GMCA GREATER MANCHESTER COMBINED AUTHORITY

NHS in Greater Manchester

Greater Manchester Effective Use of Resources:

Operational Policy

Version: 4.3 (20 May 2020)

Contents

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Equality Analysis

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

1. Introduction and Purpose

1.1 The government's priorities for modernising the NHS are underpinned by achieving careful management of overall NHS resources. The priorities are designed to ensure that people, wherever they live, have access to high quality services and care. Consequently, the commissioners of services in Greater Manchester (GM) are working to improve the cost effectiveness of services. The aim is to secure the greatest health gain from the resources available by making decisions based on evidence about clinical effectiveness balanced with known population needs. The commissioning process leads to resource allocation decisions following a strict process that includes careful deliberation of population needs in the context of the evidence base for the services to be provided, using a clear prioritisation process which decides what is and isn't commissioned.

1.2 This process takes account of, the recommendations issued by the National Institute for Clinical Excellence (NICE), and independent advice and expertise, e.g. the Cochrane database to further support the objective allocation of resources based on evidence.

1.3 This policy document sets out the operational framework that will underpin the part of this process relating to Individual Funding Requests (IFRs) (exceptional cases) and Individual Prior Approvals (IPAs). This policy will enable the commissioning of "one off" provider services for named patient requests for a treatment or drug not covered by existing contracting arrangements to be carried out in a similarly robust manner to the main contracting round. This decision making process needs to be ethical, equitable and firmly embedded in the governance structure. This decision making process is managed on behalf of GM Clinical Commissioning Groups (GMCCGs) by the GM EUR Team. The governance and accountability arrangements are detailed at Appendix 2.

1.4 This policy does NOT apply to those areas managed by other commissioners, e.g. NHS England or areas which are excluded from the GM EUR service. Current exclusions to the GM EUR Team are: mental health referrals; placements for mental health, learning disabilities, children's placements and services for children which are jointly commissioned by the NHS and other statutory organisations; or continuing care and other high cost and/or long term placements, unless by prior agreement with GM and costed accordingly.

1.5 This policy DOES cover requests where the following applies:

- The patient is either a temporary or permanent resident within a GMCCG area and is eligible for NHS services.
- The drug, procedure or device is not covered by contracts or service level agreements with current service providers or by other collaborative and consortium commissioning arrangements, or it falls within a CCG Effective Use of Resources Policy, and there is a

requirement for commissioner funding approval, because the treatment is not routinely commissioned, or should only be commissioned in specific circumstances.

- The referrer is the patient's GP or NHS hospital consultant or other clinician. Requests will not be accepted from patients or their relatives/carers.
- The use of e-requests. GP practices will be encouraged, through appropriate support, to use the electronic version of the procedure/treatment specific funding request forms from the 1st April 2017. This is in line with the move to a paperless NHS by 2018. Also see section 8.1
- The scope of the treatment requests are detailed in section 2.3.

1.6 This policy operates within the Ethical Framework attached as Appendix 1.

1.7 Access schemes which may be periodically offered by commercial companies or the manufacturers of treatments to introduce their products to market in cases where there may be some clinical effect. These access schemes are a matter for their promoters and do not establish any precedent for IFR requests.

2. Background and Scope

2.1 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 take into account 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. 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.

2.2 This policy should support the planning and prioritisation process undertaken by commissioners. It is not intended to be used as a population tool and will not act as a short cut in place of the formal system that agrees service developments. It may however, flag areas where there is a need for a service development and ensure that this need is brought to the attention of the appropriate commissioner.

2.3 This policy does however cover those occasions when a clinician on behalf of a patient may wish to request funding for a treatment which is not routinely commissioned or where they believe that there are exceptional clinical circumstance(s) which will make the treatment more effective for the individual in question. Examples of when this may occur are:

- When there is a commissioning policy 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

- When 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

- When the commissioner has not yet considered the available evidence and so has not yet made a decision as to whether or not the requested treatment should be made available.

This policy also covers:

- those requests where the condition is extremely rare and it is unlikely there will ever be evidence of cost effectiveness at a population level for the normal commissioning process to apply.

AND

- those requests where there is a contract but where agreed criteria must apply in each case for the procedure/drug to be commissioned and/or where the commissioner has stipulated that prior funding approval must be given. These are also referred to as Individual Prior Approvals (IPAs).

2.4 Where a decision is made on an IFR and where further requests for the same treatment are anticipated, the GM EUR Steering Group may develop commissioning policies or commissioning decision making guidance to be ratified by CCGs. Any such policies/guidance will then be used to inform the decision making process of any future similar or related requests (see section 12.3).

2.5 Referring clinicians acting on behalf of a patient to compile and submit a clinically appropriate funding request, will be responsible for ensuring that all relevant supporting information is provided to the GM EUR Team to enable full and due consideration of the request. All requests will be sent to the GM EUR Team. Anyone enquiring about individual funding will be informed of the process and the GM or respective local CCG's EUR treatment policy. Some GM EUR treatment policies require specific clinicians to submit a request, please see individual policies for further details. Depending on the nature of the request further action at this stage could include:

- Clarification of the needs of the patient, if necessary, through further discussion with the referring clinician if not already included in the request.
- Consideration of whether the needs of the patient could be met within existing service agreements, and clarifying the reasons why this might not be appropriate if not already included in the request.
- Consideration of the evidence for effectiveness of the treatment, if it is not offered within an existing service agreement. This could include reviewing relevant literature and taking opinion from relevant specialists, locally and elsewhere.
- Consideration of other relevant information – for example, previous funding decisions, previous decisions regarding commissioning priority value, existing policy documents etc.
- Review of the available evidence to determine if the patient meets the criteria where restricted access has been agreed for low clinical value procedures or to clarify that a patient meets criteria in relevant guidance, e.g. NICE.
- Seek further views, if appropriate from the patient (if this is not clear from the requesting doctor's information) and/or a relevant patient support or disorder based organisations (e.g. British Thoracic Society) and/or professional associations (e.g. Royal College of Physicians).
- In some requests, it may be considered appropriate to suggest that the patient is referred to a named relevant specialist – usually within a service agreement – for a second opinion and further advice before a formal request is made or as part of the request consideration process.
- Requesting non-identifiable photographs, preferably medical illustrations if available to support the decision making process. It should be noted that it is <u>not</u> mandatory for photographs to be provided by the patient and any photographs received will not form the sole basis of the decision. These should be and relevant to the request. If not supplied when requested, a decision will be made on the basis of the information available at the time.

2.6 Individual Funding Requests to be considered for funding will need to meet the following five conditions to be funded (this does not apply in the case of IPAs):

- The clinician makes an individual request for funding for treatment in connection with a presenting medical condition for which the CCGs have a policy, but the patient does not meet the criteria, and the clinician is claiming that the patient has exceptional clinical circumstances;

AND

- There is sufficient evidence to show that, for the individual patient, the proposed treatment is likely to be clinically effective;

AND

- Applying the approach that the CCGs take to the assessments of costs for other treatments outside this policy, the cost to the CCGs of providing funding to support the requested treatment is justified in the light of the benefits likely to be delivered for the individual patient by the requested treatment;

AND

- There are unlikely to be further requests on behalf of patients similar to the patient for whom the request is being made (unless this is a "test case", i.e. an urgent request ahead of a commissioning policy being developed/adopted).

AND

- The IFR Panel determine that the patient is clinically exceptional to other patients (see section 3 below)

3. Determination of Clinical Exceptionality

3.1 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 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. 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 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.

Where a 'not for routine commissioning' clinical commissioning policy is in place in relation to a treatment, CCGs will have been aware when making that policy that in most studies, some patients will respond better than others to the treatment and indeed, a small group may respond significantly better than the average. This should have been taken into account in developing the policy. Consequently, in considering whether a request for an 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 general policy applies, and whether there is evidence to support this view.

3.2 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, 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.

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 clinical commissioning policy that covers the patient pathway. In this way, an improvement can be made to that policy 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.

3.3 Clinical exceptionality: severity

Should severity be cited by the requesting clinician as part of the argument for exceptionality, the request 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.

3.4 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.

3.5 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.

3.6 Clinical Exceptionality: non clinical and social factors

The 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. Whilst everyone's individual circumstances are, by definition, unique and on compassionate grounds, reasons can always be advanced to support a case for funding, it is likely that the same or similar arguments could be made for all or many of the patients who cannot routinely access the care requested.

Non clinical and social factors have to be disregarded for this purpose in order to be confident of dealing in a fair manner in comparable cases. If these factors were to be included in the decision making process, a CCC IFR Panel 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 a policy of non-discrimination in the provision of medical treatment. If, for example, treatment 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 CCG IFR Panel should not make.

3.7 Clinical Effectiveness

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

Clinical evidence that considers the efficacy of a particular treatment will be carefully considered by a CCG IFR Panel. It is the sole responsibility of the referring 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 referring clinician makes explicit linkages between the grounds under which exceptionality is claimed and the sections of the submitted research literature that are considered to support the clinician's view regarding the differences between the patient's clinical position and that of other patients in the group, and regarding the patient's anticipated response to the requested treatment.

When considering clinical effectiveness, the IFR Panel will consider:

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

4. Ongoing Treatment

4.1 Patients moving into the GM area should have their care transferred to an existing pathway as soon as clinically appropriate. Inclusion within a local pathway offers clinical benefits to patients. Where a patient is already on a waiting list for a procedure at another provider when s/he moves into the GM area, s/he should be offered the option of transferring to the local pathway. Patients may choose to maintain their position on the other provider's waiting list on the understanding that ongoing or subsequent care will be transferred to the relevant GM pathways at the appropriate time.

4.2 Patients undergoing treatment approved outside of GM will need to apply for continuing funding using the GM EUR process.

4.3 Continuation of a treatment at the end of a clinical trial will only be considered as an IFR in clinically exceptional circumstances because appropriate post trial arrangements should have been agreed in advance of the trial taking place.

4.4 Patients may access treatment in line with patient choice and if they have been receiving treatment elsewhere in the country when they move into the GM area, they can choose to remain with their existing provider outside of GM.

4.5 If an IFR Panel has approved treatment previously and has not advised of any restrictions on ongoing care, continuation of treatment can be agreed by the Clinical Triage Team if clinically appropriate. The case will be referred back to Panel if the Clinical Triage Team believes this is indicated.

4.6 Patients are entitled to request a second consultant opinion within an NHS funded clinic. Third or fourth opinions for the same clinical condition will not normally be supported unless there are extenuating circumstances.

5. The National Institute for Health and Care Excellence (NICE)

5.1 Providers and commissioners are required to implement published NICE Technical Appraisal Guidance (TAG) within 3 months from the date of issue. Where a clinical decision has been taken to treat in accordance with a NICE TAG prior to the end of the 3 month implementation period, funding approval is not required by the commissioner.

5.2 Where a NICE TAG has been issued which conflicts with any treatment set out in the PbR Drugs List, PbR Devices List or CCG EUR treatment List, then the NICE TAG will take precedence, as a national mandatory requirement upon all parties.

5.3 Where there is a proposal to use a treatment or drug for which NICE has published a TAG, but the patient does not meet the criteria set out in the guidance, a request for funding approval should be made to the relevant commissioner.

5.4 NICE Clinical Guidelines are a valuable source of good practice but their implementation is discretionary. Clinical Guidelines will only be implemented following a full review (through existing trust/CCG mechanisms) of their implications in terms of increased/reduced activity and requirement for additional investment.

5.5 NICE Interventional Procedure Guidance (IPG) considers only the efficacy and safety of a procedure and the level of consent, audit and clinical governance required. IPGs do not consider cost effectiveness. Where IPGs are considered by Commissioners to be Service Developments, a business case, or similar proposal, is required to be submitted for approval by the commissioner before the provider can begin offering the treatment

6. Continuing or Additional Privately Funded Care

6.1 Patients have a right to revert from privately funded care to NHS funding at any point during their care, providing the treatment is routinely available. In such circumstances GMCCGs will expect their care to be transferred to NHS pathways. Where the individual is requesting funding to continue their care within the private facility, which is outside of NHS contracted arrangements, or where the treatment is not routinely available, an IFR would need to be submitted for consideration through the GM EUR process. Patients will need to meet the conditions for approval (see paragraph 2.6).

6.2 Relating to co-payment of treatment GM will follow the "*Guidance on NHS Patients Who Wish to Pay for Additional Private Care"* (Department of Health, 23 March 2009), the key points of which are:

- NHS organisations should not withdraw NHS care simply because a patient chooses to buy additional private care.

- Any additional private care must be delivered **separately** from NHS care.
- The NHS must never charge for NHS care (except where there is specific legislation in place to allow charges) and the NHS should never subsidise private care.
- The NHS should continue to provide free of charge all care that the patient would have been entitled to had he or she not chosen to have additional private care.
- NHS Trusts and Foundation Trusts should have clear policies in place, in line with these principles, to ensure effective implementation of this guidance in their organisations. This includes protocols for working with other NHS or private providers where the NHS Trust or Foundation Trust has chosen not to provide additional private care.

6.3 If a request is made for the continuation of a course of treatment that has been initiated privately for a treatment that is not normally commissioned, e.g. alternative therapies the request will be managed as a new request for that treatment. In the event that funding is approved this will start from the date of approval (retrospective funding will not be approved).

7. Retrospective Funding

7.1 Funding requests received relating to treatment delivered in the past will NOT be funded retrospectively or 6.2 applies.

7.2 If a case is deemed by the Clinician in charge to be too urgent to await the completion of the GM EUR process, then the provider can take the risk of commencing treatment prior to a decision being made (this only applies if requests are received by the GM EUR Team before the date treatment starts). The case will then be put through due process as for any other request without those responsible for the decision knowing that treatment has commenced. The request will be managed in the same way as all other requests to ensure equity; the fact that treatment has started will not then affect the decision in any way.

8. Referral to Treatment Times (RTT)

8.1 The GM EUR Team is aware of the national patient access target for the NHS, which measures the patient's journey from referral to first definitive treatment, which should not exceed 18 weeks. The GM EUR Team will endeavour to process Individual Prior Approval requests to support CCGs/Trusts in achieving these targets. However, Trusts should be mindful of the timescales for consideration of requests via the GM EUR process (see section 10). Where possible, funding approval should be sought by the patient's GP, for treatments included within GM CCG EUR policies, prior to referral to NHS Trusts.

8.2 Where a primary care clinician is submitting an Individual Funding Request (exceptional case) for consideration on the grounds of clinical exceptionality RTT will only apply once a GM CCG has confirmed funding approval as this treatment would not usually be routinely commissioned.

9. Request Process and Stages (for Individual Funding Requests and Prior Approvals)

9.1 Request Submissions

Since the beginning of 2017 treatment specific funding request forms have been available for GM EUR treatment policies on GP clinical systems and for providers on the EUR Treatment List contained within the GM Prior Approval Scheme of the NHS Contract.

9.1.1 Treatment specific funding request forms, where available, must be used for all requests from the 1st April 2019. These forms can be found on all of the GP Clinical Systems across Greater Manchester. These must be submitted electronically to gm.eur@nhs.net. Where no treatment

specific funding request form is available the GM Generic EUR Treatment form should be used. All forms must be completed by a clinician. Forms will not be accepted where this has been completed by the patient.

8.1.2 All forms must be received as typewritten only. Handwritten funding requests will be returned to the requester for amendment. This is to ensure that all content is legible and the best case made on behalf of the patient.

8.1.3 Every applicable section of the form will need to be completed in full in order for the request to progress in a timely manner. Any form which is incomplete may result in the decision process being delayed.

9.2 Checking

9.2.1 All requests will be received by the GM EUR Team on behalf of all GMCCGs. These will be checked to ensure that they should not be sent to another commissioning organisation, e.g. NHS England (NSHE) see https://www.england.nhs.uk/commissioning/

NOTE: it is the responsibility of the requesting clinician to ensure that the request is sent to the appropriate organisation. Where a clinician is unsure they should contact the relevant organisation (NHSE for example) to discuss the case.

9.3 Screening

9.3.1 Appropriate requests will be screened by the GM EUR Team. Requests need to contain sufficient information to allow the request to be assessed against the mandatory criteria in the policy. They will be checked for completeness and further information requested from the appropriate clinician and/or the patient where indicated. The request will then be checked against prior approval criteria, commissioning policies or commissioning decision making guidance. These will be the GM EUR treatment policies or where applicable local policy statements inherited from local predecessor organisations.

9.3.2 If the required information has been provided and the necessary evidence is available a decision will be made at screening in accordance with GM EUR treatment policy criteria or local policy statements (where appropriate). Where information is missing this will be requested from the requestor and the request reviewed when this is forthcoming. However in some cases to avoid unfairly raising expectations a decision will be made on the information provided in the request submitted by the referrer.

9.3.3 Any requests clearly meeting the EUR treatment policy criteria will be approved and the clinician and patient will be notified within two working days of the date of the decision.

9.3.4 Any requests clearly not meeting the required EUR treatment policy criteria will be refused funding and the clinician and patient will be notified within two working days of the date of the decision.

9.3.5 Any request where there is doubt relating to agreed EUR treatment policy criteria or where clinical exceptionality is being claimed will be passed to the Clinical Triage Team for review. Where clinical exceptionality is claimed on the basis of conditions normally cited the request will be declined in line with the appropriate GM EUR treatment policy or local policy statement.

9.3.6 Decisions will be notified within 2 working days of the date of the decision

9.4 Clinical Triage

9.4.1 The GM Clinical Triage Team comprises of a GP, Consultant in Public Health/Specialty Doctor in Public Health, Medicines Management lead and a representative from the GM EUR Team. This

group convenes on a regular basis to review all requests which require clinical input and to determine if the clinical circumstances presented meet the criteria specified in the CCG EUR local Policy or GM EUR treatment policy not dealt with at the screening stage. There must be agreement by all the parties involved before a decision can be signed off. It is the role of the GM Clinical Triage Team to make clinical decisions in accordance with the CCG EUR local policy or GM EUR treatment policy, or where delegated authority has been given following a precedent decision made by a CCG IFR Panel. The GM Clinical Triage Team may not take decisions on requests which require consideration of clinical exceptionality, but may decide whether a request contains such evidence of clinical exceptionality, which would require further consideration by a CCG IFR Panel. However the GM Clinical Triage Team may decline a request if they feel that clinical exceptionality is not demonstrated in an individual case.

9.4.2 If the Clinical Triage Team cannot reach consensus, or there is evidence of clinical exceptionality, or this could be a precedent decision for a number of patients or the request is of a complex nature that will benefit from a full IFR Panel decision then the request will be taken to the IFR Panel of the patient's host CCG.

9.4.3 Decisions will be notified within two working days of the date of the GM Clinical Triage meeting.

9.4.4 The GM Clinical Triage Team will approve requests for ongoing care where they deem treatment to still be clinically appropriate. The case will be referred to Panel if GM Clinical Triage believes this is indicated.

9.5 IFR Panels

9.5.1 The exact constitution and membership of IFR Panels will be determined by individual GM CCGs. Model Terms of Reference for IFR Panels and Process Review Panels are attached as appendices 3 and 4. These Panels will be convened and resourced by the CCGs but the preparation of papers, agendas, minutes and action arising will be managed by the GM EUR Team.

9.5.2 Patients/clinicians will be notified of the decision within two working days of the date when the GM EUR Team received the approved minutes of the IFR Panel meeting. Draft minutes of the IFR Panel meeting will be forwarded to the IFR Panel Chair for approval, within 2 working days of the IFR Panel meeting.

9.5.3 Details of all decisions made at screening and Clinical Triage for routine and urgent requests will be made available to all CCG IFR Panel meetings; the management information report will be a standing item on the agenda

9.5.4 Patients are not able to attend an IFR Panel to present their case.

9.5.5 Decisions will be notified within two working days of the date of the minutes being ratified by the Chair of the IFR Panel.

9.6. Urgent requests / priority cases

9.6.1 The GM EUR Service identifies an urgent request as one where a failure to provide the specifically requested treatment within 72 hours will have very serious negative consequences for the patient. In these requests, the provider may initiate treatment whilst awaiting a funding decision (the IFR Panel will assess the request without knowing that treatment has commenced) or when a provider believes the IFR request requires a quick decision (i.e. before the next meeting of the CCG IFR Panel) and where the GM EUR Clinical Triage Team believes the Trust has appropriately managed the request and it genuinely cannot wait until the next CCG IFR Panel meeting.

Note: if the request requires a quick decision because, in the view of the GM EUR Clinical Triage Team the Trust has not appropriately managed the request (i.e. given the patient a date for

surgery before asking whether or not funding is available) the Trust will need to act in good faith and carry the financial risk of the request being declined and the request will be handled in the usual way.

9.6.2 The GM EUR Service has agreed with each GMCCG a process for handling urgent requests that require IFR Panel consideration.

9.6.3 Priority cases are those where a treatment needs to be given within a certain timeframe that does not allow enough time for the request to be prepared for panel consideration. **NOTE:** This excludes those cases where treatment has been booked prior to authorisation being received**.**

Where a clinician has stated that a case requires an urgent response but that case does not meet the GM EUR definition of urgent i.e. intervention within 72, then provided a clinical case has been made by the referring clinician that case will treated as a priority case. Cases where the GM EUR Team whilst screening the request is of the opinion that a request is time sensitive this will then be prioritised.

Examples are:

- Drugs needed for severe cases of the disease being treated.
- Eating disorders where there is rapid weight loss or the BMI is dangerously low.
- EEA/Cross Border Team requests that have a short response time attached to them.
- IVF if female is nearing the age cut-off for accessing the treatment and delay in processing will prevent treatment starting before the cut-off date.
- Mental health cases (not excluded from the service) where a place of safety is needed.

9.7 Clarification of the IFR process – meetings with patients

9.7.1 At any stage during the process of considering a funding request, the patient can ask for an informal meeting with the GM EUR Team and the relevant PALS/Patient Services if appropriate, who can advise the patient of the process. This is a non-clinical meeting and the GM EUR Team are unable to discuss clinical aspects of the case. Patients may bring someone along to provide support.

9.8 Length of time funding approvals are valid

9.8.1 If due to unforeseen circumstances treatment was unable to be commenced/delayed funding approval will be valid for a maximum of 12 months provided the patient's clinical circumstance remain unchanged from the time the funding approval was given.

9.8.2. If the patient's circumstances have changed and/or the funding approval has expired then a new request should be submitted for consideration. Any new request will be considered against current policy criteria.

10. Appeal Process

10.1 An appeal against a decision made at screening or clinical triage must come from the clinician who submitted the request.

If the requesting clinician feels that not all the available evidence has been considered when the decision was made they can ask for the request to be reconsidered at any stage of the process (with the exception of when an IFR Panel made the decision – see below). The requesting clinician should include his/her grounds for appeal. Appeals will not be accepted simply because the requesting clinician and/or the patient disagree with the decision, unless the clinician is of the

opinion a key piece of information has not been taken into consideration. Should new information/evidence be submitted then the request will be reconsidered by the GM EUR Team.

NOTE: Appeals against a decision made by an IFR Panel cannot be considered as an IFR Panel decision is final; however, if further information is submitted which the IFR Panel has not considered then a case will be reviewed and if this information has not been previously considered will be referred back to an IFR Panel in order for further consideration. (Also see section for Process Review)

10.2 Where a case has been declined by a CCG IFR Panel a clinician can request a Process Review to determine whether the process outlined in this document has been followed. The request for a Process Review should clearly indicate which element of the process wasn't followed and/or which piece of evidence wasn't considered when the IFR Panel reached their conclusion.

10.3 It is the responsibility of the relevant CCG to convene and resource the Process Review Panel within 3 months of receiving a written request for a Process Review from a clinician. If the patient or clinician request the Process Review to be re-arranged or a conflict of interest is discovered, the CCG will have 3 months to reconvene and resource the Process Review Panel from the date of this being notified to the CCG. The CCG will however make every effort to reconvene as soon as possible. The GM EUR Team will provide all the required information, prepare the papers and support the CCG Process Review Panel meeting.

10.4 The role of the CCG Process Review Panel is to review the request and the actions taken at each stage, to ensure that the process described in the GM EUR Operational Policy has been followed and all relevant actions taken. It is not the role of the CCG Process Review Panel to make a further funding decision in respect of the request.

10.5 Should the CCG Process Review Panel decide that due process had been followed, and the IFR Panel decision stands, there will be no further recourse of appeal within the CCG. If the CCG IFR Panel did not follow due process, it will return the request to the CCG IFR Panel to address any issues identified by the Process Review Panel.

10.6 This process does not in any way affect the individual's right to seek redress via alternative routes (e.g. the Parliamentary and Healthcare Ombudsman, Judicial Review).

10.7 Any new funding request for the same condition/treatment that has previously been considered by an IFR Panel must contain new clinical information e.g. a change in severity of symptoms. The new funding request will be reviewed against the previous request by the GM Clinical Triage Team and if it does not contain any new clinical information the request will be rejected and closed and will not progress through the GM EUR Process.

11. Timescales and Funding Mechanisms

11.1 The table below describes the different funding mechanisms. The mechanism for funding as described in the table below is detailed in the CCG Treatment Lists, the PbR Excluded Drugs List and PbR Excluded Devices List

Approval	Definition	Funding process
Individual Funding Request (Exceptional Case) Approval	A decision has been taken not to commission a specific treatment	The treatment must not be undertaken without funding approval from commissioners. Funding may only be approved if there is evidence of clinically exceptional circumstances.

Individual Prior Approval	The specific treatment falls outside of routinely commissioned arrangements, for example, PbR excluded drugs/devices and/or where there is no commissioning policy. The Commissioner has specifically requested that funding is sought for a particular treatment.	The treatment must not be undertaken without funding approval from commissioners. Clinically exceptional circumstances do not always have to be demonstrated.
Notified Approval	Commissioners will be notified of a planned treatment (usually high cost).	Funding approval is not required.
Monitored Approval	The specific treatment may be undertaken in line with agreed EUR policy criteria / routine commissioning arrangements.	Funding approval is not required and the CCG do not need to be notified of the planned treatment. Audits may be undertaken to ensure adherence with agreed commissioning arrangements.
Service Development Approval	The specific intervention is new, or new at a particular Trust and is likely to benefit a population of patients with similar needs.	A business case, or similar proposal, is required to be submitted for approval by the commissioner before the provider can begin offering the treatment.

11.2 Funding requests must be considered carefully and with the benefit of all the required information. Clinicians are encouraged to submit funding requests in a timely manner which has regard to the standard decision-making timescales set out below. As far as possible clinicians should avoid waiting until a request becomes urgent.

11.3 The timescales below are for a first decision and excludes the time taken to process any appeals. An appeal against a decision to decline funding will be processed in accordance with Section 9 of this policy. The timescales below do not cover requests being submitted to the incorrect organisation for consideration (e.g. requests sent to CCGs for consideration rather than NHS England or vice versa).

For treatments/procedures that require Individual Prior Approval (IPA) the GM EUR Service will process these within 28 operational days following the date the request was received, subject to the timely provision of all of the information specified within a Prior Approval Scheme. Treatment must not commence until the provider has received written notice of funding approval (see section 7.2).

For treatment/procedures where funding is being requested on the grounds of clinical exceptionality (IFR) the GM EUR Service will process these within 90 operational days following the date of the request was received, subject to the timely provision of all of the information specified within a Prior Approval Scheme. Treatment must not commence until the provider has received written notice of funding approval (see section 7.2).

11.4 If the additional information is not received within 15 working days of the date the additional information had been requested, then a decision will be made on the basis of the information available or the file closed if there is insufficient information to reach a decision. However a

clinician and/or the patient may contact the service and request an extension to the timescales to allow the further information to be submitted.

11.5 Screening decisions will be notified within two working days of the date of the decision.

11.6 Clinical Triage decisions will be notified within two working days of the date of the GM Clinical Triage meeting

11.7 IFR Panel decisions will be notified within two working days of the date of the minutes being ratified by the Chair of the IFR Panel.

12. Implementation and Process Improvement

12.1 A review of EUR decisions will be performed intermittently by the GM EUR Service, providing an assurance process to decision-making arrangements, and to enable learning to be incorporated into reviews of the standards set in this process.

12.2 A GMCCG may request an audit of EUR decisions undertaken on their behalf by the GM EUR Service. Such audits would be organised by the CCG using their internal audit processes. Requests should be submitted to the GM EUR Team Manager.

13. Policy Development

13.1 Within the GM EUR service there is a Policy Development Team that will support the development and implementation of commissioning GM treatment policy recommendations at a GM level. This area of work will be overseen by the GM EUR Steering Group on behalf of the GMCCGs. The Policy Development Team will manage an ongoing programme of work, which has been prioritised by the GM EUR Steering Group. The Terms of Reference for the GM EUR Steering Group are detailed at Appendix 5. This work schedule will be reviewed on a bi-monthly basis by the GM EUR Steering Group to allow insertion of any high priority or pressing issues. Any urgent policy requirements may also be prioritised by the GM EUR Steering Group outside of scheduled meetings via email.

13.2 An initial work schedule was produced by the Policy Development Team from the list of inherited policies (those developed by GM PCTs and adopted by their successor GMCCGs). The rationale for prioritisation of policies for development by the GM EUR Steering Group has predominantly been driven by the inherited variation of local CCG policies particularly, those where there are large numbers of funding request received or which are considered to be contentious. Now the majority of the variations have been addressed and GM EUR treatment policies are in place the GM EUR Steering Group will work with CCG Directors of Commissioning (DOC) and Chief Finance Officers (CFO) to identify future GM EUR treatment policies for development.

New topics will be prioritised by the GM EUR Steering Group and added to the work plan as each policy is finalised. The GM EUR screening and Clinical Triage process will continue to identify new topics to be added to the list of potential policies to be developed. Horizon scanning will also be undertaken to determine any potential high priority policy requirements. A maximum of 8 GM EUR treatment policy recommendations will be under development at any one time to allow time for regular review of existing GM EUR treatment policies.

13.3 When 5 or more similar requests for treatments are received from clinicians these will either be identified to CCG commissioning leads for possible service development or added to the list of topics for policy development. The length of time taken to reach 5 requests will affect the priority of the topic on the policy development list – 5 in 6 months will have a higher priority than 5 in 6 years.

13.4 For each GM EUR treatment policy a full literature and evidence review will be undertaken as well as an equality analysis. A description of epidemiology and need may also be provided, where

appropriate, along with an economic assessment. Based on the evidence review the GM EUR treatment policy will be drafted and where appropriate criteria for access to the service or treatment will be developed.

13.5 GM EUR treatment policy recommendations will be approved by the GM EUR Steering Group, prior to being published for a period of clinical engagement. Feedback from the period of clinical engagement will be fed into the policy development, as appropriate; before the final GM EUR treatment policy recommendation is agreed by the GM Steering Group for consideration by the GM DOC/CFOs.

13.6 Once a GM EUR treatment policy recommendation has been formally agreed by the GM EUR Steering Group the policy will be sent to Mersey Internal Audit Agency (MIAA) to identify which procedure and diagnostic codes are relevant to the policy.

13.7 GM EUR treatment policy recommendations that have been formally agreed by the GM EUR Steering Group will be considered by the GM DOC/CFOs. The Joint Commissioning Board (JCB) has given GM DOC/CFOs delegated authority to approve the implementation of GM EUR treatment policies across Greater Manchester. The following apply:

- All new GM EUR treatment policies must have DoC/CFO approval to implement.
- If an existing GM EUR treatment policy is later revised and the changes to the commissioning criteria are considered to be material the revised policy would also need DoC/CFO approval to implement.

The governance for getting each GM EUR treatment policy approved through GM DoCs and GM CFOs will be dependent on the financial implications of each policy:

- If the commissioning criteria in a new GM EUR treatment policy would **r**esult in a saving across GM, then the policy would require GM DoC approval to implement. The financial analysis will be produced at a GM level rather than individual CCG level. This approval will be reported at the next GM CFO meeting “for information”.
- If the commissioning criteria in a new GM EUR treatment policy would result in an increase in costs of less than £200k across GM then this would not be considered financially material. GM DoCs can approve this policy, under the delegated decision making of each DoC. The financial analysis will be produced at a GM level rather than individual CCG level. This approval will be reported at the next GM CFO meeting “for information”.
- If the commissioning criteria would result in an increase of over £200k across GM then it would be considered a material change. A more in-depth financial assessment and report would need to be prepared that shows the impact on each CCG. The GM EUR treatment policy would need to be approved by both GM Docs and GM CFOs.

13.8 Once a new or revised GM EUR treatment policy has been ratified by DOC/CFOs the policy will be implemented for Bury, HMR, Manchester, Oldham, Salford, Stockport, T&G, Trafford and Wigan CCGs. Whilst Bolton CCG will take the policy to their Governing Body for ratification before it is implemented for their CCG. Once approved through the governance process new and revised GM EUR treatment policies will still be taken through individual GM CCG governance arrangements for information only.

13.9 GM EUR treatment policy recommendations will be reviewed one year from the date of approval by the GM DOC/CFOs and thereafter at a date agreed by the GM EUR Steering Group unless new evidence warrants earlier review (see section 14 – Policy Review).

13.10 The GM EUR Steering Group may review GM EUR treatment policies within the timeframe for review, following the release of new national guidance, e.g. NICE.

13.11 Appeals against a GM EUR treatment policy on the basis of the evidence used (either because it is believed that insufficient evidence was taken into account or there is new evidence available) will be reviewed by the GM EUR Steering Group and depending on the nature of the appeal; a policy review may be undertaken. Such policy reviews will be prioritised alongside other policies requiring development.

13.12 GM EUR Steering Group members will be responsible for ensuring their respective CCGs are fully engaged with the policy development at the clinical engagement stage and for ensuring their CCG's views are represented. GM EUR Steering Group members will also be responsible for driving the consideration of GM EUR treatment policy recommendations within their CCG. GM EUR treatment policy recommendations will be presented to the GM DOC/CFOs by a nominated CCG EUR sponsor.

14. Policy Review

14.1 GM EUR treatment policy recommendations will be reviewed one year from the date of approval by the GM DOC/CFOs and thereafter at a date agreed by the GM EUR Steering Group unless new evidence warrants earlier review (detailed in section 12).

14.2 The GM EUR Policy Development Team will review the related evidence and inform the GM EUR Steering Group of the outcome of this review. The GM EUR Steering Group will decide if there is substantial new evidence to support a full policy review. Policies requiring a full review will be prioritised by the GM EUR Steering Group against other policies that may require development and will follow the GM EUR Policy Development Process.

14.3 The GM EUR Steering Group may decide, based on the outcome of the evidence review, that the GM EUR treatment policy remains current and recommend that the policy is reviewed again after an agreed period of time or amended or withdrawn. If the GM EUR Steering Group feel there is a significant change to what can and cannot be commissioned in the policy, the policy will go out for a further period of clinical engagement and then go through the governance process again for approval.

14.4 Where an existing GM EUR treatment policy has been reviewed and the GM EUR Steering Group considers the changes to be non-material the policy will not be required to go through the governance process again. If an existing GM EUR treatment policy is later revised and the changes to the commissioning criteria are considered to be material the revised policy would go to DoC/CFOs approval to implement.

15. Delivery Outputs

15.1 Delivery Outputs from the GM EUR Service:

- The development of the GM EUR Operational Policy
- The management of the GM EUR Steering Group
- The management of the GM EUR governance arrangements
- The development of GM EUR treatment policies, containing an equality analysis, an evidence review, activity levels, costs & commissioning arrangements, alongside the expected procedure (OPCS-4) and diagnosis (ICD10) codes.

- Sharing the above codes with DSCRO, CCG BI Leads and CCG Contract Leads
- The development of GM EUR policy summary documents to be uploaded to GM GP clinical systems (EMIS, TPP and VISION)
- The development of treatment specific funding request forms, including automated forms (Bluteq)
- Population of costing tools where relevant
- The development and maintenance of CCG treatment lists
- The co-ordination of CCG websites re: GM EUR treatment policies
- The co-ordination of clinical engagement
- The co-ordination of notification letters to CCG Contract Leads advising of any changes to the PbR Drugs List, PbR devices List and CCG EUR Treatment Lists.
- Close working with NHS England re: their Evidence Based Intervention Programme as a demonstrator site, representing Greater Manchester
- Notification of GM EUR policy developments to CCG partners, regarding any clinical pathway implications.
- Liaison with Medicines Optimisation to ensure PbR excluded drugs and PbR excluded devices are up to date in the treatment lists document
- Processing of Individual Funding Requests (IFRs) and Individual Prior Approvals (IPAs)
- Management of invoices relating to IFRs
- Administrative support provided to IFR and Process Review Panels
- FOIs
- MP letters & complaints

16. Changes to Funding Mechanisms in GM EUR Treatment Policies

16.1 If an individual CCG wishes to change from the mechanism Monitored Approval to Individual Prior Approval within a GM EUR policy they must contact the GM EUR Service to discuss the options available to them. CCG will be required to consider and discuss the use of an electronic automated system where one is available e.g. Blueteq in the first instance. If the use of an electronic automated system is not an option available then the impact of the change in funding mechanism and the impact this will have on the GM EUR Team will need to fully worked up before any change is implemented.

Appendix 1: Ethical Framework

The Ethical Framework is the tool that underpins decision making in priority setting, both for policy-making and when considering individual patients' requests for funding of treatments 'not normally funded' by the GMCCGs.

Evidence of clinical and cost effectiveness

The GM EUR Team will seek to obtain the best available evidence of clinical and cost effectiveness using robust and reproducible methods. Methods to assess clinical and cost effectiveness are well established. The key success factors are the need to search effectively and systematically for relevant evidence, and then to extract, analyse, and present this in a consistent way. Choice of appropriate clinically and patient-defined outcomes needs to be given careful consideration, and where possible quality of life measures and cost utility analysis should be considered.

The GMCCGs will promote treatments for which there is good evidence of clinical effectiveness in improving the health status of patients and will not normally commission a treatment unless it has been shown to be clinically effective.

Issues such as safety and drug licensing will also be carefully considered. When assessing evidence of clinical effectiveness the outcome measures that will be given greatest importance are those considered important to patients' health status. Patient satisfaction will not necessarily be taken as evidence of clinical effectiveness. Trials of longer duration and clinically relevant outcomes data may be considered more reliable than those of shorter duration with surrogate outcomes. Reliable evidence will often be available from good quality, rigorously appraised studies. Evidence may be available from other sources and this will also be considered. Patients' evidence of significant clinical benefit is relevant.

When weighing the relative priority of different treatments the GMCCGs will consider the strength of health benefit; the size of any potential health benefit (deaths prevented, quality of life years gained) and the probability of individual and population health benefit.

The GMCCGs will compare the cost of a new treatment to the existing care provided and will also compare the cost of the treatment to its overall benefit, both to the individual and the community. They will consider technical cost-benefit calculations (e.g. quality adjusted life years), but these will not by themselves be decisive. The GM EUR Team and CCG IFR Panels may use the ethical framework to guide context-specific judgment about the relative priority that should be given to each topic.

In considering very high cost interventions, the GMCCGs may conclude that an intervention is not cost effective even if it is proven to be clinically effective in saving or extending the lives of patients. Where a decision is made that a high cost intervention is not to be routinely funded, the GMCCGs via the GM EUR Team and IFR Panels will always consider the exceptional circumstances of an individual request for a high cost intervention.

Equity

GMCCGs believe that people should have access to health care on the basis of need. There may also be times when some categories of care are given priority in order to address health inequalities in the community. However, save as set out below, the GMCCGs will not discriminate on the grounds of personal characteristics, such as age, gender, sexual orientation, gender identity, race, religion, lifestyle, social position, family or financial status, intelligence, disability, physical or cognitive functioning. In some circumstances the above factors may be relevant to the clinical effectiveness of a proposed treatment or the cost effectiveness of an intervention. These factors, along with other medical conditions from which a patient is suffering, may affect the capacity of an individual or groups within the population to benefit from the treatment. In such circumstances, as an exception to the above policy, the GMCCGs are entitled to limit access to defined treatments by reference to some of the above factors.

Health care need and capacity to benefit

Health care should be allocated justly and fairly according to need and capacity to benefit, such that the health of the population is maximised within the resources available. The GMCCGs will consider the health needs of people and populations according to their capacity to benefit from health care interventions. So far as possible, they will respect the wishes of patients to choose between different clinically and cost effective treatment options, subject to the support of clinical evidence. This approach leads to three important principles:

In the absence of evidence of health need, treatment will not generally be given solely because a patient requests it.

A treatment of little benefit will not be provided simply because it is the only treatment available.

A treatment which effectively treats 'life-time' or a long-term condition is considered equally to urgent and life prolonging treatments.

Cost of treatment and opportunity costs

The GMCCGs are required by the Health and Social Care Act 2012 not to exceed their annual budget. The GMCCGs therefore have a legal duty to take account of the cost of treatment. The cost of treatment is significant because investing in one area of health care inevitably diverts resources from other uses. This is known as opportunity costs and is defined as benefit foregone, or value opportunities lost, that would accrue from the notion of scarcity of resources. Prioritisation decisions must be taken with full consideration of the consequences for funding other priorities.

Needs of the community

One of the GMCCGs' key objectives is to make decisions to improve the health of its population and reduce health inequalities. Some of these decisions are promoted nationally. Others are produced locally and should be made with reference to local Joint Strategic Needs Assessment and local public engagement processes. Sometimes the needs of the community may conflict with the needs of individuals. There can be difficult decisions where an individual patient needs a considerable investment to support their health but where the same money could be used to greater overall effect for a group of patients, and the GMCCGs cannot afford both sets of treatment.

Policy drivers

The Department of Health issues guidance and directions to NHS organisations.

Directions require the GMCCGs to give priority to some categories of treatment for some patients. The CCGs are legally required to consider (but not necessarily implement in full) Department of Health Guidance. Both directions and guidance may affect the way in which health service resources are allocated by the GMCCGs.

Clinical exceptional need

It is good practice not to impose a blanket ban on any treatment, GMCCGs recognise that there may be requests in which a patient has exceptional clinical circumstances which may justify funding for treatment that is denied to other patients. Each request of this sort will be considered on its own merits in the light of the clinical evidence. The GM EUR operational policy outlines the procedures that are in place to consider such requests that a referring clinician considers to be clinically exceptional, on their individual merits.

Appendix 2: Governance and Accountability

GMCCGs retain overall responsibility for the effective use of resources and for the availability, implementation and resourcing of an IFR process.

GMHCC is under a contractual agreement with the CCGs in GM to manage the EUR/IFR process on behalf of the CCGs.

The GM EUR Team will manage all requests in line with the GM EUR Operational Policy and will further support that process through the development of commissioning policies for procedures of limited clinical effectiveness and services not currently included in contracts, which result in IFR requests. These policies will be based on the best available evidence of effectiveness and will be reviewed regularly (see section 11 of the GM EUR Operational Policy).

GMCCGs will retain responsibility for ensuring they have effective IFR Panels and a process for convening and delivering a Process Review Panel when required.

Ultimate responsibility in the case of a judicial review rests with the CCG.

The GM Head of EUR will ensure that the GM EUR Team adheres to set standards for making decisions in a timely way. The length of time taking to reach a decision can vary depending on the individual complexities of each case.

The GM EUR Team will provide a summary of all funding decisions on individual requests to the relevant CCG IFR Panels and will flag up through the Governance arrangements any issues that may have implications for wider GMCCG policy, particularly candidates for service developments.

The GM EUR Senior Officers will produce a monthly report summarising the outcomes of relevant decisions to the IFR Panels.

All funding decision letters will outline the reasons for the decision that has been made.

If patients, or referring clinicians, feel that they have been dealt with unfairly, they can ask for a review of the decision making process.

The recording of reasons for decisions made by the relevant teams at each stage of the process, including the minutes of the relevant IFR Panel, are available on request by the individual concerned in accordance with the Data Protection Act 1998) subject to any exemptions that may be applicable to the disclosure).

It is the responsibility of the GM Head of EUR to ensure that the GM EUR Team meets the required competencies for their roles, and has access to appropriate training to maintain their competence.

Training of IFR Panel members and Process Review Panel members will be the responsibility of the individual CCGs.

The GM EUR Steering Group (see Appendix 5) has oversight for the development of all EUR treatment policy recommendations on behalf of the CCGs.

The GM DOC/CFOs will ratify GM EUR treatment policy recommendations for implementation.

Appendix 3: Example Terms of Reference for a CCG Individual Funding Request Panel

(Please refer to individual GM CCG's own ToR)

Purpose

The CCG IFR Panel will meet monthly to review requests for funding for treatments not currently covered by commissioning arrangements or for treatments excluded from those arrangements

The Panel will adopt a consensus approach to decision making where unanimous view cannot be reached on an individual request.

The Panel will consider requests on an individual named basis for treatments either not covered by commissioning arrangements or where a treatment is specifically excluded from those arrangements.

The Panel will be responsible for assessing the clinical effectiveness of the procedure and then the cost effectiveness of the requested treatment based on the evidence available to them at the time. For requests where a treatment is excluded from commissioning arrangements the Panel will review the evidence to determine whether or not the request under consideration is exceptional and should therefore have access to that treatment funded by the NHS.

Membership

- General Practitioner representative
- 2 additional members with a clinical background
- Finance representative
- Medicines Management representative
- Public Health representative
- Lay representative (expert patient/patient participation)
- A Senior Commissioner from the CCG

The Chair of the Panel will be determined by the CCG lead.

The Panel may co-opt additional members (with or without voting rights as deemed necessary) when required, particularly when specialist expertise is needed and may be establish as sub group to deal with decisions that may include co-opted members, Where a person is to be co-opted onto the Panel for the purposes of participating in any of its meetings the decision to co-opt that individual (along with whether or not he or she may have voting rights) shall be put to a vote of the regular voting members at the start of the relevant meeting.

Administrative support

Meetings will be arranged and resourced by the CCG and managed by their nominated lead officer.

Preparation of agendas and all request papers, recording the outcomes of the meeting, taking any actions arising and ensuring letters are sent to the requesting clinician and patient within agreed timescales is the responsibility of the GM EUR team on behalf of the CCG.

Ensuring a suitable venue is available is the responsibility of the CCG lead for IFR.

Quoracy

At least 4 members of the Panel should be present, one of which should be medically qualified, e.g. a doctor and one clinically qualified, e.g. nurse, allied health professional etc.

Chairs action / urgent decisions

In clinically urgent situations a request may be considered in advance of the Panel using the mechanism agreed in the GM EUR Operational Policy/Standard Operating Procedures.

Training of IFR Panel members

Training of IFR Panel members is the responsibility of the CCG but will be supported by the GM EUR Team.

Members should attend at least one meeting per quarter to maintain continuity and expertise.

Confidentiality

All requests will treated as highly confidential as the majority will contain sensitive and/ or clinical information.

Papers will be sent to members via either registered post or a secure e-mail service, e.g. NHS.net.

Consent will be obtained from the patient prior to the meeting.

All confidential papers will be gathered for shredding at the end of the meeting.

Review

These terms of reference will be reviewed annually or sooner if there are relevant changes in legislation or local/national guidance.

Appendix 4: Example Terms of Reference for a CCG Process Review Panel
(Please refer to individual CCG's own ToR)

Purpose

The CCG Process Review Panel will meet on an adhoc basis when a clinician acting on a patient's behalf has appealed a Panel decision and they have not submitted additional evidence which would require the request to be further considered by the IFR Panel in accordance with the EUR Process.

The Panel will meet in private but the patient and or a representative will be asked to attend to ensure that their views are fully accounted for. A member of the original IFR Panel will attend the Process Review Panel to present the case and answer any questions.

The Panel will adopt a consensus approach to decision making where a unanimous view cannot be reached. If consensus cannot be reached on any point the decision of the chairperson will be final.

The Panel will consider each stage of the process that the request has gone through to ensure that all reasonable attempts have been made to find relevant evidence of effectiveness and that all aspects of the request have been considered in the round.

The Panel should assure itself that all stages of the process have been recorded.

The Panel is there to decide if due process has been followed and to identify any areas where further consideration needs to be made if any.

It is not the role of the CCG process review Panel to make a further funding decision or overturn the IFR Panel decision; however, it may return the request to the IFR Panel to address any issues identified following the process review.

Panels may consider more than one request at a time provided there is sufficient time for each request to be dealt with fully.

Membership

The chair of the CCG process review Panel will be the lay person representing the CCG provided they have had the necessary training, if not an alternative chair must be agreed prior to the meeting.

- Lay representative of the CCG
- General Practitioner member of the CCG commissioning group (not currently a member of the IFR Panel)
- A representative of the CCG board (in addition to the GP representative)
- The CCG Accountable Officer
- A Public Health Consultant

Panel members may cover more than one of these representative functions, e.g. the lay representative could also be the Board representative if one of the Non-Executive Directors is nominated.

All CCG Process Review Panel members must not have been involved in any of the IFR decision making stages.

Administrative support

Meetings will be arranged and resourced by the CCG and managed by their nominated lead officer.

Preparation of agendas and all request papers, recording the outcomes of the meeting, taking any actions arising and ensuring letters are sent to the requesting clinician and patient within agreed timescales is the responsibility of the GM EUR Team on behalf of the CCG.

Ensuring a suitable venue is available is the responsibility of the CCG lead for IFR.

Quoracy

All members of the Panel must be present.

Training of Process Review Panel members

Training of IFR Panel members is the responsibility of the CCG but will be supported by the GM EUR Team.

CCG Process Review Panel members should ensure that they have received adequate and appropriate training.

Confidentiality

All appeals will treated as highly confidential as the majority will contain sensitive and/or clinical information.

Papers will be sent to members via either registered post or a secure e-mail service (NHS net).

Consent will be obtained from the patient prior to the meeting.

All confidential papers will be gathered for shredding at the end of the meeting.

Review

These Terms of Reference will be reviewed annually or sooner if there are relevant changes in legislation or local/national guidance.

Appendix 5: Terms of Reference – Greater Manchester Effective Use of Resources (EUR) Steering Group (v4.0)

Purpose

The Greater Manchester Effective Use of Resources Steering Group (GMEURSG) has been established to support Greater Manchester Clinical Commissioning Groups (GMCCGs) to deliver quality healthcare by developing policy recommendations for the purpose of managing access to healthcare interventions that are unlikely to be clinically effective, or should only be performed in specific circumstances.

Responsibilities

The GMEURSG **will**:

- Manage a GM EUR work programme.
- Prioritise specific policies for development.
- Produce EUR guidance and Policy Recommendations for GMCCGs, including input into policy development and final approval.
- Drive the consideration of GM EUR treatment policy recommendations within GMCCGs.
- Make GM EUR treatment policy recommendations on non-prescribeable devices in collaboration with the Greater Manchester Medicines Management Group (GMMMG) as Clinical Standards Board for Medicines.

The GMEURSG **will not**:

- Make policy or commissioning decisions on behalf of GMCCGs.
- Make policy recommendations on drugs/medicines (this falls under the responsibility of GMMMG).
- Make policy recommendations on interventions covered by a relevant specialist commissioning policy (this falls under the responsibility of NHS England's teams).

Membership

The GMEURSG is a clinical decision making group working on behalf of GMCCGs and members will need to have delegated authority from their individual CCG.

The GMEURSG will seek representation from all GMCCGs and the membership will consist of:

- Chair (GP EUR / IFR Panel Chair)
- Representatives of GMCCGs (IFR Clinical Panel Chairs/Members)
- A GM CCG Commissioning Representative
- Representatives of Greater Manchester Effective Use of Resources Service.

Each member of the group is nominated by the relevant CCG with the understanding that those nominated should be recognised by their respective organisation as representing their views.

Deputising arrangements

- Each CCG **must** appoint a nominated deputy to attend meetings on their behalf. Members must send a representative, preferably with a clinical background and appropriate authority and experience, wherever possible, if they are unable to attend.
- In the absence of the Chair, the meeting will be chaired by the Deputy Chair. The Deputy Chair should be a clinical professional elected by the GMEURSG.

Responsibilities of individual members and deputies

- Accept ownership of GMEURSG decisions.
- Undertake work, as necessary, between meetings, including the review of policies during the development phase.
- Promote communication between the GMEURSG and relevant GMCCG colleagues, including the Joint Commissioning Board (JCB) of Greater Manchester Health and Care Commissioning.
- Take specific views, as appropriate, from the GMEURSG to individual GMCCGs for comment and feed the responses back.
- Commit to regular attendance of GMEURSG meetings to ensure continuity and balance of input into decision making.
- Be an enthusiastic, motivated and active participant in the GMEURSG.

In attendance

Other individuals may be invited to attend the meeting for the purpose of providing advice and/or clarification to the group, for example:

- Secondary care clinicians
- Specialist commissioning representatives
- Clinical network representatives
- Health economic specialists representatives
- GMCCG commissioning representatives

Quorum

For the GMEURSG to be quorate it will require a minimum of 6 CCG clinical representatives to be present and represented at each meeting. If the meeting is quorate then the decisions taken at the meeting will be binding on these CCGs not present. Where quoracy cannot be achieved due to unexpected events, the Chair may decide to proceed with the meeting and ratify any decisions outside of the meeting. In such circumstances, the chair will seek the views of the absent party in order to ratify the decisions taken.

Membership of the group will be reviewed annually.

Meeting frequency

The group will meet bi-monthly. Ad-hoc meetings may be arranged as required.

Communication

Draft minutes and recommendations will be circulated following the meeting to members and ratified in the subsequent meeting. Any inaccuracies within the minutes should be communicated prior to the subsequent meeting, where possible.

Decision making

- Decisions will be made following a full evidence review of the intervention. The group will take into consideration evidence of clinical effectiveness, safety and patient benefits.

- The group believes that health care should be allocated justly and fairly, according to need and the capacity to benefit, such that the health of the population is maximised within the resources available. This means that a treatment of little or no, benefit will not be recommended for commissioning, simply because it is the only treatment available.
- The group will take a consensus approach to decision making where a unanimous view cannot be reached.
- Where there is limited or ambiguous evidence or the topic is clinically controversial, specialists in a particular field may be co-opted to offer expert advice for specific meetings when required, e.g. clinical specialists or health economists. This is at the discretion of the group members and is dependent on the particular intervention being discussed.
- If any upcoming interventions are of particular interest to clinicians, then a written report summary on the new intervention can be submitted for prioritisation by the group. A copy of the report must be received by the EUR Policy Team two weeks prior to the meeting of the group.
- GM EUR policies will be reviewed one year from the date of approval by the Greater Manchester Directors of Commissioning (DOC) / Chief Finance Officers (CFO) and thereafter at a date agreed by the GMEURSG unless new evidence warrants earlier review.

Declaration of conflict of interest

Members will be expected to declare any conflicts of interests and/or an unusual interest or specialist knowledge of a particular area at all meetings and the chair will determine how those discussions will be conducted.

National Institute for Health and Care Excellence (NICE) Guidance

Where a policy statement is subsequently superseded by new NICE Clinical Guidance, the policy statement will be reviewed in line with the new NICE recommendation.

Challenge to policy

All challenges to a policy will be considered by the GM EUR Steering Group.

Appeals against a GM EUR Policy Statement on the basis of the evidence used (either because it is believed that insufficient evidence was taken into account or there is new evidence available) should be directed to the GM EUR Policy Team at: gm.policyfeedback@nhs.net. Such appeals will be reviewed by the GMEURSG and depending on the nature of the appeal; a policy revision will be undertaken. Such policy revisions will be prioritised alongside other policies requiring development.

Reporting

The GMEURSG is accountable to the Greater Manchester Joint Commissioning Board (JCB). Reports containing details of GM EUR treatment policy recommendations that have been developed; along with adoption by each CCG will be provided routinely. The reports will also include details of GM EUR treatment policies that have been recently reviewed.

Reporting to the group

Any sub-group established to undertake business as required, will be accountable to and report to the GMEURSG.

Governance

GM EUR treatment policy recommendations will be formally agreed by the GMEURSG.

GM EUR treatment policy recommendations that have been formally agreed by the GM EUR Steering Group will be considered by the GM DOC/CFOs. The Joint Commissioning Board (JCB) has given GM DOC/CFOs delegated authority to approve the implementation of GM EUR treatment policies across Greater Manchester. The following apply:

- All new GM EUR treatment policies must have DoC/CFO approval to implement.
- If an existing GM EUR treatment policy is later revised and the changes to the commissioning criteria are considered to be material the revised policy would also need DoC/CFO approval to implement.

The governance for getting each EUR treatment policy approved through GM DoCs and GM CFOs will be dependent on the financial implications of each policy:

- If the commissioning criteria in a new GM EUR treatment policy would result in a saving across GM, then the policy would require GM DoC approval to implement. The financial analysis will be produced at a GM level rather than individual CCG level. This approval will be reported at the next GM CFO meeting "for information".
- If the commissioning criteria in a new GM EUR treatment policy would result in an increase in costs of less than £200k across GM then this would not be considered financially material. GM DoCs can approve this policy, under the delegated decision making of each DoC. The financial analysis will be produced at a GM level rather than individual CCG level. This approval will be reported at the next GM CFO meeting "for information".
- If the commissioning criteria would result in an increase of over £200k across GM then it would be considered a material change. A more in-depth financial assessment and report would need to be prepared that shows the impact on each CCG. The GM EUR treatment policy would need to be approved by both GM Docs and GM CFOs.

Once a new or revised GM EUR policy has been ratified by DOC/CFOs the policy will be implemented for Bury, HMR, Manchester, Oldham, Salford, Stockport, T&G, Trafford and Wigan CCGs. Whilst Bolton CCG will take the policy to their Governing Body for ratification before it is implemented for their CCG. Any future requests for that treatment/procedure will be assessed against the GM EUR policy. New and revised GM EUR policies will policies still be taken through individual GM CCG governance arrangements for information only.

Administrative support

- Administrative support, relating to the scheduling of meetings and associated room bookings; ensuring that the meetings are quorate and the cancellation of meetings, where necessary, will be provided by the GM EUR Policy Development Team.
- The GM EUR Policy Development Team will provide administration support for each meeting, this includes: the preparation and dissemination of agenda and papers in advance of the meeting; attendance at each meeting to present policy statements; production of formal minutes to record the decisions taken by the group, and undertaking any necessary actions required by the group.
- Any queries relating to GM EUR treatment policies will be handled by the GM EUR Policy Development Team.

Media enquiries

All media enquiries relating to outputs from the GM EUR Steering Group will be dealt with by the Chair of the Group and the GM Head of EUR with support from the GM Communications Team.

Date TOR agreed

August 2013

Date last updated

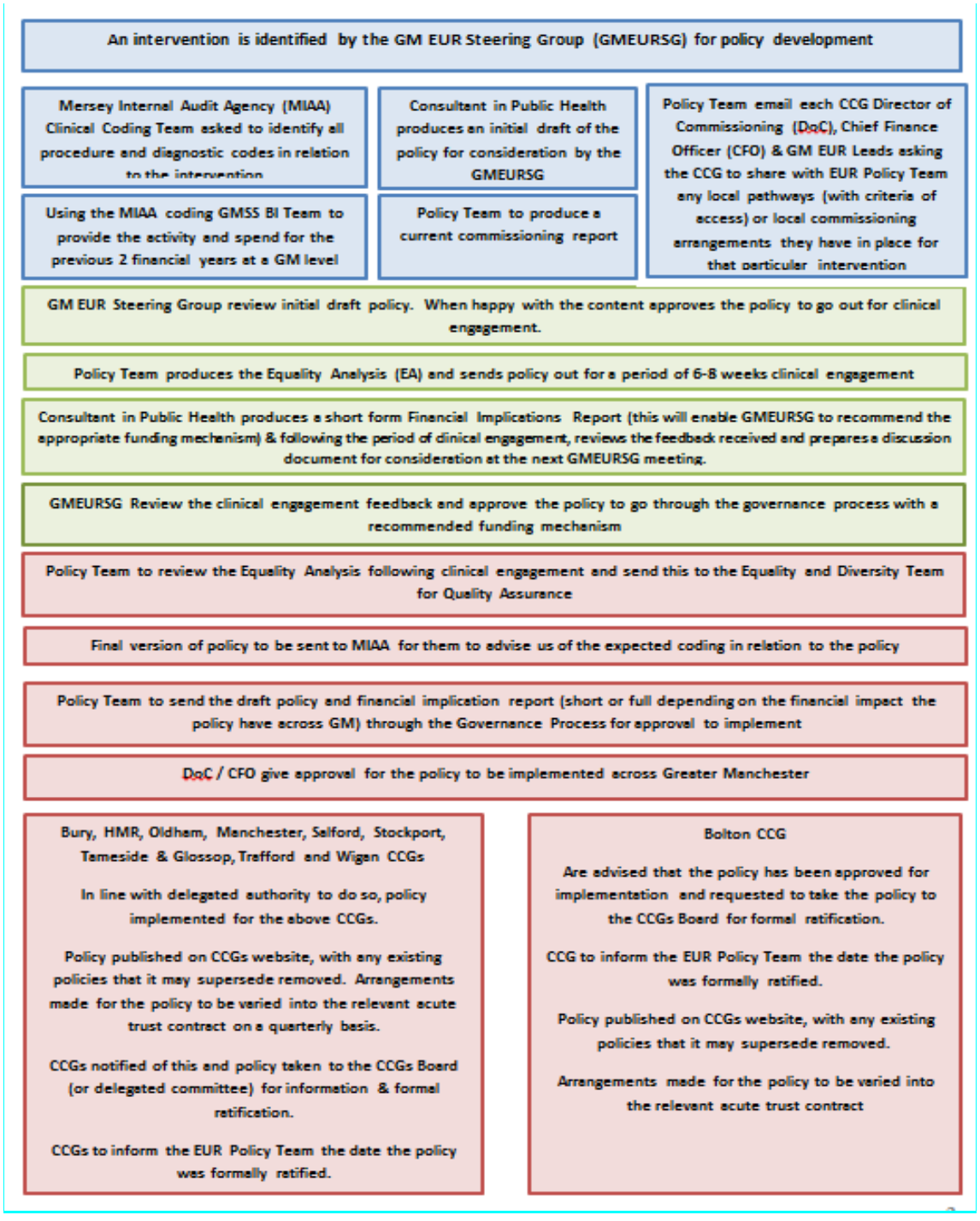
March 2019

Glossary

Term	Definition
Annual commissioning process	Is the process by which major funding decisions are taken, including the allocation of new money coming into the NHS. This involves a complex process of prioritisation informed by a series of decisions.
Clinical effectiveness	A measure of the extent to which a treatment achieves pre-defined clinical outcomes in a target patient population.
Clinical Exceptionality	Described in this document means 'a person to which the general rule is not applicable'.
Clinical Triage	A clinical team which is part of the GM EUR service that will consider the appropriateness of funding an IFR/IPA on behalf of GMCCGs.
Cost effectiveness	An assessment as to whether a healthcare intervention provides value for money.
Effective Use of Resources	An aim to secure the greatest health gain from the resources available for the local population.
Effective Use of Resources Policy	Sets out the funding criteria for specific treatments which may be considered to be of limited clinical value or inappropriate to be funded by the NHS.
Individual Funding Request (IFR) (Exceptional Case)	Is a request submitted by a clinician when a decision has been taken not to commission a specific treatment. Funding will only be approved if there is evidence of clinical exceptional circumstances.
Individual Funding Request (IFR) Panel	The process used by a GMCCG to consider the appropriateness of funding an IFR.
Individual Prior Approval (IPA)	A request submitted by a healthcare provider in accordance with contractual arrangements, which specify that for certain procedures, funding approval is required prior to initiating treatment.
Resource allocation	The process of allocating funding to healthcare providers to meet

	the health needs of the local population based on pre-determined priorities.
Screening	An administrative process to determine if an IFR/IPA meets the criteria specified in EUR policies.

Appendix 6: Flow Chart of the GM EUR Policy Development Process



The Joint Commissioning Board (JCB) has given the Greater Manchester Directors of Commissioning (DoCs) and Greater Manchester Chief Finance Officers (CFOs) delegated authority to approve the implementation of GM EUR Policies across Greater Manchester the following would apply:

- All new GM EUR Policies must have DoC/CFO approval to implement.

- If an existing GM EUR Policy is later revised and the changes to the commissioning criteria are considered to be material the revised policy would also need DoC/CFO approval to implement.

The governance for getting each EUR policy approved through GM DoCs and GM CFOs will be dependent on the financial implications of each policy:

- If the commissioning criteria in a new GM EUR policy would result in a saving across GM, then the policy would require GM DoC approval to implement. The financial analysis will be produced at a GM level rather than individual CCG level. This approval will be reported at the next GM CFO meeting "for information".

- If the commissioning criteria in a new GM EUR policy would result in an increase in costs of less than £200k across GM then this would not be considered financially material. GM DoCs can approve this policy, under the delegated decision making of each DoC. The financial analysis will be produced at a GM level rather than individual CCG level. This approval will be reported at the next GM CFO meeting "for information".

- If the commissioning criteria would result in an increase of over £200k across GM then it would be considered a material change. A more in-depth financial assessment and report would need to be prepared that shows the impact on each CCG. This policy would need to be approved by both GM Docs and GM CFOs.

Appendix 7: General Data Protection Legislation (GDPR)

General Data Protection Legislation

The GM EUR Team processes requests for treatments and procedures for a named patient. Key identifiers are needed to ensure that the team are able to match the request to the right patient and CCG. The EUR service has no control over the identifiers used by clinicians and patients and therefore can't restrict the identifiers used. However we would expect as a minimum expect clinicians to submit requests with included the NHS number.

The information received is processed under the category 'legitimate interests of the data controller'. This is because the purpose (processing a request for funding) can't be processed by any other means as cases are required to be looked at on an individual level. To achieve this there needs to be a flow of clinical information in order to support the decision making process as the service doesn't have access to a patient's medical records.

The GM EUR team holds the following data about patients:

- Name,
- Address,
- Date of birth,
- Diagnoses,
- Relevant past medical history,
- Communications with the patient (or their representative), clinician and/or others involved in a patients care.

The data is held electronically on a secure system and can only be accessed by authorised individuals in order to process a request for a named treatment or procedure. Sometimes the GM EUR Team is required to share this data with other people during the decision making process. These people are other clinicians who work alongside the GM EUR team as well as members of the patient's local Clinical Commissioning Group who are responsible for providing treatments and procedures in the area that the patient lives. The GM EUR Team will only share the minimum information required for the request to be considered, and all information will be handled securely, confidentially and in accordance with the General Data Protection Act 2018. The information will be held for a period of 8 years in line with the NHS's retention policy and will be destroyed confidentially.

If a patient objects to the GM EUR Team sharing their information they are asked to immediately inform the GM EUR Team in writing or via email of this. If a patient does not want the EUR Team to process this information or for it to be shared with the relevant individuals who are responsible for making a decision, then the GM EUR Team may be unable to process the request for funding.

If a patient wish to see what information the GM EUR Team holds on them then they can make a Subject Access Request to the relevant department at their local Clinical Commissioning Group.

If a patient wishes to make a complaint about the way that the GM EUR Team process their data then they should contact the Information Commissioners Office at https://ico.org.uk/ or by telephoning them direct on 0303 123 1113. Alternatively they can write to them at Information Commissioner's Office, Wycliffe House, Water Lane, Wilmslow, SK9 5AF.

Note: The GM EUR Team doesn't have access to patient records and relies upon information provided by the referring clinician.

The above approach was approved by the GM EUR Steering Group on the 18th July 2018 and will reviewed on an annual basis.

Appendix 8: Provider Requirements

General Terms

This appendix has been agreed by the provider and commissioner. Refusal of payment for treatments undertaken must be backed by full contract documentation, either in the form of the GM EUR Operational Policy referenced within a signed contract document, or by an agreed notification letter. Any amendments to the PbR Excluded Drugs and Devices Lists or EUR treatment policies will be notified by letter and must be implemented within 1 month, or other timescale negotiated on a treatment by treatment basis if there are pathway/waiting list implications.

Individual commissioners may, in clinically exceptional circumstances agree treatments that fall outside of the commissioning arrangements described within the policy. Any such arrangements should be agreed in the normal way as detailed in this policy.

The PbR Drugs List, PbR Devices List and CCG EUR treatment List should not be used to delay treatments through the introduction of bureaucratic processes, or as a means of introducing a routine requirement for requests for funding approval as a means of introducing monitoring processes. The above lists, as far as is practically possible, set out the criteria upon which treatments are to be commissioned. The commissioners will work towards having EUR treatment policies included that reflect the criteria and thresholds for undertaking treatments.

It is the responsibility of the provider to ensure that treatments which are contained within the PbR Drugs List, PbR Devices List and CCG EUR treatment List, requiring funding approval are not undertaken without prior commissioner funding approval. Referrals should be returned to the referring primary care clinician if they do not meet the criteria specified.

It is expected that where a primary care clinician wishes to refer a patient for a specific intervention detailed within the PbR Drugs List, PbR Devices List and CCG EUR treatment List, it will be the primary care clinician's responsibility to seek funding approval prior to referring the patient for treatment.

Where a referral is made for a clinical opinion and a clinical decision is taken relating to a treatment contained the PbR Drugs List, PbR Devices List and CCG EUR treatment List, the process for obtaining prior funding approval, as indicated, should be followed by the secondary care clinician.

This policy does NOT apply to those areas managed by other commissioners, e.g. NHS England or areas which are excluded from the EUR service. See section 1.4 of this policy for further details.

If there is ambiguity about whether prior funding approval is or is not required; clarity needs to be sought from the commissioner. Enquiries should be directed to the Greater Manchester EUR Team, who manage the EUR process on behalf of Greater Manchester (GM) CCGs. Email: gmirf.gmcsu@nhs.net Tel: 0161 290 4901.

Urgent requests

On very rare occasions, it may not be possible to request funding approval before the commencement of treatment, for example, where there is a view that treatment must commence on an emergency basis immediately following diagnosis. Under these circumstances, it will be the responsibility of the provider, to decide whether or not the treatment will be given before a decision on funding is received. In any such circumstance, the provider will be required to retrospectively submit an individual prior approval/individual funding request. This will be considered against the same criteria which would apply to a request submitted prior to treatment commencing. Requests after treatment has commenced will not be used by the provider as a route to circumvent the principles set out in this policy. Treatments started prior to funding approval being received and deemed not to be justified by the relevant commissioner, will not be chargeable.

Where there is an urgent clinical need to provide treatment, i.e. failure to provide treatment within 72 hours will have very serious negative consequences for the patient, a funding request should be submitted for consideration. Such requests will be processed in accordance with section 8.6 of this policy.

Retrospective Funding

Individual prior approval/individual funding requests relating to non-emergency/urgent treatment delivered in the past will NOT be funded retrospectively. Please see section 6 of this policy for further details.

Continuation of Treatment following a clinical trial

Commissioners will not normally fund a patient's treatment as a consequence of a registered clinical trial which has ethical and research governance approval. In line with the Medicines Act 2004 and the Declaration of Helsinki, the responsibility for ensuring a clear exit strategy from a trial and that those benefiting from treatment will have ongoing access to it, lies with those conducting the trial. Acute Trusts/Providers must discuss the financial implications with commissioners of on-going clinical trials at least 12 months before funding may be required. Patients must be made aware that funding of new drugs and technologies they are receiving as part of a clinical trial may not be available once the trial comes to an end. Research governance committees need to ensure that financial implications of trials are considered and resolved before agreement is given for trials; they will need to agree exit criteria for trials prior to the trial commencing.

Continuation of a treatment at the end of a clinical trial will only be considered in clinically exceptional circumstances because appropriate post trial arrangements should have been agreed in advance of the trial taking place. An Individual Funding Request (Exceptional Case) Approval request should be submitted.

Experimental and unproven treatments

Where a clinician wishes to use an unproven or experimental treatment for an individual patient, the provider will be expected to obtain Individual Funding Request (exceptional case) approval for the use of the treatment from the relevant commissioner prior to use, even if the treatment is not included on the EUR Treatment List. The GM Experimental and Unproven Treatment Funding Request form should be used.

Introduction of new drugs and technologies

Providers should not introduce new drugs/technologies on an ad-hoc basis through the mechanism of individual prior approval/individual funding requests. To do so risks inequity, since the treatment will not be offered openly and equally to all with equal need. There is also the risk that diversion of resources in this way will destabilise other areas of health care which have been identified as priorities by the commissioners. The commissioner expects consideration of new drugs/technologies to take place within the established planning frameworks of the NHS. This will enable clear prioritisation against other calls for funding and the development of implementation plans which will allow access for all patients with equal need.

In clinically exceptional circumstances, commissioners may consider a business case in year but only if it can be demonstrated that the savings made on superseded treatments will be greater than the investment in the new technology.

Where patterns emerge in individual prior approval or individual funding request applications, the CCG may indicate that these are indicative of a service development, which needs to be considered through the service development funding mechanism.

In order to avoid inappropriate delays in patients receiving new treatments, the trust/provider must ensure that their Horizon Scanning initiatives to identify new drugs and their Drug and Therapeutics Committee process for the approval of new drugs are harmonised. It is the trust's/provider's responsibility to advise the CCG, through the appropriate contracting provision of their decisions.

If Providers approve drug usage on a concessional basis through their Drug and Therapeutic committees, the cost of the drugs will not be passed onto Commissioners.

Continuation of treatment undertaken 'at risk' by a provider or privately by the patient

Where an application is approved on the basis that the patient has demonstrated clinically exceptional circumstances, the commissioner will not accept responsibility for the costs of any treatment provided by the provider trust prior to authorisation being given by the commissioner. A similar approach will be adopted if a treatment has been funded initially by a pharmaceutical company or other third party.

Appendix 9: Version History

Version	Date	Details
0.2	14/06/2013	Consultation – sent to Greater Manchester stakeholders for comments.
0.3	24/07/2013	Review of comments received following consultation. The following significant changes were made: • Inclusion of version control • Inclusion of contact details • Clarification of children's services in paragraph 1.4. • Confirmation that paragraph 2.6 does not apply to prior approvals • Replacement of the word 'or' in paragraph 3.1 with 'and as a result of that difference' • Insertion of a paragraph relating to retrospective funding (paragraph 6 – all following paragraph numbers have been amended to reflect this). • IFR Appeal Panel has been changed to Process Review Panel throughout, including Appendix 4. • Clarification of the role of the Process Review Panel has been included in paragraph 8.5, 8.6 and Appendix 4. • Inclusion of a section relating to roles and responsibilities in Appendix 2. • Amendment to Membership in Appendix 4 to reflect that panel members may cover more than one representative function. • Inclusion of a paragraph in Appendix 5 (Challenge to Policy Section) to reflect that where an appeal is received on the basis of the evidence used to develop the policy, these will be considered by the GM EUR Steering Group.
0.4	07/08/2013	Amended following comments from Greater Manchester EUR Steering Group: • Appendix 5 TOR, GM EUR Steering Group: Membership – second bullet point amended to state 'IFR **Clinical** Panel Chairs/Members. • Deputising Arrangements – first bullet point amended to clarify that nominated deputies do not need to be clinical but must have a clinical background. It would also be the CCG who must appoint a deputy and not individual members. • Insertion of a paragraph relating to conflict of interests.
0.5	03/09/2013	• Amendment to sections 12.4, 12.6, Appendix 2 and Appendix 5 to reflect the governance arrangements agreed by CCG Chief Operating Officers. • Amendment to Quorum paragraph in Appendix 5.
0.6	19/09/2013	Insertion of section 7 to incorporate Referral to Treatment (RTT) Guidance.
0.7	08/10/2013	Amendment to 8.2.1 to reflect that only requests which are the commissioning responsibility of CCGs will be acknowledged within 1 working day.
0.8	20/12/2013	Amendments to sections 12.4, 12.6, 13.0 and final paragraph on page 20 to reflect the governance arrangements agreed by the AGG on the 03/12/2013.
0.9	08/01/2014	Amendments to reflect the current process – amendments made to sections, 2.5, 4.2, 11.2 and 12.7. Removal of section 4.3 (section 4.4 has now been renumbered 4.3). Insertion of section, 11.3.
0.10	16/01/2014	Inclusion of governance arrangements in GM EUR Steering Group Terms of Reference
0.10	14/01/2014	Policy considered by Greater Manchester Heads of Commissioning and Greater Manchester Chief Finance Officers.

1.0	04/02/2014	Policy ratified by Greater Manchester Association Governing Group (AGG).
1.1	07/02/2014	Amendment to section 3.1 (second bullet point in notes) to read: *'Social and/or psychological factors alone will not be taken into account to determine exceptionality. However, they may be taken into account when considering all of the patient's circumstances in the round.'*
1.2	04/06/2014	• Amendment to section 12.4 to reflect revised Greater Manchester Governance arrangements. • Amendment to Appendix 5 – Governance Arrangements to reflect revised Greater Manchester Governance arrangements. • Inclusion of new paragraphs related to GM EUR Policy Review – 12.7, 12.8 and 12.9. Paragraphs 12.10 and 12.11 have been renumbered. • Changed all reference to GMCSU to NWCSU • Amendments to section 1 as follows:- 1.5 clarified what is meant by procedures classed as low clinical value in bullet point 2 - It falls within a CCG Effective Use of Resources Policy, and there is a requirement for commissioner funding approval, because the treatment is not routinely commissioned, or should only be commissioned in specific circumstances.
1.3	12/12/2014	• Amendment to Section 1.5 Bullet point 3 reworded to read – The referrer is the patient's GP or NHS hospital consultant or other clinician. Requests will not be accepted from patients or their relatives/carers. • Amendment to Section 1.5 Bullet point 4 - The CCG has agreed that there should be a prior approval process managed by the GMCSU EUR Service on their behalf has been removed from this section as it is covered in second bullet point in this section. • Amendment to Section 1.5 additional bullet point added to advise the scope of the treatment requests are detailed in section 2.3 • Amendment to Section 2.3 Bullet point 1 - word 'either' removed. • Amendment to Section 2.3 Bullet point 4 changed to read 'those requests where the condition is extremely rare and there is therefore insufficient evidence of cost effectiveness at a population level for the normal commissioning process to apply. • Amendment to Section 2.4 wording changed to read Where a decision is made on an IFR basis and where further requests for the same treatment are anticipated, the NWCSU EUR team will develop commissioning policies or commissioning decision making guidance to be ratified by CCGs. Any such policies/guidance will then be used to inform the decision making process of any future similar or related requests (see section 12.3) This will then be used to inform the decision making process for any future similar or related requests (see section 11.3). • Amendment to Section 2.5 Bullet point 6 to start with 'Review of the available evidence to determine if the…. • Amendment to Section 2.6 Bullet point 1 to read Either the clinician makes an individual request for funding for treatment in connection with a presenting medical condition for which the CCGs have a policy, but the patient does not meet the criteria, and the clinician is claiming that the patient has exceptional clinical circumstances; • Amendment to Section 2.6 Bullet point 4 – slight change to working 'no' removed and likely changed to unlikely. • Removed Section 2.7 • Addition to Section 4 to include 4.4 Patients may access treatment in line with patient choice and if they have been receiving treatment elsewhere in the country when they move back into the Greater Manchester area, they

		can choose to remain with their existing provider outside of Greater Manchester. • Amendment to Section 5.1 to read as follows: Patients have a right to revert from privately funded care to NHS funding at any point during their care, providing the treatment is routinely available. In such circumstances Greater Manchester CCGs will expect their care to transferred to NHS pathways. Where the individual is requesting funding to continue their care within the private facility, which is outside of NHS contracted arrangements, or where the treatment is not routinely available, funding would need to be considered through the IFR process. Patients will need to meet the conditions for approval (see paragraph 2.6). • Amendment to Section 5.2 – following words added to start of first paragraph – 'Relating to co-payment of treatment' …… • 8.4.1; 8.4.2; 8.4.3; 8.5.1; 8.5.2 – the words 'EUR Policy' added before criteria. • 8..5.1 – additional sentences added - It is the role of the clinical triage team to make clinical decisions in accordance with the CCG EUR policy, or where delegated authority has been given following a precedent decision made by a CCG IFR Panel. The clinical triage team may not take decisions on requests which require consideration of exceptionality, but may decide whether a request contains such evidence of clinical exceptionality, which would require consideration by a CCG IFR Panel. • 8.5.2. – removed as this is not the current process • 8.5.3 (now 2) reworded to include '....consensus, or there is evidence of clinical exceptionality or.....' • Added point 8.6.4. Patients are not able to attend panel to present their case • 8.8.1 added the following sentence. Patients may bring along someone to provide support. • 8.7.1 amended to now read 'the provider may initiate treatment, whilst awaiting a funding decision' • Amendment to Section 9 – Appeals Process – taken out that the patient has the right to appeal a decision. Appeals will only be accepted from the requesting clinician. • Amendment to Section 9.1 replaced the word reviewed with reconsidered • Amendment to Section 9.6 to include a final sentence stating 'should the process review panel decide that due process had not been followed, and the IFR panel decision stands, there will be no further recourse of appeal within the CCG.' • Amendment to Appendix 3 – Model Terms of Reference for a CCG Individual Funding Request Panel – Membership – to include:- 'The Panel may co-opt additional members (with or without voting rights as deemed necessary) when required, particularly when specialist expertise is needed and may be establish as sub group to deal with decisions that may include co-opted members, Where a person is to be co-opted onto the panel for the purposes of participating in any of its meetings the decision to co-opt that individual (along with whether or not he or she may have voting rights) shall be put to a vote of the regular voting members at the start of the relevant meeting.' • Amendment to Appendix 4 – Model Terms of Reference for a CCG Process Review - first paragraph reworded to provide further clarity, now reads 'The CCG process review panel will meet on an ad-DoC basis when a clinician acting on a patient's behalf has appealed a panel decision and they have not submitted additional evidence which would require the request to be further considered by the IFR Panel in accordance with the EUR Process. • Membership to include that a member of the original IFR Panel will attend to

		present the case and answer any questions. • Amendments to Appendix 5 – Terms of Reference – Greater Manchester Effective Use of Resources (EUR) Steering Group – Decision Making Under deputising arrangement section changed the work representative to deputy in the second sentence. • Reviews – an annual rather than 2 year review date will be applied to each policy.
1.4	07/06/2016 09/06/2016	Format of policy and references to NWCSU and North West Commissioning Support Unit changed to GMSS and Greater Manchester Shared Services. New GMSS footer added to cover page.
1.5	01/09/2016	• The version control of the document has been moved to end of the document. • Throughout the document 'Head of Effectiveness and Equitable Access' amended to read Head of Effective Use of Resources' <u>Background and Scope</u> • Section 2.3 – The 4th bullet point amended – words 'there is therefore insufficient' replaced by 'it is unlikely there will ever be' • Section 2.4 - The word 'basis' removed from the first sentence and 'GMSS EUR Team will' amended to read EUR Steering Group may'. Last sentence of this section removed. • Section 2.5 - The 3rd sentence in the first paragraph the following has been added '*the Greater Manchester or'*. The following sentence added to the first paragraph '*Some GM EUR policies require specific clinicians to submit an application, please see individual policies for further details*.' The 1st bullet point regarding consent removed. • Following sentence added to the final bullet point *'If not supplied when requested a decision will be made on the basis of the information available at the time.'* • Section 2.6 - The first sentence words *'to be considered'* added after Individual Requests. Also amended to read following *'five'* conditions rather than *'four'* with 5th bullet point added. <u>Determination of Clinical Exceptionality</u> • Section 3 - The word 'clinical' added before each reference to exceptionality. Under '*Note:'* The 1st sentence of the 5th bullet point amended and 2 further sentences added. <u>Ongoing Treatment</u> • Section 4.1 - words 'at the appropriate time' added to final sentence. • Section 4.3 - word 'clinically' added before exceptional circumstances. • Section 4.5 - added <u>Continuing or Additional Privately Funded Care</u> • Section 5.1 – 3rd sentence amended from *'funding would need to be considered through the IFR process'* to read *'an IFR would need to be submitted for consideration through the EUR process'* <u>Retrospective Funding</u> • Section 6.1 - 'IRFs' amended to read 'funding requests' • Section 6.2 - '*GM IFR'* amended to read '*GM EUR'* <u>Request Process and Stages (for Individual Funding Requests and Prior Approvals</u> <u>Acknowledgement</u> • Section 8.1 - removed *'For details of the stages outlined below please refer to the GMSS EUR Standard Operating Procedures document. A copy of the GMSS EUR Standard Operating Procedures may be requested by emailing the GMSS policy team at policyfeedback.gmcsu@nhs.net.'*

		Checking • Section 8.2.1 – The following NOTE' has been added *'it is the responsibility of the referring clinician to ensure that the request is sent to the appropriate organisation. Where a clinician is unsure they should contact the relevant organisation (NHSE for example) to discuss the case'.* Screening • Section 8.3.1 – Following added as the second sentence '*Applications need to contain sufficient information to allow the request to be assessed against the mandatory criteria in the policy.'* • The final 2 sentences have been amended from '*Initially, these will be the EUR policies developed by the relevant PCT. PCT policies will gradually be replaced by GM policies, agreed and ratified by the CCGs'* to read '*These will be the Greater Manchester EUR policies or where applicable local policy statements inherited from local predecessor organisations'.* • Section 8.3.2 - has been amended regarding information contained in the funding application. • Section 8.3.5 – Following words added to the first section *'(this is not ordinarily cited by others)'* and a second sentence added as follows '*Where clinical exceptionality is claimed on the basis of conditions normally cited the request will be declined in line with the appropriate GM EUR policy or local policy statement.'* Clinical Triage • Section 8.4.1 - has been amended regarding the clinical triage group • Section 8.4.4 – added regarding requests for ongoing treatment. IFR Panels • Section 8.5.5 – added regarding notification of panel decisions Clarification of the IFR Process – Meetings with Patients • Section 8.7.1 – amended Appeals Process • Section 9.1 – has been amended regarding if a clinician disagrees with the decision • Section 9.2 – amended. • Section 9.3 – removed *'If the above stages have all been followed and the patient and the requesting clinician is still disagrees with the decision they can request a CCG process review panel, who will undertake a review of the process followed to reach that decision.'* • Section 9.3 (previously 9.4) – In first sentence words *'the appeal against an IFR panel been received* replaced with *'receiving a written request for a process review from a clinician.'* • Section 9.7 – added regarding new funding requests for the same condition/treatment that have previously been declined by an IFR Panel. Timescales • Section 10.1 – removed regarding timescales in the Standard Operating Procedures. • Section 10.2 now 10.1 - first sentence amended and sentence added to the end of the paragraph. Policy Development • Sections 12.2 & 12.3 – have been amended to reflect the current position. • Section 12.4 – Following sentence added after the first sentence:- '*Once a GM EUR policy recommendation has been formally agreed by the GM EUR Steering Group the policy will be sent to Mersey Internal Audit Agency to identify which procedure and diagnostic code are relevant to the policy*.' • Section 12.6 – *'full/restricted consultation'* amended to read '*a period of clinical engagement'* • Section 12.7 - In the first sentence *'and annually thereafter*' amended to

		read *'and thereafter at a date agreed by the GM EUR Steering Group unless new evidence warrants earlier review* (*see section 13 – Policy Review)..*' The rest of this section has been moved to Section 13 – Policy Review. • Section 12.10 – 'consultation' amended to 'clinical engagement' in the first sentence. <u>Policy Review</u> • Amended to reflect the new arrangements for review of GM EUR Policies. <u>Appendix 1: Ethical Framework</u> • Clinical Exceptional Need - 'Exceptional Need' amended to read 'Clinical Exceptional Need' • Third sentence amended from *'The GM EUR operational policy outlines the procedures that are in place to consider such exceptional requests on their merits.'* to read *'The GM EUR operational policy outlines the procedures that are in place to consider such requests that a referring clinician considers to be clinically exceptional on their individual merits.'* <u>Appendix 2 Governance & Accountability</u> • 6th paragraph reworded and 3rd sentence removed • 8th paragraph 'EUR Officer' amended to read 'EUR Senior Officers'. • 9th paragraph 'IFR' amended to read 'funding'. <u>Appendix 3 – Terms of Reference for CCG Individual Funding Request Panel</u> • The word 'Model' changed to 'Example' in the title of this section and (Please refer to individual CCG's own ToR) added <u>Appendix 4 – Terms of Reference for CCG Process Review Panel</u> • The word 'Model' changed to 'Example' in the title of this section and (Please refer to individual CCG's own ToR) added <u>Appendix 5 – Terms of Reference – Greater Manchester Effective Use of Resources (EUR) Steering Group</u> • Reviews - amended from *'An annual review date will be applied to each policy statement unless further information is likely before this period'* to read '*Greater Manchester EUR Policy Recommendations will be reviewed one year from the date of approval by the AGG and thereafter at a date agreed by the GM EUR Steering Group unless new evidence warrants earlier review*' • Governance – following added as second sentence in this section '*Once a GM EUR policy recommendation has been formally agreed by the GM EUR Steering Group the policy will be sent to Mersey Internal Audit Agency to identify which procedure and diagnostic code are relevant to the policy.*' • Administrative Support – Final bullet point amended to read EUR Policy Team • Glossary – Exceptionality amended to read Clinical Exceptionality
1.6	07/10/2016	<u>Section 1 - Introduction</u> • Following sentence removed from section 1.3 '*It will build on earlier Greater Manchester EUR/IFR policies.'* • The following bullet point added to section 1.5 *'Requires the use of e-requests. It is expected the GP practices will use the electronic version of the procedure/treatment specific funding request forms from the 1st April 2017. This is in line with the move to a paperless NHS by 2018.'* <u>Section 2 - Background and Scope</u> • Section 2.3 Final bullet point, final sentence word 'Individual' add before Prior Approvals and '(IPA's) in brackets at the end of the sentence. • Section 2.5 First bullet point, 'referring clinician' amended to read 'requesting clinician' • Section 2.5 Final bullet point reworded from:- • 'Requesting photographs where relevant in support of an objective decision.

		These should be non-identifiable and relevant to the request. If not supplied when requested a decision will be made on the basis of the information available at the time.' • To read:- • *'Requesting non-identifiable photographs, preferably medical illustrations if available to support the decision making process. It should be noted that it is <u>not</u> mandatory for photographs to be provided by the patient and any photographs received will not form the sole basis of the decision. These should be and relevant to the request. If not supplied when requested a decision will be made on the basis of the information available at the time.'* <u>Section 3 - Determination of Clinical Exceptionality</u> • First paragraph in 3.1 reworded from: *'Clinical Exceptionality means 'a person to which the general rule is not applicable'. Greater Manchester sets out the following guidance in terms of determining clinical exceptionality; however the over-riding question which the IFR process must answer is whether each patient applying for clinical exceptional funding has demonstrated that his/her circumstances are clinically exceptional. A patient may be able to demonstrate clinical exceptionality by showing that s/he is:'* • To read: *'Clinical Exceptionality means 'a person to which the general rule is not applicable'. Greater Manchester sets out the following guidance in terms of determining clinical exceptionality; however the over-riding question which the IFR process must answer is whether each clinician claiming clinical exceptionality on behalf of their patient has demonstrated that his/her circumstances are clinically exceptional. A clinician together with the patient may be able to demonstrate clinical exceptionality by showing that s/he is:'* <u>Section 4 - Ongoing Treatment</u> • Section 4.5 - Reword from: *'If an IFR panel has approved treatment previously and has not advised of any restrictions on ongoing care, continuing treatment can be agreed by the clinical triage if clinically appropriate. The case will be referred back to panel if clinical triage believes this is indicated.'* • *To read: '*If an IFR panel has approved treatment previously and has not advised of any restrictions on ongoing care, continuation of treatment can be agreed by the clinical triage team if clinically appropriate. The case will be referred back to panel if the clinical triage team believes this is indicated.' <u>Section 9 - Appeal Process</u> • Section 9.3 Reworded from: *'It is the responsibility of the relevant CCG to convene and resource the process review panel within 3 months of receiving a written request for a process review from a clinician. A request for a process review will not be accepted from a patient. The GMSS EUR team will provide all the required information, prepare the papers and support the CCG process review panel meeting.'* • To read: *'It is the responsibility of the relevant CCG to convene and resource the process review panel within 3 months of receiving a written request for a process review from a clinician. If the patient or clinician request the process review to be re-arranged or a conflict of interest is discovered, the CCG will have 3 months to reconvene and resource the process review panel from the date of this being notified to the CCG. The CCG will however make every effort to reconvene as soon as possible. The GMSS EUR team will provide all the required information, prepare the papers and support the CCG process review panel meeting.'* • Section 9.7 following words added to the end of the last sentence '*and will not progress through the EUR Process'*.
1.7	01/11/2016	<u>Section 14 - GP Clinical Systems</u> • 14.1 GMSS Effective Use of Resources and Data Quality Teams will work

		together to develop, implement and maintain GP clinical systems that will allow easy access to EUR policies for GP practice staff. • 14.2 New GM EUR Policies will be added to the clinical systems on a quarterly basis e.g. July, October, January and April once these have been ratified by all 12 GM CCGs. • 14.3 It is expected the GP practices will use the electronic version of the procedure/treatment specific funding request forms from the 1 April 2017. This is in line with the move to a paperless NHS by 2018.
1.8	06/12/2016	Section 10 - Timescales - added the timescales taken for acknowledging and processing funding requests.
2.0	23/12/2016	Changes made to the GM EUR Operational Policy since it was ratified by the AGG in February 2014 were reviewed by the AGG virtually during December 2016. The AGG proposed the following changes be made:- • All references to 'Heads of Commissioning' in the policy changed to 'Directors of Commissioning'. Section 1 - Introduction • Bullet point 4 to be reworded from 'It is expected that GP practices will use the electronic version of the procedure/treatment specific funding request forms from the 1st April 2017.' To now read 'GP practices will be encouraged, through appropriate support, to use the electronic version of the procedure/treatment specific funding request forms from the 1st April 2017.' Section 7 - Referral to Treatment Times (RTT) • Bullet point 7.1 the words 'Individual Prior Approval (IPA)' added to the second sentence before the word requests. '(see Section10)' added at the end of the third sentence. • Added bullet point 7.2 - Where a clinician is submitting a funding request for consideration on the grounds of clinic exceptionality RTT will only apply once a CCG has confirmed funding approval. Section 8 - Request Process and Stages • Bullet point 8.3.5 the words "that is not ordinarily cited by others" have been removed. Also the words 'a decision' at the end of the first sentence replaced by 'review'. Section 9 - Appeals Process • Under bullet point 9.1 the following sentence has been removed 'Appeals will not be accepted from a patient.' • Under bullet point 9.2 the following sentence has been removed 'A request for a process review will not be accepted from the patient.' Section 10 - Timescales • Under bullet point 10.2 in the first sentence of the second paragraph and the first sentence of the third paragraph the words 'aims to process these' has been replaced with 'will process these'. (see section 7.2) added to the end of the second and third paragraphs. Section 14 • 'GP Clinical Systems' removed • Section 14 - Delivery Outputs added Glossary Section • Individual Funding Request - has been reworded for clarity. Subject to the above changes being made the AGG approved that the updated version of the EUR Operational Policy could be implemented (Version 2.0).
2.1	26/05/2017	• Section 8.6 title changed from 'Urgent Requests' to 'Urgent Requests/Priority Cases' • The following wording added as clause 8.6.3:

		'Priority cases are those where a treatment needs to be given within a certain timeframe that does not allow enough time for the request to be prepared for panel consideration ***NOTE:*** *This excludes those cases where treatment has been booked prior to authorisation being received.* *Where a clinician has stated that a case requires an urgent response but that case does not meet the GM EUR definition of urgent i.e. intervention within 72, then provided a clinical case has been made by the referring clinician that case will treated as a priority case. Cases where the GMSS EUR Team whilst screening the request is of the opinion that a request is time sensitive this will then be prioritised.* *Examples are:* • *Drugs needed for severe cases of the disease being treated* • *Eating Disorders where there is rapid weight loss or the BMI is dangerously low* • *EEA/Cross Border Team Requests that have a short response time attached to them ,* • *Negative Pressure Wound Therapy (NPWT/VAC)* • *IVF if female is nearing the age cut-off for accessing the treatment and delay in processing will prevent treatment starting before the cut-off date* • *Mental Health Cases (not excluded from the service) where a place of safety is needed'*
3.0	24/11/2017	Policy reviewed and the following changes made: • *GMSS 'IFR' Team* changed to *GMSS 'EUR' Team* throughout the document. • Contact Details – *Enquiries relating to 'an Individual Funding Request (IFR)'* changed to '*Enquiries relating to a funding request*'. Section 1 – Introduction and Purpose • 1.3 - *'(exception cases)'* added after '*Individual Funding Requests (IFRs)'* in the first sentence. • 1.4 - Following added to end of last sentence: *'unless by prior agreement with GMSS and costed accordingly.'* • Section 2 - Background and Scope: 2.6 - *'Funding'* in the first sentence added between *'Individual'* and *'Requests'. 'Either'* deleted from beginning of the first bullet point. • Section 4 - Ongoing Treatment: Bullet point added to 4.6: '*Patients are entitled to request a second consultant opinion within an NHS funded clinic. Third or fourth opinions for the same clinical condition will not normally be supported unless there are extenuating circumstances.'* • Section 8 - Request Process and Stages • 8.2.1 - *'12'* deleted from before 'GMCCGs' and NHS England link updated. • 8.5.1 - '*Each CCG IFR Panel will have a named GMSS EUR Team member as their contact person within the GMSS EUR Team*.' Deleted from final sentence. • 8.6.1 - First sentence slightly reworded for clarity. • 8.6.2 - *'Exact details of the urgent request procedure for each CCG can be found in the GMSS EUR Standard Operating Procedures.'* changed to: *'The EUR Service has agreed with each GM CCG a process for handling urgent requests that require IFR Panel consideration.'* • 8.7.1 - '*an IFR'* changed to '*funding request'.* Section 9 – Appeals Process • 9.1 - *'unless they are of the opinion a key piece of information has not been taken into consideration'* added to end of the third sentence and NOTE reworded from *'Appeals against a decision made by an IFR Panel can't be considered as an IFR Panel decision is final; however if further information is submitted which the IFR Panel have not considered then a case may be*

		referred back to an IFR Panel in order for a decision to be made.' to: *'Appeals against a decision made by an IFR Panel can't be considered as an IFR Panel decision is final; however if further information is submitted which the IFR Panel has not considered then a case will be reviewed and if this information has not been previously considered will be referred back to an IFR Panel in order for further consideration'.* • 9.7 – Second sentence reworded from *'If the new funding request does not contain any new clinical information the request will be rejected and closed and will not progress through the EUR Process.'* to: *'The new funding request will be reviewed against the previous request by the Clinical Triage Team and if it does not contain any new clinical information the request will be rejected and closed and will not progress through the EUR Process.'* <u>Section 10 – Timescales</u> • 10.2 - *'of'* removed before *'the request was received'* in the first sentence. • 10.3 - '*or the file closed if there is insufficient information to reach a decision*' added to the end of the first sentence. <u>Section 12 – Policy Development</u> • 12.2 - *'policy'* changed to *'policies'* in the final sentence. • 12.4 - *'inherited PCT policy'* replaced by *'local CCG policy for that treatment/procedure'* In the final sentence *'IFRs'* replaced with *'funding requests'* • 12.9 - *'will be undertaken'* replaced by *'may be undertaken'* in the first sentence. In the second sentence the word *'revisions'* replaced by *'reviews'.* • <u>Section 13 - Policy Review:</u> 13.2 – *'CCG'* added before *'governance process'* in the final sentence. • <u>Appendix 2: Governance and Accountability:</u> 1^{3th} paragraph reworded from: *'Training for the members of the GMSS EUR Team the Clinical Triage team and the IFR Panels as well as the Process Review Panel will be organised when training needs are agreed with the GMSS EUR Team. This will cover healthcare ethics, communicating with patients, evaluation of evidence and legal issues among others.'* to: *'Training of IFR Panel members and Process Review Panel members will be the responsibility of the individual CCGs.'* • <u>Appendix 5: Terms of Reference – Greater Manchester Effective Use of Resources (EUR) Steering Group:</u> Updated version added following review by the GM EUR Steering Group at their November 2017 meeting.
4.0	27/03/2019	Branding updated from Greater Manchester Shared Services to Greater Manchester Health Care Commissioning. GMSS EUR Service amended to read GM EUR Service and GMSS EUR Policy Team amended to read GM EUR Policy Development Team throughout the document. 'GM EUR policy' amended to read 'GM EUR treatment policy' for consistency throughout the document'. The term 'application' changed to 'request' throughout the document and 'referring' clinician changed to 'requesting' clinician. Section 1 Introduction and Purpose – Point 1.7 (Access Schemes) added. <u>Section 1.5 Electronic Requests</u> – the words 'Also see section 8.1' added to the end of the 4th bullet point.

		Section 3 Determination of Clinical Exceptionality – Updated in line with NHS England's Commissioning Policy: Individual Funding Requests. Section 4 Ongoing Treatment. Following sentences removed for 4.2 'If there is evidence of effectiveness at an individual level, even if this is not the case at a population level, then ongoing treatment is likely to be approved. Where approval was time limited or subject to evidence of effectiveness, funding approval for continued treatment would need to be sought at the end of the agreed period. Section 7 Referral to Treatment Times (RTT) 7.2 reworded for clarity. Section 8 Request Process and Stages (for IFRs & IPAs) 8.1 'Acknowledgements' removed and Replaced by 8.1 'Request Submissions'. 8.8 Length of time funding approval is valid added Section 9 Appeals Process 9.1 Reworded for clarity. Section 10 Timescales 10.1 '*All requests for CCG approval will be acknowledged within 1 working day of receipt (as date stamped)'* has been removed and replaced with *Funding requests must be considered carefully and with the benefit of all the required information. Clinicians are encouraged to submit funding requests in a timely manner which has regard to the standard decision-making timescales set out below. As far as possible clinicians should avoid waiting until a request becomes urgent.'* Section 11 Implementation and Process Improvement Point 11.1 has been removed '*The GM Head of EUR in partnership with the Chairpersons of the CCG IFR Panels is responsible for implementing the GM EUR Operational Policy and GM policies related to drugs, procedures and devices, and for EUR decision making and budgetary control.' and subsequent points renumbered.* Section 12 Policy Development Points 12.4 onwards amended to reflect updated process. Point 12.11 Removed – '*The Clinical Governance process will be used to provide the required quality assurance for this area of work'* Section 13 Policy Review 13.1 'AGG' changed to 'GM DOC/CFOs' 13.2 'CCG' removed from final sentence 13.4 Added Section 14.1 Delivery Outputs Changed from 'Delivery Outputs of GM EUR Policy Development Process to read 'Delivery Outputs of GM EUR Service'. Additional bullet points added to reflect this change. Section 15 Changes to Funding Mechanisms – Section added. Appendix 2 Governance and Accountability

		Final paragraph reworded from 'The AGG will ratify GM EUR Policy Recommendations as a Level A decision. However, CCGs may choose to veto this decision, which will allow them to locally ratify GM EUR Policy Recommendations through their own governance route, or to implement alternative policies that it has developed through its own mechanisms.' To 'The GM DOC/CFOs will ratify GM EUR Policy recommendations for implementation.' <u>Appendix 6 - Flow Chart of the GM EUR Policy Development Process</u> - added <u>Appendix 7 – General Data Protection Legislation (GDPR)</u> – added
	10/06/2019	<u>Section 7 Referral to Treatment Times (RTT)</u> 7.2 Amended to read - Where a 'primary care' clinician <u>Section 10 Timescales</u> – Updated to include a definition of the different types of funding mechanisms. <u>Section 9 Appeal Process</u> 9.1 First paragraph reworded from '*If a patient wishes to appeal against a decision made at screening or clinical triage then they should in the first instance discuss this with the clinician who has submitted the request. This is because appeals will not be accepted without the support of the clinician who submitted the request.'* TO *An appeal against a decision made at screening or clinical triage must come from the clinician who submitted the request.* Second paragraph, third sentence amended from – '*Appeals will not be accepted simply because the requesting clinician and/or the patient disagree with the decision, unless <u>they</u> are of the opinion a key piece of information has not been taken into consideration.*' TO '*Appeals will not be accepted simply because the requesting clinician and/or the patient disagree with the decision, unless the clinician is of the opinion a key piece of information has not been taken into consideration.'* <u>Appendix 5 – Terms of Reference – Greater Manchester Effective Use of Resources (EUR) Steering Group</u> updated to v4.0 following review by the GM EUR Steering Group.
4.1	14/10/2019	<u>Section 5 - The National Institute for Health and Care Excellence (NICE)</u> This section has been added and subsequent sections reworded. <u>Section 9.1 - Request Submission</u> The first paragraph has been amended from '*Since the beginning of 2017 treatment specific funding request forms have been available for GM EUR treatment policies on GP clinical systems and for Acute Trusts on the EUR Treatment List contained within the EUR Schedule.* ' To '*Since the beginning of 2017 treatment specific funding request forms have been available for GM EUR treatment policies on GP clinical systems and for providers on the EUR Treatment List contained within the GM Prior Approval Scheme of the NHS Contract'* 9.1.2 – The following sentences have been added '*Where no treatment specific funding request form is available the GM Generic EUR Treatment form*

		should be used. All forms must be completed by a clinician. Forms will not be accepted where this has been completed by the patient.' Section 9.3 Screening Added '*9.3.6 Decisions will be notified within 2 working days of the date of the decision'* Section 9.6 - Urgent requests/priority cases Removed the following bullet point from the examples in 9.6.3 • Negative Pressure Wound Therapy (NPWT/VAC). Section 11 – Timescales and Funding Mechanisms The following have been added:- 11.5 Screening decisions will be notified within two working days of the date of the decision. 11.6 Clinical Triage decisions will be notified within two working days of the date of the GM Clinical Triage meeting 11.7 IFR Panel decisions will be notified within two working days of the date of the minutes being ratified by the Chair of the IFR Panel. Section 15 – Delivery Outputs The words '/EUR Schedules to incorporate into provider contracts' have been removed from the 9th bullet point. The following bullet point has been amended from:- *'The co-ordination of contract variations in line with agreed GM EUR treatment policies changes'* To *'The co-ordination of notification letters to CCG Contract Leads advising of any changes to the PbR Drugs List, PbR devices List and CCG EUR Treatment Lists.'* Appendix 8 – Provider Requirements added
4.2	13/02/2020	The Greater Manchester (GM) Effective Use of Resources (EUR) Policy Team and EUR Team contact telephone numbers updated.
4.3	20/05/2020	Email addresses of GM EUR Team and GM EUR Policy Team updated.