NHS
Greater Manchester

Greater Manchester Individual Funding Requests Operational Policy

Version 1.1 (May 2025)

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1. Introduction

The NHS is under a statutory duty 'to promote comprehensive healthcare within the resources available'. It is not an absolute obligation to provide every treatment that a patient, or group of patients, may demand.

The NHS is entitled to consider the resources available to it and the competing demands on those resources.

The precise allocation of resources and the process for prioritising the allocation of those resources is a matter of judgement. In line with the NHS Constitution, this policy aims to facilitate and support making those judgements at a named patient level by identifying those individuals who should receive care on the NHS where their request is an exception to current contracting arrangements/commissioning policies, or where the request is for an exceptional health care need.

The Greater Manchester (GM) Individual Funding Request (IFR) Service processes Individual Funding Requests. The GM IFR Service can be contacted by email: gm.eur@nhs.net or by phone: 0161 290 4901.

The Greater Manchester IFR Service website contains information on the GM IFR Service.

An Equality Impact Assessment has been carried out on this policy. For more information please email: gm.policyfeedback@nhs.net

1.1 Status

1.1.1 This policy is an operational policy.

1.2 Purpose and scope

1.2.1 Every year, the resources that the NHS in Greater Manchester receives are allocated to the services and treatments provided for patients. The NHS in Greater Manchester decides the treatments it will invest in on an annual basis through a prioritisation process so that, as far as possible, funding is shared fairly and appropriately, considering the competing demands on the NHS's budget.

1.2.2 When a new service or a change to a service is proposed, it would not be fair for that to bypass the prioritisation process and be funded without comparing it to other possibilities for investment. Because of this, NHS Greater Manchester Integrated Care's default position is that a new service will not be routinely commissioned until it has been assessed through the full-service development process.

1.2.3 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 have their treatment paid for when other patients would not. In such cases, NHS clinicians can ask the NHS in Greater Manchester on behalf of a patient, to fund a treatment which would not usually be provided by the NHS in Greater Manchester for that patient. This request is called an Individual Funding Request (IFR).

1.2.4 Funding for additional treatments outside the prioritisation process 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. It is because of this that very careful consideration is required before the decision is taken to fund a treatment for an individual that is not usually available.

1.2.5 This policy sets out the process that will be followed when considering IFR's.

1.2.6 This policy will apply to individuals eligible for NHS services where NHS Greater Manchester Integrated Care is the responsible commissioner.

AND

a) the patient's particular clinical circumstances fall outside the criteria for funding set out in that GM PLCV commissioning statement and the treating clinician believes the patient may have an exceptional healthcare need.

OR

b) NHS Greater Manchester Integrated Care has a clinical policy statement that states that the treatment is not routinely commissioned and the treating clinician believes the patient may have an exceptional healthcare need;

OR

c) the patient's medical condition has rare clinical features, which render it impossible to carry out clinical trials for the intervention in question, and the treating clinician therefore wishes to use an existing treatment on an experimental basis and they believe the patient may have an exceptional healthcare need

1.2.7 Individual Funding Requests (IFRs) applications can be made when there is a belief that the patient has an exceptional health care need:

AND

a) there is a GM PLCV commissioning statement or NICE Technology Appraisal (TA) for the patient's presenting condition which does not currently fund the treatment in question, because the available evidence does not support prioritising that treatment for population use within the available resource constraints. This is usually because the treatment falls below commonly accepted thresholds of clinical effectiveness or cost effectiveness, or a combination of both.

OR

b) the commissioner has undergone a prioritisation of competing service developments for available resources and the treatment in question is a low priority for NHS resources when compared to the other health needs of the population.

OR

c) When the commissioner has not yet considered the available evidence and so has not yet decided as to whether or not the requested treatment should be made available.

AND

There is a belief that the patient has an exceptional health care need.

1.2.8 This policy also covers those requests where the condition is extremely rare, and it is unlikely there would ever be evidence of cost effectiveness at a population level for the normal commissioning process to apply.

1.2.9 This policy does not apply to/cover:

- Requests that fall under the NHS England's commissioning responsibility;
- Requests that constitute as a service development or where there may be a gap in service;
- Requests that appear to have been submitted to remedy a patient complaint / miscommunication.
- Requests to move to a non-commissioned/private provider to avoid NHS waiting list times;
- Requests for mental health assessments or treatment;
- Requests for inpatient packages of care;
- Requests which fall outside the remit of this service where there is a separate locality arrangement in place for funding approval;
- Requests where there are likely to be a group of patients also seeking the same treatment;
- Requests for a treatment that could be provided through Continuing Healthcare or paid for from a patient's allocated personal health budget.

1.2.10 This document is particularly relevant to all providers treating patients registered with a GM General Practitioner (GP). It is equally important to all those who are involved in supporting/monitoring the provision of such care, for example, Commissioning; Finance; Contracting and Business Intelligence Teams.

1.2.11 This document is based on NHS England's Commissioning Policy: Individual Funding Request.

2. Definitions

2.1 The following terms are used in this document:

Clinically Exceptional

The patient's health problem is significantly clinically different to the cohort of apparently similar patients, and as a consequence of this, the patient is expected to benefit significantly more than the general cohort.

More information on determining clinical exceptionality can be found in section 4 of

this document.

Equality Impact Assessment (EIA)

An Equality Impact Assessment (EIA) is an evidence-based approach designed to help NHS GM ensure that it's policies, practices, events, and decision-making processes are fair and do not present barriers to participation or disadvantage any protected groups from participation.

Ethical Framework

It sets out 15 ethical principles, some of which relate to legal and statutory duties, that have to be adhered to.

Evidence Based Interventions (EBI) Programme and Guidance

The Evidence-Based Interventions (EBI) Programme is a clinical initiative led by the Academy of Medical Royal Colleges (AoMRC) in partnership with NHS England and NHS Improvement, as well as NHS Clinical Commissioners and the National Institute for Health and Care Excellence. The aim of the EBI programme is to improve the quality of care being offered to patients by reducing unnecessary interventions and preventing avoidable harm.

Evidence Review

A review of the best available evidence about what works and what doesn't work in health care in relation to a particular intervention/treatment.

Exceptional Health Care Need

An exceptional health care need is a rare or unique health problem that has a proposed solution which is known to work, provides good benefits at an acceptable risk and at an affordable cost.

GM Procedures of low clinical value (PLCV) Commissioning Statements

For the purpose of this policy, these are defined as systematically developed commissioning statements which detail when certain interventions are not routinely commissioned across GM OR are restricted, and specific criteria must be met before treatment commences.

GM Clinical Policy Development Team

Supports the development and implementation of clinical policy statements at a GM level.

GM Procedures of low clinical value PLCV Steering Group

Develops PLCV commissioning statements for the purpose of managing access to healthcare treatments that are unlikely to be clinically effective or should only be performed in specific circumstances.

Greater Manchester Medicines Management Group (GMMMG)

GMMMG and its subgroups consist of GPs, pharmacists and other key healthcare professionals. Who seek to identify and champion the appropriate use of medicines across Greater Manchester taking into account cost effectiveness, quality, equity and patient safety.

Individual Funding Request (IFR)

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 have their treatment paid for when other patients would not. In such cases, NHS clinicians can on behalf of a patient, ask NHS GM to fund a treatment which would not usually be provided by NHS GM for that patient. This request is called an Individual Funding Request (IFR).

NHS England Specialised Commissioning Policies

NHS England Specialised Services – These are specialised services that support people with a range of rare and complex conditions. Specialised services are not available in every local hospital because they have to be delivered by specialist teams of doctors, nurses and other health professionals who have the necessary skills and experience.

National Institute for Health and Care Excellence (NICE)

They provide national guidance and advice to improve health and social care.

Royal Medical Colleges

Are professional bodies with responsibility for setting standards within their field.

The National Health Service Act 2006, The Health & Social Care bill 2012 and The Health & Care Act 2022

Are Acts of Parliament which sets out the structure of the NHS in England and their duties.

Requesting Clinician

For the purposes of this policy this should be the clinician/team who have determined that an IFR should be made and not another clinician acting as messenger.

Service Development

A service development is any aspect of healthcare which the ICB has not historically agreed to fund, and which will require additional and predicable recurrent funding.

3. Consideration of Individual Funding Requests (IFRs)

3.1 Individual Funding Requests to be considered for funding should meet the following five conditions to be processed by the GM IFR service:

a.i) The clinician is making an individual request for funding for treatment in connection with a presenting medical condition for which there is a GM commissioning statement, or NICE Technology Appraisal, but the patient does not meet the criteria, and the clinician is claiming that the patient has an exceptional health care need;

OR

a.ii) The clinician is making an individual request for funding for a treatment which is not routinely commissioned and the clinician is claiming that the patient has an exceptional health care need;

AND

b) There is enough evidence to show that, for the individual patient, the proposed treatment is likely to be clinically effective;

AND

c) Applying the approach that the commissioners take to the assessments of costs for other treatments outside this policy, is the cost of the requested treatment being delivered, justified as being likely to provide a satisfactory benefit to the patient at an acceptable risk, and at an affordable cost"

AND

d) There are unlikely to be further requests on behalf of patients like the patient for whom the request is being made.

AND

e) The Greater Manchester Individual Funding Request (IFR) Panel determines that the patient has an exceptional health care need and is therefore clinically exceptional to other patients (see below).

4. Consideration of exceptionality for the health care need

4.1 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 GM IFR Panel.

4.2 'Exceptional' in IFR terms means a person to whom the general rule should not apply[1]. This implies that there is likely to be something about their clinical situation which was not considered when formulating the general rule. Very few patients have clinical circumstances which are genuinely exceptional. To justify funding for treatment for a patient which is not available to other patients, and is not part of the established care pathway, the GM 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 fund 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.

4.3 Where a 'not for routinely commissioned' GM PLCV commissioning statement is in place in relation to a treatment, the commissioners will have been aware when making that commissioning statement 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 commissioning statement. Consequently, in considering whether a request for an IFR 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 commissioning statement applies, and whether there is evidence to support this view.

4.4 Clinical exceptionality: failure to respond to standard care

4.4.1 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 commissioning statement.

4.4.2 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.

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

- If the usual treatment is only effective for a proportion of patients (even if a high proportion), this leaves a proportion of patients within the group for whom it is already known that the usual treatment is not available or is not clinically effective. The fact that this particular patient falls into that group is unlikely to be a proper ground on which to base a claim that they are exceptional as an individual.

- As regards side effects, as an example, all patients who are treated with long-term high-dose steroids will develop side-effects (typical and well-recognised) and thus developing these side effects and wishing to be treated with something else does not make the patient exceptional.

- If the usual treatment cannot be given because of a pre-existing co-morbidity 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.

4.4.4 If the proposed intervention is thought to offer a benefit to patients in these groups generally (i.e. those with more severe disease or those with common co-morbidities), the question is whether there is sufficient justification, including consideration of factors such as clinical effectiveness of the treatment in question, likely value for money, priority and affordability, for making a change to the commissioning statement that covers the patient pathway. In this way, an improvement can be made to that commissioning statement to benefit the whole subgroup of patients of which the requesting patient is potentially just one such person. This change needs to be considered as a service development and not as an IFR.

4.5 Clinical exceptionality: severity

4.5.1 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.

4.6 Clinical exceptionality: genotypes

4.6.1 When the argument for clinical exceptionality is based on the patient having a specific genotype (genetic profile), the GM IFR Service 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.

4.7 Clinical exceptionality: multiple grounds

4.7.1 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 GM IFR Service.

4.7.2 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.

4.8 Clinical Exceptionality: other non-clinical factors including mental health

4.8.1 The GM IFR 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.

4.8.2 Non-clinical factors, including mental health, have to be disregarded for this purpose in order for the GM IFR Service to be confident of dealing in a fair manner in comparable cases. If these factors were to be included in the decision-making process, the GM IFR Service would not know whether it is being fair to other patients who cannot access such treatment and whose non-clinical factors, including mental health, would be the same or similar.

4.8.3 Consideration of non-clinical factors would also be contrary to the NHS's policy of non-discrimination in the provision of medical treatment. If, for example, treatments were 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 GM IFR Service should not make.

4.8.4 Psychological factors are often referred to in support of a patient's funding request, for the purpose of the IFR process, these are considered to also be non-clinical factors and may be omitted from IFR paperwork. Clinicians are asked to bear this policy in mind and not to refer to non-clinical factors to seek to support the application for individual funding. In order to avoid prejudicing the GM IFR

process, such material will be edited out, or the GM IFR Service will return applications to clinicians for editing.

4.8.5 Photographs are not to be submitted for use in the consideration of exceptionality. Cosmetic appearance is not considered when judging exceptionality. A detailed description of any functional impairment is much more important. Any photographs received will be returned to the sender upon receipt.

5. Clinical Effectiveness

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

5.2 Clinical evidence that considers the efficacy of a particular treatment will be carefully considered by the GM IFR Service. It is the sole responsibility of the requesting clinician to provide this information to support the decision-making process. 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 requesting 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.

5.3 When considering clinical effectiveness, the GM IFR Panel will consider:

- How closely the patient matches the patient population from whom the results are derived in any study relied on by the clinician
- The plausibility of the argument that the patient will achieve the anticipated outcomes from treatment, based on the evidence supplied
- The impact of existing co-morbidities on both the claim for exceptionality and treatment outcome
- Any complications and adverse events of the treatment including toxicity and rates of relapse. The GM IFR 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.

6. Good Use of NHS Resources

6.1 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.

6.2 This criterion is only applied where the GM IFR Panel has already concluded that the criteria of an exceptional healthcare need and clinical effectiveness have been met. Against this criterion the GM 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 exceptionality and clinical effectiveness, the GM IFR Panel members 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. This reflects the fact that the only way to provide the funding for treatment under IFRs, i.e. outside GM PLCV commissioning statements which are developed through the structured prioritisation process, is to divert resources away from current services.

6.3 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.

6.4 Due to the very nature of the cases considered by the GM IFR Panel, 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.

6.5 However, the GM 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.

6.6 In applying this criterion GM IFR Panel members will draw upon their professional and analytical skills and knowledge of the NHS system and how it works.

7. Experimental and Unproven Treatments

7.1 This section outlines how the IFR criteria will be interpreted and applied where the treatment being sought is experimental or unproven.

7.2 Where the case for an exceptional healthcare need has been accepted but the treatment is experimental or unproven, there is a need to scrutinise the likelihood that the treatment will be clinically effective and consider carefully whether funding the treatment would be a good use of NHS resources. This is because it is important that decisions on clinical practice and commissioning statements are based on sound clinical evidence. To ensure the effective and equitable use of NHS funding, experimental treatments must be undertaken judiciously, responsibly and for clearly defined purposes.

When an individual case has been found to be exceptional, the treatment proposed might, by definition, be unproven, and therefore the GM IFR Panel

must carefully consider whether funding of such treatments is a good use of NHS resources as described above. However, this section of the policy applies to the categories of experimental or unproven treatment which are described below.

7.3 What is an experimental treatment

7.3.1 A treatment may be considered experimental where any of these points apply:

- The treatment is still undergoing clinical trials and/or is a drug yet to undergo a phase III clinical trial for the indication in question;
- The treatment does not have marketing approval from the relevant government body for the indication in question;
- The treatment does not conform to a usual clinical practice 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; or
- The treatment is rarely used, novel, or unknown and there is a lack of authoritative evidence of safety and efficacy.

7.4 How are IFRs for experimental treatments considered

7.4.1 The experimental basis of the treatment will become relevant when the GM IFR Panel assesses the likely clinical effectiveness of the treatment for the patient and then, primarily, when the GM IFR Panel considers the degree of confidence it has on the safety and efficacy of the treatment for the patient and whether it would be a good use of NHS resources.

7.4.2 Where evidence about the treatment is not yet available for public scrutiny, or there is limited evidence for one of the reasons set out above, the GM IFR Panel may have limited confidence in the evidence that has been presented.

7.4.3 As preliminary requirements before agreeing to fund an experimental treatment, the GM IFR Panel will need reassurance:

- That the decision to agree to an exception to the general policy on treatment for the condition is made for very clear and explicit reasons which are consistent with the NHS Greater Manchester Integrated Care priority setting principles; and
- That funding experimental treatments is done in a way that will contribute to the knowledge base.

7.4.4 The GM IFR Panel will not fund treatment in response to an IFR if it considers that it would be more appropriate for the treatment to be the subject of research trials. Primary research into novel treatments should be progressed through the usual research funding routes and will not be funded through this

IFR policy.

7.4.5 The GM IFR Panel will consider a funding request for an experimental treatment where there is either:

- Evidence from small and often heterogeneous case reports;
- Evidence solely of short-term outcomes; or
- Evidence of effectiveness in a similar condition to the clinical circumstance under consideration.

7.4.6 In assessing whether to fund treatment in these cases, the GM IFR Panel will make a decision having regard to:

- The potential benefit and risks of the treatment; and
- The biological plausibility of benefit based on other evidence; and
- An estimate of cost of the treatment and the anticipated value for money; and
- The priority of the patient's needs compared to other competing needs and unfunded developments.

7.4.7 The clinician will be expected to provide as much information as possible about the treatment, relevant research upon which the claim for biological plausibility of the treatment is based and costs, as well as clinically relevant information on the patient and factors that indicate a good response to treatment. In addition, the clinician must identify the clinical markers and clinical outcomes that will be monitored to assess treatment response.

7.4.8 The options for consideration by the GM IFR Panel in these instances are:

- Not to fund;
- Fund a trial of treatment but make on-going treatment subject to the demonstration of clinical benefit for the individual patient using criteria agreed in advance with the clinical team. This option is only available where there is a course of treatment or long-term treatment. It is not suitable for on one-off treatment such as a surgical intervention;
- In all cases, contribution to any relevant clinical database or population registry which is operating.

8. Information submitted to the Greater Manchester IFR Service

8.1 All applications must be accompanied by written support and evidence provided by the clinician treating the patient in line with the GM IFR Standard Operating Procedure (SOP).

8.2 It is the requesting clinician's responsibility to ensure that all the appropriate and required information is provided to the GM IFR Service in a timely fashion

consistent with the urgency of the request. This includes full copies of all the published papers of clinical evidence that have been cited. The clinician must provide a list of the published papers that have been submitted and indicate which points within them are relevant in respect to the IFR application and criteria. This is to ensure the GM IFR Service are clear about the points the clinician is making and the process relevant to the case. If relevant information is not submitted, decision making will be delayed because the case cannot be fairly considered without adequate evidence. In all instances the requesting clinician must state whether or not they consider there are likely to be similar patients in the same situation (in accordance with the definition set out in this policy) and, if so, how many such similar patients there are or are likely to be in the opinion of the requesting clinician in England in any given 12 month period.

8.3 As outlined previously, information that is immaterial to the decision being made will not be considered.

8.4 The GM IFR Service expects providers to have oversight of the applications submitted by their clinical staff. The GM IFR Service expects every IFR for a drug to be sanctioned by the provider's Board-level Medical Director or equivalent such as a Drug & Therapeutic Committee (D&TC) and reserves the right to return unconsidered IFRs to the provider.

8.5 Ultimately the NHS Greater Manchester IFR decision is whether NHS Greater Manchester Integrated Care will reimburse a provider for a particular treatment intervention for the individual patient. However, that decision does not itself determine whether a clinician actually undertakes that treatment.

9. Summary of the GM IFR process

The remainder of this policy summarises the key stages in the GM IFR process. Full details of the process are set out in the GM IFR Standard Operating Procedures: The Management of Individual Funding Requests.

9.1 Being the subject of an IFR is an anxious time for patients and their carers and so it is important that neither patients nor clinicians should have their expectations raised that a treatment will be funded under the IFR policy unless the GM IFR Panel could properly come to the view that the criteria under this policy are met in an individual case. A GM IFR Patient Guide has been developed which explains the IFR process.

9.2 The screening process described in this Policy is intended to be fair to all parties, including the other patients funded by the wider NHS in Greater Manchester and the GM IFR Panel, by only sending cases to a panel meeting if there is some reasonable prospect that the GM IFR Panel will accept that the criteria under this policy are met in the individual case. This means the GM IFR Panel can then apply all of its time to those cases which have a prospect of success.

9.3 Screening for Sufficient Information

9.3.1 Any IFR requests will first be screened by the GM IFR Service in accordance with the procedures set out in the GM IFR SOP to establish

whether the request falls within the commissioning responsibility of NHS Greater Manchester Integrated Care and has sufficient clinical or other necessary information for it to be properly considered.

9.3.2 The GM IFR Panel can only approve funding if a patient has an exceptional health care need and thus clinical exceptionality has been proven as outlined in this policy. It follows that the GM IFR Service should not allow an application to go forward to the GM IFR Panel unless there is information to support the contention that each of the essential criteria is met. A strong application on one part of the criteria cannot make up for an absence of proper evidence to support another of the tests that the GM IFR Panel must apply in order to make a decision that funding should be approved.

9.4 Screening for service developments

9.4.1 If, in the opinion of the GM IFR Service considering a submitted IFR in relation to a patient, 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 commissioning statement or service specification which needs to be considered by the appropriate commissioner to determine whether it will be routinely commissioned. The request will not be progressed through the IFR route from that point and will be returned to the requesting clinician.

9.5 Screening for clinical exceptionality/Exceptional Health Care Need

9.5.1 All IFRs submitted to the GM IFR Service will be considered to identify whether the patient has an exceptional healthcare need and thus presenting a potential case for clinical exceptionality. The GM IFR Service contains non-clinical and clinical staff and their experience and understanding of the information required by a GM IFR panel enables them to make these decisions. They have delegated authority from the NHS Greater Manchester Integrated Care to make these judgements and will seek additional clinical input at their discretion. If the GM IFR Service considers that there is not an arguable case for clinical exceptionality, the IFR will not proceed further through the process and will be returned to the clinician with advice.

9.5.2 An IFR will be considered as indicating an "arguable case" for clinical exceptionality if the GM IFR Service consider that there is some realistic prospect that the GM IFR Panel (properly applying this policy) would conclude that the patient has an exceptional healthcare need and is therefore considered to be clinically exceptional.

9.5.3 A case would not progress where the GM IFR Service are confident that, based on the available information, if the GM IFR Panel properly apply this policy, it would come to a conclusion that the patient does not have an exceptional healthcare need and is therefore not clinically exceptional.

9.5.4 If the GM IFR Service have any reasonable doubt about whether a case satisfies the criterion of exceptionality, it should be forwarded to the GM IFR Panel.

9.5.5 If a case is returned to the applicant by the GM IFR Service, the

explanation provided may enable the requesting clinician to submit new clinical information to augment the original argument for clinical exceptionality.

9.5.6 The GM IFR Service will only reconsider a case if new and relevant clinical information is provided.

9.5.7 The GM IFR Service can request advice, e.g. relating to a treatment pathway and lines of therapy within that, from within Greater Manchester's clinical advice structure.

9.6 Decisions on funding

9.6.1 The GM IFR Panel works on behalf of NHS Greater Manchester Integrated Care and makes decisions in respect of funding for individual cases. The GM IFR Panel will work to the published GM IFR Operating Policy and each request will be processed by following the GM IFR SOP. This will ensure that all requests are considered in a consistent, fair and transparent way, with decisions based on the available clinical evidence presented by the treating clinicians.

9.6.2 The requesting clinician is advised to set out as clearly as possible and in detail the clinical evidence and the basis on which they consider that the patient's clinical circumstances are exceptional and fulfil the criteria in this policy.

9.6.3 The clinician should not assume particular knowledge of the GM IFR Panel for the condition from which their patient is suffering or the relevant area of medical practice. This is because the GM IFR Panel will contain a range of individuals with a variety of skills and experiences. The GM IFR Panel will not necessarily include a clinician with expertise in the condition for which treatment is being sought. This is appropriate because not only is the question one of demonstrable exceptionality (resting on the differences between this patient and others with the condition) but the GM IFR Panel must consider whether it is appropriate to divert resources away from other services in order to fund the requested treatment.

9.6.4 The GM IFR Panel will make its decision based on the criteria in this policy with reference to any other GM PLCV commissioning statements or NICE mandated guidance relevant to the application or interpretation of the criteria.

9.6.5 In reaching its decision, the GM IFR Panel will consider whether there are justifiable grounds for funding the requested treatment against the criteria in this policy and if so what those grounds are.

9.6.6 The GM IFR panel in all circumstances will take into account published evidence of clinical effectiveness and likely value for money relating to the proposed treatment.

9.6.7 It is also open to the GM IFR Panel to conclude, notwithstanding the decisions taken by the GM IFR Service, that:

- The request should be properly classified as a service development. In this case the request will be refused and the GM IFR Service will direct the applicant to the appropriate commissioner to submit a service

development, if this is known;

OR

- Further information or evidence is required before the GM IFR Panel can take a decision on whether funding should be given, in which case further information will be requested through the GM IFR Service. This can be sought from the clinician, from within Greater Manchester's clinical advice structure or from other clinical advisers as considered appropriate.

9.6.8 In considering individual cases, the GM IFR Panel will take care to avoid identification bias. This term describes the effect on decision makers of being presented with the detail of an individual's life. In these circumstances, it is hard to separate from the emotion behind a decision. Decision makers are more likely to decide in favour of that individual, even when this is at the expense of others who cannot be identified as clearly (also see section on non-clinical factors, paragraphs 19-22).

9.6.9 The GM IFR Panel will also take care to avoid "rule of rescue". This is the imperative people feel to 'rescue' individuals facing avoidable death or ill health. For example, supporting the effort to prolong life where there is little prospect of improvement, or death is unavoidable or there is little published evidence to support the requested treatment option in relapsed/refractory stages of the individual's disease/condition. Where the GM IFR Panel consider that application of the rule of rescue would form the basis for treatment, funding will be declined.

9.6.10 The GM IFR Panel may consider written views expressed by the patient or the clinical team, if based on clinical factors, but will reach its own views on:

- The likely clinical outcomes for the individual patient of the proposed treatment; **and**

- The quality of the evidence presented to support the request.

9.6.11 The GM IFR Panel is entitled to approve the request contingent on the fulfilment of such conditions as it considers fit. These might include, for example, a specific outcome reporting frequency or the involvement of a specialist unit in the management of the case.

9.6.12 The GM IFR Panel is entitled but not obliged to commission its own reports from any duly qualified or experienced clinician, medical scientist or other person, concerning the evidence that the treatment is likely to be clinically effective in the case of the individual patient. Reference to nationally recognised evidence syntheses may be used where they address the specific issues under consideration.

9.6.13 The GM IFR Panel will give written reasons for its decisions to fund or not to fund a treatment in accordance with this policy.

9.6.14 The GM IFR Panel may agree a request for a patient's treatment but then reject similar requests for the same treatment for other patients, if it becomes apparent that there is a cohort of patients for which this treatment would apply.

A decision made by the GM IFR Panel is not a precedent decision that can be applied to other similar requests. (Please also see previous point 10.4.1).

9.7 Review of the decision

9.7.1 Where the GM IFR Panel has not supported funding for a requested treatment or has approved the treatment subject to conditions, the requesting clinician will be entitled to ask that the process which led to the decision of the GM IFR Panel be subject to review, if the clinician believes the decision was not taken in line with 10.7.4 (below).

9.7.2 All requests for a review must be made within 28 days of the date when the decision is communicated to the patient. The request must be supported by the requesting clinician who must explain his or her reasons for considering that the decision taken by the GM IFR Panel was either procedurally improper and/or misunderstood the medical evidence and/or was, in his or her opinion, a decision which no reasonable GM IFR panel could have reached.

9.7.3 The role of the GM IFR Review Panel is to determine whether the GM IFR Panel has followed the procedures as written in the GM IFR SOP, has properly understood and considered the evidence presented to it and has come to a reasonable decision based on the evidence.

9.7.4 The GM IFR Review Panel will consider whether the process followed by the GM IFR Panel was fair and consistent, based on whether the decision reached:

1. Was taken following a process which was consistent with the policies of the GM IFR Service;

2. Was a decision which a reasonable GM IFR Panel was entitled to reach;

3. Understood, took into account and weighed, all the relevant evidence; and

4. Did not take into account any irrelevant factors.

9.7.5 In the event that the GM IFR Review Panel considers that there was any procedural error in the GM IFR Panel's decision, the GM IFR Review Panel will consider whether there was any reasonable prospect that the GM IFR Panel could have come to a different decision had that error not been made.

9.7.6 If the GM IFR Review Panel considers that there was no reasonable prospect of the GM IFR Panel coming to a different decision, then the GM IFR Review Panel will approve the decision notwithstanding the procedural error. If the GM IFR Review Panel considers that there was a reasonable prospect that the GM IFR Panel may have come to a different decision had the error not been made, the GM IFR Review Panel will require the GM IFR Panel to reconsider the decision.

9.7.7 The GM IFR Review Panel does not have power to authorise funding for the requested treatment but can request the GM IFR Panel to reconsider the case and make recommendations as to the GM IFR Panel's approach to that

consideration.

9.7.8 In the circumstances of a formal legal challenge, an internal review of the process taken leading to a decision will automatically be triggered by NHS Greater Manchester Integrated Care.

9.8 Urgent decisions for Individual Funding Requests

9.8.1 A GM IFR Panel usually meets according to a schedule designed to provide frequent and timely opportunities to consider applications. Cases are initially reviewed within 5 working days by the GM IFR Service and the GM IFR Panel meets monthly. However, these can be stood up or down depending on need. Although it may seem that there should be a route by which certain cases could bypass the usual process and decisions could be taken on the same day, this has the potential to introduce unfairness into the process. This is because:

- Cases submitted outside the usual process are unlikely to have been able to gather the necessary research evidence upon which a decision can be properly taken

- In such circumstances the information on the probability of a response to treatment and the nature of that response is unlikely to be clear

- As a result of these uncertainties it is probable that decisions would be subject to the 'rule of rescue' in a way that cases considered in the usual process would not

- It would be impossible to convene a properly constituted panel in a very short timescale. Decisions taken by one or two panel members acting alone, increases risks of coming to the wrong decision

- A trust is able to begin treatment and seek retrospective approval and if successful, reimbursement

- Although starting a treatment without advance confirmation of funding may present a financial risk to a Trust, if there is confidence that the patient is exceptional and there is a high likelihood of a good response, there should be confidence that the case has a high likelihood of being funded retrospectively.

9.8.2 Providers must take all reasonable steps to minimise the need for urgent requests to be made through the GM IFR process, for example, by making requests promptly and providing all necessary information with a request. If provider clinicians are considered by the GM IFR Service not to be taking all reasonable steps to minimise urgent requests to the GM IFR process, the GM IFR Service may refer the matter to the clinician's Chief Executive or equivalent.

9.8.3 In the unlikely event that the case is so urgent that it requires a decision on treatment before the GM IFR Panel next meets (i.e. death or significant and irreversible loss of function is likely to occur before the meeting), the relevant provider will be advised to consider taking its own decision to commence treatment before the funding decision is made.

9.8.4 If a treatment is started by the provider in these circumstances and where the GM IFR Panel is satisfied that a case was urgent and the case was submitted within two working days of the intervention taking place, it will not refuse to determine the IFR application on the basis that it is retrospective. In these circumstances, if the GM IFR Panel supports the IFR request, the funding for the treatment will be backdated to the date on which the application was made.

10. Length of time funding approvals are valid

10.1 It is expected that where funding for a treatment has been agreed via the GM IFR process, the treatment is commenced within 12 months of the agreement letter being issued. If treatment cannot be commenced within this time period, it will be at the discretion of the GM IFR Service, on an individual patient basis, whether to extend the length of time funding has been approved for or request a new application be submitted for consideration.

11. Service Developments

11.1 The term refers to all decisions which have the consequence of committing the NHS GM to new expenditure for a cohort of patients, including:

- New services
- New treatments including medicines, surgical procedures and medical devices
- Developments to existing treatments including medicines, surgical procedures, and medical devices
- New diagnostic tests and investigations
- Quality improvements
- Requests to alter existing GM PLCV commissioning statement, such as adding an indication for treatment, expanding access to a different patient sub-group or lowering the threshold for treatment
- Support for establishing new models of care
- Requests to fund a number of patients to enter a clinical trial
- Funding a clinical trial

11.2 It is not unusual for clinicians to request funding approval via the IFR process for a patient who represents the first of a group of patients wanting a particular treatment. Any IFR application that is representative of such a group represents a service development, and as such it is difficult to envisage circumstances in which the patient can properly be classified to have exceptional circumstances. Therefore, the IFR route is not the appropriate route to seek funding approval for such patients, and therefore the request should not, and will not, be presented to the IFR Panel for a decision on funding approval unless a clear and compelling case is made to suggest that the individual is genuinely different from the identified cohort.

12. Implementation

12.1 Availability

This policy will be available to all stakeholders on the GM Integrated Care website, GP clinical systems and acute trust intranet sites.

12.2 Responsibility

12.2.1 All the organisations within Greater Manchester listed below are responsible for ensuring that the relevant employees within their organisation have read and understood this document and are competent to carry out their duties in accordance with the procedure described:

- Secondary Care Providers
- Primary Care Providers
- Independent Providers
- GM Integrated Care

13. Duties and responsibilities

NHS GM

NHS GM has responsibility for setting the strategic context in which organisational process documents are developed, and for establishing a scheme of governance for the formal review and approval of such documents.

NHS GM Chief Executive Officer

The NHS GM Chief Executive Officer has overall responsibility for the strategic direction and operational management, including ensuring that NHS GM process documents comply with all legal, statutory and good practice guidance requirements.

GM IFR Service Lead

Is responsible for the drafting, updating and implementation of this policy.

Employees of

- Secondary Care Providers
- Primary Care Providers
- Independent Providers
- GM Integrated Care

Are all responsible for ensuring they follow the processes laid out in this policy in relation to their role.

All Employees

All employees, including temporary and agency employees are responsible for:

- Compliance with relevant process documents. Failure to comply may result in disciplinary action being taken.
- Cooperating with the development and implementation of policies and procedures and as part of their normal duties and responsibilities.
- Identifying the need for a change in policy or procedure as a result of becoming aware of changes in practice, changes to statutory requirements, revised professional or clinical standards and local / national directives, and advising their line manager accordingly.
- Identifying training needs in respect of policies and procedures and bringing them to the attention of their line manager.
- Attending training / awareness sessions when provided.

14. Training implications

The training required to comply with this policy are that all members of staff who are involved with the GM IFR Service should have completed the mandatory training on IFR Decision Making and Ethical Frameworks for Priority Setting.

15. Related documents

15.1 The GM Procedures of Low Clinical Value (PLCV) Operational Policy. This policy details the process that will be followed when new GM PLCV commissioning statements are developed or existing GM PLCV commissioning statements are reviewed. GM PLCV Operational Policy

15.2 The Evidence Base Intervention (EBI) guidance, resources and programme developments documents which can be found on the AoMRC website

15.3 The GM IFR Patient Guide has been developed which explains the IFR process for patients.

15.4 Guidance notes for clinicians submitted an Individual Funding Request (IFR). Guidance notes for clinicians on exceptionality

15.5 Guidance on Who Pays? Determining which NHS commissioner is responsible for commissioning healthcare services and making payments to providers

15.6 Guidance on NHS patients who wish to pay for additional private care (publishing.service.gov.uk)

16. Legislation and statutory requirements

Health and Care Act 2022.

Health and Social Care Act 2012.

Human Rights Act 1988.

Equality Act 2010 guidance.

"Priority Setting: managing individual funding requests". The NHS Confederation, 2008. NHS Institute for Innovation and Improvement.

The NHS Constitution for England.

The Operating Framework for the NHS in England.

17. Monitoring, Review and Archiving

17.1 Monitoring

17.1.1 NHS GM will agree a method for monitoring the dissemination and implementation of this policy. Monitoring information will be recorded in the policy database.

17.2 Review

17.2.1 NHS GM will ensure that this policy document is reviewed in accordance with the timescale specified at the time of approval. No policy or procedure will remain operational for a period exceeding three years without a review taking place.

17.2.2 Employees who become aware of any change which may affect a policy should advise their line manager as soon as possible. NHS GM will then consider the need to review the policy or procedure outside of the agreed timescale for revision.

17.2.3 For ease of reference for reviewers or approval bodies, changes should be noted in the 'document history' table on the front page of this document.

17.2.4 NB: If the review consists of a change to an appendix or procedural document, approval may be given by the policy sponsor and a revised document may be issued. Review to the main body of the policy must always follow the original approval process.

17.3 Archiving

17.3.1 NHS GM will ensure that archived copies of superseded policy documents are retained in accordance with Records Management: Code of Practice for Health and Social Care 2016.

Version Control

Version	Date	Details	Page number
1.0	June 2022	Approved for implementation by the GM Elective Care Board	
1.1	Feb 2025 May 2025	Policy transferred to new NHS GM template for policies. More detail added to the document to give further clarity on the process that is followed by the GM IFR Service for Individual Funding Requests. Approved for implementation by NHS GM Clinical Effectiveness Governance (CEG) Committee. Policy made accessibility compliant	