NHS
Surrey Heartlands
Clinical Commissioning Group

CLIN01

Clinical Commissioning Policy: Individual Funding Requests

Policy number	CLIN01
Version	1.0
Approved by	Quality and Performance Board
Name of originator/ author	Andrea Golding / Georgina Randall
Owner (director)	Colin Thompson
Date of last approval	8th July 2020
Next approval due	8th July 2023

Version control sheet

Version	Date	Author	Status	Comments / changes since last version
0.1	22.05.2020	Andrea Golding / Georgina Randall	DRAFT	Post consultation with provider chief pharmacists and chief operating officers, members of the IFR panel and ECI team Complete re-write from v3
0.2	29.05.2020	Clare Johns / Maria Bruce	DRAFT	EQIA review
0.3		Andrea Golding/ Georgina Randall	DRAFT	Consultation with ICP directors (Surrey Heath also)
1.0	06.07.2020	Andrea Golding/ Georgina Randall	DRAFT	Final approval at Quality and Performance Board
1.0	08.07.2020	Quality and Performance Board	FINAL	Approved by Quality & Performance Board

Equality statement

Surrey Heartlands Clinical Commissioning Group (CCG) is committed to promoting equality and diversity in all its activities and to promote inclusive processes, practices and culture.

- We will strive to work to eliminate any unlawful or unfair discrimination including direct or indirect discrimination, discrimination by association, discrimination linked to a perceived characteristic, harassment and victimisation.
- We will remain proactive in taking steps to ensure inclusion and engagement for all the people who work for and with us.
- We will continue to strive towards a culture that is diverse and inclusive that recognises and develops the potential of all staff and service users.
- We recognise the business benefits and opportunities of having a diverse community of staff who value one another and realising the contribution they can make to achieving the CCG's vision.

This includes promoting equality and diversity for all irrespective of:

- age*
- disability*
- ethnic group*
- gender*
- gender reassignment*
- religion or belief*
- sexual orientation*
- marriage and civil partnership*
- pregnancy and maternity*
- carers
- people with diverse communication needs

*Under the Equality Act (2010) these are known as "protected characteristics".

The CCG aims to meet the diverse needs of our service, population and workforce, ensuring that none are placed at a disadvantage over others. We take into account the Human Rights Act 1998 and promote equal opportunities for all. We embrace the seven staff pledges in the NHS Constitution that represent a commitment by the NHS to provide high-quality working environments for staff. This policy is consistent with these pledges.

This document has been assessed to ensure that no employee or member of the public receives less favourable treatment based on their protected characteristics.

Members of staff, volunteers or members of the public are invited to request assistance with this policy if they have particular needs. If the member of staff has language difficulties and difficulty in understanding this policy, the use of an interpreter will be considered.

Equality analysis

Equality analysis is a way of considering the effect on different groups protected from discrimination by the Equality Act, such as people of different ages. There are two reasons for this:

- to consider if there are any unintended consequences for some groups
- to consider if the policy will be fully effective for all target groups

Title of Policy: Clinical Commissioning Policy: Individual Funding Requests and associated appendices (including Standard Operating Procedure)	**Policy Ref:** CLIN01
Assessment conducted by (name, role): Clare Johns (Lead Commissioning Pharmacy Technician – Pharmaceutical Commissioning- Surrey Heartlands CCG) Maria Bruce (Continuing Healthcare (CHC) programme manager- Surrey Heartlands CCG)	**Date of analysis:** 28th May 2020
Give a brief summary of the policy. Explain its aim. To provide users of the policy with a framework for decision making. To ensure that all decisions made, by the CCG, regarding funding for treatments are made in a fair, open and consistent manner	
Who is intended to <u>benefit from</u> this policy? *Explain the aim of the policy as applied to this group.* All users of the policy will benefit because they will have a framework to work from and all individual patients and their clinicians can be assured that the CCG has a robust policy & process in place in relation to individual funding requests.	
1. Evidence considered: *What data or other information have you used to evaluate if this policy is likely to have a positive or an adverse impact upon protected groups when implemented?* The IFR policy and the associated standard operating procedure (SOP) were considered in providing this EQIA	
2. Consultation: *Give details of all consultation and engagement activities used to inform the analysis of impact.* Request for clarification on the policy and SOP were required during the EQIA process with the IFR (ECI) team and the pharmaceutical commissioning team.	

3. **Analysis of impact:** *In the boxes below, identify any issues in the policy where equality characteristics require consideration for either those abiding by the policy or those the policy is aimed to benefit, based upon your research.* *Are there any likely impacts for this group? Will this group be impacted differently by this policy? Are these impacts negative or positive? What actions will be taken to mitigate identified impacts?*	
a) **Age** Ageism is prejudice or discrimination on the grounds of a person's age. Ageism can affect anybody, regardless of their age	Neutral impact The patient's age is available to the IFR team but all information is anonymised prior to the decision making process (IFR panel)
b) **Disability** A person has a disability (by law) if they have a physical or mental impairment which has a substantial and long-term adverse effect on that person's ability to carry out normal day-to-day activities.	Neutral impact Patients will be asked for consent for personal & clinical information to be shared with appropriate teams at the CCG. Where a patient is not able to give informed consent, a carer or patient representative will give that consent on behalf of the patient.
c) **Gender reassignment** Gender reassignment is a personal, social, and sometimes medical process by which a person's gender appears to others to have changed. Anyone who proposes to, starts or has completed a process to change his, her or their gender is protected from discrimination under the Equality Act. A person does not need to be undergoing medical supervision to be protected.	Neutral impact
d) **Marriage or civil partnership** This is the relationship between two people who are husband and wife, or a similar relationship between people of the same sex (as defined by Marriage (Same Sex Couples) Act 2013). Civil partners must be treated the same as married couples on a wide range of legal matters.	Neutral impact

e) **Pregnancy and maternity (adoption is covered within this)** Pregnancy - being pregnant or expecting a baby. Maternity is the period after the birth or adoption and is linked to maternity and adoption leave in the employment context.	Neutral impact
f) **Race** Race characteristics refers to a group of people defined by their race, colour and nationality (including citizenship) ethnic or national origins.	Neutral impact
g) **Religion and belief** Religion refers to any religion while belief comprises religious and philosophical beliefs including lack of belief. Generally, a belief should affect your life choices or the way you live for it to be included in the definition.	Neutral impact
h) **Sex** This is defined as a person's legal sex; in the UK this is recognised as either being a man or a woman. Sex is more commonly referred to as gender identity, which is the internal sense of being male, female, a combination of male and female, or neither male or female.	Neutral impact The patient's gender is available to the IFR team but all information is anonymised prior to the decision making process (IFR panel)
i) **Sexual orientation** Refers to a persons' orientation or attraction towards; the same sex, opposite sex or to both sexes.	Neutral impact
j) **Carers** A carer is anyone, including children and adults who looks after a family member, partner or friend who needs help because of their illness, frailty, disability, a mental health problem or an addiction and cannot cope without their support. The care they give is unpaid.	Neutral impact Patients will be asked for consent for personal & clinical information to be shared with appropriate teams at the CCG. Where a patient is not able to give informed consent, a carer or patient representative will give that consent on behalf of the patient.

4. Monitoring: *How will you review/monitor the impact and effectiveness of your actions?*

An equality impact assessment will be completed each time there is a review of the IFR policy.

Contents

1. Introduction

1.1 This publication is an update of the existing published policy on the management of individual funding requests (IFRs) and outlines the conditions and criteria, which are used for decision making. The processes for progression and consideration of IFR applications are outlined in the Standard Operating Procedures document.

1.2 The main objective of the Individual Funding Request policy is to ensure that Surrey Heartlands Clinical Commissioning Group (the CCG) resources are used appropriately and fairly, and that applications for funding are assessed using a fair and transparent process.

1.3 A primary responsibility of the CCG is to make decisions about which treatments and services should be funded for their designated population. This includes applying robust criteria to the question of how services and treatments should be funded.

1.4 When a new service or a change to a service is proposed, it would not be fair for that to bypass the prioritisation process and be funded without comparing it to other possibilities for investment. Because of this, the CCG's default position is that a new service will not be routinely commissioned until it has been assessed through the full service development process.

1.5 Commissioners are subject to a statutory duty not to exceed their annual financial allocation. Where a clinician identifies a treatment outside the available contracts, the subsequent request for additional funding can represent a challenge to providing the best care for the individual patient and the population as a whole. Any additional calls on resources to fund an individual's treatment are, therefore, likely to mean reducing the funding that is available elsewhere. The decision to fund a treatment that is not usually provided is only taken after very careful consideration and is regarded as an equity issue where the CCG will consider whether it can justify funding a particular patient when others from the same patient group are not being funded for the requested treatment.

1.6 On an individual basis, there may be situations where a clinician believes that their patient's clinical situation is so different to other patients with the same condition that they should have their treatment paid for when other patients would not. In such cases, NHS clinicians can ask the CCG, on behalf of a patient, to fund a treatment that would not usually be provided by the CCG for that patient. This request is called an Individual Funding Request (IFR). However, this route should only be used in exceptional circumstances and not as an alternative route to submitting a treatment through the service development process.

1.7 Funding for additional treatments outside the development process can only be done by reducing the funding that is available for other established treatments.

There is not an allocated separate budget to meet the costs of providing treatments agreed through the IFR process. It is because of this that very careful consideration is required before the decision is taken to fund a treatment for an individual that is not usually available.

2. Legislative Framework

2.1 The IFR Policy and those using the IFR policy are directed to take into account those duties and legal obligations as outlined in the following legislation:

- NHS Act 2006
- Equality Act 2010
- Health and Social Care Act 2012
- The NHS Constitution 2015

3. Scope

3.1 This policy provides guidance on the CCG's decision to fund treatments for individual patients that are not included in existing CCG contracts with NHS providers.

3.2 The policy applies to patients registered within a GP practice within Surrey Heartlands CCG.

3.3 IFRs must only be submitted, for the treatment of an NHS patient, by a clinical practitioner who will be directly responsible for administering the treatment ("the requesting clinician"). Patients may not submit applications directly. Providers must have a NHS Provider contract to provide the service requested.

3.4 IFRs can be made if:

- there is a CCG clinical commissioning policy and/or NICE Technology Appraisal (TA) 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 condition when compared to the typical patient population with the same condition; or
- The treatment is not normally funded and the CCG does not have a clinical commissioning policy for the requested treatment for patients suffering from the same medical condition as the patient for which the treatment is being request, i.e. a policy does not yet exist, and the clinician considers the patient meets the criteria in the IFR policy.

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

3.6 There is evidence that the patient presents with exceptional clinical circumstances[1], that is:

a. There is a CCG clinical commissioning policy and/or NICE Technology Appraisal (TA) 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 condition when compared to the typical patient population with the same condition and (if relevant) at the same stage of progression, and because of that difference their patient is likely to receive material additional clinical benefit from treatment that would not be plausible for any typical patient.

OR

b. There is not a relevant CCG clinical commissioning policy and/or NICE Technology Appraisal (TA) 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.

3.7 IFRs can be made for all the CCGs 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. So that the CCG can be fair to all patients, decisions on whether or not to fund this new development will be taken in line with the CCGs ethical framework.[2] In these circumstances, the request will not proceed through the IFR process.

4. Exceptions

There are a number of exceptions as shown below; these are outside of the scope of the IFR policy:

4.1 NHSE Commissioned Services

4.1.1 In April 2013, the NHS England (NHSE) Single Operating Model for directly commissioned services was implemented. NHSE is responsible for the consideration of IFRs for NHSE Prescribed Services. Prescribed Services are defined in the Manual of Prescribed Services and the associated Identification Rules and include Specialised Services Available from: https://www.england.nhs.uk/commissioning/spec-services/key-docs/

4.1.2 These are the responsibility of NHSE and therefore the CCG will not accept any IFRs for these services or drugs associated with them.

4.2 Requests for Clinical Equipment

4.2.1 Funding requests for clinical equipment does not fall under the remit of the Effective Commissioning Initiative / Medicines Management Team, and will be forwarded onto the Surrey Community Equipment Service.

4.3 Patients changing responsible commissioner

4.3.1 Where the commissioner has assumed responsibility for exercising the Secretary of State's functions under the NHS Act 2006 in respect of a patient where (a) the patient has been previously provided with one or more particular treatments by another NHS commissioning body and wishes the CCGs to continue to commission those treatments for the patient, and (b) a patient in the same clinical circumstances would not routinely have been provided with those particular treatments by the commissioner, the policy of the commissioner is that it will operate a presumption in favour of continuing to provide the particular treatments to the individual patient.

4.3.2 The commissioner reserves the right not to continue funding for all or any of the treatments if, in the individual circumstances of the case, the commissioner has a good reason for refusing to commission a particular treatment for the patient. A good reason could include where the commissioner considers that:

- The particular treatment is likely not to be clinically effective; or
- The particular treatment is likely not to be cost effective for the patient; or
- The commissioner had a concern a patient had arranged or may have arranged to change their responsible commissioner wholly or partly in order to obtain the requested treatment; or

- Where the continuation of the funding for this particular treatment may create a level of inequity with other local patients so that the commissioner considers that the particular treatment should not be funded.

4.3.3 The commissioner 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, are equitable and appropriate.

4.3.4 The patient's future healthcare needs, including consideration of whether to provide the patient with any further courses of treatment of the type previously provided will be determined through the commissioner's usual local decision making mechanisms (this may include an IFR continuation request).

5. Further explanation of the IFR criteria

5.1 Clinical Exceptionality

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

5.1.2 'Exceptional' in IFR terms means a person to whom the general rule should not apply[3]. This implies that there is likely to be something about their clinical situation which was not considered when formulating the general rule. Very few patients have clinical circumstances which are genuinely exceptional. To justify funding for treatment for a patient which is not available to other patients, and is not part of the established care pathway, the IFR Panel needs to be satisfied that the clinician has demonstrated that this patient's individual clinical circumstances are clearly different to those of other patients, and that because of this difference, the general policies should not be applied. Simply put, the consideration is whether it is fair to fund this patient's treatment when the treatment is not available to others. It should be stressed that an IFR is not a route to "have another look" at the general rule, or to protest that the general rule is ungenerous.

5.1.3 Where a 'not for routine commissioning' clinical commissioning policy is in place in relation to a treatment, the CCG 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.

5.1.4 Clinical exceptionality: failure to respond to standard care

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

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

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

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

5.1.4.5 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.

5.1.4.6 If the usual treatment cannot be given because of a pre-existing co-morbidity which is unrelated to the condition for which the treatment is being sought under the IFR or is not unusual in the relevant patient group or generally, the fact that the co-morbidity is present in this patient and its impact on treatment options for this patient is unlikely to make the patient clinically exceptional. As an illustration, some comorbidities are

common in the general population, for example, diabetes which affects around 7% of adults, or asthma which affects at least 10% of the population. Diabetes and its treatments affect many other conditions; for example, steroids make glucose control more difficult. With any condition there will be a recognised proportion who also have a comorbidity which is common in the general population, and thus a patient cannot be exceptional by virtue of also having a comorbidity which is common in the general population.

5.1.4.7 If the proposed intervention is thought to offer a benefit to patients in these groups generally (i.e. those with more severe disease or those with common co-morbidities), the question is whether there is sufficient justification, including consideration of factors such as clinical effectiveness of the treatment in question, likely value for money, priority and affordability, for making a change to the clinical commissioning policy that covers the patient pathway. In this way, an improvement can be made to that policy to benefit the whole subgroup of patients of which the requesting patient is potentially just one such person. This change needs to be considered as a service development and not as an IFR.

5.1.5 Clinical exceptionality: severity

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

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

5.1.6 Clinical exceptionality: multiple grounds

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

5.1.6.2 If it is determined that none of the individual factors on their own mean that the patient's clinical circumstances are considered exceptional, the combined effect of those factors as a whole will be considered. In this way a decision can be reached on whether the patient's clinical circumstances are exceptional, bearing in mind the difference between the range of factors that can always be found between individuals and the definitions used here of exceptional clinical circumstances.

5.1.7 Clinical Exceptionality: non clinical and social factors

5.1.7.1 The IFR process only considers clinical information. Although initially it may seem reasonable to fund treatment based on reasons grounded in a moral or compassionate view of the case or because of the individual's situation, background, ambition in life, occupation or family circumstances, these reasons bring into play a judgement of 'worthiness" for treatment. As a central principle, the NHS does not make judgements about the worth of different individuals and seeks to treat everyone fairly and equitably. Consideration of these non-clinical factors would introduce this concept of 'worth' into clinical decision making. It is a core value that NHS care is available - or unavailable - equally to all. Whilst everyone's individual circumstances are, by definition, unique and on compassionate grounds, reasons can always be advanced to support a case for funding, it is likely that the same or similar arguments could be made for all or many of the patients who cannot routinely access the care requested.

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

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

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

5.2 Clinical Effectiveness

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

5.2.2 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 responsibility of the referring clinician to provide suitable and relevant information. Inevitably, the evidence base put forward in support of an IFR is unlikely to be as robust as in more common presentations of the condition or the more usual use of the treatment. However it is important that the referring clinician makes explicit linkages between the grounds under which exceptionality is claimed and the sections of the submitted research literature that are considered to support the clinician's view regarding the differences between the patient's clinical position and that of other patients in the group, and regarding the patient's anticipated response to the requested treatment.

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

- How closely the patient matches the patient population from whom the results are derived in any study relied on by the clinician
- The plausibility of the argument that the patient will achieve the anticipated outcomes from treatment, based on the evidence supplied
- The impact of existing co-morbidities on both the claim for exceptionality and treatment outcome
- Any complications and adverse events of the treatment including toxicity and rates of relapse. The Panel will take account of side effects when considering the benefits from the treatment
- The likely impact of the treatment on quality of life using information as available

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

5.3 A Good use of NHS Resources

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

5.3.2 This criterion is only applied where the Panel has already concluded that the criteria of clinical exceptionality and clinical effectiveness have been met. Against this criterion the Panel balances the degree of benefit likely to be obtained for the patient from funding the treatment against cost. Having regard to the evidence submitted and the analysis they have carried out when considering clinical exceptionality and clinical effectiveness, Panel members will consider the nature and extent of the benefit the patient is likely to gain from the treatment, the certainty or otherwise of the anticipated outcome from the treatment and the opportunity costs for funding the treatment. This means considering, for example, how significant a benefit is likely to be gained for the patient, and for how long that benefit will last.

5.3.3 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.

5.3.4 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.

5.3.5 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.

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

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

5.4 Experimental and Unproven Treatments

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

5.4.2 Where the case for clinical exceptionality has been accepted but the treatment is experimental or unproven, there is a particular need to scrutinise the likelihood that the treatment will be clinically effective and consider carefully whether funding the treatment would be a good use of NHS resources. This is because it is important that decisions on clinical practice and policy are based on sound clinical evidence. To ensure the effective and equitable use of NHS funding, experimental treatments have to be undertaken judiciously, responsibly and for clearly defined purposes.

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

5.4.4 What is an experimental treatment?

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

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

5.4.5 How are IFRs for experimental treatments considered?

5.4.5.1 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.

5.4.5.2 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.

5.4.5.3 As preliminary requirements before agreeing to fund an experimental treatment, The CCG will need reassurance:

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

5.4.5.4 The Panel will not fund treatment in response to an IFR if it considers that it would be more appropriate for the treatment to be the subject of research trials. Primary research into novel treatments should be progressed through the usual research funding routes and will not be funded through this IFR policy.

5.4.5.5 The CCG will consider a funding request for an experimental treatment where there is either:

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

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

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

5.4.5.7 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.

5.4.5.8 The options for consideration by the CCG in these instances are:

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

5.4.5.9 In all cases, contribution to any relevant clinical database or population registry which is operating.

5.5 Funding for cases following a Clinical Trial

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

6. Information submitted to the IFR Team

6.1 The requesting clinician is required to confirm that s/he has discussed the proposed treatment with the patient (or has offered such a discussion) before the application is made for funding on his/her behalf.

6.2 The requesting clinician is required to confirm that s/he has made the patient aware of the implications of embarking on the IFR process, the fact that it may take some time before a decision can be made.

6.3 The requesting clinician should complete the consent section of the form to confirm that the patient is aware of the application and has agreed to their personal clinical information being shared within appropriate teams of the CCG.

6.4 If the requesting clinician considers that the patient does not have capacity to give informed consent this should be indicated and explained in the IFR application.

6.5 In these circumstances the submission should also confirm whether consent has been obtained instead from a patient representative.

6.6 It is the responsibility of the requesting clinician to ensure that the patient's clinical circumstances are adequately described in the application.

6.7 IFR applications should be supported by published electronic copies of the clinical research evidence papers or other supporting documents (e.g. Trust Guidance or supporting clinical letters). Evidence should directly support the use of the requested treatment for the condition in cases such as the patient in question, and the requesting clinician must provide a list of the published papers that have been submitted and indicate which points within them are relevant in respect to the IFR application and criteria and should highlight links between the evidence submitted and the particular patient circumstances. Evidence should be submitted as pdf or word documents. The IFR team are unable to accept abstracts or web links. This is to ensure the IFR screening group and IFR Panel are clear about the points the clinician is making and the relevance to the case.

6.8 If relevant information is not submitted, decision making will be delayed because the case cannot be fairly considered without adequate evidence. In all instances the referring clinician must state whether or not they consider there are likely to be similar patients in the same situation (in accordance with the definition set out in this policy) and, if so, how many such similar patients there are or are likely to be in the opinion of the referring clinician in the Surrey Heartlands CCG (approximately 1.2 million population) in any given 12 month period.

6.9 It is the responsibility of the requesting clinician to ensure that all clinical information required in support of an application is provided, including the rationale for clinical exceptionality.

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

6.11 All sections of the IFR form must be completed in full for the request to progress. Any request form which is incomplete will be returned to the requesting clinician for completion and the application will not progress until such time as it is completed and resubmitted.

6.12 The CCG expect providers with which it contracts to have oversight of the applications submitted by their clinical staff. The CCG expect every IFR to be sanctioned by the provider's Board-level Medical Director or equivalent and reserves the right to return unconsidered IFRs to the provider and refer recurrent

inappropriate funding requests to the Chief Executive (or equivalent) of the relevant provider.

6.13 Should a decision be made by the provider to start treating a patient due to clinical urgency, and an IFR application is still desired, a completed IFR application must be submitted to the IFR team within two working days of the intervention first taking place. The IFR team will not process applications that fall outside of this timeline.

6.14 If the IFR has been received within this timeline and the IFR Panel subsequently supports the funding of the IFR request, treatment funding will be back dated to the date on which the application was made. Costs will not be reimbursed if the IFR Panel decline the request.

6.15 Ultimately the CCG's IFR decision is whether the CCGs will reimburse a provider for a particular treatment intervention for the individual patient. However, that decision does not itself determine whether a clinician actually undertakes that treatment. The trust is at liberty to resource the treatment.

7. Roles and Responsibilities

7.1 Surrey Clinical Priorities Committee (SCPC) and Surrey & North West Sussex Area Prescribing Committee (APC)

7.1.1 The SCPC and the APC are responsible for the development and review of commissioning policies for procedures and medicines respectively.

7.1.2 The SCPC and the APC apply robust process to decision making across the CCG's population. They have delegated authority from and report to the Surrey Heartland's CCG Executive Board and both of these committees will use an ethical framework to support and underpin the decision making processes to facilitate fairness and transparency in the allocation-setting process and support consistent commissioning policy.

7.1.3 The same ethical framework is applied when making a decision with regards to the funding of an individual patient's treatment via the IFR Policy.

7.2 Effective Commissioning Initiative (ECI) Team

7.2.1 The ECI team will manage the IFR policy and administer the IFR process. They will be supported by the Pharmaceutical Commissioning team with regards to the IFR process for prescribed items, and by Public Health (Surrey County Council) with regards to the IFR process for interventions (non-prescribed items).

7.3 Clinicians submitting request

7.3.1 Clinicians are responsible for ensuring that patient consent is obtained and that application forms are suitably completed and submitted as per this Policy.

7.4 Provider trusts

7.4.1 Provider trusts are responsible for oversight of the applications submitted by their clinical staff.

8. Summary of the IFR process

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

8.2 Screening process for IFR requests

Why are applications subject to screening?

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

8.2.2 The screening process described in this Policy is intended to be fair to all parties, by only sending cases 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.

8.3 Screening for Sufficient Information

8.3.1 Any IFR requests will first be screened by ECI and/or Pharmaceutical Commissioning teams (the IFR team) in accordance with the procedures set out in the CCG IFR SOP to establish whether the request falls within the commissioning responsibility of the CCG, and has sufficient clinical or other necessary information for it to be properly considered. Where the IFR team conclude that there is insufficient information, it will be returned to the referring clinician specifying the additional information required.

8.3.2 The IFR Panel can only approve funding if all of the criteria in the policy are satisfied. It follows that the screening team should not allow an application to go forward to the IFR Panel unless there is information to support the contention that each of the essential criteria is met. A strong application on one part of the criteria

cannot make up for an absence of proper evidence to support another of the tests that the IFR Panel must apply in order to make a decision that funding should be approved.

8.3.3 Screening for service developments

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

8.3.4 Screening for clinical exceptionality

8.3.4.1 IFRs will be considered by an IFR screening group to determine whether the request appears to present an arguable case for clinical exceptionality.

8.3.4.2 The IFR screening group includes clinical members from the IFR panel (as outlined in the IFR SOP) and their understanding of the information required by an IFR Panel enables them to make these decisions. They have delegated authority from the CCG to make these judgements and will seek additional clinical input at their discretion. If the screening group considers that there is not an arguable case for clinical exceptionality, the IFR will not proceed further through the process and will be declined.

8.3.4.3 An IFR will be considered as indicating an "arguable case" for clinical exceptionality if the screening group consider that there is some realistic prospect that the IFR Panel (properly applying the policy) would conclude that the patient is clinically exceptional. A case would be turned down only where the screening group is confident that, based on the available information, if the IFR Panel properly apply this policy, it would come to a conclusion that the patient is not clinically exceptional. If the screening group has any reasonable doubt about whether a case satisfies the criterion of exceptionality, it will be forwarded to the IFR Panel.

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

8.3.4.5 Screening groups can request advice, e.g. relating to a treatment pathway and lines of therapy within that, from within the CCG's clinical advice structure.

8.4 Decisions on funding

8.4.1 The IFR Panel works on behalf of the CCG and makes decisions in respect of funding for individual cases. The Panel has delegated authority from the budget holder to make funding decisions on their behalf, up to a designated financial limit; any applications that are above the agreed threshold are reviewed by the Chief Finance Officer or equivalent.

8.4.2 The IFR Panel will work to the published CCG IFR Policy and each request will be processed by following the CCG IFR SOP, which includes an ethical framework for decision making. This will ensure that all requests are considered in a consistent, fair and transparent way, with decisions based on the available evidence presented by the treating clinicians and the CCG commissioning principles.

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

8.4.4 The patient / patient representative, or their clinical or non-clinical representative, is not entitled to attend the Panel in person. This is to ensure objective decision making by the IFR Panel in a fair and equitable manner to all patients.

8.4.5 The clinician should not assume particular knowledge of the Panel for the condition from which their patient is suffering or the relevant area of medical practice. This is because the Panel will contain a range of individuals with a variety of skills and experiences.

8.4.6 The Panel will not necessarily include a clinician with expertise in the condition for which treatment is being sought. This is appropriate because not only is the question one of demonstrable exceptionality (resting on the differences between this patient and others with the condition) but the Panel must consider whether it is appropriate to divert resources away from other services in order to fund the requested treatment.

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

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

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

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

- The request should be properly classified as a service development. In this case the request will be refused and the ECI or Pharmaceutical Commissioning teams will direct the applicant to the service development procedures; or
- Further information or evidence is required before the IFR Panel can take a decision on whether funding should be given, in which case further information will be requested through the IFR team. This can be sought from the clinician, from within the CCG's clinical advice structure or from other clinical advisers as considered appropriate.

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

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

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

8.4.14 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.

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

9. Review of the decision

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

9.2 All requests for a review must be made within 28 days of the date when the decision is communicated to the patient. The request will 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.

9.3 The request for a review will be initially considered by the IFR screening group. If they consider that, on the basis of the information provided, there is an arguable case for a review of the IFR process or the Panel's decision, a formal IFR Review Panel meeting will be recommended to CCG Clinical Director for Planned Care.

9.4 If the screening group reviewing the case does not accept the grounds put forward for a review, they will report the rationale for their decision to the CCG Clinical Director for Planned Care who will consider and, if in agreement, will ratify the decision. The CCG Clinical Director for Planned Care will then write to the referring clinician and/or the patient/patient representative explaining the reasons for the decision not to review the IFR Panel decision.

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

9.6 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 CCG;
- Was a decision which a reasonable IFR Panel was entitled to reach;
- Understood, took into account and weighed, all the relevant evidence; and
- Did not take into account any irrelevant factors.

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

9.8 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.

9.9 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.

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

10. Urgent decisions for Individual Funding Requests

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

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

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

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

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

11. Policy approval, ratification and review process

11.1 The IFR Policy will be subject to review after three years and at any stage at the request of management, or following a change in legislation or national guidance.

12. Policy publication

12.1 The IFR Policy will be:

- Published on the CCGs website
- Sent to all GP Practices within the CCG
- Made available to all CCG staff
- Shared with all relevant stakeholders
- Included in all appropriate CCG contracts

13. References

- NHS England IFR Policy, November 2017
- High cost drugs service development guideline. Greater Manchester Medicines Management Group (GMMMG) Guidance July 2013

1. To note: In parts of this policy we refer to clinically exceptionality as shorthand for patients being different, as described here.
2. 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
3. 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 development.

14. Appendix 1 – Procedural Document Checklist for Approval

Title of document being reviewed:		Yes/No/ Unsure	Comments/ Details
A	**Is there a sponsoring director?**	Yes	
1.	**Title**		
	Is the title clear and unambiguous?	Yes	
	Is it clear whether the document is a guideline, policy, protocol or standard?	Yes	
2.	**Rationale**		
	Are reasons for development of the document stated?	Yes	
3.	**Development Process**		
	Do you feel a reasonable attempt has been made to ensure relevant expertise has been used?	Yes	NHS England, Landmark Chambers (solicitors)
	Is there evidence of consultation with stakeholders and users?	Yes	Policy circulated to providers for comment
4.	**Content**		
	Is the objective of the document clear?	Yes	
	Is the target group clear and unambiguous?	Yes	
	Are the intended outcomes described?	Yes	
5.	**Evidence Base**		
	Is the type of evidence to support the document identified explicitly?	Yes	
	Are key references cited?	Yes	
6.	**Approval**		
	Does the document identify which committee/group will approve it?	Yes	Quality & Performance Board
7.	**Dissemination and Implementation**		
	Is there an outline/plan to identify how the document will be disseminated and implemented amongst the target group? Please provide details.	Yes	Published on CCG website

Title of document being reviewed:		Yes/No/ Unsure	Comments/ Details
8.	**Process for Monitoring Compliance**		
	Have specific, measurable, achievable, realistic and time-specific standards been detailed to monitor compliance with the document? Complete Compliance & Audit Table.	Yes	
9.	**Review Date**		
	Is the review date identified?	Yes	3 year review
10.	**Overall Responsibility for the Document**		
	Is it clear who will be responsible for implementing and reviewing the documentation i.e. who is the document owner?	Yes	

Approval			
Executive Director Name	Colin Thompson	Signed off on (date)	09.06.2020
Committee Chair Name	Julia Dutchman-Bailey	Signed off on (date)	08.07.2020
On behalf of the	Quality and Performance Board	Approved on (meeting date)	06.07.2020

15. Appendix 2 – Compliance and Audit Table

Criteria	Measurable	Frequency	Reporting to	Action Plan/ Monitoring
This document will form part of the IFR Audit as required	100%	As dictated by auditors	Quality & Performance Board	Audit log
Process amendments	100%	Monitored on an ongoing basis	Quality & Performance Board	Policy version control