Commissioning Policies: Funding of Treatment outside of Clinical Commissioning Policy or Mandated NICE Guidance

A. In-year service development

B. Individual Funding Requests

C. Funding for experimental and unproven treatments

D. Continuing funding after clinical trials

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Contents

1 Scope

This document sets out four distinct NHS England policies for funding treatments which are not currently routinely commissioned or subject to a mandated guidance from NICE.[1]

The treatments may not be commissioned because an individual falls outside the category of patients covered by an existing clinical commissioning policy, a NICE technology appraisal or NICE highly specialised technology appraisal, or because a clinical commissioning policy does not exist for the relevant treatment. [2]

NHS England is committed to providing the most effective, fair and sustainable use of finite resources. When considering funding for individual patients, NHS England will consider whether it can justify approval when others from the same patient group are not being funded for the same treatment. NHS England has previously published and consulted upon key qualifying principles when considering the funding of new treatments:

- NHS England will normally only accord priority to treatments or interventions where the intervention should offer equal or greater benefit than other forms of care routinely commissioned by the NHS;

- While considering the benefit of stimulating innovation, NHS England will not confer higher priority to a treatment or intervention solely on the basis it is the only one available; and

- The intervention must be available to all patients within the same patient group other than for clinical contra-indication. Because it is a core NHS value that the NHS is available to all, NHS England will not take account of non-clinical factors in making that judgement.

As a direct commissioner of services, NHS England has to make challenging decisions about which services are routinely commissioned, which might include drugs, diagnostics and medical technologies, as well as interventions. For specialised services, NHS England makes decisions through an annual commissioning prioritisation round. To help ensure these decisions are made effectively, transparently and lawfully, NHS England uses a set of prioritisation principles. However, there may be occasions when decisions need to be made in year, and in rare circumstances these decisions may need to be taken urgently.

There will always be patients whose clinical circumstances do not fit with the criteria as defined in clinical commissioning policies or NICE mandated guidance. In these cases, clinicians treating such patients may make a request for funding treatment for that individual through an ‘individual funding request’ or IFR. This request may be made for all services for which NHS England is the responsible commissioner.

[1] NICE Technology Appraisals or Highly Specialised Technology Appraisals
[2] And hence the default position is ‘not routinely commissioned’

Clinicians, on behalf of their patients, may also be faced with situations to consider using an experimental or unproven treatment in the absence of alternatives available in routine practice. Most such situations can be determined by the local provider organisation through their own defined policies and procedures. More expensive treatments are sometimes provided for compassionate use by the manufacturer, on occasions the clinician and provider needs to ask NHS England to make decisions about providing funding for such a treatment.

NHS England and NICE need high quality information from clinical trials to form clinical policy or to undertake appraisals. Those organisations considering initiating a trial are required to take steps to ensure those patients enrolling are informed of the arrangements of the continuation of funding after the clinical trial is complete.

This document sets out NHS England's four policies which apply to these circumstances. These are:

A. **In-year service development policy** – decisions on introducing a new clinical commissioning policy for a treatment or changes to an existing clinical commissioning policy that takes place in-year. The policy applies only to specialised services.

B. **Individual funding requests policy** – applications by NHS clinicians, on behalf of an individual patient, for funding for a treatment that is not routinely commissioned by NHS England or subject to a mandated guidance from NICE. Funding for all services that are directly commissioned by NHS England may be considered through this process.

C. **Funding experimental and unproven treatments policy** – funding experimental or unproven treatments outside a clinical trial and on continuing funding following such a trial of a treatment which is not part of a formal clinical research framework.

D. **Continuing funding after clinical trials policy** – continuing funding after a clinical trial, whether NHS England funded, commercially-funded or non-commercially funded.

The policies apply equally to any patient needing medical treatment, where the Secretary of State for Health has directed that NHS England is the responsible commissioner for the provision of that medical treatment as part of NHS care to that person.

Throughout this document a 'treatment' refers to any healthcare intervention provided or proposed to be provided by an NHS clinician.

2 Equality statement

NHS England has a duty to have regard to the need to reduce health inequalities in access to health services and health outcomes achieved as enshrined in the Health and Social Care Act 2012. NHS England is committed to fulfilling this duty as to equality of access and health outcomes, to having regard to the need to promote equality more generally, and to avoiding unlawful discrimination on the grounds of gender, race, disability (including learning disability), age, sexual orientation, religion, belief, gender reassignment, pregnancy and maternity or marital or civil partnership status.

In carrying out its functions, NHS England will have due regard to the different needs of protected equality groups, in line with the Equality Act 2010. This document is compliant with the NHS Constitution and the Human Rights Act 1998. This applies to all activities for which NHS England is responsible, including policy development, review and implementation.

3 A. In-year Service Development Policy

3.1 Plain Language Summary

NHS England is responsible for the direct commissioning of services for a number of complex conditions, some of which are rare – so-called 'specialised services'. Through accelerating development of innovative new drugs and treatments each year, many of which apply to specialised services, decisions have to be made on how to make the best use of limited NHS resources and services.

In the case of specialised services, NHS England decides annually which will be funded routinely through an annual commissioning prioritisation round. It is important that the way in which those decisions are made is fair and equitable to all patients. Deciding between potential new treatments can be complicated and needs to be delivered in a transparent way.

NHS England may also decide to introduce new treatments in-year. These changes to services are known as 'in-year service developments'. It is usually only cost neutral or cost saving service developments that will be introduced in this way, because ordinarily their clinical effectiveness and value for money would need to be considered alongside those for other new treatments. There are some treatments that become available at short notice where there is a strong impact on clinical outcomes supported by the highest quality clinical research that need additional resources to introduce. The In-year Service Development policy allows these to be considered.

To ensure a fair and transparent approach, NHS England will use the same process for clinical policy development as used for propositions considered in the annual commissioning prioritisation round to make decisions on in-year service developments. In-year service developments mean that NHS England can introduce more cost-effective, affordable and beneficial treatments ahead of the annual decisions, and can decommission services where appropriate.

3.2 Overview

An in-year service development is any change to the portfolio of treatments that are defined by clinical policy by NHS England for a defined group of patients, which are not made as part of NHS England's annual commissioning prioritisation round for service developments. The change to service provision might be an entirely new treatment or a change of access criteria to existing treatments. The clinical policy position determined by NHS England might be for 'routine commissioning' or 'not routinely commissioned'.

For specialised services, most discretionary investment decisions are made through the annual commissioning prioritisation round, details of which are published online.[3] To maintain the fair distribution of additional funding service developments should only be considered in-year if they are seeking resources according to limited criteria, because it requires reallocating funds that have already been set aside for planned developments for other patients in that financial year.

[3] https://www.england.nhs.uk/commissioning/spec-services/key-docs/

Proposals for in-year service developments will be considered against the same principles that are used in the annual relative commissioning prioritisation round. The principles are set out at Annex A1.

In addition, proposals for in-year service developments that require additional resources will need to demonstrate why they are of such high priority as to warrant being considered ahead of the annual prioritisation round. The cost-benefit priority of the development is considered against those service developments approved for funding at the last annual round. The fact that a patient group may be in need of the treatment immediately does not, on its own, demonstrate high priority.

In-year service developments include, but are not restricted to:

- New treatments including medicines, surgical procedures and medical devices, and new diagnostic tests and investigations. In such cases, NHS England may make a recommendation to NICE for an evidence review;
- Quality improvements;
- Requests to alter an existing policy (a 'policy variation') including to reflect availability of treatment across the NHS. This change could involve adding in an indication for treatment, expanding access to a different patient sub-group and/or changing the threshold for treatment
- Decommissioning of clinical services;
- Pump priming to establish new ways of delivering services; and
- Requests to fund a number of patients to enter a clinical trial and commissioning a clinical trial, including excess treatment costs.

Proposals for building in-year service developments are made by clinical leads endorsed by the relevant Clinical Reference Group(s).

3.3 Information required

The mechanism for identifying and processing proposals for an in-year service development is defined in the methods document for forming clinical policy.

In line with the approach taken for NHS England's annual commissioning prioritisation round, the relevant NHS England national programme of care board (www.england.nhs.uk/commissioning/spec-services/npc-crg/) will submit a detailed case to the Clinical Priorities Advisory Group (CPAG). As is the requirement for proposals considered in the annual commissioning prioritisation round this case must comprise a detailed clinical policy proposition, supported by a clinical evidence review; activity impact assessment; financial impact assessment; service impact assessment; engagement report; public consultation response report and an equality report. Where there is clinical urgency, CPAG may recommend to NHS England to introduce a service development without public consultation.

3.4 Decisions on funding

Decisions on funding will be made by NHS England, based on recommendations from CPAG. For a positive recommendation to be considered, NHS England will require evidence that the proposed service development:

- Demonstrates potential for such an exceptional degree of improved patient outcomes that at first consideration it would be unreasonable for NHS England to delay a consideration of the proposal until the next annual commissioning round;and

- Would have been highly likely to have been supported by NHS England in the last annual commissioning prioritisation round, with clear indication of how it would have been ranked relative to other service developments; or

- Constitutes an investment that will allow NHS England to meet NHS Constitution delivery requirements.

Where NHS England's clinical panel determines that the development is of sufficient clinical merit, it will ask CPAG to consider the extent to which the proposed in-year service development meets the principles that are used in NHS England's annual commissioning prioritisation round. Developments that are cost-neutral or cost-saving to NHS England that provide the same or an improvement in clinical benefit will not have to demonstrate that they are high priority, but will need to be considered against the commissioning prioritisation principles.

Proposed in-year service developments should be assessed against all of the prioritisation principles, and for those where this may be the case, CPAG will be asked to reach an overall judgement as to whether the strength of the evidence has demonstrated support for a recommendation for routine commissioning.

CPAG will make a recommendation to NHS England on whether or not the proposed in year service development should be routinely commissioned, and where there are additional resource implications how the proposed service development would have ranked relative to the last annual commissioning prioritisation round.

Based on this advice, the options for NHS England are to:

- Give approval to the proposed service development;

- Delay a decision pending further evidence on the proposed service development, which NHS England will commission as it considers appropriate; or

- Conclude that there is clinical merit in funding the requested treatment, but consider that NHS England should delay funding because the development is not affordable in the current year or does not otherwise have sufficient priority.

In extremely rare circumstances, an urgent decision may be needed on an in-year service development. This situation may arise where a patient's clinical situation is sufficiently urgent that it would not be appropriate to wait for a decision through the in-year service development process. The process for dealing with clinically critically urgent (CCU) cases is set out in standard operating procedure[4].

[4] https://www.england.nhs.uk/commissioning/wp-content/uploads/sites/12/2015/06/ccu-pub-doc-11062015.pdf

3.5 Annex A1: Prioritisation Principles

Relative Prioritisation Principles

- NHS England will normally only accord priority to treatments or interventions where here is adequate and clinically reliable evidence to demonstrate clinical effectiveness
- NHS England will normally only accord priority to treatments or interventions where there is measureable benefit to patients
- NHS England may agree to fund interventions for rare conditions where there is limited published evidence on clinical effectiveness
- The treatment or intervention should demonstrate value for money

Process Principles

- NHS England will follow its normal good practice in making prioritisation decisions in a transparent way, documenting the outcomes at all stages of the process
- NHS England will involve the diversity of stakeholders including the public and patients in the development of proposals and take appropriate account of their view
- NHS England will take into account all relevant guidance
- Compliance with the Equality Act 2010 (equality) and Health and Social Care Act 2012 (inequalities) by delivery of an equality / inequalities impact assessment for each policy proposal

Qualifying Principles

- NHS England will normally only accord priority to treatments or interventions where the intervention should offer equal or greater benefit than other forms of care routinely commissioned by the NHS
- While considering the benefit of stimulating innovation, NHS England will not confer higher priority to a treatment or intervention solely on the basis it is the only one available
- The intervention must be available to all patients within the same patient group (other than for clinical contra-indication)

4 B. Individual Funding Requests Policy

4.1 Plain Language Summary

Every year, the resources that NHS England receives are allocated to services and treatments that can be provided for patients. Any additional funding for treatments is therefore likely to mean reducing the funding that is available for other, more established treatments. The decision to fund a treatment that is not usually provided is only taken after very careful consideration.

There may be situations where a clinician determines that their patient's clinical situation is so different to other patients with the same condition that they should have different treatments to the rest of those patients. In such cases, NHS clinicians can ask NHS England, on behalf of a patient, to pay for a treatment which would not usually funded by NHS England for that patient. This request is called an Individual Funding Request (IFR).

IFRs can be made if NHS England:

- Has a policy to either routinely commission or not routinely commission for a group of patients who have the same medical condition but the individual patient's clinical circumstances do not match the policy and their condition sets them apart from others who do not have routine access under the policy; or

- Does not have a policy to fund the requested treatment for patients with a specific medical condition, usually: (a) because the condition is affecting the patient in an unusual way due to other clinical factors and as a result, the usual treatment for the condition is not suitable; or (b) the condition is extremely rare and so a policy has never been developed; often very few doctors will have treated a case before.

IFRs can be made for all NHS England's directly commissioned services. If there is evidence that other patients could present with the same condition and equally benefit from the treatment, the request will be considered as a change in routine clinical commissioning policy instead of an IFR. Decisions on whether or not to fund will be taken in line with NHS England's ethical framework.[5]

For specialised services, any change in routine commissioning policies will be considered through the in-year service development route or annual commissioning prioritisation process.

4.2 Overview

Every year, the resources NHS England receives are allocated to services and treatment that can be provided for patients. Any additional calls on resources to fund an individual's treatment is therefore likely to mean reducing the funding that is available for treating other people with established treatments. The decision to fund a treatment that is not usually provided is only taken after very careful consideration.

[5] NHS England (2013) Commissioning Policy: Ethical framework for priority setting and resource allocation, https://www.england.nhs.uk/wp-content/uploads/2013/04/cp-01.pdf

Very occasionally a clinician may think that their patient's clinical situation is so different to other patients with the same condition that they should have different treatments to others. In such circumstances, clinicians, on behalf of their patient, may make an Individual Funding Request or "IFR" to NHS England for funding a treatment for a patient that is not routinely commissioned by NHS England. Individual Funding Requests may be made for any of NHS England's directly commissioned services.

NHS England will consider such a request if a patient has a condition for which NHS England has commissioning responsibility and either:

- NHS England has a policy to either routinely commission or not routinely commission for a group of patients who have the same medical condition but the individual patient's clinical circumstances do not match the policy and their condition sets them apart from others who do not have routine access under the policy; or

- NHS England does not have a clinical commissioning policy for the requested treatment for patients suffering from the same medical condition as the requesting patient.

NHS England will only provide funding in response to an Individual Funding Request, if it is satisfied that the case meets all of the following criteria:

- There is evidence of 'clinical exceptionality' i.e. when a clinician believes that their patient is clearly different to other patients with the same condition, or where their patient might benefit from the treatment in a different way to other patients;

- There is high quality published evidence that the requested treatment is likely to be clinically effective for this individual patient;

- That the requested treatment is likely to be a cost-effective use of NHS resources; and

- The patient's individual clinical circumstances are such that it is unlikely that there are other patients with similar clinical conditions. Otherwise the IFR may be considered as an in-year service development instead.

NHS England's IFR team will carry out an initial screening. If the request proceeds, decisions on whether to fund the request will be made by NHS England's IFR Panel. Details of the IFR team, IFR Panel and the processes it will follow are set out in the Standard Operating Procedure for IFRs, which includes the Terms of Reference for the IFR Panel.

4.3 Information submitted to the Panel

All applications must be accompanied by written support and evidence provided by the clinical team treating the patient in line with the NHS England *Standard Operating Procedure: The Management of Individual Funding Requests.*

It is the referring clinician's responsibility to ensure that the appropriate information is provided to NHS England. If relevant information is not submitted, decision making will be delayed. In all instances the referring clinician must state whether or not they consider there are likely to be similar patients in the same situation and, if so, how many such similar patients there are or are likely to be in England in any 12 month period.

Information that is immaterial to the decision will not be considered by the IFR Panel. This information includes non-clinical factors relating to the patient – including age, marital status or employment – or information which does not have a direct connection to the patient's clinical circumstances. This information is irrelevant because it is an NHS value that its services are equally available to all regardless of their personal characteristics or circumstances, and are determined only by clinical factors.

Providers and clinicians should follow NHS England clinical commissioning policies in the advice and guidance given to patients prior to making the decision to treat a patient. NHS England expects providers with which it contracts to have oversight of this process. NHS England would expect every individual funding request to be sanctioned by the provider's Board-level Medical Director or equivalent and reserves the right to return unsanctioned individual funding requests to the provider un-assessed and refer recurrent inappropriate funding requests to the Chief Executive (or equivalent) of the relevant provider.

Ultimately NHS England's IFR decision represents a decision as to whether to NHS England will reimburse a provider for a particular intervention for the individual. However, that decision does not itself determine whether a clinician decides to undertake that treatment.

4.4 Screening process for IFR requests

4.4.1 Screening for Sufficient Information

Any IFR requests will first be subject to a screening by NHS England's IFR team to determine whether the request has sufficient clinical or other information for it to be properly considered. Where the IFR team conclude that there is insufficient information, it will be returned to the applicant specifying the additional information required.

4.4.2 Screening for Clinical Exceptionality

All individual funding requests submitted to NHS England will be screened by the IFR team to determine whether the request presents an arguable case for clinical exceptionality. The IFR team have delegated authority from NHS England to make these judgements and will seek additional clinical input in making the decision at their discretion.

Requests made under the IFR process will be classified as a request for a service development if, in the opinion of NHS England, there are likely to be a defined group of patients in similar clinical circumstances who form a cohort.

Such patients will be regarded as forming a cohort if the information in the application, supplemented by other published sources if needed, leads NHS England to believe that there are likely to be other patients across the whole of England in any single financial year:

- Who are in the same or similar clinical circumstances as the patient who is the subject of the request or their clinical condition is such that they could make a similar request; and

- Who could reasonably be expected to benefit from the requested treatment to the same or a similar degree as the patient on whose behalf the request is made.

It is possible that a cohort of relevant patients may be identified from the first application for an intervention if it is clear that the patient is representative of a whole group of similar patients.

If a decision is made by the IFR team based on the application and other information available to NHS England that the request is properly classified as a request for a service development then the request will be refused. This decision will be made without referring the case to the IFR Panel.

The requesting patient or clinician will be entitled to appeal the decision to classify the treatment as a service development, but should do so on the basis of clinical exceptionality, by arguing that the clinical circumstances of the patient are such that he or she is not in fact representative of a cohort. For any appeal, the requesting clinician may submit new clinical information to substantiate the argument for clinical exceptionality. The IFR team will reconsider a decision if new and relevant clinical information is provided.

For specialised services, where it is determined under the IFR process that the application represents a service development, the IFR team will inform the relevant Clinical Reference Group to consider whether the request has broader clinical support to be considered for service development, either in-year or as part of the annual commissioning prioritisation round.

4.4.3 Screening for Arguable Basis

If the screening process determines that the request has sufficient information for clinical exceptionality, the IFR team will then determine whether the documentation sets out an arguable basis on how the request meets the remaining IFR criteria. If the IFR team concludes that, applying the criteria contained in this policy, the IFR Panel could not properly approve the request, it will refuse the request. Otherwise it will pass the request to the IFR Panel for consideration.

4.5 Decisions on funding

The decision on funding will be made by the IFR Panel. The IFR Panel will make its decision based on the criteria in this policy with reference to any other NHS England published clinical policies or NICE mandated guidance relevant to the application or interpretation of the criteria. In reaching its decision on whether the patient is able to demonstrate 'exceptional clinical circumstances', the IFR Panel will consider:

- Whether there is evidence to suggest that the patient is likely to derive significantly more clinical benefit from the treatment than other patients who were suffering from the same condition at the same stage of the condition's progression; and

- Whether there are justifiable grounds for funding the requested treatment for this patient when other patients with the same presenting condition at substantially at the same stage of the condition's progression will be denied access to requested treatment, and if so what those grounds are.

The fact that a patient has exhausted all NHS treatment options available for a particular condition is unlikely, on its own, to be sufficient to demonstrate exceptional clinical circumstances.

Similarly, the fact that the patient has not responded to existing treatments or has had to discontinue existing treatments as a result of side effects where a recognised proportion of patients with the same presenting medical condition at this stage are, to a greater or lesser extent, refractory to or will experience side effects from existing treatments is unlikely to be on its own sufficient to demonstrate exceptional clinical circumstances.

Equally, should a patient be thought to have a severe form of the condition, the application should make clear how this patient differs from others who would be categorised as having the severe manifestation of the condition as described by the usual clinical assessment tools that distinguish the categorisation. The panel will expect the application to make explicit whether there are factors associated with the severity of the condition that are prognostic of the expected treatment response.

The IFR panel in all circumstances will take into account published evidence of clinical effectiveness and value for money relating to the proposed treatment. Where it is argued that such evidence is not available because of the rarity of the patient's condition, the IFR panel should consider the request in line with the Experimental and Unproven Treatments policy. Rarity of a condition is unlikely in itself to demonstrate exceptional clinical circumstances.

It is also open to the IFR Panel to conclude, notwithstanding the screening decisions taken by the IFR team that the criteria apply such that:

- The request should be properly classified as a service development, in which case the request will be refused and the relevant Clinical Reference Group will be informed so that potential consideration can be given to it as an in-year services development or part of annual prioritisation; or

- Further information or evidence is required before the Panel can take a decision on whether funding should be given, in which case further information will be requested through the IFR team.

NHS England will only take account of clinical factors relating to an individual patient, not factors related to patients generally or to the likely impact on other identifiable individuals of IFR applications.

In considering individual cases, the IFR Panel will take care to avoid identification bias or “rule of rescue” i.e. the imperative people feel to ‘rescue’ identifiable individuals facing avoidable death or ill health, or a preference for identifiable individuals’ lives over statistical measures of lives.

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

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

- The quality of the evidence presented to support the request

The IFR Panel is entitled to make approval of the request contingent on the fulfilment of such conditions as it considers fit.

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

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

4.6 Review of the decision

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

All requests for a review must be made within 28 days of the date when the decision is communicated to the patient. The request must be supported by the referring clinician who must explain his or her reasons for considering that the decision taken by the IFR Panel was either procedurally improper and/or misunderstood the medical evidence and/or was, in his or her opinion, a decision which no reasonable IFR panel could have reached. Any such review will be considered by the IFR Review Panel.

The role of the IFR Review Panel is to determine whether the IFR Panel has followed NHS England procedures, has properly considered the evidence presented to it and has come to a reasonable decision based on the evidence.

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

- Was taken following a process which was consistent with the policies of NHS England;
- Was a decision which a reasonable IFR panel was entitled to reach;
- Took into account and weighed all the relevant evidence; and
- Did not take into account any irrelevant factors.

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

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

The IFR Review Panel does not have power to authorise funding for the requested treatment but can require the IFR Panel to reconsider the case and make recommendations as to the IFR Panel's approach to that consideration. The IFR Review Panel may also request one of the Officers authorised to take urgent decisions to exercise that power on behalf of the IFR Panel.

4.7 Urgent Decisions for Individual Funding Requests

There will be occasions when an urgent decision is needed on funding for treatment under the IFR policy. A case is considered urgent where the patient faces a substantial risk of death or significant and irreversible loss of function. A national IFR Panel meets fortnightly, which NHS England considers negates the requirement for a separate decision making process for urgent IFR cases.

In any case, providers must take all reasonable steps to minimise the need for urgent requests to be made through the IFR process, for example by making requests promptly and providing all necessary information with a request. If provider clinicians are considered by NHS England not to be taking all reasonable steps to minimise urgent requests to the IFR process, NHS England may refer the matter to the provider's Chief Executive or equivalent.

In the unlikely event that the case is so urgent that it requires a decision on treatment before the IFR Panel next meets, the relevant provider will be advised to consider taking its own decision to commence treatment before the funding decision is made.

If a treatment is started by the provider in these circumstances and where the IFR Panel is satisfied that a case was urgent and the case was submitted in a timely manner, it will not refuse to determine the IFR application on the basis that it is retrospective. In these circumstances, if the IFR Panel grants the IFR request the funding for the treatment will be back-dated to the date on which the application was made.

4.8 Annex B1: IFR Guidance Note

4.8.1 What is meant by exceptional clinical circumstances?

NHS England must have good reasons for granting IFR funding on an exceptional basis because this means making an exception to approved commissioning policies and/or care pathways. These policies and pathways will usually have been adopted after having careful regard to clinical evidence, value for money, and affordability and after patient and professional engagement, and should not be lightly departed from. There can be no exhaustive definition of the conditions which are likely to come within the definition of exceptional clinical circumstances. The word 'exceptional' means 'a person, thing or case to which the general rule is not applicable'.

Requests under the IFR process often argue that an individual should be treated differently from other apparently similar patients and that their treatment should be funded when other patients will not be funded. The reasons put forward for this may be grounded in the moral or compassionate case for funding or because of the individual's background, occupation) or family circumstances. However the NHS does not make the judgements about the "worth" of different individuals that consideration of background occupation or circumstances may imply. It is a core value that the NHS is available, or unavailable, equally to all. The IFR Panel should bear in mind that, whilst everyone's individual circumstances are, by definition, unique, and on compassionate grounds reasons can always be advanced to support a case for funding, very few patients have clinical circumstances which are genuinely exceptional, so as to justify funding for treatment for that patient which is not available to other patients. The following points constitute general guidance to assist the IFR Panel. However, the overriding question which the Panel needs to task itself remains: has it been demonstrated by the clinician that this patient's clinical circumstances are exceptional such that the general rule should not be applied to them?

If a patient has a condition for which there is an established care pathway, the IFR Panel may find it helpful to ask itself whether the clinical circumstances of the patient are such that they are exceptional as compared with the relevant subset of patients with that same medical condition at the same stage of progression (where progression is relevant).

The fact that a patient has failed to respond to, or is unable to be provided with, one or more treatments usually provided to a patient with his or her medical condition (either because of a co-morbidity or because the patient cannot tolerate the side effects of the usual treatment) may be a basis upon which an IFR Panel could find that a patient is exceptional. However, 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.

For example:

- If the usual treatment is only effective for a proportion of patients (even if a high proportion), this leaves a proportion of patients for whom the usual treatment is not available or is not clinically effective. If there is likely to be a

significant number of patients for whom the usual treatment is not clinically effective or not otherwise appropriate (for any reason), 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.

- If the usual treatment cannot be given because of a pre-existing co-morbidity which could not itself be described as exceptional in this patient group, 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 exceptional.

The most appropriate response in each of the above two situations, is to consider whether there is sufficient justification (including consideration of factors such as clinical effectiveness, value for money, priority and affordability) to make a change to the policy adopted by NHS England for funding that patient pathway so that a change can be made to that policy to benefit a subgroup of patients (of which the requesting patient is potentially just one such person). This change needs to be considered as a service development.

Requests are increasingly being submitted with the argument for clinical exceptionality based on the patient having a specific genotype. In these circumstances, the IFR Panel will require evidence of how the specific genotype would make the patient A) different to others clinically and B) able to benefit to a greater degree than others without or with a different phenotype.

4.8.2 Non-clinical factors

Everyone's life is highly individual and valuable. Social and non-clinical personal factors will not be taken into account by the IFR panel. Quite often IFR requests seek to influence the IFR panel by describing how a person (or those close to them) will fail to achieve their full ambition in life in the absence of the requested treatment. These often include factors such as having children/not having children, being a carer/not being a carer, admission to university or another place of study or a person's role or achievements in society.

Non-clinical and social factors have to be disregarded for this purpose in order for the IFR Panel to be confident of dealing in a fair and even handed manner in comparable cases. If non-clinical factors are included in the decision making process, NHS England does not know whether it is being fair to other patients who are denied such treatment and whose social factors are entirely unknown.

Consideration of social factors would also be contrary to NHS England's policy of non-discrimination in the provision of medical treatment. If, for example, treatment were to be provided on the grounds that this would enable an individual to stay in paid work, then this would potentially discriminate in favour of those working compared to those not working. That may be unlawful, and even if not these are not value judgements which the IFR panel should make.

The policy of NHS England is that it should continue to apply these principles in individual applications for funding approval. NHS England 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. This includes disregard of the impact of the clinical condition on non-clinical factors. For example restored mental function could be a clinical impact. The fact that the patient could then resume their studies is not.

Accordingly, in reaching a decision as to whether a patient's circumstances are exceptional, NHS England 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.

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

4.8.3 Proving the case that the patient's circumstances are exceptional

The onus is on the clinician making the request to set out the grounds clearly for the IFR Panel on which it is said that this patient is exceptional. The grounds will usually arise out of exceptional clinical manifestations of the medical condition, as compared to the general population of patients with the medical condition from which the patient is suffering.

These grounds must be set out on the form provided by NHS England. The clinician should clearly set out any factors which he or she invites the IFR Panel to consider as constituting exceptional clinical circumstances. If, for example, it is said that the patient cannot tolerate the usual treatment because of the side effects of another treatment they are receiving, the referring clinician must explain how usual it is for the patient with this condition not to be able to be provided with the usual treatment.

If a clear case as to why the patient's clinical circumstances are said to be exceptional is not made out, NHS England is obliged to refuse the application. NHS England recognises that the requesting clinician and the patient, together, are usually in the best position to provide information about the patient's clinical condition as compared to a subset of patients with that condition. The referring clinician is advised to set out the evidence in detail because the Panel will contain a range of individuals with a variety of skills and experiences but may well not contain clinicians of that specialty. NHS England therefore requires the requesting clinician, as part of their duty of care to the patient, to explain why the patient's clinical circumstances are said as to be exceptional.

The policy of NHS England is that there is no requirement for the IFR Panel to carry out its own investigations about the patient's circumstances in order to try to find a ground upon which the patient may be considered to be exceptional nor to make assumptions in favour of the patient if one or more matters are not made clear within the application. Therefore, clinicians are asked to take a balanced approach to completion of the IFR forms, and if a clear case of exceptionality is not made out by written evidence before the IFR Panel, the IFR Panel would be entitled to turn down the application.

4.8.4 Multiple claimed grounds of exceptionality

There may be cases where clinicians and/or patients seek to rely on multiple grounds to show that their case is exceptional. In such cases the IFR Panel should look at each ground individually to determine (a) whether the factor is capable, potentially, of making the case exceptional and (b) whether it does in fact make the patient's case exceptional. The IFR Panel may conclude, for example, that a factor is incapable of supporting a case of exceptionality (and should therefore be ignored) on one ground, but it might be relevant on another ground. That is a judgment within the discretion of the IFR Panel.

If the IFR Panel is of the view that none of the individual factors on their own make the patient's clinical circumstance exceptional, the IFR Panel should then look at the combined effect of those factors which are, in the IFR Panel's judgment, capable of supporting a possible finding of exceptionality. The IFR Panel should consider whether, in the round, these combined factors demonstrate that the patient's clinical circumstances are exceptional, reminding itself, of the difference between individual distinct circumstances and exceptional clinical circumstances.

4.8.5 An "arguable basis" for the application

The Court of Appeal[6] 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 the patients whose cases do not make it for IFR consideration.

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 Screening Process described in the policy is intended to be fair to all parties, including the IFR Panel and the other patients funded by NHS England, 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.

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."Realisitic" 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

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

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.

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 come to a conclusion that funding ought to be refused.

The IFR Panel can only approve funding if all of 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 are 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.

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.

4.8.6 Funding for patients coming out of a clinical trial

Save in the most exceptional cases, NHS England does not anticipate that it 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.

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. NHS England 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.

There may be very occasional trials in which the number of patients in England is potentially very small and thus where the numbers of potential others 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 NHS England 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.

4.8.7 Personal health budgets

People with complex health care needs have the right to ask for a personal health budget (PHB), subject to certain conditions. A PHB is an amount of money to support the planned and agreed healthcare and wellbeing needs of an individual. PHBs, therefore, give people more independence over how their healthcare money is spent. For more on the operation of PHBs see: http://www.personalhealthbudgets.england.nhs.uk/.

IFRs relate to cases where money is identified to fund healthcare based on exceptionality of the individual, following a referral from an NHS clinician. Having a PHB would not therefore exclude the patient from making an IFR to meet assessed needs beyond those included in the PHB.

5 C. Funding for experimental and unproven treatment policy

5.1 Plain Language Summary

It is important that decisions on clinical practice and policy are based on sound evidence. To ensure the effective and equitable use for NHS funding, experimental treatments have to be undertaken judiciously, responsibly and for clearly defined purposes.

NHS England will not normally consider funding a treatment that does not have evidence demonstrating that it is clinically and cost effective. It would be difficult to justify funding a treatment with uncertain outcomes, when there are many treatments with clear benefits that the NHS is not able to afford. In addition, there are a number of routes through which research can rigorously examine and assess new treatments, which are the proper routes for assessing unproven treatments.

There are some exceptional circumstances where a clinical trial or research might not be possible. In such circumstances NHS England may consider a trial of treatment for the individual, on the same basis as the IFR policy and process.

NHS England aims to ensure that new treatments are not introduced without clear plans for what will happen when the study ends, including stopping treatments where appropriate. It would be unethical for a clinician to start a treatment if plans to continue treatment after the trial are not clear.

5.2 Overview

NHS England aims to provide as comprehensive a healthcare service as possible across all patient groups and across the entire patient pathway, within the available resources. It is difficult to justify funding an experimental treatment with outcomes which are either unproven or unclear when many proven interventions and important elements of healthcare remain either unfunded or are not fully accessed by sections of the population.

Given that the demand for healthcare will always exceed the resources available to fund treatment, it is justifiable to give the funding of experimental treatments a lower priority than funding the provision of core services and treatments of proven benefit.

Except in circumstances set out in this policy, interventions which are judged to be experimental or not to be of proven effectiveness will not routinely be funded.

A treatment may be considered experimental where:

- 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;

- There are no relevant articles published in the peer-reviewed journals available on the treatment for the indication in question;

- The treatment does not have marketing approval from the relevant government body;

- The treatment does not conform to usual clinical practice in the view of the majority of medical practitioners in the relevant field;

- The treatment is being used in a way other than that previously studied or that for which it has been granted approval by the relevant government body; or

- The treatment is rarely used, novel, or unknown and there is a lack of authoritative evidence of safety and efficacy.

As commissioners of healthcare, NHS England will consider two further criteria: (a) the evidence is not yet available for public scrutiny; and (b) the decision maker does not have confidence in the evidence that has been presented.

Preliminary requirements before agreeing to fund an experimental treatment, NHS England will need reassurance of two things:

- That the decision to agree to an exception to the general rule is made for very clear and explicit reasons which are consistent with the NHS England's priority setting principles; and

- That funding experimental treatments is done in a way that will contribute to the knowledge base.

There are a number of common scenarios in which explicit funding of an experimental treatment might be considered by NHS England, which are set out below.

5.3 Rare clinical situations where trials are judged impossible

For rare clinical situations where the commissioner judges that trials will be impossible to carry out, requests for funding will be considered under NHS England's IFR policy process.

In these cases, NHS England will give consideration to supporting an existing treatment in an experimental context for an individual patient's clinical situation provided that the clinician making the application is able to demonstrate that running a clinical trial for the treatment in the clinical situation in question is impossible or improbable for ethical, clinical or methodological reasons.

It is important for NHS England to distinguish between instances where trials are impossible or improbable, and those where the research community and industry have not prioritised a trial. There may be circumstances where the potential for trials is restricted because of the nature of the treatment and/or the epidemiology of the disease. However, rarity is not sufficient ground for accepting a lack of evidence.

Having excluded for consideration cases where trials are possible, NHS England will consider a funding request in which there is either:

- No evidence, or only anecdotal evidence;
- Evidence from small and often heterogeneous case reports;
- Evidence solely of short term outcomes; or
- Evidence of effectiveness in a similar condition to the clinical circumstance under consideration.

In assessing these cases, NHS England will make a decision having regard to:

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

The clinician will be expected to provide as much information as possible about the treatment, relevant research upon which the claim for biological plausibility of the treatment is based, costs, as well as clinically relevant information on the patient. In addition, the clinician will identify the clinical markers and clinical outcomes that will be monitored to assess treatment response.

The options for consideration by NHS England in these instances are:

- Not to fund;
- Fund on the condition that the patient enters a properly conducted *'n of 1'* trial (if and when this option is open to the NHS);
- Fund a 'trial of treatment' but make on-going treatment subject to the demonstration of clinical benefit for the individual patient using criteria agreed in advance with the clinical team.. This option is only available where there is a course of treatment or long-term treatment. It is not suitable for on one-off treatment such as a surgical intervention; or
- Fund with no evaluation requirements, although a report of the outcomes will be required.

In all instances, contribution to any relevant clinical database or population registry which is operating will be an additional condition before NHS England gives approval of funding for the treatment. Primary research into novel treatments will not be funded through this route.

5.4 Treatments currently being studied

The situation may arise of a treatment that is currently being evaluated, but that requires the commissioner to sponsor either one or more individual patients to enter into a trial. Most research is industry-sponsored and, therefore, this scenario does not commonly arise.

However, the NHS regularly funds excess service costs of non-industry trials such as those conducted by the Medical Research Council. This funding arises out of the Concordat that exists between the Department of Health and research bodies. Trials under this arrangement are listed on the National Institute of Health Research (NIHR) Clinical Trials Register. In addition, local professional bodies may also support trials. It is important to establish what the status of a trial is, who has sponsored it and which bodies contribute to funding the trial.

NHS England may be asked to explicitly fund trials in two ways:

- A request to support a trial by funding a number of patients or any qualifying patient to enter the trial – in these instances the request should be treated as a service development.

- A request to support a single patient to enter a trial – this request should be managed under the Individual Funding Request (IFR) policy and process.

In both these instances the following should be considered:

- Potential strategic importance of the treatment – The strategic importance is a judgement as to whether the trial will address the key goals and priorities of NHS England. This type of trial is rare, as most funding requests for experimental treatments are for second, third and fourth line treatments for the seriously ill, as a last resort. Equally rare are requests to fund patients in trials which address specific questions for an existing and established treatment;

- Quality of the trial – whether or not it is going to generate the sort of information needed to come to a view on the treatment; and

- Ownership of the data – Public funds should not be used to support trials where there is no guarantee that the results will be put into the public domain and the data subject to external scrutiny.

5.5 Treatments for which there are adequate trials

It is not uncommon to have a situation where a treatment is supported by trials but there remains some uncertainty about the treatment. In these instances the requirement for on-going evaluation may be legitimate. Issues that might result in a commissioner deeming that a treatment should only be made available if there is on-going evaluation include, but are not limited to:

- Where there are concerns about the true nature of the benefit, risks and/or long term outcomes;

- Where a treatment's true place in managing a clinical condition has yet to be established;

- Where there is potential for significant variation in clinical practice, which might otherwise be difficult to control;

- Where it is not known how best or where to deliver the treatment e.g. dose, frequency, sequencing, concurrent treatment, duration of treatment, location; and

- Where there is a good chance that real-life effects and /or costs may differ from those seen in clinical trials because of difference in context, patient mix, treatment delivery, service provision and so on.

NHS England may wish to apply conditions when funding treatments in this category.

6 D. Continuing funding after clinical trials Policy

6.1 Plain Language Summary

As with experimental and unproven treatment, NHS England does not fund the continuation of treatment started as part of a clinical trial unless there has been explicit agreement between the trial organisers and NHS England before the trial began.

Arrangements for continuing funding for treatment after a clinical trial should be agreed ahead of setting up the trial, regardless of the source of funding.

The organisers of the trial must tell patients who enter clinical trials what arrangements have been made for continued funding for people who are found to have a clinical benefit from the trial treatment. Patients have a right to this information and clinicians should ensure that patients have received it, and have considered it before consenting to take part in a trial.

6.2 Overview

In line with the ethical approval requirements of the Health Research Authority for clinical trials, NHS England expects organisations planning a trial to determine in advance of the trial commencing the arrangements as to funding of post-trial treatment for those patients for whom the trial has shown a clinical benefit. Organisations should also to ensure that trial participants are aware of them as part of the consenting process. No assumption can be made that this funding responsibility would fall to NHS England without NHS England's explicit written approval prior to commencement of the trial.

Organisations are expected to communicate clearly with patients and their clinicians about those arrangements as part of the process of gaining their consent to participate in the trial. It is the responsibility of the NHS provider of treatment and the patient's clinician to ensure that patients are fully informed about the circumstances in which commercial funding is being provided, for how long funding will be provided and what will happen when it is withdrawn. It is also the responsibility of the NHS provider and the patient's clinician to ensure that such arrangements are explicitly approved by the relevant governance committee. NHS England expects that the patient's prior informed consent is documented.

The provider of this treatment and the clinician should take care to ensure that participants in a trial do not assume that NHS England will fund treatment unless NHS England has given a written commitment to that effect. It is not enough not to lead a patient to believe that NHS England funding will be available: they must be expressly warned that it will not be.

Agreement by NHS England to continue to fund a treatment for a patient on a clinical trial does not represent a policy decision by NHS England to fund that treatment for other patients who were not part the trial. A request to fund the treatment in question for a general cohort of patients regardless of participation in the clinical trial will be

assessed and prioritised under NHS England's annual prioritisation framework for investments in specialised services in the normal way or, exceptionally, determined under its policy for In-year service developments, as appropriate.

To note that this policy does not apply to those products that would be considered through the Cancer Drugs Fund process.

6.3 NHS England-funded trials

NHS England will fund an individual patient's on-going access to the treatment after the completion of the clinical trial for that treatment:

- Where the clinical trial has been funded (wholly or in part) by NHS England; and

- Where the treatment has been demonstrated through a formal clinical review to deliver clinical benefit to the patient.

Treatment will be funded only for as long as the patient's supervising clinician agrees that the treatment is clinically appropriate.

An agreement by NHS England to continue to fund a treatment for a patient who meets the above criteria does not represent a policy decision by NHS England to fund that treatment for other patients who were not part of the clinical trial.

A request to fund the treatment in question for a general cohort of patients regardless of participation in the clinical trial will be assessed and prioritised under NHS England's annual prioritisation framework for investments in specialised services in the normal way or, exceptionally, determined under its policy for In-Year Service Developments, as appropriate.

Where commissioning responsibility for a patient on a clinical trial transfers to NHS England from another NHS commissioner, and there is written evidence of an agreement to fund on-going treatment costs by the previous NHS commissioner, NHS England will honour funding commitments made by the patient's previous NHS commissioner subject to the terms of its Changing Responsible Commissioner policy

6.4 Commercially and non-commercially funded trials

Where a clinical trial of a treatment has been initiated and sponsored by a manufacturer of pharmaceuticals or medical devices, or by some other commercial organisation, NHS England considers that responsibility for funding on-going access to a treatment rests with those parties.

For non-commercially funded clinical trials, other than those funded wholly or partly by NHS England itself, NHS England will consider a request that is made before the clinical trial commences to provide funding for on-going access to treatment if the clinical trial is to be wholly funded by non-commercial bodies and is sanctioned by the National Institute for Health Research.

For NIHR sponsored research, and when it would be the responsible commissioner, NHS England will honour any commitment given by an existing or previous NHS commissioning body to fund treatment beyond the end of the trial, providing it is safe to do so, continuation of treatment would be consistent with the findings of the trial and it is affordable.

6.5 Continuing costs following experimental or unproven treatment

As for any clinical trial, NHS England will not usually fund a patient's treatment at the end of an experimental treatment without written agreement prior to commencement of any trial.

Where commissioning responsibility for a patient transfers to NHS England from another NHS body, provider trusts seeking funding will need to provide evidence of a prior agreement from the NHS organisation that was the responsible commissioner at the date that the trial of treatment commenced.

Should a provider make an application to NHS England for a service development at the end of a 'trial of treatment' to support funding for the treatment in question in relation to a cohort of patients, the application will be assessed and prioritised under NHS England's annual commissioning prioritisation process for specialised services or, if appropriate, as an in-year service development.

7 References

7.1 Documents which have informed this set of policies

- Early Access to Medicines Scheme https://www.gov.uk/government/publications/early-access-to-medicines-scheme-eams-how-the-scheme-works https://www.gov.uk/guidance/apply-for-the-early-access-to-medicines-scheme-eams#overview

- National Health Service Commissioning Board and Clinical Commissioning Groups (Responsibilities and Standing Rules) Regulations 2012.

- The National Health Service Act 2006 (as amended by Health and Social Care Act 2012)

- Department of Health, The NHS Constitution for England, March 2013 https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/170656/NHS_Constitution.pdf

- The National Prescribing Centre, Supporting rational local decision-making about medicines (and treatments), February 2009, http://www.npc.co.uk/local_decision_making/resources/handbook_complete.pdf

- The National Health Service Procurement, Patient Choice and Competition (No. 2) Regulations 2013

- The National Specialised Commissioning Group: Funding of treatments for patients leaving clinical trials (March 2008). The Medicines for Human Use (Clinical Trials) Regulations 2004. (Statutory Instrument 2004 Number 1031. Original: http://www.legislation.gov.uk/uksi/2004/1031/contents/made, Amendment: http://www.legislation.gov.uk/uksi/2006/1928/contents/made

- World Medical Association Declaration of Helsinki, Ethical Principles for Medical Research Involving Human Subjects. Latest revision: 64th WMA General Assembly, Fortaleza, Brazil, October 2013. http://www.wma.net/en/30publications/10policies/b3/index.html

- Letter from the National Patient Safety Agency, National Research Ethics Service to all UK NHS Research Ethics Committees March 2008.

- The National Prescribing Centre, Supporting rational local decision-making about medicines (and treatments), February 2009, http://www.npc.co.uk/local_decision_making/resources/handbook_complete.pdf

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- Department of Health letter, Requirements to support research in the NHS, Gateway number 12153, July 2009.

- Guidance on funding Excess Treatment Costs related to non-commercial research studies and applying for subvention (April 2009).pdf

- The National Institute for Health and Care Excellence (Constitution and Functions) and the Health and Social Care Information Centre (Functions) Regulations 2013 http://www.legislation.gov.uk/uksi/2013/259/contents/made

- The National CB's Commissioning Policy (reference): Ethical Framework to underpin priority setting and resource allocation

- Department of Health: HSG(97)32:Responsibilities for meeting Patient Care Costs associated with Research and Development in the NHS. http://www.dh.gov.uk/en/Researchanddevelopment/A-Z/DH_4016456

- McKie J, Richardson J. The rule of rescue, SocSciMed.2003 Jun; 56(12):2407-19

7.2 Glossary

Benefit	The positive impact that a healthcare service or intervention has on an individual patient, or a cohort of patients. Clinical benefit can be measured in different ways (for example: survival after surgery, or ability to function in the ordinary tasks of living).
Clinical effectiveness	Clinical effectiveness is a measure of the extent to which a treatment achieves pre-defined clinical outcomes in a specific group of patients.
Clinical Reference Group	NHS England has established Clinical Reference Groups (CRGs) covering all of the specialised services that are directly commissioned by NHS England. They are responsible for preparing national specialised service level strategy and developing specialised service contract products such as specifications and policies.
Clinical trial	A study to determine whether a treatment is safe and effective. It is carried out with a sample of patients, usually after laboratory studies and studies with healthy volunteers have been conducted. The trial is set up to answer one or more questions. For example, does the treatment work and does it have any adverse side effects? If so, how serious are they?
Commissioning	Commissioning is the process of planning, funding and monitoring healthcare services. As a commissioner of some healthcare services NHS England uses the commissioning process to drive quality, efficiency and equity, and improve outcomes for patients. It commissions specialised services, primary care, healthcare for people in justice settings, some services for the armed forces and some public health services.
Co-morbidity	Co-morbidity refers to the presence of two or more health problems in the same person.
Cost effectiveness	Cost effectiveness is an assessment as to whether a healthcare intervention provides value for money.
Efficacy/ Efficacious treatment	A treatment is efficacious where it has been shown to have an effect in a carefully controlled and optimal environment. However, it is not always possible to have confidence that data from trials which suggest that treatments will be efficacious will translate into clinically meaningful health gain and more specifically the specific health gain of interest. This is the difference between disease-oriented outcomes and patient-oriented outcomes. For example a treatment might have demonstrated a change in some physiological factor which is used as a proxy measure for increased life expectancy but this relationship might not be borne out in reality.

Individual funding request	An IFR is a request to NHS England to fund a treatment or intervention for an individual who, it is claimed, presents with exceptional circumstances, such that NHS England is asked to make an exception to approved commissioning policies and/or care pathways.
National Institute for Health and Care Excellence	NICE is a public body that provides national guidance and advice to improve health and social care. It develops guidance, standards and information on high quality health and social care. It also advises on ways to promote healthy living and prevent ill health.
National Institute for Health Research	The mission of NIHR is to maintain a health research system in which the NHS supports outstanding individuals, working in world-class facilities, conducting leading-edge research focused on the needs of patients and public. It aims to establish the NHS as an internationally recognised centre of research excellence.
NHS trust	NHS Trusts are established by legislation to provide healthcare services.
Opportunity cost	Opportunity cost is the loss of the ability for the NHS to fund other healthcare interventions when a decision is made to apply NHS resources to a particular healthcare intervention
Provider	An organisation that provides healthcare services to patients.
Research Ethics Committees	NHS Research Ethics Committees safeguard the rights, safety, dignity and well-being of patients who choose to participate in research. They review applications for research and give an opinion about the proposed participant involvement and whether the research is ethical. RECs are independent of research sponsors.
Service development	A service development is an application to NHS England to amend the clinical commissioning policy of NHS England to provide that a particular healthcare intervention should be routinely funded by NHS England for a defined group of patients.
Treatment	Treatment means any form of healthcare intervention which has been proposed by a clinician and is proposed to be administered as part of NHS commissioned and funded healthcare
Trial protocol	A document that describes how a clinical trial will be conducted.
Value for Money	Value for money in general terms is the utility derived from every purchase or every sum spent.