

Exceptional Cases and Individual Funding Request (IFR) Policy

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1. Introduction

Central East Integrated Care Board (CE ICB) is driven by one question “What best serves our population?” This principle underpins everything we do. The NHS exists to serve the needs of all its patients, but NHS resources must be targeted towards clinically appropriate interventions to ensure the right patients receive the right care, at the right time, in the right place. Central East 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 sets out the principles, processes and responsibilities in relation to Exceptional Cases and Individual Funding Requests (IFRs) and how requests for treatment that fall outside of existing policies and service agreements will be considered.

This policy is supplementary to all Central East ICB Clinical Policies produced by the Central East ICB Clinical Policies Group, and guidelines, pathways, and recommendations produced by the Area Prescribing Committee (APC). These documents are approved by the Central East ICB Utilisation Management & Quality Improvement Committee. They reflect local priorities, and aim to:

- Ensure optimal clinical effectiveness and appropriateness in a patient's clinical pathway.
- 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 the clinical policies, guidelines, pathways and recommendations is paramount for effective and equitable use of NHS resources. 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. This ensures the fair allocation of resources for its population in line with the NHS Constitution (2015).

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 Central East ICB, on behalf of a patient, to approve a treatment which would not usually be provided. In the vast majority of cases, there is local or national policy/guidance/position, and if a clinician believes their patient is an exception to the rule, these are called Exceptional Cases. Where there is no policy/guidance/position they are called Individual Cases. Both are managed through the Individual Funding Requests (IFR) process and will hereby be referred to as IFRs (See section 4.1).

Not all treatments can be provided by the NHS and the decision to provide one treatment which has not been budgeted for directly reduces the resources available for other treatments and services. There is not an allocated separate budget to meet the costs of providing treatments agreed through the IFR process. The IFR panel has delegated authority to approve funding outside of what is agreed within commissioning contracts. Therefore, very careful consideration is required before a decision is taken which can justify funding a treatment for an individual that is not usually available for others and not considered to be a local healthcare priority. The fact that the ICB is not funding a healthcare need due to resource constraints does not indicate that the ICB is breaching its statutory obligations.

Where an outstanding healthcare need is identified which can be applied to a group of patients (a cohort) who could derive equal benefit from the intervention, a business case should be submitted for consideration of a service development (see section 4.6).

The IFR Policy and process ensures that each request is considered in a lawful, fair and transparent way. The IFR team carry out Clinical Triage and Screening of applications to determine if the IFR meets this policy criteria. If the IFR proceeds beyond this stage, the case will be heard by the Central East ICB IFR and Exceptional Cases Panel (see section 6).

1.1 Interim Process Arrangements

In April 2026, Central East Integrated Care Board became a new legal entity, superseding the Hertfordshire and West Essex ICB, Cambridgeshire and Peterborough ICB and Bedfordshire, Luton and Milton Keynes ICB. All Clinical Policies and this IFR policy have been aligned to ensure equal and fair access for all patients in the Central East ICB area. Transformation work is underway to prioritise full alignment of administrative and digital processes. During the transition period, the established processes for each legacy ICB will continue in line with their approved policies and Standard Operating Procedures. These are

- Hertfordshire and West Essex ICB - Evidence Based Interventions and Individual Funding Requests Team Standard Operating Procedures v2.1 January 2025.
- Bedfordshire, Luton and Milton Keynes ICB – IFR Policy v3 Nov 2024.
- Cambridge and Peterborough ICB - Exceptional and Individual Funding Request Policy v8 Jul 2022.

2. Equality Statement

Central East ICB is committed to meeting its duties under both: The Equality Act (2010) and The Public Sector Equality Duty (2011). 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. Central East ICB considers each individual within our population to be of equal value. We will not discriminate between individuals or groups on the basis of any protected characteristics. However, where treatments have a differential impact as a result of age, disability, sex or other characteristics of the patient, it is legitimate to take such factors into account.

3. Purpose and Scope

This policy applies to:

- All Central East ICB staff members, including Board Members of the ICB and Practice Representatives involved in the ICB's Policy making processes, whether permanent, temporary or contracted in under a contract for service (either as an individual or through a third-party supplier).
- All patients registered with a GP Practice in the Central East ICB area.

- All healthcare providers to Central East ICB's patients.

This policy covers the following:

- All IFR applications for adults and children where the ICB is the responsible commissioner.
- The principles and arrangements to consider requests which do not fall within existing ICB contracts.
- The structure and function of the ICB's IFR and Exceptional Cases Panel.

This policy does not include the specific process arrangements which are covered in the separate Standard Operating Procedures (SOP) or legacy place based IFR policies (see section 1.1).

These processes 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."*

3.1 Determining the Responsible Commissioner

In accordance with NHS England's policy, Who Pays? (July 2025) the ICB is responsible for assessing needs and commissioning health services to meet all the reasonable requirements of its patients with the exception of:

- Services commissioned directly by NHS England (e.g. high-secure psychiatric services, relevant prescribed specialised services and the majority of health services for prisoners/those detained in 'other prescribed accommodation', serving members of the armed forces and those family members who are registered with Defence Medical Services (DMS) GP practices in England etc.)
- Public Health services commissioned by Local Authorities or NHS England.
- Services provided by UK Health Security Agency (health protection) and the Office for Health Improvement and Disparities (health promotion).

NHS England has its own policies for handling requests for treatments and services on behalf of the above patients and these can be found at [NHS commissioning » Key documents](#)
Where Central East ICB IFR Service identifies that the patient is the responsibility of another Integrated Care Board, the requesting clinician will be notified.

3.2 Requests for treatment abroad

NHS England (NHSE) is responsible for receiving, processing and making determinations for overseas treatment in line with local ICB clinical policies. More information can be found at [Going abroad for medical treatment - NHS](#).

4. Content

4.1 IFR and Exceptional Cases Criteria

The ICB will only consider funding in response to an IFR, if the IFR panel 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 Central East ICB Clinical policy or APC guideline, pathway or recommendation, NICE Technology Appraisal (TA) guidance or Highly Specialised Technology (HST) Appraisal guidance or ICB position 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, Central East ICB position, clinical policy or 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 (see section 4.3) **AND** a good use of NHS resources (see section 4.5).

4.2 Clinical Exceptionality in Detail

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 IFR panel needs to be satisfied that the clinician has demonstrated that this patient's individual clinical circumstances are clearly different to those of other patients, and that because of this difference, the general policies should not be applied. Simply put, the consideration is whether it is fair to 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, Central East 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 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 considered using the NHS England IFR policy (2023) as follows.

4.2.1 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 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.

4.2.2 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.

4.2.3 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.

4.2.4 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.

4.2.5 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, Central East 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 Central East 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.

4.3 Clinical Effectiveness

This criterion is only applied where the IFR Screening Group/Panel has already concluded that the criterion of clinical exceptionality has been met.

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 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.

4.4 Clinical Effectiveness from Independently Funded or Arranged Treatment.

The clinical impact of a period of independently funded or arranged treatment is not typically considered in the Individual Funding Request (IFR) process because of the principles and policies governing NHS funding. Here are the key reasons:

- **Equality of Access:** The NHS is founded on the principle of providing equitable access to treatment for all, based on clinical need rather than ability to pay. Considering the outcomes could inadvertently favour those who can afford to pay for or benefit from independently funded care, creating inequities.
- **Precedent and Policy:** NHS policies are designed to ensure that funding decisions are based on established criteria, such as clinical effectiveness, cost-effectiveness, and evidence-based guidelines.
- **Evidence Base:** The IFR process focuses on the evidence of clinical and cost-effectiveness for the requested treatment as it applies to NHS patients in general.

- **Funding Rules:** The IFR process is intended to evaluate requests for treatments that are not routinely commissioned, based on the clinical exceptionalism of the patient. A trial of treatment does not necessarily establish exceptionalism unless there is clear evidence that the patient's clinical situation significantly differs from others in the same cohort.
- **Risk of Bias:** If a trial of treatment outcomes were taken into account, it could introduce bias in funding decisions, favouring those who have had an opportunity to demonstrate benefit through a trial. This could distort the impartiality of the NHS funding process.
- **Sustainability of NHS Resources:** NHS commissioners must consider the sustainability of resources. Making funding decisions based on independently funded treatment outcomes might lead to additional financial pressures on the NHS, as more patients could adopt this approach to influence funding decisions.

In conclusion, while the clinical impact of independently arranged treatment may be relevant to an individual patient, Central East ICB adhere to consistent, equitable, and evidence-based policies to ensure fairness and sustainability in their funding decisions.

4.5 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 exceptionalism and clinical effectiveness have been met. Against this criterion the IFR Panel balances the degree of benefit likely to be obtained for the patient from funding the treatment against cost.

Having regard to the evidence submitted and the analysis they have carried out when considering clinical exceptionalism and clinical effectiveness, the IFR Panel 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 Panel should also take into account its ability to impose conditions on any funding it agrees, for example to monitor the impact of the funded treatment. In applying this criterion, the IFR Panel will draw upon their professional and analytical skills and knowledge of the NHS system and how it works.

4.6 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 in the Central East ICB area 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 will be 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 APC 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 Utilisation Management Programme Board, Clinical Policy Group and/or Area Prescribing Committee so that they may consider introducing the proposed service development on an interim basis.

4.7 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 Central East ICB area. This general rule is in line with NHS England guidance Who Pays? (2020). The IFR 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.

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

Occasionally patients move into the area and become the responsibility of Central East ICB (by registering with a GP in this area) 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 clinical review of treatment and confirmation of ongoing benefit to support ongoing funding.

4.9 One-Off Referrals to Non-Contracted Providers

When an IFR relates to treatment to be provided by a non-contracted Provider including independent sector Providers not routinely commissioned by the ICB and all the criteria for funding are met, the ICB will require assurance of the quality and safety of the service Provider from the requesting clinician before the request can be approved.

4.10 Personal Health Budgets & Equipment

The IFR service does not routinely fund equipment or placements in long term care. Personal Health Budgets and voucher schemes may be available through other pathways such as All Age Continuing Care, Complex Care, Section 117 or Personal Wheelchair Budgets (PWB). Some patients may be offered a trial of equipment within NHS services which results in positive outcomes and demonstrable benefit. However, this alone does not entitle patients to Individual Funding. As there will be several patients in broadly the same clinical circumstances, a business case should be developed. Equipment should either be provided routinely within the service contract arrangements or not provided equally to all. IFRs should only be submitted for patients where it can be demonstrated that all criteria of this IFR policy are met. Should a request for equipment be submitted, it must be clear which NHS service will 'own' the equipment, keep an asset log, arrange service and maintenance, and what arrangement would be in place to pay suppliers.

4.11 Specialised Treatments

It is important that when a patient reaches a stage in their treatment pathway that requires a specialised intervention, the patient should be referred to an officially designated, accredited centre (usually commissioned by NHSE) to ensure a high quality of care. Central East ICB will not support specialised treatment at undesignated centers not commissioned to undertake specialised activity.

4.12 Experimental Treatments and Clinical Trials

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.

The 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 IFR team will apply the NHS England IFR policy (2023) section on experimental, uncertain, and unproven treatments when considering such requests.

4.13 Funding for Cases Following a Clinical Trial.

Central East 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 several 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. Definitions

The term 'treatment' used throughout this document includes all interventions, surgery, drugs and devices provided under medical supervision

Business Case - A business case is a structured proposal to the ICB that sets out the justification for funding a treatment or service, demonstrating clinical effectiveness, cost-effectiveness and alignment with ICB priorities. It should provide evidence of the outstanding healthcare need, options considered, expected outcomes and financial implications as well as identify risks and detail how they will be managed. The purpose of a business case is to support transparent, equitable and accountable decision-making within the Integrated Care Board and to support transparent and equitable decision-making (see section 4.6).

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

Utilisation Management - Utilisation Management refers to the process of ensuring that healthcare resources are used effectively, appropriately and in a way that delivers the best possible outcomes for patients, improving experience, value for money and delivering the ICB's statutory responsibilities. The IFR and Clinical Policy functions sit within the Utilisation Management directorate in the ICB.

Individual Funding Requests (IFRs) and Exceptional Case Requests – These are requests to the ICB to fund healthcare for an individual who falls outside the range of services and treatments that the ICB has agreed to routinely commission. IFRs include both Exceptional and Individual Cases. The ICB will only provide funding if the IFR panel is satisfied that the case meets the IFR criteria (see section 4.1).

Clinical Policies – Central East ICB clinical policies are 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.

The National Institute for Health and Care Excellence (NICE) provides national guidance and advice to improve health and social care. NICE Technology Appraisals ((TA) approving drugs and technologies for funding within the NHS) need to be implemented within the allocated time frame of the Appraisal being published. The ICB will seek to ensure implementation of NICE TA's as soon as possible within the statutory requirement period as laid out in the individual TA. The ICB recognise that delays may occur where significant service change and/or development are required as part of the implementation

Not Normally Funded / 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. Applications for these procedures and treatments can be made to the IFR Team but should only be made where the patient demonstrates true clinical exceptionalality by definition of this policy.

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

Prior Approval (PA) - Is a process in which clinicians demonstrate, by application to the IFR Team, how a patient meets the criteria set out within the relevant clinical 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 but only for patients who meet the defined criteria. Prior approval can be applied to or removed from any criteria-based policy and is considered on a patient-by-patient basis by the IFR team.

Threshold Approvals – Those procedures which are routinely commissioned by Central East 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. 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.

6. Roles and Responsibilities

This policy applies to all Central East ICB staff members, whether permanent, temporary or contracted-in (either as an individual or through a third-party supplier). The roles and responsibilities are listed below by hierarchy of accountability.

The ICB's Chief Executive Officer has overriding accountability for the actions of the IFR Service and the IFR and Exceptional Cases Panel.

The Central East ICB Utilisation Management & Quality Improvement Committee has delegated the responsibility of approving the IFR Policy and Clinical Policies

The Executive Clinical Director for Utilisation Management is responsible for the overall management of the IFR Service and the processes that deliver the IFR Policy ensuring that quality and consistency is applied.

IFR & Exceptional Cases Panel - Responsible for ensuring the cases it receives are considered in a fair and transparent way, with decisions based on this IFR policy, available published evidence of clinical effectiveness and likely value for money relating to the proposed treatment. The IFR panel has delegated authority from Central East ICB to make decisions in respect of funding for individual and exceptional cases and can approve funding outside of clinical policy and service contracts. The Panel acts independently and consists of a range of doctors, public health experts, pharmacists and relevant ICB Leads that have not been involved in the patient's care. The IFR panel will report any significant issues and risks arising to the Central East ICB Utilisation Management & Quality Improvement Committee / Utilisation management Programme Board or any issues relating to clinical policy or prescribing guidelines to the Clinical Policies Group or APC. The IFR 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 (Appendix 2 for further details).

Area Prescribing Committee (APC) for Central East ICB – 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 the Central East ICB area.

The 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 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.

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) – The Central East 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 clinical policies which describe procedures that are not routinely commissioned or are only routinely commissioned when certain clinical criteria (or thresholds) are met.

Public Health Consultant / Associate Clinical Director - Provides clinical support and advice to the 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 treatment. They assess the quality and applicability of the presenting evidence, 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 Central East ICB Clinical Policies Group and Area Prescribing Committee.

Senior / Lead Pharmaceutical Advisors - Provide specialist pharmaceutical support and advice concerning drug IFR cases including efficacy, safety, clinical and cost effectiveness to the IFR team, screening group meetings and IFR Panel.

GP Advisors / Clinical Leads – Practicing GPs who may provide clinical support and advice to the IFR Team during clinical triage, screening IFR Panel. Will contribute to the Clinical Policies Group and clinical pathway workstreams.

IFR Screening Group – The screening group includes the Senior Manager or Manager for Prior Approval and Exceptional Cases, Associate Director/Public Health Consultant 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. This applies to new requests and appeals for reconsideration of a declined request.

The screening group will report any significant issues and risks arising to the Central East ICB Utilisation Management & Quality Improvement Committee or any issues relating to clinical policy or prescribing guidelines to the Clinical Policies Group or APC. The Screening Group will make decisions in line with this IFR policy, the Standard Operating Procedures, and the Screening Group terms of reference.

Clinical Policies and Exceptional Cases Team – Lead by a Senior Manager for Clinical Policies, Audit and Effectiveness and a Senior Manager for Prior Approval and Exceptional Cases and supported by managers, officers and senior administrative assistants this team is collectively responsible for the day to day processing of Prior Approval and IFR applications and communicating with the applicants. Ensuring that clinical decisions are evidence-based, legally robust, and aligned with this policy and local/national clinical guidance and policies, facilitating the IFR Panel and Clinical Policies Group and representing the team in these groups. Lead on the development, implementation, and oversight of clinical commissioning policies and the clinical audit and effectiveness process. Report activity and escalate issues or concerns to the Associate Director or IFR Panel or Clinical Policies Group as appropriate. Review processes and implement changes to enhance the team's efficiency and effectiveness.

Applicants - Applications must be made by appropriate secondary/tertiary care specialist NHS clinicians who have in depth knowledge of the patient clinical picture and proposed treatment. This should be an NHS Consultant or other highly specialist 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.

Given the grounds for clinical exceptionality and the complexity of such requests we would not expect IFR applications to be made by GPs. It is for the same reason that patients cannot apply for their own funding and only an appropriate NHS specialist clinician can apply on the patient's behalf if, in their professional opinion, it is appropriate to do so.

Applicants are expected to submit a full and complete IFR application form and all necessary supporting evidence. Should the 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 Standard Operating Procedures to avoid delays in patient care. Should a clinician believe that a delay in any definitive funding decision may put their patient's life at risk, they should proceed to treat the patient, but this will be at their own organisation's financial risk and funding may not be provided.

Patients - The IFR process is clinician-led, and all applications must be made by an NHS clinician. Due to the risk of introducing unconscious bias and inequality in decision making, it is not appropriate for patients to submit applications or attend the IFR Panel and Central East ICB is 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. 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/>

7. Appeals

Clinicians can appeal against the decision of the IFR panel on the following grounds.

7.1 Reconsideration Requests

If a requesting clinician believes they have significant new clinical evidence that they did not provide in their first submission, which they consider may have made a difference to the decision made if it had been available to the IFR Panel, then the clinician can submit the new clinical evidence and request reconsideration of the decision. The request will be reviewed through the triage and screening process to identify whether it discloses relevant and significant material or information which was not originally put before the IFR Panel. If the new information is considered to be material, the case will be presented at the next appropriate IFR Panel. If there is no additional information, the case will not be re-presented to the IFR Panel for further consideration and the IFR team will write back to the referring clinician explaining this and uphold the IFR Panel decision.

7.2 Process Reviews

The requesting clinician may make a request to Central East ICB for a process review of an IFR panel decision if they believe due process has not been followed. Such requests must be lodged in writing to the IFR Team within 30 working days of the date of the letter setting out the IFR Panel decision. The requesting clinician is responsible for ensuring that all relevant information to support the appeal is provided at the outset and set out the grounds on which the Central East IFR Panel decision is being challenged. A review can only be requested on the grounds set out below.

The process will be reviewed by another ICB's IFR Panel outside of the Central East ICB area. All members of the External IFR Process Review Panel should have had no prior involvement in the case. The External IFR Process Review Panel shall consider all the papers which were put before the Central East IFR Panel. There will be no representation at the External IFR Process Review meeting from the Central East ICB IFR Panel or the requesting clinician and / or the patient / patient representative. The External IFR Process Review Panel will not consider new information (i.e., that was not put before the Central East IFR Panel, including on any reconsideration). If there is significant new information, not previously considered by the Central East ICB IFR Panel, it can only be referred and considered as set out in the 'Reconsideration Requests' in section 7.1. In reaching its decision the External IFR Process Review Panel should apply the same approach and tests as set out in the Central East ICB IFR policy.

The review will consider whether the decision reached by the IFR Panel:

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

The External IFR Process Review Panel will refer the case back to the IFR Panel with any points for reconsideration clearly detailed.

The Central East IFR team will write to the requesting clinician and the Central East IFR Panel Chair within 5 working days of receipt of the outcome of the review meeting. This is to inform them of the outcome with the reasons for the External IFR Review Panel decision. It is the responsibility of the requesting clinician to provide the outcome to their patient at this stage.

If the External IFR Review Panel determines that the Central East IFR Panel needs to reconsider the case, the Central East IFR Panel should reconvene within 10 working days of the date of decision letter from the Chair of the External IFR Process Review Panel. The Central East ICB IFR Panel will reconsider its decision and in doing so will formally address the points raised by the External IFR Process Review Panel. A finding of failure in the process of handling an IFR does not necessarily mean that the decision reached at a re-consideration by the Exceptional Cases Panel will be different. The ultimate decision will be provided to the requesting clinician who will be asked to share the decision with their patient.

7.3 Feedback relating to Clinical Policies

Any feedback related to Central East ICB Clinical Policies will be referred to the Clinical Policies Group.

8. Complaints

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

Patients can make a formal complaint to the Central East ICB Patient Experience Team at any point in the IFR process. Should there be any concern that the decision reached by the IFR Panel met any of

the criteria in section 7.2 an internal process review would be initiated, and the case will be referred back to the IFR panel for reconsideration:

The ICB has no obligation to commence or continue funding a treatment whilst any complaint, reconsideration request or process review is underway. Should a clinician believe that a delay in any definitive funding decision may put their patient's life at risk, they should proceed to treat the patient, but this will be at their own organisation's financial risk and funding may not be provided.

9. Monitoring Compliance

Monitoring and Review of the IFR policy and process will take place regularly to ensure that decision making is fair, consistent and that IFR cases are being considered at the appropriate stage of the process. The Resource Utilisation Programme Board will receive reports from the IFR Team to enable the process to be evaluated including the consistency of decision making and to consider any improvements that could be made.

The IFR team will consider any feedback received relating to the IFR policy and process to contribute to ongoing improvements.

This policy will be monitored by the IFR team and IFR Panel as it is applied to daily practice. Any issues will be raised to the Senior Manager or Associate Director who are responsible for reviewing and updating the policy. The IFR Team will participate in internal peer audit and feedback on funding decisions relating to IFRs. Any trends or themes are captured and reported in the IFR report as well as learning opportunities for clinical decision makers which are included in regular training and reflection sessions (see section 10).

10. Education and Training

All members of the Triage, 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 ICB staff must be up to date with mandatory ICB training.

11. Associated Documentation

IFR Screening Group and Panel members are recommended to read.

- 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/Publication/sandstatistics/Publications/PublicationsPolicyAndGuidance/DH_093413

12. 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. NHS England - Who Pays? (July 2025) [NHS England » Who Pays?](#)
4. Equality Act (2010) <https://www.legislation.gov.uk/ukpga/2010/15/contents>
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/>

Appendix 1 Glossary of abbreviations

Abbreviation	Meaning
APC	Area Prescribing Committee
CPG	Clinical Policies Group
GP	General Practice / Practitioner
HWE	Hertfordshire and West Essex
ICB	Integrated Care Board
ICS	Integrated Care System
IFR	Individual Funding Request
NHS	National Health Service
NHSE	National Health Service England
NICE	National Institute for Health and Care Excellence
PA	Prior Approval

PALS	Patient Advise and Liaison Service
SOP	Standard Operating Procedures
TOR	Terms of reference

Appendix 2. IFR Panel Terms of Reference

Individual Funding Request Panel

Terms of Reference

1. Purpose

The Individual Funding Request (IFR) and Exceptional Cases Panel (hereafter called the IFR panel) is authorised by Central East Integrated Care Board (CE ICB) to take decisions on its behalf relating to the approval or otherwise of IFR and Exceptional Case Requests. The purpose of the IFR panel is to consider requests for drugs or treatments which fall outside of existing service agreements, clinical policies, or locally agreed guidelines. The IFR Panel will determine whether a case for clinical exceptionality has been made and is a good use of NHS resources, and will decide whether the request should be approved, declined, or redirected in line with Standard Operating Procedures. This will ensure that all requests are considered in a fair and transparent way in line with Central East ICB's commissioning principles and outcomes are based on the available clinical evidence presented by the requesting clinicians.

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

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

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 Central East ICB IFR policy, NHS Constitution (2023), Quality Care Commission's Fundamental Standards (2022) and other statutory regulations and in accordance with the ICB commissioning principles.

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

2. Membership

The core membership of the IFR panel shall include:

- Lay member / Patient representative (Chair).
- Associate Clinical Director Evidence Based Clinical policy (Public Health Consultant/Specialist) or nominated deputy.
- Senior Manager Clinical Policies and Exceptional Cases or nominated deputy.
- Clinical Lead or nominated deputy.
- Nursing member of the Quality team.
- ICB Commissioner.
- Pharmaceutical Advisor or nominated deputy (for drug cases only).

Other non-voting subject matter experts may be co-opted in where available/required.

- Consultant Psychiatrist (for mental health cases).
- Secondary care representative or nominated deputy (where available).
- Specific commissioner in an advisory role.
- Finance team representative.

In the event of the Chair of the committee being unable to attend all or part of the meeting, a replacement will be nominated from within the Membership to deputise for that meeting.

Public Health trainees can also contribute to the work of the IFR process as part of their training. They can attend IFR Panels as non-voting members.

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

3. Quorum

The Panel will be quorate when the following members are present as a minimum. No formal business shall be transacted where a quorum is not reached.

- Lay member / Patient representative (Chair).

- Associate Clinical Director Evidence Based Clinical policy (Public Health Consultant/Specialist) or Clinical Lead or nominated deputy.
- Senior Manager Clinical Policies and Exceptional Cases or a Nursing member of the Quality team or nominated deputy.
- ICB Commissioner.
- Pharmaceutical Advisor or nominated deputy (for drug cases only).

4. Frequency of meetings and attendance.

The IFR Panel is held monthly, or more frequently if required, dependent on cases being presented. Where there are no cases for discussion the IFR Panel will not be required to meet. In the rare circumstance that a funding request requires urgent IFR Panel consideration, the Panel may convene an emergency meeting.

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

5. Authority

The IFR Panel is granted delegated authority from the Central East ICB Governing Body to make decisions in accordance with the ICB's Standing Financial Instructions (SFIs) and Scheme of Reservation and Delegation (SORD). This delegated authority reflects and upholds the financial governance arrangements in place for the Exceptional and Individual Funding Request process.

The IFR Panel is authorised to make the following conclusions:

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

The IFR Panel should make a definitive decision based on the information presented to it. Any requests for further information or clarity from the applicant should have been made during the triage and screening stage wherever possible.

If, after the panel has made a definitive decision, additional information is subsequently provided by the clinician, the case can be reconsidered and will follow the triage and screening process again before being put to the panel.

Any Panel members who have any conflicts of interest with a particular case will be excluded from the discussion of that case, will leave the meeting and rejoin for any other case discussions.

Decisions will usually be made based on consensus. Should the respective Panel members not agree to the response to a request, the IFR Panel chair has the casting vote.

The IFR Panel is not authorised to make case by case decision making for service developments where the patient represents a group of patients who may benefit from the same treatment. The IFR Team, Screening Group and Panel shall routinely screen IFRs to see whether they represent a service development. The key question used to screen out as a service development is 'are there likely to be other similar patients in Central East ICB?'

If there is evidence that the patient may be representative of other similar patients and forms a defined group, the Panel can only consider approving funding for individual cases if the patient is clinically exceptional to the patient group in question and the requested intervention has evidence of safety, efficacy, and cost effectiveness/good use of NHS resources (as per IFR policy). Otherwise, for groups of patients who do not meet the IFR policy criteria, the provider will be requested to consult with their Trust Medical Director and/or Chief Pharmacist to follow normal procedures for introducing new services/treatments via a business case as per section 4.6 of the IFR policy.

6. Roles and responsibilities

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

The Lay member/Patient Representative will chair the meeting.

The Public Health Consultant/Associate Medical Director, GP Clinical Lead or Senior Pharmaceutical Advisor will be allocated cases to present at the meeting. The case presentation will include the clinical background to the case, including review of the evidence provided by the submitting clinician.

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

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

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

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

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

- Facilitating and scheduling the IFR Panel meetings in advance.
- Preparing clinical cases and informing Panel members not less than 5 working days before the meeting.
- Agreeing the agenda with the Exceptional Cases Manager/ Senior Manager.
- Providing written notice of meetings, and anonymised case papers to the panel members, not less than 5 working days before the meeting.
- Taking the minutes and keeping a record of matters arising and issues to be reported/actioned.
- Producing an action tracker and reporting progress to the Panel.
- Producing and circulating minutes for the IFR Panel members within five working days of the meeting.
- Communicating the outcome letter to the applicant within five working days of the meeting.

The Exceptional Cases Manager or Senior Manager is responsible for drafting the outcome letter. IFR Panel members are responsible for maintaining the standards of professional practice as set by the ICB's code of conduct, the appropriate regulatory body and other national good governance practices, for example the Seven Principles of Public Life (Nolan, 1995).

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

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

7. Reporting arrangements

The IFR Panel will report any significant issues and risks arising to the Central East ICB Utilisation Management & Quality Improvement Committee or Resource Utilisation Programme Board and any issues relating to clinical policy or guidelines to the Central East ICB Clinical Policies Group or the Area Prescribing Committee.

8. Accountability

The IFR Panel is accountable to Central East ICB Utilisation Management & Quality Improvement Committee.

9. Training

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

10. Annual review of the IFR panel

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

- Review that these Terms of Reference have been complied with and whether they remain fit for purpose.

- Determine whether the planned activities for the IFR triage process, Screening Group and IFR Panel responsibilities for the previous year have been discharged sufficiently and are in line with the IFR Policy and SOP and relevant terms of reference.
- Recommend any changes and / or actions it considers necessary, in respect of the above.
- Provide the Central East ICB Utilisation Management & Quality Improvement Committee with a report as required, which details the outcome of the annual review.

11. References.

1. The Seven Principles of Public Life, Lord Nolan (1995)
<https://www.gov.uk/government/publications/the-7-principles-of-public-life>
2. The NHS Constitution of England (2023) Department of Health and Social Care.
<https://www.gov.uk/government/publications/the-nhs-constitution-for-england/the-nhsconstitution-for-england>
3. Quality Care Commission. The Fundamental Standards (2022) <https://www.cqc.org.uk/what-we-do/how-we-do-our-job/fundamental-standard>

APPENDIX 3 – Equalities Impact Assessment

Date Completed: 12/02/2026

Policy title	Central East ICB Exceptional Cases and Individual Funding Request (IFR) Policy v1.0
Description of proposed policy change	The policy consolidates three legacy IFR policies (Cambridgeshire & Peterborough, Bedfordshire Luton & Milton Keynes, and Hertfordshire & West Essex) into a single unified IFR policy for Central East ICB. It removes operational processes (held in a separate SOPs for future alignment) and harmonises definitions, criteria, governance, and decision-making principles across the new ICB footprint.
Purpose of the change	To ensure a consistent, transparent, and equitable approach to Individual Funding Requests and Exceptional Case Requests across the Central East ICB area. The unified policy aims to reduce unwarranted variation, strengthen fairness, and ensure decisions are based solely on clinical need, clinical effectiveness, and good use of NHS resources.
Population affected	All patients registered with a GP practice within Central East ICB. All NHS clinicians submitting IFR applications. Providers delivering care to Central East ICB patients. IFR Panel members, Screening Group members, and clinical advisors.
Assessment of protected characteristics	
Age	No negative impact identified. IFR decisions are based on clinical evidence and exceptionality, not age. Children and older adults may have different evidence bases or clinical presentations, but the policy allows for specialist input where required.

	Impact: Neutral.
Disability	Potential for indirect impact where disability-related comorbidities affect treatment options. The policy explicitly excludes non-clinical factors but allows clinically relevant comorbidities to be considered. Accessible communication formats may be required. Impact: Low risk / Neutral with mitigations.
Sex	No differential impact identified. Sex-specific conditions are assessed on clinical grounds only. Impact: Neutral.
Gender reassignment	No direct impact identified. Some trans patients may have limited evidence bases for certain treatments. The policy allows for specialist advice where needed. Impact: Low risk / Neutral with mitigations.
Pregnancy and maternity	No negative impact identified. Pregnancy-related clinical considerations are handled through standard clinical pathways. Urgent IFRs can be prioritised where delay would be unsafe. Impact: Neutral.
Race (including ethnicity and nationality)	No negative impact identified. Some conditions have different prevalence or genetic patterns across ethnic groups; the policy allows genotype-based exceptionality where evidence supports it. Accessible communication may be required for patients with limited English proficiency. Impact: Low risk / Neutral with mitigations.
Religion or belief	No negative impact identified. Some treatments may conflict with religious beliefs, but IFR decisions are based on clinical need; alternative treatments are considered through routine pathways. Impact: Neutral.
Sexual orientation	No differential impact identified. Impact: Neutral.
Marriage and civil partnership	No differential impact identified. Impact: Neutral.
Socio-economic considerations	
The policy explicitly excludes non-clinical and social factors from IFR decision-making to ensure fairness. This prevents inequity based on income, employment or personal circumstances. Patients from deprived backgrounds may require additional communication support, but this is addressed operationally. Impact: Neutral.	
Mitigations and safeguards	
<ul style="list-style-type: none"> • Accessible formats and interpreting services available for patient communication. • Specialist clinical input (paediatrics, public health, pharmacy) available to support equitable decision-making. • Annual monitoring of IFR outcomes to identify any unintended disparities. • Clear separation of clinical and non-clinical factors to prevent discrimination. • Appeals process available where new clinical information emerges. 	
Conclusion	
The unified IFR Policy is compliant with the Equality Act 2010 and the Public Sector Equality Duty. No protected group is disadvantaged by the policy. The policy strengthens fairness by harmonising legacy	

approaches and ensuring decisions are based solely on clinical need, clinical effectiveness, and good use of NHS resources. With the mitigations in place, the overall equality impact is assessed as low.