Derby and Derbyshire
Integrated Care Board

NHS Derby and Derbyshire Integrated Care Board

Individual Funding Requests

KEY POLICY MESSAGES	
1.	Has been developed to outline the process for the management of Individual Funding Requests by DDICB and the criteria to be used for decision making
2.	Specifies the statutory duties for the ICB
3.	Ensures due regard.

VERSION CONTROL

Title:	NHS Derby and Derbyshire Integrated Care Board Individual Funding Request Policy
Supersedes:	Version 5.1 – June 2019
Description of Amendment(s):	This publication is an update of the existing published policy on the management of Individual Funding Requests (IFRs) and outlines the criteria which are used for decision making.
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Author:	Helen Moss Individual Decisions and Project Manager
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List of Referenced Policies:	Derby & Derbyshire Integrated Care Board Ethical Framework Policy Derby & Derbyshire Integrated Care Board Experimental and unproved Treatment Policy
Key Words section (metadata for search facility online):	Individual Funding Request Clinical Exceptionality Decision Making Incidence and Prevalence
Reference Number:	C71
Target Audience:	ICB approved policies apply to all employees, contractors, volunteers, and others working with the ICB in any capacity. Compliance with ICB policy is a formal contractual requirement and failure to comply with the policy, including any arrangements which are put in place under it, will be investigated and may lead to disciplinary action being taken. ICB Clinical Leaders, Foundation Trusts, GP practices, Public Health Specialists, Pharmacists, Healthcare professionals who wish to apply for funding which sits outside of normal commissioning arrangements.

CONTENTS

1. INTRODUCTION

1.1 The NHS exists to serve the needs of all of its patients but also has a statutory duty financially to break even (Health & Social Care Act 2012). NHS Integrated Care Boards (ICBs) have a responsibility to uphold the pledges of the NHS Constitution, to provide health benefit for the whole of their population, and to commission appropriate care to meet the clinical needs of individual patients. The ICB receives fixed budgets from Central Government with which to commission the healthcare required by its population. Commissioned services include those provided through primary, secondary and tertiary care NHS providers, the independent sector, voluntary agencies and independent NHS contractors and in-house service providers.

The ICB has a statutory responsibility to have in place a process for considering funding for individuals who seek NHS commissioned services outside of established commissioned services.

1.2 DDICB do not expect to make significant decisions about funding outside the process that is routinely used and in particular do not expect to commit significant new resources in year to the introduction of new healthcare technologies (including drugs, surgical procedures, public health programmes), since to do so risks ad hoc decision making and can destabilise previously identified priorities.

1.3 The intended audience is those responsible for the operation of the Individual Funding Request process and related decision making. It will also be of interest to those wishing to apply for funding of treatments under the IFR policy. It should be read in conjunction with the following policies:

- DDICB Ethical Framework for Decision Making Policy
- DDICB Experimental and Unproven Treatments Policy

1.4 DDICB is the statutory body responsible for the consideration of IFRs for those patients registered with a Derbyshire GP practice whose identified clinical needs sit outside routine commissioning.

1.5 There is a single process in place for the management of all IFRs. Decisions are made at each stage of the process by an IFR Screening Pair, IFR Panel and IFR Process Review Panel.

2. PURPOSE OF THE INDIVIDUAL FUNDING REQUEST POLICY

2.1 The IFR process set out in this policy will be used to consider individual requests for funding where a service, intervention or treatment falls outside service agreements.

2.2 This process will ensure that each request for individual funding is considered in a fair and transparent way, with decisions based on the best available evidence and in accordance with the ICB commissioning principles.

3. OVERVIEW OF INDIVIDUAL FUNDING REQUEST POLICY

3.1 Every year, the resources DDICB receives are allocated to services and treatments that can be provided for patients, through development and review of commissioning policies which apply robust criteria to the question of how the services and treatments should be funded. Any additional calls on resources to fund an individual's treatment are, therefore, likely to mean reducing the funding that is available elsewhere. The decision to fund a treatment that is not usually provided is only taken after very careful consideration. DDICB regards the matter of funding for an individual patient as an equity issue, in which it will consider whether it can justify funding a particular patient when others from the same patient group are not being funded for the requested treatment.

3.2 Very occasionally, a clinician may think that their patient's clinical situation is so different to other patients with the same condition that it is appropriate that they should have different treatments compared to other patients with the same condition. In such circumstances, treating clinicians, on behalf of their patient, may make an IFR request to DDICB for a treatment that is not routinely commissioned by DDICB. This route should only be used in exceptional circumstances and not as an alternative route to submitting a treatment for scrutiny through the Service Development process.

It is important to draw a distinction between the IFR policy and process, which is part of an overall NHS prioritisation framework, and "Access Schemes" which may be periodically offered by commercial companies or the manufacturers of treatments to introduce their products to market in cases where there may be some clinical effect. Those "Access Schemes" are a matter for their promoters and do not establish any precedent for IFR requests.

3.3 IFRs can be made against all DDICB commissioned services where a patient is not usually eligible for treatment. However, if there is evidence that other patients with the same condition could derive a similar type and degree of benefit from the treatment, the request will be considered as a new development in services for that group of patients. In this case the clinician will need to consider proposing this treatment for development of a clinical policy. So that DDICB can be fair to all patients, decisions on whether to fund this new development will be taken in line with the DDICB ethical framework. In these circumstances, the request will not proceed through the IFR process.

4. WHEN WILL DDICB CONSIDER FUNDING?

4.1 DDICB will only provide funding in response to an IFR, if it is satisfied that the case meets the following criteria:

- There is evidence that the patient presents with exceptional clinical circumstances[1], that is:
    - There is an DDICB clinical commissioning policy, NICE Technology Appraisal (TA) guidance and/or other relevant mandatory/statutory guidance that

[1] To note: in parts of this policy we refer to clinical exceptionality as shorthand for patients being different, as described here

governs whether to fund or not fund the treatment for the patient's condition, and a clinician can show that their patient is in a different clinical condition or stage when compared to the typical patient population with the same condition and (if relevant) at the same stage of progression, and because of that difference their patient is likely to receive material additional clinical benefit from treatment that would not be plausible for any typical patient.

OR

- There is not a relevant DDICB clinical commissioning policy NICE Technology Appraisal (TA) guidance and/or other relevant mandatory/statutory guidance in place for the management of the patient's condition or combination of conditions, and the patient's clinical presentation is so unusual that they could not be considered to be part of a defined group of patients in the same or similar clinical circumstances. Where a patient represents a cohort a service development should be undertaken, which is outside of the IFR process.

OR

- There is not a relevant DDICB commissioning policy, NICE Technology Appraisal (TA) Guidance in place for the management of the patient's conditions, or combination of conditions, and there is evidence to suggest that both the incidence and prevalence criteria set out below are met

  - Incidence i.e., the number of new cases of a disease in a defined population within a specified period of time

    The intervention for a particular condition at the same stage of progression of that condition is expected to be initiated for two or fewer patients per million population per year.

  - Prevalence i.e. the number of cases of a disease in a defined population at a point in time

    The total number of patients on the intervention for a particular condition at the same stage of progression of that condition is less than 10 patients per million population at any one time

AND

- There is a basis for considering that the patient is likely to gain more clinical benefit from the requested treatment than other patients to whom the policy applies.

AND

- It is considered that the requested treatment is likely to be a good use of NHS resources.

4.2 DDICB IFR team will carry out an initial screening as described in the section of this policy *'Screening process for IFR requests'*. If the request proceeds beyond the screening stage, decisions on whether to fund the request will be made by DDICB IFR

Panel. Details of the IFR team, IFR Panel and the processes that are followed, are set out in the DDICB *Standard Operating Procedures: The Management of Individual Funding Requests*, which includes the Terms of Reference for the IFR Screening Pair, IFR Panel and IFR Review Panel.

4.3 This policy explains each of the criteria outlined in turn.

5. FURTHER EXPLANATION OF THE IFR CRITERIA

5.1 Clinical exceptionality

There can be no exhaustive description of the situations which are likely to come within the definition of exceptional clinical circumstances. The onus is on the clinician making the request to set out the grounds for clinical exceptionality clearly for the IFR Panel.

'Exceptional' in IFR terms means a person to whom the general rule should not apply[2]. This implies that there is likely to be something about their clinical situation which was not considered when formulating the general rule. Very few patients have clinical circumstances which are genuinely exceptional. To justify funding for treatment for a patient which is not available to other patients, and is not part of the established care pathway, the IFR Panel needs to be satisfied that the clinician has demonstrated that this patient's individual clinical circumstances are clearly different to those of other patients, and that because of this difference, the general policies should not be applied. Simply put, the consideration is whether it is fair to fund this patient's treatment when the treatment is not available to others. It should be stressed that an IFR is not a route to "have another look" at the general rule, or to protest that the general rule is ungenerous.

Where a 'not for routine commissioning' clinical commissioning policy is in place in relation to a treatment, DDICB will have been aware when making that policy that in most studies, some patients will respond better than others to the treatment and indeed, a small group may respond significantly better than the average. This should have been taken into account in developing the policy. Consequently, in considering whether a request for an IFR should be made, the clinician should consider whether this individual patient is likely to respond to the treatment in a way that exceeds the response of other patients in the group to which the general policy applies, and whether there is evidence to support this view.

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

[2] In this context the "general rule" might be a policy that describes those patients who can access the intervention, or it may be that where there is no policy governing the treatment in this condition in the interest of fairness to all patients, the position is that it will not be commissioned ahead of policy development

5.2 Clinical exceptionality: failure to respond to standard care

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

Many conditions are progressive and thus inevitably there will be a more severe form of the condition – severity of a patient's condition does not in itself usually indicate exceptionality. Many treatments have side effects or contraindications, and thus intolerance or contraindication of a treatment does not in itself, usually indicate exceptionality.

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

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

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

If the usual treatment cannot be given because of a pre-existing co- morbidity which is unrelated to the condition for which the treatment is being sought under the IFR or is not unusual in the relevant patient group or generally, the fact that the co-morbidity is present in this patient and its impact on treatment options for this patient is unlikely to make the patient clinically exceptional. As an illustration, some comorbidities are common in the general population, for example, diabetes which affects around 7% of adults, or asthma which affects at least 10% of the population. Diabetes and its treatments affect many other conditions; for example, steroids make glucose control more difficult. With any condition there will be a recognised proportion who also have a comorbidity which is common in the general population, and thus a patient cannot be exceptional by virtue of also having a comorbidity which is common in the general population.

If the proposed intervention is thought to offer a benefit to patients in these groups generally (i.e. those with more severe disease or those with common co-morbidities), the question is whether there is sufficient justification, including consideration of factors such as clinical effectiveness of the treatment in question, likely value for money,

priority and affordability, for making a change to the clinical commissioning policy that covers the patient pathway. In this way, an improvement can be made to that policy to benefit the whole subgroup of patients of which the requesting patient is potentially just one such person. This change needs to be considered as a service development and not as an IFR.

5.3 Clinical exceptionality: severity

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

- Whether there is evidence that the patient's presentation lies outside the normal spectrum for that condition. Preferably, a recognised scoring or classification system should be used to describe the patient's condition.
- Whether there is evidence that the patient has progressed to a very severe form of the condition much more rapidly than the range of progression that is documented and usually observed within the natural history of the condition.
- How the patient is expected to benefit from the treatment sought and in what quantifiable way.
- That there is evidence that the impact of the condition on this patient's health is significantly greater than its impact on the rest of the patient group, e.g. the condition is usually a mild disease, but the presenting case is an extremely severe presentation; and
- That there is a plausible argument that the severity of the condition is prognostic of good response to treatment.

5.4 Clinical exceptionality: genotypes

When the argument for clinical exceptionality is based on the patient having a specific genotype (genetic profile), the IFR Panel will require evidence of the prevalence of the genotype in the patient group. The applicant will need to show how the specific genotype would make the patient a) different to others in terms of clinical management and b) able to benefit from the treatment to a greater degree than others with the same or different symptoms of the condition.

5.5 Clinical exceptionality: multiple grounds

There may be cases where clinicians seek to rely on multiple factors to show that their case is clinically exceptional. In such cases each factor will be looked at individually to determine (a) whether the factor is capable, potentially, of making the case exceptional and (b) whether it does in fact make the patient's case exceptional. One factor may be incapable of supporting a case of exceptionality (and should therefore be ignored), but it might be relevant on another factor. That is a judgment within the discretion of the IFR screening pair and IFR Panel.

If it is determined that none of the individual factors on their own mean that the patient's clinical circumstances are considered exceptional, the combined effect of those factors as a whole will be considered. In this way a decision can be reached on whether the

patient's clinical circumstances are exceptional, bearing in mind the difference between the range of factors that can always be found between individuals and the definitions used here of exceptional clinical circumstances.

5.6 Individual patient

An Individual Patient is determined by reviewing the incidence and prevalence of the requested intervention for a particular condition at the same stage of progression of that condition. If DDICB has no policy for the intervention being requested for a particular condition, then the IFR Panel can only consider the request if both the incidence and prevalence criteria that are set out below are met or the patient has exceptional clinical circumstances compared to the cohort of patients (however small) with the presenting condition.

In some cases, DDICB may have adopted policies for small numbers of patients which have often been developed regionally i.e. functional electrical stimulation, surrogacy. If the request is covered by such a policy, then it should be viewed as a request to change the policy and therefore will not be considered under the IFR Policy, even if the incidence and prevalence criteria are met.

An IFR request for an individual patient will be considered by the IFR Panel on its individual merits with the decision on whether to fund a requested intervention based on the evidence of clinical, cost effectiveness, affordability and safety. If both the prevalence and incidence criteria are not met, then the ICB will not consider that the request represents an individual patient. In these circumstances, funding can only be provided if a decision is made by the ICB to develop a policy for the requested intervention for a group of patients, including the requesting patient; unless the patient has exceptional clinical circumstances compared to the cohort of patients (however small) with the presenting condition. Such a change must happen through the normal commissioning process (which will require the development of a business case and for the treatment to be prioritised against other developments) or through the ICB agreeing to develop a policy outside this process. Once the policy is developed it will apply to all similar patients. However the IFR process is not the process for the ICB to develop such policy.

- Incidence i.e., the number of new cases of a disease in a defined population within a specified period of time. The intervention for a particular condition at the same stage of progression of that condition is expected to be initiated for two or fewer patients per million population per year.

- Prevalence i.e. the number of cases of a disease in a defined population at a point in time. The total number of patients on the intervention for a particular condition at the same stage of progression of that condition is less than 10 patients per million population at any one time.

5.7 Non-clinical and social factors

The IFR process only considers clinical information. Although initially it may seem reasonable to fund treatment based on reasons grounded in a moral or compassionate view of the case or because of the individual's situation, background, ambition in life, occupation or family circumstances, these reasons bring into play a judgement of

'worthiness" for treatment. As a central principle, the NHS does not make judgements about the worth of different individuals and seeks to treat everyone fairly and equitably. Consideration of these non-clinical factors would introduce this concept of 'worth' into clinical decision making. It is a core value that NHS care is available - or unavailable - equally to all. Whilst everyone's individual circumstances are, by definition, unique and on compassionate grounds, reasons can always be advanced to support a case for funding, it is likely that the same or similar arguments could be made for all or many of the patients who cannot routinely access the care requested.

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

Consideration of social factors would also be contrary to DDICB policy of non-discrimination in the provision of medical treatment. If, for example, treatment was to be provided on the grounds that this would enable an individual to stay in paid work, this would potentially discriminate in favour of those working compared to those not working. These are value judgements which the IFR screening pair and IFR panel should not make.

Clinicians are asked to bear this Policy in mind and not to refer to social or non-clinical factors to seek to support the application for individual funding. In order to avoid prejudicing the IFR process, such material will be edited out or applications returned to clinicians for editing by the IFR team and on recommendation by the screening pair.

5.8 Clinical effectiveness

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

Clinical evidence that considers the efficacy of a particular treatment will be carefully considered by the IFR panel. The IFR screening pair may consider the plausibility and relevance of the efficacy of a particular treatment and share their view to support the IFR panel. It is the sole responsibility of the referring clinician to provide this information. Although the IFR team will not be responsible for undertaking any evidence searches. DDICB reserve the right to conduct searches to check if additional evidence is available. Inevitably, the evidence base put forward in support of an IFR is unlikely to be as robust as in more common presentations of the condition or the more usual use of the treatment. However it is important that the referring clinician makes explicit linkages between the grounds under which exceptionality is claimed and the sections of the submitted research literature that are considered to support the clinician's view regarding the differences between the patient's clinical position and that of other patients in the group, and regarding the patient's anticipated response to the requested treatment.

When considering clinical effectiveness, the IFR panel will consider:

- How closely the patient matches the patient population from whom the results are derived in any study relied on by the clinician

- The plausibility of the argument that the patient will achieve the anticipated outcomes from treatment, based on the evidence supplied

- The impact of existing co-morbidities on both the claim for exceptionality and treatment outcome

- Any complications and adverse events of the treatment including toxicity and rates of relapse. The panel will take account of side effects when considering the benefits from the treatment

- The likely impact of the treatment on quality of life using information as available

- Reported treatment outcomes and their durability over the short, medium and longer term, as relevant to the nature of the condition. The requesting clinician must demonstrate why they consider that the proposed treatment will be effective for the whole period for which it will be given.

5.9 Affordability

As each ICB is duty bound not to exceed its budget, the IFR Panel will be expected to consider the affordability of the treatment being requested in relation to the overall resources of the ICB for healthcare. The affordability is significant as investing in one area of health care inevitability diverts resources from other uses. This is known as opportunity costs and is defined as benefit foregone, or value of opportunities lost, that would accrue by investing the same resources in the best alternative way.

5.10 A good use of NHS resources

The requesting clinician will be expected to explain why they consider the treatment for which funding has been applied for will be a good use of NHS resources.

This criterion is only applied where the Panel has already concluded that the criteria of clinical exceptionality or individuality, and clinical effectiveness have been met. Against this criterion the Panel balances the degree of benefit likely to be obtained for the patient from funding the treatment against cost. Having regard to the evidence submitted and the analysis they have carried out when considering clinical exceptionality and clinical effectiveness, Panel members will consider the nature and extent of the benefit the patient is likely to gain from the treatment, the certainty or otherwise of the anticipated outcome from the treatment and the opportunity costs for funding the treatment. This means considering, for example, how significant a benefit is likely to be gained for the patient, and for how long that benefit will last. These factors need to be balanced against the cost of the treatment and the impact on other patients of withdrawing funding from other areas in order to fulfil the IFR. This reflects the fact that the only way to provide the funding for treatment under IFRs, i.e. outside commissioned clinical policies which are developed through the structured prioritisation process, is to divert resources away from current services.

When determining whether a treatment would be a good use of NHS resources it is very important to consider the length of time for which funding of a treatment is being requested, in relation to the duration of the evidenced efficacy of the treatment i.e.

whether the clinical evidence indicates short, medium or long-term effectiveness of a particular treatment, together with the associated costs related to the activity.

Due to the very nature of the cases considered by the IFR Panel, the degree to which effectiveness can be considered certain is likely to be limited, and this will be a relevant factor when considering whether funding would be a good use of NHS resources.

However the Panel should also take into account its ability to impose conditions on any funding it agrees, for example to monitor the impact of the funded treatment.

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

5.11 Experimental and unproven treatments

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

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.

When an individual case has been found to be exceptional, the treatment proposed might, by definition, be considered to be unproven, and this is why the Panel must carefully consider whether funding of such treatments is a good use of NHS resources as described above. However this section of the policy applies to the particular categories of experimental or unproven treatment which are described below.

5.12 What is an experimental treatment?

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

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

5.13 How are IFRs for experimental treatments considered?

The experimental basis of the treatment will become relevant when the Panel assesses the likely clinical effectiveness of the treatment for the patient and then, primarily, when the 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.

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

As preliminary requirements before agreeing to fund an experimental treatment, DDICB 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 DDICB Ethical Framework; and
- That funding experimental treatments is done in a way that will contribute to the knowledge base.

The 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.

DDICB will consider a funding request for an experimental treatment where there is either:

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

In assessing whether to fund treatment in these cases, DDICB will make a decision having regard to:

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

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

identify the clinical markers and clinical outcomes that will be monitored to assess treatment response.

The options for consideration by DDICB in these instances are:

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

5.14 Funding for cases following a clinical trial

Save in the most exceptional cases, DDICB does not anticipate that it will agree a request under this IFR policy to fund patients at the end of a clinical trial. This is because arrangements to continue treatments from which patients have benefited during a trial should be agreed with the sponsor of the research at the outset of the trial and information should have been given to patients as part of the process of patients signing up to participate in the trial. Even if this is not the case, patients coming out of a clinical trial will almost inevitably represent a group of patients for whom a policy should be developed under the Service Development policy, because there will be a number of patients in broadly the same clinical circumstances, and so it is very unlikely that the patient will be able to show clinical exceptionality within this policy.

5.15 Request to continue funding for treatments commenced "at risk" by providers or by others (including patients)

On occasions, a request is received where a provider Trust has commenced an unfunded treatment prior to asking for or receiving confirmation that the ICB will approve funding. Evidence that the patient is responding to the treatment is then presented as part of the case for ICB funding. The provider trust's decision to commence treatment in advance of any decision by the ICB to fund is a clear risk taken by the trust and/or patient. The ICB accepts no responsibility for the decision taken by the provider trust in these circumstances.

In considering a request for funding the ICB will apply the criteria set out in this policy as it would for any other request and accords no special privileges because the unfunded treatment was given by a provider trust. The ICB policy is that, unless a decision has been taken to approve routine funding for a treatment, the treatment will only be commissioned for an individual patient if the clinician is able to demonstrate that the patient has exceptional clinical circumstances. The fact that a patient has responded to a drug or other treatment in a manner which was anticipated for a proportion of patients who are commenced on the treatment is unlikely to be sufficient to demonstrate exceptional clinical circumstances. Where such an application is approved on the basis of the clinician demonstrating that the patient has exceptional clinical circumstances (as defined in this policy), the ICB will not accept responsibility

for the costs of any treatment provided by the provider trust prior to authorisation being given by the ICB.

A similar approach will be adopted if a treatment has been funded initially by a pharmaceutical company or other third party. There are occasions where the initial stages of an unfunded treatment have been funded privately by the patient. The ICB will consider any information submitted on behalf of a patient in support of their case that the patient has exceptional clinical circumstances. This may include evidence derived from treatment that has been purchased privately and used by the patient. However, this potentially opens the way for a limited group of patients who can afford to fund a treatment that the ICB does not usually fund to be able to demonstrate benefit by virtue of access to private care and then submit this as a reason to justify NHS funding for the treatment in their particular case. This is a potentially inequitable approach and, in order to ensure that the ICB does not act in an inequitable manner, the issue of exceptional clinical circumstances will therefore continue to be the criteria applied by the IFR process. Accordingly, the ICB adopts no presumption in favour of continuing treatment which has been previously paid for privately by the patient. As stated above, evidence that a treatment works as anticipated for a proportion of patients in the patient's clinical circumstances is unlikely, in itself, to provide evidence of exceptionality.

5.16 Decisions inherited from other ICBs e.g. a patient who moves

Occasionally patients move into the area and become the responsibility of a local ICB when a treatment option has already been approved by the ICB that was previously responsible for the patient's care. The ICB policy is that, subject to resource constraints, it will normally agree to continue the treatment providing the care pathway has been initiated by a responsible NHS consultant and the requested treatment remains clinically appropriate

5.17 Treatment in another country

Requests for NHS funded treatment abroad will be considered by NHS England in accordance with the current processes for accessing treatment in European Economic Area (EEA) countries via the S2 route and the Directive route.

5.18 Request to Continue Funding of Care commenced privately – e.g. reverting to NHS care

Requests to Continue Funding of Care Commenced privately e.g. reverting to NHS care Patients who are having private treatment have a right to revert to NHS funded treatment at any point during their care. However, if they wish to exercise this right, the ICB will expect their care to be transferred to locally NHS commissioned services. Funding for the individual to continue care in a private facility or to transfer to an NHS provider with which a clinician consulted privately has a contract of employment will not routinely be authorised unless they form part of local pathways.

Where personal clinical circumstances may make such funding appropriate the case will require consideration by the IFR Screening pair/panel.

5.19 Information submitted to the DDICB IFR team

All applications must be accompanied by written support and evidence provided by the clinician treating the patient in line with the DDICB IFR Standard Operating Procedures

It is the referring clinician's responsibility to ensure that all the appropriate and required information is provided to DDICB in a timely fashion consistent with the urgency of the request. Applications need to be in a typed format to ensure that they are fully legible. The clinician must provide a list of the published papers that have been submitted and indicate which points within them are relevant in respect to the IFR application and criteria. This is to ensure the IFR screening pair and IFR panel are clear about the points the clinician is making and the relevance to the case. If relevant information is not submitted, decision making will be delayed because the case cannot be fairly considered without adequate evidence. In all instances the referring clinician must state whether or not they consider there are likely to be similar patients in the same situation (in accordance with the definition set out in this policy) and, if so, how many such similar patients there are or are likely to be in the opinion of the referring clinician in Derbyshire in any given 12-month period.

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

DDICB expects providers with which it contracts to have oversight of the applications submitted by their clinical staff. DDICB expects every IFR to be sanctioned by the provider's Board level Medical Director or equivalent and reserves the right to return unconsidered IFRs to the provider and refer recurrent inappropriate funding requests to the Chief Executive (or equivalent) of the relevant provider.

Ultimately DDICBs IFR decision is whether DDICB will reimburse a provider for a particular treatment intervention for the individual patient. However, that decision does not itself determine whether a clinician actually undertakes that treatment. The trust is at liberty to resource the treatment within its own Governance and internal agreement process.

6. SUMMARY OF THE IFR PROCESS

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

Screening process for IFR requests

6.1 Why are applications subject to screening?

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

The screening process described in this Policy is intended to be fair to all parties, including the other patients funded by DDICB and the IFR Panel, by only sending

cases to a panel meeting if there is some reasonable prospect that the IFR Panel will accept that the criterion under this policy is met in the individual case. This means the IFR Panel can then apply all of its time to those cases which have a prospect of success.

6.2 Screening for sufficient information

Any IFR requests will first be screened by DDICB IFR team in accordance with the procedures set out in the DDICB IFR SOP to establish whether the request falls within the commissioning responsibility of DDICB and has sufficient clinical or other necessary information for it to be properly considered. All requested will need to be submitted in a typed format and each section of the IFR form will need to be completed in full in order for the request to progress. Where the IFR team conclude that there is insufficient information, or the form has not been completed or is not in a typed format it will be returned to the referring clinician specifying the additional information required.

The IFR Panel can only approve funding if all of the criteria in the policy are satisfied. It follows that the IFR Screening Pair should not allow an application to go forward to the IFR Panel unless there is information to support the contention that each of the essential criteria is met. A strong application on one part of the criteria cannot make up for an absence of proper evidence to support another of the tests that the IFR Panel must apply in order to make a decision that funding should be approved.

6.3 Screening for service developments

If, in the opinion of the IFR screening pair considering a submitted IFR in relation to a patient, there is likely to be a defined group of patients in similar clinical circumstances to that patient, the application will be classified as a request for development of a new policy or service specification which needs to be considered by the DDICB to determine whether it will be routinely commissioned. The requesting clinician will then be redirected to the relevant contact point to start the process in that policy. The request will not be progressed through the IFR route from that point.

6.4 Screening for clinical exceptionality and individuality

All IFRs submitted to DDICB will be considered by the IFR Screening Pair to determine whether the request appears to present an arguable case for clinical exceptionality, or the case can be considered to represent an individual patient. The IFR screening pair, consists of a Senior Public Health professional and Assistant Director of medicines Management & Clinical Policies from the ICB (as outlined in the IFR SOP). Their understanding of the information required by an IFR panel enables them to make these decisions. They have delegated authority to make these judgements and will seek additional clinical input at their discretion. If the screening pair considers that there is not an arguable case for clinical exceptionality or individuality the IFR will not proceed further through the process and will be declined.

An IFR will be considered as indicating an "arguable case" for clinical exceptionality if the IFR Screening pair consider that there is some realistic prospect that the IFR Panel (properly applying the policy) would conclude that the patient is clinically exceptional. A case would be turned down only where the IFR Screening Pair are confident that, based on the available information, if the IFR Panel properly apply this policy, it would come to the same conclusion that the patient is not clinically exceptional. If the IFR

Team have any reasonable doubt about whether a case satisfies the criterion of exceptionality, it should be forwarded to the IFR panel.

If a case is returned to the applicant from the screening stage, the explanation provided may enable the requesting clinician to submit new clinical information to augment the original argument for clinical exceptionality or individuality. The IFR screening pair will reconsider a case if new and relevant clinical information is provided.

6.5 Decisions on funding

The IFR Panel makes decisions in respect of funding for individual cases and is accountable to the Clinical Policy Advisory Group and through it to the Population Health Strategic Commissioning Committee with a direct reporting relationship to the ICB Board. The IFR Panel will work to the published DDICB IFR Policy, and each request will be processed by following the DDICB IFR SOP. This will ensure that all requests are considered in a consistent, fair and transparent way, with decisions based on the available evidence presented by the treating clinicians in line with the DDICB Ethical Framework.

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

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

The IFR Panel will make its decision based on the criteria in this policy with reference to any other DDICB published clinical commissioning policies or NICE mandated guidance relevant to the application or interpretation of the criteria.

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

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

It is also open to the IFR Panel to conclude, notwithstanding the screening decisions taken by the IFR screening pair, that:

- The request should be properly classified as a service development. In this case the request will be refused, and the requesting clinician will be informed to consider submitting a business case to the ICB ; or

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

In considering individual cases, the IFR Panel will take care to avoid identification bias. This term describes the effect on decision makers of being presented with the detail of an individual's life. In these circumstances, it is hard to separate from the emotion behind a decision. Decision makers are more likely to decide in favour of that individual, even when this is at the expense of others who cannot be identified as clearly (also see section on non-clinical factors, (Section 5.7of the IFR Policy).

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

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

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

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

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

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

6.6 Reconsideration

If the referring clinician and/or the patient/guardian or carer believes that there is further relevant information that was not considered by the Panel, they may ask the ICB to reconsider the case specifically in the light of this information. The additional information must be submitted to the IFR Officer within 10 working days of the date of the letter from the IFR panel setting out the panel decision. The ICB Screening Pair will determine, normally within 12 working days, whether the additional information significantly alters the nature and strength of the evidence that was submitted to the initial panel meeting.

If the new information is considered to be significant, a further panel meeting will be convened normally within 30 working days of the triage meeting. If the new information is not considered to be significant, the referring clinician and the patient/guardian or carer will be informed by letter with reasons for the decision not to refer the request back to the IFR Panel.

6.7 Review of the decision

Where the IFR Panel has not supported funding for a requested treatment or has approved the treatment subject to conditions, the patient or requesting clinician is entitled to ask that the process which led to the decision of the IFR Panel be subject to a Review.

All requests for a Review must be made within 20 days of the date when the decision is communicated to the patient. The request will be supported by the referring clinician who must set out the grounds on which the IFR panel decision is being challenged. A review can be requested on two grounds. It is believed that:

- The IFR panel failed to follow due process and, as a result, the decision reached by the panel was difference to the one that would be reached if due process had been followed
- The IFR panel did not take into account, or weigh appropriately, all relevant evidence when applying the DDICB Decision Making Framework.

The request for a Review will be initially considered by a Public Health Consultant/Specialist not involved in the original IFR application. If the Public Health Consultant/Specialist considered that there is an arguable case to support the review a formal review panel meeting will be convened. The role of the IFR Review Panel is to determine whether the IFR Panel has followed the procedures as written in the DDICB IFR SOP, has properly understood and considered the evidence presented to it and has come to a reasonable decision based on the evidence.

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

- Was taken following a process which was consistent with the policies of DDICB
- Was a decision which a reasonable IFR Panel was entitled to reach.
- Understood, took into account and weighed, all the relevant evidence; and
- Did not take into account any irrelevant factors.

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

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

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

In the circumstances of a formal legal challenge, an internal review of the process taken leading to a decision will automatically be triggered by DDICB.

6.8 Urgent decisions for Individual Funding Requests

An IFR Panel usually meets according to a schedule designed to provide frequent and timely opportunities to consider applications. Cases are screened within 12 working days and the IFR panel meets on a monthly basis, if required. Consequently cases can be processed quickly if necessary. Although it may seem that there should be a route by which certain cases could bypass the usual process and decisions could be taken on the same day, this has the potential to introduce unfairness into the process. This is because:

- Cases submitted outside the usual process are unlikely to have been able to gather the necessary research evidence upon which a decision can be properly taken
- In such circumstances the information on the probability of a response to treatment and the nature of that response is unlikely to be clear
- As a result of these uncertainties it is probable that decisions would be subject to the 'rule of rescue' in a way that cases considered in the usual process would not
- It would be impossible to convene a properly constituted panel in a very short timescale. Decisions taken by one or two panel members acting alone, increases risks of coming to the wrong decision
- A trust is able to begin treatment and seek retrospective approval and if successful, reimbursement

There is a provision for cases to be processed more quickly than the 30-working day standard (stated in the SOP). Providers must take all reasonable steps to minimise the need for urgent requests to be made through the IFR process, for example, by making requests promptly and providing all necessary information with a request. If requesting clinicians are considered by DDICB not to be taking all reasonable steps to minimise urgent requests to the IFR process, DDICB may refer the matter to the clinician's Chief Executive or equivalent.

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

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

6.9 Identifying urgent cases

The Screening pair can determine that a case is clinically urgent after consultation with the patient's clinician

Urgent meetings will be convened at the request of the Chair as outlined in the IFR Panel Terms of Reference.

Decisions that are made urgently outside of the formal IFR panel meeting will be taken to the next meeting of the IFR panel for information.

7. EQUALITY STATEMENT

7.1 The ICB aims to design and implement policy documents that meet the diverse needs of our services, population and workforce, ensuring that none are placed at a disadvantage over others. It takes into account current UK legislative requirements, including the Equality Act 2010 and the Human Rights Act 1998, and promotes equal opportunities for all. This document has been designed to ensure that no one receives less favourable treatment due to their protected characteristics of their age, disability, sex (gender), gender reassignment, sexual orientation, marriage and civil partnership, race, religion or belief, pregnancy and maternity. Appropriate consideration has also been given to gender identity, socio-economic status, immigration status and the principles of the Human Rights Act.

7.2 In carrying out its function, the ICB must have due regard to the Public Sector Equality Duty (PSED). This applies to all activities for which the ICB is responsible, including policy development, review and implementation.

8. DUE REGARD

8.1 This policy has been reviewed in relation to having due regard to the PSED of the Equality Act 2010 to eliminate discrimination; harassment; victimisation; to advance equality of opportunity; and foster good relations between the protected groups.

9. REFERENCES/SUPPORTING DOCUMENTS

- DDICB Ethical Framework for Decision Making Policy
- DDICB Experimental and Unproven Treatments Policy
- NHS Derby & Derbyshire ICB Individual Funding Request Policy, published 2019
- ICB commissioning principles – DDICB five-year Plan 2023-2028