Midlands and Lancashire
Commissioning Support Unit

Individual Funding Requests Decision Making Policy

A Cheshire and Merseyside Collaborative Document

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Contents

1. Introduction

1.1 The ICB has been established under the National Health Service Act 2006 as the statutory bodies charged with the function of commissioning healthcare for patients for whom they are statutorily responsible.

1.2 The ICB receives a fixed budget from NHS England to enable it to fulfil this duty and i[1]; and, as part of discharging this obligation, has to decide how and where finite local resources are allocated.

1.3 The need and demand for healthcare is always greater than the resources available to a society to meet it. It is evident, therefore, that it will not be possible for the ICB to commission the entire healthcare that is needed by the population it serves and, as a result, it will need to prioritise its commissioning intentions, based on the needs of the local population.

1.4 In carrying out its functions, the ICB acts with a view to securing that health services are provided in a way which promotes the NHS Constitution and will promote awareness of the NHS Constitution among patients, staff, and members of the public. Patients have a right to expect that the ICB will assess and prioritise the health requirements of the local community and commission the services to meet those needs as considered necessary.

1.5 In discharging its obligations, the ICB acknowledges that patients have a right to expect that local decisions on the funding of treatments which have not been considered by the National Institute for Health and Care Excellence (NICE) in its Technology Appraisal (TA) programme will be made rationally following a proper consideration of the evidence.

1.6 Those with responsibility for healthcare budgets have to take decisions about priorities at three levels: one, when developing strategic plans (the main priorities); two, when deciding year on year which investment and disinvestments to make; and three, at the individual patient level.

1.7 The ICB's clinical commissioning policies outline decisions taken on the funding of specific treatments, specifically listing those procedures that are not funded or where funding will only be made available if specific criteria are met. A routine programme of work takes place to regularly review these policies to ensure they remain fit for purpose and evidence based, as well as to develop new policies. This work will continue to ensure that patients are able to access efficacious treatments in a fair and equitable way.

1.8 In preparing its policies and in defining the principles on which those policies are based, the ICB is mindful of the NHS Constitution, of relevant legislation, and of court decisions.

[1] Section 223H National Health Service Act 2006: Financial duties of clinical commissioning groups: expenditure

1.9 ICB's aspire to have policies that address a wide range of possible circumstances. However, exceptionality considers circumstances that are not addressed in the established clinical commissioning policy. Therefore, the more circumstances that are addressed in the policy itself, the fewer will be the number of circumstances in which exceptionality needs to be granted. A good and comprehensive policy is likely to mean that the need to consider exceptions is limited, although the ICB will nevertheless consider every case for exceptionality on its merits.

1.10 To support the commissioning process the ICB considers funding for individual patients through the application of the IFR processes. Noting that, while the NHS does not want to carry out procedures or treatments which have little health benefit in general, there may be overwhelming health benefits for an individual patient. In these cases, a clinician, on behalf of a patient, will explain the clinically exceptional circumstances and request that these are considered through the IFR process, where it will be decided if the NHS will fund the procedure.

1.11 In terms of IFRs, clinical exceptionality is defined as a circumstance in which there is a policy or equivalent which does not normally provide for a particular service to be commissioned but in which a particular patient has a feature which leads to a decision that the policy will not be applied, and the service will be commissioned for that particular patient. The ICBs' commissioning policies include provision to consider exceptionality and this policy describes how that consideration will take place.

2. Purpose

2.1 The IFR policy and processes within the IFR governance framework are the means by which the ICB takes into account and prioritises requests for individuals with unusual clinical circumstances, which cannot be accommodated through its other commissioning processes. Being part of the ICB's priority setting processes, the decisions taken by the ICB must be guided by the same principles as priority setting for the rest of the organisation.

2.2 This document is part of a governance framework adopted by the ICB in Cheshire and Merseyside to inform the commissioning of IFRs. This consists of:

- Individual Funding Requests Standard Operating Procedure;
- Individual Funding Requests Management Policy;
- Individual Funding Requests Decision Making Policy; (This Policy)
- Clinical Commissioning Policies (AKA Procedures of Limited Clinical Priority (PLCP))

2.3 Each policy in that framework is a separate public document in its own right but may be applied with reference to other policies in that suite.

2.4 The purpose of this policy is to define an IFR and describe the deliberations, discussions and considerations that take place when reviewing a request for individual funding with a view to assisting the implementation of the IFR process.

2.5 This policy applies in circumstances when an IFR has been received for a treatment or intervention:

- For a commissioned service in accordance with a clinical commissioning policy or equivalent; or
- For a commissioned service as an exception to a clinical commissioning policy or equivalent; or

- For a rare case for which the ICB would not expect to commission a service and there is no clinical commissioning policy; or
- For a service that has not yet been commissioned relating to a probable cohort of patients (a potential service development and new clinical commissioning policy);

2.6 A commissioning policy or equivalent could be:
- A formally adopted policy of the ICB;
- A NICE Health Technology Appraisal that has been in force for more than three months and therefore has mandatory status;
- Non-mandatory guidance that the ICB has adopted as a policy;
- A service specification;

2.7 This policy should not be reference for patients who already meet criteria for funding of their treatment under any other ICB policy as it deals specifically with the application and management of the IFR processes.

2.8 This document references the five principles adopted by all ICBs to commission only treatments or services which accord with the key principles:
- Appropriateness
- Effectiveness
- Cost-effectiveness
- Ethics
- Affordability

Appendix 1 provides more details of the Statement of Principles adopted by an ICB.

2.9 In addition to the definition of clinical exceptionality, relevant ICB policies for the consideration of IFRs in a number of specific circumstances are also referenced, including:
- requests for interventions for which no local commissioning policy exists;
- requests for interventions for which there is NICE guidance (Technology Appraisals, Clinical Guidelines, Interventional Procedures Guidance);
- requests to fund treatment as part of clinical research;
- requests to provide funding for continuation of treatment commenced as part of clinical research;
- requests to provide funding for continuation of treatment commenced in the private sector;
- requests for retrospective funding;
- requests for treatments commenced as a "trial of treatment" which have not been sanctioned by the ICB;
- requests for treatments commenced on the NHS by another responsible commissioner;
- requests for parallel/co-funding (NHS and private care);
- requests for access to care/treatment from a provider not listed on the national Free Choice Network;

3. IFR Definition

3.1 The NHS Confederation defines an individual funding request as a request to fund treatment that does not have services already agreed through existing commissioning arrangements and is within the commissioning responsibility of ICB. However, for the purposes of this document and suite of policies, a wider definition is used, i.e., an individual funding request is a request to fund treatment that is within the commissioning responsibility of the ICB and which either does not have services already agreed through existing commissioning arrangements or requires prior approval on an individual patient basis.

3.2 Reasons for not having a commissioned service include:

- the medical condition in question is rare;
- the treatment is new or unproven in effectiveness;
- the treatment is a high cost intervention;
- the treatment is of value and clinical benefit, but funding is not available from the prioritisation process.

3.3 An individual funding request is not a request to fund a service development, to fund an existing commissioned service where the ICB has not commissioned the whole pathway of care or to fund treatment from a provider of the individual's choosing where that is not the usual provider of that service for the ICB.

3.4 A service development is a change to the ICB's portfolio of service agreements such that a particular new healthcare intervention shall be routinely commissioned for a defined group of patients. Service developments are likely to result from a prioritisation process. Some requests for healthcare may more appropriately be considered as service developments than as individual funding requests; this is particularly likely when a significant number of similar requests are anticipated.

4. IFR Decision Making Process

4.1 The IFR process is described in more detail in the IFR Standard Operating Procedure and IFR Management Policy; however, the legal framework that supports the IFR decision making process is summarised in Appendix 2 and the Decision Making Process is illustrated in Appendix 3.

4.2 The purpose of the process is to justify funding a treatment or intervention for a patient that 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 their patient's individual clinical circumstances are clearly different to those of other patients, and that because of the 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.

4.3 Where a 'not routinely commissioned' 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 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.

4.4 An application seeking to establish that a patient should be treated as an exception to an established ICB commissioning policy or equivalent ("the Standard Policy") will normally explain:

- why the patient in question is materially different to the usual population of patients to whom the Standard Policy applies in terms of the principle or principles on which the Standard Policy is based; and
- why that material difference means the Standard Policy should not apply.

4.5 The IFR route should only be used in clinically exceptional circumstances.

4.6 The ICB via the IFR Team will carry out an initial screening as described in the IFR Standard Operating Policy. If the request proceeds beyond the screening stage, decisions on whether to fund the request will be made by the IFR Panel. Details of the IFR team, IFR Panel and the processes that are followed are set out in this policy and its procedures and include Terms of References are relevant.

5. Responsible Commissioner

5.1 The ICB will only consider funding for treatments/services that are within its commissioning responsibility as described by NHS England's guidance 'Who Pays? Determining responsibility for payments to providers' (August 2013).

5.2 In line with that guidance the following criteria will be used to assess whether a treatment/service and its indication for use are the commissioning responsibility of the ICB.

a. Is the treatment for which funding is requested associated with a service, treatment of a patient group described as the commissioning responsibility of the ICB in the published Manual for Prescribed Specialised Services, the associated Identification Rules, a published ICB Clinical Commissioning Policy or Service Specification?
b. Is the patient for whom the treatment/service is requested one of the groups of patients for whom the ICB directly commissions services?

5.3 If any of the above applies, the ICB is the responsible commissioner. Services are commissioned by the ICB for the population where the patient is eligible for NHS treatment.

5.4 This policy does not cover IFRs for treatments and services which are the commissioning responsibility of NHS England. If a request for treatment that is not the commissioning responsibility of the ICB is received, the requester will be advised accordingly, and the case record closed.

6. Individual Funding Criteria

6.1 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:

  - There is an ICB clinical commissioning policy, NICE Technology Appraisal (TA) guidance or Highly Specialised Technology (HST) appraisal guidance that 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 circumstance 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 ICB clinical commissioning policy, NICE Technology Appraisal (TA) guidance or Highly Specialised Technology (HST) appraisal guidance in place for the management of the patient's condition or combination of conditions, and the patient's clinical presentation is so unusual that they could not be considered to be part of a defined group of patients in the same or similar clinical circumstances for whom a service development should be undertaken.

  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.

6.2 IFRs can be made for the ICB's directly commissioned services. 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 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 or service.

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

6.4 IFR requests will normally be refused in the following circumstances:

a. Where an IFR results from a patient who has paid for treatment who then wishes to have their treatment continued by the same provider but funded by the NHS for whatever reason (e.g., an insurance company refuses to pay the treatment costs, or a patient can no longer afford treatment). The provider and/or the GP will be asked to refer the patient to NHS funded services for an assessment of whether the requested care is clinically required and available within existing service agreements held by the ICB;
b. Where the IFR requested is also available elsewhere within a Trust with which the ICB have a contract, this will be handled within normal contractual processes;
c. Where the IFR is made retrospectively, and it cannot be demonstrated that treatment was needed as a clinical emergency;
d. Where the patient does not take up treatment within six months of approval being given, a new application for funding must be made;
e. Where an IFR is made by a non-NHS clinician based in a private provider with whom the ICB does not hold a contract;
f. Where an IFR is made for a treatment within a private provider, when equivalent NHS services are available;

7. Clinical Exceptionality

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

7.2 'Clinically 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.

7.3 Clinical exceptionality is defined as:

- The patient has a clinical picture that is significantly different to the general population of patients with that condition **and as a result of that difference**; the patient is likely to derive greater benefit from the intervention than might normally be expected for patients with that condition.

7.4 Application of Clinical Exceptionality is defined further in Appendix 4 (An "arguable basis" for the application).

7.5 As there can be no exhaustive description of the situations which are likely to come within the definitions of clinical exceptionality, for the purpose of considering IFRs consistently the section provides general guidance to aid the understanding of specific circumstances.

[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 interests of fairness to all patients, the position is that it will not be commissioned ahead of policy/service development.

Arguments

7.6 The following arguments, if fully and satisfactorily explained, validated and substantiated, will normally be accepted as demonstrations of clinical exceptionality. References are made to annexes included at Appendix 5, which provide further explanation:

a. That, for consideration against a policy based on appropriateness, the purpose of the requested intervention in this patient is different to the purpose in the usual population of patients to whom the policy applies, such that for this patient the ICB considers the service to be appropriate within the context of the Statement of Principles (Appendix 1). (Reference Annex 2).
b. That, for consideration against a policy based on effectiveness, this patient is different to the usual population of patients in that the evidence of effectiveness on which the policy relies is not relevant to this patient, and that there is alternative, high quality and positive research evidence that is relevant to the intervention in this patient.
c. That, for consideration against a policy based on cost-effectiveness, the cost-effectiveness of the requested intervention in this patient is different to the cost-effectiveness in the usual population of patients to whom the policy applies, such that for this patient the expected cost per QALY is clearly below the current NICE threshold.
d. That, for consideration against a policy based on ethics the circumstances of this patient, is different to the purpose in the usual population of patients to whom the policy applies, such that the concern about ethics is not relevant to this patient.
e. That, for consideration against a policy based on affordability, the need, urgency or cost is different to that in the usual population of patients to whom the policy applies, such that for this patient the requested service is affordable. In considering such requests the ICB may nevertheless consider whether there is a mechanism to deliver the funding without disadvantage to other patients.

7.7 The following arguments may be considered as a case or part of a case for exceptionality, but will be interpreted with caution (please see the annexes in Appendix 5 for further explanation):

a. The policy being applied does not regard the intervention as according with the principle of appropriateness, but the purpose of the treatment in this patient is to address pain, or some other feature that would place the intervention within the definition of appropriateness. (Annex 2)
b. This patient is a particularly severe case. (Annex 3)
c. A criterion in the policy is not suitable for application to this particular patient. (Annex 4)

7.8 The following arguments will not normally provide a basis for a determination of exceptionality (please see the annexes in Appendix 5 for further explanation):

a. The policy is flawed. (Annex 5)
b. The wrong policy has been applied. (Annex 6)
c. One or more previous cases have been decided in a certain way and the ICB is obliged to apply that 'precedent' in the present case. The ICB will instead judge each case on its merits, having due regard to whether there have been previous cases. (Annex 7)
d. This patient is clinically suitable for treatment. (Annex 8)
e. This patient only narrowly fails to meet the criteria in the policy.
f. The patient has already tried the treatment and it has worked. (Annex 9)
g. The patient healthcare intervention sought should be funded simply on the basis that the patient is suffering problems with psychological wellbeing as a result of the condition or of the unavailability of funding. (Annex 10)

h. NICE guidance (or other non-mandatory guidance) says that it should be funded. (Annex 11)
i. The patient's circumstances are unusual. (Annex 12)
j. The end of a commissioned pathway has been reached.

7.9 The ICB defines exceptionality solely in clinical terms. Personal or social circumstances will not be taken into consideration. In essence it is a question of equity. To consider personal, social or other non-clinical factors could introduce inequity by implying that some patients have a higher intrinsic social worth than others with the same condition.

7.10 The ICB considers that, in general, clinicians will be best placed to advance arguments as to exceptionality such as those set out above on behalf of patients. The ICB therefore encourages patients to seek support from a clinician when making an application under this policy. However, the ICB will accept applications made by patients without clinical support and will not reject such an application simply because it has been made by a patient.

Failure to respond to standard care

7.11 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.

7.12 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 tolerance or contraindication of a treatment does not in itself, usually indicate exceptionality.

7.13 So, in order to support an IFR on the basis of failure to respond to a 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:

a. 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 know 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.
b. 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.
c. If the usual treatment cannot be given because of 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 co-morbidities 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 co-morbidity which is common in the general population, and thus a patient cannot be exceptional by virtue of also having a co-morbidity which is common in the general population.

7.14 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 patient 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.

Severity

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

a. 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.
b. 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;
c. How the patient is expected to benefit from the treatment sought and in what quantifiable way;
d. 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
e. That there is a plausible argument that the severity of the condition is prognostic of good response to treatment.

Genotypes

7.16 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.

Multiple grounds

7.17 There may be cases where clinicians and/or patients seek to rely on multiple grounds to show that their case is clinically exceptional. In such cases the IFR decision making process will consider each ground individually to determine (a) whether the factor is capable, potentially, of making the case clinically exceptional and (b) whether it does in fact make the patient's case clinically exceptional. One factor may be incapable of supporting a case of

exceptionality (and should therefore be ignored), but it might be relevant on another ground. That is a judgement within the discretion of the IFR screening group and IFR Panel.

7.18 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.

7.19 If the proposed intervention is thought to offer a benefit to a cohort of patients with common co-morbidities, then consideration should be given to making a change to the Integrated Care Board policy that covers the patient pathway. This should be considered for a service development and requires an ICB decision.

Non-clinical and social factors

7.20 It is common for an application for individual funding to be made on the grounds that a patient's personal circumstances are clinically exceptional. This assertion can include details about the extent to which other persons rely on the patient, or the degree to which the patient has contributed or is continuing to contribute to society. The ICB understand that everyone's life is highly individual. However, including non-clinical, social factors in any decision-making raises at least three significant problems.

7.21 **One:** across the population of patients who make such applications, the IFR decision making team is unable to make an objective assessment of material put before it relating to non-clinical factors. This makes it very difficult, upon consideration, to be confident of dealing in a fair and even handed manner in comparable cases.

7.22 **Two:** The essence of an individual funding application is that the ICB is making funding available on a one-off basis to one patient, where other patients with similar conditions would not get such funding. If non-clinical factors are included in the decision making process, the ICB does not know whether it is being fair to other patients who are denied such treatment and whose social factors are entirely unknown.

7.23 **Three:** The ICB is committed to a 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; then this would potentially discriminate in favour of those working compared to those not working. A decision to offer a treatment to one patient and not another on the basis that the funded patient was working and the patient denied funding was out of work, would be considered a breach of ethical principles, setting a precedent for the ICB to always favour those in work over those not currently in work.

7.24 The same can be said of many other social factors such as having children / not having children, being a carer / not being a carer and so on. Requests to fund treatment for adolescents on the grounds that they wish to go to university (thereby deploying the argument that not funding treatment would inhibit the individual from fulfilling their true potential) or because of a person's role in society (e.g., professional) are also discriminatory and would contribute to social inequality.

7.25 Generally, the ICB does not take into account social factors in deciding what treatment to provide, unless a service is specifically designed to address health inequality or a prevailing inequity of access to normally provided care or treatment.

7.26 In general, the NHS treats the presenting medical condition and does not inquire into the background factors which led to that condition as the basis on which to decide whether to make treatment available or not. The policy of the ICB is that it should continue to apply this general principle in individual applications for funding approval. The ICB will therefore seek to invest in treatment based on the presenting clinical condition of the patient and not based on the patient's non-clinical circumstances.

7.27 Accordingly, in reaching a decision as to whether a patient's circumstances are clinically exceptional, the ICB is required to follow the principle that non-clinical or social factors, including social value judgments about the underlying medical condition or the patient's circumstances, are not relevant.

7.28 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.

Exceptions

7.29 It is not possible to foresee all the reasons why a person's application should be dealt with as an exception to the ICB's standard commissioning policies. The ICB is entitled to determine what constitutes exceptionality in each particular case. However, the assessment of exceptionality should be undertaken with due regard to provisions of this policy and its appendices.

8. Clinical Effectiveness

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

8.2 Clinical evidence that considers the efficacy of a particular treatment will be carefully considered by the IFR screening groups and IFR Panel. It is the sole responsibility of the referring clinician to provide this information and the IFR Teams 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 clamed 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.

8.3 When considering clinical effectiveness, the IFR Panel will consider:

a. How closely the patient matches the patient population from whom the results are derived in any study relied on by the clinician;
b. The plausibility of the argument that the patient will achieve the anticipated outcomes from treatment, based on the evidence supplied;
c. The impact of existing co-morbidities on both the claim for exceptionality and treatment outcome;

d. 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 of the treatment;
e. The likely impact of the treatment on quality of life using information as available;
f. 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.

8.4 Evidence reviews will be supported by Public Health Specialists and/or Senior Medicines Management representatives as required.

9. Good Use of NHS Resources

9.1 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 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.

9.2 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.

9.3 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.

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

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

10. General Policy Statements

10.1 General policy statements follow to further ensure consistency of application and thus support of a robust IFR governance framework.

Interventions for which no local ICB policy exists

10.2 If a request is received for individual patient funding (as defined above) for a service or treatment for which the ICB has no policy, then the default position is that the ICB will not offer that funding. However, the ICB may decide to move away from that default position and in doing so it may consider:

a. whether a policy for this service or treatment, based on the principles of appropriateness, effectiveness, cost effectiveness, ethics and affordability would be likely to permit funding to be offered;
b. whether there is a usual pathway for the management of similar patients within service agreements, and if so whether there are good reasons why this patient should be managed differently to those similar patients;
c. whether there is authoritative guidance that, while not having policy status, may be relevant and helpful. The use of such guidance is at the discretion of the ICB;

10.3 On the basis of that consideration, the ICB shall decide how to respond to that request.

Services or treatments for which there is NICE guidance (Technology Appraisals, Clinical Guidelines, Interventional Procedures Guidance) or equivalent

10.4 The ICB shall comply with the requirements of any of the following in relation to its residents requesting a health care intervention that falls within the ICB commissioning remit:

a. an Act of Parliament or other statute;
b. a direction from a court of England and Wales;
c. guidance issued by the National Institute for Health and Care Excellence (NICE) in its technology appraisal category;
d. other guidance that the ICB is required to regard as mandatory.

10.5 Non-mandatory guidance shall not be regarded as ICB policy unless or until the ICB formally adopts it as policy through its due governance process. The ICB shall have regard to relevant non-mandatory guidance issued by NICE and NHS England. In instances where the ICB determines not to follow such non-mandatory guidance, it will provide an explanation for this decision. In addition, the ICB may at its discretion take into account guidance from other sources. Factors to be taken into account when considering such guidance include, without limitation: -

a. the evidence base cited in support of such guidance;
b. whether the guidance is applicable to the commissioning of health care interventions by the NHS in England.

Treatment as part of clinical research

10.6 The ICB recognises that treatments which are being studied via clinical research have, by their very nature, potential risks and benefits which are as yet unquantified. The ICB does not wish to stifle innovation and may support the undertaking of high-quality research in line with its priorities. However, the IFR route is not appropriate for consideration of applications to fund clinical research for groups of patients.

10.7 Consideration of requests to the ICB to support treatment costs either during or after a clinical trial (which may be a trial sponsor's precondition for allowing a patient to enter a clinical trial) has been delegated to those responsible for IFR decision-making because it is a decision to fund a treatment which is not normally funded at the patient level and it will commit additional, often substantial, resource from the ICB. This decision therefore has to be subject to normal priority setting processes at the level of the individual.

10.8 Clinicians may, on behalf of their patients, make an individual funding request to the ICB for treatment that is not normally commissioned by the ICB, in circumstances where an individual patient is suitable to enter a clinical trial which is dependent on ICB funding for the treatment costs of the trial. The ICB's default position is not to fund treatment for an individual as part of clinical research. However, the ICB reserves the discretion, via the IFR decision-making process, to authorise or not to authorise funding in each individual case.

10.9 Clinicians may, on behalf of their patients, make an individual funding request to the ICB for approval prior to the patient entering a clinical trial to fund continuation of funding of treatment after the trial has been completed. The ICB will not generally fund continuation of treatment without this prior approval.

10.10 The ICB observes the usual arrangement, in accordance with the Medicines for Human Use (Clinical Trials) Regulations 2004 and the Declaration of Helsinki adopted by the World Medical Assembly, that at the conclusion of the study, patients entered into the study are entitled to be informed about the outcome of the study and to share any benefits that result from it, for example, access to interventions identified as beneficial in the study or to other appropriate care or benefits. The ICB expects research ethics committees or equivalent local committees to require that no clinical trial is approved unless funding is identified by those conducting the trial and explicitly approved by the proposed funder to ensure that any patients in a trial who benefit from the treatment in the trial are able to continue the treatment. To satisfy this requirement the ICB may, at its discretion and if other aspects of this policy are satisfied, make a provisional offer of funding before research ethics committee authorisation is confirmed, but that funding will be conditional on research ethics committee authorisation being confirmed before the treatment commences.

Continuation of treatment commenced as part of clinical research

10.11 IFR requests may be submitted for funding continuation of treatments previously commenced in the following circumstances:

a. where the trial in question has been funded, wholly or in part, by the ICB; or
b. where the trial in question has been funded by the manufacturer of the intervention, or where the intervention has been provided by the manufacturer on a "compassionate use" basis outside of a formal clinical trial; or

c. where the trial in question has been a non-commercially funded clinical trial, covered by Department of Health Guidance HSG (97) 32.

10.12 The ICB's position is that the continued provision of a treatment after the end of a clinical trial is the responsibility of those individuals or parties that have initiated and sponsored either the clinical trial or drug company sponsored treatment, and that this position remains until the trial results are available. Subject to the terms of this policy, the ICB may fund access to the treatment which was the subject of the clinical trial after the completion of a clinical trial funded as described in paragraph 10.11 when:

a. the treatment which was the subject of the clinical trial has been demonstrated to deliver clinical benefit to the patient; and
b. the ICB has been enabled to consider all available evidence relating to the benefits and harms of the trial treatment on the trial population, responsibility for the continuation of funding remaining with the drug company until they make their results clearly available.

10.13 The provision of funding to continue a treatment to a patient who leaves a clinical trial where the treatment costs have been funded as described in paragraph 10.11 does not represent a policy decision by the ICB to fund that treatment for other patients who were not part of the clinical trial. Any application for a service development to support funding for the treatment in question will be assessed and prioritised under the ICB's service development policy in the normal way.

10.14 Where funding has been provided to a patient under paragraph 10.11a of this policy, the ICB reserves the right to seek a formal clinical review of the patient's present and future healthcare needs and to consider whether the decision to provide the patient with on-going funding for the treatment which was the subject of the clinical trial, or any other treatment provided to the patient, is equitable and appropriate. The ICB shall have regard to its other commissioning policies and its Statement of Principles for healthcare commissioning when conducting any such review.

10.15 The policy of the ICB is that it will not provide funding for a patient's treatment at the end of a clinical trial that has been funded as described in paragraph 10.11b, unless the Group has given its prior written agreement or, where commissioning responsibility for a patient has transferred from another NHS body to the ICB, written agreement has been provided by the NHS commissioning organisation which was the responsible commissioner for the patient when the trial was commenced. Service providers seeking such funding from the ICB will need to provide clear evidence of any such agreement.

10.16 The ICB may, at its discretion, consider providing funding for on-going access to treatment after the end of trials as described in paragraph 10.10c only if:

a. the clinical trial was wholly funded by non-commercial bodies; and
b. the trial was sanctioned by the National Institute for Health Research database (http://public.ukcrn.org.uk/search/Portfolio.aspx); and
c. it has been demonstrated that the patient has benefited clinically from the treatment provided as part of the clinical trial; and
d. the ICB determines that, given other demands upon its resources, the expenditure to support the on-going treatment can be justified and the ICB can afford that expenditure.

10.17 It is the responsibility of the organisation conducting the trial, usually a service provider organisation, and the patient's clinician to ensure that patients are fully informed, before entering trials of the type described in paragraph 10.11b, that NHS funding for the continuation of treatment delivered as part of a clinical trial that has been sponsored by a pharmaceutical or medical devices company, or provided on a "compassionate use" basis, may not be provided unless it has previously been agreed in writing by the patient's responsible NHS commissioner at the outset of the trial. Patients should also be informed about the circumstances in which "compassionate use" funding is being provided, how long this funding will be provided and what will happen when it is withdrawn. All such arrangements must be explicitly approved by the relevant service provider governance body (for example the Drugs and Therapeutics Committee). The patient should agree to their management plan on discontinuation of treatment. This process of obtaining informed consent includes making patients aware of this commissioning policy. The patient's consent should be documented.

Continuation of treatment commenced in the private sector

10.18 The ICB will not pick up funding for continuation of treatment commenced in the private sector either in the UK or abroad unless the treatment would normally be provided within standard NHS treatment pathways and unless the patient satisfies the eligibility criteria in any relevant ICB policy.

Retrospective funding

10.19 Requests for funding must be submitted before treatment is initiated. Retrospective approval for individually funded requests will not normally be approved. However, any request will be considered on its merits and in accordance with any separate policy in force at the time.

Treatments commenced as a "trial of treatment" which have not been sanctioned by the ICB

10.20 The policy of the ICB is that it will not agree the funding of a patient's treatment at the end of a 'trial of treatment' for treatments which are not routinely commissioned by the ICB.

10.21 Funding will only be provided when the ICB has given its prior written agreement. This is also a requirement where a patient has transferred from another NHS body that the trial of treatment was commenced. Provider trusts seeking funding will need to provide evidence of any such agreement

Treatments commenced on the NHS by another responsible commissioner

10.22 This policy applies to any patient for whom the ICB is the responsible commissioner.

10.23 Where responsibility for providing NHS services to a particular patient has been transferred to the ICB, the ICB will, subject to the terms of this policy, honour existing funding commitments made by the patient's previous commissioner.

10.24 The ICB will also, subject to the terms of this policy, honour existing funding commitments made by publicly funded healthcare services in Wales, Scotland, Northern Ireland, the Isle of Man or the Channel Islands where responsibility for providing NHS services to a particular patient has transferred to the ICB from health bodies in those countries.

10.25 Where paragraphs 10.23 or 10.24 above apply, the ICB reserves the right to seek a formal clinical review of the patient's future healthcare needs and to consider whether the decision to provide the patient with any further courses of treatment of the type previously provided, and of any other nature, is equitable and appropriate. The ICB shall have regard to its other commissioning policies and its ethical framework for priority setting and resource allocation when conducting any such review.

10.26 The rights under paragraphs 10.23 and 10.24 above shall not apply if the patient would not, for any reason, have continued to have had the treatment in question commissioned for the patient by the patient's previous responsible commissioning organisation.

10.27 This policy should be read in conjunction with the Department of Health's responsible commissioner guidance, currently: "Who Pays? Establishing the Responsible Commissioner".

Co-funding (NHS and private care)

10.28 The ICB defines "co-funding" as any arrangement under which the cost of an episode of care within the NHS is part-funded by an NHS commissioner and part-funded by the patient. Co-funding is not permitted within the NHS, apart from the limited forms of co-payment which exist under current legislation. The ICB will not enter into any agreement which is not permitted.

Parallel funding (NHS and private care)

10.29 The ICB defines "parallel funding" as any arrangement under which a patient pays for additional private healthcare while continuing to receive care from the NHS.

10.30 If a request is received for a patient to self-fund part of their care which would otherwise not be funded by the ICB, the ICB 's default position will be to commission as follows, in accordance with national guidance in force at that time.

10.31 In keeping with current guidance, the ICB will only enter into a commissioning arrangement of parallel funding if:

- the provision of private and NHS funded care is not within the same episode of care;
- the provision of private and NHS funded care is kept separate in relation to time and place, except in circumstances where to do so would pose overriding concerns of patient safety.

10.32 The ICB will not make any contribution to the privately funded care to cover the cost of treatment that the patient could have accessed via the NHS.

10.33 When a patient wishes to pay privately for additional treatment which is not commissioned by the ICB, the patient will be required to pay all costs associated with the privately funded episode of care (including assessments, inpatient and outpatient attendances, diagnostic tests, medication, appliances or equipment and rehabilitation). This also includes complications of treatment where these are solely a consequence of the privately funded treatment, except where the patient is admitted under emergency care.

10.34 If a patient wishes to receive a combination of treatments (e.g., medicines, procedures, appliances, equipment, services. etc.), some of which are not routinely commissioned by the NHS, the patient is entitled to access the NHS-funded elements of care and can consult a clinician privately for those elements which are not commissioned by the NHS. If the NHS element of care cannot be delivered separately (in relation to time and place) to the private element of care, the ICB may consider a joint funding arrangement provided that there would be a clinical disadvantage to the patient in separating the treatment, the patient clearly satisfies all necessary policy criteria for the NHS funded element, the cost to the ICB is no greater than it would have been if the NHS component was funded separately, and the funding arrangement accords with any statutory or mandatory guidance in force at the time. Otherwise, parallel funding cannot be supported, and the patient will be required to fund all costs associated with the proposed treatment.

Access to treatment by a provider not listed on the national Free Choice Network

10.35 The ICB expects that clinicians will refer patients appropriately for secondary and tertiary care using established pathways covered by local contractual arrangements. The ICB considers this to be the default position.

10.36 The ICB acknowledges that there may be circumstances where a patient wishes to have their treatment provided by an alternative provider.

10.37 Under the 'Free Choice' policy (2008), patients can choose from any clinically appropriate and "accredited provider" in England. An "accredited provider" includes NHS Foundation Trusts and independent sector hospitals which meet the quality and cost criteria specified by the Department of Health. All "accredited providers" are listed on the 'Free Choice Network' which is accessible to all GPs via the Choose and Book System.

10.38 In accordance with the current guidelines set out in the NHS Choice Framework 2014-15, and the rights to extended choice set out in the NHS Constitution, the ICB may allow patients to choose to be referred to any "accredited provider" who can offer the appropriate level of care in the following situations:

- if a patient is being referred for their first appointment as an outpatient with physical or mental health problems;
- if a patient is being referred by their GP for a diagnostic test;
- if a patient is being referred to maternity services.

10.39 The ICB will not commission the referral unless the patient meets the intervention-specific commissioning policy criteria or, in the absence of a commissioning policy, the request is in accordance with the ICB's principles for commissioning health care.

10.40 This policy does not apply to patients undergoing urgent or emergency treatment.

10.41 In the situation where a patient requests funding abroad, the ICB will consider funding in accordance with national guidance.

Experimental and unproven treatments

10.42 This section outlines how the IFR criteria will be interpreted and applied when the treatment being sought is, in itself, experimental or unproven.

10.43 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 decision 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.

10.44 When an individual case has been found to be exceptional, the treatment proposed might, by definition, be considered to be unproven, and his 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.

What is an experimental treatment?

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

a. 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;
b. The treatment does not have marketing approval from the relevant government body for the indication in question;
c. The treatment does not conform to a usual clinical practice in the relevant field;
d. 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
e. 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?

10.46 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.

10.47 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.

10.48 As preliminary requirements before agreeing to fund an experimental treatment, the ICB will need reassurance:

a. That the decision to agree to an exception to the general policy on treatment for the condition is made for very clear and explicit reasons which are consistent with the ICB's priority setting principles; and
b. That funding experimental treatments is done in a way that will contribute to the knowledge base.

10.49 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 funding through this IFR policy.

10.50 The ICB will consider a funding request for an experimental treatment where there is either:

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

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

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

10.52 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.

10.53 The options for consideration by the ICB in these instances are:

a. Not to fund;
b. 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 a one-off treatment such as a surgical intervention;
c. In all cases, contribution to any relevant clinical database or population registry which is operating.

Treatment following a clinical trial

10.54 The IFR route will not be used to fund ongoing treatment for patients whose treatment has started as part of a clinical trial. The responsibility for ensuring a clear exit strategy from a trial and whether those benefiting from the treatment will have on-going access to it, lies with those conducting the trial (as in the Medicines for Human Use (Clinical Trials) Regulation 2004 and the Declaration of Helsinki).

10.55 Except in the most exceptional cases, the ICB does not anticipate that is will make an IFR decision to fund patients coming out of a clinical trial. Patients coming out of a clinical trial will almost inevitably represent a "service development" because there will be other patients in broadly the same clinical circumstances, or the patient will not be able to show exceptional clinical circumstances. The IFR process will thus rarely be the right way to decide funding applications in such cases.

10.56 The fact that a patient has been in a trial where the treatment is proved to have a clinically beneficial effect is highly unlikely, of itself, to amount to exceptional clinical circumstances because there will almost certainly be other patients who are or could be (if identified) in similar clinical circumstances and who could benefit from the requested treatment. The ICB is mindful that clinical trials should not be used as a way of proving that treatments have clinically beneficial effects in individual cases in order to support an IFR application and thus seeking to by-pass its prioritisation processes. It is therefore right that IFR applications for funding for patients coming out of a clinical trial should be exceptional and subject to additional scrutiny and special criteria.

10.57 There may be very occasional trials in which the number of patients nationally is potentially very small and thus where the numbers of potential patients may not justify the application being treated as a service development. In such a case it may be possible for an IFR case to be justified by evidence from a clinical trial. However, the ICB expects these to be very rare cases and even where this is the case it may well be appropriate to treat the application within the service development policy.

11. Review and Monitoring of this policy

11.1 This policy will be subject to further review to ensure it continues to meet legislative and national objectives and to provide accurate and up-to-date guidance to support the IFR process.

11.2 Addenda to the policy will be added subsequent to any review and a decision on the need to re-issue the policy will be based on the significance of the amendments required.

12. Documents which have informed this policy

a) Department of Health, The National Health Service Act 2006, The National Health Service (Wales) Act 2006. NHS Act 2006, as amended by Health and Social Care Act 2012. https://www.legislation.gov.uk/ukpga/2006/41/pdfs/ukpga_20060041_en.pdf http://www.legislation.gov.uk/ukpga/2012/7/pdfs/ukpga_20120007_en.pdf (accessed 23/02/2018);

b) NHS Confederation Priority Setting Series, 2008
   a. Priority setting: an overview
   b. Priority setting: legal consideration
   c. Priority setting: strategic planning
   d. Priority setting: managing new treatments
   e. Priority setting: managing individual funding requests

   http://www.nhsconfed.org/~/media/Confederation/Files/Publications/Documents/Priority%20setting%20managing%20individual%20funding%20requests.pdf (accessed 23/02/2018)

c) Department of Health, 'Guidance on NHS Patients who wish to Pay for Additional Private Care' (March 2009) https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/404423/patients-add-priv-care.pdf

d) NHS England 'Who Pays? Determining responsibility for payments to providers' (August 2013) https://www.england.nhs.uk/wp-content/uploads/2014/05/who-pays.pdf (accessed 23/02/2018);

e) Department of Health, The NHS Constitution (July 2015). https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/480482/NHS_Constitution_WEB.pdf

f) Department of Health, 'NHS Choices Framework' (April 2016) https://www.gov.uk/government/publications/the-nhs-choice-framework

g) NHS England – Commissioning Policies: Funding of Treatment outside of Clinical Commissioning Policy or Mandated NICE Guidance (October 2016) https://www.engage.england.nhs.uk/consultation/af642939/supporting_documents/genericcommissioningpolicies.pdf

h) Midlands and Lancashire Commissioning Support Unit - A collaborative Individual Funding Request process for Lancashire Clinical Commissioning Groups (June 2016)

i) NHS England – Specialised Commissioning – Service Development Policy (September 2017) https://www.england.nhs.uk/publication/specialised-commissioning-service-development-policy-and-process/

j) NHS England – Commissioning Policy – Individual Funding Requests (November 2017) https://www.england.nhs.uk/publication/commissioning-policy-individual-funding-requests/

k) NHS England - Standard Operating Procedure: The Management of Individual funding Requests (November 2017) https://www.england.nhs.uk/publication/standard-operating-procedures-individual-funding-requests/

l) NHS England – Specialised Commissioning – Application form to make an Individual Funding Request (November 2017) https://www.england.nhs.uk/publication/standard-operating-procedures-individual-funding-requests/

Appendix 1 – Commissioning Decisions – Statement of Principles

The ICB will have established their own policy as standalone documents. However, the purpose of this Appendix is to enable reference to the principles adopted by all ICBs to commission only treatments or services which accord with the key principles:

1. Appropriateness
2. Effectiveness
3. Cost-effectiveness
4. Ethics
5. Affordability

In preparing its policies and in defining the principles on which those policies are based, the ICB is mindful of the NHS Constitution, of relevant legislation, and of court decisions.

The NHS Constitution commits the ICB:

- to provide best value for taxpayers' money and the most-effective, fair and sustainable use of finite resources;
- to make decisions in a clear and transparent way;

The Health and Social Care Act 2012 requires the ICB:

- to arrange for the provision of [certain health services] to such extent as it considers necessary to meet the reasonable requirements of the persons for whom it has responsibility';
- to arrange the provision of certain healthcare services for the population residing within its area;

The Court of Appeal (e.g., R v Northwest Lancashire Health Authority Ex parte A, D & G, July 29th, 1999) recognises that:

- it is an unhappy but unavoidable feature of state funded health care that [ICB] have to establish certain priorities in funding different treatments from their finite resources. It is natural that each [ICB], in establishing its own priorities, will give greater priority to life-threatening and other grave illnesses than to others obviously less demanding of medical intervention. The precise allocation and weighting of priorities is clearly a matter of judgment for each [ICB], keeping well in mind its statutory obligations to meet the reasonable requirements of all those within its area for which it is responsible. It makes sense to have a policy for the purpose - indeed, it might well be irrational not to have one.

ICB's aspire:

- to deliver health-care when that health-care is essential;
- to contribute to the prevention of ill health;
- to promote wellbeing; and
- to influence the values and attitudes of society when those values and attitudes define a health state as being abnormal.

In addressing the latter, the ICB regards it as often beneficial to society to extend the range that is perceived as normal, and to avoid situations where disease is defined sociologically rather than pathologically.

1. APPROPRIATENESS

1.1 The principle of appropriateness refers to the questions of:

a. whether the commissioning of the service falls within the remit of the ICB;
b. whether the purpose of the service is to maintain or improve an essential component of health status;
c. whether the service will use the best means of achieving its purpose;

1.2 The ICB will commission a treatment or service only where it is satisfied that it meets the criteria, including the criteria for appropriateness, set out in this Statement of Principles.

1.3 To accord with the principle of appropriateness, a treatment or service must meet one or more of the following criteria:

a. it has the intended outcome of preventing, diagnosing or treating a medical condition, defined as: a medical condition as any illness, injury or impairment in which there is an abnormality in the structure or function of the body or mind.
   - 'Treating' is defined as providing a healthcare service with the intention of curing a medical condition, halting, or delaying its progress, reducing its impact, relieving symptoms, or delivering alternatives to impaired biological functions.
   - An abnormality in the structure or function of the body or mind is defined as a situation where either:
     - a part of the body or mind is substantially impaired in the delivery of one or more of its functions; or
     - a part of the body or mind is substantially impairing another part in the delivery of one or more of its functions; or
     - there is a threat that (a) or (b) will happen imminently;

     (This definition does not apply to an abnormality of appearance which may be defined separately in policies for cosmetic services.)
b. it enhances dignity at the time of death;
c. It has the intended outcome of preventing unwanted pregnancy;
d. it provides part of such services or facilitates for the care of pregnant women, women who are breastfeeding and young children as may be reasonably required;
e. it is considered by the ICB to be necessary in order to meet a legal requirement.

1.4 Even if one or more of the criteria in section 1.3 is met, the ICB may decide that a treatment or service is not appropriate for it to commission for one or more of the following reasons:

a. The ICB is aware that there are different ways of managing a particular condition, and after giving the matter due consideration and taking relevant advice in the course of setting a policy it has decided that one particular way of managing that particular condition is normally more appropriate than others. The ICB's position will depend on the condition in question. In some circumstances it may take a view that it prefers to commission services that address the underlying problem rather than simply the symptoms (or vice versa). In other circumstances it may prefer to commission services that adopt a palliative approach. In other circumstances it may prefer to commission services that preserve certain other bodily functions.
b. The timing of a particular treatment is clinically unfavourable e.g., in relation to development, reproduction, weight loss etc.
c. For investigations and diagnostic services, the information being sought would not substantially affect the clinical management of the patient.
d. The particular service provider is not within the range of choices offered by the ICB for the service in question or the rights to extended choice set out in the NHS constitution.

e. The service falls within the defined remit of another public sector commissioner.
f. The ICB considers that other services competing for the same ICB resource more clearly have a purpose of preserving life or of preventing grave health consequences. “Services likely to prevent grave health consequences”, defined as those which:
   - prevent or relieve major pain, disability, or physical discomfort; or
   - directly treat a diagnosed mental health condition; or
   - maintain dignity at the time of death; or
   - deliver healthcare which is reasonably requires for pregnant and newly delivered women, women who are breastfeeding and young children; or
   - overcome an impairment which is preventing the patient from living a healthy lifestyle; or
   - satisfy equivalent definitions or criteria within specific policies, especially those policies relating to assisted conception and cosmetic procedures.
g. The ICB defines major pain, disability, or physical discomfort; in the context of appropriateness, as a situation where that pain, disability or physical discomfort:
   - Is the dominant feature of the condition, and
   - Is of a level of severity that would lead most people to seek healthcare for that feature of the condition alone, and
   - Is preventing usual activities, or is significantly disrupting the sleep pattern, and
   - Is present for all or most of the time, and
   - Is not primarily related to certain activities which could be avoided without detriment to health, and
   - Has a plausible basis, and
   - (For surgical treatments or services) either is likely to be permanent, or if short term is not relieved by medication, and
   - Is recognised by the clinician's providing treatment as the main feature that will be addressed by any treatment or service.

   On rare occasions an extreme odour that prevents social contact may be regarded as a disability in this context.

   Treatment that is likely to support the patient to be employable (or to benefit from education) is likely to accord with the principle of appropriateness, as the ICB recognises education and employment as important determinants of health. It is unlikely that such a treatment or service will have employability as its only treatment purpose. However, a treatment intention of enabling the patient to have a particular employment will not normally be sufficient to accord with the principle of appropriateness, and a policy that did regard such a treatment or service as appropriate may discriminate against people without that particular career aspiration. The ICB will also disregard an individual’s circumstances and intentions in relation to whether or not they could engage in employment or education or would wish to do so when deciding to fund a treatment or service that is likely to support their employability or ability to engage in education.
h. The ICB considers that the use of health care for the problem in question would amount to excessive medicalisation, which would be detrimental either at the level of the individual patient or at the level of the population. “Excessive medicalisation”, defined as a situation which:
   - An offer of healthcare may create or perpetuate a perception in society that a condition is an illness;
   - An offer of healthcare may reduce or restrict the range of variation which society considers to be normal;
   - An offer of healthcare for a particular presentation may distract from the more appropriate strategy of enabling and empowering the patient to cope with and manage the condition themselves;

- An offer of state funded healthcare may promote the misunderstanding that the NHS should fund every possible biological intervention, whereas some biological interventions should be regarded as a good which the individual should prioritise themselves against other calls on their personal budgets.

i. The treatment is new and has not yet been considered or prioritised for inclusion in the ICB's service agreement portfolio.

1.5 If the ICB considers a treatment or service to be appropriate, then it may commission it, provided that it also accords with the principles of effectiveness, cost-effectiveness and ethics.

2. EFFECTIVENESS

2.1 The ICB defines an effective treatment or service as one which is capable of achieving its intended outcome, and of doing so with the benefits exceeding any harm done.

2.2 The ICB will commission a treatment or service only where it is satisfied that it meets the criteria, including the criteria for effectiveness, set out in this Statement of Principles.

2.3 The ICB may satisfy itself that a treatment meets the criteria for effectiveness by considering the content and quality of the available evidence, including evidence of plausibility (i.e., a rational basis for expecting the treatment to work) and evidence obtained from research.

2.4 If the ICB is satisfied by evidence in relation to a particular treatment or service that the probable effect on a population of patients is that the benefits of the treatment or service will substantially outweigh the harm done by the treatment or service, then the ICB regard the treatment or service as effective.

2.5 If the ICB is satisfied by evidence in relation to a particular treatment or service that the probable effect on a population of patients is that the harm done by the treatment or service will substantially outweigh the benefits of the treatment or service, then the ICB will regard that treatment or service as not being effective.

2.6 If the ICB is satisfied by evidence in relation to a particular treatment or service that the probable effect on a population of patients is that the harm done by the treatment or service and the benefits of the treatment or service are balanced with neither substantially outweighing the other, then the ICB will not regard that treatment or service as according with the Principle of Effectiveness.

2.7 If the ICB does not have sufficient evidence to decide whether that the probable effect on a population of patients is that the benefits of the treatment or service substantially outweigh or are substantially outweighed by the harm done by the treatment or service, then the ICB will not regard that treatment or service as according with the Principle of Effectiveness. However:

2.8 The ICB shall consider any evidence offered by the patient or their clinical advisors.

2.9 If the ICB concludes that there is a deficit in the evidence available for a particular treatment or service, then it may move to a position of being uncertain whether the treatment or service is effective. In such a circumstance it may commission a treatment or service only in

accordance with the Policy for Individual Funding Request Decision Making, which considers funding services in a research context.

3. COST-EFFECTIVENESS

3.1 The ICB defines a treatment or service that is cost-effective as one which achieves a greater health gain than alternative uses of the same money by the ICB.

3.2 The ICB will consider the cost-effectiveness of a treatment or service only if it has judged that the treatment or service is effective, in accordance with section 2.

3.3 In circumstances when a treatment or service is regarded as appropriate and effective, the ICB may commission that treatment or service only if it is also satisfied that the cost is reasonable in relation to the expected benefits and adverse effects and may refer to the NICE threshold for cost per quality adjusted life year that may be in force at the time.

3.4 The ICB may consider a treatment or service not to be cost-effective if it fails to meet any national or local value for money or cost-effectiveness criterion that may be in force at the time.

3.5 The ICB recognises that the costs, expected clinical benefits and expected clinical dis-benefits of a particular treatment may vary from patient to patient and therefore the ICB may adopt a policy to commission a service only for those patients for whom the balance between costs and net expected benefits is the most favourable.

3.6 In comparing two possible treatment options the ICB may consider the relative and marginal costs and benefits and will decide which service to commission accordingly.

3.7 The ICB may consider cost-effectiveness at the population level as well as at the individual level in order to ensure equity of health outcomes.

4. AFFORDABILITY

4.1 The ICB aspires to use the Principle of Cost-Effectiveness to assist it to make commissioning decisions that make best use of resources. However, the ICB reserves the right to consider affordability above cost-effectiveness given the need for the ICB to prioritise the use of resources in accordance with the other principles set out in this policy.

5. ETHICS

5.1 The ICB defines ethical healthcare as that which is provided justly and fairly according to need, and in accordance with in accordance with systems of accepted beliefs and in accordance with values of relevant professional bodies such that the health of the population is maximised within the resources available. A healthy population is one in which health and wellbeing are prevalent in a fair and sustainable fashion.

5.2 The ICB's default position is that the treatment or service can be delivered ethically.

5.3 The ICB will commission treatments or services based on the health and healthcare needs of their resident population, as assessed by the ICB. In doing so, they will seek to reduce health inequalities within the population.

5.4 The ICB's commissioning policies, in line with the Equality Act 2010 will not discriminate on the basis of age, disability, gender reassignment, marriage or civil partnership, pregnancy and maternity, race, religion or belief, sex, or sexual orientation. The ICB will also not discriminate on social disadvantage, lifestyle, occupation, offending background, trade union membership, financial status, or family status (including responsibility for dependents).

5.5 The ICB will also apply the human rights principles of Freedom, Respect, Equality, Dignity and Autonomy when developing and applying commissioning policies, ensuring that they respect people's human rights in line with the Human Rights Act 1998 and the NHS Constitution.

5.6 All commissioning policies will be developed in line with the “Brown principles” of Equality and Inclusion. Specifically, E&I data will be sought at an early stage of the policy development and/or review process, to ensure that available information is taken into account during that process. All draft commissioning policies will be subject to equality impact assessment and the ICB will use the results of this assessment to influence the content of the policy as well as to identify any protected groups who should be specifically consulted or engaged with about each draft policy.

5.7 The ICB will not commission a service that does not follow the usual pathway, if the sole purpose of commissioning it would be to enable a patient to bypass a policy criterion that other patients are expected to follow.

5.8 The ICB will not commission a service if the sole reason for commissioning it would be because that service is commissioned by another Commissioning Organisation or Commissioning Organisations.

Appendix 2 – Legal context to decision making

This document sets out the legal and ethical considerations relevant to the IFR process.

ICB Responsibilities and Regulations

1 The foremost amongst these considerations are the following patient rights, specified under the NHS Constitution[3] 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."

2 Part 7 of the National Health Service Commissioning Board and Integrated Care Boards (Responsibilities and Standing Rules) Regulations 2012[4] 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

3 Under the NHS Act 2006[5] (as amended by the Health and Social Care Act 2012 ("HSCA)) the ICB[6]ICBs, the following applies[7]:

4 "An Integrated Care Board 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:
…
(c) medical, dental, ophthalmic, nursing and ambulance services,
…
(e) 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,
(f) such other services or facilities as are required for the diagnosis and treatment of illness."

5 In addition to this duty to meet the above requirements, the ICB has 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, the ICB 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.

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[3] The NHS Constitution March 2010
http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/@dh/@en/@ps/documents/digitalasset/dh_113 645.pdf

[4] National Health Service Commissioning Board and Clinical Commissioning Groups (Responsibilities and Standing Rules) Regulations 2012/2996 February 2012

[5] The NHS Act 2006
3http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/@dh/@en/documents/digitalasset/dh_063171.pdf

[7] Section 3 of the NHS Act 2006 (as amended)

6 So, 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.

7 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.

8 The ICB 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

9 Decisions made by public bodies including ICB's 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.

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

Equality Duties

11 The main impact of the Equality Act 2010[8] 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.

12 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.

[8] http://www.legislation.gov.uk/ukpga/2010/15/contents

The Human Rights Act 1998

13 The Human Rights Act 1998[9], 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 14 (the requirement for non-discrimination against groups because of their sex, race, religion, disability, disease).

Statutory duty of quality

14 The ICB needs 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:

- s14P (Duty to promote NHS Constitution);
- s14Q (Duty as to effectiveness, efficiency and economic value);
- s14R (Duty as to improvement in quality of services);
- s14T (Duties as to reducing inequalities);
- s14U (Duty to promote involvement of each patient) and
- s14V (Duty as to patient choice).

15 As part of the statutory duty of quality the ICB will ensure that the process for assessing and making decisions about individual funding requests should be timely and flexible enough to respond rapidly where the health of an applicant mandates a more urgent decision.

Ethical Considerations

16 The four principles widely used in medical ethics are:

- Autonomy: respecting the decision-making capacities of individual people to make their own reasoned informed choices
- beneficence: considering the balance between the benefits of an intervention against its risks and costs and choosing the one with greater benefit to the individual patient
- non maleficence: avoiding the causation of harm and ensuring any is proportionate to the benefits of treatment
- distributive justice: sharing benefits equitably, and risks and costs fairly; so that patients in similar positions should be treated in a similar manner irrespective of age, sex, race, disability, and employment.

Patient's Right to Choice

17 ICB's have 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.

[9] http://www.opsi.gov.uk/acts/acts1998/ukpga_19980042_en_3#sch1

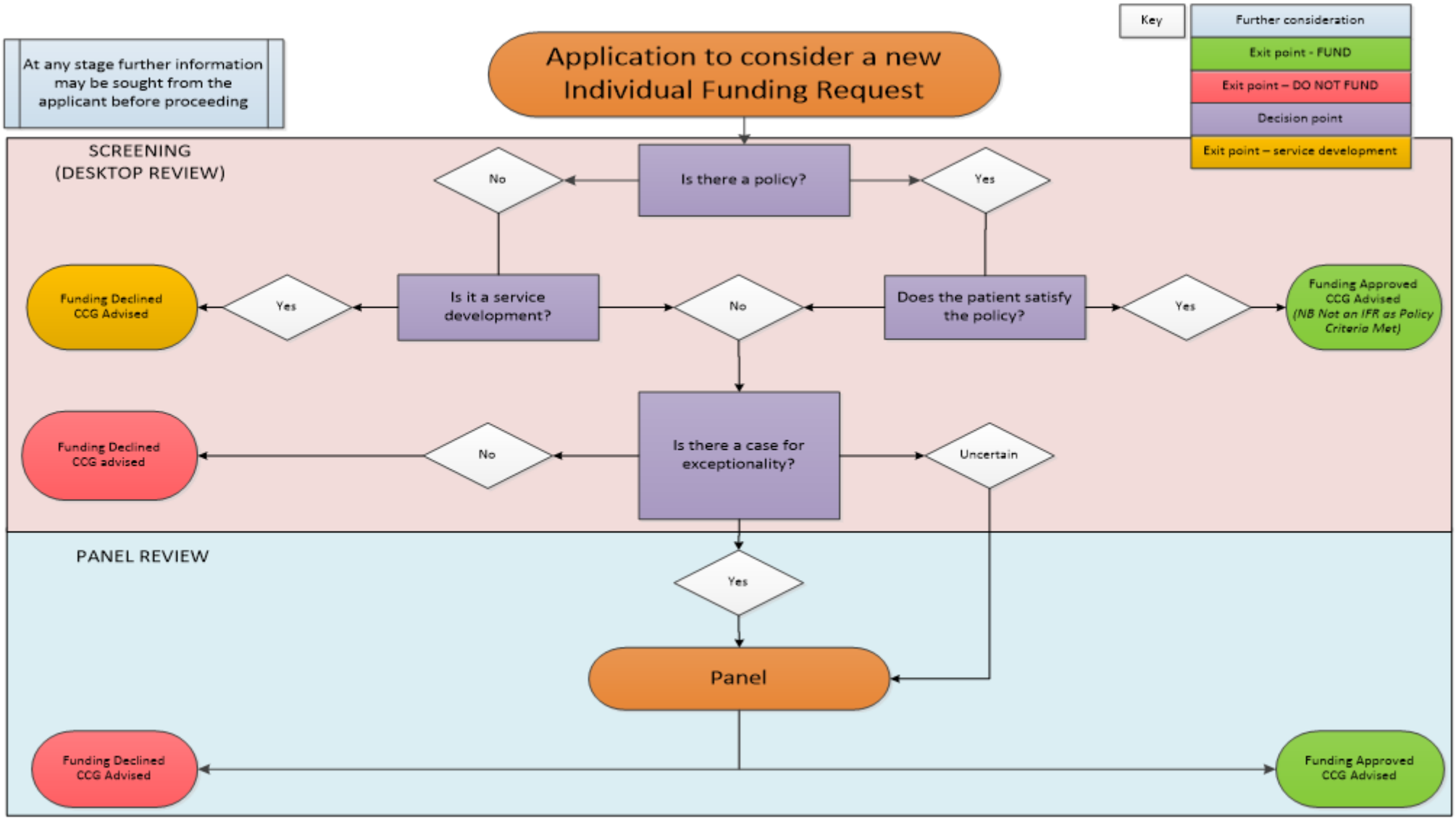
18 The NHS Constitution sets out certain rights that patients have in relation to choice. In addition, the Department of Health (2014/15) Choice Framework outlines the services where patients have a right to choice.[10]

19 ICB's 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.

20 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.

[10] https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/299609/2014- 15_Choice_Framework.pdf

Appendix 3 – Individual Funding Request (IFR) Decision Making Flow



Appendix 4 – An "arguable basis" for the application

1 The Court of Appeal[11] has confirmed that *"Exceptionality is essentially an equity issue that is best expressed by the question: On what grounds can the [NHS commissioner] justify funding this patient when others from the same patient group are not being funded?"* This policy adopts a strict approach to IFR funding in order to be fair to all patients whose cases do not make it for IFR consideration.

2 It is important that patients and clinicians should not have their hopes 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 Screen Process described in the policy is intended to be fair to all parties, including the IFR Panel and the other patients funded by the ICB, by only permitting cases proceed to a panel meeting if there is some reasonable prospect that the IFR Panel will accept that the criteria under this policy are 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.

3 The test that the IFR Team must apply when screening is whether there is "an arguable basis" for considering that the criteria under this policy are met on the facts of the individual case. This will exist where there is a realistic prospect that the IFR Panel, applying the decision making process set out in this policy, could properly come to the view that funding should be approved on the basis of the material in the application. "Realistic" means "more than fanciful", it does not mean "likely". The IFR Team should turn down an application if it is clear to them that the clinician has not provided a proper case to meet any of the essential criteria in this policy (i.e., material which appears to be relevant and potentially capable of demonstrating compliance with the criteria). This could be because, for example, no proper case has been made on the papers submitted to the IFR Team that the patient's clinical circumstances are exceptional as compared to other patients with the same condition at the same stage of the condition's progression (where relevant). It could be because there is no proper case that the requested treatment could be considered to be clinically effective or cost effective, applying the terms of the policy.

4 A case should not be turned down if the IFR Team consider that there is some realistic prospect that the application might be allowed by the IFR Panel (properly applying the policy). A case should be turned down only where the IFR Team are confident that, if the IFR Panel properly apply this policy, it will conclude that funding ought to be refused.

5 The IFR Panel can only approve funding if all the criteria in the policy are satisfied. It follows that the IFR Team should not allow an application to go forward to the IFR Panel unless there is an arguable basis for 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 be satisfied about before it could make a decision that funding should be approved.

6 If the IFR Team have any reasonable doubt about whether a case satisfies the criteria in the policy, it should be forwarded to the IFR Panel.

[11] Condliff, R (on the application of) v North Staffordshire PCT (2011)

Appendix 5 – Annexes

Annex 1

1 The policies adopted by the ICB are based explicitly on one or more of the five principles of appropriateness, effectiveness, cost-effectiveness, ethics, and affordability.

2 If a policy does not normally provide for the ICB to commission a service because it has a purpose which the ICB does not aspire to deliver (the principle of appropriateness) then a successful case would need to demonstrate that the purpose in the patient in question is different to the purpose of that treatment in the usual population of patients to whom the policy applies.

3 If a policy does not normally enable the ICB to commission an intervention because research evidence shows that it is does not achieve its purpose (the principle of effectiveness) then a successful case would need to demonstrate that the research evidence is not applicable to the patient in question as that patient is fundamentally different to the research population.

4 If a policy does not normally enable the ICB to commission an intervention because it is not considered to be cost effective, then a successful case would need to demonstrate that it would be cost effective for the patient in question, when compared with the alternative management of that patient if the service was not commissioned.

5 If a policy does not normally enable the ICB to commission an intervention because it is not considered to be ethical, then a successful case would need to demonstrate that it would be unethical to be commissioned for the patient in question. That case may need to consider the impact l on the whole population and not just on the patient in question.

Annex 2

1 A demonstration that the purpose of the treatment in this patient would place the intervention within the definition of appropriateness in the context of the Statement of Principles, is indeed a valid case for exceptionality to a policy based on the Principle of Appropriateness. However, the ICB may require a clear and detailed explanation before accepting exceptionality. A simple statement that the problem is causing pain, or discomfort or is limiting activities is insufficient. The case must clearly show, with explanation:

- that the definition of major pain, disability, or physical discomfort, in the Statement of Principles is met, and
- that there is a plausible reason why the problem is causing those symptoms, and
- that there is good reason to expect that the intervention will substantially improve those symptoms.

Annex 3

1 Severity cannot normally be regarded as part of a case for exceptionality if the policy being applied is based on appropriateness, effectiveness, or ethics.

2 In the case of a policy based on cost-effectiveness or affordability, the spectrum of severity is likely to have been considered at the time when the policy (often originating as NICE Guidance) was drafted. However, it is possible that there could be cases of extreme severity beyond what could have been expected at the time of drafting the policy. If in such a case there is also an expectation that the intervention would result in a greater benefit (e.g., from a worse level of health than other patients at baseline to the same level of health as other patients at outcome) at the same cost, then the NICE cost-effectiveness threshold could be met for these patients but not for the usual patient population. Such may be the format of a valid case for exceptionality. However, it would need to be demonstrated:

- that the severity in this patient is beyond what had been envisaged when the policy was drafted, and
- that for this patient the cost per QALY would be below the NICE threshold.

Annex 4

1 The default position is that all policy criteria will be applied as written. However, there are circumstances in which the ICB may decide, on the basis of a case from the applicant or the applicant's advisors that a particular policy criterion can either be set aside or interpreted differently for a particular patient. There are two categories in which this may happen:

2 When the circumstances of the particular patient make a criterion irrelevant. By way of example, if a fertility services policy set a minimum age for egg harvesting, which was intended for application for women who had unsuccessfully attempted to conceive, but a 15 year old women (i.e. younger than the age set in the policy needed to have cancer treatment which would damage her ovaries and was requesting egg harvesting and storage before that treatment, then it may be considered that the age limit was irrelevant for that patient - NB this example is illustrative only and does not refer to this ICB's actual policy for that circumstance).

3 When the patient has not been tested against a particular criterion but has been tested against an alternative standard. If the ICB is convinced by the applicant that the alternative standard is equivalent (i.e., it covers the same clinical ground and is at least as stringent as the policy criterion), and the patient does meet that alternative standard, and there are good reasons why the alternative test was used, then the ICB may decide that it is excessively pedantic to require the patient to be re-tested against the policy criterion.

Annex 5

1 The process of exceptionality is designed to consider individual cases and not to change policy. There are separate processes for changing policy, which include a three year review and an interim review if there are any issues raised or national changes that impact on the policy. If as part of considering individual cases, concerns about the policy are identified,

then the policy may be reviewed before its review date, and the patient may be reconsidered against the new policy. Research evidence is continually produced and the need to take account of new research is a major reason why policies are reviewed periodically. However, a policy system can be robust only if policies remain in force until they are formally reviewed. Therefore, research evidence published before the date on which a policy was adopted can be used as a case for exceptionality against that policy. However, research evidence published subsequent to that date can be used as a suggestion that the ICB should expedite a review of the policy but not as part of a case for exceptionality.

2 Notwithstanding the paragraph above, the ICB may apply discretion in accordance with paragraph 4.1 of this policy, and cases of great severity and urgency may be subject to that discretion when new and overwhelming evidence of effectiveness is published, and when the ICB's director of finance has confirmed that funding can be made available for this and other similar cases that may arise.

Annex 6

1 A case that the wrong policy has been applied, or that there had been other irregularities in the process of considering the patient's request, is a matter for appeal and not for exceptionality.

Annex 7

1 In considering arguments based on previous decisions, the ICB may take into account the facts that:

- no two cases are identical,
- reference to other cases may breach the confidentiality of the patients involved in those other cases,
- the ICB retains the right to apply discretion in relation to any case for exceptionality.

Annex 8

1 A statement that the patient is clinically suitable for treatment places the patient within the usual population of patients to whom the policy applies, and not as an exception to it.

Annex 9

1 This policy statement derives from section 9 of the General Policy for Individual Funding Request Decision Making. Notwithstanding that section, there may be some interventions with a robust evidence base of success in selected patients, where policy is that the patient would need to have undergone a trial of the proposed treatment before a commitment is made to using it on a longer term. In such circumstances that trial of the treatment would be within the contract and considering its outcome would be a valid part of applying that policy.

2 Good research into the effectiveness of healthcare interventions usually involves large numbers of patients, using a controlled and ideally randomised study design, with a long period of follow up. The experiences of individual patients may simply involve a placebo effect, may not be sustained into the future, and may not include an objective assessment of the balance between costs and benefits. If the patient has received private sector treatment

to try out a generally unproven intervention, then to accept the results of that trial as exceptionality would be inequitable to patients who could not afford private treatment and would fail to satisfy the commissioning principle of ethics. If the patient had received the trial from an NHS funded provider, then that provider may have been acting out with the contract specification and the matter of continuation would be a matter between the patient and that provider.

3 Therefore, evidence that the patient has a claim that a patient has tried out a treatment with claims of success does not amount to a case of exceptionality against a policy based on the principle of effectiveness or cost-effectiveness.

Annex 10

1 Interventions for which the intended outcome is to directly address the distress or disability associated with a diagnosed mental health condition, may be regarded as according with the principle of appropriateness. That gives the ICB the freedom to commission psychiatric and psychological interventions for patients with a mental illness.

2 Potentially a person wishing to have an intervention that is not normally commissioned on grounds of appropriateness could claim that they are distressed / depressed / suffering problems with psychological wellbeing as a result of the condition or of the unavailability of funding. Therefore, they would suggest that they were an exception to the policy in that the purpose of their intervention was to address the distress or disability associated with a diagnosed mental health condition.

3 Such claims could be interpreted in two ways, and each interpretation may be valid for some patients. However, neither interpretation would support a claim of exceptionality. Those interpretations are:

4 The patient has a mental illness (which may be the illness of depression or may be some other mental illness). A mental illness is an abnormality of the mind. That abnormality may involve a structural problem or a chemical imbalance in the brain, or simply an anomaly in the way in which the mind is operating at that time. However, it is an illness in its own right, and is best managed by using psychiatric and psychological interventions to address the root of the problem. It is not usually best managed by addressing other features of the patient's life which may be the focus of the illness but are not the primary cause of the mental illness. If such features are addressed, then the illness will remain, and the focus of the mental illness may simply shift to another focus. For this reason, a mental illness is not usually regarded as a matter of exceptionality for a request for a non-mental health intervention.

5 The patient's psychological symptoms are reactive to the physical problem or to the lack of funding availability. In that circumstance there is no mental illness. Such a reaction, even if referred to as depression, is simply a normal and indeed expected reaction to an undesired circumstance. It is therefore not a matter of exceptionality.

6 In any individual case, the ICB will consider a case for exceptionality based on expert clinical psychiatric advice that the provisions of this paragraph do not apply in the case of that particular patient.

Annex 11

1 Mandatory NICE guidance (Health Technology Assessment Appraisals) automatically becomes ICB policy and should be applied. Therefore, no case for exceptionality should be based on the patient satisfying the criteria for treatment under mandatory NICE guidance.

2 Other NICE guidance, and other non-mandatory guidance are not ICB policy (unless explicitly adopted as such) and it remains a matter of discretion for the ICB to decide whether to adopt such guidance as policy. If such guidance is not adopted, it has no force within the ICB and a case for exceptionality based on the patient satisfying such guidance is not valid.

Annex 12

1 Rarity does not itself form a case or part of a case for exceptionality. However, circumstances leading to the granting of exceptionality may (or may not) be rare.