THE INDIVIDUAL FUNDING REQUEST POLICY

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Equality Statement

Promoting equality and addressing health inequalities are at the heart of Shropshire Clinical Commissioning Group (SCCG) and Telford and Wrekin Clinical Commissioning Group's (T&WCCG) 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 SCCG and T&WCCG receive are allocated to the services and treatments provided for patients. SCCG and T&WCCG decide 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 SCCG and T&WCCG's 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, SCCG and T&WCCG'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.

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 SCCG or T&WCCG on behalf of a patient, to fund a treatment which would not usually be commissioned by the CCG 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 Shropshire CCG and Telford and Wrekin CCG consider funding in response to an IFR?

SCCG and T&WCCG 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 a SCCG clinical commissioning policy, a T&WCCG clinical commissioning policy or a NICE Technology Appraisal (TA) guidance that either doesn't support the intervention or the patient doesn't meet the criteria for treatment. It is believed that the patient is clinically exceptional and likely to receive additional clinical benefit from treatment

compared to another patient with the same condition and at the same stage of disease progression.

OR

- There is not a relevant SCCG clinical commissioning policy, T&WCCG 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 similar clinical circumstances for whom a service development should 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 and is affordable within the CCG's budget.

Individual Funding Requests Policy Overview

1. Every year, the resources SCCG and T&WCCG receive 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, 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. SCCG and T&WCCG regard 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 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 SCCG or T&WCCG for a treatment that is not routinely commissioned by the CCG. IFRs may be made in respect of SCCG or T&WCCG 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 SCCG or T&WCCG's 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 CCGs can be fair to all patients, decisions on whether or not to fund this new development will be taken in line with the CCG'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.

When will Shropshire CCG and Telford & Wrekin CCG consider funding?

5. SCCG and T&WCCG will only provide 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 a SCCG clinical commissioning policy, a T&WCCG clinical commissioning policy or NICE Technology Appraisal (TA) guidance in place that either doesn't support the intervention or the patient doesn't meet the criteria for treatment. It is believed that the patient is clinically exceptional and likely to receive additional clinical benefit from treatment compared to another patient with the same condition and at the same stage of disease progression.

OR

- There is not a relevant SCCG clinical commissioning policy, T&WCCG 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 similar clinical circumstances for whom a service development should 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 and is affordable within the CCG's budget.

6. SCCG and T&WCCG's IFR teams 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 CCG's IFR Panel (Stage Two) Details of the IFR team, IFR Panel and the processes that are followed, are set out in the SCCG and T&WCCG's *Standard Operating Procedures: The Management of Individual Funding Requests* (IFR SOP), which includes the Terms of Reference for the IFR Screening Group, IFR Panel and IFR Review Panel.

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

Further explanation of the IFR criteria

Clinical Exceptionality

8. 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.

9. 'Exceptional' in IFR terms means a person to whom the general rule should not apply[3]. 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.

10. Where a 'not for routine commissioning' clinical commissioning policy is in place in relation to a treatment, SCCG and T&WCCG 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

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. Again 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. So, 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 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) and thus 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 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. As an illustration, some co-morbidities 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 co-morbidity which is common in the general population, and thus a patient cannot 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 groups generally (i.e. those with more severe disease or those with common co-morbidities), 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

15. Should severity be cited by the requesting 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 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 exceptionality: genotypes

16. When the argument for clinical exceptionality is based on the patient having a specific genotype (genetic profile), the IFR Panels 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 exceptionality: multiple grounds

17. 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 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 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 have to be disregarded for this purpose in order for the IFR screening groups 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, SCCG and T&WCCG 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 SCCG and T&WCCG's policies 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 groups and IFR Panels should not make.

22. 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 teams and on recommendation by the screening groups.

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 groups and IFR Panels. It is the sole responsibility of the referring clinician to provide this information and the IFR teams 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.

25. When considering clinical effectiveness, the IFR Panels 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 on quality of life using information as 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 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 CCG 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 take into account 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, in itself, 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 have to 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 to be unproven, and this is why the IFR 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?

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 and then, primarily, when the IFR Panel considers 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, SCCG and T&WCCG 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 SCCG and T&WCCG's 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. SCCG and T&WCCG 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, SCCG and T&WCCG will make a decision 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 SCCG and T&WCCG 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, SCCG and T&WCCG do 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 CCG's Commissioning Policy – "Continuing funding after the completion of a clinical trial".

Information submitted to the Shropshire CCG and Telford & Wrekin CCG IFR Teams

45. All applications must be on the CCG's IFR template, submitted electronically and accompanied by written support and evidence provided by the clinician treating the patient in line with the SCCG and T&WCCG IFR SOP.

46. It is the referring clinician's responsibility to ensure that all the appropriate and required information is provided to SCCG and T&WCCG 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 screening groups and IFR panels 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 such similar patients there are or are likely to be in the opinion of the referring clinician in the relevant CCG in any given 12 month period.

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

48. SCCG and T&WCCG expect providers with which it contracts to have oversight of the applications submitted by their clinical staff. The CCG 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.

49. Ultimately SCCG and T&WCCG IFR decisions are whether the CCG 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: The Management of Individual Funding Requests.*

Screening process for IFR requests

Why are applications subject to 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 Panels could properly come to the view that the criteria under this policy are met in an individual case.

51. The screening process described in this Policy is intended to be fair to all parties, including the other patients funded by SCCG and T&WCCG and the IFR Panels, by only sending cases to a panel meeting if there is some reasonable prospect that the IFR Panels will accept that the

criteria under this policy are met in the individual case. This means the IFR Panels can then apply all of its time to those cases which have a prospect of success.

Screening for Sufficient Information

52. Any IFR applications will first be screened by SCCG and T&WCCG's IFR teams in accordance with the procedures set out in the CCG's IFR SOP to establish whether the request falls within the commissioning responsibility of the CCG and has sufficient clinical or other necessary information for it to be properly considered. Where the IFR teams conclude that there is insufficient information, The IFR template will be returned to the referring clinician specifying the additional information required.

53. The IFR Panels can only consider funding if all of the criteria in the policy are satisfied. It follows that the IFR screening teams should not allow an application to go forward to the IFR Panels 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 Panels 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 screening teams considering a submitted IFR application 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 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 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 IFR applications submitted to SCCG and T&WCCG will be considered by the IFR screening teams to determine whether the request appears to present an arguable case for clinical exceptionality. The IFR screening teams are drawn from the clinical members of the IFR panels (as outlined in the IFR SOP) and their understanding of the information required by an IFR panel enables them to make these decisions. They have delegated authority from SCCG and T&WCCG to make these judgements and will seek additional clinical input at their discretion. If the screening teams consider that it appears 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 screening teams consider that there is some realistic prospect that the IFR Panels (properly applying the policy) would conclude that the patient is clinically exceptional. A case would be turned down only where the IFR screening teams are confident that, based on the available information, if the IFR Panels properly apply this policy, they would come to a conclusion that the patient is not clinically exceptional.

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 screening teams will reconsider a case if new and relevant clinical information is provided.

58. Screening teams can request advice, e.g. relating to a treatment pathway and lines of therapy within that from appropriate clinicians/CCG Managers.

Decisions on funding

59. The IFR Panels work on behalf of SCCG and T&WCCG and make decisions in respect of funding for individual cases. The IFR Panels will work to the published SCCG and T&WCCG IFR Policy and each request will be processed by following the SCCG and T&WCCG 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 treating clinicians and the SCCG and T&WCCG 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 clinician should not assume particular 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 Panels will contain a range of individuals with a variety of skills and experiences. The IFR Panels 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 Panels must consider whether it is appropriate to divert resources away from other services in order to fund the requested treatment.

62. The IFR Panels will make decisions based on the criteria in this policy with reference to any other SCCG or T&WCCG published clinical commissioning policies or NICE mandated guidance relevant to the application or interpretation of the criteria.

63. In reaching their decision, the IFR Panels 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 panels 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 Panels to conclude, notwithstanding the screening decisions taken by the IFR screening teams, 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 Panels can take a decision on whether funding should be given, in which case further information will be requested through the IFR teams. This can be sought from the clinician, from within the CCGs' clinical advice structure or from other clinical advisers as considered appropriate.

66. In considering individual cases, the IFR Panels 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 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 19-22).

67. The IFR Panels 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 Panels consider that application of the rule of rescue would form the basis for treatment, funding will be declined.

68. The IFR Panels 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 Panels 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.

70. The IFR Panels 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.

71. The IFR Panels 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 Panels 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 of the IFR Panel be subject to review.

73. All requests for a review must be made within 28 days of the date when the decision is communicated to the patient. 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.

74. The request for a review will be initially considered by a CCG Director not involved in the original IFR application. 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 Review Panel meeting will be recommended to the relevant CCG's Accountable Officer.

75. If the Director reviewing the case does not accept the grounds put forward for a review, they will report the rationale for their decision to the relevant CCG's Accountable Officer who will consider and, if in agreement, will ratify the decision. The relevant CCG's Accountable Officer will then write to the referring clinician and/or the patient/patient representative explaining the reasons for the decision not to review the IFR Panel decision.

76. The role of the IFR Review Panel is to determine whether the IFR Panel has followed the procedures as written in the CCG's IFR SOP, and has considered the evidence presented to it and has come to a reasonable decision based on the evidence.

77. 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 policies of Shropshire CCG and Telford & Wrekin CCG;

- 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 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 error not been made.

79. 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 error not been made, the IFR Review Panel will require the IFR Panel to reconsider the decision.

80. The IFR Review Panel does not have power to authorise funding for the requested treatment but can require 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 formal legal challenge, an internal review of the process taken leading to a decision will automatically be triggered by the relevant CCG.

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 when received and the IFR panel meets monthly. Consequently cases can be processed very quickly 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 Trust, as the CCGs do not routinely support retrospective funding.

83. There is a provision for cases to be processed more quickly than the 30 working day standard (stated in the SOP). 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, SCCG and T&WCCG may refer the matter to the clinician's Chief Executive or equivalent.

84. In the unlikely event that the case is so urgent that it requires a decision on treatment before the IFR Panels next meet (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.

Adopted from NHS England Individual Funding Requests 2017