NHS
South West London

South West London Integrated Care Board (ICB)

Individual Funding Requests (IFR) Policy:

Policy Number: SWL ICB CL07

	Name	Role & Organisation	Date
Author	Zoli Zambo Gill Schram	SWL ICB Head of EBI Programmes	Various dates to 15/02/2022 Then ICB logo and language updates June 2022
Reviewers	Dr Iain Cruickshank Philippa Blatchford Dr Ash Paul	SWL IFR Chair & Lay Member Lead Pharmacist Commissioning (Croydon) SWL ICB EBI Public Health Consultant	
Authoriser	Caroline Morris	SWL ICB Director of Collaborative Commissioning	June 2022
Approvals	Approved in principle at SMT 7 April 2022 Approved by the SWL Integrated Care Board (ICB) 1 July 2022		
Applies to:	Governing Body Members, Committee Members and all staff and services working for, or on behalf of NHS South West London ICB		
Effective date:	July 2022		
Review date:	June 2024		

Controlled Document

The current version of this document is always available electronically via SharePoint or the intranet. All other electronic or paper versions of this document sourced from any network drive, email or other sources are uncontrolled and should be checked against the current SharePoint or intranet version prior to use.

Target Audience	All staff working for, or on behalf of NHS South-West London ICB, and available to the public via the SWL ICB website
Brief Description	This policy is a guide to the Individual Funding Request (IFR) process for South-West London.

Version control

Version	Date	Author	Status	Comments / changes since last version
0.1	20/02/2021	Zoli Zambo	DRAFT	Policy based on NHSE and Surrey Heartlands IFR policies with amendments by SWL ICB IFR Policy Development Group, and legal advice by Capsticks in Sept-2020
0.2	Feb 2021	Zoli Zambo/ Gill Schram	DRAFT	Amendments made following SWL Policy Development Team review and input
0.3	29/12/2021			
0.4	10/01/2022			
0.5	28/01/2022			
0.6	01/02/2022			
0.7	10/02/2022			
V1.0	15/02/2022	Gill Schram	FINAL	
V2.0	June 2022	Gill Schram	FINAL	ICB language and logo updates

Table of Contents

1. Introduction

1.1 This publication is an update of existing published South-West London (SWL) policy on the management of individual funding requests (IFRs), and outlines the conditions and criteria used in IFR decision-making.

1.2 The main objective of the IFR policy is to ensure that resources within the South-West London Integrated Care Board (ICB) 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 SWL ICB is to make decisions about which treatments and services should be funded for the designated population. This includes applying robust criteria to the question of how the services and treatments should be funded.

1.4 The SWL ICB is subject to a statutory duty not to exceed annual financial allocations. Where a clinician identifies a treatment that falls outside of contracting and procurement arrangements, the subsequent request for this funding can represent a challenge to providing the best care for the individual patient whilst balancing this against the population as a whole (any additional calls on funding resources for an individual are likely to mean reducing the funding that could be made available elsewhere). The decision to fund a treatment which is not usually funded is therefore only taken after very careful consideration and is regarded as an equity issue, where the ICB 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.

2. Principles of an Integrated Care System (ICS)

2.1 In line with planned transition to the Integrated Care System (ICS) in 2022, this policy has been developed to ensure that it works to the core ICS principles, with the ICS playing a critical role in aligning action between partners to achieve their shared purpose: *to improve outcomes and tackle inequalities, to enhance productivity and make best use of resources and to strengthen local communities.*

2.1 The core principles are:

- System leadership, partnerships and change capability: When it comes to contracting and procurement activities, this will be done with strong collaboration of all partners across the system in a proactive and transparent manner.

- System architecture and strong financial management and planning: Ensuring there is value for money and appropriate incentives to support strategy and planning and health objectives across the system.
- Integrated care models: Integration of services and teams will be considered for service models and transformation projects.
- Track record of delivery: Robust contract management and engagement to ensure services are being delivered as needed and are demonstrating positive impact on population health outcomes.
- Coherent and defined population: Developing services that respect patient flows across SWL as a system whilst promoting patient choice and standard availability.

3. Legislative Framework

3.1 The SWL ICB IFR Policy and those accessing it are directed to take into account all duties and legal obligations as outlined in the following legislation:

- The NHS Act, 2006
- Equality Act, 2010
- Health and Social Care Act, 2012
- The NHS Constitution, 2015
- White Paper: Integration and Innovation: working together to improve health and social care for all, February 2021
- The NHS Long Term Plan, January 2019
- The NHS Interim People Plan, June 2019
- The NHS Choice Framework, January 2020

4. Scope

4.1 This policy provides guidance on the way in which the SWL ICB will consider funding for treatment for individual patients for whom it is responsible that is not included in existing ICB contracts.

4.2 The policy applies to patients registered with GP practices across the South-West London ICB region, as well as to others within the region for whom it has a statutory responsibility to fund treatment.

4.3 IFRs must only be submitted for the treatment of an NHS patient, by the “treating clinician” who will be directly responsible for administering the treatment, and who works within a provider Trust with a current NHS contract in place for the intervention or service requested. Patients may not submit applications directly but can supply impact statements alongside the IFR application.

4.4 IFRs can be made if:

- There is an ICB clinical policy and/or NICE Technology Appraisal (TA) in-place, and the patient has clinically exceptional circumstances that can be evidenced,

OR

- There is no ICB clinical policy and or NICE TA and it is not expected that a clinical policy is developed in the next 12 months to determine funding,

OR

- The IFR funding has been previously agreed and requires renewal or re-evaluation.

4.5 The ICB will only provide funding in response to an IFR if it is satisfied that the case is within the above scope, and in addition that it meets the following criteria:

- That 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.

5. Clinical Exceptionality

5.1 This section is pertinent if the application is submitted on the basis that there is a ICB clinical policy and/or NICE Technology Appraisal (TA) funding policy in-place and the patient has clinically exceptional circumstances.

In practice, this means that an intervention is either:

- Not available for the general population at all (i.e., not for routine funding)

OR

- The patient does not meet the criteria set in the policy to access the intervention.

5.2 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 clearly set out the grounds for clinical exceptionality within the IFR request.

5.3 “Exceptional” in IFR terms means a person to whom the general rule should not apply. This implies that there is likely to be something about their clinical situation which was not considered when formulating the general rule[1].

5.4 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 from those of other patients, and that due to 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 "re-review" the general rule, or to protest that the general rule is ungenerous.

5.5 Where a ‘not for routine funding’ ICB clinical policy is in place in relation to a treatment, the ICB will, when defining the policy, have been aware and taken account of the fact 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. 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.

5.6 Where a patient does not meet the criteria set in the applicable ICB policy or NICE TA, but there are relevant exceptional clinical circumstances which were not considered in developing the criteria, the IFR application must show that the patient would be disadvantaged by applying the policy.

5.7 Clinical exceptionality: failure to respond to standard care

5.7.1 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 when formulating the general policy.

5.7.2 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.

5.7.3 Therefore, 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.

5.7.4 For example: If the usual treatment is only effective for a proportion of patients (even if a high proportion), this leaves a proportion of patients within the group for whom it is already known that the usual treatment is not available or is not clinically effective. The fact that a particular patient falls

into that group is unlikely to be sufficient basis for stating the patient's case for exceptionality.

5.7.5 As an example of side effects: 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.

5.7.6 If the usual treatment cannot be given because of a pre-existing comorbidity 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.

5.8 Clinical exceptionality: severity

In the cases where severity is cited by the requesting clinician in making the case for exceptionality the application should make the following clear:

5.8.1 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,

5.8.2 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,

5.8.3 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,

5.8.4 That there is a plausible argument that the severity of the condition is prognostic of good response to treatment.

5.9 Clinical exceptionality: multiple grounds

5.9.1 There may be cases where clinicians seek to rely on multiple factors to demonstrate exceptionality. In such cases, each factor will be subject to individual review to determine (a) whether it has the potential 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. The judgement on this lies within the discretion of the IFR screening group and panel.

5.9.2 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 robustly reached on whether the patient's clinical circumstances are exceptional, bearing in mind the differences between the range of factors that can always be found between individuals, and the definitions of exceptionality described above.

6. Clinical Effectiveness

6.1 Clinical effectiveness is a measure of the extent to which a treatment achieves predefined clinical outcomes in a specific group of patients. Clinical evidence that considers the efficacy of a particular treatment will be carefully considered by the IFR panel.

6.2 Interventions that are not available for the general population at all (i.e., not for routine funding) will require the IFR application to argue comprehensively that the requested intervention is going to be clinically effective for the patient in question. This is particularly pertinent if the ICB has written into policy that this is not an intervention that can funded for the population. In such cases it must be substantiated that the patient in question will benefit more than the average patient.

6.3 If the intervention is funded by the ICB but the patient does not meet the criteria set in the relevant policy to access the intervention, it must be shown that the patient would benefit from the intervention in the same way as those who currently have access to the intervention.

6.4 It is the responsibility of the applicant to provide all suitable and relevant information in support of the request, whilst it is acknowledged that the evidence base put forward in support of an IFR is unlikely to be as robust as either in the more common presentations of the condition, or the more usual use of the treatment.

6.5 However, it is important that the applicant makes explicit linkages between the grounds under which the IFR is being claimed, and the relevant 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.

6.6 The IFR Panel: Consideration of Clinical Effectiveness

When considering clinical effectiveness, the IFR panel will take into account:

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

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

6.6.3 The benefits of the proposed intervention, compared to the standard treatment for the condition,

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

6.6.5 Any complications and adverse events of the treatment including toxicity and rates of relapse. The panel will consider side effects when considering the benefits from the treatment,

6.6.6 The likely impact of the treatment on quality of life, using supporting information as available,

6.6.7 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 it is considered that the proposed treatment will be effective for the whole period for which it will be given.

7. Good Use of NHS Resources

7.1 The requesting clinician will be expected to explain why it is considered that the treatment for which funding has been applied for will be a good use of NHS resources. This criterion is only applied where the IFR panel has already concluded that the IFR application is within its scope to determine, and the clinical effectiveness of the intervention is established.

7.2 Against this criterion, the IFR panel will balance the degree of benefit likely to be obtained for the patient from funding the treatment, against the cost. Using the evidence submitted together with the conducted analysis, the panel will consider the nature and extent of the benefit that 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.

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

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

7.5 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.

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

8. Policy Exceptions

Exceptions to the policy are outlined below within this section. These lie outside of the scope of the SWL ICB IFR Policy and its associated decision-making.

Note however that the IFR panel may provide advice on any specific individual case that is brought to its attention and apply the same principles of decision making.

8.1 NHS England Contracted Services

8.1.1 Some NHS services are directly contracted by NHS England (NHSE). These are defined in the Manual of Prescribed Services and the associated Identification Rules and include Specialised Services. This is available from:

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

8.1.2 The services outlined are the responsibility of NHSE, and the IFR panel will not accept any IFRs for these services or drugs associated with them. Note also that the IFR panel cannot overrule or change decisions made by NHSE as it does not have the authority to procure and contract such services.

8.2 ICB Contracted Services Covered Elsewhere

8.2.1 The following services routinely require specialist panels to determine which packages of care or interventions are provided. IFRs received for these case types will therefore be redirected, to be determined in the appropriate forum:

- Mental health referrals and placements
- Continuing healthcare (CHC) requests
- Personal healthcare budget requests
- Children's placements
- Learning disability requests
- Transport requests
- Equipment requests

9. Experimental and Unproven Treatments

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

9.2 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 must be undertaken judiciously, responsibly and for clearly defined purposes.

9.3 When an individual case has been found to be exceptional, the treatment proposed might, by definition, be considered 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.

9.4 What is an experimental treatment?

9.4.1 A treatment may be considered experimental where any of the following points apply:

- The treatment is still undergoing clinical trials and/or is a drug for which a phase III clinical trial has not yet been undertaken 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
- If it is part of a pilot study

9.5 How are IFRs for experimental treatments considered?

9.5.1 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.

9.5.2 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.

9.5.3 As preliminary requirements before agreeing to fund an experimental treatment, the IFR Panel will need reassurance that:

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

9.5.4 The Panel will not approve funding for 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.

9.5.5 The IFR panel 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.

9.5.6 In assessing whether to approve the funding for treatment in these cases, the IFR panel 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.

9.5.7 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.

9.5.8 The options for consideration by the IFR panel in these instances are:

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

10. Funding for cases following a Clinical Trial

10.1 Except in the most exceptional cases, the IFR Panel 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 service development should be developed, because there will be a cohort 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.

11. Overview of the IFR Process

This section of the policy summarises the key stages in the IFR process, all stages of which apply a standard set of questions relevant to each stage, these questions being pre-determined to ensure fairness and transparency to all parties.

11.1 Stage 0: IFR Application Submission

11.1.1 Only the patient's treating clinician can submit an IFR application using the appropriate SWL ICB IFR application form.

11.1.2 It is the requesting clinician's responsibility to ensure that all the appropriate and required information is provided in a timely fashion, consistent with the urgency of the request. This includes full copies of all the published papers of clinical evidence that has been cited. The clinician must provide a list of the published papers that have been submitted and indicate which points within them are relevant in respect to the IFR application and criteria. This is to ensure that clarity is provided to IFR service about the points the clinician is making and the relevance to the case. If relevant information is not submitted, decision making will be delayed as the case cannot be fairly considered without adequate evidence.

11.2 Stage 1: Administrative Screening

11.2.1 The primary function of administrative screening is to ensure that the application has been completed in full and that the request falls within the scope of the SWL ICB IFR process. This will also ensure that all applications intended for other ICBs, other ICB-contracted services covered elsewhere and requests to NHS England can be promptly re-directed, or, if appropriate to inform the applicant when the requested intervention is routinely available.

11.3 Stage II: Clinical Triage

11.3.1 The function of clinical triage is to review the assessment undertaken by the administrative screening stage and assess the clinical merits of the case. The clinical information in the application will be assessed to ensure that all relevant aspects are covered in sufficient detail for the IFR Panel. A request may be made to the applicant to provide further information regarding the case prior to its discussion at the IFR panel. The request may be rejected at this stage if it is considered that there is not a reasonable prospect that the panel will accept that the criteria under this policy are met in the individual case.

11.4 Stage III: IFR Panel Discussion

11.4.1 Any IFR application that is deemed eligible for IFR panel discussion by clinical triage will be forwarded for discussion at the next available panel meeting. Cases will be presented by a Case Manager and will be assessed against the SWL IFR ethical decision-making framework[2] (attached as Appendix A). As above, cases should only be submitted to IFR panel if there is reasonable prospect that the panel will accept that the criteria under this policy are met in the individual case.

11.5 IFR Panel Decision Making

11.5.1 The IFR panel works on behalf of the ICB in making decisions in respect of funding for individual cases. The panel has delegated authority from the budget holder to make funding decisions on its behalf, up to a designated financial limit, as determined by Finance; any applications that are above the agreed threshold are reviewed by the Chief Finance Officer or equivalent.

11.5.2 The IFR panel will work to the published ICB IFR Policy and ethical framework for decision-making (attached as Appendix A). This will ensure that all requests are considered in a consistent, fair and transparent manner, with decisions based on the available evidence presented by the treating clinicians and the ICB contracting and planning principles.

11.5.3 The applicant is advised to set out as clearly as possible and in detail, the clinical circumstances and the evidence supporting the funding request via IFR, and how it meets the criteria for doing so.

11.5.4 The patient / patient representative, or 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.

11.5.5 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 the patient and others with the condition) but the panel must consider whether it is appropriate to divert resources from other services to fund the requested treatment.

11.5.6 The IFR panel will make the decision based on the criteria within this policy, with reference to any other ICB-published clinical policies or NICE mandated guidance relevant to the application or interpretation of the criteria.

11.5.7 In reaching the 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.

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

11.5.9 It is also within the jurisdiction of the IFR panel to conclude:

11.5.9.1 That the request should be properly classified as a Service Development. In this case the request will be refused and the Evidence Based Interventions

or Pharmaceutical planning teams will direct the applicant to the Service Development Procedures; or

11.5.9.2 Further information or evidence is required before a decision can be made by the IFR panel.

11.5.10 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 may be difficult to separate emotion from the decision, and decision makers as a result may be more likely to decide in favour of the individual, even when this is at the expense of others who cannot be identified as clearly.

11.5.11 The IFR panel will also take care to avoid "rule of rescue". This is the imperative that 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 or condition. Where the IFR panel considers that the application of the "rule of rescue" would form the basis for treatment, funding will be declined.

11.5.12 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.

11.5.13 The IFR panel is entitled, but not obliged to request 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.

11.5.14 The IFR panel will give written reasons for its decisions to approve or not to approve the funding for a treatment in accordance with this policy.

12. Review of the IFR Panel Decision: Appeals

12.1 Both the requesting clinician and the patient are entitled to enquire about the process that resulted in the IFR decision by submitting a written request within 28 days of the decision communicated to them by the SWL ICB IFR service.

12.2 Any appeal requests must be supported by the referring clinician and explain the reason(s) for considering that the decision taken by the IFR panel was either procedurally improper, AND/OR that the medical evidence was misunderstood.

12.3 All such requests will be first screened by Clinical Triage to check if there is any new information provided that was not made available by the requesting clinician at the time of the IFR panel decision.

12.4 If there is new information contained in the appeal request the case will be forwarded to the next available IFR panel with the agreement of the requesting clinician.

12.5 In all other cases the Senior Responsible Officer (SRO) will be informed of the appeal raised, together with the summary detail of the case and an assessment of the grounds for the appeal, using the standard assessment for appeals. Based on this the SRO will make the recommendation to either:

- Request a formal review via the IFR Appeal Panel,

OR

- Ratify the IFR decision.

12.6 In all cases the SRO will inform the requesting clinician and the patient of the next steps or of the outcome and explain the rationale for the decision.

12.7 Cases processed via the IFR Appeals Panel will determine whether the IFR panel has:

- Followed the procedures as written in the SWL ICB The Management of Individual Funding Requests Standard Operating Procedure (SOP),
- Properly understood and considered the evidence presented to it and has come to a reasonable decision based on the evidence.

12.8 Based on this the Appeals Panel will recommend to either:

- Uphold the original IFR decision - as there was no reasonable prospect of reaching a different outcome,

OR

- Request the IFR panel to re-consider the case, by highlighting errors in the IFR decision making.

12.9 In all cases the SRO will inform the requesting clinician and the patient about the next steps or the outcome and explain the rationale for the decision.

12.10 The full details of the appeals process are covered in the SWL ICB The Management of Individual Funding Requests Standard Operating Procedure (SOP).

13. Making the Case for IFR Funding

13.1 The requesting clinician is responsible for ensuring that a strong, arguable case is presented to the IFR panel on behalf of the patient. It is not appropriate to use the IFR process for service developments outside the established contracting and planning processes. Such requests are not suitable to be processed and will be redirected.

13.2 Only requests that meet the scope set out in Section 4 of the policy will be assessed by the IFR service and in line with the SWL ICB The Management of Individual Funding Requests Standard Operating Procedure (SOP). Applicants are encouraged to ensure they are aware of the process and anticipate the questions that will require a response, by reviewing the relevant documentation.

13.3 There are three main points on which the applicant is required to provide a substantiated response:

13.3.1 Question 1: Why is the application needed in the first place?

Here it needs to be considered what the standard treatment is and why this is not suitable or appropriate, explaining why this treatment is being proposed. Explaining the relevant medical history of the patient is critical to enable the IFR panel to appreciate the extenuating clinical circumstances. Requests with reliance on the psychological impacts must be supported by specialist psychological assessment and evidence that these issues cannot be resolved without the proposed intervention.

Please note that social factors are excluded from the assessment and only clinical arguments taken forward.

13.3.2 Question 2: What is the evidence that this intervention is clinically effective?

The application must comprehensively argue that the requested intervention will be clinically effective for the patient in question. Arguing this point will require as strong as evidence as possible, but the IFR panel appreciates that in some instances the evidence of clinical effectiveness is based on expert opinion rather than on randomised control trials or systematic reviews.

Please note that members of the IFR panel may undertake evidence reviews to ensure that the evidence presented is balanced and that it considers the short- and long-term effectiveness of the intervention, particularly for the patient in question.

13.3.3 Question 3: Why is the proposed intervention a good use of NHS resource?

Clinical effectiveness or a recommendation by NICE itself are no guarantee that the ICB can fund and afford the treatment. The application must cover the full costs of treatment provision and demonstrate the anticipated benefits and the duration and certainty of those. If applicable, offset costs (preventing costs occurring now or in the future) may also be considered but with the understanding that these cannot be guaranteed. As with evidence for clinical effectiveness the stronger the evidence the higher certainty the IFR panel can place on such arguments whenever these are available. Please see the SWL ICB The Management of Individual Funding Requests Standard Operating Procedure (SOP) for further details on the above.

14. Policy publication

14.1 This IFR Policy will be:

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

15. References

- NHS England IFR Policy, November 2017
- High-cost drugs service development guideline. Greater Manchester Medicines Management Group (GMMMG) Guidance July 2013
- To note: In parts of this policy, we refer to clinically exceptionality as shorthand for patients being different, as described here.
- [1]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 contracted ahead of policy
- [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

Appendix A: The SWL ICB Ethical Decision-Making Framework

1.0 Purpose

The purpose of the SWL ICB IFR Ethical Decision-Making Framework ("EDMF") is to support consistent and fair decision-making applied by NHS South-West London Integrated Care Board (SWL ICB), in relation to Individual Funding Request (IFR) applications.

2.0 Introduction

The SWL ICB has a number of statutory duties. At times, these duties may be in conflict with others. For example, the ICB has a duty to provide reasonable healthcare services to the SWL population but must also not exceed annual financial allocated budgets.

ICBs as public bodies are accountable for the decisions made and must demonstrate that the decisions are based on sound principles and after careful consideration of all relevant factors, with reference to local conditions, and with a conscious intent to avoid discrimination. Decisions and actions taken must withstand scrutiny with regard to the following:

- Meeting statutory duties
- Legality
- Reasonableness
- Proportionality
- Procedural propriety
- Legitimate expectations
- Equality and non-discrimination

3.0 Scope

The SWL ICB IFR panel is a quasi-legal entity, making funding decisions on behalf of the SWL ICB for individual patient cases only. As such, the scope of this EDMF covers IFR funding decisions taken by SWL ICB in relation to applications submitted to the SWL IFR Service. It is expected that such applications will be specific to individuals, but it is noted that in some circumstances these decisions may be applicable to small cohorts of patients where developing a policy is impractical.

4.0 Principles of Ethical Decision Making

"Ethical Decision-Making Framework" refers to the process of evaluating and choosing among alternatives in a manner consistent with ethical principles. In

making ethical decisions, it is necessary to recognize and eliminate unethical options and select the best ethical alternative.

The SWL ICB has four principles for ethical decision-making relevant to IFR decisions. These are:

- Rationality
- Inclusivity
- Good use of NHS resources
- Clarity and transparency

4.1 Rationality

The SWL ICB has a responsibility to make rational decisions and to act fairly in balancing competing claims on resources between different patient groups and individuals. The ICB is committed to lawful, evidence-based healthcare. Decisions are to be made on the basis of legality, and a reasonable evaluation of the available clinical evidence.

Rational decisions will use reason and logic to assess likely outcomes, the wider context in which treatments can be provided locally, the implications for service delivery, for clinical pathways, and the scale and nature of clinical benefits, costs and risks.

4.2 Inclusivity

The SWL ICB considers every individual within its population to be of equal value. It will procure and provide healthcare services based solely on clinical need, within the resources available. It will not discriminate unlawfully between individuals or groups on the basis of age, gender, gender identity, sexual orientation, race, religion, lifestyle, occupation, social position, financial status, family status (including responsibility for dependents), intelligence, disability, or physical or cognitive functioning. However, where treatments have a differential impact resulting from age, sex or other patient characteristics, it is legitimate to take such factors into account.

The SWL ICB has a responsibility to address health inequalities across its population. It acknowledges the proven links between social inequalities and those in health, access to healthcare and health needs. Higher priority may therefore be allocated to interventions addressing health needs in sub-groups of our population who currently have poorer than average health experience (e.g., higher rates of morbidity or poorer rates of access to healthcare).

4.3 Good use of NHS Resources

The SWL ICB is duty-bound to remain within allocated budget and the cost of treatment must be considered as a result. This is important because investing in one area of health care will inevitably divert resources from other areas. This is known as the “opportunity cost” and is defined as benefit foregone, or value of opportunities lost, that would accrue by investing the same resources in the best alternative way.

The SWL ICB must ensure that the decision taken demonstrates both value for money and appropriate use of NHS funding, based on the needs of the individual patient and the wider population. This means applying careful consideration and balance between benefit, harm and costs in the short-medium- and longer-terms.

4.4 Clarity and transparency

The SWL ICB will specify and consistently apply the relevant policies and processes to ensure that decision-making is fair and transparent. The information provided and the processes followed by the decisions-makers will be clearly documented.

4.5 Considerations

The SWL ICB IFR panel will adhere to the above principles which are embedded in its decision-making and, as such reflected in the SWL ICB IFR policy and the SWL ICB The Management of Individual Funding Requests Standard Operating Procedure (SOP). The consistent application of all will ensure that the decision-making of the SWL ICB IFR Service is compliant with the four principles set out herein.

Appendix B: Summary of IFR judicial cases and judgements

This section references a number of judicial cases and judgements of relevance to the NHS IFR process:

1. R versus Cambridge Health Authority [1995]
R v Cambridge Health Authority | [1995] EWCA Civ 49 | England and Wales Court of Appeal (Civil Division) | Judgment | Law | CaseMine

2. Condliff, R (On the Application Of) versus North Staffordshire Primary Care Trust [2011]
Condliff, R (On the Application Of) v North Staffordshire Primary Care Trust | [2011] EWHC B8 (Admin) | England and Wales High Court (Administrative Court) | Judgment | Law | CaseMine

3. Rose R (on the application of) versus Thanet Clinical Commissioning Group [2014]
https://www.casemine.com/judgement/uk/5a8ff7ce60d03e7f57eb23ca

4a. National Aids Trust (Claimant) versus National Health Service Commissioning Board (NHS England) and The Secretary of State for Health and The Local Government Association [2016]

National Aids Trust v NHS Commissioning Board (judiciary.uk) (High Court judgment)

4b. The Queen on the Application of the National AIDS Trust (First Respondent) and The National Health Service Commissioning Board (NHS England) [Appellant], The Local Government Association [Second Respondent] and The Secretary of State for Health [2016)

http://www.bailii.org/ew/cases/EWCA/Civ/2016/1100.html [Court of Appeal judgment]]

5. R (on the application of SB) versus NHS England [2017]
https://www.bailii.org/ew/cases/EWHC/Admin/2017/2000.html

Appendix C: Definition of Service Developments

Any addition to an existing high-cost drug pathway (or device pathway) will be construed as a service development and must be subject to service development and priority setting rules.

A service development is any aspect of healthcare which the ICB has not historically agreed to fund, and which will require additional and predicable recurrent funding.

The term refers to all decisions which have the consequence of committing the ICB to new expenditure for a cohort of patients, including:

- New services
- New treatments including medicines, surgical procedures, and medical devices
- Developments to existing treatments including medicines, surgical procedures, and medical devices
- New diagnostic tests and investigations
- Quality improvements
- Requests to alter existing policy, such as adding an indication for treatment, expanding access to a different patient sub-group or lowering the threshold for treatment
- Support for establishing new models of care
- Requests to fund a number of patients to enter a clinical trial
- Funding a clinical trial

It is not unusual for clinicians to request funding approval via the IFR process for a patient who represents the first of a group of patients wanting a particular treatment. Any IFR application that is representative of such a group represents a service development, and as such it is difficult to envisage circumstances in which the patient can properly be classified to have exceptional circumstances. Therefore, the IFR route is not the appropriate route to seek funding approval for such patients, and therefore the request should not and will not be presented to the IFR Panel for a decision on funding approval unless a clear and compelling case is made to suggest that the individual is genuinely different from the identified cohort.

Appendix D: IFR Equality Impact Assessment

Stage 1: Initial Screening The aim of the screening is to identify any negative impact that will need mitigation put in place to reduce the impact			
5	**What evidence is available to suggest that the proposed service / policy / function could have an impact on people from the protected characteristics?** **Document reasons, e.g. research, results of consultation, monitoring data and assess relevance as: *Not relevant or Relevant Low / Medium / High***		
	Protected Characteristic	**Relevance**	**Evidence**
	Introduction to this section: The purpose and intent of the SWL ICB Individual Funding Request (IFR) policy is to provide guidance on the way in which the ICB will consider funding for treatment for individual patients for whom it is responsible but which treatment is not included in existing ICB contracts. **As such it is in place to act as a mechanism for addressing some of the inequality that may be introduced by blanket funding decision-making, so by definition it focuses on ensuring equality on the protected characteristics, whilst working to maintain a balance to ensure that resources within the South-West London ICB are used appropriately and fairly, and that applications for funding are assessed using a fair and transparent process.** IFR decision-making is based on every person's individual circumstance and socio-economic background cannot be taken into account. The IFR policy and process, by design has a significant impact on improving access to treatment to some patients within the protected characteristics groups, as follows:		
a	Race	Medium	Example: Application for treatment of rare disease not seen across every race
b	Religion / Spirituality	Medium	Example: e.g., the seeking of alternative treatments for Jehovah's Witnesses who don't allow the use of blood products
c	Sex	Not relevant	Not relevant as not visible within the triage and panel decision-making process
d	Disability	Medium	Disability (both physical and mental) – examples are: funding for speech generating devices, and the current development of an open and upright MRI Policy as an alternative to standard bore MRI
e	Sexual Orientation	Not relevant	Not relevant as not visible within the triage and panel decision-making process

f	Age	Not relevant	Not relevant as not visible within the triage and panel decision-making process/all age groups fall within scope
g	Pregnancy/maternity	Medium	SWL ICB ACT/Fertility Preservation Policy which covers heterosexual, same-sex and single women, with evidence-based age factors reflected within the Policy https://swlondonccg.nhs.uk/wp-content/uploads/2020/05/SWLCCG-ACT-and-Fertility-Preservation-Policy.pdf
h	Gender Reassignment	Not relevant	Not relevant, the responsibility for this sits with NHSE
j	Marriage and Civil Partnership	Not relevant	Not relevant as this is not visible to the IFR triage and decision-making process
j	Carers	Not relevant	Not relevant
If you assess all the above factors as **not relevant**, please proceed to section 12. If you assess any of the above factors as **relevant**, continue to Stage 2, Full Equality Impact Assessment.			

Stage 2: Full Equality Impact Assessment	
6	**What engagement and / or consultation has been undertaken? For example with service users or staff.**
• Seminar/workshop held in 2020 with the St. George's breast surgeons in regards to the treatments for older teens • Capsticks legal review of the IFR Policy, in light of the 2016 High Court ruling on "exceptionality" National Aids Trust v NHS Commissioning Board (judiciary.uk) And subsequent loss of NHS appeal in the same year: http://www.bailii.org/ew/cases/EWCA/Civ/2016/1100.html • ECI Policy – consultation not required as the then CCGs (now the SWL ICB) were required to implement national policy	
7	**Are there service user, public or staff concerns that the proposed service / policy / function may be discriminatory, or have an adverse impact on people from the protected characteristics?**
No. The revised policy reflects and adopts the broader findings of the 2016 High Court ruling and subsequent appeal, and has undergone legal Capsticks review to ensure that this has been achieved from a legal perspective within the policy	
If there are **no concerns**, proceed to section 12. If **there are concerns,** amend service / policy / function to mitigate adverse impact, consider actions to eliminate adverse impact, or justify adverse impact.	

8	**Can the adverse impact be justified?**
Not applicable. The purpose of the updated policy is to address any adverse impact	
9	**What changes were made to the service / policy / function as result of information gathering?**
• The incorporation of the wider adoption of "exceptionality" that is in-line with the findings of the 2016 High Court ruling and its subsequent appeal • To reflect the ICB landscape within which the policy will be applied (via the adoption of the core principles of an ICS model) • To include an Ethical Decision-Making Policy within its framework • To include a description of Service Developments, as an introduction to the requirement for a separate Service Developments policy	
10	**What arrangements will you put in place to monitor impact of the proposed service/policy/function on individuals from the protected characteristics?**
• An audit of the demographic information relating to the protected characteristics contained within the IFR applications • Case learning • A review of cases approved verses those not approved • Ongoing interface meetings with clinicians and the clinical networks	
11	**List below actions you will take to address any unjustified impact and promote equality of outcome for individuals from protected characteristics. Consider actions for any procedures, services, training and projects related to the service / policy / function which have the potential to promote equality.**

Action	Lead	Timescales
1) Action planning from point 10 above	• Gill Schram • IFR Policy Development Group	FY 2022/23
2) A review of queries/ complaints and whether/how they should drive policy refresh	• As above	FY 2022/23 and ongoing
3) A review of how the applications and interactions with clinicians then feed into iterative IFR process development	• As above	FY 2022/23 and ongoing

12	Review date	
Author: Gill Schram Job title: Interim Head of Cancer & EBI Programmes Signed: Signed electronically Date: 18th February 2022		
Approved by: Melissa Berry Title: Program Director Equality, Diversity and Inclusion Signed:  Date: 18th/ 02/2022		