


Individual Funding Requests and Prior Approval Policy July 2024

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2.0	Jan 2024	Jo Oliver RN Dr Samantha Chepkin Colin Sach Saskia Vercaeren Angela Kenny	Changes reflect the developments from alignment and formation of ICB. Pulls process towards alignment with NHS England IFR team. Includes the role of GP Clinical Advisors and the Screening group. Removes the IFR process appeal panel. Includes updated SOP and TOR for IFR panel and Screening group. Updated patient information leaflet. Updated information around mental health services and related IFRs.



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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 and effective use of resources is both a national and local priority.

Hertfordshire and West Essex (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 Colleges. 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, recommended by the HWE ICB Clinical Policies Group, and HWE Area Prescribing Committee (APC) guidelines, pathways, and recommendations, 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 and HWE APC guidelines, pathways and recommendations is paramount for effective and equitable use of NHS resources and to support system recovery from COVID-19. These policies enable commissioners to prioritise those patients with the greatest capacity to benefit and to restrict investigations, treatments and procedures which have limited or no clinical benefit.

HWE ICB has processes to ensure the policies and recommendations are complied with. These include **Threshold Approvals**, where 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, and optimal use of limited resources.



For relevant High-Cost drugs, forms are completed by clinicians to assure that eligibility is fulfilled in line with locally agreed routine commissioning criteria. This process is not managed by the EBI/IFR team and is dealt with by the Pharmacy and Medicines Optimisation Team (PMOT).

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 of patients a business case should be submitted for consideration of a service development (*see section 5.5*).

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 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 Standard Operating Procedures (SOP) which includes the structure and function of the EBI and IFR Team, Screening Group 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 assurance 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

Area Prescribing Committee (APC) - HWE APC is the strategic local decision-making group with responsibility to promote rational, evidence-based, high quality, safe and cost-effective medicines use and optimisation across Hertfordshire and West Essex ICS.

The HWE APC is part of a system-wide approach to supporting evidence-based investment, and disinvestment, in line with the strategic priorities of the Integrated Care System and Integrated Care Board. The HWE APC provides a forum for local stakeholders to consider and make recommendations in ways that are robust, transparent, consistent and take account of regional and national recommendations using an explicit ethical framework and decision-making criteria. HWE APC prescribing recommendations, based on evidence reviews and local priorities, support appropriate clinical decision making. These recommendations set out whether a drug treatment is routinely commissioned and, if so, what criteria should be met.

Clinical Policies Group (CPG) - HWE ICB CPG ensures clinical policies support the delivery of evidence-based, high-value, safe, equitable, cost-effective, and affordable care, in line with Integrated Care System (ICS) strategic priorities and annual planning. CPG produces and maintains a set of Evidence Based Interventions (EBI) policies which describe procedures that are not routinely commissioned or are only routinely commissioned when certain clinical criteria (or thresholds) are met.

Drugs - IFR cases for drugs covered by this policy are High-Cost drugs (and devices that are the responsibility of HWE APC), excluded from national tariff/NHS payment scheme for which the ICB is the responsible commissioner and other drugs/devices considered by, and that fall under the remit of HWE APC and assigned locally as an excluded treatment.

EBI and IFR Team – This refers to the team which maintains overall responsibility for the management and processing of prior approval and IFR funding applications (including IFRs for drugs) received for patients registered with a GP in Hertfordshire and West Essex.

Evidence Based Interventions (EBI) – Procedures that are either subject to local EBI policies or are included in the national EBI programme.

Individual Funding Requests (IFR) – IFRs include both Exceptional and Individual Cases. The ICB will only provide funding in response to an IFR, if it is satisfied that the case meets the following criteria:



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

An exceptional case - Where the ICB is responsible for commissioning the service/treatment, there is a local or national EBI policy or HWE APC guideline, pathway or recommendation, 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, but the patient does not meet the criteria **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.

Or

An individual case – Where there is no relevant locally commissioned service, local or national EBI policy, HWE APC guideline, pathway or recommendation, NICE Technology Appraisal (TA) guidance or Highly Specialised Technology (HST) Appraisal guidance and/or other relevant mandatory/statutory guidance in place for the management of the patient's condition or combination of conditions, **AND** the patient's clinical presentation is so unusual that they could not be considered to be part of a defined group of patients in the same or similar clinical circumstances for whom a service development could be undertaken.

AND in both cases, there is a basis for considering that the requested intervention is likely to be clinically effective for the patient **AND** a good use of NHS resources.

IFR Panel – have been authorised by HWE ICB to take decisions on its behalf on IFRs, including both individual and exceptional cases and can approve funding outside of policy on individual or exceptional grounds in line with this IFR policy, the IFR Standard Operating Procedures and the IFR Screening Group and Panel terms of reference.

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.

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 used 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. A list 3 proposal was published by AoMRC in Jan 2022 and a final list 3 document was published in May 2023.



Not Normally Commissioned – Those procedures and treatments 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 and treatments can be made to the EBI and IFR Team but should only be made where the patient demonstrates true clinical exceptionalality (*see below and section 5.7 for definitions of exceptionalality*).

Patient Groups - A small defined group of patients in the same or similar clinical circumstances. HWE ICB IFR team consider there to be a patient group when there are likely to be other patients in the local HWE area in the same or similar clinical condition.

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.

Screening Group - 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 exceptionalality of their patient compared with other patients with the condition prior to progressing it to the IFR Panel. The Screening Group also ensures that all relevant information is sought ahead of panel. This applies to new requests and appeals for reconsideration of a declined request. The Screening Group will make decisions in line with this IFR policy, the Standard Operating Procedures, and the Screening Group terms of reference.

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.

Treatments - The term ‘treatment’ used throughout this document includes all interventions, investigations, drugs, and devices provided under medical supervision.

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 NHS healthcare professional applying appropriately within their scope of expertise. For High-Cost Drug related IFRs, the application must come from the NHS Consultant or Specialist Team responsible for their care.



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 *section 5.6*).

Applicants are expected to submit a full and complete application form and all necessary supporting evidence. Drug requests must be made using the Individual Case Requests form. 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 line with the timelines specified in the Service Operational Procedures to avoid delays in patient care.

4.1 Roles and Responsibilities within the organisation

Administration team - Responsible for supporting all aspects of the EBI and IFR process including IFR Panel meetings, the HWE ICB Clinical Policies Group and the clinical audit process, liaising 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.

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 the EBI and IFR team 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.

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.

Clinical Fellow/ GP registrar - Medically qualified doctors who provide clinical support and advice. Support the EBI & IFR team to perform audits. They also perform systematic reviews of literature to support the EBI & IFR team and HWE ICB Clinical Policies Group.

GP Clinical Leads – Practising GPs who provide clinical support and advice to the Clinical Decisions Lead/Nurse and Clinical Fellows/GP registrars for initial triage of PA and IFR cases. Support with decision making in the Screening group and IFR Panel. Will contribute to the Clinical Policies Group and clinical pathway workstreams.



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. These will be for cases escalated by the screening group. The IFR panel 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. The panel may also be asked to review appeal cases previously considered by other external ICB IFR panels in line with their IFR process. Please see the IFR Panel Terms of Reference for further details.

Pharmaceutical Advisor - Provides specialist pharmaceutical support and advice concerning drug IFR cases to the IFR team, screening group meetings and IFR Panel in line with the SOP. Provides specialist input on IFR drug cases including efficacy, safety, clinical and cost effectiveness.

Screening Group – The screening group includes the Clinical Decisions Lead/Nurse or Clinical Fellow, 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. 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.

Public Health Consultant/Associate Medical Director - Provides clinical support and advice to the EBI & IFR team, screening group meetings and IFR Panel. Their role is to give public health advice in relation to clinical appropriateness, clinical 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/Associate Medical Directors will interface with the HWE ICB Clinical Policies Group and Hertfordshire and West Essex Area Prescribing Committee

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.



5.1 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). The Screening group/Panel will confirm where indicated the timescales and clinical information required for review to confirm efficacy, safety, and tolerance to treatment. Where funding for treatment is approved, treatment must commence within 12 months (usually within 6months) of the date of approval. Clinicians will need to submit a new IFR application if treatments are not started within this time limit.

5.2 Decisions Inherited from Other Commissioners e.g., patients who move.

Occasionally patients move into the area and become the responsibility of the ICB (by registering with a GP in Hertfordshire or West Essex) when a package of care or treatment option has already been approved by the ICB that was previously responsible for the patient's care. The ICB's policy is that, subject to resource constraints, it will normally agree to continue the treatment providing the care pathway has been initiated by a responsible NHS clinician and the requested treatment remains clinically appropriate and effective. The ICB retains the right to ask for a review of treatment and confirmation of ongoing benefit to support ongoing funding.

5.3 Personal Health Budgets

IFR does not routinely fund equipment, 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. IFRs should only be submitted for patients with an exceptional healthcare need where it can be demonstrated that the criteria of this IFR policy are met.

5.4 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.

5.5 Business Cases 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 locally 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. Applicants are advised to liaise with their Trust Medical Director or Chief Pharmacist to develop a business case which should be submitted via usual agreed processes e.g., commissioning managers or for drug related submissions, via the Area Prescribing Committee and not through IFR. The patient group must wait until a policy/APC guidance/service development is approved. However, 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.

5.6 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 *section 5.7.5*).

The IFR process is clinician led and all applications must be made by an NHS clinician. Deliberations at the Screening group and IFR Panel will be based on evidence of individual clinical exceptionalism and will not consider issues relating to social or personal circumstances.

Due to the risk of introducing unconscious bias and inequality on decision making, it is not appropriate for patients to attend the Screening Group or the IFR Panel and HWE ICB are not legally bound to invite them. However, patients can submit a supporting statement. 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 5.7.4*). 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/>

5.7 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 exceptionalism 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/recommendation is in place in relation to a treatment, HWE ICB will have been aware when making that policy/recommendation 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.

Arguments for clinical exceptionalism 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 (2023) as follows.

5.7.1 Clinical exceptionalism: 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 exceptionalism. Many treatments have side effects or contraindications, and thus intolerance or contraindication of a treatment does not in itself, usually indicate exceptionalism.

So, to support an IFR on the basis of failure to respond to standard care, the IFR screening group / 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.

5.7.2 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.

5.7.3 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.

5.7.4 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.

5.7.5 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 must 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.

5.8 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 screening group / 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.

5.9 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 screening group/Panel 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.

5.10 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 (2023) section on experimental, uncertain, and unproven treatments when considering such requests.

5.11 Funding for cases following a clinical trial.

Apart from the most exceptional cases, HWE ICB does not anticipate that it will agree a request under this IFR policy to fund patients at the end of a clinical trial. This is because arrangements to continue treatments from which patients have benefited during a trial should be agreed with the sponsor of the research at the outset of the trial and information should have been given to patients as part of the process of patients signing up to participate in the trial. Even if this is not the case, patients coming out of a clinical trial will almost inevitably represent a group of patients for whom a policy should be developed under the Service Development policy as there will be a number of patients in broadly the same clinical circumstances. In this instance it is very unlikely that the patient will be able to show clinical exceptionality within this policy.



5.12 Mental Health Funding Requests

In Hertfordshire the ICB commissions mental health services for adults and children from Hertfordshire Partnership Foundation NHS Trust (HPFT), Hertfordshire Community Trust (HCT), and other providers such as some voluntary sector.

Hertfordshire Adults - Most adult mental health services in Hertfordshire are available through contracts held by the Integrated Health and Care Commissioning Team (IHCCT) and are accessed through referral to HPFT. The HWE ICB IFR team does not process requests for adult mental health services which fall outside of these contracts. Requests are sent by clinicians securely to a mental health clinical lead at lhctt.quality@nhs.net for consideration of individual funding. On occasion, 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 HWE ICB IFR panel. The IFR panel will make a funding decision and/or provide advice in line with the IFR policy, SOP and IFR panel terms of reference. IHCCT remain responsible for the administration process of the case in question and the dissemination of the outcome.

Hertfordshire Children & Young People - Children and Young Peoples Mental Health Services (CYPMHS) in Hertfordshire are available through various contracts held by the Integrated Health and Care Commissioning Team (IHCCT) and are accessed through various referral and drop in routes. The Providers of such support are vast and come from providers such as HPFT, HCT, counselling providers and voluntary community social enterprise (VCSE) providers. These provisions range from traditional therapeutic support to digital mental health and wellbeing provision. When someone's needs fall outside of the offer within Hertfordshire CYPMHS then a request for Tertiary Services may be completed. Traditionally these requests would be sent to the Clinical Commissioner in IHCCT for review and an agreement decision via camhs.hertfordshire@nhs.net. Alternatively, where a tertiary provider falls under the low volume activity (LVA) route clinicians may be able to make a provider-to-provider referral.

Requests for consideration of individual funding outside contracted services should be submitted to the HWE ICB IFR team where evidence can demonstrate that the patient is clinically exceptional, and the requested intervention/treatment is likely to be clinically safe, effective and a good use of NHS Resources. All applications will be reviewed for consideration of individual funding in line with this HWE ICB IFR policy and will be presented to the HWE ICB IFR panel where appropriate.

West Essex Adults - West Essex Mental Health and Learning Disabilities team commission on behalf of the west Essex population for adults (18 years plus) including Secondary Mental Health services which are provided by Essex Partnership University NHS Trust (EPUT). Requests for



consideration of individual funding outside contracted services should be submitted to the HWE ICB IFR team where evidence can demonstrate that the patient is clinically exceptional, and the requested intervention/treatment is likely to be clinically safe, effective and a good use of NHS Resources. All applications will be reviewed for consideration of individual funding in line with the HWE ICB IFR policy and will be presented to the HWE ICB IFR panel where appropriate.

West Essex Children & Young People - West Essex community Child and Adolescent Mental Health Services (CAMHS) for children and young people are delivered by North East London NHS Foundation Trust (NELFT) and commissioned as part of the Southend, Essex & Thurrock (SET) CAMHS Commissioning Collaborative. The age range covered is up to the 18th birthday; the provider will work in partnership with education settings and local authorities to ensure age-appropriate services for young people with special educational needs (SEN). Individual funding requests for a child or young person's mental health service which fall outside of the contracted community SET CAMHS service provision should be submitted to the Essex wide Individual Placements Team hosted by North East Essex CCG via neeccg.ipreferrals@nhs.net

6. Monitoring compliance

This policy will be monitored by the EBI and IFR team and IFR Panel as it is applied to daily practice. Any issues will be raised to the Clinical Decisions Lead or Associate Medical Director who are 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 PA 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 the Screening Group and IFR Panel 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 should engage in peer review and feedback processes for learning opportunities and to ensure fair and consistent decision making. All members of HWE ICB staff must be up to date with HWE ICB mandatory training.

8. Associated documentation

IFR Screening Group and Panel members are recommended to read.

- Herts & West Essex Area Prescribing Committee Ethical 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 (2023)
<https://www.england.nhs.uk/wp-content/uploads/2017/11/B2086-commissioning-policy-individual-funding-requests-v3.pdf>
3. Equality Act (2010) <https://www.legislation.gov.uk/ukpga/2010/15/contents>
4. Hertfordshire and West Essex Integrated Care System: Draft Prioritisation Framework and Agreed Principles for completion of the Prioritisation Framework
5. Medicines for Human Use (Clinical Trials) Regulations 2004.
<https://www.legislation.gov.uk/uksi/2004/1031/contents/made>
6. 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/>
7. Academy of Medical Royal Colleges. Evidence-based Interventions
<https://www.aomrc.org.uk/ebi/>



Appendix 1 – Glossary of abbreviations

Abbreviation	Meaning
AoMRC	Academy of Medical Royal Collages
CAMHS	Child and Adolescent Mental Health Service
CCG	Clinical Commissioning Group
CYPMHS	Children and Young Peoples Mental Health Services
EBI	Evidence Based Interventions
ENH	East and North Hertfordshire
EPUT	Essex Partnership University NHS Trust
GP	General Practice / Practitioner
HCT	Hertfordshire Community Trust
HMMC	Hertfordshire Medicines Management Committee
HPFT	Hertfordshire Partnership Foundation Trust
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
NELFT	North East London NHS Foundation Trust
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
SEN	Special Educational Needs
SET	Southend, Essex & Thurrock
SOP	Standard Operating Procedures
TOR	Terms of reference
VCSE	Voluntary community social enterprises.
WE	West Essex



Appendix 2. Equality Impact Assessment and Health Inequality Impact Assessment (EqIA)

Equality Analysis

Title of policy, service, proposal etc being assessed:

Individual Funding Requests and Prior Approval policy

What are the intended outcomes of this work? Include outline of objectives and function aims.

Ultimately to protect NHS resources and uphold commissioning arrangements while ensuring safe, clinically and cost effective, evidence-based care is given to patients fairly and at the right time in their care pathways.

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 NHS England IFR policy and process.

Clarify and publish under what circumstances funding will be approved or declined in line with commissioning contracts and agreements.

Provide a clear, criteria and process for applicants and members of the IFR team and IFR Panel to apply fairly and consistently to all funding requests.

How will these outcomes be achieved? What is it that will actually be done? What is it that the proposal will stop, start or change?

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? e.g., staff, patients, service users, partner organisations etc. If you believe that there is no likely impact on people explain how you've reached that decision and send the form to the equality and diversity manager for agreement and sign off

Patients

GPs

Clinicians and their supporting teams in ISPs, secondary care acute providers, contracted tertiary providers, community providers.

ICB Clinical Decision Makers and IFR panel team.



Evidence

Impact Assessment Not Required There may be occasions the papers presented do not require a decision and/or will have no impact (positive or negative) on people from the equality and health inequality groups, for example papers presented for information or for assurance. Where you can show that this is the case use this box to explain why. You will not need to complete the rest of the template. The template will still need to be sent to Paul Curry who will, if it is the case, confirm that no equality impact assessment is required.

Impact Assessment Required What evidence have you considered?

Against each of the protected characteristics below list the main sources of data, research and other sources of evidence (including full references) reviewed to determine impact on each equality group.

If you are submitting no evidence against a protected characteristic, please explain why.

If there are gaps in evidence, please state how (and when) you will gather evidence and review the equality impact assessment in the Next Steps section of this document.

Evidence for all groups could include population data and service usage data,

Age Consider and detail age related evidence. This can include safeguarding, consent and welfare issues.

The IFR policy applies to patients of all ages and does not discriminate against any age group.

IFR decisions are considered alongside the relevant evidence-based intervention (EBI) policy, Area prescribing committee (APC) guideline, or other national policy or guidance which will specify the relevant age groups who may or may not be funded.

Disability Detail and consider disability related evidence. This can include attitudinal, physical and social barriers as well as mental health/ learning disabilities.

This policy will be applied equally, irrespective of disability. This group of patients may require additional support from clinicians or patient advocates to have the processes within the policy explained. A plain text or large print version can be made available on request.

Gender reassignment (including transgender) Detail and consider evidence on transgender people. This can include issues such as privacy of data and harassment.

This policy will be applied equally, irrespective of cis/trans-gender status.

Marriage and civil partnership Detail and consider evidence on marriage and civil partnership. This can include working arrangements, part-time working, caring responsibilities.

No impact expected. This policy will be applied equally, irrespective of marital/civil partnership status.

Pregnancy and maternity Detail and consider evidence on pregnancy and maternity. This can include working arrangements, part-time working, caring responsibilities.

This policy will be applied equally, no impact expected on pregnancy and maternity

Race Detail and consider race related evidence. This can include information on difference ethnic groups, Roma gypsies, Irish Travellers, nationalities, cultures, and language barriers.

This policy will be applied equally, irrespective of race.



Religion or belief Detail and consider evidence on people with different religions, beliefs or no belief. This can include consent and end of life issues.

No impact expected. This policy will be applied equally, irrespective of religion.

Sex Detail and consider evidence on men and women. This could include access to services and employment.

This policy will be applied equally, irrespective of sex.

Sexual orientation Detail and consider evidence on heterosexual people as well as lesbian, gay and bisexual people. This could include access to services and employment, attitudinal and social barriers.

No impact expected. This policy will be applied equally, irrespective of sexual orientation.

Carers Detail and consider evidence on part-time working, shift-patterns, general caring responsibilities.

No impact expected.

Other identified groups Detail and consider evidence on groups experiencing disadvantage and barriers to access and outcomes. This can include different socio-economic groups, geographical area inequality, income, resident status (migrants, asylum seekers).

The EBI and IFR team can only process applications for patients who are registered with a GP in Hertfordshire and West Essex. 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:

This is not a new process, policy update only.

Summary of Analysis

Considering the evidence and engagement activity you listed above, please summarise the impact of your work. Consider whether the evidence shows potential for differential impacts, if so state whether adverse or positive and for which groups and/or individuals. How you will mitigate any negative impacts? How you will include certain protected groups in services or expand their participation in public life?



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. This is the part of the Public Sector Equality Duty (see page 2).

Eliminate discrimination, harassment and victimisation

The proposed policy provides clear and transparent criteria for IFR and Prior Approval decision making. This will ensure consistent decision making by clinicians and commissioners. It will also support patients in understanding what is and is not funded locally on the NHS. Together, this will reduce the risk of patients being treated unequally due to discrimination.

Advance equality of opportunity

As above.

Promote good relations between groups

This policy demonstrates that HWE ICB are continually committed to reviewing and updating policies with the consideration of equalities and inclusion for all groups

Next Steps

Please give an outline of what you are going to do, based on the gaps, challenges and opportunities you have identified in the summary of analysis section. This is your action plan and should be SMART.

The policy will be presented to the ICB Executive Team for ratification. Once approved it will be circulated to all contracted providers with a 30 day contractual change notice for dissemination. The policy will then be published and active on the HWE ICB Clinical guidance website.

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.

This EQIA will be shared with the commissioning committee and stored within the policy review folder for future reviews



Health Inequalities Analysis

Evidence

1. What evidence have you considered to determine what health inequalities exist in relation to your work? List the main sources of data, research and other sources of evidence (including full references) reviewed to determine impact on each health inequality group. If there are gaps in evidence, state what you will do to mitigate them.

1. Reviewing funding applications within the ICB.
2. Researching local and national demographics.
3. Considering national guidance (some of which has had EqlAs undertaken at a national level)

Impact

2. What is the potential impact of your work on health inequalities? Can you demonstrate through evidenced based consideration how the health outcomes, experience and access to health care services differ across the population group and in different geographical locations that your work applies to?

A reduction in health inequalities for groups with protected characteristics. Intention is to work with business intelligence colleagues to analyse activity and what impact that has on local health inequalities.

3. How can you make sure that your work has the best chance of reducing health inequalities?

Regular policy reviews and researching local and national policies, guidance and statistics in relation to the relevant inequity identified.

Monitor and Evaluation

4. How will you monitor and evaluate the effect of your work on health inequalities?

Intention is to work with business intelligence colleagues to analyse activity and what impact that has on local health inequalities.

For your records

Name of person(s) who carried out these analyses: Jo Oliver

Date analyses were completed: 19/01/2024

Equality and Diversity Lead Sign off – Paul Curry

An equality impact assessment has been completed and when considering equity and equality and, considering the requirement to show a proportionate means of achieving a legitimate aim, it is likely that decision makers will have sufficient information to be able to show Due Regard, as required by the Equality Act 2010. Paul Curry, Equality and Diversity Lead, 30 January 2024



