Hertfordshire and West Essex Integrated Care System

NHS Hertfordshire and West Essex Integrated Care Board

Evidence Based Interventions and Individual Funding Requests Team

Standard Operating Procedures

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Contents

Introduction

Comprising of a team of administrators, nurses, medically qualified clinical fellows, clinical advisors, and public health consultants/associate medical directors, the EBI & IFR team maintain overall responsibility for the management and processing of prior approval (PA) applications and Individual Funding Requests (IFRs) received for patients registered with a GP in Hertfordshire and West Essex. All requests are processed in line with these Standard Operating Procedures (SOP), the Hertfordshire and west Essex Integrated Care Board (HWE ICB) IFR Policy, and the Screening group and IFR Panel Terms of Reference.

When considering any funding request, all members of the EBI & IFR team and IFR panel will aim to:

- Promote consistency, fairness, and equity.
- Ensure that the decisions are based on clinical evidence.
- Ensure effective use of resources.
- Ensure decisions are rational, reasonable, and transparent.
- Improve the rigor of the processes.
- Apply the definitions and principles of the IFR policy.

Prior Approval

1. The Prior Approval Administration and Triage Process

1.1 Where required, Hertfordshire and west Essex Integrated Care System (HWE ICS) Primary and Secondary care clinicians must submit an application to the Evidence Based Intervention and Individual Funding Request (EBI and IFR) Team to demonstrate how a patient meets current thresholds within the relevant EBI policy. Supporting evidence in the form of clinic letters and/or objective data to support the patient's application should be included, for example x-ray reports, scan results, optician reports, medical photography, clinical scores, etc.

1.2 Completed applications are submitted via the Blueteq database or by email to the EBI and IFR team which are then reviewed by the Clinical Decisions Lead/Nurse and/or a medically qualified Clinical Fellow.

1.3 Where eligible, some applications submitted via Blueteq will receive an instant approval.

1.4 The Clinical Decisions Lead/Nurse or medically qualified Clinical Fellow determines whether the information provided demonstrates the threshold criteria in the relevant local or national EBI policy have been met. If it is clear the criteria have been met, the request will be approved. If it is clear the criteria have not been met, the request will be declined. If it is unclear, further information will be requested.

1.5 All applications will be responded to within five working days. The clock starts on the first full working day after the application has been received by the EBI and IFR Team. A request for further information will stop the clock and the 5-day response time will start again on the full working day after the information requested is received.

1.6 Should a clinician feel that 5 working days may cause a delay which would put the patient's life at risk, the EBI & IFR team will endeavour to respond within 2 working days. Clinicians must contact the EBI & IFR team to state the rationale for clinical urgency. Where no rationale is presented, the case will be processed within 5 working days.

1.7 At any point in the Prior Approval process, the EBI & IFR team can ask for further information. It will be requested from the applying clinician only. It is the responsibility of the applicant to submit what is required in a timely manner to avoid delays in patient care. The EBI & IFR team will only request this information once. If the requester does not provide a response within 20 working days, the request record will be closed. Such a request can be reopened on submission of the additional information and will follow the above process again.

1.8 Requests which are more complex in nature, or where criteria do not seem to be met but additional information and/or clinic letters/diagnostic reports have been submitted, will be reviewed by the Clinical Fellow, or escalated to a Public Health Consultant/Associate Medical Director or Clinical Lead to determine if criteria have been met or not.

1.9 Where it is clear a patient does not meet criteria and where an application has been declined but a clinician feels the patient has exceptional clinical circumstances and wishes to appeal, a Clinically Exceptional Case form should be completed and submitted and will follow the IFR process outlined in section 2.

1.10 It is the responsibility of the applicant to inform the patient of the outcome of the funding application. The EBI & IFR team will not routinely copy patients into correspondence relating to Prior Approval requests except where necessary e.g., those relating to specialist fertility services containing essential information.

1.11 Where prior approval has not been appropriately obtained, any treatments or services provided would be considered as unauthorised activity. This will trigger an audit process to investigate and establish the cause and a solution to ensure the relevant policy and pathway is followed appropriately.

1.12 Should the clinician wish to challenge the clinical policy content, they should contact the chair of the Clinical Policies Group directly. Disagreement with the relevant policy will not be taken into account when considering a prior approval application.

The IFR Process

2. IFR timescales and urgent cases

2.1 Depending on the clinical priority, the timeframe for providing a substantive response to an IFR from the date of the receipt of a fully completed IFR or Exceptional Case form is as follows:

Routine - 4 to 6 weeks (maximum 30 working days)
Immediate - 3 weeks as delay will not be clinically appropriate. (Max 15 working days)
Most Urgent - 5 working days as the patient's life is at risk.

The clinical priority must be indicated on the application form by the applying clinician.

2.2 This working day period discounts any working days where the EBI &IFR team are awaiting information sought from the requesting clinician. If further information is required from the requester, the timeline for the request is stopped until this is received. Once the additional information is received the clock will start again with a 3-week timeframe for routine and immediate requests and 5 working days for most urgent requests.

2.3 At any point in the IFR process, the EBI & IFR team can ask for further information to clarify the request. Should further information be required, it will be requested from the applying clinician only. It is the responsibility of the applicant to submit what is required in a timely manner to avoid delays in patient care. The EBI & IFR team will only request this information twice. If the requester does not provide a response within 20 working days a chasing letter will be sent. If the IFR team receive no response after further 20 working days, the request record will be closed. Such a request can be reopened on submission of the additional information and will follow the timelines in section 2.2.

2.4 Should a case need to progress to the weekly IFR Screening Group, the clock will be stopped from the point this decision is made (recorded by moving to the Screening Group folder on Blueteq) and will recommence the full working day after the Screening Group meeting.

2.5 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 the relevant 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. Where no evidence of clinical urgency can be identified within the application, the IFR team will downgrade the request and inform the applicant of the new timeframe in which they can expect a response.

2.6 The IFR team makes funding decisions in line with the HWE ICB IFR policy. However, the clinical responsibility and decision to treat a patient lies with the treating clinician and/or the Trust. If a patient presents as clinically urgent and it is not safe to wait for the outcome of any IFR application, clinicians should seek advice from their Medical Director and/or Chief Pharmacist.

2.7 It is recognised that urgent clinical decisions are occasionally required. If a non-routinely commissioned treatment is started by a provider in very urgent circumstances before submitting an IFR, the IFR team will consider a retrospective application, but only if the IFR team is satisfied that the case was urgent. However, funding is not guaranteed, and this will be at the providers own financial risk. 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 2 days of the intervention first taking place. Costs will not be reimbursed if the request is declined.

3. IFR Administrative screening and triage

3.1 On receipt of the IFR application, the case is recorded on Blueteq. The Clinical Decisions Lead/Nurse or Clinical Fellow will verify whether sufficient information is included and ask the applicant for more information if required.

3.2 Upon receipt of a completed IFR application, cases will be initially triaged by the Clinical Decisions Lead/Nurse, Clinical Fellow, or reviewed by a Pharmaceutical Advisor (for drug cases).

3.3 If an individual meets the criteria for funding within a local HWE ICB or national Evidence Based Intervention (EBI) policy or commissioned service, the requester will be advised of this, and the request does not proceed further as an IFR.

3.4 Where a routinely commissioned treatment is subject to Prior Approval, the IFR team will signpost the applicant to the appropriate application form and the prior approval process outlined in section 1 will be followed. Similarly, where a drug is routinely commissioned the applicant will be signposted to Blueteq HCD system or offered appropriate advice.

3.5 Clinicians are advised that if they are unsure about whether something is commissioned at their trust or provider, they should discuss with their organisation’s contracts team whether the treatment is covered by their contract, in the first instance.

3.6 The standard Hertfordshire and West Essex (HWE) ICB IFR application form must be used for all Individual Case IFRs and all Drug requests.

3.7 For Exceptional Case requests - The standard Hertfordshire and West Essex (HWE) ICB Clinically Exceptional Case application form must be used.

3.8 Requests will not be progressed if not completed on the appropriate HWE ICB form. These forms can be found alongside the published IFR policy online. These are controlled documents and should therefore always be accessed from the ICB website to ensure the most up to date version is used. Copies should not be saved onto local or network drives. Printing more copies than are needed for immediate use is also not recommended, as downloaded or printed versions are not controlled.

3.9 Submissions on IFR forms from other commissioning organisations cannot progress through the HWE ICB IFR process. This is to ensure that all HWE ICB Exceptional Case and 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 HWE ICB's commissioning responsibility is not submitted on the HWE ICB IFR, or Exceptional Case form the requester will be asked to resubmit their request using this form.

3.10 Every section in the Exceptional Case or IFR form needs to be completed in full for the request to progress. Any request form which is incomplete will be returned to the requester for completion and the application will not progress any further until it has been completed and resubmitted.

3.11 Forms must be received as typewritten only. Handwritten forms may be returned to the requester for amendment. This is to ensure that all content is legible, and the best case made on behalf of the patient.

3.12 The request must come from an NHS 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 or referring into the proposed service.

3.13 Requests will not be accepted from a patient or their non-clinical representative. This 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, to ensure the process is fair and equitable to all patients.

3.14 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. Non-clinical factors cannot be considered and should not be submitted. This is described in more detail in the IFR Policy.

3.15 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 and clinical information being shared with HWE ICB. The HWE ICB Privacy Notice provides details on how the ICB collects, stores, uses, protects, and shares patient information. Please see https://www.hertsandwestessex.ics.nhs.uk/privacy/#how-the-icb

3.16 The HWE ICB guide, Individual Funding *'Individual funding requests – information for patients'* can be found on the ICB website and can be given to patients to ensure that the patient has received sufficient information to support informed consent to the application.

3.17 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 consent to be obtained or confirmed.

3.18 Requests should be supported by any 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 encouraged to provide copies of the MDT/DTC minutes of the discussion to the IFR team, alongside the application. For drug requests the Chief / Deputy Chief Pharmacist must also support the application.

3.19 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 patient circumstances. Evidence should be submitted in full text as pdf or word documents. The IFR team are unable to accept abstracts or web links.

3.20 The following are considered by HWE ICB to be inappropriate or inadequate applications and will be returned to the applicant with an explanation why it cannot be progressed.

- The request is not submitted in line with the requirements of the IFR policy and process.
- The request is not submitted on the relevant HWE ICB application form.
- The treatment requested is covered by another ICB policy or process.
- The request is for a service or procedure that is commissioned by another organisation where funding is not the responsibility of the ICB.
- Where no information is submitted in support of the individual's clinical exceptionality.
- A request based on rarity unsupported by current UK population prevalence or incidence data.
- Where no information is submitted to demonstrate the clinical effectiveness of the treatment.

3.21 The skills and expertise required by the Clinical Decisions Lead/Nurse or Clinical Fellow or Pharmaceutical Advisor at initial triage stage are the ability to:

- Determine who is responsible for commissioning the intervention.
- Determine whether an existing HWE ICB policy covers the intervention.
- Liaise with relevant colleagues such as commissioners/contract managers to determine if the intervention is already funded through existing contracts and commissioned services or possible alternatives.
- Identify what further information is needed to complete or support the application (for example, whether alternatives have been tried or ruled out; the rationale for any deviation from any agreed clinical pathways etc)
- Interpret HWE ICB definitions of exceptionality and individuality in the context of the clinical information that is presented.

3.22 Decisions will be made based on the information made available and the Clinical Decisions Lead/Nurse or Clinical Fellow or Pharmaceutical Advisor will be able to consider the following options:

- Redirect to routine commissioning or prior approval.
- Inform the applicant if treatment can proceed (without funding approval) in line with an existing contract/ commissioning policy.
- Signpost to the responsible commissioner should this not be HWE ICB.
- Defer the request and ask for more information from the applying clinician where application is incomplete or contains insufficient detail.
- Progress the request to the Screening Group where there are arguable grounds for clinical exceptionality or wider discussion is required.
- Decline the request without reference to the screening group or IFR Panel as does not meet criteria, no grounds for exceptionality presented or identified, or insufficient response to a request for further information.
- Discuss the request directly with a Public Health Consultant/Associate Medical Director or Clinical Lead and decline with their agreement.

3.23 The outcome of the request will be communicated to the applicant in line with the process and timescales detailed in section 2. This will usually be copied to the patient's GP and to the patient (unless the applicant requests for them not to be copied in or where the IFR team feel the information is particularly sensitive and it would be more appropriate for the information to be relayed to the patient by their treating clinician).

3.24 Where an IFR or Exceptional Case request is declined, the patient's clinician can submit a reconsideration request with new clinical information. The case will follow the initial triage or drug review process again prior to being presented at the screening group meeting. Where there is no new information but the applying clinician does not agree with the decision, the case will be discussed at the screening group meeting with a Public Health Consultant/Associate Medical Director or Clinical Lead and other professionals relevant to the case.

4. The Screening Group

4.1 Applications that have been initially triaged or reviewed for progression will be reviewed by a screening group which will usually meet weekly. The Screening group includes the Clinical Decisions Lead/Nurse, Public Health Consultant/Associate Medical Director or Clinical Lead, Pharmaceutical Advisor (for drug requests) or Commissioning Leads in an advisory role for cases relating to their commissioning responsibilities.

The purpose of the screening group is to determine whether an application is appropriate to be considered as an IFR. This includes considering whether the ICB is the relevant commissioner and whether the applicant 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. If it does, the case will be progressed to the IFR panel. The screening group also ensures that all relevant information is sought ahead of panel.

4.2 The cases and all supporting information will be reviewed, and discussions will be guided using the screening document, the IFR policy and the relevant EBI or other relevant clinical policy or local recommendations. The screening group will reach one of the following outcomes:

- Redirect the request if approval can be made via routine commissioning or prior approval.
- Inform the applicant if treatment can proceed (without funding approval) in line with an existing contract/ commissioning policy.
- Redirect the request to another responsible commissioner.
- Decline the funding request where exceptionality cannot be clearly identified.
- Uphold an initial triage decision to decline funding.
- Request more information from the applying clinician.
- Refer the case to the monthly IFR Panel meeting where decisions cannot be agreed by members of the screening group meeting.
- Progress the case to the IFR panel if an arguable case for exceptionality is identified.

4.3 Where a clinician believes they have significant new clinical evidence that they did not previously provide, they can appeal for reconsideration of their case by the screening group and submit the new information. The case will be triaged and progressed to the screening group for reconsideration.

4.4 To avoid requests remaining unresolved for long periods of time, the screening group will endeavour to only ask for further information once and will make every effort to be explicitly clear what information is required. Should insufficient information be submitted in response, the screening group will make a decision based on the information made available to them.

4.5 The screening group outcome will be communicated by HWE ICB IFR team within 5 working days of the screening meeting and within the timescales detailed in section 2. 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 and to the patient (unless the applicant requests for them not to be copied in or where the IFR team feel the information is particularly sensitive and it would be more appropriate for the information to be relayed to the patient by their treating clinician).

4.6 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.

4.7 The screening group will report any significant issues and risks arising to the ICB Executive Team or any issues relating to clinical policy to the HWE ICB Clinical Policies Group or HWE APC.

5. The IFR Panel

5.1 The IFR Panel will usually be held monthly and as required. The EBI & IFR administration team are responsible for organising and servicing the meeting. All documents will be made available to the Panel one week prior to the meeting and will be completely anonymised and redacted to protect patient confidentiality and minimise the potential for identification bias.

5.2 A nominated clinical member of the IFR Panel will introduce the case at the meeting. The IFR Panel will then discuss the case. The IFR panel will explore the grounds for clinical exceptionality presented; consider the likely clinical effectiveness; and consider if the proposed investigation, treatment, or service would likely be a good use of NHS resources. The IFR panel will then reach a decision on whether funding can be approved under the IFR policy.

5.3 The monthly IFR Panel meeting will consider cases where:

- There is uncertainty about whether the treatment falls within existing policy.
- Evidence for exceptionality is unclear / the weekly screening group were unable to reach a decision.
- Arguable grounds for exceptionality are presented.
- Reconsideration of a request previously heard and declined by the IFR Panel; or
- The IFR Panel is asked to perform a process review of cases previously considered by other external ICB panels in line with their IFR process.

5.4 The IFR Panel shall be entitled to approve, decline, or redirect Individual Funding Requests and will consider all requests in line with the IFR policy and the IFR Panel Terms of reference.

5.5 The IFR Panel can 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 may request an update on the clinical outcome of treatment. Provider trusts and their clinicians are required to comply with such requests. Funding is conditional on this.

5.6 The IFR Panel may 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.

5.7 The IFR Panel outcome will be communicated by HWE ICB IFR team within 5 working days of the meeting. 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 and to the patient (unless the applicant requests for them not to be copied in or where the IFR team feel the information is particularly sensitive and it would be more appropriate for the information to be relayed to the patient by their treating clinician).

5.8 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.

5.9 Minutes will be taken at the meeting by an EBI and IFR Administrator, sent to the IFR panel chair and saved on the patient's Blueteq record.

6. Reconsideration Requests

6.1 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, then the clinician can submit the new clinical evidence and request reconsideration of the decision.

6.2 The Clinical Decisions Lead/Nurse or Clinical Fellow or Pharmaceutical Advisor (for drug cases) should review the reconsideration request, discuss it at the screening group and decide whether it discloses relevant and significant material or information which was not originally before the IFR Panel.

6.3 If the new information is considered to be material, the case will be presented at the next appropriate IFR Panel and will follow the IFR panel process detailed in section 5.

6.4 If there is no additional information, the case will not be re-presented to the IFR Panel for further consideration and the IFR team will write back to the referring clinician and/or the patient explaining this and uphold the IFR Panel decision.

7. Process Reviews

7.1 The requesting clinician, the patient or a patient representative may make a request to HWE ICB for a process review of an IFR panel decision.

7.2 Such requests must be lodged in writing to the EBI & IFR Team within 6 weeks of the date of the letter setting out the IFR Panel decision.

7.3 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 section 7.7.

7.4 The process will be reviewed by another ICB's IFR Panel outside of Hertfordshire and West Essex. All members of the external IFR Process Review Panel should have had no prior involvement with the case.

7.5 The External IFR Process Review Panel shall consider all the papers which were before the originating IFR Panel. There will be no representation at the external IFR process review meeting from the HWE ICB IFR Panel or the requesting clinician and / or the patient / patient representative. The external IFR process review panel will not consider new information (i.e., that was not before the IFR Panel, including on any reconsideration). 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 Requests' in section 6.

7.6 In reaching its decision the External IFR Process Review Panel should apply the same approach and tests as set out in the HWE ICB IFR policy and this SOP.

7.7 The review will consider if the decision reached by the IFR Panel:

- Was taken following a process inconsistent with HWE ICB IFR policy, SOP and TOR.
- Failed in a material way properly to consider the evidence presented to it.
- Had taken into account irrelevant factors.
- Failed to take account of a material fact.
- Was a decision that no reasonable IFR Panel could have reached on the evidence before the Panel.

7.8 The external IFR process review Panel will be able to uphold the originating IFR Panel's decision or refer the case back to the IFR Panel with detailed points for reconsideration.

7.9 The HWE IFR team will write to the requesting clinician, the patient / patient representative and GP, and the IFR Panel Chair within 5 working days of receipt of the outcome of the review meeting. This is to inform them of the outcome with the reasons for the IFR review panel decision.

7.10 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 external IFR process review panel. The HWE ICB IFR Panel will reconsider its decision and in doing so will formally address the detailed points raised by the external IFR process review panel.

8 Complaints

8.1 All patients have the option of raising an informal concern via their NHS Trust Patient Advice and Liaison Service (PALs).

8.2 Patients or clinicians can make a formal complaint to the HWE ICB Patient Experience Team at any point in the IFR process.

8.3 Complaints will be investigated and responded to within the time frames set out in the ICB Complaints Policy.

8.4 All complaints received by the ICB and responses provided are reviewed and authorised by the HWE ICB Chief Executive Officer (CEO). Should there be any concern that the decision reached by the IFR Panel met any of the following criteria, an internal process review would be initiated, and the case will be referred back to an appropriate IFR panel for reconsideration:

- Was the decision taken following a process inconsistent with HWE ICB IFR policy, SOP and TOR?
- Failed in a material way properly to consider the evidence presented to it.
- Had taken into account irrelevant factors.
- Failed to take account of a material fact.
- Was it a decision that no reasonable IFR Panel could have reached on the evidence before the Panel?

8.5 Complaints should be submitted to the HWE ICB Patient Experience Team
email: hweicbwe.patientfeedback@nhs.net
Telephone: 01992 566122.

Appendices

Appendix 1 – IFR Screening Group Terms of Reference

Individual Funding Request Screening Group Terms of Reference

1. Purpose

The Individual Funding Request (IFR) Screening Group, also known as the Pre-screen Group, is authorised by the Hertfordshire and West Essex Integrated Care Board (HWE ICB) to take decisions on its behalf relating to the suitability of IFR applications (including exceptional cases). The purpose of the screening group is to determine whether an application is appropriate to be considered as an IFR. This includes considering whether the ICB is the relevant commissioner and whether the applicant 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. If it does, the case will be progressed to the IFR panel. The screening group also ensures that all relevant information is sought ahead of panel.

The Screening Group will:

- Confirm that any application is appropriate to be considered as an IFR i.e., that:
    - the ICB is the responsible for commissioning the service, intervention, treatment, or test.
    - the service, intervention, treatment, or test is not already funded through existing contracts and commissioned pathways.
    - that the patient does not meet the clinical criteria for routine commissioning set out in any relevant local or national clinical (Evidence Based Intervention) policies.
- Determine whether the request appears to present an arguable case for clinical exceptionality based on the clinical information presented and the HWE ICB definitions of exceptionality and individuality set out in the IFR policy.
- Identify what, if any, further information is needed to complete or support the application (for example, whether alternatives have been tried or ruled out; the rationale for any deviation from any agreed clinical pathways etc) prior to reconsideration by the Screening Group or progression to the IFR Panel.

The Screening Group will decide in each case whether the request should be declined, redirected, or progressed to the IFR panel and will work in accordance with the published HWE ICB IFR policy and IFR Standard Operating Procedures (SOP).

This will ensure that all requests are considered in a fair and transparent way in line with HWE ICB's commissioning principles and outcomes are based on the available clinical evidence presented by the requesting clinicians.

2. Membership

The IFR Screening Group will have a core membership of:

- HWE ICB Public Health Consultant/Associate Medical Director or GP Clinical Lead.
- HWE ICB Clinical Decisions Lead/Nurse
- HWE ICB Senior Pharmaceutical Advisor (for drug cases only)

The Screening Group can invite a relevant HWE ICB Commissioning lead, to attend the meeting in an advisory role as required, but they will not be considered as part of the core membership. Public Health trainees and clinical fellows can also contribute to the work of the IFR process and attend the IFR screening meetings as part of their training.

3. Quorum

All core members must be present for the meeting to be quorate. No formal business shall be transacted where a quorum is not reached.

4. Frequency of meetings

The Screening Group will normally be held once a week by videoconference. However, in the extremely rare event a case could not wait for the next weekly meeting, an urgent video conference will be convened.

5. Authority

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

The screening group has the following outcomes available to it.

- Redirect any request which should be funded via an alternative commissioning route (for example where it is routinely funded or NHSE's commissioning responsibility).
- Decline the request when no case for clinical exceptionality, as defined by the HWE ICB IFR policy, has been presented or when the application does not meet any other requirements set out in the HWE ICB IFR policy.
- Progress the application for consideration of approval by the IFR panel where there is a clear or possible arguable case for clinical exceptionality compared to other patients with the same condition.
- Ask for more information to support decision making, either by the Screening Group or IFR Panel.
- Redirect/Decline the request where it is indicative that a service development should be considered rather than an Individual Funding Request (i.e., there may be a group of patients who could equally benefit from the service, treatment, intervention, or test).

The core members of the IFR Screening Group should agree on the outcome of a case. If a consensus cannot be achieved the case will go forward for consideration by the IFR Panel with explicit reasons given by the members who have indicated that it requires an IFR panel decision.

It is not the role of the IFR Screening Group to make commissioning policy on behalf of HWE ICB. However, it will raise policy or commissioning issues or risks arising with the Area Prescribing Committee (APC), Clinical Policies Group (CPG), relevant commissioners and/or ICB Executive Team, as appropriate.

6. Roles and responsibilities

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. IFRs will be allocated an individual case reference number. All documentation that has been received regarding the case will be available to the Screening Group.
The Clinical Decisions Nurse/Lead will Chair the meeting.
The Public Health Consultant/Associate Medical Director or GP Clinical Lead, Senior Pharmaceutical Advisor, Clinical Decisions Lead /Nurse, Clinical Fellow 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.

In considering the funding requests, the Screening Group will aim to:

- Promote consistency, fairness, and equity.
- Ensure effective use of resources, and that the decisions are based on clinical evidence.
- Improve the rigor of the processes ensuring decisions are rational, reasonable, and transparent.
- Explore the grounds for relevant clinical exceptionality presented and apply the IFR policy.
- Consider rare cases where no commissioning policy/service exists on an individual basis.

The Clinical Decisions Lead/Nurse or Clinical Fellow will produce a summary of the key information from the Screening Group discussion using the pre-panel screening document (PPSD) during the meeting.
The Clinical Decisions Lead/Nurse is responsible for drafting the outcome letter.
The outcome letter will be communicated to the applicant by the IFR administration team within five working days of the meeting in line with the EBI & IFR Team SOP.

7. Accountability

The IFR Screening Group is accountable to HWE ICB Commissioning Committee.

8.Reporting and Monitoring

The IFR Screening Group will report any significant issues and risks arising to the HWE ICB Executive Team and any issues relating to clinical policy or guidelines to the HWE ICB Clinical Policies Group or HWE Area Prescribing Committee.

9.Training

All core members of the IFR Screening Group must undergo mandatory IFR training. This training will be refreshed at least annually to ensure that all members maintain the appropriate skills and expertise to function effectively. Ad hoc members e.g., clinical fellows, commissioning leads are encouraged to undertake training appropriate to their role.

10. Review of Terms of reference

The terms of reference of the Screening Group will be reviewed by the core members annually.

Appendix 2 – IFR Panel Terms of Reference

Individual Funding Request Panel
Terms of Reference

1. Purpose

The Individual Funding Request (IFR) and Exceptional Cases Panel (hereafter called the IFR panel) is authorised by the Hertfordshire and West Essex Integrated Care Board (HWE ICB) to take decisions on its behalf relating to the approval or otherwise of individual funding requests. The purpose of the IFR panel is to consider requests on behalf of HWE ICB where a service, intervention or treatment falls outside of existing service agreements, policies, or locally agreed guidelines.

The IFR Panel will determine whether a case for clinical exceptionality has been made and is a good use of NHS resources, and will decide whether the request should be approved, declined, or redirected in line with the HWE ICB IFR policy and IFR Standard Operating Procedures (SOP). This will ensure that all requests are considered in a fair and transparent way in line with HWE ICB's commissioning principles and outcomes are based on the available clinical evidence presented by the requesting clinicians.

The IFR Panel meeting will usually consider cases in the following scenarios:

- There is uncertainty about the responsible commissioner or whether the treatment falls within existing policy, which has been unable to be resolved, and is causing undue delay and risk to a patient.
- Arguable grounds for exceptionality are presented.
- Consideration of requests reviewed by the IFR Screening Group where no decision could be made, for example there was no consensus or evidence for exceptionality is unclear.
- Reconsideration requests of cases previously heard and declined by the IFR Panel.
- A process review of cases previously considered by other external ICB panels in line with their IFR process.

The IFR Panel has the delegated authority to make exceptions to the commissioning policies and healthcare contracts of the ICB and commit financial resources within the frameworks agreed and operates in accordance with the ICB Standing Financial Instructions/ Standing Orders and the Detailed Scheme of Delegation.

The ICB has a robust process in place to ensure compliance with the HWE ICB IFR policy (2024), NHS Constitution (2023), Quality Care Commission's Fundamental Standards (2022) and other statutory regulations and in accordance with the ICB commissioning principles.

The IFR Panel also has a delegated responsibility for ensuring compliance with the core values of the NHS Constitution and contributing evidence towards elements of the Guiding Principles identified in the NHS Constitution Framework (2023).

2. Membership

The core membership of the IFR panel shall include:

- Lay member / Patient representative (Chair)
- Associate Medical Director (Public Health Consultant/Specialist) or nominated deputy.
- Clinical Decisions Lead/Nurse or nominated deputy.
- GP representative/ Clinical Lead or nominated deputy.
- Nursing member of the Quality team
- ICB Commissioner
- Pharmaceutical Advisor or nominated deputy (for drug cases only)
- Director of Finance or nominated deputy (for request values over £50,000)

Other members where available/required.

- Secondary care representative or nominated deputy (where available).
- Specific commissioner in an advisory role.
- Finance team representative.

In the event of the Chair of the committee being unable to attend all or part of the meeting, they will nominate a replacement from within the Membership to deputise for that meeting.
Additional members may be co-opted, and the IFR Panel can decide whether additional co-opted members have decision making rights in the IFR Panel discussions for the duration of their co-opted time, e.g., Public Health Registrars, Commissioners for Children/Young People or Mental Health Services.
For particularly complex cases, other individuals with clinical expertise and skills may also be included on the IFR panel. Public Health trainees can also contribute to the work of the IFR process as part of their training. They can attend IFR Panels as non-voting members.

The IFR Panel is not obliged to allow patients to attend the Panel meeting. The IFR process is clinician led and all deliberations at the IFR Panel will be based on evidence provided by the clinician of individual clinical exceptionality, clinical effectiveness and use of NHS resources and will not consider issues relating to social or personal circumstances in line with the IFR policy. It is also crucial to minimise the risk of unconscious bias influencing funding decisions. It is, therefore, not appropriate for patients to attend the IFR Panel and the Commissioners are not legally bound to invite them. Patients may submit a supporting statement if they wish to do so.

3. Quorum

The Panel will be quorate when all core members are present. No formal business shall be transacted where a quorum is not reached.

4. Frequency of meetings and attendance.

The IFR Panel is held monthly dependent on cases being presented. Where there are no cases for discussion the IFR Panel will not be required to meet.
Should a case need urgent IFR Panel consideration, the Panel will convene an emergency meeting. In the extremely unlikely event that this is not possible, and the case cannot wait, an urgent decision will be made by virtual discussion, via Blueteq entries, email, MS Teams meeting, or phone between the Panel members using the same quoracy principles set out in section 3 (See HWE EBI & IFR Team SOP regarding urgent requests).

Attendance will be monitored and members of the IFR Panel should make every effort to attend every scheduled Panel meeting or arrange suitable cover.

5. Authority

The IFR Panel has delegated authority from the ICB to make decisions in respect of funding for individual cases.
Decisions will usually be made based on consensus. Should the respective Panel members not agree the response to a request, the IFR Panel chair has the casting vote.

The IFR Panel is authorised to make the following conclusions:

- Approve the funding request based on exceptionality and in line with the IFR policy.
- Decline the funding request.
- Redirect the request if it should be funded via an alternative commissioning route.
- Redirect/Decline the request where it is indicative of that a service development should be considered rather than an Individual Funding Request (i.e., there may be a group of patients who could benefit equally from the treatment).

The IFR Panel should make a definitive decision based on the information presented to it.

If additional information is subsequently provided by the clinician, the case can be reconsidered.

Any request for funding over £50,000.00 will require the HWE ICB Director of Finance or nominated deputy to attend the IFR Panel meeting.

The IFR Panel is not authorised to make case by case decision making for service developments where the patient represents a group of patients who may benefit from the same treatment.

The IFR Team, Screening Group and Panel shall routinely screen IFRs to see whether they represent a service development. The key question used to screen out as a service development is ‘are there likely to be other similar patients in HWE ICB?’

If there is evidence that the patient may be representative of other similar patients and forms a defined group, the Panel can consider approving funding for individual cases if the patient is clinically exceptional to the patient group in question **and** the requested intervention has evidence of safety, efficacy, and cost effectiveness/good use of NHS resources (as per IFR policy).

Otherwise, for groups of patients who do not meet the IFR policy criteria, the provider will be requested to consult with their Trust Medical Director and/or Chief Pharmacist to follow normal procedures for introducing new services/treatments via a business case.

The patient group is then obliged to wait until an EBI policy/Area Prescribing Committee guidance/service development is approved using normal governance processes.

In the extremely rare circumstance that the clinical situation of one or more patients within the eligible patient group is so urgent that it would not be appropriate to wait for a decision to be made through the full service development process (i.e. the patient(s) are at risk of imminent significant and irreversible clinical deterioration), or that significant risks have been identified, the IFR Panel will inform the Executive Team, Clinical Policy Group and/or Area Prescribing Committee so that they may consider introducing the proposed service development on an interim basis.

6. Roles and responsibilities

It is the responsibility of the IFR Team to manage all requests and correspondence received relating to each case in line with the IFR policy and SOP.
IFRs will be allocated an individual case reference number.
All documentation received regarding the case will be available to the IFR Panel.
The Lay member/Patient Representative will chair the meeting.
The Public Health Consultant/Associate Medical Director, GP Clinical Lead or Senior Pharmaceutical Advisor will be allocated cases to present at the meeting. The case presentation will include the clinical background to the case, including review of the evidence provided by the submitting clinician.

In considering the funding requests, the IFR Panel will aim to:

- Promote consistency, fairness, and equity.
- Ensure effective use of resources.
- Ensure that the decisions are based on clinical evidence.
- Maintain the rigour of the processes ensuring decisions are rational, reasonable, and transparent.
- Explore the grounds for relevant clinical exceptionality presented and apply the IFR policy.
- Consider rare cases where no commissioning policy/service exists on an individual basis.

The IFR Panel will review any views expressed by the patient or the requesting clinicians concerning the likely clinical outcomes for the individual patient of the proposed treatment.

The IFR Panel can, but are not obliged, to commission its own reports from any duly qualified or experienced clinician, medical scientist, or other person having relevant skills concerning the case that is being made regarding the clinical effectiveness of the proposed treatment.

The IFR Panel shall be supported administratively by the EBI & IFR administration team in line with the IFR SOP whose duties in this respect will include:

- Facilitating and scheduling the IFR Panel meetings in advance.
- Preparing clinical cases and inform Panel members not less than 5 working days before the meeting.
- Agreeing the agenda with the Clinical Decisions Lead/Nurse.
- Providing written notice of meetings to Panel members, and the papers, not less than 5 working days before the meeting.
- Taking the minutes and keeping a record of matters arising and issues to be reported/actioned.
- Producing an action tracker and report progress to the Panel.
- Producing and circulating minutes to the IFR Panel members within five working days of the meeting.
- Communicating the outcome letter to the applicant within five working days of the meeting.

The Clinical Decisions Lead/Nurse is responsible for drafting the outcome letter.

IFR Panel members are responsible for maintaining the standards of professional practice as set by the ICB's code of conduct, the appropriate regulatory body and other national good governance practice, for example the Seven Principles of Public Life (Nolan, 1995).

The IFR Panel will protect the confidentiality of personal information in line with the ICB Information Governance procedures.

The Panel will comply with the Conflicts of Interest Policy and receive declarations of interest at each meeting with a quarterly register of interest maintained by the IFR Team administrator.

7. Reporting arrangements

The IFR Panel will report any significant issues and risks arising to the HWE ICB Executive Team and any issues relating to clinical policy or guidelines to the HWE ICB Clinical Policies Group or HWE Area Prescribing Committee.

8. Accountability

The IFR Panel is accountable to HWE ICB Commissioning Committee.

9.Training

All members of the IFR Panel must undergo mandatory IFR training. This training will be refreshed at least annually to ensure that all members maintain the appropriate skills and expertise to function effectively.

10. Annual review of the IFR panel

The IFR Panel will undertake a yearly self-assessment to:

- Review that these Terms of Reference have been complied with and whether they remain fit for purpose.
- Determine whether the planned activities for the IFR triage process, Screening Group and IFR Panel responsibilities for the previous year have been discharged sufficiently and are in line with the IFR Policy and SOP, and relevant terms of reference.
- Recommend any changes and / or actions it considers necessary, in respect of the above.
- Provide the Executive Team or Commissioning Committee with a report as required, which details the outcome of the annual review.

11. References.

1. The Seven Principles of Public Life, Lord Nolan (1995) https://www.gov.uk/government/publications/the-7-principles-of-public-life
2. The NHS Constitution of England (2023) Department of Health and Social Care. https://www.gov.uk/government/publications/the-nhs-constitution-for-england/the-nhsconstitution-for-england
3. Herts & West Essex ICB Individual Funding Requests and Prior Approval Policy (v2.0 2024)
4. Quality Care Commission. The Fundamental Standards (2022) https://www.cqc.org.uk/what-we-do/how-we-do-our-job/fundamental-standards