NHS Devon

Individual Funding Request Policy

NHS Devon

One Devon

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Policy Sponsor	Chief Medical Officer
Policy Lead	Rebecca Owen, Clinical Effectiveness Governance and IFR Panel Manager
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Date	**Change**	**Comments**
12/05/2025	Policy Amendment	Routine review of policy. Edited to reflect new Policy Lead and minor formatting. No material changes to content required.
07/10/2024	Policy Amendment	Minor changes to update web links, new email address and formatting
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01/04/2022	Policy Amendment	Minor update to NHS Devon CCG
01/09/2019	Policy Amendment	
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Equality, diversity and inclusion statement

NHS Devon is committed to the promotion of equal opportunities, addressing health inequalities and fostering of good relations between people protected under the terms of the Equality Act 2010, the Health and Social Care Act 2012 and Human Rights legislation. We are equally committed to the elimination of unlawful discrimination, harassment and victimisation. To demonstrate this commitment, we develop, promote and maintain policies, strategies and operating procedures. Every effort is made to ensure that patients, employees, contractors or visitors do not experience discrimination; either directly or indirectly, because of their vulnerability; disadvantage; age; disability; gender reassignment; marriage and civil partnership; pregnancy and maternity; race; religion and belief; sex (gender) or sexual orientation.

All staff must comply with this policy. Compliance must reflect our organisational commitment to and policy on, equality, diversity and inclusion. In addition, each manager and member of staff involved in implementing this policy must give due regard to the needs of those protected under law.

If you, or any other groups, believe you are discriminated against under the terms of the Equality Act, the Health and Social Care Act 2012 or Human Rights legislation by anything contained in this document; or you need this document in an alternative format, for example, large print, Braille, Easy read or other languages; please contact our Patient Advice and Complaints Team:

Tel: 0300 123 1672 Email: d-icb.patientexperience@nhs.net

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1. Introduction

The Individual Funding Request Panel is constituted in order to make decisions relating to individual requests, from an NHS clinician, for treatments which are not routinely commissioned within Devon. This process is a statutory duty under Regulations 34- 35 of the National Health Service Commissioning Board and Clinical Commissioning Groups (Responsibility and Standing Rules) Regulations 2012 (SI 2012 No 2996). The policy is guided by the legislative duties bestowed on ICBs under the National Health Service Act 2006 (as amended by the Health and Social Care Act 2012), NHS Constitution 2021, the Human Rights Act 1998, and Equality Act 2010, amongst others.

2. Purpose and objectives

Every year, the resources that NHS Devon ICB (the ICB) receives are allocated to the services and treatments provided for patients. One of the key challenges for commissioners is how to strike the right balance between providing services that meet the needs of the majority and accommodating the differing needs of individual patients. Commissioning at scale by its very nature focuses upon common conditions. As a result, it cannot be undertaken in a way that meets all needs of all patients in any one clinical group or addresses the specific needs of patients with less common conditions.

NHS Devon ICB has clear commissioning policies, setting out those cost-effective, evidence-based services that they consider a priority and will routinely fund, and those services that are considered less of a priority or for which access criteria must be met. The ICB also has clear clinical pathways, referral and treatment guidance, as set out in the Joint Formularies and Referral guidance documents. In order to commission an equitable service, it is expected that patients and clinicians follow this guidance in the absence of a clear clinical reason why this is not appropriate. All funding has an opportunity cost; that is, funding spent on one intervention or treatment is not available to spend on another. A decision not to fund a particular treatment or intervention may be based upon a lack of evidence of effectiveness, unacceptable safety concerns, poor cost-effectiveness or because the treatment is given a low priority for funding compared to other treatments. Decisions to fund or not fund a particular treatment are taken in line with the above considerations and the ICB decision making framework.

Very occasionally, a clinician may think that their patient's clinical situation is different to other patients with the same condition and that it is appropriate that they should have different treatments to others. In such circumstances, clinicians, on behalf of their patient, may make an Individual Funding Request (IFR) to the ICB for a treatment that is not routinely commissioned by the ICB.

As the resources the ICB receives are allocated to services and treatments that can be provided for patients, 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. The ICB 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. Scope

The policy applies when the requested intervention is a ICB commissioning responsibility. IFRs can be made for all ICB commissioned services, however, this route should only be used in exceptional circumstances and not as an alternative route to submitting a treatment for scrutiny through the Planned Care and clinical effectiveness process.

However, if there is evidence that there are other patients with the same condition who could derive a similar type and degree of benefit from the treatment, the request is really for 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 the ICB can be fair to all patients, decisions on whether or not to fund this new development will be taken in line with the ICB's decision making processes. In these circumstances, the request will not proceed through the IFR process.

IFRs can be made if:

- there is an ICB commissioning policy, clinical pathway or NICE Technology Appraisal (TA) guidance that governs the funding of treatment for the patient's condition, and a clinician can show that their patient is in a different clinical condition when compared to the typical patient population with the same condition;

OR

- the treatment is not normally funded and the ICB does not have a clinical commissioning policy or pathway for the requested treatment for patients suffering from the same medical condition as the patient for which the treatment is being requested;

AND

- the clinician considers the patient meets the criteria in this IFR policy.

4. Definitions

Terms	Definition
IFR	Individual Funding Request
TDRP	Treatment Decision Review Panel

5. IFR process

The circumstances when the ICB will consider funding an IFR.

The ICB 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, that is:

- The referring clinician can show that their patient is in a different clinical condition 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

- 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

AND

- There is a basis for considering that the requested treatment is likely to be clinically effective for this individual patient;

AND

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

Further information regarding the IFR criteria is found in the Appendix.

Funding for experimental and unproven treatments

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.

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.

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 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. If 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, 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 decision making frameworks and processes; 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.

The ICB 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, the ICB 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 the ICB in these instances are:

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

Funding at the end of a clinical trial

Save in the most exceptional cases, the ICB does not anticipate that they 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.

Making an application

Applications will only be accepted from an NHS clinician who has current and direct involvement in the patient's NHS care. All applications must be accompanied by written support and evidence provided by the clinician in line with the ICB IFR Standard Operating Procedure (SOP).

It is the referring clinician's responsibility to ensure that all the appropriate and required information is provided on the application to the ICB in a timely fashion consistent with the urgency of the request. This includes full copies of all the published papers of clinical evidence that have been cited. The clinician must provide a list of the published papers that have been submitted and indicate which points within them are relevant in respect to the IFR application and criteria. This is to ensure the 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 the ICB area in any given 12-month period.

The ICB expects providers with which it contracts to have oversight of the applications submitted by their clinical staff.

For applications made by clinicians in Secondary Care, Trust support is mandatory for the application to be considered by the panel. The application will not progress in the absence of this support. Requests should be supported by a relevant multidisciplinary team (MDT) and, for applications in relation to medicines, the trust Drugs and Therapeutics Committee or equivalent. It is anticipated that Drugs and Therapeutics Committee(s) (or equivalent) will include representation from Chief Pharmacist and Medical Director or their deputies. It is mandatory to provide copies of the MDT/DTC minutes of the discussion to the IFR team, alongside the application.

Urgent cases

The IFR Panel meets according to a schedule designed to provide frequent and timely opportunities to consider applications. The IFR panel meets monthly. Consequently, cases are processed in a timely manner. Using a different process for urgent cases has the potential to introduce unfairness. 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 possible that decisions would be subject to different decision-making processes than those considered in the usual way. It would be difficult to convene a properly constituted panel in a very short timescale. Decisions taken by one or two panel members acting alone, increases risks of inconsistency of decision making.

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), an IFR urgent panel can be convened. It is anticipated that these cases would occur rarely i.e., less than 2-3 times per year. If a treatment is considered urgent as above, and a Panel cannot be convened, the provider Trust is expected to have procedures in place via the medical director to authorise such treatments. It is expected that a retrospective application will be made to the IFR Panel, and the outcome will be fed back to the Trust for learning and audit purposes.

Summary of IFR process

The IFR Panel works on behalf of the ICB and makes decisions in respect of funding for individual cases. The IFR Panel will work to the published ICB IFR Policy and each request will be processed by following the ICB IFR SOP. Patients or their representatives are unable to attend the IFR Panel. 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 and the ICB commissioning principles.

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 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. The Panel will contain individuals with a variety of skills and experiences and is unlikely to include a clinician with expertise in the condition for which treatment is being sought. This is appropriate because the question is one of demonstrable exceptionality (resting on the differences between this patient and others with the condition) and 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 ICB published clinical commissioning policies or pathways 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 and likely value for money relating to the proposed treatment.

It is also open to the IFR Panel to conclude that 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 referring clinician, or from other clinical advisors as considered appropriate.

In considering individual cases, the IFR Panel will take care to avoid making decisions based on non-clinical factors

The IFR Panel will also take care to be aware of the “rule of rescue”. This is the powerful human desire to rescue a single identified endangered life, regardless of cost, at the expense of nameless individuals who may therefore be denied health care. Where the IFR Panel consider that application of the rule of rescue would be the sole criteria for determining exceptionality, funding will be declined.

The IFR Panel will consider written views expressed by the patient and/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.

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, the patient's representative or requesting clinician will be entitled to ask that the process which led to the decision of the IFR Panel be subject to review.

All requests for a review must be made within 30 working days of the date when the decision is communicated to the patient. The request must be supported by the referring clinician who must explain his or her reasons for considering that the decision taken by the IFR Panel was either procedurally improper and/or misunderstood the medical evidence and/or was, in his or her opinion, a decision which no reasonable IFR panel could have reached.

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

The Treatment Decision 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 and clinical pathways of the ICB, and its statutory obligations.
- 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 Treatment Decision Review Panel considers that there was any procedural error in the IFR Panel's decision, the Treatment Decision 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 Treatment Decision Review Panel considers that there was no reasonable prospect of the IFR Panel coming to a different decision, then the Treatment Decision 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 Treatment Decision Review Panel will require the IFR Panel to reconsider the decision.

The Treatment Decision 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.

6. Accountabilities, Duties and Responsibilities

Chief Executive Officer	The Chief Executive Officer has ultimate accountability for the strategic direction and operational management of NHS Devon, including compliance with all legal, statutory and policy requirements.
Policy Sponsor	The Policy Sponsor is responsible for: • ensuring that policy is appropriate for consideration for approval; • endorsing this policy ahead of submission for approval; • with the Policy Lead, maintaining and updating procedures/protocols and other supporting documents for this policy
Policy Lead / Author	It is the responsibility of the Policy Lead / author to: • ensure as far as possible that the policy is in line with Department of Health and Social Care guidance, legal requirements and advice from clinical bodies; • to complete a QEIA and Implementation Plan where required • undertake a fair and proportionate consultation period with the relevant stakeholders as part of the document's development • to ensure that the policy is in alignment with NHS Devon's strategy and values • ensure that the policy is developed, approved, disseminated and monitored as set out in the document; with Policy Sponsors, maintaining and updating procedures / protocols and other supporting documents for this policy.
Line Managers	Line managers have a responsibility to ensure their staff comply with NHS Devon policies and standards within their areas of responsibility.
All Staff	Employed or engaged staff have a duty to comply with NHS Devon policies and standards as outlined in their contracts of employment and codes of conduct.

7. Implementation

All staff will be informed of the approval of the Policy via the Staff Bulletin which will provide a link to the document on the NHS Devon Intranet.

NHS Devon Senior Managers, or their designated representatives, will implement this policy by:

- Notifying all staff of its existence. New staff will be informed of this policy as part of their induction.
- Destroying all superseded paper-based versions of the policy and electronic versions retained in their area.
- Having adequate knowledge of, and / or access to, all relevant legislation in order to ensure that compliance with such legislation is maintained.
- Discussing with staff as part of their regular one-to-ones how they seek to achieve their individual objectives around policy review and maintenance.

8. Approval and Review

The approval route for this policy is via the Chief Medical Officer and Chief Nursing Officer.

This policy will be reviewed in 2028, or sooner if required, in order to ensure that it is current, relevant and reflects the strategic aims, objectives, organisational structures and responsibilities of NHS Devon.

9. Monitoring compliance and effectiveness

A yearly report to the ICB Quality committee will provide oversight of the key performance indicators for the IFR process. This will also highlight any legal challenges and the result of subsequent internal investigation.

10. Impact Assessment

An Equality and Quality Impact Assessment (EQIA) is not required for this policy as it has received a review and refresh only.

11. References

Other related policy documents

Nil

Legislation and statutory requirements

Statutory basis

The policy is guided by the legislative duties bestowed on ICBs under the National Health Service Act 2006 (as amended by the Health and Social Care Act 2012), NHS Constitution 2021, the Human Rights Act 1998, and Equality Act 2010, amongst others.

ICB Responsibilities and Regulations

The foremost amongst these considerations are the following patient rights, specified under the NHS Constitution and underpinned by law:

"You [the patient] have the right to access NHS services. You will not be refused access on unreasonable grounds."

"You [the patient] have the right to expect local decisions on funding of other drugs and treatments to be made rationally following a proper consideration of the evidence. If the local NHS decides not to fund a drug or treatment you and your doctor feel would be right for you, they will explain that decision to you."

Part 7 of the National Health Service Commissioning Board (Responsibilities and Standing Rules) Regulations 2012 make specific provision in relation to the funding and commissioning of drugs and other treatments by ICBs, including providing for a duty to give reasons for funding decisions.

Legal and financial duties and the duty to provide services

Under the NHS Act 2006 (as amended by the Health and Social Care Act 2012 ("HSCA) the ICBs; NHS England and the Secretary of State have a concurrent duty to provide a comprehensive health service. For ICBs, the following applies:

"A clinical commissioning group must arrange for the provision of the following to such extent as it considers necessary to meet the reasonable requirements of the persons for whom it has responsibility: …

- medical, dental, ophthalmic, nursing and ambulance services,

…

- such other services or facilities for the prevention of illness, the care of persons suffering from illness and the aftercare of persons who have suffered from illness as he considers are appropriate as part of the health service,

- such other services or facilities as are required for the diagnosis and treatment of illness."

In addition to this duty to meet the above requirements, ICBs have a statutory obligation to maintain financial balance. When considering whether or not to commission specific treatments for groups of people with the same medical condition, ICBs will assess the clinical and cost effectiveness of the treatment, the benefits to patients in terms of quality of life and the priority of this treatment or service in relation to others already commissioned or proposed for commissioning. A treatment of very little benefit is unlikely to be commissioned simply because it is the only treatment available, this ensures that limited resources are used to provide the greatest health benefit.

At an individual or patient group level, treatment will not generally be funded solely because a patient requests it. The ICB will not normally fund treatment for one patient, which is not available to all other patients with the same clinical need, except in the context of this policy.

ICBs will not discriminate on grounds of personal characteristics, such as age, gender, sexual orientation, race, religion, lifestyle, social position, family or financial status, intelligence or cognitive functioning and will act in compliance with duties under the Equality Act 2010. However, funding decisions will be made on the basis that the patient is more likely to benefit significantly more than other patients with the same clinical condition.

Administrative Law

Decisions made by public bodies including ICBs can be challenged in the Administrative Court by way of judicial review. The traditional grounds for judicial review are that the public body:

- acted beyond its lawful powers
- came to a decision which no other reasonable ICB could have reached
- acted unfairly, because it did not follow proper procedures
- breached the patient's human rights
- breached the Equality Act 2010.

These grounds are the basis for the Review Process set out in this document.

Equality Duties

The main impact of the Equality Act 2010 has been the duty on health bodies to monitor their compliance – extending the race equality monitoring to gender, religious belief and sexual orientation where this is relevant – and to give due regard to the public sector equality duty. This policy complies with the Equality Act 2010.

The ICB has a duty to comply with public sector equality duty, part of the Equality Act 2010, and must, in the exercise of their functions, have due regard to the need to:

- Eliminate unlawful discrimination, harassment and victimisation and other conduct prohibited under the Act
- Advance equality of opportunity between persons who share a relevant protected characteristic and persons who do not share it
- Foster good relations between persons who share a relevant protected characteristic and persons who do not share it

The Human Rights Act 1998

The Human Rights Act 1998, Article 6 requires a fair hearing for determining civil rights and proportionality of decision-making which the courts consider a fair balance between protection for individual rights and the interests of the community. The proportionality test involves balancing different interests – such as those of the individual applicant for treatment funding with those who await service improvements that depend on the availability of new funding. Other key considerations are Articles:

- 2 (the right to life);
- 3 (the right not to be subjected to inhumane or degrading treatment);
- 8 (the right to respect for privacy and family life);
- 12 (the right to marry and found a family); and
- 14 (the requirement for non-discrimination against groups because of their sex, race, religion, disability, disease).

Statutory duty of quality

ICBs need to demonstrate compliance with a statutory duty of quality, in accordance with the NHS Act 2006 (as amended by the HSCA) with specific consideration of the following points in section 14:

- s.14P (Duty to promote NHS Constitution);
- s14Q (Duty as to effectiveness, efficiency and economically);
- s14R (Duty as to improvement in quality of services);
- s14T (Duties as to reducing inequalities);
- s 14U (Duty to promote involvement of each patient) and
- s 14V (Duty as to patient choice).

The ICB has a statutory duty as to patient choice under section 14V of the NHS Act, which sets out that each ICB must, whilst carrying out its functions, act with a view to enabling patients to make choices in respect of aspects of health services provided to them. The NHS Constitution sets out certain rights that patients have in relation to choice. In addition, the Department of Health (2014/15) Choice Framework outlines the services where patients have a right to choice. The ICB must also consider Part 8 of the NHS CB and ICBs (Responsibilities and Standing Rules) Regulations 2012, which provides a specific duty of choice in relation to elective referrals, and the NHS (Procurement, Patient Choice and Competition) (No. 2) Regulations 2013/500 in relation to choice of alternative provider.

The right to choice excludes referrals for persons needing urgent or emergency treatment; persons detained under the Mental Health Act 1983, serving members of the Armed Forces and prisoners (including those on temporary release), those needing urgent or emergency care, maternity services, high secure psychiatric services or drug and alcohol misuse services commissioned or provided by local authorities.

APPENDIX A – Clinical Exceptionality

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

1.2 'Exceptional' in IFR terms means a person to whom the general rule should not apply. In this context the 'general rule' might be a policy that describes those patients who can access the intervention, or it may be that there is no policy governing the treatment in this condition, but it is not routinely provided.

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, treatment should be offered. 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.

1.3 Where a 'not for routine commissioning' clinical commissioning policy is in place in relation to a treatment, the ICB 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 will 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.

1.4 **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. These considerations are likely to have been taken into account in formulating the general policy. Many treatments have side effects or contraindications, and thus intolerance or

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

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

- As regards side effects, as an example, all patients who are treated with long-term high-dose steroids will develop side-effects (typical and well-recognised) and thus developing these side effects and wishing to be treated with something else does not, in itself, 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, the fact that the co-morbidity is present in 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 solely 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.

1.5 **Clinical exceptionality: severity**

Many conditions are progressive, or variable in nature, 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. 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 evidence or a plausible argument that the response to treatment is likely to be good despite the severity of the condition.

1.6 **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 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.

1.7 **Clinical exceptionality: non-clinical and social factors**

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

As a central principle, the NHS does not make judgements about the worth of different individuals and seeks to treat everyone fairly and equitably. Consideration of these non-clinical factors would introduce this concept of 'worth' into clinical decision making. It is a core value that NHS care is available - or unavailable - equally to all. Whilst everyone's individual circumstances are, by definition, unique, 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 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, the ICB would not know whether they are being fair to other patients who are unable to access such treatment and whose non-clinical and social factors are unknown but may be the same or similar.

Consideration of social factors would also be contrary to the ICB's policy of non-discrimination in the provision of medical treatment. If, for example, treatment were to be provided on the grounds that this would enable an individual to stay in paid work, this would potentially discriminate in favour of those working compared to those not working or those who are retired.

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.

APPENDIX B – Clinical Effectiveness

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

1.2 Clinical evidence that considers the efficacy of a particular treatment will be carefully considered by the IFR Panel. It is the sole responsibility of the referring clinician to provide this information and the IFR panel will not be responsible for undertaking any evidence searches. 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 patient's anticipated response to the requested treatment.

1.3 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 the frequency and severity 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.

APPENDIX C – Good use of NHS Resources

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

1.2 This criterion is only applied where the Panel has already concluded that the criteria of clinical exceptionality 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 being unable to fund other areas in order to fund the IFR. This reflects the fact that the only way to provide the funding for treatment under IFRs is to use resources from a finite pot.

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

1.4 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.

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