a patient where the request is, properly analysed, the first patient of a group of patients considered in need of 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 hospital consultants 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 HSCB 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 HSCB 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.

This IFR policy 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 HSCB 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 be 3 or more patients in the population served by the HSCB.

If the numbers of patients for whom the treatment is requested per year reaches 3 or more, the HSCB will treat this as a service development requiring a commissioning policy.

If the number of patients presenting per year is less than 3, the IFR Screening Panel will consider whether an IFR is appropriate.

If the estimated cost for an individual patient is less than £150,000 per year, funding decisions can be made through the RSC. Where the numbers of patients and costs are projected to exceed this threshold, the HSCB Specialist Services Commissioning Team will be notified.

Total annual expenditure for all IFRs should not exceed £8m. If costs are projected to exceed this, the HSCB will notify the Department as early as possible. This will be kept under review.

## 2. EXCEPTIONAL CLINICAL CIRCUMSTANCES

### 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 RSC should bear in mind that whilst everyone's individual circumstances are, by definition, unique, only a small proportion of 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?

- It may be possible to demonstrate exceptional clinical circumstances where the patient has a medical condition or circumstance which is so rare that the result of the HSCB prioritisation process provides no established treatment care pathway for that condition.
- If a patient has a condition for which there is an established care pathway, the RSC 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 the panel could find that a patient has exceptional clinical circumstances.
- 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 clinical circumstance. For example:
  - i. 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 has exceptional clinical circumstances.

- ii. If the usual treatment cannot be given because of a pre-existing co-morbidity which could not in itself be described as an exceptional clinical circumstance 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 demonstrate the patient has exceptional clinical circumstances.

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, cost-effectiveness, priority and affordability) to make a change to the policy adopted by the HSCB 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 HSCB policy in place that describes the availability of the requested intervention and the 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 HSCB 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. Across the population of patients who make such applications, the HSCB is unable to make an objective assessment of material put before it relating to nonclinical factors. This makes it very difficult for the IFR Screening 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 HSCB 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 HSCB/RSC 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 HSCB 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 HSCB has not, therefore, been mandated to distribute resources based on these divisions within society. Such a decision would also set a precedent for the HSCB 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.

The HSC 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.

The HSC 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 HSCB is that it should continue to apply these principles in individual applications for funding approval. The HSCB 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 principle that non-clinical factors, including social value judgements about the underlying medical condition or the patient's circumstances, are not relevant.

Hospital consultants are asked to bear this policy in mind and not refer to non-clinical factors to support the application for individual funding.

### **Proving the case that the patient has exceptional clinical circumstances**

The onus is on the clinical applicant to set out the grounds clearly for the RSC on which it is said that this patient has exceptional clinical circumstances and is likely to benefit

from the proposed treatment more than other patients with the same clinical condition at the same stage of disease.

These grounds must be set out on the IFR application form and should clearly set out any factors which the hospital consultant invites the RSC 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 hospital consultant 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 RSC can do no other than refuse the application. The RSC recognises that the patient's referring hospital consultant 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 hospital consultant 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 hospital consultants of that specialty. The HSCB and RSC therefore require the referring hospital consultant, as part of their duty of care to the patient, to explain why the patient's clinical circumstances are said to be exceptional.

There is no requirement for the RSC to carry out its own investigations about the patient's clinical circumstances in order to find a ground upon which the patient may be considered 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 exceptional clinical circumstance is not made out by the paperwork placed before the RSC, the panel would be entitled to turn down the application.

### **Multiple claimed grounds of exceptional clinical circumstance**

There may be cases where hospital consultants seek to rely on multiple grounds to show their case is clinically exceptional. In such cases the panel should look at each factor individually to determine: (a) whether the factor was capable of making the case an exceptional clinical circumstance; and, (b) whether it did in fact make the patient's case an exceptional clinical circumstance. The panel may conclude, for example, that a factor was incapable of supporting a case of exceptional clinical circumstance and should therefore be ignored. That is a judgment within the discretion of the RSC panel.

If the RSC 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 exceptional clinical circumstances. 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 exceptional clinical circumstance where the patient has a medical condition or clinical circumstance which is so infrequent /unpredictable that the result of the HSCB prioritisation process provides no established treatment care pathway for that patient.

### **3. RARITY**

#### ***Assessment of requests to fund existing treatments outwith licensed clinical indications for patients with rare clinical circumstances***

The assessment of these funding requests should be distinguished from requests on the grounds of exceptional clinical circumstance. 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 hospital consultant wishes to use an existing treatment outwith its licensed indication. 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 clinical trial involving sufficient patients formally to evaluate the proposed treatment.

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.3, the case can be considered by the RSC. 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. CLINICALLY CRITICALLY URGENT TREATMENT OUTSIDE ESTABLISHED POLICY**

It is recognised that on occasion there will be a need to manage funding requests for designated, specialised treatments that are considered by the referring hospital consultant as potentially clinically critically urgent where the following criteria apply:

- There is no HSCB clinical commissioning policy or agreed interim commissioning position defined through a published policy statement;
- There is no endorsed NICE Technology Appraisal for the treatment and indication;
- The patient represents a cohort of patients with the same condition at the same stage of the disease;
- The treatment is clinically critically urgent because the patient is at risk of imminent significant and irreversible clinical deterioration (life threatening or major loss of function);
- The evidence for the use of the treatment must be convincing and likely cost-effectiveness well within the usual thresholds.

Hospital consultants who are responsible for the care of a patient presenting as clinically critically urgent who are at risk of imminent significant and irreversible clinical deterioration (life threatening or major loss of function), and who believe that an intervention not routinely commissioned would be effective and cost effective may request consideration of a proposed intervention through the IFR process.

The IFR policy will initially apply, but where a request is declined as an IFR because the patient is representative of a cohort and therefore an IFR is not appropriate **and** the request meets **all** of the above criteria, an application may proceed under the following arrangements. Although no longer considered as an IFR, such requests will be considered using the IFR governance infrastructure, although the basis of the decision will be different.

Decisions whether, or not, to treat in clinically urgent situations must be made in a timely manner. Therefore the process for clinically urgent requests will need to consider whether the treatment is effective, and likely to be commissioned in the next commissioning round or via an in-year service development. In this situation the decision-makers may arrive at an interim position allowing the treatment to be initiated for this patient (and for others who are brought to the attention of the RSC in the same clinical circumstances).

However because this clinically urgent request process cannot be as comprehensive in approach as regular clinical commissioning policy development processes so that a rapid decision may be reached, the strength of the evidence base must be convincing and likely to be cost-effective well within usual thresholds. This recognises the increased likelihood of over-estimating the clinical effectiveness of treatment when the research evidence base is under-developed or cannot be subject to detailed scrutiny, and the risk of diverting resources away from more cost-effective health care for other patients.

All requests for funding interventions that may be clinically urgent should be submitted as an IFR application by the referring hospital consultant with a clear indication of the degree of urgency and the reasons for this urgency. The clinically critically urgent nature of the situation does not justify the submission of sparse information to the RSC, indeed the referring hospital consultant should submit detailed supporting information at application or as soon as possible thereafter. The referring hospital consultant should indicate the degree of urgency and a timescale for decision.

The IFR application that has been presented as urgent should be assessed against the criteria set out above by the IFR Screening Panel. Where the criteria are met the IFR Screening Panel should undertake the following steps from the information presented to the RSC:

- Ascertain with the referring hospital consultant whether the application is clinically critically urgent: the patient is at risk of imminent significant and irreversible clinical (life threatening or major loss of function) deterioration within the next 4 months. The expected timeframe of the deterioration should be stated;
- Advise the referring hospital consultant the application has now been directed into the clinical commissioning policy process and may be considered as an in-year service development proposal or into the routine policy development programme;
- Advise the referring hospital consultant of the likely timescales when these are known;
- If not already provided, require the referring hospital consultant to seek a second, independent opinion from another HSC professional with equivalent or higher specialty expertise. This should be an opinion on the clinical effectiveness of the requested treatment at the stage of the condition in the patient's care pathway. Opinion on alternative treatments or interventions should be obtained as part of the advice. It should not require a second physical assessment of the patient though it may require the sharing of existing clinical test results.
- Advise the referring hospital consultant that the IFR process will assess the application using similar criteria as for in-year service development policy, i.e. an interim commissioning position:
  - What is the quality and quantity of evidence in support of the treatment? The HSCB, as commissioner, and the RSC will expect to be presented with a substantial body of good quality evidence before agreeing to change policy to commission a treatment in-year. Experimental treatments will not be supported.

- What are the proven benefits of the treatment? The proven benefits must be substantial in that the treatment is likely to resolve the clinically urgent issue.
- What is the overall net cost of the proposed intervention and does it represent good value for money? And again The intervention must demonstrate a high probability of being cost-effective well within usual thresholds used by the HSCB.
- How many patients are likely to be treated and what will the part-year effect of funding be? The likely expenditure must be justifiable having regard to the clinically urgent criteria set out above and the likely impact to the overall budget for specialised commissioning.

An interim commissioning position to commission the service in-year (until a definitive decision is reached through the in-year service development process or annual prioritisation round) will not be approved unless the HSCB can reach a clear conclusion that the following tests are satisfied: the proposed service development is both supported by strong sufficient evidence that is clinically effective and cost-effective well with usual thresholds.

Having considered the above and any other relevant factor the RSC can either:

- Give approval, creating an interim commissioning position, and forward the potential service development for consideration through the service development process;

OR

- Decline to approve, creating an interim commissioning position, and forward for consideration through the service development process in the same way as other IFR requests for cohorts.

The interim commissioning position (whether to fund [recommend] or not) applies only until the service/intervention has been considered through the in-year service development process or annual prioritisation process. Patients who have treatment initiated through an interim commissioning position that is subsequently changed through the policy development and prioritisation process may complete their current episode of treatment if they and their hospital consultant believe it is appropriate to do so.

## 5. 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

HSC organisations should make decisions rationally following proper consideration of the evidence and be clear about the reasons for their decisions.

The purpose of giving 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 reasons<sup>10</sup>:

*“(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.*

Where a public body gives reasons for its decision these reasons ought to be proper, adequate, and intelligible and enable the person affected to know why the decision has been made. These can be expressed in a few sentences but they need to have sufficient detail so that the patient knows that the main aspects of his case have been properly considered.

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<sup>10</sup> See Flannery v Halifax Estate Agents [200] 1 WLR 377 at 381.

To ensure that reasons given for an IFR decision are appropriate, the RSC ought to ensure that the decision document (which will usually be the letter to the patient or their hospital consultant) explains both the decisions that the RSC reached on each element and states a précis as to why the panel reached that decision.

### **General advice on giving reasons**

Whether the RSC has or has not given reasons will 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 RSC.

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 referring clinician put forward specific factors which were said to support his or her claim to be 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 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.



## Appendix B: Documents which have informed this policy

- The NHS CB Interim Commissioning Policy: Individual funding requests, April 2013, <https://www.england.nhs.uk/commissioning/wp-content/uploads/sites/12/2016/08/cp-03.pdf>
- The NHS CB Commissioning Policy (reference): Ethical Framework to underpin priority setting and resource allocation <https://www.england.nhs.uk/wp-content/uploads/2013/04/cp-01.pdf>
- McKie J, Richardson J. The rule of rescue. Soc Sci Med. 2003 Jun; 56(12):2407-19.
- <https://www.nice.org.uk/news/feature/what-social-values-should-nice-consider-when-balancing-fairness-with-efficiency>
- Faculty of Public Health. FPH Position Statement. Describing exceptionalality for funding panels. 2012. Available from: [http://www.fph.org.uk/policy\\_reports](http://www.fph.org.uk/policy_reports). Accessed 11/12/12.

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January 2017