NHS
Bedfordshire, Luton and Milton Keynes
Integrated Care Board

Individual Funding Request (IFR) Policy

Document Control	
Document Owner:	Chief Transformation Officer
Document Author(s):	Audit and Compliance Managers
Directorate:	Commissioning and Contracting
Approved By:	The Board of the Integrated Care Board
Date of Approval:	01-07-2022
Date of Next Review:	01-07-2024
Effective Date:	01-07-2022

Version Control			
Version	**Date**	**Reviewer(s)**	**Revision Description**
Final v1.0	01-07-2022		The Board of the Integrated Care Board adopted the approved policy.

Implementation Plan

Development and Consultation:	The following individuals were consulted and involved in the development of this document: ▪ The Integrated Care Boards IFR Steering Group
Dissemination:	Staff can access this document via the website and will be notified of new / revised versions via the staff briefing. 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 Board of the Integrated Care Board
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 to the IFR Policy as outlined at section 2.3 of the 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

Table of Contents

1.0 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 six and at 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 and Decision Making Framework at Appendix 7.

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/

2.0 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.

2.1.2 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

2.2 Determining the Responsible Commissioner

2.2.2 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 (such as relevant primary care services, high-secure psychiatric services, prescribed specialised services, secondary care dental 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)
- Public Health services commissioned by Local Authorities or NHS England
- Services provided by Public Health England (PHE) including health protection and promotion services.

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/wp-content/uploads/2017/11/comm-policy-indivdual-funding-requests.pdf
- www.england.nhs.uk/publication/manual-for-prescribed-specialised-services/
- www.england.nhs.uk/publication/nhs-england-drugs-list/

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

2.3 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 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

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

2.5.1 Treatments that are not normally funded or are funded based on a criteria agreed by the ICB are detailed in Evidence Based Intervention (EBI) Clinical Policies, previously referred to locally as Procedures of Low Clinical Effectiveness (POLCE) or Procedures of Low Clinical Value (POLCV). All the ICB 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 for the ICB are available at:
www.medicines.bedfordshirelutonandmiltonkeynes.icb.nhs.uk/

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

2.5.2.1 **The National Institute for Health and Care Excellence (NICE)** provides national guidance and advice to improve health and social care. NICE

Technology Appraisals (approving drugs and technologies for funding within the NHS) need to be implemented within the allocated time frame (up to three months) of the Appraisal being published. The ICB will seek to ensure implementation of NICE Technology Appraisals as soon as possible within the three month statutory requirement period. The ICB recognise that delays may occur where significant service change and/or development are required as part of the implementation.

2.5.2.2 **The Priorities Forum** represents a range of NHS organisations across Hertfordshire, West Essex, Bedfordshire, Luton and Milton Keynes. The Forum produces clinical guidelines that include thresholds for referral and interventions with the purpose of helping ICB's choose how to allocate their resources. The recommendations from the Forum influence the ICB's EBI policy content and new policy development.

2.5.2.3 **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/

2.6 **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/

3.0 Definitions

3.1 The term 'treatment' used throughout this document includes all interventions, drugs and devices provided under medical supervision. More defined terminology in relation to this policy is incorporated at Appendix 8: 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 providing care

to a patient, 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, procedure or intervention is likely to be clinically effective and is a good use of NHS resources.

3.3 An **Exceptional Case** is where there is a ICB Commissioning Policy, a NICE Technology Appraisal (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 clinician must be able to show that their patient is in a different clinical condition when compared to the typical patient population 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** is 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 to be 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, 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. The onus is on the clinician making the request to set out the grounds for clinical exceptionality clearly within the IFR application.

4.0 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 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.

4.2.1 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.

4.3 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.

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

4.4 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. This Policy is clear that where a cohort of patients exists, a request cannot be considered through the IFR process and should instead be considered as a service development proposal.

4.4.1 A service development is any aspect of healthcare which the ICB has not historically agreed to fund and which will require additional and predictable recurrent funding. Further information can be found at Appendix 5: Guidance on Service Developments and Cohorts of Similar Patients.

4.5 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 money 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/

4.6 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 Requests is laid out at section 6.16 and 6.17 of the Policy.

5.0 Roles and Responsibilities

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

5.2 **The Board of the ICB** is responsible for approving the IFR Policy, associated Appendices to the Policy and any revisions following the review timetable. The Board will receive an annual report of the overall activity to provide assurance on the IFR Process, including decisions made by the Exceptional Cases Panel.

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

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

5.5 **The identified Senior Commissioning Manager** 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. The identified Senior Commissioning Manager will review processes, implement changes to ensure service efficiency and effectiveness along with escalating any issues or concerns to the Chief Transformation Officer or nominated Associate Director when required.

5.6 **The ICB's IFR Service** is part of a portfolio of work delivered by the Audit and Compliance Team. The Team provides administrative support at each stage of the IFR process including:

- Logging and monitoring all IFR applications
- Preparing cases for Clinical Triage and the Exceptional Cases Panel, highlighting where the request has been submitted as Urgent
- 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.

5.7 **Clinical Triage** will assess each IFR application to ensure that clinical exceptionality is clearly detailed and evidenced within the IFR application form. Clinical Triage takes place by nominated GPs with the support of the IFR Service and wider colleagues as required. Clinical Triage has delegated authority from the Exceptional Cases Panel to filter any requests which are not determined to be an IFR. These may be requests where:

- The patient already meets criteria and therefore is appropriate to treat
- The IFR application represents a service development
- Sufficient clinical information has not been included within the IFR application.

5.8.1 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 clinical 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 and individual case 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 individual cases. The Panel acts independently and consists of a range of doctors, public health experts, pharmacists and relevant the 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. The Terms of Reference for the Exceptional Cases Panel is available at Appendix 6.

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

5.11.2 **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.

5.12.1 **The Exceptional Cases Panel** will receive a bi-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 and patients to feedback on their experience of the process as part of the evaluation of the IFR Policy and to contribute to ongoing improvements.

6.0 The Individual Funding Request (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 all patients who are treated with long term high dose steroids will develop side effects (typical and well recognised) and thus developing these side effects and wishing for 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 for which the treatment is being sought under the IFR or is not unusual in the relevant patient group or generally, the fact that the comorbidity is present in this patient and its impact on treatment options for this patient is unlikely to make the patient clinically exceptional. As an illustration, some comorbidities are common in the general population for example diabetes (which affects around 7% of adults) or asthma (which affects at least 10% of the population). Diabetes and its treatments affect many other conditions, for example steroids make glucose control more difficult. With any condition, there will be a recognised proportion 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.

6.2.6 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 4.4 Service Developments and Appendix 5: Guidance on Service Developments and Cohorts of Similar Patients.

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 the 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 Having regard to the evidence submitted and the analysis they have carried out when considering clinical exceptionality and clinical effectiveness, the Exceptional Cases Panel members will consider the nature and extent of the benefit the patient is likely to gain from the treatment, the certainty or otherwise of the anticipated outcome from the treatment and the opportunity costs for funding the treatment. 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 treatment under IFRs (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 members 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 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 treatments have to be undertaken judiciously, responsibly and for clearly defined purposes.

6.8.4 The experimental 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.

6.8.5 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.

6.8.6 As preliminary requirements before agreeing to fund an experimental 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.

6.8.7 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.

6.8.8 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.

6.8.9 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).

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.

6.12.2 Should a local consultant feel that a referral outside existing pathways is a priority for a particular patient, the consultant should ask for the case to be considered by the ICB. The consultant should not refer the patient to another Provider without first obtaining the agreement of the ICB. The ICB will decline to fund any patient referred to another Provider where funding agreement has not been obtained prior to the referral being made.

6.13 Decisions Inherited from other Integrated Care Boards

6.13.1 Occasionally patients move into the area and become the responsibility of the ICB (when they register with an ICB GP Practice) and a treatment option has

already been started by another ICB that was previously responsible for the patient's care. Bedfordshire, Luton & Milton Keynes ICB will normally honour such decisions where the care pathway has already been initiated, providing that the treatment is in line with the ICB's Ethical & Commissioning Principles at Appendix 4. The patient's care will be transferred to locally commissioned services as soon as clinically appropriate.

6.14 Joint Funding Arrangements

6.14.1 Where joint funding is required between the ICB and a Bedfordshire, Luton or Milton Keynes Local Authority, the relevant joint funding procedures between the organisations will be followed. Equally, where there is a dispute regarding funding contributions, the relevant Dispute Resolution Procedure will be followed.

6.15 One-Off Referrals to Non-Contracted Providers

6.14.2 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 referring clinician before the request can be approved.

6.16 Urgent Treatment Requests

6.16.1 Clinicians must take all reasonable steps to minimise the need for urgent requests to be made through the IFR Process by making requests promptly (in line with timescales set within the IFR Process at section 6.20) 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.

6.16.2 In this context, references to clinical urgency are to risks of adverse clinical outcome to the individual patient if a decision on the IFR is not provided within a maximum 40 working day timescale. These risks should be made explicit in the application together with the reason that the application has not been made earlier.

6.16.3 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.

6.16.4 In cases where urgent consideration can be justified following Clinical Triage, an extraordinary Exceptional Cases Panel may be convened. This could be

either in person or virtually, in order to expedite decision making. 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 would be impossible to convene a properly constituted Panel in a very short timescale
- A Provider Trust is able to begin treatment and seek retrospective approval and if successful, reimbursement.

6.16.5 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.

6.17 Urgent Requests and Retrospective Funding

6.17.1 In the unlikely event that a decision is required before the next scheduled Exceptional Case Panel, where 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 approval for funding should be sought. Approval must be sought within two days of treatment commencing.

6.17.2 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 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.

6.17.3 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 determine 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.

6.18 Summary of the Individual Funding Request (IFR) Process

6.18.1 The following summary explains the process for managing IFR's 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.

6.19 Applying for an IFR

6.19.1 An IFR application must be made by the registered NHS clinician responsible for the patients care in relation to the IFR application. For High Cost Drug (HCD) related IFRs, the application must come from the Consultant or Specialist Team as these drugs as per the licensed use, must be initiated in secondary or tertiary care.

6.19.2 Only requests completed on the ICB's IFR application form will be considered in line with this Policy.

6.19.3 Requests should be submitted electronically using the IFR application form found on the relevant clinical system and also 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/
All patient information submitted is to be anonymised and the required identifiers to include the patients NHS Number, Date of Birth, GP and GP Practice to protect patient confidentiality and ensure objectivity. All IFR applications will be handled in accordance with the ICB's Information Governance policies.

6.19.4 For clinicians who have access to the Blueteq database, an IFR can be applied directly on the platform. For all others, IFR applications must be sent to blmkicb.ifr@nhs.net where the IFR Service will upload the application onto Blueteq on behalf of the requesting clinician. The IFR will be acknowledged within three working days.

6.19.5 The requesting clinician should complete the consent section of the IFR application form to confirm that the patient is aware of the IFR and has agreed to their personal clinical information being shared.

6.19.6 If the requesting clinician considers that the patient does not have capacity to give informed consent for an IFR, this should be indicated and explained on the consent section of the IFR application form. In these circumstances, the

request should also confirm whether consent has been obtained instead from a patient representative (a person who has the legal authority to take decisions about medical care and treatment on behalf of a patient who lacks capacity to take these decisions themselves) and if not, the basis on which the IFR is being made by the clinician.

6.19.7 It is the responsibility of the clinician submitting the IFR application to ensure that all relevant information along with sufficient clinical evidence of published research papers or other documentary evidence is included to support the application.

6.19.8 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.

6.20 Timescales for routine and urgent cases

6.20.1 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 6.17 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

6.20.2 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.

6.21 Administrative Screening

6.21.1 The IFR Service Officer will verify the IFR application is complete and will 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.

6.21.2 Urgent requests identified at administrative screening will be considered in line with section 6.20 of the IFR process.

6.22 Clinical Triage

6.22.1 IFR applications will be initially screened as part of a Clinical Triage process by a nominated Clinical Triage GP. 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.

6.22.2 As part of the initial screening, the Clinical Triage GP will:

- Identify 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.

6.22.3 The Clinical Triage GP will consider the following outcomes:

- Request the IFR Service convenes an extraordinary Exceptional Cases Panel for time critical urgent cases
- Refer drug cases to the ICB's Commissioning Lead Pharmacist
- Seek advice from commissioners/contract managers regarding suitable commissioned services or possible alternatives
- Defer the request, and ask for more information from the referring clinician
- Take the request to the Clinical Triage meeting if required
- Decline the request without reference to the Clinical Triage meeting or Exceptional Cases Panel if the claim for exceptionality is not supported by the evidence provided

6.22.4 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.

6.23 Clinical Triage Meeting

6.23.1 Complex cases or cases where there may be clearly defined grounds for exceptionality will be reviewed weekly at a Clinical Triage meeting where required. The Clinical Triage meeting will consist of at least one GP and other relevant specialists for example a Commissioning Lead Pharmacist and/or Public Health Consultant.

6.23.2 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 meeting:

- Decline the IFR application
- Defer the request, and seek further clinical information to clarify specific issues relating to the case from the referring clinician
- Where a clinician has challenged a decision, additional clinical information could be considered by the Clinical Triage meeting for review. A decision may be revised based on new information received or the case may be referred to the Exceptional Cases Panel
- Refer the case to the Exceptional Cases Panel

6.23.3 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.

6.24 The Exceptional Cases Panel

6.24.1 Individual Funding Requests that have been Clinically Triaged in line with section 6.22 of the IFR Process 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.

6.24.2 The case will be prepared by the IFR Service in line with the Exceptional Cases Panel Terms of Reference at Appendix 6.

6.24.3 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.

6.24.4 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 at Appendix 7 is used by the Exceptional Cases Panel to enable a consistent approach to decision making and assessment of exceptionality in each individual case.

6.24.5 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.

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

6.25 Decisions on Funding

6.25.1. 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

6.26 Approving an IFR

6.26.1 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 in the same financial year, and who could reasonably be expected to benefit to the same or similar degree from the requested treatment)
- There is sufficient evidence to show that, for the particular patient, the proposed treatment is likely to be clinically effective

- There is sufficient evidence to show 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.

6.26.2 Where the IFR is approved, 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. The ICB may refuse to fund treatment in these cases if further funding approval has not been sought or the evidence of benefit is poor.

6.26.3 Where funding for treatment is approved, treatment must commence within 12 months of the date of approval. Where a clinician may feel there are exceptional clinical circumstances as to why the timeline may not be met, the referring 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 that event, the new application will be considered against the policies prevailing at the time, which may differ from those applied in the original decision.

6.26.4 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.

6.27 Declining an IFR

6.27.1 The Exceptional Cases Panel will decline the request 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.

6.27.2 In cases where the Exceptional Cases Panel finds the patient is not 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. See Appendix 5: Service Developments and Cohorts of Similar Patients.

6.27.3 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 policy are unlikely to be achieved.

6.27.4 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 Transformation Officer or Chief Primary Care Officer (as appropriate).

6.28 The IFR Appeals Process

6.28.1 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 in writing to the ICB's IFR Service within six calendar weeks 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.

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

6.28.3 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

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

6.29 Progressing an Appeal

6.29.1 Appeals will be handled on behalf of the ICB's by an external ICB's IFR Panel. The external ICB'S IFR Panel will consider whether the decision of the ICB Exceptional Cases Panel was valid in terms of process, factors considered and criteria applied.

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

6.29.3 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

6.29.4 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 patient or their 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

6.29.5 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.

6.29.6 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.

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

6.30 Complaints

6.30.1 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/

The ICB's Complaints contact details are as follows:

Patient Enquiries and Complaints
Bedfordshire, Luton & Milton Keynes Integrated Care Board
Head Quarters, Arndale House

3rd Floor, 37 The Mall
Luton, LU1 2LJ

Email: blmkicb.contactus@nhs.net
Telephone: 0800 148 8890

6.31 Assurance and Reporting

6.31.1 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.

6.31.2 Decisions made by the Clinical Triage GPs will be audited by the identified Senior Commissioning Manager to ensure consistency in the application of the ICB's IFR Policy.

6.31.3 A report of the activities of the Individual Funding Request process will be presented to the Board of the ICB annually. The report will contain assurance on the IFR Process, including decisions made by the Exceptional Cases Panel and Key Performance Indicators (KPIs).

6.31.4 The ICB will also provide an opportunity for requesting clinicians and patients to feedback on their experience of the process as part of the evaluation of the IFR Policy and to contribute to ongoing improvements

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 (IFR) Policy
Date of assessment:	IFR Policy originally assessed and signed off on 21/08/2021
Screening undertaken by:	Audit and Compliance Manager in conjunction with Deputy Chief Nurse

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).	There are no fundamental changes as a result of aligning previous CCG IFR Policies or changing to the Integrated Care Board template that will impact any specific patient group.	
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.	There are no fundamental changes as a result of aligning previous CCG IFR Policies or changing to the Integrated Care Board template that will impact any specific patient group.	
Gender reassignment The process of transitioning from one gender to another.	There are no fundamental changes as a result of aligning previous CCG IFR Policies or changing to the Integrated Care Board template that will impact any specific patient group.	
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'.	There are no fundamental changes as a result of aligning previous CCG IFR Policies or changing to the Integrated Care Board template that will impact any specific patient group.	

Pregnancy and maternity Pregnancy is the condition of being pregnant or expecting a baby. Maternity refers to the 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.	There are no fundamental changes as a result of aligning previous CCG IFR Policies or changing to the Integrated Care Board template that will impact any specific patient group.	
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.	There are no fundamental changes as a result of aligning previous CCG IFR Policies or changing to the Integrated Care Board template that will impact any specific patient group.	
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.	There are no fundamental changes as a result of aligning previous CCG IFR Policies or changing to the Integrated Care Board template that will impact any specific patient group.	
Sex A man or a woman.	There are no fundamental changes as a result of aligning previous CCG IFR Policies or changing to the Integrated Care Board template that will impact any specific patient group.	
Sexual orientation Whether a person's sexual attraction is towards their own sex, the opposite sex, to both sexes or none.	There are no fundamental changes as a result of aligning previous CCG IFR Policies or changing to the Integrated Care Board template that will impact any specific patient group.	
Carers Individuals within the ICB which may have carer responsibilities.	There are no fundamental changes as a result of aligning previous CCG IFR Policies or changing to the Integrated Care Board template that will impact any specific patient group.	
Please summarise the improvements which this policy offers compared to the previous version or position.		
IFR's are received from a patient's treating clinician and considered on a case by case basis. This is not a new area of work and the ICB IFR Policy reflects national NHS England policy where ever		

possible. The service will be delivered by the ICB's Audit and Compliance Team to meet policy criteria and process
Has potential disadvantage for some groups been identified which require mitigation?
No – (If there are significant impacts and issues identified a full Equality / Quality Impact Assessment (EQIA) must be undertaken.)

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:	07/01/2021
Screening undertaken by:	Linda Harris- Head of IG/DPO

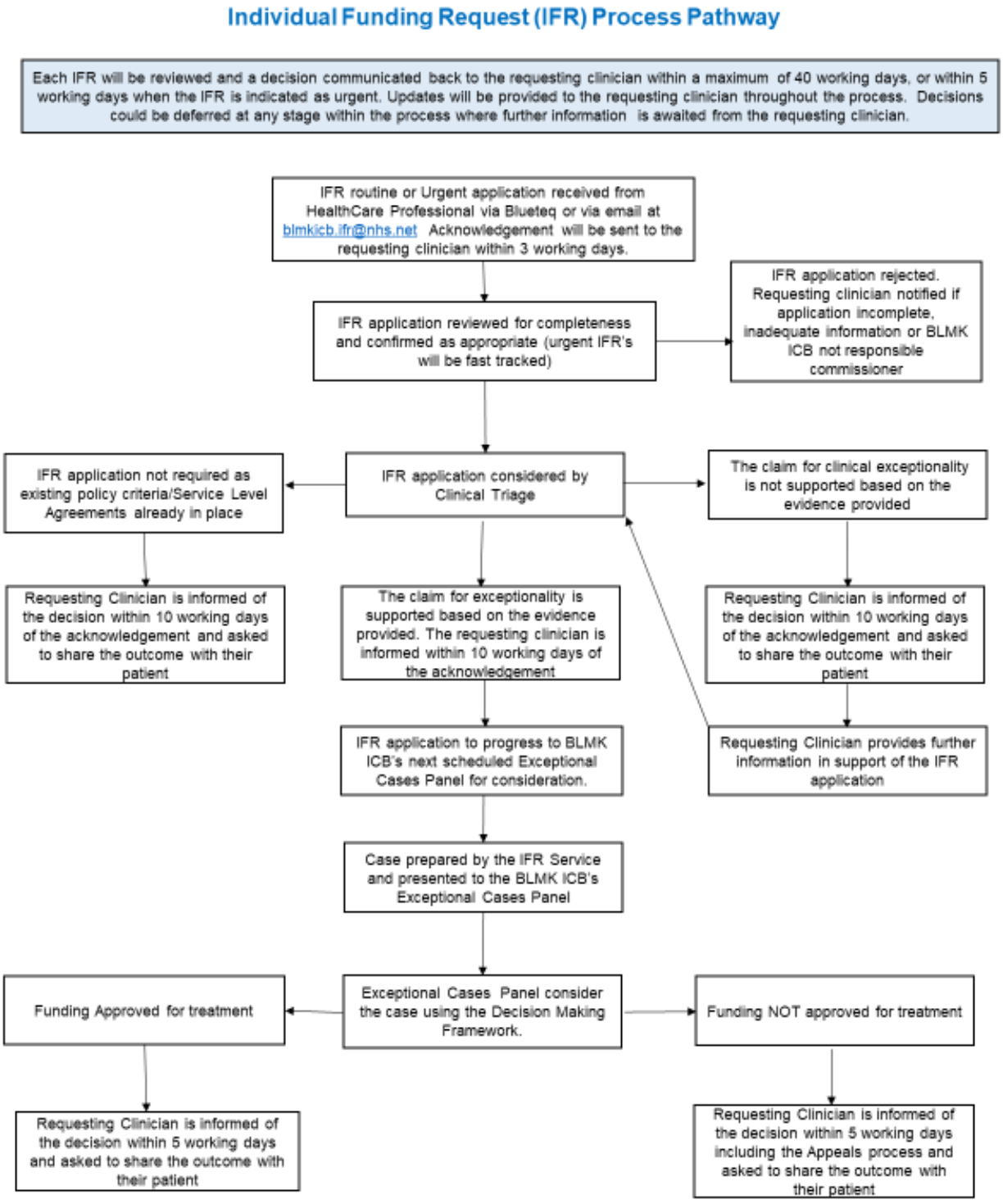
Please note a full stage 2 Data Protection Impact Assessment has been undertaken on the IFR Policy and is available at: www.bedfordshirelutonandmiltonkeynes.icb.nhs.uk/what-we-do/individual-funding-requests/individual-funding-request-ifr-policy-process-and-resources/

Stage 1 – DPIA form **please answer 'Yes' or 'No'**

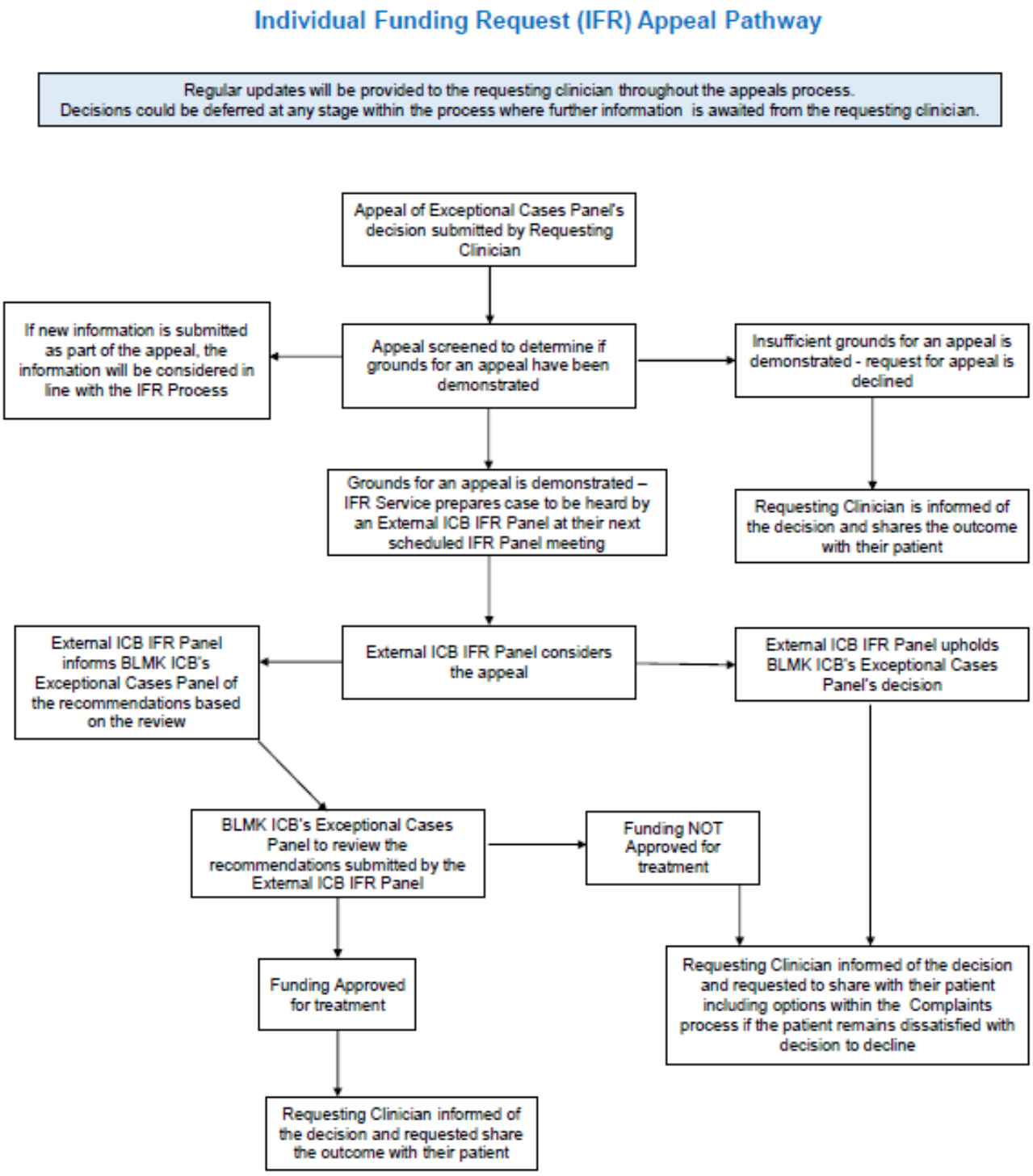
1.	**Will the policy result in the processing of personal identifiable information / data?** This includes information about living or deceased individuals, including their name, address postcode, email address, telephone number, payroll number etc.	Yes
2.	**Will the policy result in the processing of 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?**	Yes / 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



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 - Guidance on Service Developments & Cohorts of Similar Patients

1.0 Introduction

Bedfordshire, Luton and Milton Keynes Integrated Care Board's (the ICB) Individual Funding Request (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 IFR Policy is clear that where a cohort exists, a request cannot be considered through the IFR process and should instead be considered a service development proposal. This document provides further guidance on service developments and cohorts of similar patients.

2.0 Service Developments

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.

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

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

It is normal to consider funding new developments during the annual commissioning round, however in-year service developments (i.e. developments presented outside the annual commissioning round) can also be considered but if agreed, may result in disinvestment elsewhere.

It is not unusual for clinicians to request funding via the IFR process for a patient who actually represents the first of a group of patients wanting a particular treatment. Any IFR application that is representative of such a group represents a service development, and as such it is difficult to envisage circumstances in which the patient can properly be classified to have exceptional circumstances.

The IFR route is therefore not the appropriate route to seek funding for such patients, and therefore the IFR will not progress unless a clear and

compelling case is made to suggest that the individual is genuinely different from the identified cohort.

3.0 Cohorts of similar patients

Where the presenting clinical circumstances are representative of a small group of other patients the decision to fund or not is a commissioning policy decision, not a funding decision for an individual patient (i.e. it has wider funding implications). Treating a request as a commissioning policy decision within the wider context of the commissioning and priority setting, ensures that the outcome of the decision is applied equally to all other patients who have the same presenting clinical circumstances.

The ICB has set a level at which cases will require a commissioning policy decision. Once this level is met, the IFR route to funding can only be used if the patient is clinically exceptional to the cohort.

A commissioning policy decision will be required where the number of patients for whom the treatment will be requested per year is likely to exceed three or more patients in the population serviced by the ICB. If the number of patients reaches three or more, the ICB will treat this as a service development and therefore outside of the IFR process.

4.0 Screening for Service Developments

As set out in the IFR Policy, the IFR process will screen requests for service developments. Where a request meets the criteria to be considered a service development rather than an Individual Funding Request, the IFR process cannot consider the request. In these circumstances the IFR Service will either:

- Decline the IFR and advise the Provider making the application to prioritise a service development and if supported internally, invite the Provider to submit a business case either as part of the annual commissioning round, or as an in year service development proposal

- Decline the IFR and escalate the issue to commissioners within the ICB to initiate an assessment of the clinical importance of the service development with a view to developing a policy and determining its priority for funding either in year or as part of the next annual commissioning round.

As a general rule, the first approach will be applied to requests that originate from within a secondary care Provider organisation, and the second will be applied to requests that originate from a GP Practice. However, the ICB will use its discretion to determine the most appropriate action in each case.

Appendix 6 - Exceptional Cases Panel Terms of Reference

Date of Issue:	In line with IFR Policy ratification	**Review Date:**	In line with IFR Policy review

1. Purpose and Duties

1.1. The Exceptional Cases Panel (the Panel) is authorised by NHS Bedfordshire, Luton and Milton Keynes Integrated Care Board (the ICB) to assess cases for exceptionality in accordance with the ICB's Individual Funding Request (IFR) Policy.

1.2. In considering the cases, the Panel will aim to promote consistency, fairness and equity, ensuring effective use of resources and that the decisions are based on clinical evidence.

1.3. The Panel will also consider rare cases where no commissioning policy/service exists on an individual basis.

1.4. The Panel will provide an opinion to the Hertfordshire, West Essex and BLMK Priorities Forum on guidance revisions and guidance in development.

1.5. The Panel may also be asked to review cases previously considered by other external ICB Panels in line with their IFR Policy and Appeals process.

2. Membership and Voting

2.1. The membership of the Panel shall include:

Position	Role	Voting Rights
GP Board member of the ICB	Chair	Yes
Lay Board member of the ICB	Vice Chair	Yes
Nominated GPs x 2		Yes
Public Health Consultant or nominated deputy		Yes
Executive Director or nominated deputy		Yes
Commissioning Lead Pharmacist or nominated deputy		Yes*
IFR Service nominated Lead or nominated Pharmacy Lead for Medicines* cases	Case presenter	No
Panel Administrator	Notes of discussion, actions and decisions	No

* Medicines related cases only

2.2. Panel members will seek to reach decisions by consensus where possible, but if a consensus cannot be achieved, decisions will be taken by a majority vote with each Panel member present having an equal vote. If the Panel is equally split, then the Panel Chair will have the casting vote.

Other individuals with specific expertise and skills may be requested to attend the Panel on a non-voting basis, as and when necessary, in order to clarify funding issues for complex cases.

3. Quorum

3.1. The Panel will be quorate if three of the core members are present and must include a GP representative.

3.2. Where the case presented is related to a pharmaceutical (drug) request, a Commissioning Lead Pharmacist in addition to a GP representative will be required to form part of the quoracy (as per 3.1) for that particular case.

3.3. No formal business shall be transacted where a quorum is not reached.

4. Frequency of meetings and attendance

4.1. The Panel is held on a monthly basis dependent on the cases being presented. Where there are no cases for discussion, the Panel will not be required to meet.

4.2. Panel members should make every effort to attend every scheduled Panel meeting. The Panel Administrator will monitor attendance and will report on this annually.

4.3. Where a case is deemed clinically urgent, an extraordinary Panel will be established, consisting of the same quoracy principles set out in section 3.

4.4. The Panel is not obliged to allow patients to attend the Panel. The IFR process is clinician led and all deliberations at the Panel will be based on evidence of individual clinical exceptionality and will not take into account issues relating to social or personal circumstances.

4.5. Patients may submit a supporting statement, but this will be limited to clinical issues i.e. what effect the condition has on the patient's activities of day to day living. Any reference to social or personal circumstances will be redacted.

4.6. Where the Panel is to be held virtually, the video conferencing platform must be approved for use by the ICB in compliance with Information Governance and Data Protection requirements.

5. Authority

5.1. The Panel will consider cases in line with the financial authority as set by the ICB's Standing Financial Instructions (SFIs).

5.2. Where individual cases exceed the ICB's SFI financial limits, the case will require further approval by the Chief Transformation Officer

6. Reporting

6.1. The Panel reports to and is responsible to the Board of the ICB

6.2. The Panel will report annually to the Board of the ICB the number of cases considered, case outcomes, alongside any issues and risks arising.

7. Documentation

7.1. All cases will be anonymised before consideration by the Exceptional Cases Panel.

7.2. The IFR Service nominated Lead as outlined at section 2.1 will produce a summary of the key information using the Decision Framework Document which will be considered by the Panel. All other documentation that has been received regarding the case will also be available to the Panel.

7.3. All papers relating to the case in consideration will be made available to Panel members electronically no less than 5 working days prior to the meeting. For urgent cases, Panel members will be provided with papers at the earliest opportunity. Only those Panel members that have accepted an invitation to attend the Panel will receive papers for the case.

7.4. Formal minutes of the Exceptional Cases Panel will be recorded in writing and supported by an action log. The Decision Making Framework for each case will record the Panel discussion and overall decision. The Decision Making Framework for each case will be provided to the Panel Chair within 5 working days for final sign off.

7.5. The Panel Chair will write to the requesting clinician advising of the Panel's decision within 5 working days of the Panel meeting.

8. Training

8.1. All members of the Panel will be required to undergo mandatory training arranged by the ICB. Training will include Data Protection and the legal and ethical framework for IFR decision making.

8.2. The ICB's Panel members will work to the ICB's IFR Policy, commissioning processes and structures.

8.3. Training will be annually refreshed to ensure that all Panel members maintain the appropriate skills and expertise to function effectively.

9. Terms of Reference Review

9.1. The Panel Terms of Reference will receive an initial first year review and thereafter will be reviewed every two years as a minimum, unless the Panel has indicated an earlier review is necessary.

9.2. Any amendments to the Terms of Reference will require approval by the Board of the ICB

Appendix 7 –Exceptional Cases Panel Decision Making Framework

Bedfordshire, Luton and Milton Keynes Integrated Care Board (the ICB) Exceptional Cases Panel Decision Making Framework V2

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:

Cont/

The ICB's IFR Decision Making Framework

No.	Points for Consideration			Decision: Yes/No
	Individual need for care	**Definitions/considerations**	**Discussion Notes**	**Decision**
1a.	Does the ICB have a policy to cover the treatment which is made available to patients with the presenting medical condition?	1a. If the 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.		
1b.	Did the Panel reach the view that the patient had demonstrated **exceptiona**l **clinical circumstances** in this individual case?	1b. Exceptionality: Significantly different clinically to the group of patients with the condition in question and at the same stage of progression of the condition		
	Clinical effectiveness	**Definitions/considerations**	**Discussion Notes**	**Decision**
2.	Does the Panel consider that there is robust 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 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 robust 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**	3b. Exceptionality**:** Likely to gain significantly more clinical benefit from the intervention		

	greater clinical benefit than other patients with the same clinical condition and stage of disease?	than might be expected from the average patient with the condition		
	Cost effectiveness 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)			
4b.	What are the absolute costs involved in funding this treatment and how does this demonstrate value for money?	4b. Consider whether there are any cost neutral considerations that can be clearly evidenced including reduction in hospital admissions etc.		
4c.	Does the evidence indicate the treatment requested is likely to be cost-effective **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?	5a. 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?	5b. Consider if funding would divert resources away from the general ICB population		
	Other factors to consider	**Definitions/considerations**	**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?	6b. 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/ monitor-ing**
7.	**Funding Approved:**			Any conditions/ review mechanis ms required. Outcome measures to be monitored and date of review)
8.	**Funding Denied:**		**Reasons for Decision?**	

Appendix 8 - 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.