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INDIVIDUAL FUNDING REQUEST-DRUGS PANEL COMMISSIONING POLICY

DOCUMENT CONTROL SHEET

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What is it for?	To ensure that decision making in respect of Individual Funding Requests is consistent across Norfolk and Waveney.
Evidence base	
Who is it aimed at and which settings?	This policy outlines the conditions and the criteria which are used for decision making when considering IFR requests and applies to any person for those procedures for whom NWICB is the responsible commissioner for NHS care.
Consultation	
Impact Assessment:	
Other relevant approved documents	
References:	Equality Act 2010 Health and Social Care Act 2012 NHS Constitution Human Rights Act 1998 [1] http://www.legislation.gov.uk/ukpga/2012/7/contents/enacted [1] http://www.legislation.gov.uk/ukpga/2010/15/contents [1] https://www.gov.uk/government/publications/the-nhs-constitution-for-england [1] http://www.legislation.gov.uk/ukpga/1998/42/contents [1] www.fph.org.uk/policy-reports
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Version control

Revision Date	Summary of Changes	Author(s)	Version Number
30.12.22	References to CCG changed to ICB and up to date logos added.	Jackie Cotton	V4
15.05.23	Details around threshold of delegated responsibility for funding added to P11 – 4th bullet point.	Jackie Cotton	V5

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1 EQUALITY AND DIVERSITY IMPACT ASSESSMENT

In reviewing this document, as a minimum, the following questions where considered:

- Are the aims of this document clear?
- Are responsibilities clearly identified?
- Has the document been reviewed to ascertain any potential discrimination?
- Are there any specific groups impacted upon?
- Is this impact positive or negative?
- Could any impact constitute unlawful discrimination?
- Are communication proposals adequate?
- Does training need to be given? If so, is this planned?

Adverse impact has been considered for age, disability, gender, race/ethnic origin, religion/belief/sexual orientation. The ICB have satisfied themselves that the document is non-discriminatory. Please also see detailed Equality Impact Assessment (EIA).

2 PURPOSE OF THE POLICY

NHS Norfolk & Waveney ICB (hereafter referred to as the ICB) wishes to operate a across the NHS Norfolk and Waveney area. For that purpose, the ICB has agreed to operate two individual policies and to work within two IFR Panels, one for non-drug requests and one for drug requests.

The ICB will appoint a chair for each IFR Panel and will ensure that there is clinical representation at each IFR Panel meeting. The voting ICB representatives will have delegated authority to make decisions on behalf of the ICB.

The ICB remains accountable for its own decisions made in respect of IFRs in line with the legal duties of ICBs set out in The Health and Social Care Act 2012[i].

The IFR-Drugs Panel will be administered by the ICB Medicines Optimisation Team. Norfolk County Council (NCC) will provide Public Health advice as part of the Core Offer to the ICB. The ICB may leave the arrangement by giving 3 month's written notice.

The policy will be reviewed every three years or sooner at the request of the Chair & Chief Executive.

This policy outlines these conditions and the criteria which are used for decision making when considering IFR requests and applies to any person for those procedures for whom the ICB is the responsible commissioner for NHS care.

The ICB has a duty to have regard to the need to reduce health inequalities in access to health services and health outcomes achieved as outlined in the Health and Social Care Act 2012.The ICB is committed to ensuring equality of access and non-discrimination, irrespective of age, gender, disability (including learning disability), marriage and civil partnership, pregnancy and maternity, race, religion or belief or sexual orientation. In carrying out its functions, the ICB will have due regard of the Equality Act 2010[ii], the NHS Constitution[iii] and the Human Rights Act1998[iv].

3 SCOPE

This policy applies to any patient for whom the NHS Norfolk and Waveney ICB is the Responsible Commissioner for that person or needs medical treatment where the ICB is the responsible Commissioner for the provision of that medical treatment as part of NHS care

Clinicians, on behalf of their patients, are entitled to make a request (an "individual funding request") to the IFR Panel for treatment to be funded by the ICB that is not normally commissioned by the ICB under defined conditions namely:

- The request does not constitute a service development
  AND
- The patient is suffering from a medical condition for which the ICB has a policy but where the patient's particular clinical circumstances falls outside the criteria set out in the existing commissioning policy for funding the requested treatment. – a request for exceptional funding

OR

- The patient is suffering from a medical condition, or requesting a treatment, for which the NHS Norfolk and Waveney ICB has no policy - a request for individual funding

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 decisions will be reported to the referring clinician for communication with the patient.

The ICB IFR-Drugs Panel cannot consider any request for indications or therapies commissioned by NHS England (See NHS England 'The Manual' for a list of the prescribed specialised services https://www.england.nhs.uk/commissioning/spec-services/key-docs/

Applications should be made direct to NHS England.

4 SCREENING INDIVIDUAL FUNDING REQUESTS

4.1 Screening for service developments

All individual funding requests submitted to the ICB will be subject to screening 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 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.

4.2 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.

4.3 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.

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

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

The numbers of patients to the IFR-Drugs Panel for whom the treatment will be requested per year is likely to be 2 or more patients in the population served by the Norfolk & Waveney ICB. Upon receipt of the second or third request for funding a business case/clinical commissioning policy will be requested. (The IFR-Drugs Panel will continue to have the right to make decisions on any further similar applications for funding whilst a policy is in the process of being produced, but it should be noted that the time limit on the production of the policy should not be open ended.)

OR

The cost of funding the requested treatment for an individual is likely to result in considerable expenditure to the ICB.

If the numbers of patients for whom the treatment is requested is likely to be below 2 per year the IFR-Drugs Panel will consider the request for funding. Where the numbers of patients are likely to be 2 or (or more) or the costs are likely to be considerable the ICB will be notified.

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

Where an IFR has been classified as a service development for a cohort of patients, the options open to the IFR-Drugs Panel include:

- 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 ICB 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

4.5 Screening for incomplete submissions

If a request is not categorised as a service development, it will be subject to a screening process 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-Drugs 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 to enable this request to proceed. The request can be resubmitted at any point.

4.6 Screening to assess whether the request raises a case which ought to go to the IFR-Drugs Panel

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-Drugs Panel unless there is no reasonable prospect that the IFR-Drugs Panel (applying the tests set out in this policy) will approve the request

5 ASSESSMENT OF IFRS WHICH HAVE PASSED SCREENING

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

An exceptionality request can be made in relation to a medical condition where the ICB has a Commissioning Policy or has a positive NICE TA recommendation but the patient's clinical circumstances or the requested treatment falls outside the ICB Policy. These exceptionality requests should be completed by the clinician with reference to the relevant generic and/or treatment specific commissioning policy.

The IFR-Drugs 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-Drugs Panel will act as follows:

- The IFR-Drugs 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-Drugs 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 IFR-Drugs Panel shall seek to make decisions in accordance with the NHS ethical framework & principles, 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 IFR-Drugs Panel shall seek to make decisions in accordance with the 1998 Human Rights Act
- The IFR-Drugs Panel will not make recommendations for treatments available to individual patients, or other clinically similar patients, on the basis of non-clinical factors.
- The IFR-Drugs Panel shall have discretion to determine whether the proposed treatment is a justifiable expenditure for the ICB. The IFR-Drugs 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.
This patient group represents a distinct group of exceptions and so are assessed in line with the ICB commissioning policy on experimental and unproven treatments.

In the absence of such a policy, the IFR-Drugs Panel shall be entitled to approve funding an experimental treatment for patients with rare clinical conditions or clinical circumstances.

In considering whether or not to agree to fund the treatment the IFR-Drugs 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-Drugs panel should consider whether or not the request is a service development or trial

Identification bias
The IFR-Drugs 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[1].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 the same presenting medical condition at this stage are, to a greater or lesser extent, refractory to existing treatments is unlikely, of itself, to be sufficient to demonstrate exceptional circumstances.

6 INFORMATION SUBMITTED TO THE IFR-DRUGS PANEL

All applications must be accompanied by written support and evidence provided by the clinical team treating the patient in line with the ICB Procedure for the Management of Individual Funding Requests. It is the clinician's responsibility to ensure that the appropriate information is provided to the ICB 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.

[1] McKie J. Richardson J. The rule of Rescue *Soc.Sci.Med.* 2003 June:56(12) 2407-19

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.

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.

An electronic request form must be completed by the referring clinician. The request forms are available on the Knowledge Anglia website or email norfolkicd@nhs.net

Requests for patients covered by NHS England's responsibilities should be sent directly to NHS England. If such requests are sent to the address above, the requesting clinician will be informed that they will need to submit a request to NHS England via england.ifr@nhs.net

It is not within the IFR-Drugs Panel's remit to consider applications which have been refused by NHS England.

If further information is required to prepare the case for consideration by the IFR-Drugs Panel this may delay presentation to the IFR-Drugs Panel. All required information from the provider hospital trust/clinician must be sent to the IFR-Drugs Panel Administrator at least 10 working days before the scheduled date of the IFR-Drugs Panel at which the case is to be considered.

All applications must be accompanied by written support and evidence provided by the clinical team treating the patient explaining:

- Whether the request for funding is an individual request or an exceptional request.
- The clinical circumstance of the patient. The Clinical Team is required to present a full report to the IFR-Drugs Panel which sets out a comprehensive and balanced clinical picture of the history and present state of the patient's medical condition, the nature of the treatment requested and the anticipated benefits of the treatment.
- The planned treatment and the expected benefits and risks of treatment. The Clinical Team shall describe the anticipated clinical outcomes for the individual patient of the proposed treatment and the degree of confidence of the Clinical Team that the outcomes will be delivered for this particular patient.
- The evidence on which the clinical opinion is based. The clinician shall refer to, and include, copies of any clinical research material which supports, questions or undermines the case that is being made that the treatment is likely to be clinically effective in the case of the individual patient.
- The costs of treatment. The Clinical Team shall set out the full attributable costs of and connected to the treatment. The IFR-Drugs Panel shall be entitled but not obliged to commission its own reports from any duly qualified or experienced clinician or other duly qualified person concerning the full attributable costs of and connected to the treatment.
- Whether or not there are likely to be similar patients either within the NHS Norfolk and Waveney ICB area or across the region. For exceptionality requests the clinician must also provide the case for treating this patient and no other apparently similar patients.

7 APPROVAL OF INDIVIDUAL FUNDING REQUESTS

The IFR-Drugs 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 the section "Screening for Service Developments" (page 7), the IFR-Drugs Panel is satisfied that there is no cohort of similar patients. If there is a cohort of similar patients the IFR-Drugs 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 under the section "The Policy" (page 5) 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 ICB can afford the treatment. **The Chair of the IFR Panel has delegated responsibility to approve funding requests up to a maximum of £50,000 per annum, after approval by the IFR Panel. Responsibility for approving requests for funding over £50,000 per annum has been delegated to the Chief Executive Officer or Executive Director of Finance after approval by the IFR Panel.**

The IFR-Drugs Panel is not required to accept the views expressed by the patient or the clinical team concerning the likely outcomes for the individual patient of the proposed treatment, but it 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-Drugs Panel has about the likelihood of the proposed treatment delivering the proposed clinical outcomes for the individual patient.

The IFR-Drugs 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.

The IFR-Drugs Panel may make such approval contingent on the fulfilment of such conditions as it considers fit.

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

8 COMMUNICATION OF DECISIONS

The referring clinician making the request will be informed of the IFR-Drugs Panel's decision as soon as practicable via email and/or by letter within 10 working days (in practice this is likely to be sooner.) Patient confidentiality will be maintained at all times.

All decisions will be sent to the referring clinician for communication to the patient,

9 REVIEW OF THE DECISION

Where the IFR-Drugs 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-Drugs Panel be reviewed. All requests for a review must be supported by the senior treating clinician in writing to the Chair of the IFR-Drugs Panel and copied to the IFR-Drugs Panel

Administrator within 30 working days (i.e. 6 weeks) of the date of the IFR-Drugs Panel's decision. The clinician must clearly outline the reasons as to why the decision taken by the IFR-Drugs panel was:

- procedurally improper and/or
- that it misunderstood the medical evidence and/or
- was in the clinician's opinion a decision which no reasonable IFR panel would have reached.

The IFR-Drugs Panel Chair will consider the clinician's request and refer the case to the IFR-Drugs Panel Administrator within 15 working days. The IFR-Drugs Panel Administrator will then notify the NHS Norfolk and Waveney ICB and arrange for an IFR Review Panel to be set up. The IFR Review Panel for IFR-Drugs Panel applications will be the Non-Drugs Panel. The IFR Review Panel will reach a decision within 30 working days of the IFR-Drugs Panel Administrator referring the case back to the ICB. The IFR Review Panel will set out its decision and the reasons for it as soon as practicable in writing via e-mail or letter to both the IFR-Drugs Panel and the referring clinician. It is the responsibility of the referring clinician to notify the patient in a timely manner of the IFR Review Panel decision

In any case where further relevant information becomes available which has not been considered by the IFR-Drugs Panel, the referring clinician may ask the IFR-Drugs Panel to reconsider the case specifically in the light of this further information

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

The IFR Review Panel shall consider whether:

- The process followed by the IFR-Drugs Panel was consistent with the operational policy of the ICB
- The decision reached by the IFR-Drugs Panel:
    - was taken following a process which was consistent with the policies of the ICB
    - 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.

If the IFR Review Panel considers that there was no reasonable prospect of the IFR-Drugs 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-Drugs Panel may have come to a different decision if the IFR-Drugs Panel had not made the procedural error, the IFR Review Panel shall require the IFR-Drugs 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-Drugs Panel and/or to request one of the Officers authorised to take urgent decisions to consider exercising that power.

Should the referring clinician or patient remain dissatisfied with the IFR Review Panel decision, either of them may pursue the matter through the NHS Complaints Procedure.

10 CO-OPERATION OF PROVIDER TRUSTS

The ICB requires provider trusts and clinicians to take the ICB commissioning policies into account in the advice and guidance given to patients prior to making the decision to treat a patient. The ICB expects the management of its provider trusts to have oversight of this process. The ICB 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 unassessed and refer recurrent inappropriate funding requests to the Chief Executive of the relevant provider trust.

11 URGENT TREATMENT DECISIONS

The ICB 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 ICB's normal policies. In such circumstances the ICB 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-Drugs 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 ICB 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 ICB not to be taking all reasonable steps to minimise urgent requests to the IFR process, the ICB 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 in the ICB Standard Operational Procedures (SOP) for the Management of Individual Funding Requests.
- Where an urgent decision needs to be made to authorise treatment for an individual patient outside the ICB's normal policies, the decision will be made by an individual authorised to do so by the ICB (the Authorised Senior Health Professional – "ASHP"). The ICB AO or deputy will be contacted in such cases and asked to nominate an ASHP.
- The ASHP or the extraordinary IFR Panel (as described in the ICB'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 ASHP 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 ASHP and the IFR-Drugs 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 ASHP and the extraordinary IFR-Drugs 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.
- Where the ASHP considers that there is sufficient time to consult the Chair and/or members of the IFR-Drugs Panel before making an urgent decision, the ASHP shall do so and shall take any views into consideration before making a decision

- A written record must be made of any such urgent request and the decision made, and these will be reviewed and ratified by the full membership of the IFR-Drugs Panel at the next IFR-Drugs Panel meeting.
- For all urgent requests, the IFR-Drugs Panel will aim to make a decision within 10 working days of receipt of the request. Trusts should treat all urgent and life-threatening situations based on the clinical need.

PLEASE NOTE FOR REQUESTS MARKED AS URGENT A DECISION WILL BE GIVEN WITHIN 10 WORKING DAYS.

IF THE REFERRING CLINICIAN CONSIDERS THAT TREATMENT CANNOT BE DELAYED AND DECIDES TO TREAT IMMEDIATELY THEN THE COST OF SUCH TREATMENT IS INCURRED AT THE RISK OF THE PROVIDER.

APPENDIX A: GUIDANCE NOTES

The UK Faculty of Public Health has published a statement describing the concept of exceptionality[v]:

"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:

- Represents a service development for a cohort of patients
- Is on grounds of clinical exceptionality where there are commissioning arrangements in place
- Is on grounds of rarity and no commissioning arrangements exist
- Is for a new intervention or for use of an intervention for a new indication, where no commissioning arrangements exist

SERVICE DEVELOPMENTS AND COHORTS OF SIMILAR PATIENTS

Service Developments

A service development is any aspect of healthcare which the ICB 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 ICB 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 subgroup 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 during Horizon Scanning.

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 ICB 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 ICB 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 individual funding 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 ICB 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 ICB 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 ICB 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 ICB will consider the development of a clinical drug commissioning policy where the number of patients for whom the treatment will be requested per year is likely to be 2 or more patients in the population served by the ICB.

If the numbers of patients for whom the treatment is requested per year reaches 2 or more, the ICB will treat this as a service development requiring a commissioning policy. If the number of patients presenting per year is less than 2, the ICB will consider whether an IFR is appropriate.

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-Drugs 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?

- 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 ICB prioritisation process provides no established treatment care pathway for that treatment.
- 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 comorbidity 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 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 ICB 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 a ICB policy in place that describes the availability of the requested intervention and the patient (or their clinician 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

The ICB does not discriminate on grounds of social factors (for example, but not limited to: age, gender, ethnicity, employment status, parental status, marital status, religious/cultural factors). Social factors will not be taken into account in determining whether exceptionality has been established.

The ICB does not generally make treatment for patients under its policies dependent on the patient's social or personal circumstances. Accordingly, when making decisions as to whether treatment should be provided to a patient which is not provided to patients generally, the IFR-Drugs Panel shall adopt the same approach.

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 ICB understands 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 ICB:

- The ICB 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 ICB has not, therefore, been mandated to distribute resources based on these divisions within society. Such a decision would also set a precedent for the ICB 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.
- Across the population of patients who make such applications, the ICB 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 ICB 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 ICB does not know whether it is being fair to other patients who are denied such treatment and whose non-clinical factors are entirely unknown.

Generally, the NHS does not take into account non-clinical factors in deciding which 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 enquire 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 ICB is that it should continue to apply these principles in individual applications for funding approval. The ICB will therefore seek to commission treatment based on the presenting clinical condition of the patient and not based on the patient's nonclinical 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 ICB 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 ICB 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 ICB 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-Drugs 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 or unpredictable that the result of the ICB prioritisation process provides no established treatment care pathway for
that patient

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 are below the agreed threshold figure, the case can be considered by the ICB IFR-Drugs 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.

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.

FUNDING FOR CASES FOLLOWING A CLINICAL TRIAL

Save in the most exceptional cases, it is not anticipated that a request will be agreed under this IFR policy to fund patients at the end of a clinical trial. This is because arrangements to continue treatments from which patients have benefited during a trial should be agreed with the sponsor of the research at the outset of the trial and information should have been given to patients as part of the process of patients signing up to participate in the trial. Even if this is not the case, patients coming out of a clinical trial will almost inevitably represent a group of patients for whom a policy should be developed under the Service Development policy, because there will be a number of patients in broadly the same clinical circumstances, and so it is very unlikely that the patient will be able to show clinical exceptionality within this.

GIVING REASONS

The NHS Constitution requires NHS organisations to make decisions *'rationally following a proper consideration of the evidence'* and be clear about the reasons for their decisions. The ICB 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 the ICB 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:

"(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 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 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-Drugs Panel ought to ensure that the decision document (which will usually be the letter to the patient or their clinician or GP) goes through the tests under this policy, and explains both the decisions that the IFR-Drugs 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 ICB IFR-Drugs Panel has or has not discharged the duty to give reasons 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-Drugs 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.

DEFINITIONS

Treatment means any form of healthcare intervention which has been proposed by a clinician and is proposed to be administered as part of NHS commissioned and funded healthcare.

The IFR-Drugs Panel is the committee of ICB clinicians who have been given authority by the ICB Governing Body to make individual funding request decisions on its behalf in line with the legal duties of ICB set out in The Health & Social Care Act 2012

An individual funding request is a request received from a clinician which seeks funding for a single identified patient for a specific treatment.

Clinical circumstances mean a full history of the patient's medical condition, a full description of the patient's present medical condition and as comprehensive an assessment of the patient's future medical condition and prognosis as the Clinical Team treating the patient is able to provide.

Exceptional clinical circumstances refers to a patient who has clinical circumstances which, taken as a whole, are outside the range of clinical circumstances presented by a patient within the normal population of patients with the same medical condition and at the same stage of progression as the patient.

Biological Plausibility is a method of reasoning used to establish a cause-and-effect relationship between a biologic factor and a particular disease

Clinical Commissioning Group is a statutory organisation responsible for purchasing health and care services for patients.

Experimental and unproven treatments are medical treatments or proposed treatments where there is no established body of evidence to show that the treatments are clinically effective. The reasons may include the following:

- The treatment is still undergoing clinical trials for the indication in question.
- The evidence is not available for public scrutiny.

- The treatment does not have approval from the relevant government body.
- The treatment does not conform to an established clinical practice in the view of the majority of medical practitioners in the relevant field.
- The treatment is being used in a way other than that previously studied or for which it has been granted approval by the relevant government body.
- The treatment is rarely used, novel, uncertain or unknown and there is a lack of evidence of safety and efficacy.
- There is some evidence to support a case for clinical effectiveness but the overall quantity and quality of that evidence is such that the commissioner does not have confidence in the evidence base and/or there is too great a measure of uncertainty over whether the claims made for a treatment can be justified.

A policy refers to a written document determining whether or not a particular treatment is commissioned.

A policy variation occurs when an existing policy is changed. When there is a proposal which would result in increased access to a treatment (for example by lowering the threshold for treatment or adding a new indication for treatment) the policy variation is a service development and will be treated as such.

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[i] http://www.legislation.gov.uk/ukpga/2012/7/contents/enacted
[ii] http://www.legislation.gov.uk/ukpga/2010/15/contents
[iii] https://www.gov.uk/government/publications/the-nhs-constitution-for-england
[iv] http://www.legislation.gov.uk/ukpga/1998/42/contents
[v] www.fph.org.uk/policy-reports