NHS West Yorkshire
Integrated Care Board

Commissioning Policy: Individual Funding Requests

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Contents

Equality statement

Promoting equality and addressing health inequalities are at the heart of the West Yorkshire Integrated Care Board's (WYICB) values. Throughout the development of this policy statement, we have:

- given due regard to the need to eliminate discrimination, harassment and victimisation, to advance equality of opportunity, and to foster good relations between people who share a relevant protected characteristic (as cited under the Equality Act 2010) and those who do not share it.

- given regard to the need to reduce inequalities between patients in access to, and outcomes from healthcare services and to ensure services are provided in an integrated way where this might reduce health inequalities.

Plain language summary

Every year, the resources that the WYICB receives are allocated to the services and treatments provided for patients. The WYICB decides the treatments that it will invest in on an annual basis. As far as possible, funding is shared fairly and appropriately, considering the competing demands on the WYICB's budget. When a new service or a change to a service is proposed, it would not be fair for that to bypass the prioritisation process and be funded without comparing it to other possibilities for investment. Because of this, the WYICB's default position is that a new service will not be routinely commissioned until it has been assessed through the full service development process.

On an individual basis, there may be situations where a clinician believes that their patient's clinical situation is so different to other patients with the same condition that they should have their treatment paid for when other patients would not. In such cases, NHS clinicians can ask the WYICB, on behalf of a patient, to fund a treatment which would not usually be provided by the WYICB for that patient. This request is called an Individual Funding Request (IFR).

Funding for additional treatments outside the prioritisation process can only be done by reducing the funding that is available for other established treatments. There is no allocated separate budget to meet the costs of providing treatments agreed through the IFR process. It is because of this that very careful consideration is required before the decision is taken to fund a treatment that is not usually available for an individual.

When does this policy apply?

IFRs can be made if:

- there is a WYICB clinical commissioning policy, NICE Technology Appraisal (TA) guidance or Highly Specialised Technology (HST) Appraisal and / or other relevant mandatory / statutory guidance that governs whether to fund or not fund the treatment for the patient's condition, and a clinician can show that their patient is in a different clinical condition when compared to the typical patient population with the same condition; or

- the treatment is not normally funded and the WYICB does not have a clinical commissioning policy for the requested treatment for patients suffering from the same medical condition as the patient for which the treatment is being requested, i.e. a policy does not yet exist, and the clinician considers the patient meets the criteria in the IFR policy.

When will the WYICB consider funding in response to an IFR?

The WYICB will only provide funding in response to an IFR, if it is satisfied that the case meets the following criteria:

- There is evidence that the patient presents with exceptional clinical circumstances, that is:

    - there is a WYICB clinical commissioning policy, NICE Technology Appraisal (TA) guidance or Highly Specialised Technology (HST) Appraisal guidance and / or other relevant mandatory / statutory guidance that governs whether to fund or not fund the treatment for the patient's condition, and a clinician can show that their patient is in a different clinical condition when compared to the typical patient population with the same condition and (if relevant) at the same stage of progression, and because of that difference their patient is likely to receive material additional clinical benefit from treatment that would not be plausible for any typical patient.

OR

    - there is no relevant WYICB clinical commissioning policy, NICE Technology Appraisal (TA) guidance or Highly Specialised Technology (HST) Appraisal guidance and / or other relevant mandatory/statutory guidance in place for the management of the patient's condition or combination of conditions, and the patient’s clinical presentation is so unusual that they could not be considered to be part of a defined group of patients in the same or similar clinical circumstances for whom a service development could be undertaken.

AND

- There is a basis for considering that the requested treatment is likely to be clinically effective for this individual patient;

AND

- It is considered that the requested treatment is likely to be a good use of NHS resources.

IFRs can be made for services that the WYICB directly commissions or remains the accountable commissioner. However, if there is evidence that other patients with the same condition could derive a similar type and degree of benefit from the treatment, the request is really for a new development in services for that group of patients. This is not the role of the IFR process. In this case the clinician will need to consider proposing this treatment for development of a clinical policy or service development.

Changes in routine commissioning policies are considered through the service development route. In this way, the WYICB can be sure that the opportunities for developments for patients across a wide range of conditions can be considered in a fair and equitable way.

Individual Funding Requests policy

Overview

1. Every year, the resources that the WYICB receives are allocated to services and treatments that can be provided for patients, through development and review of commissioning policies which apply robust criteria to the question of how the services and treatments should be funded. Any additional calls on resources to fund an individual's treatment are likely to mean reducing the funding that is available elsewhere. The decision to fund a treatment that is not usually provided is only taken after very careful consideration. WYICB regards the matter of funding for an individual patient as an equity issue in which it will consider whether it can justify funding a particular patient when others from the same patient group are not being funded for the requested treatment.

2. Very occasionally, a clinician may think that their patient's clinical situation is so different to other patients with the same condition that it is appropriate that they should have different treatments to others. In such circumstances, clinicians, on behalf of their patient, may make an Individual Funding Request (IFR) to the WYICB for a treatment that is not routinely commissioned by the WYICB. IFRs may be made for any of the WYICB's directly commissioned services. This route

should only be used in exceptional circumstances and not as an alternative route to submitting a treatment for scrutiny through the service development process.

3. It is important to draw a distinction between the basis and approach in this IFR policy and process, which is part of an overall NHS prioritisation framework, and the access schemes which may be periodically offered by commercial companies or the manufacturers of treatments to introduce their products to market in cases where there may be some clinical effect. Those access schemes are a matter for their promoters and do not establish any precedent for IFR requests.

4. The WYICB IFR team will carry out an initial screening as described in the section of this policy 'Screening process for IFR requests'. If the request proceeds beyond the screening stage, decisions on whether to fund the request will be made by the WYICB IFR Panel. Details of the IFR team, IFR Panel and the processes that are followed, are set out in the WYICB IFR Standard Operating Procedures (SOP), which includes the Terms of Reference for the IFR Clinical Triage, the IFR Panel and the IFR Appeals Panel.

5. This policy explains each of the criteria outlined in turn.

Further explanation of the IFR criteria

Clinical Exceptionality

6. There can be no exhaustive description of the situations which are likely to come within the definition of exceptional clinical circumstances. The onus is on the clinician making the request to set out the grounds for clinical exceptionality clearly for the IFR Panel.

7. 'Exceptional' in IFR terms means a person to whom the general rule should not apply. This implies that there is likely to be something about their clinical situation which was not considered when formulating the general rule. Very few patients have clinical circumstances which are genuinely exceptional. To justify funding for treatment for a patient which is not available to other patients, and is not part of the established care pathway, the IFR Panel needs to be satisfied that the clinician has demonstrated that this patient's individual clinical circumstances are clearly different to those of other patients, and that because of this difference, the general policies should not be applied. Simply put, the consideration is whether it is fair to fund this patient's treatment when the treatment is not available to others. It should be stressed that an IFR is not a route to "have another look" at the general rule, or to protest that the general

rule is ungenerous.

8. Where a 'not for routine commissioning' clinical commissioning policy is in place in relation to a treatment, the WYICB will have been aware when making that policy that in most studies, some patients will respond better than others to the treatment and indeed, a small group may respond significantly better than the average. This should have been taken into account in developing the policy. Consequently, in considering whether a request for an IFR should be made, the clinician should consider whether this individual patient is likely to respond to the treatment in a way that exceeds the response of other patients in the group to which the general policy applies and whether there is evidence to support this view.

Clinical exceptionality: failure to respond to standard care

9. The fact that a patient has failed to respond to, or is unable to be provided with, all treatment options available for a particular condition (either because of a co-morbidity or because the patient cannot tolerate the side effects of the usual treatment) is unlikely, on its own, to be sufficient to demonstrate exceptional clinical circumstances. There are common co-morbidities for many conditions. Again, these considerations are likely to have been considered in formulating the general policy.

10. Many conditions are progressive and thus inevitably there will be a more severe form of the condition – severity of a patient's condition does not in itself usually indicate exceptionality. Many treatments have side effects or contraindications, and thus intolerance or contraindication of a treatment does not in itself, usually indicate exceptionality.

11. In order to support an IFR on the basis of failure to respond to standard care, the IFR Panel would normally need to be satisfied that the patient's inability to respond to, or be provided with, the usual treatment was a genuinely exceptional circumstance, which lies outside the natural history of the condition and is not characteristic of the relevant group of patients with the condition. For example:

    - If the usual treatment is only effective for a proportion of patients (even if this is a high proportion), this leaves a proportion of patients within the group for whom it is already known that the usual treatment is not available or is not clinically effective. The fact that this particular patient falls into that group is unlikely to be a proper ground on which to base a claim that they are exceptional as an individual.

    - As regards side effects, as an example, all patients who are treated with long-term high-dose steroids will develop side effects (typical and well-recognised). Developing these side effects and wishing to be treated with

something else does not make the patient exceptional.

- If the usual treatment cannot be given because of a pre-existing comorbidity which is unrelated to the condition for which the treatment is being sought under the IFR or is not unusual in the relevant patient group or generally, the fact that the comorbidity is present in this patient and its impact on treatment options for this patient is unlikely to make the patient clinically exceptional. As an illustration, some comorbidities are common in the general population, for example, diabetes which affects around 7% of adults, or asthma which affects at least 10% of the population. Diabetes and its treatments affect many other conditions; for example, steroids make glucose control more difficult. With any condition there will be a recognised proportion who also have a comorbidity which is common in the general population, therefore a patient cannot be exceptional by having a comorbidity which is common in the general population.

12. If the proposed intervention is thought to offer a benefit to patients in these groups generally (i.e. those with more severe disease or those with common comorbidities), the question is whether there is sufficient justification, including consideration of factors such as clinical effectiveness of the treatment in question, likely value for money, priority and affordability, for making a change to the clinical commissioning policy that covers the patient pathway. In this way, an improvement can be made to that policy to benefit the whole subgroup of patients of which the requesting patient is potentially just one such person. This change needs to be considered as a service development and not as an IFR.

Clinical exceptionality: severity

13. Should severity be cited by the referring clinician as part of the argument for exceptionality, the application should make clear:

- whether there is evidence that the patient's presentation lies outside the normal spectrum for that condition. Preferably, a recognised scoring or classification system should be used to describe the patient's condition

- whether there is evidence that the patient has progressed to a very severe form of the condition much more rapidly than the range of progression that is documented and usually observed within the natural history of the condition

- how the patient is expected to benefit from the treatment sought and in what quantifiable way

- that there is evidence that the impact of the condition on this patient's health is significantly greater than its impact on the rest of the patient group, e.g.

the condition is usually a mild disease but the presenting case is an extremely severe presentation; and

- that there is a plausible argument that the severity of the condition is prognostic of good response to treatment.

Clinical exceptionality: genotypes

14. When the argument for clinical exceptionality is based on the patient having a specific genotype (genetic profile), the IFR Panel will require evidence of the prevalence of the genotype in the patient group. The referring clinician will need to show how the specific genotype would make the patient;

    a) different to others in terms of clinical management and

    b) able to benefit from the treatment to a greater degree than others with the same or different symptoms of the condition.

Clinical exceptionality: multiple grounds

15. There may be cases where clinicians seek to rely on multiple factors to show that their case is clinically exceptional. In such cases each factor will be looked at individually to determine (a) whether the factor is capable, potentially, of making the case exceptional and (b) whether it does in fact make the patient's case exceptional. One factor may be incapable of supporting a case of exceptionality (and should therefore be ignored), but that factor might be relevant to / in conjunction with another factor (see also paragraph 17). That is a judgment within the discretion of the IFR Clinical Triage and the IFR Panel.

16. If it is determined that none of the individual factors on their own mean that the patient's clinical circumstances are considered exceptional, the combined effect of those factors as a whole will be considered. In this way a decision can be reached on whether the patient's clinical circumstances are exceptional, bearing in mind the difference between the range of factors that can always be found between individuals and the definitions used here of exceptional clinical circumstances.

Clinical exceptionality: non-clinical and social factors

17. The IFR process only considers clinical information. Although initially it may seem reasonable to fund treatment based on reasons grounded in a moral or compassionate view of the case or because of the individual's situation, background, ambition in life, occupation or family circumstances, these reasons bring into play a judgement of 'worthiness' for treatment. As a central principle, the NHS does not make judgements about the worth of different individuals and seeks to treat everyone fairly and equitably. Consideration of these non-clinical factors would introduce this concept of 'worth' into clinical decision making. It is a core value that NHS care is available or unavailable, equally to all. Whilst everyone's individual circumstances are, by definition, unique and on compassionate grounds, reasons can always be advanced to support a case for funding, it is likely that the same or similar arguments could be made for all or many of the patients who cannot routinely access the care requested.

18. Non-clinical and social factors have to be disregarded for this purpose in order for the IFR Clinical Triage and then the IFR Panel, to be confident of dealing in a fair manner in comparable cases. If these factors were to be included in the decision-making process, the WYICB would not know whether it is being fair to other patients who cannot access such treatment and whose non-clinical and social factors would be the same or similar.

19. Consideration of social factors would also be contrary to the NHS approach to non-discrimination in the provision of medical treatment. If, for example, treatment was to be provided on the grounds that this would enable an individual to stay in paid work, this would potentially discriminate in favour of those working compared to those not working. These are value judgements which the IFR Clinical Triage and the IFR Panel should not make.

20. Clinicians are asked to bear this policy in mind and not to refer to social or non-clinical factors to seek to support the application for individual funding. In order to avoid prejudicing the IFR process, such material will be edited out or applications returned to clinicians for editing by the IFR team and on recommendation by the Clinical Triage.

Clinical effectiveness

21. Clinical effectiveness is a measure of the extent to which a treatment achieves pre-defined clinical outcomes in a specific group of patients.

22. Clinical evidence that considers the efficacy of a particular treatment will be carefully considered by the IFR Clinical Triage and IFR Panel. It is the sole responsibility of the referring clinician to provide this information and the IFR team will not be responsible for undertaking any evidence searches. Inevitably, the evidence base put forward in support of an IFR is unlikely to be as robust as in more common presentations of the condition or the more usual use of the treatment. However, it is important that the referring clinician makes explicit linkages between the grounds under which exceptionality is claimed and the sections of the submitted research literature that are considered to support the clinician's view regarding the differences between the patient's clinical position and that of other patients in the group, and regarding the patient's anticipated response to the requested treatment.

23. When considering clinical effectiveness, the IFR Panel will consider:

- how closely the patient matches the patient population from whom the results are derived in any study relied on by the clinician
- the plausibility of the argument that the patient will achieve the anticipated outcomes from treatment, based on the evidence supplied
- the impact of existing comorbidities on both the claim for exceptionality and treatment outcome
- any complications and adverse events of the treatment including toxicity and rates of relapse. The Panel will take account of side effects when considering the benefits from the treatment
- the likely impact of the treatment on quality of life using any available information
- reported treatment outcomes and their durability over the short, medium and longer term, as relevant to the nature of the condition. The requesting clinician must demonstrate why they consider that the proposed treatment will be effective for the whole period for which it will be given.

A good use of NHS resources

24. The referring clinician will be expected to explain why they consider the treatment for which funding has been applied for will be a good use of NHS resources.

25. This criterion is only applied where the Panel has already concluded that the criteria of clinical exceptionality and clinical effectiveness have been met. Against this criterion the IFR Panel balances the degree of benefit likely to be obtained for the patient from funding the treatment against cost. Panel members will consider the nature and extent of the benefit that the patient is likely to gain from the treatment, the certainty or otherwise of the anticipated outcome from the treatment and the opportunity costs for funding the treatment when evaluating the evidence submitted and the analysis carried out by the referring clinician when considering clinical exceptionality and clinical effectiveness. This means considering, for example, how significant a benefit is likely to be gained for the patient, and for how long that benefit will last. These factors need to be balanced against the cost of the treatment and the impact on other patients of withdrawing funding from other areas in order to fulfil the IFR. This reflects the fact that the only way to provide the funding for treatment under IFRs, i.e. outside commissioned clinical policies which are developed through the structured prioritisation process, is to divert resources away from current services.

26. When determining whether a treatment would be a good use of NHS resources it is very important to consider the length of time for which funding of a treatment is being requested, in relation to the duration of the evidenced efficacy of the treatment i.e. whether the clinical evidence indicates short, medium or long term effectiveness of a particular treatment.

27. Due to the very nature of the cases considered by the IFR Panel, the degree to which effectiveness can be considered certain is likely to be limited, and this will be a relevant factor when considering whether funding would be a good use of NHS resources.

28. However, the Panel should also take into account its ability to impose conditions on any funding it agrees, for example to monitor the impact of the funded treatment.

29. In applying this criterion Panel members will draw upon their professional and analytical skills and knowledge of the NHS system and how it works.

Experimental and unproven treatments

30. This section outlines how the IFR criteria will be interpreted and applied where the treatment being sought is experimental or unproven.

31. Where the case for clinical exceptionality has been accepted but the treatment is experimental or unproven, there is a particular need to scrutinise the likelihood that the treatment will be clinically effective and consider carefully whether funding the treatment would be a good use of NHS resources. This is because it is important that decisions on clinical practice and policy are based on sound clinical evidence. To ensure the effective and equitable use of NHS funding, experimental treatments have to be undertaken judiciously, responsibly and for clearly defined purposes.

32. When an individual case has been found to be exceptional, the treatment proposed might, by definition, be considered to be unproven, and this is why the Panel must carefully consider whether funding of such treatments is a good use of NHS resources as described above. However this section of the policy applies to the particular categories of experimental or unproven treatment which are described below.

What is an experimental treatment?

33. A treatment may be considered experimental where **any** of these points apply:

- the treatment is still undergoing clinical trials and / or is a drug yet to undergo a phase III clinical trial for the indication in question
- the treatment does not have marketing approval from the relevant government body for the indication in question
- the treatment does not conform to a usual clinical practice in the relevant field
- the treatment is being used in a way other than that previously studied or that for which it has been granted approval by the relevant government body; or
- the treatment is rarely used, novel, or unknown and there is a lack of authoritative evidence of safety and efficacy.

What is an unproven treatment?

34. A treatment may be considered unproven when it is considered "as not demonstrated by evidence or argument to be true" or "of a new method, system, or treatment; not tried and tested".

How are IFRs for experimental or unproven treatments considered?

35. The experimental (or unproven) basis of the treatment will become relevant when the Panel assesses the likely clinical effectiveness of the treatment for the patient. The Panel will then consider the degree of confidence it has on the safety and efficacy of the treatment for the patient and whether it would be a good use of NHS resources.

36. Where evidence about the treatment is not yet available for public scrutiny, or there is limited evidence for one of the reasons set out above, the Panel may have limited confidence in the evidence that has been presented.

37. Before agreeing to fund an experimental or unproven treatment, the WYICB will need reassurance:

    - that the decision to agree to an exception to the general policy on treatment for the condition is made very clear, with explicit reasons given, which are consistent with the WYICB's priority setting principles; and

    - that funding experimental or unproven treatments is done in a way that will contribute to the knowledge base.

38. The Panel will not fund treatment in response to an IFR if it considers that it would be more appropriate for the treatment to be the subject of research trials. Primary research into novel treatments should be progressed through the usual research funding routes and will not be funded through this IFR policy.

39. The WYICB will consider a funding request for an experimental or unproven treatment where there is either:

    - evidence from small and often heterogeneous case reports;

    - evidence solely of short-term outcomes; or

    - evidence of effectiveness in a similar condition to the clinical circumstance under consideration.

40. In assessing whether to fund treatment in these cases, the WYICB will

make a decision having regard to:

- the potential benefit and risks of the treatment; and
- the biological plausibility of benefit; and
- an estimate of cost of the treatment and the anticipated value for money; and
- the priority of the patient's needs compared to other competing needs and unfunded developments.

41. The referring clinician will be expected to provide as much information as possible about the treatment, relevant research upon which the claim for biological plausibility of the treatment is based and costs, as well as clinically relevant information on the patient and factors that indicate a good response to treatment. In addition, the referring clinician must identify the clinical markers and clinical outcomes that will be monitored to assess treatment response.

42. The options for consideration by the WYICB in these instances are:

- not to fund;
- fund a trial of treatment but make on-going treatment subject to the demonstration of clinical benefit for the individual patient using criteria agreed in advance with the clinical team. This option is only available where there is a course of treatment or long-term treatment. It is not suitable for one-off treatment such as a surgical intervention;
- in all cases, contribution to any relevant clinical database or population registry which is operating.

Funding for cases following a clinical trial

43. Apart from the most exceptional cases, the WYICB does not anticipate that it will agree a request 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 service development, as there will be a number of patients in broadly the same clinical circumstances. In this instance it is very unlikely that the patient will be able to show clinical exceptionality within this policy.

Information submitted to the IFR team

44. All IFR applications must be submitted by a clinician on behalf of a patient. The clinician submitting the IFR should be the senior clinician directly involved in the specific episode of care of the patient who is best qualified to assess: the extent to which the patient will benefit from the treatment; and the clinical exceptionality of the patient compared to others with the same condition. For surgical procedures this should usually be the surgeon proposing to undertake the procedure. The clinician must be registered with their relevant professional body (e.g. GMC, NMC, HCPC).

45. All applications must be accompanied by written support and evidence provided by the referring clinician treating the patient in line with the WYICB Standard Operating Procedure (SOP).

46. It is the referring clinician's responsibility to ensure that all the appropriate and required information is provided to the WYICB IFR team in a timely fashion consistent with the urgency of the request. If relevant information is not submitted, decision making will be delayed because the case cannot be fairly considered without adequate evidence. In all instances the referring clinician must state whether or not they consider there are likely to be similar patients in the same situation (in accordance with the definition set out in this policy) and, if so, how many such similar patients there are or are likely to be, in the opinion of the referring clinician, in England, in any given 12 month period.

47. As outlined previously, information that is immaterial to the decision being made will not be considered.

48. WYICB expects providers with which it contracts to have oversight of the applications submitted by their clinical staff.

49. Ultimately the WYICB's IFR decision is whether WYICB will reimburse a provider for a particular treatment intervention for the individual patient. However, that decision does not itself determine whether a clinician actually undertakes that treatment. The trust is at liberty to resource the treatment.

Summary of the IFR process

The remainder of this policy summarises the key stages in the IFR process. Full details of the process are set out in the Standard Operating Procedures

Screening and Clinical Triage process for IFR requests

Why are applications subject to screening?

50. Being the subject of an IFR is an anxious time for patients, their family and carers. It is important that neither patients nor clinicians should have their expectations raised that a treatment will be funded under the IFR policy unless the IFR Panel could properly come to the view that the criteria under this policy are met in an individual case.

51. The screening and clinical triage process described in this policy is intended to be fair to all parties, including the other patients funded by the WYICB and the IFR Panel. Cases should only be sent to a Panel meeting if there is some reasonable prospect that the IFR Panel will accept that the criteria under this policy are met in the individual case. This means the IFR Panel can then apply all of its time to those cases which have a prospect of success.

Screening for sufficient information

52. Any IFR requests will first be screened by the WYICB IFR team in accordance with the procedures set out in the WYICB IFR SOP to establish whether the request falls within the commissioning responsibility of WYICB and has sufficient clinical or other necessary information for it to be properly considered. Where the IFR team conclude that there is insufficient information, the request will be returned to the referring clinician specifying the additional information required.

53. The IFR Panel can only approve funding if all of the criteria in the policy are satisfied. It follows that the IFR team should not allow an application to go forward to the IFR Panel unless there is information to support the contention that each of the essential criteria is met. A strong application on one part of the criteria cannot make up for an absence of proper evidence to support another

of the tests that the IFR Panel must apply in order to make a decision that funding should be approved.

Screening for service developments

54. If, in the opinion of the IFR Clinical Triage when considering an IFR in relation to a patient, there is likely to be a defined group of patients in similar clinical circumstances to that patient, the application will be classified as a request for development of a new clinical policy or service specification which needs to be considered as a service development to determine whether it will be routinely commissioned. The referring clinician will then be redirected to the relevant contact point to start the process in that policy. The request will not be progressed through the IFR route from that point.

Screening for clinical exceptionality

55. All IFRs submitted to the WYICB will be considered by the IFR Clinical Triage to determine whether the request appears to present an arguable case for clinical exceptionality. The IFR Panel have delegated authority from the WYICB to make these judgements and will seek additional clinical input at their discretion. If the Clinical Triage considers that there is not an arguable case for clinical exceptionality, the IFR will not proceed further through the process and will be declined.

56. An IFR will be considered as indicating an "arguable case" for clinical exceptionality if the IFR clinical triage consider that there is some realistic prospect that the IFR Panel (properly applying the policy) would conclude that the patient is clinically exceptional. A case would be turned down only where the IFR clinical triage are confident that, based on the available information, if the IFR Panel properly apply this policy, it would come to a conclusion that the patient is not clinically exceptional. If the IFR clinical triage have any reasonable doubt about whether a case satisfies the criterion of exceptionality, it should be forwarded to the IFR Panel.

57. If a case is returned to the applicant from the screening stage, the explanation provided may enable the requesting clinician to submit new clinical information to augment the original argument for clinical exceptionality. The IFR Clinical Triage will reconsider a case if new and relevant clinical information is provided.

58. The Clinical Triage can request advice, for example, relating to a treatment pathway from within the WYICB's clinical advice structure.

Decisions on funding

59. The IFR Panel works on behalf of the WYICB and makes decisions in respect of funding for individual cases. The IFR Panel will work to the published WYICB IFR policy and each request will be processed by following the WYICB IFR SOP. This will ensure that all requests are considered in a consistent, fair and transparent way, with decisions based on the available evidence presented by the referring clinicians and the WYICB commissioning principles.

60. The referring clinician is advised to set out as clearly as possible, and in detail, the clinical evidence and the basis on which they consider that the patient's clinical circumstances are exceptional and fulfil the criteria in this policy.

61. The referring clinician should not assume any particular knowledge of the Panel for the condition from which their patient is suffering or the relevant area of medical practice. The Panel will contain a range of individuals with a variety of skills and experiences and will not necessarily include a clinician with expertise in the condition for which treatment is being sought. This is appropriate because not only is the question one of demonstrable exceptionality (resting on the differences between this patient and others with the condition) but the Panel must consider whether it is appropriate to divert resources away from other services in order to fund the requested treatment.

62. The IFR Panel will make its decision based on the criteria in this policy with reference to any other WYICB published clinical commissioning policies or NICE mandated guidance relevant to the application or interpretation of the criteria.

63. In reaching its decision, the IFR Panel will consider whether there are justifiable grounds for funding the requested treatment against the criteria in this policy and if so, what those grounds are.

64. The IFR Panel in all circumstances will take into account published evidence of clinical effectiveness and likely value for money relating to the proposed treatment.

65. It is also open to the IFR Panel to conclude, notwithstanding the decisions taken by the IFR Clinical Triage, that:

    - the request should be properly classified as a service development. In this case the request will be refused and the IFR team direct the applicant to the service development procedures; or

    - further information or evidence is required before the IFR Panel can make a

decision on funding. In which case further information will be requested through the IFR team. This can be sought from the referring clinician, from within the WYICB clinical advice structure or from other clinical advisers as considered appropriate.

66. In considering individual cases, the IFR Panel will take care to avoid identification bias. This term describes the effect on decision makers being presented with the detail of an individual's life. In these circumstances, it is hard to separate from the emotion behind a decision. Decision makers are more likely to decide in favour of that individual, even when this is at the expense of others who cannot be identified as clearly (also see section on non-clinical factors, paragraphs 17 - 20).

67. The IFR Panel will also take care to avoid "rule of rescue". This is the imperative people feel to 'rescue' individuals facing avoidable death or ill health. For example, supporting the effort to prolong life where there is little prospect of improvement, or death is unavoidable or there is little published evidence to support the requested treatment option in relapsed / refractory stages of the individual's disease / condition. Where the IFR Panel consider that application of the rule of rescue would form the basis for treatment, funding will be declined.

68. The IFR Panel may consider written views expressed by the patient or the clinical team, if based on clinical factors, but will 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.

69. The IFR Panel is entitled to approve the request contingent on the fulfilment of such conditions as it considers fit. These might include, for example, a specific outcome reporting frequency or the involvement of a specialist unit in the management of the case.

70. The IFR Panel is entitled but not obliged to commission its own reports from any duly qualified or experienced clinician, medical scientist or other person, concerning the evidence that the treatment is likely to be clinically effective in the case of the individual patient. Reference to nationally recognised evidence syntheses may be used where they address the specific issues under consideration.

71. The IFR Panel will give written reasons for its decisions to fund or not to fund a treatment in accordance with this policy.

Review of the decision

72. Where the IFR Panel has not supported funding for a requested treatment or has approved the treatment subject to conditions, the patient or requesting clinician will be entitled to ask that the process which led to the decision of the IFR Panel be subject to review.

73. All requests for a review must be made within 30 working days of the date of the decision letter from the IFR Panel. The request for review must be supported by the referring clinician who must set out the grounds on which the IFR Panel decision is being challenged.

74. The request for a review will be initially considered by an Associate Director who has not been involved in any decision making of the original IFR request. If they consider that, on the basis of the information provided, there is an arguable case for a review of the IFR process, a formal IFR Appeals Panel meeting will be recommended to the IFR team.

75. If the Associate Director reviewing the case does not accept the grounds put forward for a review, they will report the rationale for their decision to the WY ICB Medical Director who will consider and, if in agreement, will ratify the decision. The referring clinician will then be advised in writing of the reasons for the decision not to review the IFR Panel process.

76. The role of the IFR Appeals Panel is to determine whether the IFR Panel has followed the procedures as written in the WYICB IFR SOP, has properly understood and considered the evidence presented to it and has come to a reasonable decision based on the evidence.

77. The IFR Appeals Panel will consider whether the process followed by the IFR Panel was fair and consistent, based on whether the decision reached:

    - was taken following a process which was consistent with the policies of the WYICB;
    - was a decision which a reasonable IFR Panel was entitled to reach;
    - understood, took into account and weighed, all the relevant evidence; and
    - did not take into account any irrelevant factors.

78. In the event that the IFR Appeals Panel considers that there was any procedural error in the IFR Panel's decision, the IFR Appeals Panel will

consider whether there was any reasonable prospect that the IFR Panel could have come to a different decision had that error not been made.

79. If the IFR Appeals Panel considers that there was no reasonable prospect of the IFR Panel coming to a different decision, then the IFR Appeals Panel will approve the decision notwithstanding the procedural error. If the IFR Appeals Panel considers that there was a reasonable prospect that the IFR Panel may have come to a different decision had the error not been made, the IFR Appeals Panel will require the IFR Panel to reconsider the decision.

80. The IFR Appeals Panel does not have the power to authorise funding for the requested treatment but can request the IFR Panel to reconsider the case and make recommendations as to the IFR Panel's approach to that consideration.

81. In the circumstances of a legal challenge, an internal review of the process taken leading to a decision will automatically be triggered by the Governance function in the Corporate Directorate of the WYICB.

Urgent decisions for individual funding requests

82. An IFR Panel usually meets according to a schedule designed to provide frequent and timely opportunities to consider applications. Cases are screened every working day and the IFR Panel meets once a month, consequently cases can be processed very quickly if necessary. It may seem reasonable to expect that there should be a route by which certain cases could bypass the usual process with decisions taken on the same day, however, this has the potential to introduce unfairness into the process. This is because:

- cases submitted outside the usual process are unlikely to have been able to gather the necessary research evidence upon which a decision can be properly taken
- in such circumstances the information on the probability of a response to treatment and the nature of that response is unlikely to be clear
- as a result of these uncertainties it is probable that decisions would be subject to the 'rule of rescue' in a way that cases considered in the usual process would not
- it would be impossible to convene a properly constituted Panel in a very

short timescale. Decisions taken by one or two Panel members acting alone, increase the risk of coming to the wrong decision

83. A trust is able to begin treatment and seek retrospective approval and if successful, reimbursement.

84. Although starting a treatment without advance confirmation of funding may present a financial risk to a trust, if there is confidence that the patient is exceptional and there is a high likelihood of a good response, there should be confidence that the case has a high likelihood of being funded retrospectively.

85. There is a provision for cases to be processed more quickly than the 40 working day standard (stated in the SOP). Clinicians must take all reasonable steps to minimise the need for urgent requests to be made through the IFR process, for example, by making requests promptly and providing all necessary information with a request.

86. In the unlikely event that the case is so urgent that it requires a decision on treatment before the IFR Panel next meets (i.e. death or significant and irreversible loss of function is likely to occur before the meeting), the relevant provider will be advised to consider taking its own decision to commence treatment before the funding decision is made.

87. If a treatment is started by the provider in these circumstances and where the IFR Panel is satisfied that a case was urgent and the case was submitted within two working days of the intervention taking place, it will not refuse to determine the IFR application on the basis that it is retrospective. In these circumstances, if the IFR Panel supports the IFR request, the funding for the treatment will be back-dated to the date on which the application was made.

Personal Health Budgets

88. A personal health budget (PHB) is an amount of money to support the planned healthcare and wellbeing needs of an individual, which should be agreed by their clinician. PHBs, therefore, give people more independence over how money for their healthcare is spent.

89. IFRs are applications by clinicians on behalf of their patients relating to funding for treatment that is not routinely commissioned by the WYICB, based on clinical exceptionality. PHBs by contrast are a different way to meet assessed needs that services are routinely commissioned to meet.

90. We would not expect the IFR process to be used to agree services agreed as part of a PHB. However, having a PHB in place for some aspects of a patient's care would not exclude the patient’s clinician from making an IFR request to meet needs that are not routinely met via commissioned services.