Great Yarmouth and Waveney
North Norfolk, South Norfolk
Norwich, West Norfolk
Clinical Commissioning Groups

Appendix B

Individual Funding Requests (Non-Drugs)
Frequently Asked Questions & Glossary

Contents

What is a service development?

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

All individual funding requests submitted to the CCG will be subject to screening by the IFR Panel and CCG, 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.

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.

It is common for clinicians to request an individual funding request for a patient where the request is, properly analysed, the first patient of a group of patients wanting a particular treatment. 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.

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.

When should consideration of a commissioning policy be given?

The CCG 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 CCG 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 5 or more patients in the population served by Norfolk & Waveney CCGs. Upon receipt of the fifth request for funding a business case/clinical commissioning policy will be requested. (The IFR 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.)

  OR

- The cost of funding the requested treatment for an individual is likely to result in expenditure to the Norfolk & Waveney CCGs in excess of £50,000.

If the number of patients for whom the treatment is requested is likely to be below 5 per year, the IFR Panel will consider the request for funding.

The IFR Panel is not entitled to make policy decisions for the CCG. It follows that where a request has been classified as a service development for a cohort of patients, the IFR Panel is not the correct body to make a decision about funding the request. In such circumstances the individual funding request should not and will not be presented to the IFR Panel but will be dealt with in the same way as other requests for a service development through CCG due processes (the IFR Panel will continue to have the right to make decisions on further similar applications whilst a policy is in the process of being developed).

Where an IFR has been classified as a service development for a cohort of patients, the options open to the IFR 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 CCGs 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.

What is meant by exceptionality?

The UK Faculty of Public Health has published a statement describing the concept of exceptionality[1]:

"*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.

The broad types of request that may be received are;

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

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'.

To meet the definition of 'exceptional clinical circumstances' there must be a CCG 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

[1] www.fph.org.uk/policy-reports

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

What are non-clinical factors?

The CCGs do 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 CCG will seek to commission treatment based on the presenting clinical condition of the patient and not based on the patient's non-clinical circumstances.

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

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

How do you prove 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 CCG and should clearly set out any factors which the clinician invites the panel to consider as constituting a case of exceptional clinical circumstances. 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 CCG 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.

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.

What is rarity in an IFR?

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.

What is Triage?

Requests are subject to a triage 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 Panel.

All requests will be triaged prior to presenting at the IFR Panel. Triage will consider the information provided in the request against any relevant commissioning policies and make recommendations for the panel to consider. Recommendations include;

- Approved
- Declined
- Further clinical debate required at panel

Sometimes, triage will determine that more information is required to progress the request and the referred will be contacted.

What happens with IFRs which have passed triage?

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

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

- The IFR Panel will use the information provided by the requester to compare the patient to other patients with the same presenting medical condition at the same stage of progression. Specifically, the panel may consider, based upon the evidence provided to it, whether or not the patient has demonstrated exceptional clinical circumstances which lead the panel to believe that the patient would benefit significantly more from the treatment than the other patients not meeting funding criteria.

- When making their decision, the IFR Panel is required to restrict itself to considering only the patient's presenting medical condition and the likely benefits which have been demonstrated by the evidence to be likely to accrue to the patient from the proposed treatment.

- The IFR 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 Panel shall seek to make decisions in accordance with the 1998 Human Rights Act.

- The IFR Panel will not make decisions for treatments available to individual patients, or other clinically similar patients, on the basis of non-clinical factors.

The IFR 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 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
- Where the request is in respect of more than one patient or it is clear from the nature of the request that there is likely to be more than one patient, then the IFR Panel should consider whether or not the request is a service development or trial.

What information is submitted to the IFR Panel?

All applications must be accompanied by written support and evidence provided by the clinical team treating the patient. It is the clinician's responsibility to ensure that the appropriate information is provided to the CCG 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.

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 at http://nww.knowledgeanglia.nhs.uk/KMS.aspx or email nw.ifr@nhs.net.

Requests for patients covered by NHS England's responsibilities should be sent directly to them. If such requests are sent to either of the Norfolk addresses above, they will be forwarded to NHS England.

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

- Whether or not there are likely to be similar patients either within the Norfolk and Waveney CCGs or across the region. For exceptionality requests the clinician must also provide the case for treating this patient and no other apparently similar patients.

How does the IFR Panel approve requests?

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

- The IFR Panel is satisfied that there is no cohort of similar patients. If there is a cohort of similar patients the IFR Panel shall decline to make a decision because the application is required to be treated as a request for a service development. (The IFR 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.)

- The request does not constitute a service development.

- The patient is suffering from a medical condition for which the CCG has a policy but where the patient's particular clinical circumstances fall outside the criteria set out in the existing commissioning policy for funding the requested treatment.

- The patient is suffering from a medical condition, or requesting a treatment, for which the CCG has no policy.

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

- 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 IFR 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 Panel has about the likelihood of the proposed treatment delivering the proposed clinical outcomes for the individual patient.

The IFR 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 CCG can reach a conclusion upon its position. This may include wide consultation. Where this occurs the IFR Panel may adjourn a decision on an individual case until that work has been completed.

How are IFR Panel decisions communicated?

The referring clinician making the request will be informed of the IFR Panel's decision as soon as practicable via email and/or by letter within 5 working days. Patient confidentiality will be maintained at all times.

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

What happens with urgent requests?

The CCG 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 CCG's normal policies. In such circumstances the CCG recognises that an urgent decision may have to be made before a panel can be convened. The following provisions apply to such a situation.

- An urgent request is one which requires urgent consideration and a decision because the patient faces a substantial risk of death or significant harm if a decision is not made before the next scheduled meeting of the IFR Panel.

- Urgency under this policy cannot arise as the result of a failure by the Clinical Team expeditiously to seek funding through the appropriate route and/or where the patient's legitimate expectations have been raised by a commitment being given by the provider trust to provide a specific treatment to the patient. In such circumstances the CCG expects the provider trust to proceed with treatment and for the provider to fund the treatment.

- In situations of clinical urgency the decision will be made by a clinical lead delegated by the CCG to make an urgent decision as set out in the CCG Standard Operational Procedures (SOP) for the Management of Individual Funding Requests.

- The clinical lead will as far as possible within the constraints of the urgent situation, follow the policy set out above in making the decision. The clinical lead 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 clinical lead 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.

- Where the clinical lead considers that there is sufficient time to consult the Chair and/or members of the IFR 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 Panel at the next IFR Panel meeting.

- For all urgent requests, the IFR 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.

Will the IFR Panel give reasons as to why a decision has been made?

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 CCG will give reasons for its decisions.

The purpose of a duty to give reasons is to tell the patient in general terms why the CCG reached the decision it did and the factors that it took into account in reaching the decision.

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.

Whether the CCG IFR 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 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.

Can the IFR Panel decision be reviewed?

Where the IFR Panel has declined a request or has approved the treatment subject to conditions, the patient shall be entitled to ask that the decision of the IFR Panel be reviewed. All requests for a review must be supported by the senior treating clinician in writing to the IFR Administrator within 30 working days (i.e. 6 weeks) of the date of the IFR Panel's decision. The clinician must clearly outline the reasons as to why a review is requested. It will be either;

- That further evidence can be provided by the referrer and is duly submitted; and/or
- It was in the clinician's opinion a decision which no reasonable IFR Panel would have reached.

The IFR Administrator will prepare the additionally submitted evidence for discussion at the next available panel meeting. The IFR Panel will then review it's initial decision based on any additional information received. The result of the review will be communicated to the referring clinician who must then notify the patient of the panel's decision.

Should the referring clinician or patient remain dissatisfied with the IFR Panel decision, the matter may be pursued through the NHS Complaints Procedure. This can be done by contacting: or telephone: complaintservice.snccg@nhs.net 01063 595857.

Can the IFR Panel decision be appealed against?

Where all the relevant information was available to the IFR Panel when the decision was made, but the referring clinician remains dissatisfied with the decision, they may request that it be reviewed by an IFR Appeals Panel on one of the following grounds only:

a) Due process was not followed
OR
b) The IFR Panel failed to give a clear rationale for its decision

In the case of failure to follow due process or an inadequate rationale for the IFR Panel decision, the referring clinician may request an IFR Appeals Panel review by making a formal request in writing to the IFR Administrator within 30 working days (i.e. 6 weeks) of the date of the IFR Panel's decision.

The IFR Administrator will arrange for an IFR Appeals Panel to be set up. This will normally be the next available IFR Drugs Panel.

The IFR Appeals Panel will review the process followed by the IFR Panel. The IFR Appeals Panel will reach a decision within 30 working days of the IFR Administrator referring the case to them.

The role of the IFR Appeals Panel is to determine whether the IFR Panel has followed its own procedures, has properly considered the evidence presented to it and has come to a reasonable decision upon the evidence.

In the event that the IFR Appeals Panel considers that the IFR Panel has:

- Failed in a material way to follow its own procedures; and/or
- Failed in a material way properly to consider the evidence presented to it (e.g. by taking account of an immaterial fact or by failing to take account of a material fact); and/or
- Failed to give a clear rationale for its decision;

The IFR Appeals Panel shall uphold the patient's appeal and shall refer the case for reconsideration by the IFR Panel.

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 IFR Panel.

The IFR Appeals Panel will set out its decision and the reasons for it as soon as practicable in writing via e-mail or letter to the IFR Panel and the referring clinician. It is the responsibility of the referring clinician to notify the patient in a timely manner of the IFR Appeals Panel decision.

Should the referring clinician or patient remain dissatisfied with the IFR Appeals Panel decision, the matter may be pursued through the NHS Complaints Procedure. This can be done by contacting: complaintservice.snccg@nhs.net or telephone: 01063 595857.

GLOSSARY

Appeal refers to the process where the referring clinician can request that the IFR Panel decision is assessed, either on the basis that due process was not followed by the IFR Panel or that the IFR Panel failed to give a clear rationale for its decision.

Clinical circumstances means 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.

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

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.

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.

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

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

NHS Constitution refers to the established principles and values of the NHS in England.

NICE refers to the National Institute for Health & Care Excellence. They provide national guidance and advice to improve health and social care.

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

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.

Rarity refers to a patient whose medical condition is so rare or their condition is so unusual that the clinician wishes to use an existing treatment in an experimental way.

Review refers to the process where the referring clinician can request the IFR Panel decision is reviewed, either on the basis that further evidence can be provided in support of the IFR or that the decision, in the clinician's opinion, was one which no reasonable IFR Panel would have reached.

Service Development refers to any aspect of healthcare which the CCG has not historically agreed to fund and which will require additional and predictable recurrent funding.

Social factors are, for example, (but not limited to) age, gender, ethnicity, employment status, parental status, marital status, religious/cultural factors.

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.

Triage is a process to determine whether the request has sufficient clinical and other information in order for it to be fully considered by the IFR Panel.

Urgent request requires urgent consideration and a decision because the patient faces a substantial risk of death or significant harm.