

# THE INDIVIDUAL FUNDING REQUEST (IFR) POLICY

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<b>Author(s) (name and post):</b>	Andy Riley Senior Pharmaceutical Advisor
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## **Equality Statement**

Promoting equality and addressing health inequalities are at the heart of NHS Shropshire, Telford & Wrekin Integrated Care Board (STW ICB) values. Throughout the development of this policy statement, we have:

- Had 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 defined under the Equality Act 2010) and those who do not share it; and
- Had 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 STW ICB receive are allocated to the services and treatments provided for patients. STW ICB decide if the treatments they will invest in on an annual basis through a prioritisation process so that, as far as possible, funding is shared fairly and appropriately, considering the competing demands on STW ICB budgets. 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, STW ICB's default position is that a new service will not be routinely commissioned until it has been assessed through the full-service development process. Very occasionally a development is of such importance that there should be no delay in its introduction.

In addition, there is a legal obligation to fund drugs and treatments which have been recommended for Technology Appraisals by the National Institute for Health and Care Excellence (NICE).

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 STW ICB on behalf of a patient, to fund a treatment which would not usually be commissioned by the ICB 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 not an 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 for an individual that is not usually available.

### **When will NHS STW consider funding in response to an IFR?**

STW ICB will only consider funding in response to an IFR, if they are satisfied that the case meets the following criteria:

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

- There is an STW ICB clinical commissioning policy, or a NICE Technology Appraisal (TA) Guidance that either does not support the intervention or the patient does not meet the criteria for treatment and there is evidence that the patient is clinically exceptional: i.e., likely to receive additional clinical benefit from a drug or treatment requested compared to a cohort of patients with the same condition and at the same stage of disease progression;

OR

- There is no relevant STW ICB clinical commissioning policy, or NICE Technology Appraisal (TA) guidance in place for the management of the patient's condition or combination of conditions, in which case the ICB's default position is that we will not fund, but the patient is clinically exceptional; i.e. likely to receive additional clinical benefit from a drug or treatment requested compared to a cohort of patients with the same condition and at the same stage of disease progression;

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OR

- The patient's clinical presentation is so rare (defined as a disease that affects no more than 1 person in 2,000) 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 should be undertaken and there may not be a policy covering the condition.

AND

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

AND

- It is considered that the requested drug/treatment is likely to be a good use of NHS resources and is affordable within the ICB's budget.

## **Individual Funding Requests Policy**

1. Every year, the resources STW ICB 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. In addition there is a legal obligation to fund drugs and treatments which have been recommended for Technology Appraisals by the National Institute for Health and Care Excellence (NICE). Any additional calls on resources to fund an individual's treatment are, therefore, 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. STW ICB regards the matter of funding for an individual patient as an equity issue, in which they will consider whether they 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 such a patient should have the benefit of a drug or treatment not currently commissioned for a wider cohort. In such circumstances, clinician, on behalf of their patient, may make an Individual Funding Request (IFR) to STW ICB for a treatment that is not routinely commissioned by the ICB. IFRs may be made in respect of STW ICB directly commissioned services and indeed any services that are not commissioned. 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. IFRs can be made in respect of any of STW ICB directly commissioned services. If, however, 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. In this case the clinician will need to consider proposing this treatment for development of a clinical policy. So that the ICB can be fair to all patients, decisions on whether or not to fund this new development will be taken in line with the ICB's ethical framework. In these circumstances, the request will not proceed through the IFR process.

4. 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.

## **Clinical Exceptionality**

5. 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 with the most appropriate clinical knowledge making the request to set out the grounds for clinical exceptionality clearly and robustly for the IFR Panel.

6. '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 presentation 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 with the most appropriate clinical knowledge 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.

7. Where a 'not for routine commissioning' clinical commissioning policy is in place in relation to a treatment, STW ICB 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. Consequently, in considering whether a request for an IFR should be made, the clinician with the most appropriate clinical knowledge 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 which will form the basis on an IFR application.

### **Clinical exceptionality: failure to respond to standard care**

11. 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. These considerations are likely to have been taken into account in formulating the general policy.

12. 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.

13. 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 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 or within the identified clinical cohort.
- As regards side effects, as an example, all patients who are treated with long-term high-dose steroids will develop side-effects (typical and established) and thus developing these side effects and wishing to be treated with something else does not necessarily mean this patient meets the exceptionality criteria.
- If the usual treatment cannot be given because of a pre-existing co-morbidity 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 co-morbidity is present in this patient and its impact on treatment options for this patient is unlikely to make the patient clinically exceptional. With any condition there will be a recognised proportion of patients, who also have a co-morbidity which is common in the general population, and thus a patient is unlikely to be exceptional by virtue of also having a comorbidity which is common in the general population.

14. If the proposed intervention is thought to offer a benefit to patients in these identified groups generally (i.e. those with more severe disease or those with common co-morbidities), the question is whether there is sufficient justification, including considerations like 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 identified patient. This change needs to be considered as a service development and not as an IFR.

### **Clinical exceptionalality: severity**

15. Should severity be cited by the requesting clinician as part of the argument for exceptionalality, 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 as well as;
- 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 exceptionalality: genotypes**

16. When the argument for clinical exceptionalality 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 applicant 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 exceptionalality: multiple grounds**

17. There may be cases where a clinician with the most appropriate clinical knowledge seeks 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 exceptionalality (and should therefore be ignored), but it might be relevant as impacting upon another factor. That is a judgment within the discretion of the IFR screening group and IFR Panel.

18. 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**



19. 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 or financial 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.

20. non-clinical and social factors will be disregarded for this purpose in order for the IFR screening group 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, STW ICB would not know whether they were being fair to other patients who cannot access such treatment and whose non-clinical and social factors would be the same or similar.

21. Consideration of social factors would also be contrary to STW ICB policy of non-discrimination in the provision of medical treatment. If, for example, treatment were 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 screening group and IFR Panel should not make.

22. Clinicians are asked to bear this Policy in mind when considering making an application for funding via the IFR stream and not to refer to social or non-clinical factors to seek to support the application for individual funding. In order to avoid prejudice within the IFR process, such material will be edited out of the application or the application form will be returned to the requesting clinician for editing and resubmission.

### **Clinical Effectiveness**

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

24. Clinical evidence that considers the efficacy of a particular treatment will be carefully considered by the IFR screening group and IFR Panel. It is the sole responsibility of the referring clinician with the most appropriate clinical knowledge to provide this information, 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 with the most appropriate clinical knowledge, makes explicit linkages between the grounds under which exceptionality is claimed and the sections of the submitted research literature that are considered to support their view regarding the differences between the patient's clinical position and that of other patients in the identified group, and regarding the patient's anticipated response to the requested treatment.

25. 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 co-morbidities 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 using the information available
- 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**

26. The requesting clinician with the most appropriate clinical knowledge, 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.

27. This criterion is only applied where the IFR Panel has already concluded that the criteria of clinical exceptionality and clinical effectiveness have been met. In considering this criterion the IFR Panel balances the degree of benefit likely to be obtained for the patient from funding the treatment against cost. Having regard to the evidence submitted and the analysis they have carried out when considering clinical exceptionality and clinical effectiveness, Panel members will consider the nature and extent of the benefit 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. 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 overall ICB budget.

28. 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.

29. 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.

30. However the IFR Panel should also consider its ability to impose conditions on any funding it agrees, for example to monitor the impact of the funded treatment.

31. 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**

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

32. 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 must be undertaken judiciously, responsibly and for clearly defined purposes.

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

### **What is an experimental treatment?**

34. 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.

### **How are IFRs for experimental treatments considered?**

35. The experimental basis of the treatment will become relevant when the IFR Panel assesses the likely clinical effectiveness of the treatment for the patient, the Panel should then also 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 IFR Panel may have limited confidence in the evidence that has been presented.

37. As preliminary requirements before agreeing to fund an experimental treatment, STW ICB will need reassurance:

- That the decision to agree to an exception to the general policy on treatment for the condition is made for very clear and explicit reasons which are consistent with STW ICB priority setting principles.

and

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

38. The IFR 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. STW ICB will consider a funding request for an experimental 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, STW ICB will decide having regard to:

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

41. The 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 clinician must identify the clinical markers and clinical outcomes that will be monitored to assess treatment response.

42. The options for consideration by STW ICB 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 on 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. Save in the most exceptional cases, STW ICB does not anticipate 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 policy.

44. Details of funding for these types of requests can be found in the ICB's Commissioning Policies for ongoing funding following the completion of a clinical trial.

### **Information submitted to the NHS Shropshire, Telford & Wrekin IFR Team**

45. All applications must be on the ICB's IFR Application template. All applications should be typed **and not handwritten**, submitted electronically and accompanied by written support and clinical evidence provided by the clinician with the most appropriate clinical knowledge providing treatment to the patient in line with the STW ICB IFR SOP.

46. It is the referring clinician's responsibility to ensure that all the appropriate and required information is provided to STW ICB in a timely fashion consistent with the urgency of the request. This includes full copies of all the published papers of clinical evidence that have been cited. The clinician must provide a list of the published papers that have been submitted and indicate which points within them are relevant in respect to the IFR application and criteria. This is to ensure the IFR panel are clear about the points the clinician is making and the relevance to the case. If relevant information is not submitted, the application may be returned, and the 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 similar patients there are or are likely to be in the opinion of the referring clinician in the relevant ICB in any given 12-month period.

47. STW ICB expects providers with which it contracts to have oversight of the applications submitted by their clinical staff. The ICB expects every IFR template to be sanctioned by the

provider's Board-level Medical Director or equivalent and reserves the right to return unsanctioned IFRs to the provider and refer recurrent inappropriate funding requests to the Chief Executive (or equivalent) of the relevant provider.

48. Ultimately STW ICB IFR decisions are whether the ICB 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 Provider is at liberty to resource the treatment.

### **Summary of the IFR process**

49. 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 Procedure: The Management of Individual Funding Requests.

### **Pre-screening and Screening process for IFR requests <sup>1</sup>**

#### **Why are applications subject to pre-screening and screening?**

50. Being the subject of an IFR is an anxious time for patients and their carers and so 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 could be met in an individual case.

51. The pre-screening and screening process described in this Policy is intended to be fair to all parties, including the other patients funded by STW ICB and the IFR Panel, by only sending cases 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 its time to those cases which have a reasonable prospect of success.

#### **Pre-Screening for Sufficient Information and clinical exceptionality**

52. All IFR applications will first be pre-screened by STW ICB IFR team in accordance with the procedures set out in the STW ICB IFR SOP<sup>i</sup> to establish whether the request falls within the commissioning responsibility of the ICB, is fully complete and has sufficient clinical or other necessary information for it to be properly considered. There will be consideration given to clinical exceptionality even at the pre-screening stage and any case which fails to demonstrate any basis for clinical exceptionality can be refused at the pre-screening stage. It is anticipated that at this stage, those cases returned will be those which have absolutely no chance of satisfying the clinical exceptionality criteria, but a further application properly completed with information on clinical exceptionality will be permitted. Where the IFR team conclude that there is insufficient information, the IFR template will be returned to the referring clinician specifying the additional information required. If there is sufficient information, the application will be passed to be considered at the Screening stage.

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<sup>1</sup> The Management of Individual Funding Requests Standard Operating Procedure (SOP) refers to pre-screening which is done by the IFR team, the Screening or Stage One Panel and the IFR Stage Two Panel.

53. The IFR Panel can only consider funding if all criteria specified in the policy are satisfied. It follows that neither the IFR team nor the Screening team should 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 Stage**

54. A screening panel will consider a submitted IFR application in relation to a patient and whether there is likely to be a defined group of patient's, or identified clinical cohort in similar clinical circumstances to that patient. If that is the case, the application will be classified as a request for development of a new policy or service specification which needs to be considered under the Service Development Policy to determine whether it will be routinely commissioned. The requesting clinician will be advised to make a business case to highlight the need to develop a new service, this should be redirected to the relevant contact point to start the process in that policy. The application for funding will not be progressed through to the IFR panel .

The screening panel will also consider whether the request can be funded under an existing commissioning policy or NICE TA.

The Screening panel will then consider the issue of clinical exceptionality as defined in this policy and will consider whether there is an arguable case for clinical exceptionality.

If the application makes a credible case for the patient meeting the exceptionality criteria highlighted by the IFR Policy then the application will be passed to the IFR panel.

If the IFR Screening Panel consider that there is no arguable case for clinical exceptionality, the IFR will not proceed further through the process and will be declined. The IFR Screening Panel has delegated authority to make this decision and will seek clinical input at their discretion.

55. An IFR will be considered as indicating an "arguable case" for clinical exceptionality if the Screening Panel considers 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 Screening Panel are confident that, based on the available information, if the IFR Panel properly apply this policy, they would conclude that the patient is not clinically exceptional.

56. 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 team and Screening Panel will reconsider a case if new and relevant clinical information is provided. If this new evidence supports the claim for exceptionality the case will be passed to the IFR panel.

57. The IFR Screening panel can request advice if required, e.g., relating to a treatment pathway and lines of therapy within that from appropriate clinicians/ICB Managers.

## Decisions on funding

58. The IFR Panel work on behalf of STW ICB making decisions in respect of funding for individual cases. The IFR Panel (together with those involved in the pre-screening and screening stages) have received IFR training, and they work to the approved STW ICB IFR Policy with each request being processed following the STW ICB 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 clinician with the most appropriate clinical knowledge providing treatment to the patient and the STW ICB commissioning principles.

59. The referring clinician is advised to set out clearly 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.

60. The clinician should not assume knowledge of the IFR Panel for the condition from which their patient is suffering or the relevant area of medical practice. This is because the IFR Panel will contain a range of individuals with a variety of skills and experiences. The IFR Panel 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 IFR Panel must consider whether it is appropriate to divert resources away from other services to fund the requested treatment for the individual patient.

61. The IFR Panel will make decisions based on the criteria in this policy with reference to any other STW ICB published clinical commissioning policies or NICE mandated guidance relevant to the application or interpretation of the criteria.

62. In reaching their 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.

63. The IFR panel in all circumstances will consider published evidence of clinical effectiveness and likely value for money relating to the proposed treatment.

64. It is also open to the IFR Panel to conclude, notwithstanding the screening decisions taken by the IFR panel, that:

- The request should be properly classified as a service development. In this case the request will be refused, and the applicant advised of the service development procedures; or
- Further information or evidence is required before the IFR Panel can take a decision on whether funding should be given, in which case further information will be requested through the IFR team. This can be sought from the clinician, from within the ICB's clinical advice structure or from other clinical advisers as considered appropriate.

65. In considering individual cases, the IFR Panel will take care to avoid identification bias. This term describes the effect on decision makers of being presented with the detail of an



individual's life. In these circumstances, it can be hard to separate from the emotion behind a decision.

66. 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 considers that application of the rule of rescue would form the basis for treatment, funding will be declined.

67. The IFR Panel may consider written views expressed by 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.

68. The IFR Panel are 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.

69. The IFR Panel are entitled but not obliged to commission 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.

70. The IFR Panel will give written reasons for its decisions to fund or not to fund a treatment in accordance with this policy. The written reasons reflecting the decision will be sent by email to the clinician requesting funding, it is then the responsibility of the clinician to communicate that decision to their patient.

### **Review of the decision**

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

72. All requests for a review must be made within 28 days of the date when the decision is communicated to the requesting clinician. The written decision is sent via secure NHS email to the clinician that has requested funding via the IFR route. The request will be supported by the referring clinician who must explain his or her reasons for considering that the decision taken by the IFR Panel was either procedurally improper and/or failed to consider the medical evidence and/or was, in his or her opinion, a decision which no reasonable IFR panel could have reached.

73. The request for a review will be initially considered by an ICB Director or chief not involved in the original IFR application. If they consider that, based on the information provided, there is an arguable case for a review of the IFR process (not the decision made), they will take

the decision to convene a formal IFR Review Panel meeting and inform the ICB's Chief Executive Officer or Chief Medical Officer of this decision.

74. If the Director or chief reviewing the case does not accept the grounds put forward for a review, they will report the rationale for their decision to the ICB's Chief Executive Officer or Chief Medical officer who will consider and, if in agreement, will ratify the decision. The ICB's Chief Executive Officer or Chief Medical Officer will then write to the referring clinician explaining the reasons for the decision not to review the IFR Panel decision. It is the responsibility of the clinician to communicate the outcome of the review to the patient or patient's representative.

75. The role of the IFR Review Panel is to determine whether the IFR Panel has followed the procedures as written in the STW ICB IFR Policy and has considered the evidence presented to it and has come to a reasonable decision based on the evidence.

76. The IFR Review 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 IFR Policy of STW ICB;
- 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.

77. In the event that the IFR Review Panel considers that there was any procedural error in the IFR Panel's decision, the IFR Review Panel will consider whether there was any reasonable prospect that the IFR Panel could have come to a different decision had that procedural error not been made.

78. If the IFR Review Panel considers that there was no reasonable prospect of the IFR Panel coming to a different decision, then the IFR Review Panel will approve the decision notwithstanding the procedural error. If the IFR Review Panel considers that there was a reasonable prospect that the IFR Panel may have come to a different decision had the procedural error not been made, the IFR Review Panel will require the IFR Panel to reconsider the decision. If this is the case, a different panel of decision makers will be convened to review the evidence presented in the original application for IFR funding.

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

80. In the circumstances of a formal legal challenge, an internal review of the process taken leading to a decision will automatically be triggered by STW ICB.

### **Urgent decisions for Individual Funding Requests**

81. An IFR Panel usually meets according to a schedule designed to provide frequent and timely opportunities to consider applications. Cases are pre-screened when received and the IFR panel meets regularly. Consequently, urgent applications may be accommodated if necessary. Although it may seem that there should be a route by which certain cases could bypass the usual process and decisions could be taken on the same day, 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, increases risks of coming to the wrong decision
- Starting a treatment without advance confirmation of funding may present a financial risk to a provider, as the ICB does not routinely support retrospective funding.

82. Providers 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. If provider clinicians are considered not to be taking all reasonable steps to minimise urgent requests to the IFR process, STW ICB may refer the matter to the clinician's Chief Executive or equivalent.

83. In the unlikely event that the case is so urgent that it requires a decision on treatment before the IFR Panel's next meeting (i.e. death or significant and irreversible loss of function is likely to occur before the meeting), the relevant provider may take such decisions at its own risk.

### **Documents which should be read in conjunction with this policy**

NHS STW Funding for experimental and unproven treatments – Nov 2021

NHS England – Commissioning Policy – Individual Funding Requests – November 2017

NHS STW Ethical framework for priority setting and resource allocation – Nov 2021

On-going access to treatment following a 'trial of treatment' which has not been sanctioned by NHS STW for a treatment which is not routinely funded or has not been formally assessed and prioritized – November 2021

On-going access to treatment following the completion of a trial explicitly funded by NHS STW – November 2021

NHS STW On-going access to treatment following the completion of industry sponsored clinical trials or funding – November 2021

NHS STW On-going access to treatment following the completion of non-commercially funded clinical trials – November 2021

NHS STW IFR Application form V3

## Appendix

### Individual Funding Request (IFR) Application Form

Requesters are advised to review the Shropshire Telford & Wrekin ICB IFR Policy, this may be found using the Link provided:

STW ICB requires providers and clinicians to take clinical commissioning policies into account in advice and guidance given to patients prior to making the decision to treat a patient.

It is the responsibility of the referring clinician to ensure all the appropriate and required clinical information is provided to STW ICB. This includes full text copies of all the published papers of clinical evidence that have been cited within an application, a list of the published papers submitted and an indication of which points within those papers are relevant in respect to the IFR application and criteria. Requests will only be considered on the information provided in the application and supporting papers. **Non-clinical or social factors must not be included within applications.**

Clinicians with the most appropriate knowledge providing treatment to the patient may apply via the IFR Funding stream, If a clinician is unable to provide all of the requested information they should assess if the application should be submitted or passed to another clinician who is able to provide all of the appropriate information.

The information requested at question 2g and 2h is collected for monitoring purposes in an anonymised format to assist NHS STW in ensuring that we are complying with the Equality Act 2010. This information will be redacted prior to sharing with decision makers.

**DO NOT** include patient identifiable data in any free text sections. Where there are large amounts of identifiable data included, the application may be redacted or may be returned to you for redaction and submission.

**Please note** applications presenting incomplete information will be returned for amendment / completion prior to consideration by STW ICB.

#### Section 1 - PROVIDER DETAILS

1a) Name of Provider	Click here to enter text.
1b) Name of clinician who will undertake the intervention	Click here to enter text.
1c) Job title/role	Click here to enter text.
1d) Secure NHS email	Click here to enter text.
1e) Telephone number	Click here to enter text.
1f) Address of clinician who will undertake the intervention	Click here to enter text.

#### Section 2 – PATIENT / GP DETAILS

2a) Patient first name	Click here to enter text.
2b) Patient last name	Click here to enter text.
2c) Patient NHS Number	Click here to enter text.
2d) Patient hospital number	Click here to enter text.
2e) Patient date of birth	Click here to enter a date.

2f) Patient age at time of submission	Click here to enter text.	
2g) Gender	Choose an item.	
2h) Ethnicity	Choose an item.	
2i) Patient's address	Click here to enter text.	
2j) Patient's postcode	Click here to enter text.	
2k) GP Name	Click here to enter text.	
2l) GP Practice name	Click here to enter text.	
2m) GP postcode	Click here to enter text.	
<b>Section 3 – REQUEST DETAILS</b>		
3a) Please detail the clinical reasons for urgency if appropriate i.e. the risks of adverse clinical outcome to the individual patient	Click here to enter text.	
3b) Proposed start date of treatment	Click here to enter a date.	
3c) If treatment has commenced more than 2 working days before submission of this application, please provide an explanation for the delay in application	Click here to enter text.	
3d) Proposed treatment stop date (if applicable)	Click here to enter a date.	
<b>Application Support</b>		
The IFR Policy highlights that Provider support of an IFR application is mandatory. The IFR application will not progress in the absence of this support. Requests must be supported by a relevant multidisciplinary team (MDT) or Provider Drugs and Therapeutics Committee (DTC) <b>AND</b> by the providers Medical Director.		
3e) DTC or equivalent approval and provide a copy of the minutes	Please provide details of the outcome Click here to enter text.	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
3f) MDT approval and provide a copy of the minutes	Please provide details of the outcome Click here to enter text.	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
3g) Name and email of Chief or, in exceptional circumstances to avoid delays in submission, the Deputy Chief Pharmacist (if applicable)	Click here to enter text.	

3h) Confirm that the Chief/Deputy Chief Pharmacist supports this drug application (if applicable)	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
3i) Name and email of Medical Director or, in exceptional circumstances to avoid delays in submission, the Deputy Medical Director	Click here to enter text.
3j) Confirm that the Medical Director/Deputy Medical Director supports this application	<input type="checkbox"/> Yes <input type="checkbox"/> No
<b>Consent</b>	
3k) This IFR has been discussed in full with the patient or patient representative. They are aware that they are consenting for the IFR Team to receive and review confidential clinical information about their health to enable full consideration of this funding request. <b>I confirm all of the above</b>	<input type="checkbox"/> Yes <input type="checkbox"/> No
3l) In submitting this application you are under obligation to advise the patient or patient representative of the details of the reasons for the decision. <b>I confirm that I will advise the patient or patient representative of the reasons for the decision</b>	<input type="checkbox"/> Yes <input type="checkbox"/> No
<b>Section 4 - TREATMENT</b>	
4a) Primary diagnosis most relevant to this IFR request and any relevant co-morbidities	Click here to enter text.
4b) Intervention details including treatment modality (if applicable), how and where the treatment will be given	Intervention: Click here to enter text. Modality: Click here to enter text. How will treatment be given: Click here to enter text. Where will treatment be given: Click here to enter text.
4c) Is there an existing clinical policy for this treatment and condition? <i>Please provide explicit reasons why your patient does not meet the access criteria within that policy</i>	Click here to enter text.
<b>Cost</b>	
4d) what are the costs of the intervention?	<input type="checkbox"/> Single treatment Total Cost: Click here to enter text.

<i>Where appropriate include here the total cost of the treatment, any loading doses required and the number of cycles applied for</i>	<input type="checkbox"/> multiple treatments Load dose <a href="#">Click here to enter text.</a> Subsequent doses <a href="#">Click here to enter text.</a>	Cost per treatment: <a href="#">Click here to enter text.</a> <a href="#">Click here to enter text.</a>	Total Cost: <a href="#">Click here to enter text.</a>
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4e) Additional comments on the cost of the intervention	<a href="#">Click here to enter text.</a>
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4f) What are the total costs of standard therapy ( <i>estimate annual costs if applicable</i> )?	<a href="#">Click here to enter text.</a>
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4g) Are there any offset costs ( <i>provide details</i> )?	<input type="checkbox"/> Yes <input type="checkbox"/> No <a href="#">Click here to enter text.</a>
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**Clinical Outcomes**

4h) What are the intended clinical outcomes and how will the benefits of the procedure / treatment be measured ( <i>including where appropriate the validated clinical tools to be used</i> )?	<a href="#">Click here to enter text.</a>
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4i) Within what timeframe will these outcomes be determined?	<a href="#">Click here to enter text.</a>
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4j) What 'stopping' criteria will be in place to assess when the treatment is ineffective and treatment will be withdrawn?	<a href="#">Click here to enter text.</a>
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4k) What mechanisms will be in place to provide STW ICB with clinical outcome reports if the treatment is approved? <i>Please provide detail of how you will report to STW ICB upon request</i>	<a href="#">Click here to enter text.</a>
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**Section 5 - CLINICAL BACKGROUND**

5a) Outline the background to the patient's clinical situation relevant to this request, timeline, current status and symptoms. <i>Please give validated clinical measures, named in full.</i>	<a href="#">Click here to enter text.</a>
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**Treatment History**

	Treatment	Regimen	Start	Stop	Response	Funding source
5b) Current	<a href="#">Click here to enter text.</a>	<a href="#">Click here to enter text.</a>	<a href="#">Click here to enter a date.</a>	<a href="#">Click here to enter a date.</a>	<a href="#">Click here to enter text.</a>	<a href="#">Click here to enter text.</a>



5c) Previous	Click here to enter text.	Click here to enter text.	Click here to enter a date.	Click here to enter a date.	Click here to enter text.	Click here to enter text.
5d) Previous	Click here to enter text.	Click here to enter text.	Click here to enter a date.	Click here to enter a date.	Click here to enter text.	Click here to enter text.
5e) Additional comments on current or previous treatments	Click here to enter text.					
<b>Additional Treatment Information</b>						
5f) What are the alternative standard treatments available to patients with this condition/stage of the disease and why are they not appropriate for this patient?	Click here to enter text.					
5g) Prognosis – what are the anticipated clinical benefits in this individual case of the particular treatment requested over other available options?	Click here to enter text.					
5h) Risk/benefit profile of this treatment compared to standard treatments in this individual case	Click here to enter text.					
5i) Anticipated prognosis if treatment requested is not funded	Click here to enter text.					
<b>Section 6 – CLINICAL EXCEPTIONALITY</b>						
Is there evidence that this patient has exceptional clinical circumstances, demonstrating that:						
6a) There is a STW ICB clinical commissioning policy or NICE Technology Appraisal (TA) guidance in place that either does not support the intervention or the patient does not meet the criteria for treatment. It is believed that the patient is clinically exceptional ( <i>provide details</i> ) and is likely to receive additional clinical benefit from treatment compared to another patient with the same condition and at the same stage of disease progression	<input type="checkbox"/> Yes Click here to enter text.					
<b>OR</b>						
6b) There is not a relevant STW ICB clinical commissioning policy or NICE Technology Appraisal (TA) 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	<input type="checkbox"/> Yes Click here to enter text.					

similar clinical circumstances for whom a service development should be undertaken		
<b>Genotypes</b>		
6c) When the argument for clinical exceptionality is based on the patient having a particular genotype (genetic profile) please provide evidence of the prevalence of the genotype in that patient group and how the specific genotype would make the patient:		Click here to enter text.
I. Different to others in terms of clinical management		Click here to enter text.
<b>AND</b>		Click here to enter text.
II. Able to benefit from the treatment to a greater degree than others with the same or different symptoms of the condition		
<b>Section 7 – CLINICAL SUPPORTING INFORMATION</b>		
Incidence and Prevalence – for this patient’s individual circumstances		
7a) Incidence:	Estimate the number of patients expected to be diagnosed with this specific condition per 100,000 population per year:	Click here to enter text.
	Where a patient has one or more conditions, the figures provided should be for patients expected to have the combination of conditions – <i>please provide specific details</i>	Click here to enter text.
7b) Prevalence:	Estimate the number of patients expected to have this condition per 100,000 population at any one time:	Click here to enter text.
7c) Do you consider that there are likely to be other patients presenting in England in the next 12 months with this patient’s condition at the same stage of this condition? If so, provide the number		<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A Click here to enter text.
7d) how many patients currently attend your service with this condition for which you would wish to use this treatment?		Click here to enter text.
7e) Is this case identifying a gap in service provision and therefore appropriate to be referred to the person/s who would		<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No

consider service development cases, has been discussed with commissioners? <i>If yes, please provide details</i>	Click here to enter text.
7f) Do you plan to submit a future preliminary policy proposal for consideration of funding of this treatment (rather than submit individual requests for this patient)?	<input type="checkbox"/> Yes <input type="checkbox"/> No
<b>Evidence</b>	
7g) Please provide a summary of the evidence base relevant to this application to demonstrate the clinical effectiveness, good use of NHS resources and safety of this procedure/treatment. <i>(Published papers must be provided In full in order to be considered by the IFR Panel. A list of published papers submitted must be provided with an indication of which points within them are specifically relevant to the case using the proforma at the end of the application form)</i>	Click here to enter text.
7h) Is the procedure/treatment part of a current or planned national or international clinical trial or audit?	<input type="checkbox"/> Yes <input type="checkbox"/> No
If yes, please give details	Click here to enter text.
<b>Section 8 - SUBMIT</b>	
When you have completed <u>all</u> sections of this application form and evidence <u>proforma</u> , you will need to submit the request for consideration by STW ICB IFR Team. If the IFR Team needs more information they will contact you to ask that you provide more details and if this happens, the timeline for the request is suspended until a fully completed and more robust application is received	
Specialist Clinicians are required to disclose all material facts to STW ICB as part of this process. Are there any other comments/considerations that are appropriate to bring to the attention of the IFR Team?	Click here to enter text.
Please complete in full and return this form to: <a href="mailto:stwccgsafehaven@nhs.net">stwccgsafehaven@nhs.net</a>	
<b>(hand written application forms will not be accepted)</b>	

Evidence Proforma

Please provide reference to the key evidence for clinical exceptionality, clinical effectiveness, good use of NHS resources and safety of this procedure/treatment in each of the papers submitted as part of the evidence base relevant to this application			
No.	Title submitted paper	Topics	Specific sections with key evidence (page number/paragraph or section)
1.	Article one	Clinical exceptionality	Click here to enter text.
		Clinical effectiveness	Click here to enter text.
		Good use of NHS resources	Click here to enter text.
		Safety of this procedure/treatment	Click here to enter text.
2.	Article two	Clinical exceptionality	Click here to enter text.
		Clinical effectiveness	Click here to enter text.
		Good use of NHS resources	Click here to enter text.
		Safety of this procedure/treatment	Click here to enter text.
3.	Article three	Clinical exceptionality	Click here to enter text.
		Clinical effectiveness	Click here to enter text.
		Good use of NHS resources	Click here to enter text.
		Safety of this procedure/treatment	Click here to enter text.
4.	Article four	Clinical exceptionality	Click here to enter text.
		Clinical effectiveness	Click here to enter text.
		Good use of NHS resources	Click here to enter text.
		Safety of this procedure/treatment	Click here to enter text.
5.	Article five	Clinical exceptionality	Click here to enter text.
		Clinical effectiveness	Click here to enter text.
		Good use of NHS resources	Click here to enter text.
		Safety of this procedure/treatment	Click here to enter text.
6.	Article six	Clinical exceptionality	Click here to enter text.
		Clinical effectiveness	Click here to enter text.
		Good use of NHS resources	Click here to enter text.
		Safety of this procedure/treatment	Click here to enter text.

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## IFR Terms of Reference

### Panel Membership

#### IFR Stage One Screening Panel

The role of the IFR stage one screening panel is to consider any IFR applications and supporting evidence provided against the IFR Policy and to assess if there is evidence of exceptionality and good use of NHS resource and clinical effectiveness is proven. All Panel members should be IFR Trained.

Each request will be processed by following the decision making process outlined by the policy and process. This will ensure that all requests are considered in a fair and transparent way, with decisions based on the available evidence presented by the clinicians.

Panel members	Role
IFR trained Public Health consultant	Decision Maker
IFR Trained Senior Pharmaceutical advisor, Pharmacist	Decision Maker

#### additional panel support (non-decision maker)

Administration support (IFR Operational Lead, IFR Trained)

**Frequency of meetings:** Diarised Fortnightly

**Quoracy:** 2 decision makers and 1 administration support

The role of the IFR stage 2 decision panel is to consider any IFR applications and supporting evidence provided against the IFR Policy and determine if the requested treatment meets the IFR Policy exceptionality criteria, and is good use of resource and clinically effective, If there are any commissioning policies that may already be used to provide treatment to the patient or if there is a NICE guideline that covers the requested treatment and if the requested treatment should be funded. All panel members should have attended the IFR Training.

Panel Members	Role
ICB Commissioning Lead	Decision Maker
ICB Quality Lead	Decision Maker
ICB Finance Lead	Decision Maker
ICB Deputy Director of Medicines Management (or deputy)	Decision Maker
ICB GP representative	Decision Maker

additional panel support (non-decision maker)

Administration/IFR Policy support (IFR Operational Lead)

**Frequency of meetings:** Held as required in compliance with the IFR SOP

**Quoracy:** 3 decision makers (1 clinical member and 2 others) and 1 administration/IFR Policy support

#### IFR Review Panel

The role of the review panel is to consider the process followed by the decision makers at both stage one screening panel and stage 2 decision panels for any cases where a review has been requested.

The role of the review panel is NOT to make a decision on funding or consider if the funding decision made was correct.

Each case referred for review should be assessed to assure the Chief Executive Officer or Chief Medical Officer that the correct process has been followed by each decision maker using the available evidence. If the review panel feel that the correct process was not followed, they may refer the case back to a new stage 2 decision panel for further

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consideration. The review panel can require the IFR Stage TWO Panel to reconsider the case and make recommendations as to the IFR Stage TWO Panel's approach. The review panel may not require the decision made to be challenged or changed. If during the second stage 2 decision panel meeting the original funding decision is reached, then clear reasons for the decision being upheld must be given.

If the Director or chair reviewing the case does not accept the grounds put forward for a review, they will report the rationale for their decision to the ICBs Chief Executive Officer or Chief Medical Officer, who will consider and if in agreement, will ratify the decision. The ICB's Chief Executive Officer or Chief Medical Officer will then write to the referring clinician explaining the reasons for the decision not to review the IFR Stage TWO Panel's decision.

**Panel members**

	<b>Role</b>
ICB Chief Nursing Officer/Director of Quality and Safety (Deputy CNO)	Reviewer
Director of Strategic Commissioning	Reviewer

**Frequency of meetings:** Held as required in compliance with the IFR SOP

**Quoracy:** 2 members, including 1 clinical/quality and 1 other (reports to the CEO or CMO)  
IFR Administration support will be provided to support the communication of the review decisions and to arrange any further panel meetings if required, in compliance with the IFR SOP.