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NHS England

Standard operating procedures: Individual funding requests

Version 5, 8 February 2023

Contents

Standard operating procedure statement

This document sets out how the process for managing individual funding requests (IFRs) for NHS England prescribed services will operate. Such requests are managed in line with the NHS England IFR policy.

This updated version reflects any revisions to the NHS England IFR Policy made as a result of public consultation.

Equality and health inequalities statement

Promoting equality and addressing health inequalities are at the heart of NHS England's values. Throughout the development of the policies and processes cited in this document, we have:

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

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

Introduction

Individual funding requests for NHS England prescribed services

1. This document sets out how the process for managing individual funding requests (IFRs) for NHS England prescribed services will operate. The intended audience is those responsible for the operation of the IFR process and related decision making. It will also be of interest to those wishing to apply for funding of treatments under the IFR policy. It should be read in conjunction with the following NHS England commissioning policies:

    - NHS England Commissioning Policy: Individual funding requests
    - NHS England Ethical Framework
    - NHS Commissioning Policy: Funding for clinical trials and after completion of a clinical trial
    - NHS England Commissioning Policy: Specialised Services Service Development Policy

2. NHS England is the statutory body responsible for the consideration of IFRs for services NHS England directly commissions or remains the accountable commissioner in England. These include specialised services (SS), all health services for the Armed Forces (AF), Health and Justice (H&J), and secondary care dentistry. The policies listed above describe the underpinning NHS England policy framework which will apply to the management of IFRs for services NHS England directly commissions or remains the accountable commissioner, with the exception of the Service Development Policy which relates to specialised services only. Treatments submitted for consideration of funding as IFRs inform national clinical commissioning policy development.

3. There is a single process for the operational management of all prescribed services IFRs. This process is the remit of an IFR administrative team for NHS England which is geographically distributed but flexible and responsive to requests and enquiries on a national basis. Decisions are made at each stage of the process by a nationally representative IFR Screening Group,

IFR Panel and IFR process Review Panels. Members participate on a rota basis promoting consistency and equity in decision making.

Deciding when NHS England is the responsible commissioner

4. The following criteria will be used to assess whether a treatment/service and its indication for use are the commissioning responsibility of NHS England:

    - is the treatment for which funding is requested associated with a service, treatment or a patient group described as the commissioning responsibility of NHS England in the published Manual for prescribed specialised services, the associated identification rules documents, a published NHS England clinical commissioning policy or service specification?

    - Is the patient for whom the treatment/service is requested one of the groups of patients (Armed Forces and Health and Justice) for whom NHS England directly commissions services?

    - Is the treatment for secondary care dentistry?

5. If any of the above applies, NHS England is the accountable commissioner. Prescribed services are commissioned by NHS England for patients eligible for NHS treatment in England.

6. The standard operating procedures (SOP) do not cover IFRs for treatments and services which are the commissioning responsibility integrated care boards (ICBs) as a result of the dissolution of clinical commissioning groups (CCGs). Close working relationships between NHS England and ICB IFR Teams will ensure that requests for services NHS England directly commissions or remains the accountable commissioner and ICB commissioned services are directed appropriately.

IFR timescales and urgent cases

7. The standard period for providing a substantive response to an IFR (i.e. a decision on the funding request) is a maximum period of 30 working days from the date of the receipt of an IFR form to the date the requesting clinician is informed of the outcome (inclusive).

8. This 30 working day period discounts any working days where the IFR Team are awaiting information sought from the requesting clinician. At any point in the IFR process, the IFR Team can ask for further information to clarify the request. If the requester does not provide a response to the IFR Team within 10 working days the request record will be closed and the requester informed. Such a request can be reopened on submission of the additional information.

9. IFRs must be considered carefully and with the benefit of all the required information. Clinicians are encouraged to submit IFRs in a timely manner which has regard to the standard decision-making timescale set out above. As far as possible clinicians should avoid waiting until a case becomes clinically urgent before submitting an IFR. In this context, references to clinical urgency are to risks of adverse clinical outcome to the individual patient if a decision on the IFR is not provided within a 30 working day timescale. These risks should be made explicit in the application together with the reason that the application has not been made earlier. The IFR Team will endeavour to prioritise urgent requests proportionately to their degree of urgency but it must be appreciated that for every patient whose application is fast tracked another patient's application is delayed. Not every request for urgent consideration can be complied with, which underscores the need for timely applications to be made whenever possible.

10. Under the national framework for the management of IFRs which this document outlines, screening of IFRs will be undertaken four times each week and the national IFR Panel will meet usually three times per month.

11. NHS England makes funding decisions in line with the IFR policy however, the clinical responsibility and decision to treat a patient lies with the treating clinician and/or the trust. If, pending the outcome of any IFR application, a patient is presenting as clinically urgent, clinicians should seek advice from their Medical Director.

12. Should a decision be made by the provider to start treating a patient due to clinical urgency, and an IFR application is still desired, a completed IFR application must be submitted to the IFR Team within two working days of the intervention first taking place. The IFR Team will not process applications that fall outside of this timeline. If the IFR has been received within this timeline and the IFR Panel subsequently supports the funding of the IFR request, treatment

funding will be backdated to the date on which the application was made. Costs will not be reimbursed if the IFR Panel decline the request.

The IFR process

Administrative pre-screening

13. The standard NHS England IFR application form must be used for all requests. The request will not be progressed if not completed and submitted through the online portal (Apollo). An overview of the form and links to the online portal can be found at *Appendix one – NHS England IFR application form* and is available alongside the published IFR policy and guidance for clinicians online.

14. Users are required to register with the portal. Once an account has been created and approved, applications can be submitted through: Apollo - Login. Further details on the portal, how to create an account and submitting an online application can be found online on the FutureNHS workspace (login required).

15. Submissions on IFR forms from other commissioning organisations cannot progress through the NHS England IFR process. This is to ensure that all NHS England IFR requests contain the same depth and range of information and so can be equitably presented for consideration. If a request for funding a treatment which is an NHS England commissioning responsibility is not submitted through the NHS England IFR online portal the requester will be asked to resubmit using the online portal.

16. Every section in the IFR form needs to be completed in full in order for the request to progress. Any request form which is incomplete will be returned via the portal to the requester for completion and the application will not progress any further until completed and resubmitted.

17. A request must come from a healthcare professional directly involved in the care of the patient. This should be the most senior clinician responsible for the care of the patient usually at consultant level and should be the clinician with responsibility for delivering the proposed treatment. For all prescribed services,

including non-specialised treatments for specified populations, there will be a lead clinician offering the treatment requested.

18. The request must come from a provider who is contracted by NHS England to provide services for whom NHS England directly commissions or remains the accountable commissioner which are the subject of the IFR. Providers who are not so contracted will be advised to make an appropriate referral to the relevant specialised centre who can consider whether an IFR is necessary.

19. General practitioners who request prescribed services treatments will be advised to make a referral to an appropriate clinician within a specialised provider. The IFR will not progress at this point until that is undertaken.

20. Requests will not be accepted from a patient or their non-clinical representative. This is for two reasons. Firstly, it is because it is unlikely that the patient would be in possession of the technical clinical detail that is necessary for consideration of the case and secondly, the process is to enable an NHS clinician to apply for funding to support the provision of NHS treatment by that clinician to the patient.

21. The patient / patient's representative or guardian can submit information in support of the request. A patient representative is a person who has the legal authority to take decisions about medical care and treatment on behalf of a patient who lacks capacity to take these decisions themselves. Such information can only be considered if it relates to the patient's clinical circumstances. As described in more detail in the IFR policy, non-clinical factors cannot be taken into account and should not be submitted.

22. Unless the following paragraph applies, the requesting clinician should complete the consent section of the form to confirm that the patient is aware of the application and has agreed to their personal clinical information being shared. The NHS England guide 'Individual funding requests – information for patients' should be given to patients as part of the consent process to ensure that the patient has received sufficient information to support informed consent.

23. If the requesting clinician considers that the patient does not have capacity to give informed consent this should be indicated and explained in the IFR form. In these circumstances the submission should also confirm whether consent has been obtained instead from a patient representative and, if not, the basis

on which the IFR is nevertheless being made by the clinician. Submissions which do not include either confirmation of appropriate informed consent by the patient or a patient representative, or a satisfactory clinical explanation as to why the application is being made without consent cannot be processed and must be returned for amendment.

24. Trust support is a mandatory section of the application form. The application will not progress in the absence of this support. Requests should be supported by a relevant multidisciplinary team (MDT) or trust drugs and therapeutics committee (DTC), Chief Pharmacist (or deputy) where funding for medicines are requested **and** by the provider trust Medical Director/Deputy Medical Director. It is mandatory to provide copies of the MDT/DTC minutes/record of the discussion to the IFR Team, alongside the application. For drug requests the Chief / Deputy Chief Pharmacist must also support the application.

25. IFR applications should be supported by published electronic copies of the clinical research evidence papers or other supporting documents (e.g. trust guidance or supporting clinical letters). Evidence should directly support the use of the requested treatment for the condition in cases such as the patient in question, and the requesting clinician should highlight links between the evidence submitted and the particular patient circumstances. Evidence should be uploaded to the online portal as PDF or Word documents. The IFR Team are unable to accept abstracts or web links.

26. If a request for prescribed services for Armed Forces (AF), Health and Justice (H&J) populations or for secondary care dentistry is submitted to the IFR Team, they will refer it to the relevant commissioning teams to ensure that appropriate pre-screening by those commissioners has been carried out. Requesting clinicians will be informed of this and the IFR will not proceed at this stage. Separate arrangements for considering funding for AF and H&J populations are available. NHS England Health and Justice and Armed Forces service specific policies are available at: england.nhs.uk/commissioning/policies/ssp/. Requests relating to secondary care dental services should be directed to the regional NHS England office dental team in the first instance.

27. If a request for treatment that is not the commissioning responsibility of NHS England is received, the requester will be advised accordingly and the case record closed.

28. The IFR Team will consider whether existing directly commissioned services would cover the requested treatment. If commissioning arrangements exist the IFR Team will assess whether the requested treatment specifically falls outside the relevant commissioning criteria. The IFR Team will be supported in this by commissioning and clinical colleagues e.g. specialised commissioning Programme of Care (POC) leads, AF, H&J and secondary care dentistry leads, Pharmacists, Public Health, supplier managers, service leads and Clinical Reference Groups (where required). Where commissioning arrangements exist which may apply to the patient the request will be returned to the requester with advice to review the case against the commissioning arrangements and will not progress further as an IFR until this is completed.

29. If an IFR meets all requirements to be able to proceed as an IFR, the IFR Team will begin to complete the pre-panel screening document (PPSD). This document will be the mechanism for recording and sharing information with decision makers at each stage of the IFR process. It forms a record of the outcome of screening and will detail the explicit reasons for the outcome.

The Screening Group

30. Completed IFRs, all supporting documents and the pre-panel screening document (PPSD) will be processed by the IFR Team and authorised senior health professionals (the Screening Group) as set out in the IFR policy. A national pool of screeners will contribute to Screening Group meetings on a rota basis by video call. These will usually include the IFR Team, Public Health consultants and specialists and Pharmacy leads. Representatives for AF, H&J and dental will join the Screening Group for cases relating to their commissioning responsibilities. All the documents will be made available to the Screening Group without patient identifiers to protect confidentiality and minimise the potential for identification bias. This will include the removal of patient's name, date of birth, NHS number, the name of requester, Medical Director, Chief Pharmacist (where applicable), the requesting trust and any

other identified clinicians and organisations. Where a requester has inadvertently included small amounts of non-clinical information, this will be redacted by the IFR Team prior to screening. Where there are large amounts on non-clinical information included in the form and to redact the form would materially alter the information in the form, the application will be returned to the requester with advice on resubmission.

31. The purpose of the Screening Group (*Appendix two – Terms of reference IFR Screening Group*) is to determine whether the requester appears to present an arguable case for the clinical exceptionality of their patient compared with other patients with the condition. If the screening process determines that the request is not a service development (i.e. that patient is not part of a wider group who could equally benefit from the treatment) and there is sufficient information to consider the case, the Screening Group will then determine whether the documentation sets out a clearly presented and arguable basis for how the request meets the IFR policy criteria.

32. The Screening Group may also regularly seek scientific and technical information relating to the natural history and usual course of the condition, the place of the treatment in the patient pathway or the evidence base for the requested treatment. Such advice will be sought through the NHS England clinical advice structure. Any advice received will be shared with the requester at the same time that the screening outcome is communicated.

33. A request will normally be screened and the outcome communicated by NHS England within 12 working days of the date of receipt of a completed IFR form. If further information is required from the requester, the timeline for the request is suspended until this is received.

Outcomes at IFR screening

34. The Screening Group will have the following outcomes available to them:

- if an individual meets the criteria for funding within a NHS England clinical commissioning policy or commissioned service, and this is confirmed by the Screening Group the requester should be advised of this and the request does not proceed further as an IFR. Clinicians are advised that if they are unsure about whether something is commissioned at their trust, they

should discuss with their trust contracts team whether the treatment is covered by their contract, in the first instance

- to seek further clinical information to clarify specific issues relating to the case from a reliable information source. This may be from the requester or from the NHS England clinical advice structure at the Screening Group's discretion. Information will only be sought at this stage if there is a clear understanding that an answer is necessary for a decision by the Screening Group. If this information is received within 10 working days it will be considered by the original Screening Group. If it is received after 10 working days the request will go to a new Screening Group

- to conclude that there is sufficient information for the IFR to be forwarded to the IFR Panel for consideration and an arguable case for exceptionality has been presented. The PPSD (*Appendix three – pre-panel screening document*) will be completed with the detail of the screening outcome and included as part of the pack of information for the IFR Panel to consider

- to conclude that there is sufficient information presented to enable them to reach a decision but that an arguable case on exceptionality has not been presented on the basis of the criteria for consideration as an IFR (as outlined in the IFR policy). If this is the case, the Screening Group is required to decline the request without referring the case to the IFR Panel

- where an IFR is declined by the Screening Group a written response will be sent to the requesting clinician explaining the reasons for the outcome and outlining the options that are available. This will usually be copied to the patient's GP when working practices allow.

35. The IFR Team will advise relevant requesters (via email) of the status of their application within two working days. The completed letter will be sent within seven working days of the Screening Group outcome.

36. The patient / parent or patient representative, in accordance with the patient consent arrangements, will be notified of the outcome by receiving a letter when working practices allow. The responsibility for discussing the outcome of the funding request and answering any questions which the patient may have about the request or their clinical options will lie with the requesting clinician. This is because the clinician will have the full details of the reasons

for the decision and will need to share these. The clinician should contact the patient in order to discuss the outcome and implications for future care.

37. If the Screening Group concludes that the request is either a service development, there is not sufficient information or evidence the IFR policy does not provide a right for the case to be considered by the IFR Panel and does not provide a right to request that the screening outcome should be reviewed by the IFR Process Review Panel. However, the requesting clinician may feel that in the light of the reasons for refusal, there is new clinical information that should be included. If this is so, the case can be reconsidered by the Screening Group.

Reconsideration by the Screening Group

38. If a requesting clinician believes they have significant new clinical evidence that they did not previously provide which they think may have made a difference to the decision made, or if the Screening Group sought additional advice through the NHS England clinical advice structure and the requesting clinician disagrees with that advice, then they can submit this new evidence or explain the basis of their disagreement and request reconsideration of their decision by the Screening Group. The new clinical evidence or explanation of disagreement must be completed on the reconsideration form (*Appendix four – NHS England IFR Reconsideration Form*). Reconsideration forms should be submitted via a secure email, either NHS.net or an NHS Digital accredited email. Further details on email accreditation are available at: digital.nhs.uk/services/nhsmail/the-secure-email-standard. The Screening Group will determine if the new information provides a different clinical picture warranting a different screening outcome using the reconsideration PPSD (*Appendix five - IFR reconsideration - Screening Group decision*).

39. The Screening Group will determine, normally within 12 further working days of the submission of a complete reconsideration form, whether the additional information materially alters the nature and strength of the evidence that was initially submitted.

40. If a decision is made to refer the case to IFR Panel following reconsideration, the IFR Panel decision should be communicated within 30 days of the receipt of the reconsideration request.

The IFR Panel

41. IFR Panel meetings and membership are scheduled in a rolling programme in advance. The Terms of reference for the IFR Panel are in *Appendix six – Terms of reference IFR Panel*.

42. When a request is referred for consideration by the IFR Panel, the IFR Team will book the case onto the next meeting date that has time available to consider the case and inform the requesting clinician. The case will be prepared for Panel.

43. The patient / patient representative, or their clinical or non-clinical representative, is not entitled to attend the Panel meeting. This is to ensure objective decision making by the IFR Panel in a fair and equitable manner to all patients.

44. The IFR Team will provide the IFR Panel members with an information pack which will include the original request form, any supporting documents or correspondence, the pre-panel screening document and a blank IFR Panel decision framework document (DFD) (*Appendix seven – IFR Panel decision framework document*) for use during the Panel meeting. All the documentations will be made available to the Panel completely anonymised and redacted to protect confidentiality and minimise the potential for identification bias.

45. A nominated clinical member of the IFR Panel will introduce the case at the meeting. The purpose of this case introduction is to present the clinical background and outline technical clinical factors associated with the case and allow for any clarification required by non-clinical Panel members. The presentation will not include their opinion on the clinical exceptionality of the case in question. The IFR Panel will then discuss the case in relation to the questions outlined in the IFR Panel DFD and reach a decision on whether funding can be approved under the IFR policy.

IFR Panel decision making

46. The IFR Panel works on behalf of NHS England and makes decisions in respect of funding for individual cases. It is not the role of the IFR Panel, by its decisions, to make clinical commissioning policy on behalf of NHS England.

47. The IFR Panel will apply the criteria in the IFR policy and the IFR Team record the decision of the IFR Panel against each of the questions on the IFR Panel DFD. The Panel will be clear about the rationale for the decision at each stage and this will be recorded in the document.

48. The completed DFD for each case will form the business notes of the meeting. Once reviewed by the Specialised Commissioning Medical Director, the DFD will be agreed and signed off by the Chair of the IFR Panel. Any notes made by individual Panel members should be destroyed confidentially by the members after the meeting.

Outcome at IFR Panel

49. The options available to the IFR Panel are to decide:

- to approve funding if the patient and the treatment requested meet the criteria outlined in the IFR policy. Where an IFR is approved the IFR Team will require an update on the clinical outcome of treatment from the requesting clinician in order to determine whether it has resulted in the anticipated level of benefit to the patient. An appropriate review date will be determined by the IFR Panel and recorded. The IFR system will flag when review dates are due. The IFR Team will ensure that feedback on outcomes is requested. This information is essential for processing requests for continuation of treatment. Provider trusts and their clinicians are required to comply with such requests for information on the outcome of treatment for their patients, in compliance with the IFR policy. Funding is conditional on this. (*Appendix eight – Funding for continuation requests* provides information on the process for requesting continued funding for treatment approved under an IFR).

- to decline funding on one of two grounds:

    - that there is insufficient information presented to enable the panel to reach a decision

- that the request does not meet the criteria outlined in the IFR policy.

50. The IFR Panel may wish to seek further information to clarify specific issues relating to the case. This may be from the requester or from the NHS England clinical advice structure. Where this is the case the IFR Panel Chair and Specialised Commissioning Medical Director will clearly outline the action to be taken. Any advice received from NHS England will be shared with the requester at the same time that the IFR outcome is communicated.

51. Where an IFR is declined by the IFR Panel, a written response will be sent to the clinician explaining the reasons for the decision and outlining the options that are available. This will usually be copied to the patient's GP when working practices allow. The patient / parent or patient representative, in accordance with the patient consent arrangements, will be notified of the outcome by receiving a letter when working practices allow. The responsibility for explaining the reasons for the decision (based on the information provided by NHS England) and answering any questions which the patient may have about the request or their clinical options will lie with the requesting clinician. This is because the clinician will have the full details of the reasons for the decision and will need to share these. The clinician should contact the patient in order to discuss the outcome.

52. The IFR Team will advise relevant requesters of the outcome of their application within two working days of the IFR Panel (via email). The completed outcome letter will aim to be sent within seven working days of the IFR Panel meeting.

53. Complaints at any point in the IFR process should be submitted to:

    Telephone: 0300 311 22 33
    Email: england.contactus@nhs.net
    General Post (including complaints, but not legal proceedings): NHS England, PO Box 16738, Redditch, B97 9PT

Reconsideration by the IFR Panel

54. If a requesting clinician believes they have significant new clinical evidence that they did not provide in their first submission which they consider may have made a difference to the decision made if it had been available to the IFR Panel, or if the IFR Panel sought additional advice through the NHS England

clinical advice structure and the requesting clinician disagrees with that advice, then the clinician can submit the new clinical evidence or explain the basis of their disagreement and request reconsideration of the decision by a Screening Group. The Screening Group will determine if the new information or disagreement provides a different clinical picture warranting a further referral to the IFR Panel.

55. If the new information is considered to be material the case will be presented at the next appropriate IFR Panel. The outcome of the panel reconsideration will be communicated as described for the first IFR Panel meeting.

56. With IFR reconsiderations, the focus of the IFR Panel discussion will be on the new information submitted by the clinician and this will be made clear in the rationale for the decision. The focus of the IFR Panel discussion will be on the content of the new information. A reversal of an earlier decision will not be on the basis of previously provided information only.

Review of IFR Panel decisions

Requests for a process review of the IFR Panel decision

57. The requesting clinician, the patient or a patient representative may make a request to NHS England for a process review of an IFR Panel decision.

58. The request should be made in writing, addressed to the NHS England IFR Team (england.ifr@nhs.net). Such requests must be lodged within 20 working days of the date of the letter from NHS England setting out the IFR Panel decision. The IFR Team will highlight any requests received outside this timeline, and the Specialised Commissioning Medical Director may exercise discretion in accepting a request for a review outside this time limit if there is good reason to do so.

59. Requests for a review should be clearly marked as a ‘Request for an IFR Panel review’ and sent via the IFR Team using the contact details in the IFR outcome letter.

60. The request for review must be supported by the requesting clinician who will set out the grounds on which the IFR Panel decision is being challenged. A review can only be requested on the grounds set out in the IFR policy.

61. In the circumstances of a legal challenge, an internal review of the process taken leading to a decision will automatically be triggered by NHS England.

Screening of a request for a process review

62. The request for a review will be initially considered by a Public Health Consultant / Specialist 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 process review panel meeting will be recommended to the Specialised Commissioning Medical Director.

63. If the Public Health Consultant / Specialist reviewing the case does not accept the grounds put forward for a review, they will report the rationale for their decision to the NHS England Specialised Commissioning Medical Director who will consider and, if in agreement, will ratify the decision. The NHS England Specialised Commissioning Medical Director will then write a letter to the requesting clinician and / or the patient / patient representative explaining the reasons for the decision not to review the IFR Panel decision.

Organisation of the IFR review panel

64. The IFR review panel will normally be convened within 10 working days of NHS England accepting the case for a review.

65. The Terms of reference for the IFR review panel are in *Appendix nine – Terms of reference IFR review panel*. Their role being to determine whether the IFR Panel followed the procedures as written in the IFR SOP, properly considered the evidence presented to it and came to a reasonable decision based on that evidence.

66. The IFR review panel will examine all of the papers and correspondence considered by the IFR Panel, the DFD, the decision letter and the grounds of appeal. They will examine the process followed by the IFR Panel and the decision it made. The IFR review panel will examine the issues raised in the grounds and the tests set out for a process review in the IFR policy.

67. There will be no representation at the IFR review panel meeting from the IFR Panel or the requesting clinician and / or the patient / patient representative. The IFR review panel will not consider new information (i.e. that was not before the IFR Panel, including on any reconsideration) or receive oral representations. If there is significant new information, not previously considered by the IFR Panel, it can only be referred and considered as set out in the 'Reconsideration by the IFR Panel' section above.

68. Reasons given for a process review outcome will only refer to the IFR policy as this is the basis on which the original IFR Panel decision is made.

Outcome from the IFR review panel

69. The IFR review panel will be able to reach one of two decisions:

    - uphold the decision reached by the IFR Panel
    - refer the case back to the IFR Panel with detailed points for reconsideration.

70. The IFR review panel Chair will write to the requesting clinician, the patient / patient representative and GP, and the IFR Panel Chair within seven working days of the review meeting. This is to inform them of the outcome with the reasons for the IFR review panel decision.

71. If the IFR review panel determines that the IFR Panel needs to reconsider the case, the IFR Panel should reconvene within 10 working days of the date of decision letter from the Chair of the IFR review panel. The IFR Panel will reconsider its decision and in doing so will formally address the detailed points raised by the IFR process review panel.

72. The IFR Panel is not bound to change its decision as a result of the IFR review panel's decision to refer the case back, but if the IFR Panel upholds the original decision, clear reasons must be given for not agreeing to fund the treatment request.

Monitoring and reporting of the IFR process

73. A regular report to the NHS England Specialised Services Clinical Effectiveness Team will inform the programme for national clinical commissioning policy development (for specialised services) and provide oversight of the key performance indicators for the IFR process, as outlined in this document.

74. Members of the NHS England Armed Forces, Health and Justice and secondary care Dental will provide their own reports to their directorates, as required.

1. Timeline: 30 working days from receipt to outcome
This is from receipt of an IFR form to the outcome of the request being communicated to the requester. It excludes days spent awaiting information from the requester. Monitoring and reporting will also include the average turnaround timelines. IFR managers are responsible for ensuring that the database is updated as the information is received and any action is taken.
2. External communications: activity and resolution
External communications relating to IFRs are requests for information, investigation, responses, and so on, received from people or organisations not directly involved in a request. This includes but is not limited to MP letters, complaints, media enquiries, legal communications, Parliamentary questions, Freedom of Information (FOI) requests. These communications will be reported on a monthly basis to the Clinical Effectiveness Team.

Appendix one – NHS England IFR application form

The standard NHS England IFR application form must be used for all requests. The request will not be progressed if not completed and submitted through the online portal (Apollo).

Users are required to register with the online portal. Once an account has been created, applications can be submitted through: *Apollo - Login*. Further details on the portal, how to create an account and submitting an online application can be found online here: *IFRTrustSupport/grouphome*

This is an overview of the questions contained within the application available through the online portal.

Requesters are advised to review the NHS England IFR Policy, IFR Standard operating procedures (SOP) and the Guidance for Clinicians at www.england.nhs.uk/commissioning/spec-services/key-docs/#ifr. NHS England requires provider trusts and clinicians to take NHS England clinical commissioning policies into account in the advice and guidance given to patients prior to making the decision to treat a patient.

It is the responsibility of the requesting clinician to ensure all the appropriate and required clinical information is provided to NHS England. This includes full text copies of all the published papers of clinical evidence that have been cited, a list of the published papers submitted and an indication of which points within them 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.

The information requested at question 2g and 2h is collected for monitoring purposes in an anonymised format to assist NHS England 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 or trust/requesting clinician identifiable data in sections 3 to 8 inclusive. Where there are large amounts of identifiable data included the application will be returned to you through the portal for redaction and resubmission.

Please note: Applications presenting incomplete information will be returned for amendment / completion prior to consideration by NHS England.

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.
Section 2 – PATIENT/GP DETAILS	
2a) First name:	Click here to enter text.
2b) Last name:	Click here to enter text.
2c) NHS number:	Click here to enter text.
2d) Patient's hospital no:	Click here to enter text.
2e) Date of birth:	Click here to enter text.
2f) Patient's age at time of submission:	
2g) Gender	Chose 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.
Section 3 – REQUEST DETAILS	
3a) Direct commissioned service type:	Choose an item.
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	Click here to enter text.

in application:		
3d) Proposed treatment stop date (if applicable):	Click here to enter a date.	
Application Support		
The IFR policy and SOP highlight that trust 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 trust drugs and therapeutics committee (DTC) **AND** by the provider trust Medical Director.		
3e) DTC or equivalent approval and provide a copy of the minutes:	Please provide details of outcome Click here to enter a date.	☐ Yes ☐ No ☐ N/A
3f) MDT approval and provide a copy of the minutes:	Please provide details of outcome Click here to enter a date.	☐ Yes ☐ No ☐ N/A
3g) Name and email of Chief or, in exceptional circumstances to avoid delays in submission the deputy Chief Pharmacist:	Click here to enter text - name. Click here to enter text – email.	
3h) Confirm that the Chief/deputy Chief Pharmacist supports this drug application:	☐ Yes ☐ No ☐ 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 - name. Click here to enter text – email.	
3j) Confirm that the Medical Director/Deputy Medical Director supports this application:	☐ Yes ☐ No	
Consent		
3l) 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. **I confirm all of the above.**		☐ Yes ☐ No

3m) In submitting this application you are under obligation to advise the patient or patient representative of the details of the reasons for the decision. **I confirm that I will advise the patient or patient representative of the reasons for the decision.**	☐ Yes ☐ No
3n) The patient or patient representative will receive a letter outlining that a decision has been made and what that decision is, although will not receive the detail for that decision. **I confirm that it is clinically appropriate for the patient to be informed of the outcome of this IFR.**	☐ Yes ☐ No
3o) I understand that by indicating that it is NOT clinically appropriate for the IFR Team to contact the patient or patient representative with the outcome, I will be fully responsible to do this. **I will inform the patient or patient representative of the outcome and the reasons for the decision.**	☐ Yes ☐ N/A

Section 4 – TREATM ENT

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 is an existing clinical policy for this treatment and condition? Please provide explicit reasons why your patient does not meet the access criteria within that policy.	Click here to enter text.		
Cost			
4d) What are the costs of the intervention? *Where appropriate include here the total cost of the treatment, any loading doses required and the number of cycles applied for.*	☐ Single treatment	Total cost Click here to enter text.	
	☐ Multiple treatments Click here to enter text – load dose. Click here to enter text – subsequent doses.	Cost per treatment: Click here to enter text. Click here to enter text.	Total cost: Click here to enter text.

4e) Additional comments on the costs of the intervention:	Click here to enter text.
4f) What are the total costs of standard therapy (estimate annual costs if applicable)?	Click here to enter text.
4g) Are there any offset costs (provide details)?	☐ Yes ☐ No Click here to enter text.
Clinical Outcomes	
4h) What are the intended clinical outcomes and how will the benefits of the procedure/ treatment be measured (including where appropriate the validated clinical tools to be used)? *Please include baseline data at the time of application and, if appropriate, anticipated improvement.*	Click here to enter text.
4i) Within what timeframe will these outcomes be determined?	Click here to enter text.
4j) What 'stopping' criteria will be in place to assess when the treatment is ineffective and treatment will be withdrawn?	Click here to enter text.
4k) What mechanisms will be in place to provide NHS England with clinical outcome reports if the treatment is approved? *Please provide detail of how you will report to NHS England upon request.*	Click here to enter text.
Section 5 – Clinical Background	
5a) Outline the background to the patient's clinical situation relevant to this request, timeline, current status and symptoms. *Please give validated clinical measures, named in full.*	Click here to enter text.
Treatment History	

	Treatment	Regimen	Start	Stop	Response	Funding source

5b) Current	Click here to enter text.	Click here to enter text.	Click here to enter text.	Click here to enter text.	Click here to enter text.	Click here to enter text.
5c) Previous:	Click here to enter text.	Click here to enter text.	Click here to enter text.	Click here to enter text.	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 text.	Click here to enter text.	Click here to enter text.	Click here to enter text.

5e) Additional comments on current or previous treatments	Click here to enter text.
Additional Treatment Information	
5f) What are the alternative (including NHS England commissioned) 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 prognosisif treatment requested is not funded:	Click here to enter text.

Section 6 – Clinical Exceptionality

Is there evidence that this patient has exceptional clinical circumstances, demonstrating that:

6a) There is an NHS England clinical commissioning policy, NICE Technology Appraisal (TA) guidance or Highly Specialised Technology (HST) Appraisal guidance and/or there is any other relevant mandatory/statutory guidance governing access to the requested treatment for the same condition as this patient **and** the patient is in a different clinical condition when compared to the typical patient population with the same condition and (if relevant) at the same stage of progression, **and** that because of that difference the patient is likely to receive material additional clinical benefit from treatment that would not be plausible for any typical patient. **OR**	☐ Yes Click here to enter text – provide comprehensive comments.
6b) There is not a relevant NHS England clinical commissioning policy, NICE Technology Appraisal (TA) guidance or Highly Specialised Technology (HST) Appraisal guidance and/or there is any other relevant mandatory/statutory guidance governing access to the requested treatment for the same condition as this patient in place for the management of the patient's condition or combination of conditions, **and** the patient's clinical presentation is so unusual that they could not be considered to be part of a defined group of patients in the same or similar clinical circumstances for whom a service development could be undertaken.	☐ Yes Click here to enter text – provide comprehensive comments.
Genotypes	
6c) When the argument for clinical exceptionality is based on the patient having a specific 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: I. Different to others in terms of clinical management	Click here to enter text. Click here to enter text.
AND	

II. Able to benefit from the treatment to a greater degree than others with the same or different symptoms of the condition.	Click here to enter text.

Section 7 – Clinical Supporting Information		
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 million population per year. *Please provide your calculations, and reference any supporting documents.*	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. Please provide specific details. *Please provide your calculations, and reference any supporting documents.*	Click here to enter text.
7b) Prevalence	Estimate the number of patients expected to have this condition per million population at any one time. *Please provide your calculations, and reference any supporting documents.*	Click here to enter text. Per million
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.		☐ Yes ☐ No ☐ 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 a service development that has been discussed with commissioners?		☐ Yes ☐ No Click here to enter text. - If yes, please provide details
7f) Do you plan to submit a future preliminary policy proposal for consideration of funding of this treatment (rather than submit individual requests for single patients)?		☐ Yes ☐ No
Evidence		

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. (Published papers must be provided in full in order to be considered by the IFR Panel. A list of the 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).	Click here to enter text
7h) Is the procedure/treatment part of a current or planned national or international clinical trial or audit?	☐ Yes ☐ No
If Yes, please give details: Click here to enter text.	
Section 8 – SUBMIT	
When you are satisfied that you have completed all sections you will need to submit the request for consideration by the NHS England IFR Team. If the NHS England Team needs more information they will email you to ask that you provide more details and if this happens, the timeline for the request is suspended until this is received.	
Clinicians are required to disclose all material facts to NHS England 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.

Appendix two – Terms of reference IFR Screening Group

Terms of reference
individual funding request Screening Group

1. **Purpose**

All IFRs submitted to NHS England will be considered by the IFR Screening Groups to determine whether the request appears to present an arguable case for clinical exceptionality.

The IFR Screening Group will work in accordance with the published NHS England IFR Policy and each request will be processed by following the NHS England IFR Standard operating procedures (SOP). This will ensure that all requests are considered in a fair and transparent way in line with NHS England's commissioning principles and, outcomes are based on the available clinical evidence presented by the requesting clinicians.

The Screening Group will establish whether there is an arguable case for clinical exceptionality compared to other patients with the same condition and should be put forward for consideration by the IFR Panel.

2. **Membership**

The IFR Screening Group will have a core membership of:

- NHS England specialised commissioning local team Public Health Consultant / Specialist
- NHS England regional team Pharmacy lead for specialised services
- NHS England IFR Case Manager.
- suitable representative(s) from other prescribed services for Armed Forces, Health and Justice, or secondary dental services (as required)

Additionally, senior IFR Team representatives may attend Screening Group but will not be voting members.

3. Roles and responsibilities

The IFR Case Manager will Chair the meeting and will record the decision of the IFR Screening Group against each of the questions in the pre-panel screening document.

The Public Health Consultant / Specialist and Pharmacy lead will be allocated cases to present at the meeting. The case presentation will include the clinical background to the case, including relevant syntheses of the evidence provided by the submitting clinician.

4. Frequency of meetings

The Screening Group will normally be held four times each week with papers circulated three full working days before the meeting. This should prevent the need for urgent cases being considered outside these scheduled meetings. If a case is deemed to be urgent on the advice of the NHS England Specialised Commissioning Medical Director, or nominated deputy, after consultation with the patient's clinicians, it will be put forward to an earlier Screening Group meeting and papers sent immediately.

Due to the frequency of the Screening Group meetings these will be held by videoconference.

5. Voting Rights

Only the clinical members of the IFR Screening Group will agree whether a case should go forward to the IFR Panel. If a consensus cannot be achieved the case will go forward to the next available Screening Group consisting of new clinical members. These two votes will be added to the original two votes and which should result in a majority decision. If the vote is equally split then the case will go forward for consideration by the IFR Panel with explicit reasons given by the members who have indicated it requires a panel decision.

6. Quoracy

All members must be present for the meeting to be quorate.

7. Documentation

IFRs will be allocated an individual case reference number. It is the responsibility of the IFR Team to manage all requests received and correspondence relating to each case in line with the IFR policy and SOP.

All the documents will be made available to the Screening Group without patient identifiers to protect confidentiality and minimise the potential for identification bias. This will include the removal of patient's name, date of birth, NHS number, the name of requester, Medical Director, Chief Pharmacist (where applicable), the requesting trust and any other identified clinicians and organisations.

The IFR Team will produce a summary of the key information using the pre-panel screening document (PPSD) during the meeting.

Only documentation received from the requesting clinician will be used when reaching an outcome. All other documentation that has been received regarding the case will also be available to the Screening Group.

8. Authority

The IFR Screening Group has delegated authority from NHS England to make judgements in line with the IFR policy and SOP and will seek additional clinical advice at their discretion.

It is not the role of the IFR Screening Group to make commissioning policy on behalf of NHS England.

9. Accountability

The pre-panel screening document (PPSD) is the record of the IFR Screening Group and is approved by the clinical members. The IFR Screening Group is accountable to NHS England.

10. Reporting and Monitoring

The IFR Case Manager will record the decision of the IFR Screening Group against each of the questions in the pre-panel screening document. The completed pre-panel screening document will be recorded against the individual case on the NHS England IFR database.

The requesting clinician will be advised of the outcome of the Screening Group as detailed in the IFR SOP.

11. Training

All members of the IFR Screening Group must undergo mandatory induction training approved by the NHS England. This will cover both the legal and ethical framework for IFR decision making, the NHS England commissioning processes and structures, and the interpretation of clinical evidence. This training will be refreshed annually to

ensure that all members maintain the appropriate skills and expertise to function effectively.

12. Review of Terms of reference

The terms of reference of the panel will be reviewed annually.

Appendix three – pre-panel screening document

Case No	
Condition	
Intervention	

Specialised Services	✓
Health and Justice	
Armed Forces	
Dental	

PRE-SCREENING CHECKLIST COMPLETED BY IFR CASE MANAGER		
Question	**Answer**	**Comments** (Please provide as much detail as possible)
1. Standardised terms to describe the case are:	a) The condition type	
	b) The intervention type	
2. Programme of Care (POC) and Clinical Reference Group (CRG):	a) PoC	
	b) CRG	
	Yes / No / Unclear / N/A	
3. Have all the supporting documents been provided in full text?		
4. Is the condition or treatment detailed in the Specialised Services Manual?		
5. Is this within the NHS England commissioning responsibility?		
If question 5 is "no" the process stops here		
6. Is this trust commissioned to provide this service? Or is this trust part of a clinical network?		
7. Is this treatment excluded from tariff?		
8. Is there any indication that the patient has been approved for this treatment previously?		
9. If the patient has had the requested treatment previously for the same condition how was it funded?		
10. Does NHS England have a clinical commissioning policy and/or is there NICE TA/HST and/or is there any other relevant mandatory/statutory guidance governing access to this intervention in this condition?		

If so, does the patient meet the criteria (including prior approval form criteria)?		
Additional Comments		

PRE-SCREENING OUTCOME Date:	✓	**Comments**
Proceed to Screening Group – first application		
Closed – Routinely NHSE commissioned		
Closed - ICB remit		
Other outcome – please give detail		

CHECKLIST – SCREENING TO BE COMPLETED BY SCREENING GROUP MEMBERS		
Question	**Answer**	**Screener notes / Comments (as much detail as possible)**
	Yes / No / Unclear / N/A	

11.	Is the information that has been provided in questions 1-10 correct and appropriate? If not please give details and /amendments.		
12.	If this is a drug, is it licensed for the requested indication? If this is a device does it have the relevant safety authorisations?		
13.	Does the requested treatment appear to be experimental? Or Unproven?		
14.	Are the incidence and prevalence figures clear and correct?		
15.	Is this patient part of a group of patients with similar clinical circumstances? Please provide details		
16.	Is it appropriate to consider funding through an IFR rather than research funding?		
17.	Is there another source of funding known to be available or that could be available, for example industry funding for those who have taken part in clinical trials?		
18.	Is the supporting clinical evidence provided by the requester relevant to the case and have they indicated which points within them are specifically relevant to the case?		
19.	Has a strong clinical rationale for the treatment been made for this individual patient e.g. diagnosis, biological pathway, evidence, treatment pathway and expected outcomes?		
20.	Has the application provided sufficient detail on the clinical history and provided adequate information on the responses to previous treatment?		

21.	Has the application clearly demonstrated why the patient cannot have a commissioned alternative treatment? If not, have they clearly outlined why they do not wish to use the commissioned alternative?		
22.	Are there sufficient grounds put forward in the application making an arguable case suitable for IFR Panel consideration in line with the IFR policy including clinical rationale for exceptionality and stated factors indicating likelihood or uncertainty of anticipated outcomes being achieved?		
23.	If the answer to Q22 is yes, has the application provided sufficient information in relation to clinical outcomes and how they will be monitored?		
Summary – Include clear reasons for the outcome which address all points raised by the requesting clinician. This applies to both request that are declined and those that are forwarded to IFR Panel.			

SCREENING OUTCOME Date:	✓	**Comments**
Insufficient information – further information requested		
Declined - no arguable case for IFR Panel		
Refer to IFR Panel - sufficient information for Panel		
IFR not required – NHSE commissioned		
Not for NHSE – ICB remit		
Completed pre-panel screening document shared with Screeners		

Appendix four – NHS England IFR Reconsideration Form

Requesters are advised to review the NHS England IFR Policy, IFR Standard operating procedures (SOP) and the Guidance for Clinicians at www.england.nhs.uk/commissioning/spec-services/key-docs/#ifr. NHS England requires provider trusts and clinicians to take NHS England clinical commissioning policies into account in the advice and guidance given to patients prior to making the decision to treat a patient.

It is the responsibility of the requesting clinician to ensure all the appropriate and required clinical information is provided to NHS England. This includes full text copies of all the published papers of clinical evidence that have been cited, a list of the published papers submitted and an indication of which points within them 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.

DO NOT include patient or trust/requesting clinician identifiable data in any free text sections. Where there are large amounts of identifiable data included the application will be returned to you for redaction and resubmission.

Please note: Applications presenting incomplete information will be returned for amendment/completion prior to consideration by NHS England.

1a)	Case reference number:	Click here to enter text.
1b)	NHS Number:	Click here to enter text.
1c)	Patient's age at time of resubmission:	Click here to enter text.
1d)	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.
1e)	Proposed start date:	Click here to enter a date.
1f)	If treatment has commenced more than 2 working days before submission of this application please provide an explanation for the delay	Click here to enter text.

1g) Proposed treatment stop date:	Click here to enter a date.
1h) Name and email of Medical Director:	Click here to enter text - name. Click here to enter text – email.
1i) Confirm that the Medical Director/Deputy Medical Director supports the resubmission of this application	☐ Yes ☐ No
Updated information not originally included in the IFR application	
Section 3 – request details	Click here to enter text – has there been any change to the information provided in this section of the original application form? If so provide details.
Section 4 – Treatment	Click here to enter text – has there been any change to the information provided in this section of the original application form? If so provide details.
Section 5 – Clinical Background	Click here to enter text – has there been any change to the information provided in this section of the original application form? If so provide details.
Section 6 – Clinical Exceptionality	Click here to enter text – has there been any change to the information provided in this section of the original application form? If so provide details.
Section 7 – Clinical Supporting Information	Click here to enter text – has there been any change to the information provided in this section of the original application form? If so provide details.
Tab 8 – SUBM IT	
When you are satisfied that you have completed all sections you will need to submit the request for consideration by the NHS England IFR Team. If the team needs more information they will email you to ask that you provide more details and if this happens, the information tab will be enabled for editing.	
Clinicians are required to disclose all material facts to NHS England 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 and return this form in MSWord to: **england.ifr@nhs.net**

Appendix five - IFR reconsideration - Screening Group decision

Case No	
Old Case No	
Condition	
Intervention	

Non-Urgent		**Specialised Services**	
Urgent		**Health and Justice**	
	✓	**Armed Forces**	
		Dental	

1. Standardised terms to describe the case are:	a) The condition type	
	b) The intervention type	
2. Programme of Care (POC) and Clinical Reference Group (CRG):	a) PoC	
	b) CRG	

CHECKLIST – RE-SCREENING [*See case papers for pre-screening information at original submission*] **TO BE COMPLETED BY Screening Group MEMBERS**		
Question	**Answer**	**Screener notes / Comments (as much detail as possible)**
	Yes / No / Unclear / N/A	
3. Has there been any change in NHS England's commissioning policy on this treatment, so that the patient now meets the criteria for funding without the need for an IFR? *[If yes, there is no need to consider the rest of the questions]*		*Include any update to previous pre-screening information*
4. Has the clinician provided new clinical evidence which was not included in the original IFR submission considered by the Screening Group? *[If no, there is no need to consider the rest of the questions]*		*Please provide specific details on the new information*
5. Is that new evidence significant, in that it shows a different clinical picture to that presented in the original submission which means that the Screening Group now considers there is an arguable		

case suitable for IFR Panel consideration? *[If no, there is no need to consider the rest of the questions]*		
6. How does the new information change the clinical picture?		

Summary

Include clear reasons for the outcome which address all points raised by the requesting clinician. This applies to both request that are declined and those that are forwarded to IFR Panel.

RE-SCREENING OUTCOME	**Date:**	
Outcome	✓	**Comments**
Declined - new information does not provide a different clinical picture to that presented in the original submission		
Refer to IFR Panel		

Appendix six – Terms of reference IFR Panel

Terms of reference
Individual Funding Request Panel

1. Purpose

The individual funding request (IFR) Panel will consider individual requests for NHS England commissioned and funded treatment. The IFR Panel will work to the published NHS England IFR policy and each request will be processed by following the NHS England IFR standard operating procedures (SOP). This will ensure that all requests are considered in a fair, consistent and transparent way, with decisions based on the available clinical evidence presented by the treating clinicians and NHS England commissioning principles.

2. Membership

The IFR Panel will have a core membership of:

- independent Chair
- NHS England Specialised Commissioning Medical Director or nominated clinical deputy (1 attendee per Panel)
- NHS England Specialised Commissioning Regional Director of Nursing or nominated deputy (such as an NHS England specialised commissioning quality lead) (1 attendee per Panel)
- Public Health Consultant / Specialist from an NHS England specialised commissioning regional team (1 attendee per Panel)
- Pharmacy lead from an NHS England specialised commissioning regional team (1 attendee per Panel)
- 1 - 2 further clinical members with experience in assessing evidence, clinical effectiveness and resource allocation
- NHS England specialised commissioning Programme of Care lead (2 attendees per panel) or equivalent from other prescribed services for Armed Forces, Health and Justice, or secondary dental services (as required)

- Patient and Public Voice member (1 attendee per Panel)

- IFR manager (1 attendee per Panel; ex-officio). The IFR manager will be responsible for ensuring that the panel is consistent in process and decision making and run in according to the Terms of reference. For example, that the panel dates are held in accordance with the agreed rota, core Panel members are present and papers are distributed to the panel in advance of the panel date.

Membership will consist of representatives from a minimum of two regions.

In attendance:

- For particularly complex cases, other individuals with clinical, pharmacy or commissioning expertise and skills, unconnected with the requesting provider, may also be invited to participate in a Panel meeting.

- A clinical member of the panel will introduce the case to the other members of the panel. Clinical members of the IFR Panel who have had any clinical involvement with an individual case cannot be part of the panel meeting for that request.

- An IFR Case Manager will record the decision of the IFR Panel against each of the questions in the decision framework document (DFD).

3. Chair

The IFR Panel will be Chaired by an independent Chair. Should the independent Chair not be available, the Specialised Commissioning Medical Director will assume responsibility for Chairing the Panel.

4. Frequency

The IFR Panel will normally be held three times a month in London if they are face to face meetings and using MS Teams if they are virtual meetings. Meetings will have adequate breaks.

5. Voting Rights

IFR Panel members will seek to reach decisions by consensus where possible, but if a consensus cannot be achieved, decisions will be taken by a majority vote with each Panel member present having an equal vote. If the Panel is equally split then the Chair of the panel will have the casting vote.

6. Quoracy

The Panel will be quorate if three of the core members, plus the Chair, are present. The three core members should include the Medical Director (or nominated deputy) and one other clinical member[1]. Where the Medical Director is acting as Chair, the Panel will be quorate if three of the core members are present, including one other clinical member, plus the Chair.

7. Documentation

It is the responsibility of the IFR Case Manager to manage all requests received and correspondence relating to each case as per the IFR standard operating procedures.

All cases will be anonymised appropriately before consideration by the IFR Panel (as stated in the SOP). A clinical member of the Panel will introduce the clinical background to the case, including relevant syntheses of the clinical evidence. All other documentation that has been received regarding the case will also be available to the Panel as per the SOP standards.

Patients will not be permitted to attend Panel meetings in person or be represented by any person at the meeting.

8. Authority

The IFR Panel works on behalf of NHS England and make decisions in respect of funding of individual cases. It is not the role of the IFR Panel to make commissioning policy on behalf of the NHS England.

9. Accountability

The decision framework document (DFD) for each case considered by the IFR Panel will be approved by the Chair of the IFR Panel, in conjunction with the Medical Director of the Panel. The IFR Panel is accountable to the NHS England Board.

10. Reporting and Monitoring

The IFR Case Manager will record the decision of the IFR Panel against each of the questions in the decision framework document (DFD). The completed DFD will form the business notes of an individual case.

[1] Clinical roles provide care to patients, such as nursing, medicine, midwifery, as well as a range of allied health professions such as physiotherapy, radiography and counselling.

An information manager will produce a regular report which will be considered by the NHS England Specialised Commissioning Clinical Effectiveness team and inform the consideration for clinical policy development.

11. Training

All members of the IFR Panel must undergo mandatory induction training approved by NHS England. This will cover legal considerations and case law, the principles for IFR decision making, NHS England commissioning processes and structures, and the interpretation of clinical evidence. Once a member has completed their first IFR induction training, IFR Panel members will be expected to attend annual 'refresher' IFR training sessions on an ongoing basis to ensure that all members maintain the appropriate skills and expertise to function effectively.

12. Review of Terms of reference

The Terms of reference of the panel will be reviewed annually.

Appendix seven – IFR Panel decision framework document

INDIVIDUAL FUNDING REQUEST PANEL DECISION FRAMEWORK DOCUMENT (DFD)
Notes:

1. A copy of this form is provided to each Panel member for each Panel case.
2. The summary DFD will be used to record the key points discussed by the IFR Panel and the views of the IFR Panel.
3. The summary DFD will be shared with the requester as an enclosure with the outcome letter from the IFR Panel and signed off by the senior clinical member of the panel and the panel Chair.

Panel meeting date:		**Request reference:**		
Intervention requested:				
Panel membership	**Name**	**Designation**	**Declaration of interest**	**Decision**
		Chair		**Unanimously approved** **Approved by vote: _ / x** **Unanimously declined** **Declined by vote: _ / x**
		Specialised Commissioning Medical Director		
		Nursing & Quality		
		Consultant/Specialist in Public Health		
		Pharmacy Lead		
		Programme of Care Lead		
		Programme of Care Lead		
		Patient & Public Voice		
		Clinical Member		
		Clinical Member		

		IFR Case Manager	
		IFR Lead	
		IFR Administrator	
		IFR Senior Manager	

No.	Points for decision	Discussion notes	Decision
Individual Need for Care			**Yes/No**
1.1	Does NHS England have a clinical commissioning policy and/or is there NICE TA/HST guidance and/or is there any other relevant mandatory/statutory guidance which governs access to this intervention in a group of patients with the same medical condition as the requesting patient **AND** Is this patient outside the access criteria for treatment under that policy/guidance, where applicable? *If "Yes, there is a policy/guidance and the patient is outside it", record and go to question 2.1.* *If "Yes there is a policy/guidance, and the patient is within it", the application is outside the scope of the policy, record and go to question 5.*		

	In any other case, go to question 1.2, below.		
1.2	As per 1.1 above, the panel have confirmed that there is no NHS England clinical commissioning policy or NICE TA/HST guidance and/or there is no other relevant mandatory/statutory guidance which governs access to this intervention in a group of patients with the same medical condition as the requesting patient Notwithstanding the absence of a clinical commissioning policy/guidance, is the intervention not routinely funded for this indication? *If there is no policy/NICE guidance and the intervention is not routinely funded, record, and go to question 2.2.* *In any other case, the application is outside the scope of the policy, record and go to question 5.*		

Evidence of clinical exceptionality			Yes/No
2.1	If the answer was Yes to question 1.1: Does the evidence included within the application demonstrate that the patient is in a different clinical condition when compared to the typical patient population with the same condition **AND** (if relevant) at the same stage of progression **AND** that **because of that difference** the patient is likely to receive material additional clinical benefit from treatment that would not be plausible for any typical patient? Guidance for Panel: In answering this question, have regard to the guidance on clinical exceptionality in the IFR policy (section 4, page 8-9). *If Yes, record and go to question 3.1.* *In any other case, record and go to question 5.*		

2.2	If the conditions in question 1.2 were satisfied: Is the patient's clinical presentation so unusual that they could not be considered to be part of a defined group of patients in the same or similar clinical circumstances for whom a service development could be undertaken? Guidance for Panel: To understand what is meant by "so unusual", have regard to the guidance on clinical exceptionality in the IFR policy (section 4, page 9). *If Yes, record, and go to question 3.1.* *In any other case, record and go to question 5.*		

Experimental and Unproven treatment			**Yes/No**
3.1	Is this treatment experimental [or unproven] (as defined in section 34, pages 15-16)? *If Yes, record and go to question 3.2.* *If No, record and go to question 3.3.*		

3.2	If the treatment is experimental [or unproven] as per question 3.1, what is the Panel's assessment of the following in relation to the submitted evidence of effectiveness (sections 39- 40, pages 16-17): a) The potential benefit and risks of treatment; AND b) The biological plausibility of benefit; AND c) The estimated cost of the treatment and anticipated value for money; AND d) The priority of the patient's needs compared to other competing needs and unfunded developments? Will funding the treatment contribute to the knowledge base relevant to treatment of the condition in question? Is research funding available for the treatment rather than IFR funding? (if yes, the alternative source of funding should be exhausted)		

	If the assessment of factors a-d above is satisfactory and the two questions set out above are answered positively, record and go to question 4. Guidance for Panel: keep in mind the additional requirements that the IFR policy applies to evaluating both clinical efficacy and the use of NHS resources when a treatment is experimental or unproven, see in particular paragraph 32 of the IFR policy. *In any other case, record & go to question 5.*		
3.3	If the treatment is *not* experimental and/or unproven as per question 3.1: Is there sufficient evidence to show that the proposed treatment is likely to be clinically effective in this individual case? Guidance for Panel: In answering this question have regard to the guidance on clinical effectiveness in the IFR policy (sections 23-25, page 13-14). *If Yes, record and go to question 4.* *In any other case, record & go to question 5.*		

Good use of NHS resources and affordability			**Yes/No**
4.	**Consider as a minimum:** a) What are the absolute costs involved in		

	funding this treatment, considering cost and time receiving treatment? b) Is this cost one-off or is there a need for recurrent funding? c) What benefit can the patient expect to receive and for how long? d) How certain are costs and benefits? Guidance for Panel (sections 27-29, pages 14-15): As uncertainty increases, the likelihood of the anticipated benefits being realised decreases. e) Is there another source of funding known to be available or that could be available, for example industry funding for those who have taken part in clinical trials? f) Taking these and any other factors considered relevant into account, does the panel consider that use of this drug/intervention in this individual case is a good and equitable use of NHS resources? *Record the answers and go to question 5.*		

Equalities			Yes/No
5	Guidance for Panel (sections 19-22, pages 12-13): In general issues of equality and diversity are addressed in clinical policy development (see question 6). a) Considering only clinical factors, does the application raise any clinically relevant equality concerns that have not already been considered above? b) Is the fact that the patient has a particular protected characteristic (age; disability; gender reassignment; marriage and civil partnership; pregnancy and maternity; race; religion or belief, sex; sexual orientation) clinically relevant to the application? c) Would allowing or refusing the application represent an opportunity to eliminate discrimination or to advance equality of opportunity, or to reduce health inequalities? *If the answer to any of the above questions is Yes, review the decision in light of these concerns, if they have not been discussed and recorded earlier. Be willing to reach a different decision if you consider that appropriate, and record that review.*		

	If No or after review, go to 'RECORD OF DECISION' below. *Additionally, consider question 6, although this is not part of the consideration of the IFR.*		

Policy developments			**Yes/No**
6	Has this case brought to light any issues which should be referred on within NHSE to inform policy development? If so refer them to [ ]		

RECORD OF DECISION	**SUMMARY**
Funding Approved: Summarise clearly the reasons for the decision made, which should have been detailed at each step above, addressing all the arguments for clinical exceptionality made by the requester. Include any conditions, outcome measures to be monitored and review mechanisms required. Date of review:	

Funding Declined Summarise clearly the reasons for the decision made, which should have been detailed at each step above, addressing all the arguments for clinical exceptionality made by the requester.	

Appendix eight – Funding for continuation requests

NHS England Individual Funding Request (IFR) – Funding for Continuation of Treatment Form

1. DETAILS OF ORIGINAL IFR	
IFR reference:	Date of IFR submission:

2. PATIENT PERSONAL DETAILS			
Patient Name:			
Date of Birth:		NHS Number:	
Patient Address:			
GP Name			
GP Practice name:		GP Postcode:	

3. CONSENT	
This request for funding for continuation of treatment (originally approved via the NHS England Individual Funding Request (IFR) route) has been discussed in full with the patient or patient representative[2]. 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. I confirm all of the above.	Yes ☐ No ☐
I understand that by indicating that it is NOT clinically appropriate for the IFR Team to contact the patient, I am responsible for sharing information relating to this request with the patient /patient representative. Their GP will be included in any responses and be aware of the request and its outcome.	Yes ☐ No ☐ N/A ☐
Name of Requester :	
Signature of Requester:	

[2] This means a person with legal authority to take decisions about medical care and treatment on behalf of the patient, on the basis that they lack capacity to take these decisions themselves. The source of that legal authority should be clearly identified.

Date continuation request submitted:	

Responsibility lies with the requesting clinician to present to NHS England a full continuation request submission which sets out a comprehensive and balanced picture of the history and present state of the patient's clinical condition, the nature of the treatment requested and the anticipated benefits of treatment. Requesters are advised to review the NHS England IFR policy, IFR Standard Operating procedures and the Guidance for Clinicians at www.england.nhs.uk/commissioning/spec-services/key-docs/#ifr.

4. DETAILS OF REQUESTER

Name:		Title:	
Job role:			
Provider organisation:			
Clinical department / specialty:			
Contact telephone number:			
Secure NHS.net email:			

5. trust SUPPORT

Provider Medical Director approval (**Mandatory**): Date Medical Director approval given:	Yes No
Name of provider Medical Director:	
Email address of Medical Director:	
Signature of Medical Director:	
Pharmacy contact: Name and NHS.net email address:	

6. PROVIDER SERVICE AND AUDIT

Is your organisation commissioned by NHS England to provide this service or treatment? If No, state why the patient hasn't been referred to an NHS commissioned provider:	Yes No

7. PATIENT DIAGNOSIS

Primary diagnosis related to this request:	

8. TREATMENT REQUESTED	
Name of treatment: (Include any alternative terms)	
Dose/Frequency of treatment:	
Start/Stop dates of approved treatment:	

9. CLINICAL REPORT	
i. What clinical measures were used to record the outcome of the treatment requested?	
ii. Please report on the observed response to treatment in relation to the change in the specific outcome measures identified in the original IFR application. How does this compare to the anticipated change stated in the IFR application: have these been achieved and to what extent?	
iii. Describe how the observed clinical outcomes meet the original criteria for deciding whether the treatment was successful or unsuccessful	
iv. What are the anticipated outcomes of the continued treatment requested for this patient? This should relate to the agreed 'stopping' criteria	
v. What is the future care plan for this patient, including long term plans (>2yrs)?	
vi. What are the current clinical condition/ functional status of the patient?	
vii. Any other clinical information relevant to this patient's treatment?	

10. TREATMENT / PROCEDURE COSTS	
Actual (i.e. based on observed rather than estimated) costs. Please **itemise** the costs (e.g. drug/attendance costs/ staff/ follow up/ diagnostics costs etc.). Please provide breakdown of this cost per annum, per cycle etc. as appropriate:	£……

11. DECLARATION OF INTERESTS	
Clinicians are required to disclose all material facts to NHS England as part of this process. Are there any other comments / considerations that are appropriate to bring to the attention of the IFR Team?	

For NHS England Office Use only:

1. POLICY UPDATES		
Has there been any policy updates related to this particular request and condition since the original IFR request was approved? Y / N If Y please provide details:		
2. Continuation of funding approved?	Yes	
	No	
Date of decision:		

Continuation request reviewed by:	
Reasons for decision made:	
(If approved), continuation request funded for a further:	6 months 12 months Other - please provide detail on this:

Once fully completed, please return this application to: **england.ifr@nhs.net**

Appendix nine – Terms of reference IFR review panel

Terms of reference
NHS England Individual funding request review panel

1. **Membership**

The IFR review panel will consist of:

- NHS England Specialised Commissioning Medical Director or nominated deputy
- NHS England Specialised Services National Programme of Care lead for the clinical area (or equivalent for other prescribed services for the Armed Force, Health and Justice or secondary care dentistry)
- NHS England regional Public Health Consultant / Specialist

None of the panel members should have been involved in the case prior to the IFR review panel. The IFR review panel will not consider either new information that was not available to the IFR Panel or receive oral representations.

2. **Purpose**

The IFR review panel will determine whether the original decision is valid in terms of process followed, the evidence/factors considered and the criteria applied. In deciding the outcome of a review, the IFR review panel will consider whether:

- the process followed by the IFR Panel was consistent with that detailed in the IFR SOP
- the decision reached by the IFR Panel:
    - was consistent with NHS England commissioning principles
    - had taken into account and weighed all the relevant evidence
    - had not taken into account irrelevant factors
    - indicates that members of the panel acted in good faith

- was a decision which a reasonable IFR Panel was entitled to reach.

The IFR review panel will be able to reach only one of two decisions:

- uphold the decision reached by the IFR Panel
- refer the case back to the IFR Panel with detailed points for reconsideration.

Where the IFR review panel consider that there may have been a procedural error in the decision, i.e.

a) that the decision may not have been consistent with NHS England commissioning principles

b) the IFR Panel may not have taken into account and weighed all the relevant evidence available to them

and / or

c) the IFR Panel may have taken into account irrelevant factors or reached a decision which a reasonable IFR Panel was not entitled to reach

the IFR review panel shall refer the matter to the IFR Panel if they consider that there is an arguable case that requested treatment will be approved.

If the IFR review panel considers that, notwithstanding their decision on the procedure adopted by the IFR Panel, there is no arguable case that the decision would have been different, the IFR review panel shall uphold the decision of the IFR Panel.

3. Frequency of meetings

The IFR review panel will be scheduled as needed. A case may need to be considered urgently on the advice of an authorised senior health professional after consultation with the patient's clinicians. The timing of the urgent IFR review panel will be based on the individual clinical circumstances and the risk of an adverse clinical outcome if a funding decision on treatment is delayed. The meetings will be held in London if they are face to face meetings and using MS Teams if they are virtual meetings. Meetings will have adequate breaks.

4. Voting rights

The IFR review panel members will seek to reach a decision by consensus. If this is not possible a decision will be made by a vote with each member having one vote.

5. Quoracy

All three panel members must be present for the IFR review panel to be quorate.

6. Documentation

The IFR review panel will only consider the following written documentation:

- the original treatment request form submitted to NHS England
- the IFR process records in handling the request
- the IFR Panel records, including the Decision Framework document and any additional supporting information considered by the IFR Panel
- the grounds submitted by the requesting clinician and/or the patient/patient representative in their request for review.

There will be no other representation at the IFR review panel from the IFR Panel or the requesting clinician and/or the patient/patient representative.

The IFR review panel will not consider new information or receive oral representations. If there is significant new information, not previously presented to and considered by the IFR Panel, it will be considered as set out in the section on reconsideration in the IFR SOP. All information will be anonymised before consideration by the IFR review panel.

7. Authority

The IFR review panel has the responsibility to undertake a review of IFR Panel decisions in respect of funding of individual cases. It is not the role of the IFR review panel to reach a decision on funding of an individual funding request nor does the panel make clinical commissioning policy on behalf of NHS England.

8. Accountability

The IFR review panel works on behalf of NHS England.

9. Reporting and Monitoring

The IFR Team will review on a regular basis any review panel requests and outcomes in order to evaluate the process and to consider any improvements that could be made.

10. Training

All members of the IFR review panel must undergo mandatory induction training organised by NHS England. This will cover both the legal and ethical framework for IFR decision making, NHS England commissioning processes and structures and the interpretation of clinical evidence. This training will be refreshed annually to ensure that all Panel members maintain the appropriate skills and expertise to function effectively.

11. Review of Terms of reference

The Terms of reference of the panel will be reviewed annually.

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This publication can be made available in a number of alternative formats on request.