Hertfordshire and West Essex
Integrated Care Board

Individual Funding Requests for Individual and Exceptional Cases and Prior Approval of Evidence Based Interventions

July 2022 V1.0

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1. Introduction

The NHS exists to serve the needs of all its patients but there is also widespread clinical consensus that NHS resources could be targeted towards more clinically appropriate interventions. At a time when demand is exceeding the capacity available, effective use of resources is both a national and local priority. HWE ICB has a responsibility to ensure that safe, evidence based, clinically effective interventions and services are prioritised appropriately for the whole of its population, as well as considering the clinical needs of individual patients.

This policy is in conjunction with the national Evidence-Based Interventions (EBI) programme, including the initial national statutory guidance published by NHS England (November 2018) and subsequent lists published by the Academy of Medical Royal Collages. This national programme relates to the commissioning of interventions which are clinically inappropriate, or which are appropriate only when performed in specific circumstances. HWE ICB is committed to ensuring compliance to the national Evidence-Based Interventions program which is mandated by NHS England through the NHS Standard Contract.

This policy is also in conjunction with the local HWE ICB Evidence Based Intervention policies, which supplement the national programme and reflect local priorities.

The aims of the national and local EBI programmes are to:

- Improve the quality of care offered to patients by reducing unnecessary interventions and preventing avoidable harm.
- Free up valuable resources, such as professional time, so that more effective or higher-value interventions can be carried out, and to create headroom for innovation.
- Maximise value and avoid waste.
- Reduce unwarranted variation.
- Help clinicians maintain professional practice and keep up to date with the changing evidence base and best practice.

Compliance with both national and local EBI policies is paramount for effective and equitable use of NHS resources and to support recovery from COVID-19. These policies enable commissioners to prioritise those patients with the greatest capacity to benefit and to restrict procedures which have limited or no clinical benefit.

HWE ICB has two processes to ensure the policies are complied with and EBI procedures are only undertaken for patients who meet the clinical criteria. Depending on local priorities, these policies will either be categorised as **Threshold Approvals**, meaning that providers carry out the procedures in line with the policy criteria, and such activity may be subject to retrospective audit. Alternatively, for some procedures, clinicians apply for **Prior Approval (PA)** from the EBI and IFR Team. This ensures optimal clinical effectiveness and appropriateness in a patient's clinical pathway.

On an individual basis, there may be situations where a clinician believes that their patient's clinical situation is so different to other patients with the same condition that they should receive a particular treatment when other patients would not. In such cases, NHS clinicians can ask HWE ICB, on behalf of a patient, to approve a treatment which would not usually be provided. Where there is local or national policy/guidance and a clinician believes their patient is an exception to the rule, these are called **Exceptional Case Requests** and where there is no policy/guidance they are called **Individual Case Requests.** Both are managed through the **Individual Funding Requests (IFR)** process and will hereby be referred to as IFRs. *(Please see further detailed definitions of all funding terms in section 3).*

Funding for additional treatments outside of what is routinely commissioned by HWE ICB can only be done by reducing the funding that is available for other established treatments. There is not an allocated separate budget to meet the costs of providing treatments agreed through the IFR process. Therefore, very careful consideration is required before the decision is taken to fund a treatment for an individual that is not usually available.

Where an outstanding healthcare need is identified which can be applied to a group or cohort of patients a business case should be submitted for consideration of a service development *(see section 5).* This priority setting process is underpinned by the HWE ICB Ethical Framework (2022) and the HWE ICS Prioritisation Framework (2021).

Promoting equality and addressing health inequalities are at the heart of the NHS values. Throughout the development of this policy, 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 (Equality Act, 2010) and those who do not share it; and 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.

2. Purpose

This policy has been developed in response to the disbandment of East & North Herts (ENH), Herts Valleys (HV) and West Essex (WE) Clinical Commissioning Groups (CCGs) and the formation of HWE ICB. It supersedes the previous IFR policy from ENH and HV CCGs and incorporates elements from the WECCG IFR and Exceptional Cases Panel SOP V2 Sep 2020.

This policy defines the responsibilities of HWE ICB and the activities of the EBI and IFR Team in relation to the management of Individual Funding Requests (for both Exceptional Cases and Individual Cases) and the Prior Approval of national and local Evidence-Based Interventions. This Policy covers the following:

- All IFR, exceptional cases and prior approval requests for adults and children that HWE ICB has responsibility for and excludes specialised treatments that are the responsibility of NHS England.
- The arrangements to consider funding requests that do not fall within existing contracts or are considered low priority.

This policy does not include the specific process arrangements which are covered in the separate Service Operational Procedures. This SOP will include the structure and function of the EBI and IFR Team and IFR panel and the process and timelines for managing funding requests and panel cases.

These procedures and documents demonstrate that clear and transparent processes are in place for decision making and provide reassurance to patients and clinicians that decisions are made in a fair, open, equitable and consistent manner in line with the NHS Constitution (July 2015) which informs patients "*If the local NHS decides not to fund a drug or treatment you and your doctor feel would be right for you, they will explain that decision to you*."

3. Definitions

EBI and IFR Team – This refers to the team which maintains overall responsibility for the management and processing of funding applications received for patients registered with a GP in either Hertfordshire or West Essex.

Pre-screen Panel - Consists of the Clinical Decisions Lead or Clinical Decisions Nurse, Public Health Consultant, Pharmaceutical Advisor (as required) and the IFR Co-ordinator. The pre-screen panel can be used to review complex or exceptional cases or appeals prior to consideration of presentation to the full IFR panel.

IFR Panel – Are panels that have been authorised by HWE ICB to take decisions on its behalf on IFRs, including both individual and exceptional cases.

EBI Procedures – Procedures that are either subject to local EBI policies or are included in the national EBI programme.

National EBI Programme – A clinical initiative led by the Academy of Medical Royal Collages (AoMRC), in partnership with NHSE/I, NHS Clinical Commissioners and NICE. It is designed to improve the quality of care being offered to patients by reducing unnecessary intervention and preventing avoidable harm. In addition, by only offering interventions on the NHS that are evidence-based and appropriate, the programme frees up resources that can be put to use elsewhere in the NHS. It also aims to reduce unwarranted variation. The programme sets out tests, treatments and procedures which should not be undertaken, or only undertaken when certain clinical criteria are met. List 1 was published by NHSE as statutory guidance and came into effect on 1 April 2019. List 2 was published by AoMRC in Nov 2020.
List 3 is due to be published by AoMRC in May 2022.

Local EBI Policies – HWE ICB clinical policies, based on evidence reviews and local priorities, to support appropriate clinical decision making. These policies set out whether the procedure is routinely commissioned and, if so, what clinical criteria should be met. These policies supplement the national EBI programme. They have historically also been referred to as Procedures of Limited Clinical Value (PoLCV) policies, Clinical Prioritisation Policies and Service Restriction policies.

Threshold Approvals – Those procedures which are routinely commissioned by HWE ICB and are within agreed contracts but only for patients who meet the defined criteria set out within the relevant national and local Evidence-Based Interventions policies. Clinicians can proceed to treat the patients who meet the threshold criteria and prior approval is not required from the EBI and IFR team. Notification of compliance or audit will be required according to contractual arrangements.

Prior Approval (PA) - Is a process in which clinicians demonstrate, by application to the EBI and IFR Team, how a patient meets the criteria set out within the relevant EBI policies, prior to referring to secondary or tertiary care and/or by consultants prior to listing for surgery. It applies to those procedures which are commissioned and are within agreed contracts but only for patients who meet the defined criteria. Prior approval is considered on a patient-by-patient basis by the EBI and IFR team

Not Normally Commissioned – Those procedures which have been assessed as treatments of low clinical effectiveness, having limited evidence of effectiveness, or not in line with local priorities, and which will not be approved unless there are exceptional clinical circumstances. Applications for these procedures can be made to the EBI and IFR Team but should only be made where the patient demonstrates true clinical exceptionality *(see below and p11 for definitions of exceptionality).*

Individual Funding Requests (IFR) – IFR's include both Exceptional Cases and Individual Cases (*see below*). In both cases it must be demonstrated that 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 (a cohort) with an outstanding healthcare need for whom a business case should be submitted for consideration of a service development (s*ee page 11).*

- **Exceptional Cases** - This is where there is a local or national EBI policy, NICE Technology Appraisal (TA) guidance or Highly Specialised Technology (HST) Appraisal guidance that governs whether to fund or not fund the treatment for the patient's condition, **AND** a clinician can demonstrate that their patient is in a different clinical condition when compared to the typical patient population with the same condition and (if relevant) at the same stage of progression, **AND** because of that difference, their patient is likely to receive material additional clinical benefit from treatment that would not be plausible for any typical patient. *(Detailed information around clinical exceptionality can be found on page 11)*
- **Individual Case** - Is a request received from a clinician providing care to a patient, for a specific treatment that is not covered by existing policy or for a service which is not commissioned by HWE ICB. This process allows clinicians the opportunity to make specific funding requests via its IFR process where there is a basis for considering that the patient is clinically exceptional (see page 11) **AND** the requested intervention is likely to be clinically effective (see page 13) for the patient **AND** is considered a good use of NHS resources (see page 14). These individual cases are where there is no relevant local or national EBI policy, NICE Technology Appraisal (TA) guidance or Highly Specialised Technology (HST) Appraisal guidance in place for the management of the patient's condition or combination of conditions.

4. Roles and Responsibilities

This policy applies to all HWE ICB staff members, whether permanent, temporary or contracted-in (either as an individual or through a third-party supplier).

Applicants - Applications must be made by appropriate NHS clinicians. For Prior Approval and IFRs for Exceptional Cases this is likely to be the patient's GP or Consultant but may be from a therapist or other healthcare professional applying appropriately within their scope of expertise. It is expected that the majority of IFRs for Individual Cases will be submitted by secondary/tertiary care clinicians rather than primary care clinicians. The requirement for a GP to make an IFR for an Individual Case is expected to be relatively rare given the grounds for clinical exceptionality and the complexity of such requests. However, if a GP feels that an IFR is appropriate, expert advice should be sought as appropriate. It is for the same reason that patients cannot apply for their own funding and an appropriate NHS clinician can apply on the patient's behalf if, in their professional opinion, it is appropriate to do so. Patients can however submit a supporting statement. (*See page 11 for more details*).

Applicants are expected to submit a full and complete application form and all necessary supporting evidence. Should the EBI & IFR team require further information, it will be requested from the applicant only. It is the responsibility of the applicant to submit what is required in a timely manner to avoid delays in patient care.

4.1 Roles and Responsibilities within the organisation

Clinical Decisions Lead
Responsible for managing the EBI & IFR team and its processes, ensuring that this policy is consistently applied when supporting the triage of applications and the IFR panel. Implements changes to enhance the team's effectiveness and reviews processes. Represents IFR in the Clinical Policies Group. Has oversight of the clinical audit process. Reports activity and escalates any issues or concerns to the appropriate clinical or executive groups.

Pharmaceutical Advisor
Provides specialist pharmaceutical support and advice concerning drug IFR cases to the IFR team, pre-screen panel meetings and IFR Panel. Provides specialist input on IFR drug cases including efficacy, safety, clinical and cost effectiveness.

Public Health Consultant - Provides clinical support and advice to the IFR team, pre-screen panel meetings and IFR Panel. Their role is to give public health advice in relation to clinical appropriateness, clinical effectiveness and cost effectiveness of a treatment. They also perform systematic reviews of the literature and perform individual case reviews based on clinical evidence. Public Health consultants will interface with the HWE ICB Clinical Policies Group and Hertfordshire's Medicine Management Committee (HMMC).

Clinical Fellow - Medically qualified doctor who provides clinical support and advice. Supports the team to perform audits. They also perform systematic reviews of literature to support the IFR team and HWE ICB Clinical Policies Group.

Clinical Decisions Nurse - Is responsible for applying this policy in a consistent manner when assessing clinical cases and has oversight of the administration team. The Clinical Decisions Nurse will report any issues and/or concerns to the Clinical Decisions Lead.

Administration team - Responsible for supporting all aspects of the EBI and IFR process including Panel meetings and the HWE ICB Clinical Policies Group and the clinical audit process. Liaise with clinicians, healthcare staff and patients to keep them informed of the process and signpost to relevant alternative services such as the Patient Advise and Liaison Service (PALS), Integrated Health Care Commissioning Team (IHCCT) or Child and Adolescent Mental Health Service (CAMHS) as required.

IFR Panel - The IFR panel has delegated authority from HWE ICB to make decisions in respect of funding for individual and exceptional cases in line with this policy. Accountability for those decisions rests with the ICB representatives on the Panel. Decisions will usually be made on the basis of 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. Should the Panel members not agree on the response to a request, the case will be escalated to the ICB Executive Team. The IFR panel will report any significant issues and risks arising to the ICB Executive Team via the IFR quarterly report or any issues relating to clinical policy to the HWE ICB Clinical Policies Group. The panel may also be asked to review appeal cases previously considered by other external ICB IFR panels in line with their IFR process.

Process Appeals Panel - The Process Appeals Panel are independent to the IFR panel and will screen appeals where grounds have been presented that the SOP or TOR were not followed. Should grounds for appeal be identified the case will be referred back to the IFR panel for reconsideration.

4.2 Consultation and communication with stakeholders

Any changes or updates to this policy will follow the consultation and communication processes stipulated in local contractual agreements.

5. Content

This policy applies, as appropriate, to any patient for whom HWE ICB is the responsible commissioner and who are registered with a Herts or WE General Practice. HWE ICB is responsible for commissioning services to meet the health needs of its population and is required to commission services which are evidence–based, clinically and cost effective, improve health outcomes, and reduce health inequalities whilst representing value for money.

Funding Duration

Unless otherwise stated funding is valid for 12 months from the date of the approval and whilst the patient remains registered with a GP within the HWE ICB area. This general rule is in line with NHS England guidance Who Pays? (2020).

Personal Health Budgets

IFR does not fund equipment or on-going maintenance, or placements in long term care. Personal Health Budget's and voucher schemes may be available through the Continuing Health Care Team.

Specialised Treatments

HWE ICB wants the best for its patients. It is important that when a patient reaches a stage in their treatment pathway that requires a specialist intervention, we would expect our patients to be referred to an officially designated, accredited centre (usually commissioned by NHSE) to ensure a high quality of care. The ICB will not support specialised treatment at undesignated, non-accredited centres.

Business Case for Service Development

Individual requests cannot be used as a means of 'creeping implementation' for new technologies, services or policies. Therefore, consideration needs to be given as to the likelihood of other patients having the same clinical need who could also benefit from the proposed treatment. If there is likely to be a defined group of patients in similar clinical circumstances to that patient, the application will be classified as a request for development of a new policy or service specification and a business case should be submitted via an alternative route through the ICB. The cohort must wait until a policy is approved unless there is clinical urgency and it would be unsafe to wait, in which case the IFR panel can escalate the case to an ICB executive director for expedition of the decision which will be applied fairly to all in that cohort.

Clinical Decisions

The clinical funding process only considers **clinical** information. Any information that is immaterial to the decision, including information about the social, economic or personal circumstances of the patient which does not have a direct connection to the patient's clinical circumstances, shall not be considered (*see page 13*).

The IFR process is clinician led and all applications must be made by a clinician. Deliberations at Pre-screen and Panel will be based on evidence of individual clinical exceptionality and will not take into account issues relating to social or personal circumstances.

Due to the risk of introducing unconscious bias and inequality ion decision making it is not appropriate for patients to attend the Panel pre-screen or the IFR or Process Appeals Panel and HWE ICB are not legally bound to invite them.

However, patients are encouraged to submit a supporting statement, but this needs to be limited to clinical issues i.e.: what effect the condition has on the patient's activities of day to day living. *(see Clinical Exceptionality: Non-Clinical and Social Factors section on page 13).* The EBI and IFR team can offer guidance around this process and further support can be found at https://www.nhs.uk/conditions/social-care-and-support-guide/help-from-social-services-and-charities/someone-to-speak-up-for-you-advocate/

HWE ICB does not discriminate on grounds of gender, age, sexual orientation, ethnicity, educational level, employment, disability, marital status or religion and does not generally make treatment for patients under its policies dependent on the patient's social or personal circumstances. Accordingly, when making decisions as to whether treatment should be provided to a patient which is not provided to patients generally, the IFR Panels shall adopt the same approach.

Clinical Exceptionality

There can be no exhaustive description of the situations which are likely to come within the definition of exceptional clinical circumstances. The onus is on the clinician making the request to set out the grounds for clinical exceptionality clearly for the IFR Panel. 'Exceptional' in IFR terms means a person to whom the general rule* should not apply. This implies that there is likely to be something about their clinical situation which was not considered when formulating the general rule.

*(*In this context the 'general rule' might be a policy that describes those patients who can access the intervention, or it may be that where there is no policy governing the treatment in this condition, in the interests of fairness to all patients, the position is that it will not be commissioned ahead of policy development.)*

Very few patients have clinical circumstances which are genuinely exceptional. To justify approval for treatment for a patient which is not available to other patients, and is not part of the established care pathway, the EBI and IFR team needs to be satisfied that the clinician has demonstrated that this patient's individual clinical circumstances are clearly different to those of other patients, and that because of this difference, the general policies should not be applied.

Simply put, the consideration is whether it is fair to approve this patient's treatment when the treatment is not available to others.

It should be stressed that an IFR is not a route to "have another look" at the general rule, or to protest that the general rule is ungenerous.

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

Very occasionally an IFR presents a new issue which needs a substantial piece of work before the ICB can reach a conclusion upon its position. This may include wider consultation. Where this occurs, the EBI and IFR team may postpone a decision on an individual case until that work has been completed. This may not always be clinically appropriate should the patient have clinical needs where a delay in approval would be inappropriate. In such cases funding in the interim may be considered. (*Please see the SOP for the specific arrangements*).

The EBI & IFR team apply 2 tests to exceptionality –

- Test 1 – Is the patient significantly different clinically to the general population of patients with the condition in question and at the same stage of progression of the condition in question who request that intervention?
  (by saying yes to a patient we are not setting a precedent that means we must fund other patients)
- Test 2 – Is the patient likely to gain significantly more benefit from the intervention than might be normally expected for patients with that condition who request that intervention?

Arguments for clinical exceptionality on the grounds of failure to respond to standard care, severity of condition, genotypes, multiple clinical grounds or non-clinical or social factors are guided using the NHS England IFR policy (2017) as follows;

Clinical exceptionality: failure to respond to standard care

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

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

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

- If the usual treatment is only effective for a proportion of patients (even if a high proportion), this leaves a proportion of patients within the group for whom it is already known that the usual treatment is not available or is not clinically effective. The fact that this particular patient falls into that group is unlikely to be a proper ground on which to base a claim that they are exceptional as an individual.
- As regards side effects, as an example, all patients who are treated with long-term high-dose steroids will develop side-effects (typical and well recognised) and thus developing these side effects and wishing to be treated with something else does not make the patient exceptional.
- If the usual treatment cannot be given because of a pre-existing comorbidity which is unrelated to the condition for which the treatment is being sought under the IFR or is not unusual in the relevant patient group or generally, the fact that the co-morbidity is present in this patient and its impact on treatment options for this patient is unlikely to make the patient clinically exceptional. As an illustration, some comorbidities are common in the general population, for example, diabetes which affects around 7% of adults, or asthma which affects at least 10% of the population. Diabetes and its treatments affect many other conditions; for example, steroids make glucose control more difficult. With any condition there will be a recognised proportion who also have a comorbidity which is common in the general population, and thus a patient cannot be exceptional by virtue of also having a comorbidity which is common in the general population.

Clinical Exceptionality: Genotypes

When the argument for clinical exceptionality is based on the patient having a specific genotype (genetic profile), the IFR Panel will require evidence of the prevalence of the genotype in the patient group. The applicant will need to show how the specific genotype would make the patient a) different to others in terms of clinical management and b) able to benefit from the treatment to a greater degree than others with the same or different symptoms of the condition.

Clinical exceptionality: severity

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

- Whether there is evidence that the patient's presentation lies outside the normal spectrum for that condition. Preferably, a recognised scoring or classification system should be used to describe the patient's condition.
- Whether there is evidence that the patient has progressed to a very severe form of the condition much more rapidly than the range of progression that is documented and usually observed within the natural history of the condition.
- How the patient is expected to benefit from the treatment sought and in what quantifiable way;
- That there is evidence that the impact of the condition on this patient's health is significantly greater than its impact on the rest of the patient group, e.g., the condition is usually a mild disease, but the presenting case is an extremely severe presentation; and
- That there is a plausible argument that the severity of the condition is prognostic of good response to treatment.

Clinical exceptionality: multiple grounds

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

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

Clinical Exceptionality: Non-Clinical and Social Factors

The IFR and exceptional case process only considers clinical information. Although initially it may seem reasonable to fund treatment based on reasons grounded in a moral or compassionate view of the case or because of the individual's situation, background, ambition in life, occupation or family circumstances, these reasons bring into play a judgement of 'worthiness" for treatment.

As a central principle, the NHS does not make judgements about the worth of different individuals and seeks to treat everyone fairly and equitably. Consideration of these non-clinical factors would introduce this concept of 'worth' into clinical decision making. It is a core value that NHS care is available - or unavailable - equally to all.

Whilst everyone's individual circumstances are, by definition, unique and on compassionate grounds, reasons can always be advanced to support a case for funding, it is likely that the same or similar arguments could be made for all or many of the patients who cannot routinely access the care requested. Non-clinical and social factors have to be disregarded for this purpose in order for the IFR screening groups and then IFR Panel, to be confident of dealing in a fair manner in comparable cases. If these factors were to be included in the decision-making process, HWE ICB would not know whether it is being fair to other patients who cannot access such treatment and whose non-clinical and social factors would be the same or similar.

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

Clinical Effectiveness

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

Clinical evidence that considers the efficacy of a particular treatment will be carefully considered by the IFR team. It is the sole responsibility of the referring clinician to provide this information and the IFR team will not be responsible for undertaking any evidence searches.

Inevitably, the evidence base put forward in support of an IFR is unlikely to be as robust as in more common presentations of the condition or the more usual use of the treatment. However, it is important that the referring clinician makes explicit linkages between the grounds under which exceptionality is claimed and the sections of the submitted research literature that are considered to support the clinician's view regarding the differences between the patient's clinical position and that of other patients in the group, and regarding the patient's anticipated response to the requested treatment.

When considering clinical effectiveness, the IFR Panel will consider:

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

A Good Use of NHS Resources

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

This criterion is only applied where the IFR team has already concluded that the criteria of clinical exceptionality and clinical effectiveness have been met. Against this criterion the IFR team balances the degree of benefit likely to be obtained for the patient from funding the treatment against cost.

Having regard to the evidence submitted and the analysis they have carried out when considering clinical exceptionality and clinical effectiveness, the IFR team will consider the nature and extent of the benefit the patient is likely to gain from the treatment, the certainty or otherwise of the anticipated outcome from the treatment and the opportunity costs for funding the treatment. This means considering, for example, how significant a benefit is likely to be gained for the patient, and for how long that benefit will last. These factors need to be balanced against the cost of the treatment and the impact on other patients of withdrawing funding from other areas in order to fulfil the IFR. When determining whether a treatment would be a good use of NHS resources it is very important to consider the length of time for which funding of a treatment is being requested, in relation to the duration of the evidenced efficacy of the treatment i.e. whether the clinical evidence indicates short, medium or long term effectiveness of a particular treatment.

Due to the nature of the cases considered by the IFR team, the degree to which effectiveness can be considered certain is likely to be limited, and this will be a relevant factor when considering whether funding would be a good use of NHS resources. However, the IFR team should also take into account its ability to impose conditions on any funding it agrees, for example to monitor the impact of the funded treatment. In applying this criterion the IFR team will draw upon their professional and analytical skills and knowledge of the NHS system and how it works.

Experimental and unproven treatments

It is standard practice for ICBs not to fund treatments which are still considered experimental, irrespective of the ‘potential’ health benefit for either individuals or groups of patients. Therefore, treatments which are judged experimental, uncertain or not to be of proven effectiveness will not routinely be commissioned and funding for individual patients or groups of patients within poorly designed trials will not be supported.

HWE ICB EBI and IFR team will adopt the following criteria when considering a treatment as experimental:

- The treatment is still undergoing clinical trials for the indication in question.
- There are no relevant articles published in the peer-reviewed journals available on the treatment for the indication in question.
- The treatment does not have approval from the relevant government body.

- The treatment does not conform to usual clinical practice in the view of the majority of medical practitioners in the relevant field
- The treatment is being used in a way other than that previously studied or that for which it has been granted approval by the relevant government body
- The treatment is rarely used, novel, or unknown and there is a lack of authoritative evidence of safety and efficacy

There may at times be exceptions to the above where the ICB may consider funding. The EBI and IFR team will apply the NHS England IFR policy (2017) section on experimental, uncertain and unproven treatments when considering such requests.

Drug Requests

The IFR team processes requests for drugs not routinely commissioned including:

- High-cost drugs excluded from contracts.
- Treatments where no policies exist.
- Treatments that we as a ICB have decided we will not fund routinely, or only fund in certain circumstances. This may include primary care prescribing or requests from Trusts and other providers

During daily triage should a request meet routine commissioning criteria this will be sent to the Pharmacy and Medicines Optimisation Team (PMOT) for processing. Drug requests will be considered in line with this policy on the grounds of clinical exceptionality and the same principles will be applied. The EBI and IFR team will work collaboratively with PMOT in responding to requests and draw upon their knowledge and expertise.

HWE ICB does not expect to provide funding for patients to continue medication/treatment commenced as part of a clinical trial. In line with the Medicines for Human Use (Clinical Trials) Regulations (2004) and the World Medical Association (WMA) Declaration of Helsinki (2018), the responsibility lies with those conducting the trial to ensure a clear exit strategy from a trial and that those benefiting from treatments provided within the trial setting will have on-going access to those treatments.

Mental Health Funding Requests Hertfordshire commissions its mental health services for adults and children from Hertfordshire Partnership Foundation NHS Trust (HPFT). The majority of mental health services are available through contracts held by the Integrated Health and Care Commissioning Team (IHCCT) and are accessed through referral to HPFT. The IFR team does not process requests for mental health services which fall outside of these contracts.

Requests for mental health services are managed by IHCCT in line with the ‘Requests for Mental Health Services outside the Main Contractual Arrangements’ document. Requests are sent by clinicians securely to a mental health clinical lead at Ihcct.quality@nhs.net for consideration of individual funding. On occasions the mental health commissioner may request the IFR panel to consider funding advice for complex cases and/or appeals.

In such cases the mental health commissioner will be expected to present the case including all relevant history and clinical information to the panel. The IFR panel will make a funding decision and/or provide advice in line with the IFR panel SOP. IHCCT remain responsible for the administration process of the case in question and the dissemination of the outcome.

West Essex commissions mental health services for children and young people from North East London NHS Foundation Trust (NELFT) as part of the Southend, Essex & Thurrock collaborative. The service is open to children and young people between the ages of 0-18, or up to 25 for those with special educational needs. Any child or young person experiencing mental health difficulties as well as any parent, guardian or professional can access the service for help and guidance via the Single Point of Access: 0800 953 0222 / SET-CAMHS.referrals@nelft.nhs.uk. Individual funding requests for child or young person mental health services outside of core services go to the Essex wide Individual Placements Team neeccg.iptreferrals@nhs.net.

6. Monitoring compliance

This policy will be monitored by the EBI and IFR team and IFR Panels as it is applied to daily practice. Any issues will be raised to the Clinical Decisions Lead or Associate Medical Director who is responsible for reviewing and updating the policy.

The EBI and IFR Team will participate in a quarterly internal peer audit and feedback process of funding decisions relating to Prior approval, exceptional cases and IFRs. Any trends or themes are captured and reported in the quarterly HWE ICB IFR report as well learning opportunities for clinical decision makers which are included in regular education and training sessions (*see section 7)*.

7. Education and Training

All members of IFR Panel and IFR Process Appeals Panels must be trained to a minimum standard. This includes participation in at least 2 regular IFR panels per annum (for IFR members), and an annual training event, OR can demonstrate equivalent and up to date training.

Clinical decision makers adhere to the quarterly peer review and feedback process for learning opportunities and to ensure fair and consistent decision making.

All members of staff must be up to date with HWE ICB mandatory training.

8. Associated documentation - Panel members are recommended to read;

- Herts & West Essex Ethical Framework.
- Hertfordshire and West Essex Integrated Care System: Prioritisation Framework and Agreed Principles for completion of the Prioritisation Framework.
- Priority Setting: Managing Individual Funding Requests by Dr Daphne Austin, and published by the NHS Confederation and the Primary Care Trust Network https://www.nhsconfed.org/sites/default/files/2022-05/Priority-setting-funding-requests.pdf
- Supporting rational local decision making about medicines and treatments; A handbook of good practice guidance. February 2009. National Prescribing Centre http://webarchive.nationalarchives.gov.uk/20130107105354/http:/www.npc.nhs.uk/local_decision_making/constitution_handbook.php
- Defining guiding principles for processes supporting local decision making about medicines. January 2009. National prescribing Centre, commissioned by DoH http://webarchive.nationalarchives.gov.uk/20130107105354/http:/www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_093413

9. References

1. NHS Constitution (January 2021) https://www.gov.uk/government/publications/the-nhs-constitution-for-england/the-nhs-constitution-for-england
2. NHS England Commissioning Policy – Individual Funding Requests (2017) https://www.england.nhs.uk/wp-content/uploads/2017/11/comm-policy-indivdual-funding-requests.pdf
3. Equality Act (2010) https://www.legislation.gov.uk/ukpga/2010/15/contents
4. Herts & west Essex ICB Ethical framework (2022)
5. Hertfordshire and West Essex Integrated Care System: Prioritisation Framework and Agreed Principles for completion of the Prioritisation Framework
6. Medicines for Human Use (Clinical Trials) Regulations 2004. https://www.legislation.gov.uk/uksi/2004/1031/contents/made
7. World Medical Association (WMA) Declaration of Helsinki (2018) https://www.wma.net/policies-post/wma-declaration-of-helsinki-ethical-principles-for-medical-research-involving-human-subjects/
8. Academy of Medical Royal Colleges. Evidence-based Interventions https://www.aomrc.org.uk/ebi/
9. NHS England Improvement. Evidence-Based Interventions: Guidance for CCGs (2019) https://www.aomrc.org.uk/ebi/wp-content/uploads/2021/05/ebi-statutory-guidance.pdf
10. Academy of Medical Royal Colleges. Evidence-Based Interventions List 2 Guidance (2020) https://www.aomrc.org.uk/ebi/wp-content/uploads/2021/05/EBI_list2_guidance_0321.pdf
11. Academy of Medical Royal Colleges. Evidence-based Interventions List 3 Clinical guidance Proposals (2022) https://www.aomrc.org.uk/ebi/wp-content/uploads/2022/01/EBI_List_3_cinical_guidance_Proposals.pdf

Appendices:

Appendix 1 – Glossary of abbreviations

Abbreviation	Meaning
AoMRC	Academy of Medical Royal Collages
CAMHS	Child and Adolescent Mental Health Service
CCG	Clinical Commissioning Group
EBI	Evidence Based Interventions
ENH	East and North Hertfordshire
GP	General Practice / Practitioner
HMMC	Hertfordshire Medicines Management Committee
HWE	Hertfordshire and West Essex
HV	Herts Valleys
ICB	Integrated Care Board
ICS	Integrated Care System
IHCCT	Integrated Health Care Commissioning Team
IFR	Individual Funding Request
NHS	National Health Service
NHSE	National Health Service England
NHSI	National Health Service Improvement
NICE	National Institute for Health and Care Excellence
PA	Prior Approval
PALS	Patient Advise and Liaison Service
PoLCV	Procedures of Limited Clinical Value
SOP	Service Operational Procedures
TOR	Terms of reference
WE	West Essex

Appendix 2 – IFR and Process Appeals Panel Terms of Reference

1. Introduction

The Individual Funding Request and Exceptional Cases Panel (hereafter called IFR Panel) will consider individual requests for funding where a service, intervention or treatment falls outside existing HWE ICB service agreements.

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 (2022), NHS Constitution (2021), Quality Care Commission's Fundamental Standards (2022) and other statutory regulations and in accordance with the ICB commissioning principles and Ethical Framework (2022).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 (2021).

The Process Appeals Panel are independent to the IFR panel and will screen appeals where grounds have been presented that the SOP or TOR were not followed. Should grounds for appeal be identified the case will be referred back to the IFR panel for reconsideration.

These processes will ensure that each request for individual funding is considered in a fair and transparent way, with decisions based on the best available evidence of clinical and cost effectiveness, safety, and impact on health.

The Individual Funding Request Panel Chair is directly accountable to the Chair of the Clinical Policies Group. The Process Appeals Chair is accountable to the Chair of the Executive Health & Care Commissioning Committee.

2. Membership

IFR Panel
Lay member (Chair)
GP advisor for IFR and service restrictions
Consultant or SpR* in Public Health
Commissioner
Nursing member of the quality team
Clinical Decisions Lead / Nurse
Medicines Management rep (as needed)
IFR co-ordinator

*Approved as competent by educational supervisor/under supervision

To include co-opted attendance from programme leads as and when required. Nominated & trained deputies as required for each member.

In the interest of fairness and equality for all patients and to reduce potential bias in decision making, patients will not be permitted to attend Panel meetings in person or be represented by any person at the meeting. Please see the HWE ICB IFR Policy for further details.

Process Appeals Panel
Lay Board Member – Governance/Deputy Chair (chair) or Medical Director or deputy
CCG Board Clinician or Clinical Director
Consultant or SpR* in Public Health
Commissioner
Nurse/quality representative.

*approved as competent by the educational supervisor

Process Appeal Panel members will be independent from the original IFR Panel decision. In addition to the members of the Appeals Panel, any other relevant professional may also attend with the specific agreement of the Chair of the Appeals Panel.

3. Quorum

4.1 IFR Panel

The IFR Panel will be quorate when all members are present. There will be sufficient cover (nominated and trained deputies) for all roles.

4.2 Appeal Panel

The Appeals Panel will be quorate when all members are present.

4. Frequency and notice of meetings

4.1 IFR Panel

IFR Panel meetings shall be held every two weeks to ensure timeliness of the decisions for patients.

4.2 Process Appeal Panel

Appeals will be held as required and subject to the timescales listed in the standard operating procedure.

5. Remit and responsibilities of the IFR Panel and IFR Process Appeals Panel

Any identified IFR or exceptional case requests will be processed as per the west Essex or Hertfordshire SOP.

5.1 For the IFR Panel

- Support the IFR coordinators to triage prior approval and threshold policy applications
- Consider applications for exceptions to agreed ICB service restriction policies or pathways using the agreed tests of exceptionality as detailed in the HWE ICB IFR policy.
- Consider applications for individual funding requests using the agreed tests for IFRs as detailed in the HWE ICB IFR Policy.
- Refer applications to Specialised Commissioning where they are the Responsible Commissioner
- The IFR Panel is not allowed to make precedent setting decisions about groups of similar patients
- Where applications are indicative of a new service development, the IFR Panel will refer the service development to the appropriate Transformation Manager[1]
- Where applications are indicative of a new service development or a group of similar patients, and where there is urgent outstanding clinical need, the IFR Panel will make a recommendation to the Director of Transformation or Director of Finance to decide on funding for that specific applicant.
- On occasion the HWE IBC IFR Panel may be asked by a neighbouring ICB IFR team to review a request in line with their appeal process.

5.2 For the IFR Process Appeals

- The Process Appeals Panel Lay Chair or ICB Medical Director will screen and decide if there are grounds for appeal
- The Process Appeals Panel will consider any grounds for appeal and decide whether to uphold or refute
- A process appeals panel can only dictate whether the Terms of Reference and Standard Operating Procedures were or were not followed. They cannot overturn the decision of the original panel (please refer to the SOP for full details of the grounds for appeal)
- If the Appeals Panel approves the grounds for appeal, then it will refer the application back to the IFR Panel to reconsider on those specific grounds.
- Should any subsequent grounds for appeal be submitted following this process the case will be forwarded to a neighbouring ICB IFR Panel for a further process review.

6. 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.

[1] The IFR Panel cannot exceed its terms of reference by making precedent setting decisions. Where an application is indicative of an outstanding healthcare need for a group of patients who can similarly benefit then the Panel must refer this onto the appropriate Transformation Manager. The Panel can still consider exceptionality i.e., whether the patient can be funded ahead of a decision being made for the group as a whole

7. Relationship with the Integrated Care Board

The IFR Panel and the Process Appeals Panel report to the HWE Clinical Policies Group (CPG) which in turn reports to the Executive Health and Care Commissioning Committee (EHCCC) which reports to the ICB Board. The CPG has assurance oversight of the IFR Panel. The IFR Panel provides a report to each CPG on numbers of applications reviewed, overview of decisions made, and cohorts / service developments that have been notified to the appropriate Transformation Manager. This report is also available for reporting to the EHCCC at frequencies to be determined, the Audit Committee annually and to the Board at frequency to be agreed.

8. Policy and best practice

The Panel will apply best known practice in relation to Individual Funding Requests and Exceptional Cases.
An assessment of the effectiveness of the IFR process will be undertaken annually.

9. Conduct of the committee

The IFR Panel will conduct its business in accordance with the ICB's Business Code of Conduct, the relevant national guidance and codes of conduct /good governance practice, for example the Seven Principles of Public Life (Nolan, 1995). The Panel will comply with the Conflicts of Interest Policy and receive declarations of interest at each meeting with a quarterly register of interest.

As per the IFR policy, IFR Panel members will be required to be appropriately trained and experienced in IFR processes before and during their membership.

10. Review

The IFR Panel's Terms of Reference will be reviewed annually or in light of any changes in legislation, practice or local/national guidance.

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 its planned activities and responsibilities for the previous year have been sufficiently discharged; and,
- Recommend any changes and / or actions it considers necessary, in respect of the above.
- Provide the ICB executive team with an annual report, which details the outcome of the annual review.

11. Documentation and Servicing of the IFR and Process Appeals Panel

The IFR Co-Ordinator will service the meetings of the Panel and Appeals Panel. A standard reporting template shall be used for the meetings. Agenda and papers will be issued at least 4 working days prior to each meeting.
IFRs will be entered onto the IFR database by the IFR Co-ordinator or delegated administrative support. It is the responsibility of the IFR Co-ordinator 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.

References

The Seven Principles of Public Life, Lord Nolan (1995)
https://www.gov.uk/government/publications/the-7-principles-of-public-life
The NHS Constitution of England (2021) Department of Health and Social Care.
https://www.gov.uk/government/publications/the-nhs-constitution-for-england/the-nhs-constitution-for-england
Herts & West Essex ICB Ethical Framework
Herts & West Essex ICB IFR Policy (2022)
Quality Care Commission. The Fundamental Standards (2022)
https://www.cqc.org.uk/what-we-do/how-we-do-our-job/fundamental-standards

Hertfordshire and West Essex Integrated Care System

Essex County Council

Hertfordshire

NHS

Equality analysis – full equality impact assessment

Title of policy, service, proposal etc being assessed:
Individual Funding Requests and Prior Approval of Evidence Based Interventions
What are the intended outcomes of this work? **To Inform clinicians and patients about the rationale and process of individual funding and prior approval. Update the existing policy and ensure it remains relevant and in line with NHSE**
How will these outcomes be achieved? **The team will apply this policy equally and fairly to all. Regular audits will be performed to assess cases against the policy**.
Who will be affected by this work? **Patients, ICB staff, external staff, consultants, GP's, Public health.**

Evidence

What evidence have you considered?

Age **No age discrimination in this policy**
Disability **No discrimination within policy, however this group of patients may require additional support from clinicians to have the processes within the policy explained. As this policy is for clinicians no plain text or large print version available.**
Gender reassignment (including transgender) **No impact on this group**

Marriage and civil partnership **No impact on this group**
Pregnancy and maternity **No impact on this group**
Race **No impact on this group**
Religion or belief **No impact on this group**
Sex **No impact on this group**
Sexual orientation **No impact on this group**
Carers **No impact on this group**
Other identified groups **The clinical funding team can only process applications for patients who are registered with a GP in Hertfordshire. Socio-economic status does not impact on the decision making process**

Engagement and involvement

How have you engaged stakeholders with an interest in protected characteristics in gathering evidence or testing the evidence available? **This is not a new process, policy update only**
How have you engaged stakeholders in testing the policy or programme proposals? **This is not a new process, policy update only**
For each engagement activity, please state who was involved, how and when they were engaged, and the key outputs:

Summary of Analysis

Now consider and detail below how the proposals could support the elimination of discrimination, harassment and victimisation, advance the equality of opportunity and promote good relations between groups (the General Duty of the Public Sector Equality Duty).

Eliminate discrimination, harassment and victimisation

This policy is applied equally and fairly to all patients regardless of sex, age, sexual orientation, ethnicity, educational level, employment, disability, marital status or religion, social or personal circumstances are not general used as a means to obtain funding over others.

Advance equality of opportunity

As above

Promote good relations between groups

As above

Next Steps

How will you share the findings of the equality analysis? This can include sharing through corporate governance or sharing with, for example, other directorates, partner organisations or the public. The completed EqIA will be published on the Herts and West Essex ICB website either as part of the report on the proposals or separately on the equality and diversity pages.

We will ensure that all clinicians involved in applying for funding on behalf of patients are aware of this policy and its contents; we will do as much as we can to ensure that all patients have this policy applied to them in an equal and consistent manner. We will regularly audit our funding decisions.