Bedfordshire, Luton and Milton Keynes Integrated Care Board

Individual Funding Request (IFR) Policy

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Version	**Date**	**Reviewer(s)**	**Revision Description**
V1.0	01-07-2022		Amendment made to reflect • The Quality and Performance Committee to oversee arrangements for managing Individual Funding Requests. • The Policy approval delegated to the Operational Group.
V1.1	14-02-2023	Audit & Compliance Team and Exceptional Cases Panel	Full policy review resulting in the following: Removal of patient from feedback due to anonymity. No funding for interventions where a business case has been instigated. Requirement for evidence of IFR agreed by another ICB to enable continuation of funding. Responsibilities in relation to urgent IFRs. Time period for previous patients likely to be in the same or similar clinical circumstances as current patient changed from 'in the previous financial year' to 'in the previous 12 months'. Minor amendments to update roles, links, names and information throughout the policy and where necessary, content revised to provide clarity and consistency.
V2.0	21-10-2024		Approved by the Operational Group

Implementation Plan

Development and Consultation:	The following individuals were consulted and involved in the development of this document: ▪ Bedfordshire, Luton and Milton Keynes Clinical Commissioning Group's IFR Steering Group
Dissemination:	Staff can access this document via the website and will be notified of new / revised versions via the staff briefing emails This document will be included in the organisation's Publication Scheme in compliance with the Freedom of Information Act 2000.
Training:	The following training will be provided to make sure compliance with this document is understood: ▪ In house training will be provided to relevant staff and externally sourced training will be provided as required
Monitoring:	Monitoring and compliance of this document will be carried out via: ▪ The annual report to the Quality and Performance Committee
Review:	The Document Owner will ensure this document is reviewed in accordance with the review date on page 2.
Equality, Diversity and Privacy:	Appendix 1- Equality Impact Assessment Appendix 2- Data Protection Impact Assessment
Associated Documents:	The following documents must be read in conjunction with this document: ▪ All appendices and references including those outlined at section 2 of this policy.
References:	The following articles were accessed and used to inform the development of this document: ▪ NHS Constitution-Department of Health ▪ NHS England (2018) Evidenced Based Interventions: Guidance for CCGs ▪ NHS England (2017) Commissioning Policy: Individual Funding Requests. ▪ The Equality Act (2010) ▪ NHS England (2020) Who pays? Determining which NHS Commissioner is Responsible for making payment to a Provider

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1 Introduction

1.1 NHS Bedfordshire, Luton and Milton Keynes Integrated Care Board (the ICB) aims to ensure robust governance through its formal written procedural documents, such as this document, which communicate standard organisational ways of working. These documents help clarify operational requirements and consistency within day-to-day practice. They can improve the quality of work, increase the successful achievement of objectives and support patient safety, quality and experience. The ICB aims to ensure its procedural documents are user friendly, up-to-date and easily accessible.

1.2 The ICB must design and implement procedural documents that meet the diverse needs of our service and workforce, ensuring that none is placed at a disadvantage over others, in accordance with the Equality Act 2010. The Equality Impact Assessment initial screening, which was used to determine the potential impact this policy might have with respect to the individual protected characteristics is incorporated at Appendix 1.

1.3 A Data Protection Impact Assessment is a process which helps assess privacy risks to individuals in the collection, use and disclosure of personal information. The Data Protection Impact Assessment initial screening, which was used to determine the potential impact this policy might have with respect to an individual's privacy is incorporated at Appendix 2.

1.4 It is the statutory duty of the NHS to provide comprehensive healthcare within the resources available. The ICB receives a fixed budget from the Government to commission (buy) health services for the Bedfordshire, Luton and Milton Keynes population. The treatments funded by the ICB are those regarded as safe, effective and evidence based providing the best value to patients in terms of health outcomes.

1.5 **Plain Language Summary of the Individual Funding Request (IFR) Policy**
On an individual basis, there may be situations where a clinician believes that their patient's clinical presentation is exceptionally different to other patients with the same condition and that they should have their treatment paid for when other patients would not. In such cases, NHS clinicians can ask the ICB to fund a treatment which would not normally be provided by the NHS for that patient. The requesting clinician is required to explain the expected outcomes of the treatment and why they consider the treatment is a good use of NHS resources. This request for funding is known as an Individual Funding Request (IFR). A plain language information leaflet 'IFR - a brief guide for patients' (Reference 1) is available on the ICB's website at www.bedfordshirelutonandmiltonkeynes.icb.nhs.uk/what-we-do/individual-funding-requests/individual-funding-request-ifr-policy-process-and-resources/

1.6 Not all treatments can be provided by the NHS and the decision to provide one treatment directly reduces the resources available for other treatments and services. The fact that the ICB is not funding a healthcare need due to resource constraints does not indicate that the ICB is breaching its statutory obligations.

1.7 The ICB makes decisions using a prioritisation process as to which treatments to commission, and as far as possible ensure the fair allocation of resources for its population in line with the NHS Constitution.

1.8 The commissioning process by its very nature focuses on cohorts of patients. The ICB regards funding for an individual patient as an equity matter. Funding a particular treatment for a patient when others from the same patient group are not routinely funded for the requested treatment must be carefully considered and justified.

1.9 The IFR Policy and Process will ensure that each IFR is considered in a fair and transparent way. The ICB's IFR Service will carry out an initial screening of the IFR and a Clinical Triage process will determine if the IFR meets this policy criteria. If the IFR proceeds beyond this stage, the case will be heard by the ICB's Exceptional Cases Panel. Further details are described at section 6 and in Appendices 3a and 3b. Decisions are based on the best available evidence and in accordance with the ICB's Ethical and Commissioning Principles at Appendix 4.

1.10 This Policy sets out the ICB's principles, processes and responsibilities in relation to IFRs and how requests for treatment that fall outside of existing policies and service agreements will be processed for Bedfordshire, Luton and Milton Keynes patients.

1.11 The IFR Policy, appendices to the Policy and references can be found on the ICB's website: www.bedfordshirelutonandmiltonkeynes.icb.nhs.uk/what-we-do/individual-funding-requests/individual-funding-request-ifr-policy-process-and-resources/

2 Scope

2.1 This Policy applies to all ICB staff members, including Board Members of the ICB, and Practice Representatives involved in the ICB's Policy making processes, whether permanent, temporary or contracted-in under a contract for service (either as an individual or through a third party supplier). This Policy also applies to patients registered with a GP Practice in Bedfordshire, Luton and Milton Keynes.

2.2 This Policy applies as appropriate, to all Providers of healthcare to the ICB's patients and covers the following:

- All IFR applications received on the IFR application form for adults and children where the ICB is the responsible commissioner
- The principles and arrangements to consider funding that does not fall within existing ICB contracts
- The processes in place to manage IFRs and IFR appeals
- The structure and functions of the ICB's IFR Service and Exceptional Cases Panel

2.3 **Determining the Responsible Commissioner**

2.3.1 In accordance with NHS England's policy 'Who Pays? Determining Responsibility for Payments to Providers', the ICB is responsible for assessing needs and commissioning health services to meet all the reasonable requirements of its patients with the exception of:

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

2.3.2 NHS England has its own policies for handling requests for treatments and services on behalf of the above patients and these can be found at the following links:

- www.england.nhs.uk/publication/commissioning-policy-individual-funding-requests/
- www.england.nhs.uk/publication/manual-for-prescribed-specialised-services/
- www.england.nhs.uk/publication/nhs-england-drugs-list/

2.3.3 Where the IFR Service identifies that the patient is the responsibility of another Integrated Care Board, the requesting clinician will be notified.

2.4 Clinical Policies

2.4.1 There is widespread clinical consensus that NHS resources could be more appropriately targeted towards more clinically effective, safe and cost effective interventions. At a time when demand is exceeding the capacity available, effective use of resources is both a national and local priority. The ICB uses national and local policies, the National Institute for Health and Care Excellence Guidance and Technical Appraisals as well as Evidenced Based Interventions to prioritise treatments based on available resources and competing demands.

2.4.2 **The ICB's Clinical Effectiveness Service** provides a framework for the delivery of clinical policy development that is open, transparent and compliant with the ICB's statutory duties and NHS principles. The service supports value for money and quality improvement of the ICB's commissioned services by consistently utilising an evidence based approach to clinical policy review.

2.4.3 **The Evidence Based Interventions (EBI) Programme** is a national programme, established and developed as a joint enterprise between the following national partners: the Academy of Medical Royal Colleges, NHS Clinical Commissioners, The National Institute for Health and Care Excellence (NICE) as well as NHS England and Improvement. Further information is available at: www.england.nhs.uk/evidence-based-interventions

2.4.4 **The ICB's Evidence Based Intervention (EBI) Clinical Policies** and High Cost Drug Policies set specific clinical criteria that a patient must meet before treatment takes place. Policies also state when treatment is not normally funded for patients unless there are exceptional clinical circumstances. The aim of EBI policies is to prevent avoidable harm to patients, avoid unnecessary procedures, and to free up clinical time by only offering treatment on the NHS that is evidence based and appropriate.

2.4.4.1 Treatments that are not normally funded or are funded based on a criteria agreed by the ICB are detailed in EBI Clinical Policies. All the ICB's EBI Clinical Policies are available at: www.bedfordshirelutonandmiltonkeynes.icb.nhs.uk/what-we-do/individual-funding-requests/evidence-based-intervention-policies-2/
High Cost Drug (HCD) Commissioning Policies and position statements are available at: www.medicines.bedfordshirelutonandmiltonkeynes.icb.nhs.uk/

2.4.4.2 The ICB's EBI Clinical Policies and HCD Commissioning Policies are published following robust clinical evidence review, appraisal and guidance from the following bodies:

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

2.4.6 **BLMK ICB's Clinical Policy Review Group** supports the ICB with Evidenced Based Intervention clinical policy reviews and the development of new clinical policies.

2.4.7 **The BLMK Area Prescribing Committee** consists of ICB and Hospital Trust representatives (medical, pharmaceutical and commissioning) and makes recommendations on the managed introduction of new drugs and prescribing issues that arise across the primary and secondary care interface. Further information is available at: www.medicines.bedfordshirelutonandmiltonkeynes.icb.nhs.uk/

2.4.8 **Requests for Patients in European Economic Areas (EEA)**
NHS England (NHSE) is responsible for receiving, processing and making determinations for overseas treatment in line with the ICB policies. The ICB follows the directions on treatment abroad as set out in the NHS (Cross-Border Healthcare) (England) Directions 2013 and the NHSE Policy: 'Who Pays: Determining which NHS commissioner is responsible for making payment to a provider'. For more information please refer to the Department of Health Policy: 'Cross-Border Healthcare and Patient Mobility in Europe pages on NHSE's website at www.nhs.uk/ and also from www.bedfordshirelutonandmiltonkeynes.icb.nhs.uk/what-we-do/individual-funding-requests/nhs-england-services-2/

3 Definitions

3.1 The term 'treatment' used throughout this document includes all interventions, surgery, drugs and devices provided under medical supervision. More defined terminology in relation to this policy is incorporated at Appendix 5: Glossary of Terms.

3.2 An **Individual Funding Request (IFR)** applies where the ICB is responsible for commissioning the service or treatment and there is a local policy, but the patient does not meet the criteria. The patient may be deemed to be 'clinically exceptional' and is described as an '**Exceptional Case**'. The term IFR also applies where a request is received from a clinician for a specific

treatment that is not covered by an existing policy or for a service which is not commissioned by the ICB. This is described as an '**Individual Case**'.

3.2.1 In either case there is a basis for considering that the requested treatment, is likely to be clinically effective and is a good use of NHS resources.

3.3 An **Exceptional Case** applies where there is an ICB Commissioning Policy, a NICE TA or Highly Specialised Technology (HST) Appraisal that provides guidance on whether to fund or not fund the treatment for the patient's condition. The NHS clinician must be able to show that their patient is significantly different clinically when compared to the typical patient population with the same condition and (if relevant) at the same stage of progression (and because of this difference) their patient is likely to receive material additional clinical benefit from treatment that would not be plausible for any typical patient.

3.4 An **Individual Case** applies where there is no relevant ICB commissioning policy, NICE TA or HST Appraisal guidance in place for the management of the patient's condition or combination of conditions and the patient's clinical presentation is so unusual that they could not be considered part of a defined group of patients in the same or similar clinical circumstances for whom a service development should be undertaken.

3.5 Clinical Exceptionality

3.5.1 There is no exhaustive description of the conditions which are likely to come within the definition of exceptional clinical circumstances. Clinical exceptionality in IFR terms refers to a person to whom the general rule should not apply. This implies that there is likely to be features about their clinical situation which were not considered when formulating the general rule. Very few patients have clinical circumstances which are genuinely exceptional.

3.5.2 Before applying for an IFR, NHS clinicians should consider whether their 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 clinical evidence to support this view. It is the responsibility of the clinician making the request to set out the grounds for clinical exceptionality clearly within the IFR application.

4 Policy Statement

4.1 The ICB accepts that there may be individual cases where a patient's clinical needs cannot be met through existing care pathways. The ICB has an established IFR process to consider the circumstances of individual patients

where it may be appropriate to consider a requested treatment that falls outside of existing pathways.

4.2 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 non-clinical factors would bring in the concept of worth into clinical decision making. It is a core value of the NHS that treatments are equally available, or unavailable to all.

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

4.4 The ICB does not discriminate against anyone with protected characteristics (age, disability, gender reassignment, marriage and civil partnership, pregnancy and maternity, race, religion or belief, sex or sexual orientation) or on social factors for example educational level, employment, social or personal circumstances.

4.5 Non-clinical and social factors have to be disregarded at Clinical Triage and by the Exceptional Cases Panel to ensure IFRs are dealt with in a fair manner across comparable cases.

4.6 The ICB's IFR Policy recognises that there needs to be a distinction between cases where the clinical circumstances of a patient are genuinely exceptional and cases where the presenting clinical circumstances are representative of a group (cohort) of similar patients. The ICB's IFR Policy is clear that where a cohort of patients exist, a request cannot be considered through the IFR process and should instead be considered as a service development proposal.

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

4.8 A Personal Health Budget (PHB) is an amount of money to support the planned healthcare and wellbeing needs of an individual, which should be agreed by their clinician. PHBs are a different way to meet assessed needs that services are routinely commissioned to meet and give people more

independence over how funding for their healthcare is spent. The ICB would not expect the IFR process to be used to agree services as part of a PHB. However, having a PHB in place for some aspects of a patient's care would not exclude the patient's clinician from making an IFR request in line with this Policy. For more information on the use of PHBs visit: www.bedfordshirelutonandmiltonkeynes.icb.nhs.uk/what-we-do/personal-health-budgets/

4.9 The ICB acknowledges that there may be occasions where requests for funding are received as a result of a patient's clinical need where a delay in funding would not be appropriate. The approach to Urgent IFRs is laid out at section 6.16.

5 Roles and Responsibilities

5.1 The following have specific responsibilities in relation to this Policy.

5.2 **The Board of the ICB** has delegated the responsibility of approving the IFR Policy to the Operational Group. The Board has delegated the oversight of arrangements for managing IFRs to the Quality and Performance Committee.

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

5.4 **The ICB's Chief Operating Officer** is the document owner of the IFR Policy and Process.

5.5 **The Head of Elective Delivery** is responsible for the overall management of the IFR Service and the processes that deliver the IFR Policy ensuring that quality and consistency is applied.

5.6 The **Audit and Compliance Managers** will review processes, implement changes to ensure service efficiency and effectiveness along with escalating any issues or concerns to the Chief Operating Officer or nominated Associate Director when required.

5.7 **The ICB's IFR Service** is part of a portfolio of work delivered by the Audit and Compliance Team which includes administrative staff and GP IFR Clinical Leads. The Service provides administrative support at each stage of the IFR process including:

- Logging and monitoring all IFR applications
- Preparing routine and urgent cases for Clinical Triage and the Exceptional Cases Panel
- Signposting to existing services or contracts where relevant

- Coordinating decision to requesting clinicians within time limits
- Coordinating requests for continuation of an approved IFR
- A point of contact for clinicians, patients and their representatives

5.8 **The Clinical Triage process** assesses each IFR application to ensure that clinical exceptionality is clearly detailed and evidenced. Clinical Triage takes place with the support of the IFR Service and wider clinical colleagues as required.

5.8.1 As part of the clinical triage process requests may be declined where:

- Sufficient clinical information has not been provided within the IFR application and/or the application is incomplete
- The patient already meets criteria and therefore is appropriate to treat
- The IFR application represents a service development
- Exceptional clinical circumstances have not been demonstrated

5.8.2 If there is any reasonable doubt as to whether an IFR satisfies the IFR Policy criterion of clinical exceptionality, the application should proceed to the Exceptional Cases Panel.

5.9 **Public Health Consultant** provides support and advice to the IFR Service, at Clinical Triage when required and to the Exceptional Cases Panel. Their role is to assist with public health advice about clinical appropriateness, clinical effectiveness and cost effectiveness of a treatment as well as assessing the quality and applicability of the presenting evidence. Literature reviews are also performed as part of a Public Health Consultant role.

5.10 **Commissioning Lead Pharmacist** provides specialist pharmaceutical support and advice about drug IFR cases to the IFR Service, at Clinical Triage when required and to the Exceptional Cases Panel. The Lead Pharmacist provides specialist knowledge of drug IFR cases including safety, clinical and cost effectiveness.

5.11 **The Exceptional Cases Panel** has delegated authority from the Board of the ICB to make decisions about funding for exceptional and individual cases. The Panel acts independently and consists of a range of doctors, public health experts, pharmacists and relevant ICB Leads that have not been involved in the patient's care. Any Panel members who have any conflicts of interest with a particular case will be excluded from the discussion of that case.

5.11.1 The Exceptional Cases Panel is responsible for ensuring the IFR applications it receives are considered in a fair and transparent way, with decisions based on available published evidence of clinical effectiveness and likely value for money relating to the proposed treatment.

5.12 **Financial Authority** to approve an IFR is delegated to nominated representatives of the Exceptional Cases Panel via the ICB's Standing Financial Instructions.

5.13 **Monitoring and Review of the IFR Policy and Process** will take place to ensure that decision making is fair, consistent and that IFR cases are being considered at the appropriate Clinical Triage and Exceptional Cases Panel stage of the process.

5.13.1 The Exceptional Cases Panel will receive an annual report from the Audit and Compliance Team to enable the process to be evaluated including the consistency of decision making, and to consider any improvements that could be made. The ICB will also provide an opportunity for requesting clinicians to feedback on their experience of the process as part of the evaluation of the IFR Policy and to contribute to ongoing improvements.

6 The IFR Principles, Process & Procedures

6.1 Principles

6.1.2 The IFR Service will apply the following principles when considering the case for exceptionality.

6.2 Failure to Respond to Standard Care

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

6.2.2 For an IFR to be supported on the basis of failure to respond to standard care, the evidence would need to demonstrate that the patient's inability to respond to or be provided with the usual treatment was a genuinely exceptional circumstance. The exceptional circumstances would be outside of the natural history of the condition and not characteristic of the relevant group of patients with the condition.

6.2.3 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.

6.2.4 Some patients will experience side effects but this does not indicate exceptionality. For example, the vast majority of patients treated with long term high dose steroids will develop side effects (typical and well recognised) and thus developing these side effects and requesting alternative treatments does not make a patient exceptional.

6.2.5 If the usual treatment cannot be given because of a pre-existing comorbidity which is unrelated to the condition and treatment request specified in the IFR application or is not unusual in the relevant patient group or generally, the fact that the comorbidity is present in this patient and its impact on treatment options for this patient is unlikely to make the patient clinically exceptional.

6.2.6 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 of patients who also have a comorbidity which is common in the general population, and therefore a patient cannot be exceptional by virtue of also having a comorbidity which is common in the general population.

6.2.7 If the proposed treatment is thought to offer a benefit to patients in these groups generally (i.e. those with more severe disease or those with common comorbidities), 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. See section 4.7 Service Developments.

6.3 Severity

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

- Whether there is evidence that the patient's presentation lies outside the normal spectrum for that condition. Preferably, a recognised scoring or classification system should be used to describe the patient's condition
- Whether there is evidence that the patient has progressed to a very severe form of the condition much more rapidly than the range of

progression that is documented and usually observed within the natural history of the condition

- How the patient is expected to benefit from the treatment sought and in what quantifiable way
- That there is evidence that the impact of the condition on this patient's health is significantly greater than its impact on the rest of the patient group e.g., the condition is usually a mild disease, but the presenting case is an extremely severe presentation
- That there is a plausible argument that the severity of the condition is prognostic of good response to treatment

6.3.2 Many conditions are progressive and 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 therefore intolerance or contraindication of a treatment does not usually in itself indicate exceptionality.

6.4 Multiple Grounds

6.4.1 There may be cases where clinicians seek to rely on multiple factors to show that their patient 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. These judgements are within the discretion of the ICB's IFR Clinical Triage process and the Exceptional Cases Panel.

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

6.5 Non-Clinical and Social Factors

6.5.1 In general, the NHS treats the patient's presenting medical condition and does not inquire into the background and lifestyle choices which may have contributed to that condition. The presenting medical condition is the basis on which to decide whether to make treatment available or not. The ICB will continue to apply these principles to IFR applications.

6.5.2 The ICB will seek to commission treatment based on the presenting clinical condition of the patient and not based on the patient's non-clinical or social circumstances. Clinicians are therefore required not to refer to non-clinical factors to support the application of an IFR. This includes but is not limited to, a patient's background, ambition in life, occupation or family circumstances as laid out in more detail at section 4.2 of this Policy.

6.6 Clinical Effectiveness

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

6.6.2 Clinical evidence that considers the efficacy of a particular treatment will be carefully considered throughout the IFR process. Inevitably, the evidence base put forward in support of an IFR application is unlikely to be as robust as in more common presentations of the condition or the more usual use of the treatment. However, it is important that the requesting clinician makes explicit linkages between the grounds under which clinical 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.

6.6.3 When considering clinical effectiveness, the Clinical Triage process and Exceptional Cases 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 the treatment, based on the evidence supplied
- The impact of existing comorbidities on both the claim for exceptionality and treatment outcome
- Any complications and adverse events of the treatment including toxicity, rates of relapse and 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 (using clinical evidence) why they consider that the proposed treatment will be effective for the whole period for which it will be given

6.6.4 The Exceptional Cases Panel shall be entitled, but not obliged to commission its own reports from any duly qualified or experienced clinician, medical

scientist or other person having relevant skills concerning the case that is being made that the treatment is likely to be clinically effective in the case of the particular patient.

6.7 Use of NHS Resources

6.7.1 The requesting clinician will be expected to explain why they consider the treatment being requested (by way of an IFR application) will be a good use of NHS resources.

6.7.2 This criterion is only applied where the Exceptional Cases Panel has already concluded that the criteria of clinical exceptionality and clinical effectiveness have been met in line with the Decision Making Framework (Appendix 7). Against this criterion, the Exceptional Cases Panel balances the degree of benefit likely to be obtained for the patient from funding the treatment against cost.

6.7.3 When considering clinical exceptionality and clinical effectiveness, the Exceptional Cases Panel will consider the evidence submitted to determine the nature and extent of the benefit the patient is likely to gain from the treatment, the certainty or otherwise of the anticipated outcome from the treatment and the opportunity costs for funding the treatment. Considerations will include for example, how significant a benefit is likely to be gained for the patient, and for how long that benefit will last.

6.7.4 These factors need to be balanced against the cost of the treatment and the impact on other patients of withdrawing funding from other areas in order to fulfil the IFR. This reflects the fact that the only way to provide the funding for the treatment requested, (i.e. outside commissioned clinical policies which are developed through the structured prioritisation process) is to divert resources away from current services.

6.7.5 When determining whether a treatment would be a good use of NHS resources, it is very important to consider the length of time the funding of a treatment is being requested, in relation to the duration of the evidenced efficacy of the treatment i.e., whether the clinical evidence indicates short, medium or long term effectiveness of a particular treatment.

6.7.6 Due to the very nature of the requests considered by the Exceptional Cases Panel, the degree to which effectiveness can be considered certain is likely to be limited and this will be a relevant factor when considering whether funding would be a good use of NHS resources. However, the Exceptional Cases Panel should also take into account its ability to impose conditions on any funding it agrees, for example to monitor the impact of the funded treatment.

6.7.7 In applying this criterion, the Exceptional Cases Panel will draw upon their professional and analytical skills and knowledge of the NHS system and how it works.

6.8 Experimental and Unproven Treatments

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

- The treatment is still undergoing clinical trials and/or is a drug yet to undergo a phase III clinical trial for the indication in question
- The treatment does not have marketing approval from the relevant Government body for the indication in question
- The treatment does not conform to a usual clinical practice in the relevant field
- The treatment is being used in a way other than that previously studied or that for which it has been granted approval by the relevant Government body
- The treatment is rarely used, novel, or unknown and there is a lack of authoritative evidence of safety and efficacy

6.8.2 A 'trial of treatment' refers to a situation where a clinician has exposed a patient to treatment for the purpose of assessing whether or not the patient is likely to benefit from longer term treatment.

6.8.3 A treatment may be considered unproven when it is considered 'as not demonstrated by evidence or argument to be true', or 'of a new method, system, or treatment; not tried and tested'.

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

6.8.5 The experimental or unproven basis of the treatment will become relevant when the Exceptional Cases Panel assesses the likely clinical effectiveness of the treatment for the patient. Then primarily, when the Exceptional Cases Panel considers the degree of confidence it has on the safety and efficacy of the treatment for the patient and whether it would be a good use of NHS resources.

6.8.6 Where evidence about the treatment is not yet available for public scrutiny, or there is limited evidence for one of the reasons set out above, the

Exceptional Cases Panel may have limited confidence in the evidence that has been presented.

6.8.7 As a preliminary requirement before agreeing to fund an experimental or unproven treatment, the ICB will need reassurance that the decision to agree to an exception to the general policy on treatment for the condition is made for very clear and explicit reasons which are consistent with the ICB's priority setting principles.

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

6.8.9 The ICB also does not expect to fund patients entering commercially funded clinical trials unless prior approval for funding individual patients in such trials has been obtained from the ICB. In approving the funding of individual patients for clinical trials, the ICB will also make it explicit which particular elements of the trial it is willing to fund.

6.8.10 The responsibility for providing ongoing access to a treatment is with those individuals or parties that have initiated and sponsored treatment, until such time as the ICB agrees to fund through the annual priority setting process. Where the treatment is not prioritised through the annual priority setting process, the responsibility remains with the trial initiators indefinitely.

6.9 Requests Following a Clinical Trial

6.9.1 The ICB does not expect to provide funding for patients to continue medication or treatment commenced as part of a clinical trial or Expanded Access/Compassionate Use Programme. In line with the Medicines for Human Use (Clinical Trials) Regulations 2004 and the Declaration of Helsinki, the responsibility for ensuring a clear exit strategy from a trial and ensuring that those benefiting from treatment will have ongoing access to it is the responsibility of those conducting the trial.

6.9.2 Where the ICB receives an IFR relating to a patient who has previously received treatment via a trial or Patient Access/Compassionate Use Programme, the IFR Process will adhere to the principles set out in this section.

6.9.3 It is the clinician's responsibility to ensure that prior to undertaking a clinical trial, patients are fully informed of their management plan at the end of the trial and have provided written consent. Clinicians should make patients

aware of this IFR Policy and where relevant, any requests for post-trial funding that have previously been declined.

6.9.4 The ICB will not be liable to pay the Provider under the acute services contract where the patient has been initiated on treatment or received temporary treatment before funding approval was granted by the ICB.

6.9.5 The ICB will continue to provide access to treatment for a patient leaving a clinical trial if, but only if:

- The patient was sponsored by the ICB (or by another NHS commissioner) to take part in the trial; and
- It has been demonstrated that the patient has benefited clinically from treatment

6.9.6 Should the ICB agree to funding in this context for a particular patient, this will not constitute a policy decision in relation to the treatment in question and as such, sets no precedent for the funding of other patients. The treatment in question will be assessed and prioritised as a service development in the usual way.

6.10 Drugs Used Outside of Licensed Use

6.10.1 Drugs that are used outside their licensed indications in secondary care are included in reference costs and uplifts where such use is common practice. This means these costs are included in the nationally set tariff paid to healthcare Providers.

6.10.2 Funding for new, rarely used, unlicensed and/or investigational drugs (novel/uncertain treatments) outside of a research trial will remain the responsibility of the Provider. Where there is a sufficient evidence base for such use to be considered for the routine management of patients, a business case should be submitted in advance to the commissioner to take through the due process (minimum time usually three to four months). Where a business case is intended or has been submitted, an IFR would not be considered appropriate due to a cohort of patients being identified for treatment.

6.10.3 The ICB will not normally fund novel or uncertain treatments (including research trials) other than through nationally agreed systems e.g. Medical Research Council trials. It is the responsibility of the clinician who prescribes an experimental drug to ensure compliance with their Trust's Clinical Governance processes and research ethics processes. The clinician's employer (e.g. Provider Trust) carries corporate responsibility for the care provided to the patient. The Exceptional Cases Panel may seek reassurance of the relevant governance arrangements for individual cases.

6.11 Orphan Drugs

6.11.1 To qualify for orphan designation in an orphan condition, a medicine must meet the following criteria:

- It must be intended for the treatment, prevention or diagnosis of a disease that is life threatening or chronically debilitating
- The prevalence of the condition in Great Britain must not be more than 5 in 10,000, or it must be unlikely that marketing of the medicine would generate sufficient returns to justify the investment needed for its development
- No satisfactory method of diagnosis, prevention or treatment of the condition concerned exists in Great Britain or if such a method exists, the medicine must be of significant benefit to those affected by the condition

6.11.2 Products with an orphan designation in the European Union can be considered for a Great Britain orphan marketing authorisation (MA) but this does not mean that it has to be funded by healthcare organisations.

6.11.3 The fact that a drug has been granted a MA does not impose any obligation on the ICB to fund the drug for the target patient group. The ICB has carefully considered the ethical issues around the funding of high cost drugs and other treatments for small numbers of patients but is satisfied that it would not be right to depart from its established procedures for the assessment and prioritisation of treatments.

6.11.4 The ICB will, in the absence of a direction made by the Secretary of State, commission both existing and new orphan drugs using the same decision making principles and processes as are applied to the commissioning of other treatments.

6.12 Requests for Referral to a Specialist Provider

6.12.1 These requests will include tertiary, regional or supra-regional centre or specialist private Providers. The majority of referrals to specialist centres are made by secondary care consultants. The ICB expects consultants to refer patients for tertiary/specialist care using established pathways covered by Service Level Agreements.

6.13 Decisions Inherited from other Integrated Care Boards

6.13.1 Occasionally patients move into Bedfordshire, Luton and Milton Keynes and become the responsibility of BLMK ICB (when they register with a local GP Practice) and a treatment option has been initiated in the previous ICB area. BLMK ICB will normally honour such decisions providing that the treatment is

in line with BLMK ICB's Ethical & Commissioning Principles at Appendix 4. The patient's care will be transferred to locally commissioned services as soon as clinically appropriate.

6.13.2 Should any continuation of treatment be requested relating to an IFR agreed by another ICB, BLMK ICB will require the original IFR application and outcome agreement along with information to support whether the treatment approved has been effective.

6.14 One-Off Referrals to Non-Contracted Providers

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

6.15 Urgent Treatment Requests

6.15.1 Clinicians must take all reasonable steps to minimise the need for urgent IFRs by submitting applications promptly (in line with timescales set within the IFR Process at section 6.19) and providing all necessary information with a request. As far as possible, clinicians should avoid waiting until a case becomes clinically urgent before submitting an IFR.

6.15.2 In this context, reference to clinical urgency is where there is a risk of an adverse clinical outcome (i.e. death or a significant irreversible loss of function) to the patient if an IFR decision is not provided within a maximum 40 working day timescale. These risks should be made explicit in the IFR application together with the reason that the application has not been made earlier.

6.15.3 It is the responsibility of the requesting clinician to demonstrate why the IFR application is urgent and provide all the information at the outset to avoid any delay in processing the IFR. Where an IFR is stated as urgent but there is insufficient evidence to support adverse clinical outcomes or the reason for the urgent request is not in accordance with section 6.16 of this Policy, the requester will be advised that the IFR will be handled in line with routine timescales. If further information is provided by the requesting clinician to demonstrate the urgent criteria is met, the IFR will be handled as such.

6.15.4 The IFR Service will endeavour to prioritise urgent requests proportionately to their degree of urgency but it must be appreciated that for every patient whose application is fast tracked, another patient's application is delayed. Not every request for urgent consideration can be complied with, which highlights the need for timely applications to be made whenever possible.

6.15.5 The ICB cannot be held responsible for delays to treatment where it has not been possible to confirm urgency due to the information provided or the ICB has been unable to prioritise an urgent request. Requesting clinicians should refer to section 6.16 of the IFR policy where relevant.

6.15.6 In cases where urgent consideration can be justified following Clinical Triage, an extraordinary Exceptional Cases Panel may be convened. The Exceptional Case Panel usually meets according to a schedule designed to provide frequent and timely opportunities to consider applications. Although it may seem that there should be a route by which certain cases could bypass the usual process and decisions could be taken on the same day, this has the potential to introduce unfairness into the process by way of:

- Cases submitted outside the usual process are unlikely to have been able to gather the necessary research evidence upon which a decision can be properly taken
- In such circumstances the information on the probability of a response to treatment and the nature of that response is unlikely to be clear
- As a result of these uncertainties, it is probable that decisions would be subject to the 'rule of rescue' in a way that cases considered in the usual process would not
- It may not be possible to convene a quorate Panel in a very short timescale

6.15.7 If the ICB considers that Provider clinicians are not taking all reasonable steps to minimise urgent IFR requests, the ICB may refer the matter to the clinician's Chief Executive or equivalent.

6.16 Urgent Requests and Retrospective Funding

6.16.1 In the unlikely event that a decision is required before the next scheduled Exceptional Case Panel, where the patient is on an end of life pathway or significant harm may occur to the patient as a result of a delay, (i.e. death or significant and irreversible loss of function is likely to occur before the Panel meeting), the treatment should be provided to the patient at the Provider's risk and a retrospective IFR submitted within two days of treatment commencing.

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

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

6.17 Summary of the IFR Process

6.17.1 The following summary explains the process for managing IFRs received by the ICB as outlined in the IFR Process pathway map at Appendix 3a and 3b. The summary will support IFR applications and provide guidance on decision making at each stage of the process. The ICB's Audit and Compliance Team is responsible for the operational delivery of the IFR Service.

6.18 Applying for an IFR

6.18.1 An IFR application must be made by the registered NHS clinician responsible for the patient's care in relation to the treatment requested. For High Cost Drug (HCD) IFRs, the application must come from the Consultant or Specialist Team as these drugs, as per the licensed use and/or local medicines formulary, must be initiated in secondary or tertiary care.

6.18.2 Only requests completed on BLMK ICB's IFR application form will be considered in line with this Policy. A word version of the application form is available on the relevant clinical system and at the following link: www.bedfordshirelutonandmiltonkeynes.icb.nhs.uk/what-we-do/individual-funding-requests/individual-funding-request-ifr-policy-process-and-resources/ The form should be typed (to avoid any delay in processing the IFR).

6.18.3 The ICB cannot be held responsible for delays in a Provider submitting an IFR or the IFR service processing an IFR application where the IFR Policy and process has not been followed by the requester.

6.18.4 All patient information submitted will be anonymised at the appropriate stage of the IFR process, in accordance with the ICB's Information Governance Policies.

6.18.5 IFR applications must be submitted to the IFR Service at blmkicb.ifrservice@nhs.net .The IFR will be acknowledged within three working days.

6.18.6 The requesting clinician should complete the consent section of the IFR application form to confirm that the patient, or their representative (e.g. if the

patient lacked capacity) is aware of the IFR and has agreed to their personal clinical information being shared.

6.18.7 It is the responsibility of the clinician submitting the IFR application to ensure that all relevant information is legible and correct. To ensure an equitable approach to processing IFRs, the requester will be asked to revise the IFR application and re-submit should this not be the case. It is also the responsibility of the clinician to ensure that sufficient clinical evidence of published research papers or other documentary evidence is included to support the application.

6.18.8 In line with the IFR Policy, supporting letters from the patient, clinical specialists or other health or social care professionals involved in the patient's care can also be included where appropriate. Information should only refer to clinical factors as outlined in Section 4.2 of the Policy.

6.19 Timescales for Routine and Urgent Cases

6.19.1 The IFR Service will aim to process IFR applications as quickly as possible within the time limits. The clinician should indicate the level of urgency of the case on the IFR application form in line with section 6.16 of the Policy (urgent requests) which will either be:

- Routine – decision required within a maximum of 40 working days
- Urgent – decision required within five working days

6.19.2 All requests will be treated as routine unless otherwise specified by the requesting clinician. All routine cases will be reviewed and a decision provided to the requesting clinician within a maximum of 40 working days from the date of receipt of the completed application. This 40 working day period discounts any working days where the IFR Service is awaiting information sought from the requesting clinician. At any point in the IFR process, the IFR Service can ask for further information to clarify the request if required.

6.20 Administrative Screening

6.20.1 The IFR Service Officer will initially triage the IFR application to ensure completed and ask for further information from the requesting clinician if required. If the patient is not registered with a GP Practice within Bedfordshire, Luton or Milton Keynes, the request will be handled in line with section 2.3 of the Policy.

6.20.2 Where IFR applications are substantially incomplete, illegible and/or where information is missing from mandatory fields, applications may be returned to the requestor for amendment prior to consideration by BLMK ICB. IFR

applications will be rejected at administrative screening if it is not possible to process the application at this point.

6.20.3 Urgent requests identified at administrative screening will be considered in line with section 6.16.

6.21 Clinical Triage

6.21.1 The IFR Service will initially screen IFR applications as part of a Clinical Triage process and seek additional nominated clinical representation dependent on the nature of the request. The IFR Service will aim for the outcome of the Clinical Triage process to be provided to the requesting clinician within 10 working days following acknowledgement of their request subject to the IFR Service awaiting any additional information.

6.21.2 As part of the initial screening, Clinical Triage will:

- Confirm time critical urgent cases
- Determine whether an existing ICB policy covers the intervention (the ICB's Evidence Based Intervention Clinical Policies can be found at: www.bedfordshirelutonandmiltonkeynes.icb.nhs.uk/what-we-do/individual-funding-requests/evidence-based-intervention-policies-2/
- Medicines related policies and pathways can be found at www.medicines.bedfordshirelutonandmiltonkeynes.icb.nhs.uk
- Determine if the intervention is already funded through contracts or Service Level Agreements
- Review whether there are any suitable alternative treatments available
- Confirm if the correct point in the agreed clinical pathway has been reached for the treatment or intervention being requested
- Establish whether the claim for exceptionality is supported based on the evidence supplied

6.21.3 The Clinical Triage screening process will consider the following outcomes:

- Confirm urgent IFRs to be completed within five working days
- Seek advice from commissioners/contract managers regarding suitable commissioned services or possible alternatives
- Defer the request, and ask for more information from the requesting clinician
- Decline the IFR if there is no plausible evidence to demonstrate clinical exceptionality
- If required, request review by the Clinical Triage Group meeting

6.21.4 If a decision is reached at this stage, the IFR Service will inform the requesting clinician of the decision in writing within the allocated timeframes.

6.22 Clinical Triage Group Meeting

6.22.1 Where required, IFR applications will be reviewed at the weekly Clinical Triage Group meeting. The Clinical Triage Group will consist of at least one GP IFR Clinical Lead and where relevant, other specialists (e.g Commissioning Lead Pharmacist for HCD IFRs) and/or Public Health Consultant.

6.22.2 IFR applications will be reviewed and decisions made using the same methodology as outlined in this Policy. The following outcomes are available to the Clinical Triage Group:

- Decline the IFR application
- Defer the request, and seek further clinical information from the requesting clinician to clarify specific issues relating to the case
- Where a clinician requests a review or challenges a decision, additional clinical information could be considered. A decision may be revised based on new information received
- Refer the case to the Exceptional Cases Panel
- Confirm whether an extraordinary Exceptional Cases Panel should be convened for time critical urgent requests

6.22.3 The IFR Service will inform the requesting clinician of the outcome of the Clinical Triage process within the allocated timeframes outlined at 6.20 of the process.

6.23 The Exceptional Cases Panel

6.23.1 IFRs that have been Clinically Triaged in line with section 6.22, will progress to the Exceptional Cases Panel where appropriate. Panel dates will be pre-scheduled to ensure that cases can be presented at the next sitting Panel.

6.23.2 The case will be prepared by the IFR Service in line with the Exceptional Cases Panel Terms of Reference.

6.23.3 The Exceptional Cases Panel will review presented cases and make one of the following decisions:

- Approve the funding request (within agreed financial limits)
- Decline the funding request
- Defer a decision pending receipt of further information from the referring clinician as appropriate

6.23.4 The Exceptional Cases Panel will consider each presented case in line with the ICB's Ethical and Commissioning Principles at Appendix 4. The Decision Making Framework is used by the Exceptional Cases Panel to enable a consistent approach to decision making and assessment of exceptionality in each case.

6.23.5 The Exceptional Cases Panel will record its decision and the Chair will write to the requesting clinician within five working days of the Panel meeting setting out the decision and the reasons for it. The clinician will be asked to share the outcome of the Exceptional Cases Panel's decision with their patient.

6.23.6 The ICB's Exceptional Cases Panel may also be asked to review an external Integrated Care Board's IFR Appeals in line with their IFR Policy and Appeals processes.

6.24 Decisions on Funding

6.24.1 The Exceptional Cases Panel considers the following question: *On what grounds can the ICB justify treatment for this patient when others from the same group are not being funded?* In making a request, the referring clinician must therefore provide evidence that:

- The patient is significantly different to the general population of people with the condition in question and
- The patient is likely to gain significantly more benefit from the intervention than might be normally expected for people with that condition

6.25 Approving an IFR

6.25.1 The Exceptional Cases Panel will be entitled to approve requests for funding for particular patients where the following conditions are all met:

- The request for funding for treatment is in connection with a medical condition for which the ICB has a policy but the patient falls outside the terms of that policy, or for which the ICB has no policy but the default interim position is that the ICB does not fund the requested intervention **and** where there is evidence that the patient in question has exceptional clinical circumstances
- There is no evidence to suggest that the patient is representative of a group or sub-group of patients and the Exceptional Cases Panel concludes that there are likely to be no similar patients to the requested patient (i.e. no patient within the population served by the ICB who is or is likely to be in the same or similar clinical circumstances as the requesting patient within the previous 12 months

and who could reasonably be expected to benefit to the same or similar degree from the requested treatment)

- There is sufficient evidence to demonstrate that for the particular patient, the proposed treatment is likely to be clinically effective
- There is sufficient evidence to demonstrate that for the particular patient, the proposed treatment is likely to be cost effective
- The intervention is affordable by the ICB at the point of application

6.25.2 Where BLMK ICB has approved an IFR, this approval applies to the specific treatment and timescale requested only. Clinicians will need to submit a continuation request to extend treatment, including for maintenance, replacement or repair of devices (not within warranty period). The request should state how the expected clinical benefits stated in the original IFR have been met. If BLMK ICB did not approve the IFR, the original IFR and outcome decision should be provided as part of the continuation of treatment request.

6.25.3 The ICB may refuse to fund treatment in cases where further funding approval has not been sought or the evidence of benefit is poor.

6.25.4 Where funding for treatment is approved, treatment must commence within 12 months of the date of approval. If a clinician considers there are exceptional clinical circumstances as to why the timeline may not be met, the requesting clinician must provide this information with the original funding request. Clinicians will need to submit a new IFR application if treatments are not started within this time limit. In this event, the new IFR will be considered against relevant policies prevailing at the time, which may differ from those applied in the original decision.

6.25.5 The Exceptional Cases Panel is entitled to approve the request contingent on the fulfilment of such conditions as considered suitable. These may include for example, a specific outcome reporting frequency or the involvement of a specialist unit in the management of the case.

6.25.6 Where appropriate, the Exceptional Cases Panel may delegate the review of approved IFRs with contingent measures and/or continuation requests to the Clinical Triage Group and include the criteria for any subsequent decision making within the Group's remit.

6.26 Declining an IFR

6.26.1 The Exceptional Cases Panel will decline the IFR where:

- The clinical and/or cost-effectiveness of the proposed treatment has not been demonstrated
- The patient does not have an exceptional health need but is representative of a group of patients

6.26.2 In cases where the Exceptional Cases Panel finds the patient is not clinically exceptional but is representative of a group of patients, the Panel will decline funding for the particular patient and will treat the request as a potential service development. Where appropriate, the clinician/Provider will be asked to submit a business case in support of the routine use of the treatment if there is a local need.

6.26.3 In situations where the Exceptional Cases Panel is aware that a policy decision is imminent, the Panel may decide to adjourn the decision and will advise the requesting clinician if the timescales within this IFR Policy are unlikely to be achieved.

6.26.4 In cases which could relate to a group of patients, where the Exceptional Cases Panel finds that strong evidence has been provided in support of a particular treatment, the Chair will advise the Chief Operating Officer or Chief Primary Care Officer (as appropriate).

6.27 The IFR Appeals Process

6.27.1 The requesting clinician can appeal the Exceptional Cases Panel's decision if they believe that due process has not been followed. An appeal must be made to the ICB's IFR Service at blmkicb.ifrservice@nhs.net within 30 working days of the date of notification of the Exceptional Cases Panel's decision. The clinician is responsible for ensuring that all relevant information to support the appeal is provided to the ICB at the outset.

6.27.2 The ICB has no obligation to commence or continue funding a treatment whilst an appeal is underway.

6.27.3 The request to appeal a decision made by the Exceptional Cases Panel will be Clinically Triaged which will determine whether:

- Any new evidence has been submitted that has not been reviewed by the Exceptional Cases Panel in line with the IFR Process
- There is an arguable case for an appeal that would be appropriate to continue with the appeals process
- There is no arguable case for an appeal to proceed

6.27.4 The IFR Service will advise the requesting clinician of the outcome of the Clinical Triage stage and next steps.

6.28 Progressing an Appeal

6.28.1 Appeals will be handled on behalf of the ICB by an external ICB's IFR Panel. The external ICB'S IFR Panel will consider whether the decision of BLMK

ICB's Exceptional Cases Panel was valid in terms of process, factors considered and criteria applied.

6.28.2 The external ICB's IFR Panel will not consider any new information in support of a case.

6.28.3 On receipt of an appeal, the external ICB's IFR Panel will consider whether the ICB's Exceptional Cases Panel decision was:

- Consistent with the Ethical and Commissioning Principles set out within this IFR Policy (at Appendix 4)
- Reached as the result of a decision making process which was consistent with that set out in this IFR Policy
- Consistent with previous similar decisions

6.28.4 The external ICB will consider whether the ICB's Exceptional Cases Panel in reaching its decision had:

- Taken into account and weighed properly all relevant evidence
- Given proper consideration to the claims of the clinician and accorded proper weight to his or her claims against those of other patients or groups of patients competing for scarce resources
- Taken into account only material factors
- Acted in utmost good faith
- Taken a decision that is in every sense reasonable

6.28.5 The external ICB's IFR Panel will provide its decision to the ICB's IFR Service who will in turn, advise the requesting clinician. It is the responsibility of the requesting clinician to provide the outcome of the appeal process at this stage to their patient.

6.28.6 If the external ICB's IFR Panel finds that there was a failing in the process, the case will be referred back to the ICB's Exceptional Cases Panel for re-consideration of any recommendations made. A finding of failure in the process of handling an IFR does not necessarily mean that the decision reached at a re-consideration by the Exceptional Cases Panel will be different.

6.28.7 The ultimate decision will be provided to the requesting clinician who will be asked to share the decision with their patient.

6.29 Complaints

6.29.1 Any person likely to be affected by a decision about their NHS healthcare or the process of the decision itself, has the right to make a formal complaint. Further information is available at:

www.bedfordshirelutonandmiltonkeynes.icb.nhs.uk/contact-us/complaints-and-concerns/

6.29.2 The ICB's Complaints contact details are as follows:

Enquiries and Experience Team
Email: blmkicb.contactus@nhs.net
Telephone: 0800 148 8890

6.30 Assurance and Reporting

6.30.1 The Exceptional Cases Panel will receive a report from the IFR Service to enable the process to be evaluated including the consistency of decision making, and to consider any improvements that could be made.

6.30.2 Decisions made at Clinical Triage will be reviewed to ensure consistency in the application of the ICB's IFR Policy.

6.30.3 A report of the activities of the IFR process will be presented to the Quality and Performance Committee annually. The report will contain assurance on the IFR Process, including decisions made by the Exceptional Cases Panel and Key Performance Indicators (KPIs).

Appendix 1 - Equality Impact Assessment Initial Screening

Please answer the questions against each of the protected characteristic and inclusion health groups. If there are significant impacts and issues identified a full Equality / Quality Impact Assessment (EQIA) must be undertaken. It is against the law to discriminate against someone because of these protected characteristics. For support and advice on undertaking EQIAs please contact: agcsu.equalities@nhs.net

Name of Policy:	Individual Funding Request Policy
Date of assessment:	17.06.2024
Screening undertaken by:	Audit & Compliance Team

Protected characteristic and inclusion health groups. Find out more about the Equality Act 2010, which provides the legal framework to tackle disadvantage and discrimination: https://www.equalityhumanrights.com/en/equality-act/protected-characteristics	Could the policy create a disadvantage for some groups in application or access? (Give brief summary)	If Yes - are there any mechanisms already in place to mitigate the potential adverse impacts identified? If not, please detail additional actions that could help. If this is not possible, please explain why
Age A person belonging to a particular age (for example 32 year olds) or range of ages (for example 18 to 30 year olds).	No	
Disability A person has a disability if she or he has a physical or mental impairment which has a substantial and long-term adverse effect on that person's ability to carry out normal day-to-day activities.	No	
Gender reassignment The process of transitioning from one gender to another.	No	
Marriage and civil partnership Marriage is a union between a man and a woman or between a same-sex couple. Same-sex couples can also have their relationships legally recognised as 'civil partnerships'.	No	
Pregnancy and maternity Pregnancy is the condition of being pregnant or expecting a baby. Maternity refers to the	No	

period after the birth and is linked to maternity leave in the employment context. In the non-work context, protection against maternity discrimination is for 26 weeks after giving birth, and this includes treating a woman unfavourably because she is breastfeeding.		
Race Refers to the protected characteristic of race. It refers to a group of people defined by their race, colour and nationality (including citizenship) ethnic or national origins.	No	
Religion or belief Religion refers to any religion, including a lack of religion. Belief refers to any religious or philosophical belief and includes a lack of belief. Generally, a belief should affect your life choices or the way you live for it to be included in the definition.	No	
Sex A man or a woman.	No	
Sexual orientation Whether a person's sexual attraction is towards their own sex, the opposite sex, to both sexes or none.	No	
Carers Individuals within the ICB which may have carer responsibilities.	No	
Please summarise the improvements which this policy offers compared to the previous version or position.		
Not applicable.		
Has potential disadvantage for some groups been identified which require mitigation?		
No – This policy is regarding the ICBs overall management and processing of Individual Funding Requests (IFRs), the content of which will have no negative or positive impact on any disadvantage or non-disadvantaged groups or individuals. The outcome of IFRs is based purely on clinical exceptionality. Evidence Based Intervention Policies referred to in the IFR policy each have a full separate Equality Impact Assessment.		

Appendix 2 - Data Protection Impact Assessment Initial Screening

Data protection is the fair and proper use of information about people. Before completing this form, please refer to the Data Protection Impact Assessment (DPIA) Guidance in the Information Governance (IG) section on the staff Intranet or contact the Data Protection Officer for support via blmkicb.ig@nhs.net

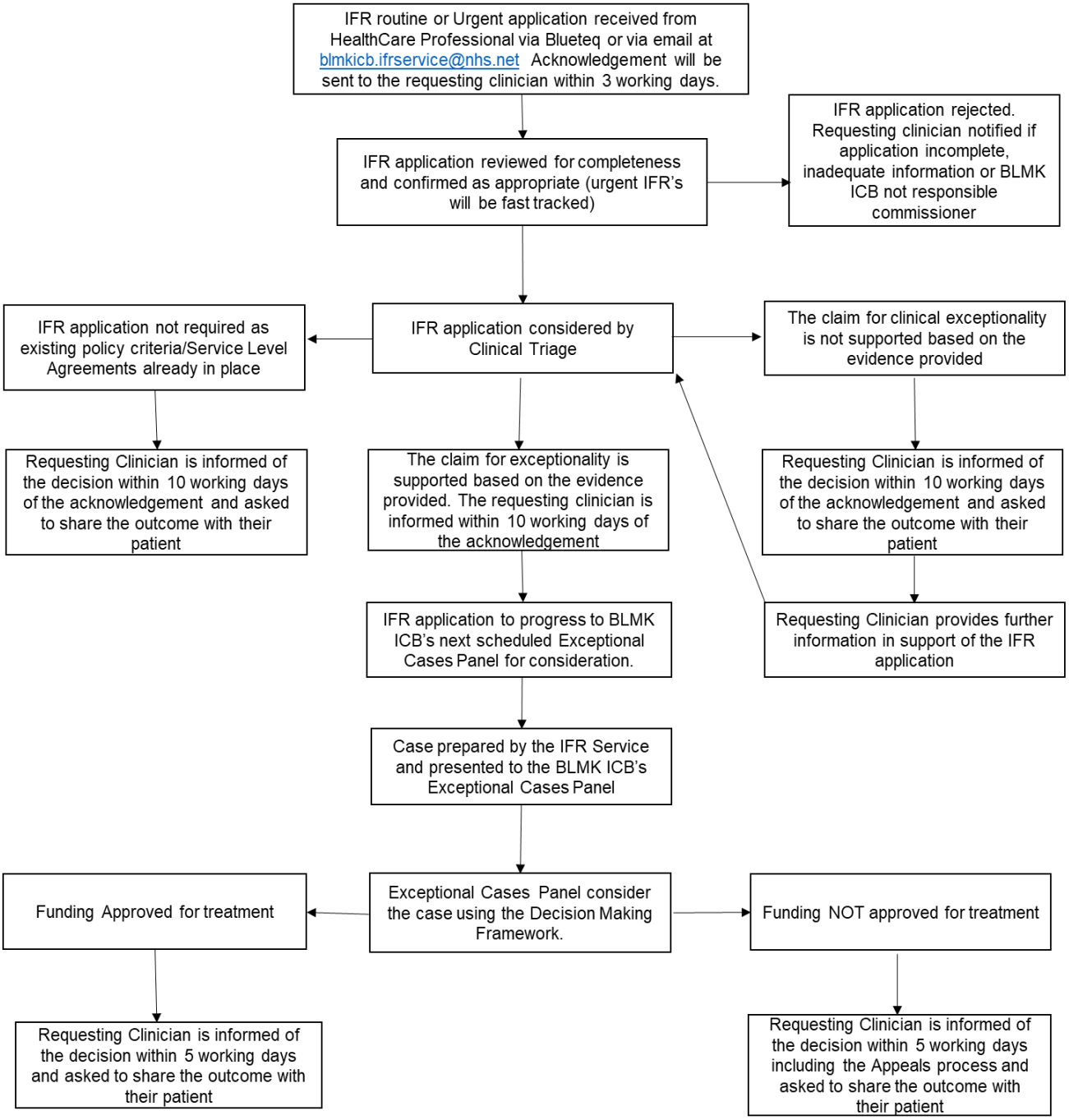
A DPIA is a process to help you identify and minimise the data protection risks. You must do a DPIA for processing that is likely to result in a high risk to individuals. You can use our screening checklist below to help you decide when to do one. If you have answered 'Yes' to any of the 10 screening questions, you must then carry out a full DPIA using the Stage 2 form, which is also available on the Intranet in the IG section.

Name of Policy:	Individual Funding Request Policy
Date of assessment:	31/5/2024
Screening undertaken by:	Audit & Compliance Team

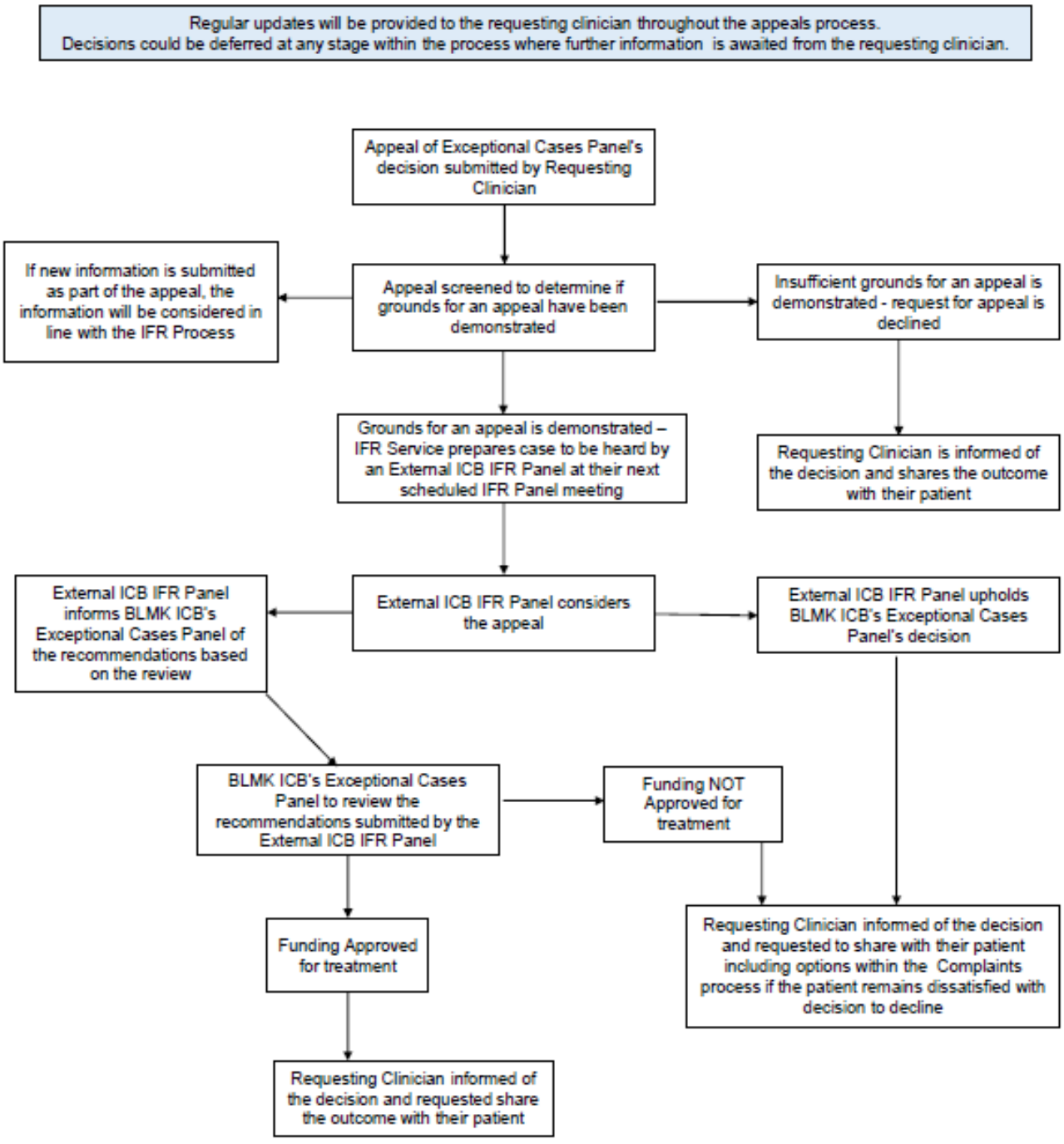
Stage 1 – DPIA form	**please answer 'Yes' or 'No'**
1. Will the policy result in the processing of personal identifiable information / data? This includes information about living or deceased individuals, including their name, address postcode, email address, telephone number, payroll number etc.	Yes
2. Will the policy result in the processing of sensitive information / data? This includes for living or deceased individuals, including their physical health, mental health, sexuality, sexual orientation, religious belief, National Insurance No., political interest etc.	Yes
3. Will the policy involve the sharing of identifiers which are unique to an individual or household? e.g., Hospital Number, NHS Number, National Insurance Number, Payroll Number etc.	Yes
4. Will the policy result in the processing of pseudonymised information by organisations who have the key / ability to reidentify the information? **Pseudonymised data -** where all identifiers have been removed and replaced with alternative identifiers that do not identify any individual. Re-identification can only be achieved with knowledge of the re-identification key. **Anonymised data -** data where all identifiers have been removed and data left does not identify any patients. Re-identification is remotely possible, but very unlikely.	Yes
5. Will the policy result in organisations or people having access to information they do not currently have access to?	Yes
6. Will the policy result in an organisation using information it already holds or has access to, but for a different purpose?	No
7. Does the policy result in the use of technology which might be perceived as being privacy intruding? e.g., biometrics, facial recognition, CCTV, audio recording etc.	No
8. Will the policy result in decisions being made or action being taken against individuals in ways which could have a significant impact on them? Including profiling and automated decision making. (This is automated processing of personal data to evaluate certain things about an individual i.e., diagnosis and then making a decision solely by automated means - without any human involvement)	No
9. Will the policy result in the collection of additional information about individuals in addition to what is already collected / held?	No
10. Will the policy require individuals to be contacted in ways which they may not be aware of and may find intrusive? e.g., personal email, text message etc.	No

Appendix 3a - Process Pathway

Each IFR will be reviewed and a decision communicated back to the requesting clinician within a maximum of 40 working days, or within 5 working days when the IFR is indicated as urgent. Updates will be provided to the requesting clinician throughout the process. Decisions could be deferred at any stage within the process where further information is awaited from the requesting clinician.



Appendix 3b - Appeal Pathway



Appendix 4 - Ethical and Commissioning Principles

Bedfordshire, Luton & Milton Keynes Integrated Care Board (BLMK ICB) Ethical and Commissioning Principles

Bedfordshire, Luton & Milton Keynes Integrated Care Board (the ICB) receives a fixed budget from central government with which to commission all healthcare required by our population. The ICB has insufficient resources to fund all types of healthcare that might be requested for its population. It is inevitable that the ICB has to make choices about which types of healthcare to commission. This document sets out the principles the ICB uses to make these decisions in order to make the process consistent, transparent and fair. These principles have been developed from the original Ethical Framework of the Bedfordshire and Hertfordshire Priorities Forum. The ICB's commissioning decisions will be based on the following principles:

1) Health Outcome

The aim of commissioning is to achieve the greatest possible improvement in health outcome for our population, within the resources that we have available. In deciding which interventions to commission, the ICB will prioritise those which produce the greatest benefits for patients in terms of both clinical improvement and improvement in quality of life.

2) Clinical Effectiveness

We will ensure that the care we commission is based on sound evidence of effectiveness. We will usually expect this to come from sources such as the National Institute for Health and Care Excellence, well designed systematic reviews and meta-analysis or randomised controlled trials.

The key success factors in evaluating clinical effectiveness are the need to search effectively and systematically for relevant evidence, and then to extract, analyse, and present this in a consistent way to support the work of prioritisation and commissioning. Choice of appropriate clinically and patient-defined outcome needs to be given careful consideration, and where possible quality of life measures and cost utility analysis should be considered.

We will promote treatments for which there is good evidence of clinical effectiveness in improving the health status of patients and will not normally recommend treatment that is shown to be ineffective. 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.

3) Cost Effectiveness

We will take into account cost-effectiveness analyses of healthcare interventions (where available) to assess which yield the greatest benefits relative to the cost of providing them. We 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. We will consider technical cost-benefit calculations (e.g. quality adjusted life years) but these will not by themselves be decisive.

4) Equity

We consider each individual within our populations to be of equal value. We will commission and provide healthcare services based solely on clinical need, within the resources available to the ICB. We will not discriminate unlawfully between individuals or groups on the basis of age, gender, gender identity, sexual orientation, race, religion, lifestyle, occupation, social position, financial status, family status (including responsibility for dependents), intelligence, disability, physical or cognitive functioning. However, where treatments have a differential impact as a result of age, sex or other characteristics of the patient, it is legitimate to take such factors into account.

The ICB has a responsibility to address health inequalities across our population. We acknowledge the proven links between social inequalities and inequalities in health, access to healthcare and health needs. Higher priority may therefore be allocated to interventions addressing health needs in sub-groups of our population who currently have poorer than average health experience (e.g. higher morbidity or poorer rates of access to healthcare).

5) Access

The ICB will ensure that the care we commission is delivered as close to where patients live as possible. Some services cannot be provided in local settings and we may need to commission some services from more distant providers in order to ensure quality, safety and value for money. The ICB will also ensure that it commissions safe services for its population.

6) Patient Choice

The ICB respects the right of individuals to determine the course of their own lives, including the right to be fully involved in decisions concerning their health care. However, this has to be balanced against the ICB's responsibility to ensure equitable and consistent access to appropriate quality healthcare for all of our patient population. In commissioning healthcare, the ICB will:

a) Ensure that in assessing the effectiveness of health care, we take account of outcomes that are important to patients and patient's experience of the care commissioned

b) Ensure wherever possible, that within the care commissioned or provided there are a range of alternative options available and that patients are given the necessary support to make an informed choice

c) Recognise that evidence of effectiveness usually relates to groups rather than individuals. We have set up an 'individual funding request' mechanism to allow individuals to be considered as an exception to commissioning policy where evidence is available to suggest that an intervention not routinely funded may be of particular benefit to them by comparison with other patients who might not be funded

d) As a general rule, decline to provide individual funding for care that is not routinely commissioned or provided solely on the basis that an individual, or a clinician involved in their care, desires it. This is in line with our responsibility to ensure consistent and equitable access to care for all our population. It reflects our concern not to fund for one individual care which could not be openly offered to everyone in our population with equal clinical need

e) Decline to provide a treatment of little benefit simply because it is the only treatment available

f) Consider treatments which effectively treat 'life time' or long-term chronic conditions equally to life-prolonging treatments and those for urgent need.

7) Affordability

The ICB may not be able to afford all interventions supported by evidence of clinical and cost-effectiveness within our available budgets. Where this is the case, further prioritisation will be undertaken based on criteria including national and local policies and strategies and local assessment of the health needs of the population, to ensure that we do not exceed our available resources.

The ICB is duty-bound not to exceed its budget and therefore the cost of treatment must be considered. The cost of treatment is significant because investing in one area of health care inevitably diverts resources from other uses. This is known as the opportunity cost and is defined as benefit foregone, or value of opportunities lost, that would accrue by investing the same resources in the best alternative way. The concept derives from the notion of scarcity of resources. A single episode of treatment may be very expensive, or the cost of treating a whole community may be high.

Needs of the Community - Public health is an important concern of the ICB and we will seek to make decisions which promote the health of the entire community. Some of these decisions are promoted by the Department of Health (such as the guidance from NICE and National Service Frameworks). Others are produced locally. The ICB also supports effective policies to promote preventive medicine which help stop people becoming ill in the first place.

Sometimes the needs of the community may conflict with the needs of individuals. Decisions are difficult when expensive treatment produces very little clinical benefit. For example, treatment may do little to improve the patient's condition or to stop or slow the progression of disease. Where it has been decided that a treatment has a low priority and cannot generally be supported, a patient's doctor may still seek to persuade the ICB that there are

exceptional circumstances which mean that the patient should receive the treatment.

9) Quality

The ICB will aim to commission high quality services as evidenced against national best practice. The quality of services will be measured where possible, not only in terms of quality of outcomes and clinical effectiveness but also in terms of process and organisational efficiency; reducing dependency on health care; the quality of patient care; and the quality of the patient experience.

10) Policy Drivers

The Department of Health and the Secretary of State issue guidance and can impose regulations to NHS organisations which may give priority to some categories of patient or require treatment to be made available within a given period. These may affect the way in which health service resources are allocated by individual groups. The ICB operates with these factors in mind and we recognise that our discretion may be affected by National Service Frameworks, NICE technology appraisal guidance, Secretary of State Directions to the NHS and performance and planning guidance.

11) Exceptional Need

There will be no blanket bans on treatment since there may be cases in which a patient has special circumstances which present an exceptional clinical need for treatment. Each case of this sort will be considered on its own merits in light of the clinical evidence. The ICB has procedures in place to consider such exceptional cases on their merits and this will be considered through the ICB's Individual Funding Request Policy.

12) Disinvestment

As well as commissioning new services on the basis of the criteria above, the ICB will keep existing services under review to ensure that they continue to deliver clinical and cost-effective services at affordable cost. Where possible, we will seek to divert resources from less effective services to more effective ones.

Appendix 5 - Glossary of Terms for Individual Funding Request Policy

Clinical exceptionality/ exceptional clinical circumstances	A person to whom the general rule should not apply. There is likely to be something about the patient's clinical situation which was not considered when formulating the general rule. Very few patients have clinical circumstances which are genuinely exceptional.
Clinically effective/ clinical effectiveness	Using knowledge from research about what works best in health care to get the best results for people.
Cohort	A group of people with a statistic in common e.g. having been born in the same year.
Commission	The process of planning services for a group of people who live in a particular area. It does not always mean paying for services but making sure that the services people need are available in that area.
Cost effective	A comparison of how much something costs in relation to how much benefit you get from it. Looking at cost-effectiveness can help you decide what to spend money on. Councils and other organisations do the same thing.
Criteria	A principle or standard by which something may be judged or decided.
Evidence based	When doctors or other care professionals use the best available evidence about what works most effectively, including evidence from people who have lived with a particular health condition, when deciding what treatment, care or support to offer you as an individual.
Evidence Based Intervention (EBI) Clinical Policy	A document that details whether a treatment is: • Not normally funded, unless a successful Individual Funding Request (IFR) is made, because they are either ineffective or have been superseded by a less invasive or more effective alternative. • Only be funded when specific clinically based criteria are met because they have only been shown to be effective in certain circumstances.
Exceptional Cases Panel	A group given authority by the Board of the ICB to process Individual Funding Requests (IFR) on behalf of the ICB
High Cost Drug (HCD)	Drugs excluded from contracts for which the ICB is the responsible commissioner.
Individual Funding Request (IFR)	An application to the ICB to seek funding for a treatment which would not usually be provided by the NHS for that patient.
National Institute for Health and Care Excellence (NICE)	An organisation that provides advice and guidance to improve health and social care services in England and Wales. NICE looks at all the evidence on what works and what doesn't and how much it costs and advises on what treatment and care should be offered to people. NICE doesn't have the power to insist that all guidance is followed in local areas.

NHS Constitution	The principles and values of the NHS in England, and information on how to make a complaint about NHS services.
NHS England	The organisation that decides what the most important health issues in England are and how NHS money should be spent. It is given money by the Department of Health and shares this out to local areas and clinical commissioning groups.
Prevalence	Proportion of people in a population who have a particular habit, a particular disease or another characteristic.
Service Level Agreement (SLA)	A communication document that makes clear what the supplier will deliver and what they will ensure. It is based on the conditions of contract and specification and does not in any way replace them.
Statutory	Required or authorised by law
Treatment	All interventions, drugs and devices provided under medical supervision.

NHS
Bedfordshire, Luton and Milton Keynes
Integrated Care Board

Appendix 6 - Exceptional Cases Panel Decision Making Framework V3.1

STRICTLY PRIVATE AND CONFIDENTIAL-NOT FOR RELEASE OUTSIDE THE PANEL

Panel meeting date:

Patient Case Number:

Notes of Guidance:

1. A copy of this form will support each IFR patient application being considered.
2. The form will be used to record the discussion notes of the Panel and will be retained by the IFR Service.
3. The Decision Making Framework information will be used to inform the outcome letter from the Chair of the Exceptional Cases Panel.

Panel Members present:

Treatment/Intervention Requested:
Brief background information:

Documents supporting the case: Please follow link

BLMK ICB's IFR Decision Making Framework

No.	Points for Consideration			Decision: Yes/No
	Individual need for care	**Definitions/considerations**	**Discussion Notes**	**Decision**
1a.	Does BLMK ICB have a policy to cover the treatment which is made available to patients with the presenting medical condition? Or	NB: If BLMK ICB has a policy for the condition in question and the patient has not demonstrated exceptional clinical circumstances, the Panel are required to turn down the application. **Exceptionality:** *Significantly different clinically to the group of patients with the condition in question and at the same stage of progression of the condition*		
1b.	Is the request for a specific treatment that is not covered by an existing policy or a service not commissioned by BLMK ICB and therefore an **'Individual Case**'? And	**Individual Case:** *Where there is no relevant ICB commissioning policy, NICE TA or HST Appraisal guidance in place for the management of the patient's condition or combination of conditions and the patient's clinical presentation is so unusual that they could not be considered part of a defined group of patients in the same or similar clinical circumstances for whom a service development should be undertaken.*		
1c.	Did the Panel reach the view that the patient had demonstrated **exceptiona**l **clinical circumstances** in this case?			

	Clinical effectiveness	Definitions/considerations	Discussion Notes	Decision
2.	Does the Panel consider that there is sufficient evidence of the clinical effectiveness of this drug/intervention? (What type of evidence has the panel considered in the decision. Are there any local/national guidelines e.g NICE/SIGN to support)	**Grading of evidence** Ia: systematic review or meta-analysis of Randomised Control Trial (RCTs). Ib: at least one RCT. IIa: at least one well-designed controlled study without randomisation. IIb: at least one well-designed quasi-experimental study, such as a cohort study. III: well-designed non-experimental descriptive studies, such as comparative studies, correlation studies, case-control studies and case series. IV: expert committee reports, opinions and/or clinical experience of respected authorities Evidence with less strength could include: Patient evidence Local data identified through previous IFRs		
	Patient Outcomes/Capacity to Benefit	**Definitions/considerations**	**Discussion Notes**	**Decision**
3a.	Is there sufficient evidence that this drug/intervention has been or is likely to be effective in this individual case			
3b.	Is the **patient likely to gain significantly greater clinical benefit** than other patients with the same clinical condition and stage of disease	**Exceptionality:** *Likely to gain significantly more clinical benefit from the intervention than might be expected from the average patient with the condition*		

	Cost effectiveness/benefit and Affordability	Definitions/considerations	Discussion Notes	Decision
4a.	Does the Panel consider that there is enough evidence to make a decision regarding the cost effectiveness of this drug/intervention? (NICE, Appraisals etc)			
4b.	What are the absolute costs involved in funding this treatment and how does this demonstrate value for money?	*Consider whether there are any cost neutral considerations that can be clearly evidenced including reduction in hospital admissions etc.*		
4c.	Does the evidence indicate/is it the ECP opinion that the treatment requested is likely to be affordable and of cost benefit in this individual case?			
	Equity/the needs of the BLMK community	**Definitions/considerations**	**Discussion Notes**	**Decision**
5a.	What will the anticipated impact be on the rest of the **patient population** should this treatment be funded for this patient?	*Consider any precedent setting of any decision to fund the treatment*		
5b.	Will it be equitable to the **wider population** to fund this treatment after consideration of the clinical needs of this patient?	*Consider if funding would divert resources away from the general ICB population*		

	Other factors to consider		Discussion Notes	
6a.	Are there any other factors which were considered relevant by the Panel?			
6b.	Where applicable, has the environmental impact of the treatment on offer been considered?	*Elements to consider may include direct carbon emissions from intervention/treatment on offer (where data is available), digital models of care etc.*		
	SUMMARY		**Outcome information**	**Oversite/monitoring**
7.	**Funding Approved:**			Any conditions/review mechanisms required. Outcome measures to be monitored and date of review? Review delegated to? Overall time period required?
8.	**Funding Denied:**		**Reasons for Decision?**	