

# **Individual Funding Requests, Prior Approval and Criteria Based Access Policy**

## DOCUMENT CONTROL SHEET

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## Implementation Plan:

<b>Development and Consultation</b>	<p>Medical Advisor          Secondary Care Consultant          (Mark Smithies)          Consultant Public health          Lay Member IFR Appeal          Director of Commissioning          Director of Quality</p>
<b>Dissemination</b>	<p>The policy is available to all CCG staff, independent Contractors and members of the public via the main CCG website and CCG clinical policies website. Information about the policy is provided by email notification to GP Practices and secondary care commissioners and is also available as documentation associated with the main provider contracts.</p>
<b>Training</b>	<p>In House training provided to all members of the team</p>
<b>Monitoring</b>	<p>Key data to be reported bi-yearly to executive team.          Internal and external audit.</p>
<b>Review</b>	<p>Six monthly as part of bi-annual report and two yearly rolling programme of review</p>
<b>Equality, Diversity and Privacy</b>	<p>Equality Impact Assessment - Privacy Impact Assessment</p>
<b>Associated Documents</b>	<ul style="list-style-type: none"> <li>• The Individual Funding Requests form</li> </ul>
<b>Documents Informing Paper</b>	<ul style="list-style-type: none"> <li>• NHS Constitution 2012</li> <li>• NHS Commissioning Board (2013) <i>Commissioning Policy (ref:NHSCB/CP/06) Experimental and unproven treatments.</i></li> <li>• NHS Commissioning Board (2013) <i>Interim Commissioning Policy(ref:NHSCB/cp/03): Individual Funding Requests</i></li> <li>• Soest, Tilmann M. von; Kvaalem, I. Lundin; W ichstrøm, L. (2012) <i>Predictors of cosmetic surgery and its effects on psychological factors and mental health: a population-based follow-up study among Norwegian females.</i> Psychological Medicine, 42(3):617-626</li> </ul>

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## 1.0 Introduction

1.1 This policy defines the responsibilities of Wiltshire Clinical Commissioning Group and the activities of the Individual Funding Request (IFR) and Prior Approval (PA) team.

1.2 Clinical Commissioning Groups (CCGs) commission local NHS health services, excluding primary care services and NHS England commissions highly specialised health services and core General Practitioner services. Both organisations use national and local policies to prioritise treatments based on available resources and competing demands. This policy relates solely to services commissioned by Wiltshire CCG. Local policies are available on our website.

1.3 The NHS exists to serve the needs of all of its patients but also has a statutory duty to financially break even. Wiltshire CCG has a responsibility to provide health benefit for the whole of its population, whilst commissioning appropriate care to meet the clinical needs of individual patients.

1.4 There will always need to be a process for considering NHS funding for an individual based on either individual clinical circumstances or exceptional clinical circumstances. Wiltshire CCG has an Individual Funding Request team to perform this function. Clinicians are entitled to make a request to the CCG for treatment to be funded on the grounds of individuality where an individual patient requires healthcare which falls outside of the range of services and treatments the CCG has agreed to commission. The IFR team also considers requests for funding for patients with more common conditions for which the CCG has commissioned care pathways, but where the patient does not fulfill the agreed criteria and is considered to be 'exceptional' to the care pathway and/or criteria.

1.5 The NHS Constitution (March 2012) informs patients they have the right to expect local decisions on funding of drug and non-drug treatments to be made rationally following a proper consideration of the evidence. It states: "If the local NHS decides not to fund a drug or treatment you and your doctor feel would be right for you, they will explain that decision to you."

1.6 In order to ensure that good quality services are available to those patients with the greatest need, it is necessary to restrict the funding of procedures which have limited or no clinical benefit. These procedures may also be referred to as low priority treatments. Therefore Wiltshire CCG has a Prior Approval system in place which ensures that certain elective procedures are subject to threshold criteria. This will mean that some procedures will only be available for patients who meet a defined set of criteria. <http://www.wiltshireccg.nhs.uk/what-we-do-and-dont-fund>

1.7 The prior approvals process assesses applications for such procedures against the set criteria. This ensures optimal clinical effectiveness and appropriateness in a patient's clinical pathway.

## 2.0 Scope

2.1 This Policy covers the following:

- All IFR and PA requests for adults and children that WCCG has responsibility for and excludes treatments that are the responsibility of NHS England.
- The arrangements to consider funding requests that do not fall within existing contracts or are considered low priority.
- The processes in place to respond to these requests and appeals.
- The structure and function of the Individual Funding Team and IFR panel

2.2 Criteria Based Access applies to treatments that are considered appropriate for patients in certain circumstances provided that specific pre-determined and evidence based access criteria have been met. Unlike PA procedures, for CBA procedures if a reviewing clinician can demonstrate that the patient meets the CBA criteria then the patient can proceed for treatment without any requirement for WCCG funding approval. Secondary care providers must ensure that evidence that the patient meets the CBA criteria is included within the patient's medical record for audit purposes.

2.3 This policy applies to any patient for whom WCCG is the Responsible Commissioner and who are registered with a WCCG General Practice. The CCG is responsible for commissioning services to meet the health needs of its population and is required to commission services which are evidence based, clinically and cost effective, improve health outcomes and reduce health inequalities whilst representing value for money.

2.4 Wiltshire CCG commissions its mental health services for adults and children from Avon and Wiltshire Mental Health Partnership NHS Trust (AWP) and for children from Oxford Health NHS Foundation Trust. The majority of adult mental health services are available through contracts held by the Community and Joint Commissioning Directorate (C&JCD) on behalf of WCCG and are accessed through referral to AWP. Children's mental health services are contracted by Wiltshire Council and are accessed through referral to Oxford Health CAMHS. The IFR team does not routinely process requests for mental health services which fall outside of these commissioned contracts. All Individual Funding Requests for adult mental health services are triaged by C&JCD to assess cases against currently commissioned services. Requests are sent by clinicians securely to the IFR team who will forward the information to a nominated mental health commissioning lead for consideration of individual funding. On occasions the mental health commissioner may request the IFR committee to consider funding advice for complex cases and/or appeals. In such cases the mental health commissioner will be expected to present the case including all relevant history and clinical information to the committee. The IFR committee will make a funding decision and/or provide advice in line with section 6.8 of this policy. C&JCD remain responsible for the administration process of the case in question and the IFR team is responsible for the dissemination of the outcome.

### 3.0 Purpose

3.1 Requests for non-commissioned care usually come under Individual Funding Requests and this policy is designed to provide assurance that the CCG processes are compatible with the requirements in the NHS Constitution.

3.2 This policy will ensure a clear and transparent process is in place for decision making and provide reassurance to patients and clinicians that decisions are made in a fair, open, equitable and consistent manner.

### 4.0 Definitions

4.1 **Criteria Based Access (CBA)** - CBA applies to treatments that are considered appropriate for patients in certain circumstances provided that specific pre-determined and evidence based access criteria have been met. Unlike PA procedures, for CBA procedures if a reviewing clinician can demonstrate that the patient meets the CBA criteria then the patient can proceed for treatment without any requirement for WCCG funding approval. Secondary care providers must ensure that evidence that the patient meets the CBA criteria is included within the patient's medical record for audit purposes.

4.2 **Prior Approval (PA)** - Is a process in which clinicians demonstrate how a patient meets set threshold criteria prior to referring to secondary care and/or by consultants prior to listing for surgery or performing a procedure for which WCCG routinely commissions and is within agreed contracts.

- Prior Approval means that a General Practitioner and/or provider must seek the agreement of the responsible commissioner to fund a treatment for an individual for an intervention which there is a CCG policy before that treatment is carried out. <http://www.wiltshireccg.nhs.uk/what-we-do-and-dont-fund>
- The Prior Approval process then compares requests for elective procedure against a set of threshold criteria for the Prior Approval process.
- On occasions patients may fall outside of the PA threshold criteria and clinicians may appeal by demonstrating how the patient is clinically exceptional. In these cases the request is then considered via the Individual Funding Request process.

4.3 **Individual Funding Request (IFR)** - Is a request received from a clinician providing care to a patient, for:

- a specific treatment that is not covered by existing policy or for a service which is not commissioned by WCCG, or
- Where the CCG is responsible for commissioning the service/treatment in question and/or a local policy is in place however the patient does not meet the criteria and is deemed to be clinically exceptional.

Arguments on the basis of exceptionality are requests where a patient is deemed to have *exceptional clinical circumstances*, i.e. a patient who has clinical circumstances which, taken as a whole, are outside the range of clinical circumstances presented by a patient within the normal population of patients with the same medical condition and at a similar stage of progression as the patient, *exceptional to the cohort*.

4.4 IFR Committee - Is the committee that represents WCCG that has been authorised to take decisions on its behalf on Individual Funding Requests. (See separate terms of reference document Appendix 1).

4.5 Cohorts- A cohort of similar patients for the purposes of this policy has been defined as the number of requests received or likely to be received per year which will require consideration of a commissioning policy. In these circumstances, the IFR route to funding may only be considered if the patient is clinically exceptional to the cohort.

The numbers of patients for whom the treatment will be requested per year is likely to be five or more patients per year from the population served by the CCG.

## **5.0 Roles and Responsibilities**

5.1 CCG CAG – Is responsible for advising on this document.

5.2 Quality & Clinical Governance Committee – Is responsible for approving this policy.

5.3 Chief Executive – Accountable Officer- Has overriding accountability for the actions of the IFR team and Panel.

5.4 Executive Team- Has oversight of the IFR bi-yearly report and will escalate any serious risks and/or concerns to the Governing Body.

5.5 Head of Medicines Management, Exceptions and Prior approvals - Has delegated responsibility to ensure this policy is applied and adhered to

5.6 The IFR Committee- The IFR committee has delegated authority from the CCGs to make decisions in respect of funding for individual cases. Accountability for those decisions rests with the CCG representatives of the committee. Decisions will be usually made on the basis of consensus. The IFR committee will report any significant issues and risks arising to CAG via the IFR bi-yearly report. The IFR panel will highlight any cohorts to the relevant commissioner to ensure services are reviewed in line with CCG priorities.

5.7 Public Health Consultant- provides support and advice to the IFR committee. Their role is to give public health advice in relation to clinical appropriateness, clinical effectiveness and cost effectiveness of a treatment

5.8 The PA/IFR administration team- Are responsible for logging and monitoring all PA/IFR applications (excluding mental health requests), coordinating responses within the set time frames and communicating with patients and clinicians regarding process and decisions. The IFR team will co-ordinate and prepare cases for the weekly pre-screen committee meeting, weekly PA meeting and the monthly IFR committee meeting. The aim is to send the committee decisions to the referring clinician and/or the patient within ten working days of the committee meeting; this is within the 30 day requirement stated within contracts and in line with the Standing Operating Procedure. If the committee decides not to fund a drug or treatment the decision letter will include an appropriate explanation.

## 6.0 PROCESSES

6.1 Psychological issues are not considered as grounds for exceptionality. This is line with WCCG guidance based on reviews of evidence <http://www.wiltshireccg.nhs.uk/what-we-do-and-dont-fund>

6.2 Information that is immaterial to the decision, including information about the social, economic or personal circumstances of the patient which does not have a direct connection to the patient's clinical circumstances, shall not be considered

6.3 IFR does not generally fund equipment or on-going maintenance, or placements in long term care. Personal Health Budget's and voucher schemes are available through the Continuing Health Care Team (CHC team). Any requests for funding of Neurology related treatments are discussed with CHC prior to processing as an IFR.

6.4 WCCG wants the best for our patients. It is important that when a patient reaches a stage in their treatment pathway that requires a specialist intervention, we would expect our patients to be referred to officially designated, accredited Centre's to ensure high quality of care. The CCG will not support specialised treatment at un-designated, non-accredited Centre's.

6.5 WCCG does not discriminate on grounds of sex, age, sexual orientation, ethnicity, educational level, employment, disability, marital status or religion. WCCG does not generally make treatment for patients under its policies dependent on the patient's social or personal circumstances. Accordingly, when making decisions as to whether treatment should be provided to a patient which is not provided to patients generally, the committee shall adopt the same approach.

6.6 The IFR committee shall have a broad discretion to determine whether the proposed treatment is a justifiable expenditure of the CCG resources. The IFR committee is, however, required to bear in mind that the resources requested to support the individual patient will reduce the availability of resources for other investments. The IFR committee may make such approval contingent on the fulfillment of such conditions as it considers fit. Very occasionally an Individual Funding Request presents a new issue which needs a substantial piece of work before the CCG can reach a conclusion upon its position. This may include wider consultation. Where this occurs, the IFR committee may adjourn a decision on an individual case until that work has been complete.

6.7 The IFR committee shall take care to avoid adopting the approach described the ‘the rule of rescue’. The fact that a patient has exhausted all NHS treatment options available for a particular condition is unlikely, of itself, to be sufficient to demonstrate exceptional circumstances. Equally, the fact that the patient is refractory to existing treatments where a recognised proportion of patients with the same presenting medical condition at this stage are, to a greater or lesser extent, refractory to existing treatments is unlikely, of itself, to be sufficient to demonstrate exceptional circumstances. The IFR committee will consider whether treating the patient is higher priority than other unfunded developments and the treatment can be afforded.

6.8 The IFR team and/or IFR committee will consider in the case of exceptional requests if there are likely to be similar patients within the local population.

For exceptionality requests the clinician must also provide the case for treating this patient and not other apparently similar patients.

6.9 The IFR process is clinician lead and all applications must be made by a clinician. Deliberations at committee will be based on evidence of individual clinical exceptionality and will not take into account issues relating to social or personal circumstances. It is therefore not appropriate for patients to attend the committee and the Commissioners are not legally bound to invite them. However, patients may submit a supporting statement but this needs to be limited to clinical issues i.e. what effect the condition has on the patient’s activities of daily living.

6.10 On occasions the IFR team may receive rare requests for treatments, drugs or services where the responsible commissioner is unclear, or there is no existing commissioned service. Such requests will be considered on an individual basis until commissioning responsibility can be ascertained. Should a cohort be identified the IFR team will treat this as a service development requiring consideration of a commissioning policy. Any emerging cohorts will be highlighted to the CCG directors via biyearly reporting for consideration and raised at the Clinical Advisory Group (CAG). The IFR team will consider patients within the cohort on their individual clinical circumstances in the interim, until a commissioning decision and/or policy are made. Should the patient have individual clinical circumstances which prevents them from utilising other existing commissioned services and the intervention is clinically appropriate funding may be approved by the IFR team on behalf of the CC

6.11 Individual requests cannot be used as a means of ‘creeping implementation’ for new technologies, services or policies. Consideration therefore needs to be given as to the likelihood of other patients having the same clinical need who could also benefit from the proposed treatment. If there are or are likely to be other patients then, properly considered the request is for a service development and not an individual application. Where a decision may affect other patients, the application should be considered as a service development and not through the IFR process. The IFR team and/or the committee shall routinely screen Individual Funding Requests to see whether they represent a service development. The key question used to screen out as a service development will be ‘are there likely to be other similar patients in the CCG?’ If there is evidence that this patient is representative of other similar patients and forms a cohort, the request will be considered on an individual basis as per the clinical evidence, but the provider will be requested to follow normal procedures for introducing new services by the submission of a fully costed business case.

6.12 The CCG does not expect to provide funding for patients to continue medication/treatment commenced as part of a clinical trial. In line with the Medicines for Human Use (Clinical Trials) Regulations 2004 and the Declaration of Helsinki, the responsibility lies with those conducting the trial to ensure a clear exit strategy from a trial and that those benefiting from treatments provided within the trial setting will have on-going access to those treatments. It is standard practice for CCGs not to fund treatments which are still considered experimental, irrespective of the 'potential' health benefit for either individuals or groups of patients. Therefore treatments which are judged experimental, uncertain or not to be of proven effectiveness will not routinely be funded and funding for individual patients or groups of patients within poorly designed trials will not be supported

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<http://www.wiltshireccg.nhs.uk/wp-content/uploads/2018/04/Clinical-Trials-02022018-vs2.pdf>

## 7.0 Experimental Treatments

7.1 The Wiltshire CCG IFR team will adopt the following criteria when considering a treatment as experimental:

- The treatment is still undergoing clinical trials for the indication in question.
- There are no relevant articles published in the peer-reviewed journals available on the treatment for the indication in question.
- The treatment does not have approval from the relevant government body.
- The treatment does not conform to usual clinical practice in the view of the majority of medical practitioners in the relevant field.
- The treatment is being used in a way other than that previously studied or that for which it has been granted approval by the relevant government body.
- The treatment is rarely used, novel, or unknown and there is a lack of authoritative evidence of safety and efficacy.

## 8.0 Drug Requests

8.1 The IFR team processes requests for Drugs which are not routinely commissioned this would include:

- High cost drugs excluded from contracts.
- New treatments where no policies exist.
- Treatments that we as a CCG have decided we will not fund routinely, or only fund in certain circumstances. This may include primary care prescribing or requests from Trusts and other providers.

8.2 If a request meets routine commissioning criteria this will be sent to the Medicines Management Team for processing. Drug requests will be considered in line with this policy on the grounds of clinical exceptionality and the same principles will be applied. The IFR Lead will work collaboratively with senior pharmaceutical leads in responding to requests and draw upon their knowledge and expertise.

## 9.0 Urgent Treatment Decisions

9.1 WCCG recognises that there will be occasions when an urgent decision needs to be made to consider approving funding for treatment for an individual patient outside of CCG policies. In such circumstances the CCG recognises that an urgent decision may have to be made before a committee can be convened. The following provisions apply to such a situation.

9.2 An urgent request is one which requires urgent consideration and a decision because the patient faces a substantial risk of significant harm (the patient's life may be in danger) if a decision is not made before the next scheduled meeting of the committee. The IFR Lead and CCG Medical Advisor are responsible for agreeing whether a case requires urgent decision after considering the nature and severity of the patient's clinical condition. Urgency under this policy cannot arise as the result of a failure by the clinical team expeditiously to seek funding through the appropriate route and/or where the patient's legitimate expectations have been raised by a commitment being given by the provider trust to provide a specific treatment to the patient. In such circumstances the CCG expects the provider trust to go ahead with treatment; however funding will not be guaranteed and may be at their financial risk.

9.3 Provider trusts must take all reasonable steps to minimise the need for urgent requests to be made through the Panel process. If clinicians from any provider trust are considered by the CCG not to be taking all reasonable steps to minimise urgent requests to the Panel, the CCG may refer the matter to the provider Trust Chief Executive.

9.4 Where an urgent decision needs to be made to authorise treatment for an individual patient, it is the responsibility of the IFR Lead to request a virtual discussion on the case. The time period within which the decision needs to be taken will be five working days of receiving the case request, or earlier depending on the individual case

9.5 The urgent decision will be made by "virtual discussion" via email or phone between the committee members.

9.6 The “virtual discussion” will, as far as possible within the constraints of the urgent situation, follow the policy set out in making the decision. The IFR team shall collect as much information about both the patient’s illness and the treatment as is feasible in the time available.

9.7 WCCG committee members shall be entitled to reach the view that the decision is not of sufficient urgency or of sufficient importance that a decision needs to be made outside of the usual process.

9.8 Decisions will be sent to the referring clinician, and/or GP, and/or the patient within five working days of receiving the case request for a virtual committee meeting. If the committee decides not to fund a drug or treatment the decision letter will include an appropriate explanation.

## 10.0 CBA Process

### The Assessment Process

10.1 The Clinical Commissioning Policies (CCP) list identifies all procedures that have Criteria Based Access (CBA) and provides details of the criteria that the patient will need to meet in order to proceed for treatment. <http://www.wiltshireccg.nhs.uk/what-we-do-and-dont-fund>

10.2 Assessment of the patient against the relevant CBA criteria can be made at any point in the patient pathway prior to treatment, but should be undertaken at the earliest possible stage in the pathway once the need for a CBA procedure has been identified. This means that assessment against the CBA criteria will either be made by the referrer prior to referral, or by the secondary care clinician following triage or initial assessment in secondary care.

10.3 Where the responsible clinician believes that a patient demonstrably meets the criteria set out in the CCP list, the patient can proceed for treatment. If the assessment is undertaken by a referring GP, that GP must ensure that details of this are included within their referral. Secondary care providers must ensure that evidence that the patient meets the CBA criteria is included within the patient’s medical record for audit purposes.

### 10.4 Consequences of Undertaking Activity That Does Not Meet the Necessary Criteria

10.5 All providers of NHS care have a responsibility for ensuring that CBA procedures, as identified on WCCG’s Clinical Commissioning Policies list, are only undertaken where the relevant clinical criteria are met.

10.6 On any occasion where a provider undertakes CBA activity where the patient does not meet the relevant criteria, that provider will not be paid for the associated activity.

### 10.7 WCCG Process for Ensuring Compliance with CBA Policy.

10.8 WCCG will undertake a quarterly audit process to review a representative sample of CBA procedures undertaken by providers to ensure that the relevant CBA criteria were met. The audit process will involve review of medical records, and an assessment of whether there is sufficient evidence to demonstrate that the CBA criteria were met.

10.9 If the audit process identifies cases where the relevant criteria were not met, or where there is insufficient evidence to provide assurance that the criteria were met, the provider will not be paid for the associated activity.

10.10 Providers will be given an opportunity to review any cases identified through the audit process, and if they are able to provide sufficient evidence within agreed timescales to demonstrate to WCCG's satisfaction that the CBA criteria were met, then the provider will be paid for the activity.

## 11.0 Prior Approvals Process

11.1 WCCG Primary and Secondary care clinicians are required to submit an application proforma to demonstrate how the patient meets current thresholds. Relevant clinical letters and/or objective data to support the patients application can be useful and may be requested; for example x-ray reports, scan results, optician reports, medical evidence, clinical scores, clinic letters etc. <http://www.wiltshireccg.nhs.uk/what-we-do-and-dont-fund>. See section 16.0 for photographic evidence.

11.2 Completed applications are sent electronically to the Prior Approval team. We aim to deal with all applications within a ten working day turn around; this is within the contractually stated 30 day timeframe and is in line with the Standard Operating Procedure. The IFR Manager determines whether or not the presenting condition requires prior approval and considers if any additional information is required. The requests are then put to the panel. Requests which clearly do not meet the criteria and where no additional information has been provided can be directly declined by the IFR Manager.

The PA Panel will aim to:

- Promote consistency, fairness and equity.
- Ensure effective use of resources, but also ensure that the decisions are based on clinical evidence.
- Improve the rigor of the processes ensuring decisions are rational, reasonable and transparent

11.3 Treatments, and services, referred to in this Policy should not be undertaken or provided without Prior Approval being obtained as indicated. Where Prior Approval has not been appropriately obtained, then any treatments or services provided will have not been legitimately delivered, and will not be funded by Wiltshire CCG. Therefore funding will not be given in retrospect after the procedure has been carried out without Prior Approval funding in place.

11.4 Where a Prior Approval application is declined clinicians can appeal the decision by submitting additional clinical evidence. Should a second request be declined then subsequently re-submitted the case will be processed as an exceptional request and will be considered by the IFR Manager and Medical Advisor as to appropriateness for IFR review. It will then be subject to the IFR pathway including the appeals process.

## 12.0 Individual Funding Requests Process

12.1 All applications to the IFR team must be on the approved request form (appendix 2). The form should be referred to for further detailed instructions on completing it. Written support and evidence should be provided by the clinician treating the patient using the request form and include any relevant research findings where appropriate.

12.2 On receipt of the funding request, the case is recorded on the database and an acknowledgement is sent to the referring clinician. The IFR Manager will verify whether sufficient information is included in the request form, and ask the referring clinician for more information if required.

12.3 The majority of IFR cases will be screened by the IFR Manager on a daily basis. Complex cases will automatically be sent to pre-screen panel meeting for discussion with a Medical Advisor, drug cases will be discussed with the relevant Senior Medicines Management Team member.

12.4 The skills and expertise required of the screening function by the Head of IFR are the ability to:

- Determine who is responsible for commissioning the intervention.
- Determine whether an existing policy covers the intervention.
- Determine if the intervention is already funded through contracts? Are there suitable alternatives?
- Is this the correct point in the agreed clinical pathway for this treatment?
- Interpret the CCG definitions of exceptionality and individuality in the context of the clinical information that is presented.

The Head of IFR will be able to consider the following options:

- Send the request on to the responsible commissioner should this not be WCCG.
- Send this on to the responsible WCCG commissioner for mental health or neurology cases.
- Gain advice from Commissioners/contract managers regarding suitable commissioned services or possible alternatives.
- Defer the request, and ask for more information from the referring clinician.
- Approve the request if covered by an existing contract/ commissioning policy.
- Take the request to the IFR committee.

12.5 Following the IFR committee meeting the team will inform the applying clinician and/or patient (as appropriate) of the decision via letter within the allocated turnaround times stated within the Standard Operating Procedure.

## 13.0 IFR Committee

13.1 The monthly committee meeting will usually consider cases where there is either:

- Uncertainty about whether the treatment falls within existing policy
- Or
- Evidence for exceptionality is unclear
- Or
- Where complaints and appeals have been heard by the prior Approvals route and the IFR committee view is required
- Or
- Where the referring clinician appeals against the decision made previously by the committee and there is new clinical information to consider.

In considering the funding requests, the committee will aim to:

- Promote consistency, fairness and equity.
- Ensure effective use of resources, but also ensure that the decisions are based on clinical evidence.
- Improve the rigor of the processes ensuring decisions are rational, reasonable and Transparent.
- Explore the grounds for any relevant clinical exceptionality presented and apply the IFR policy.

13.2 Decisions will be reached by consensus where possible, but if a consensus cannot be achieved, will be decided by a vote of the committee members. If the committee is equally split following extensive discussion then the decision will be escalated to the CCG Quality & Clinical Governance Committee.

13.3 The committee shall be entitled to approve/decline or defer Individual Funding Requests. The following will be considered:

- The committee is not authorised to approve funding for cases which are considered to form part of a service development. Providers are expected to seek funding for new treatments and services through commissioning managers by submitting a business case and not through the IFR system. However the committee can consider approving funding for individual cases where the patient is clinically exceptional to the cohort in question and the requested intervention has evidence of safety, efficacy and cost effectiveness. In addition, in rare circumstances, if a new (first time) request for an uncommissioned service is received for an individual patient, consideration for individual funding may be appropriate whilst a business case is being developed for consideration of funding for the cohort. In these circumstances it must be demonstrated that the treatment for this patient would be safe, effective and cost effective, as demonstrated by critical review of the literature. In these cases, a recommendation to develop a policy for the CCG would be made. In addition, the CCG may decide that funding for a rare condition will only be considered individually rather than commissioning a service for a cohort. In these circumstances it would be expected that a commissioning policy is developed to support decisions.

- The committee is not required to accept the views expressed by the patient or the requesting clinicians concerning the likely clinical outcomes for the individual patient of the proposed treatment. The committee is entitled to reach its own views on the likely clinical outcomes for the individual patient of the proposed treatment; and the quality of the evidence to support that decision and/or the degree of confidence that the committee has about the likelihood of the proposed treatment delivering the proposed clinical outcomes for the individual patient.
- The committee shall be entitled, but not obliged to commission its own reports from any duly qualified or experienced clinician, medical scientist or other person having relevant skills concerning the case that is being made that the treatment is likely to be clinically effective in the case of the individual patient.
- The committee shall be entitled to approve requests on the basis of exception where the following condition is met:

The committee concludes that the criteria for exceptionality in the context of the relevant CCG policy/policies and guidance note/s have been met.

In determining whether a patient is able to demonstrate exceptional circumstances the committee shall compare the patient to other patients with the same presenting medical condition at a similar stage of progression. The committee shall determine, based upon the evidence provided to the committee, whether the patient has demonstrated exceptional clinical circumstances. The evidence to show that, for the individual patient, the proposed treatment is likely to be clinically effective may be part of the case that the patient's clinical circumstances are asserted to be exceptional.

13.4 The brief meeting notes will form the minutes for these cases.

The committee will make one of the following decisions:

- Approve the funding request.
- Decline the funding request.
- Defer the request and ask for more information from the referring clinician.

Funding decisions made by the team and/or IFR committee on behalf of the organisation, may impact on various healthcare budgets within the organisation. IFR does not hold a specific budget.

13.5 Where the request is agreed, the letter may request that a report is provided on the Patient's progress to determine whether the treatment is effective. The CCG may use this Information to consider the continuation of treatment.

13.6 Where the request is refused, a clear, accurate and comprehensive explanation must be given. The letter should state that the case could be reconsidered by the IFR Panel if New and material evidence becomes available.

13.7. The refusal notification must include advice to the referring applicant about the terms on which they can make an appeal to the IFR Appeals Panel. For patients where the CCG have no patient details, it is the duty of the referring applicant to inform the patient about the appeals process.

## 14.0 Appeals to IFR Committee Decisions

The IFR Appeal process enables applicants to appeal against the decision made by the IFR committee. See appendix 3 for Terms of Reference.

14.1 The focus of the Appeals Panel is the process that the IFR committee used to reach a decision and not the decision itself. Applicants or patients wishing to complain about the decision itself should contact the relevant PALS team for advice or complaints team to make a formal complaint.

14.2 Appeal requests must be submitted in writing to the IFR Administrative Team within 30 days of the date of the decision letter to decline funding.

14.3 Appeal requests must be made by a clinician on behalf of the patient. The CCG will not accept appeals instigated by a patient, their family or other non-clinical representative (e.g. local MP).

14.4 Supporting statements from the patient and third parties can be submitted to accompany the request for consideration as part of the appeal, but no new evidence can be submitted. If new evidence is provided following a decision to decline funding, the correct procedure is to resubmit a request for reconsideration as an IFR.

14.5 The appeal request must indicate the applicant's grounds for appeal. There are three grounds for appeal that can be considered:

- **Illegality:** the refusal of the request was not an option that could lawfully have been taken by the IFR committee.
- **Procedural impropriety:** There were substantial and/or serious procedural errors in the way in which the IFR Process was conducted.
- **Irrationality:** Whether the decision was irrational in light of the information available to the committee.

14.6 The decision of the Appeals Panel is final.

## 15.0 Complaints.

Patients have the right to raise a formal complaint with the CCG via the NHS Complaints Procedure should they be unhappy with the CCG's handling of their case (i.e. staff attitude, communication or the way in which the policy or procedure has been followed, adherence to procedure). The NHS Complaints Procedure is set out to address concerns over service provision and not funding decisions. It cannot be used to investigate or influence funding decisions and the appropriate process for appeals should be followed i.e. from the referring clinician and not the patient.

## 16.0 Photographic Evidence

16.1 Photographs submitted to support an application will have all written patient identifiable information removed before the images are viewed at triage or PA panel or IFR committee.

16.2 Photographic evidence should only be submitted by/via the clinician and with the patient's consent. The clinician is responsible for informing the patient that the evidence may be viewed by the panel / committee members. Where possible facial features or other identifiable features will be removed or blacked out of photos by the Team prior to the PA and IFR meetings.

16.3 Where photographs are submitted that are not medical photographs the clinician submitting them must ensure that quality of photography is such that the panel members can identify the relevant features.

16.4 Photographs to support applications will not be emailed to panel members. Photographs should be brought to the meetings by the administrator and should be available for meeting members to view when the case that they refer to is being discussed. The administrator must be considered as the custodian of photographs and should ensure that they are returned to him/her after the case has been discussed and placed in a sealed envelope. The meeting agenda should indicate that there are photos to support the application so that members are aware when the case is being considered that there is photographic evidence.

16.5 Following each meeting where photographic evidence has been submitted the IFR manager is responsible for ensuring all hard copies of photographs are collected and destroyed. Electronic copies will be held on the record for a 12 month period as that is the length of time a decision is valid for and the photographs may be required for any appeals.

## Appendix 1 Individual Funding Request Committee Terms of Reference

### 1. Introduction

1.1 The Individual Funding Request (IFR) Committee (the IFR committee) is the committee the CCG has authorised to take decisions on its behalf on individual/exceptional funding requests. The purpose of the IFR committee is to consider funding requests on behalf of WCCG. The IFR committee will decide in each case whether funding should be approved or declined in line with the Individual Funding Requests policy for Wiltshire CCG.

1.2 The IFR committee meeting will consider cases where there is uncertainty about whether the treatment falls within existing policy or where evidence for exceptionality is claimed. Or if the referring clinician appeals against the decision made by the committee and there is new clinical information to consider.

### 2. Membership

2.1 The membership of the IFR committee shall include:

- Medical Advisor (Chair)
- Head of Medicines Optimisation, IFR and Prior Approvals (Deputy Chair)
- Public Health Consultant / Specialist or nominated deputy
- 2 GP representatives from Wiltshire CCG
- Quality representative for governance and audit
- IFR Manger or nominated deputy (non-voting member)

2.2 In the event of the Chair of the committee being unable to attend all or part of the meeting, the Deputy Chair will deputise for that meeting.

2.2.1 Additional members may be co-opted, and the IFR committee may decide whether they have decision making rights in the IFR committee discussions, e.g. Public Health Registrars and Commissioners

2.2.2 For particularly complex cases, other individuals with clinical expertise and skills may also be Included on the IFR committee can also contribute to the work of the IFR process as part of their training. They can attend IFR committee as non-voting members.

### 3. Quorum

3.1 The committee will be quorate if four of the members are present; this should include one of the GP representatives, one public health representative, the Head of IFR or nominated deputy and the IFR manager or nominated deputy. Any members unable to attend will be expected to leave their comments on each case for discussion at the IFR committee meeting. Comments will be tabled at the meeting from members who are not present. However, an IFR committee meeting with only four members present should be

the exception.

3.2 No formal business shall be transacted where a quorum is not reached.

#### **4. Frequency of meetings and attendance**

4.1 IFR committee is held on monthly basis.

4.2 Members of the IFR committee should make every effort to attend every scheduled committee meeting.

The secretary of the committee will monitor attendance and will report on this annually.

#### **5. Authority**

5.1 The IFR committee has delegated authority from the CCGs to make decisions in respect of funding for individual cases. Accountability for those decisions rests with the committee. Decisions will be made on the basis of consensus with the Chair holding deciding vote.

5.2 The IFR committee is not obliged to allow patients to attend committee. The IFR process is clinician lead and all deliberations at IFR committee will be based on evidence of individual clinical exceptionality and will not take into account issues relating to social or personal circumstances. It is therefore not appropriate for patients to attend the IFR committee and the Commissioners are not legally bound to invite them. However, patients may submit a supporting statement but this needs to be limited to clinical issues i.e.: what effect the condition has on the patient's activities of day to day living.

5.3 The IFR committee is authorised to make the following conclusions:

- Approve the funding request.
- Decline the funding request.
- Defer the request and ask for more information from the referring clinician.

#### **6. Emergency powers**

6.1 Should the case need IFR committee consideration the urgent decision will be made by virtual discussion, via email or phone between the committee members using the same quoracy principles set out in section 3 (See IFR policy regarding urgent requests; section 9. The exercise of such powers shall be reported and minuted at the next committee meeting.

## 7. Duties

- 7.1 **Decision making at IFR committee-** In considering the funding requests, the IFR committee will aim to promote consistency, fairness and equity. Ensure effective use of resources, but also ensure that the decisions are based on clinical evidence. Improve the rigor of the processes ensuring decisions are rational, reasonable and transparent. Explore the grounds for any relevant clinical exceptionality presented and apply the IFR policy. Consider rare cases where no commissioning policy/service exists on an individual basis.
- 7.1.1 The committee is not authorised to make case by case decision making for service developments where the patient represents a cohort of patients who may benefit from the same treatment. The IFR committee shall routinely screen individual funding requests to see whether they represent a service development. The key question used to screen out as a service development will be ‘are there likely to be other similar patients in the CCG?’ If there is evidence that this patient is representative of other similar patients and forms a cohort, the request will be considered on an individual basis (as per IFR policy) but the provider will be requested to follow normal procedures for introducing new services.
- 7.1.2 The IFR committee is not required to accept the views expressed by the patient or the requesting clinicians concerning the likely clinical outcomes for the individual patient of the proposed treatment. The committee is entitled to reach its own views on the likely clinical outcomes for the individual patient of the proposed treatment; and the quality of the evidence to support that decision and/or the degree of confidence that the committee has about the likelihood of the proposed treatment delivering the proposed clinical outcomes for the individual patient.
- 7.1.3 The IFR committee shall be entitled, but not obliged to commission its own reports from any duly qualified or experienced clinician, medical scientist or other person having relevant skills concerning the case that is being made that the treatment is likely to be clinically effective in the case of the individual patient.
- 7.1.4 The committee shall be entitled to approve requests on the basis of exceptionality in line with the IFR policy.

## **8. Patient confidentiality and conflicts of interest**

Any IFR committee members who believe they may have had any clinical involvement with a particular case will excuse themselves from the case. Confidentiality is the responsibility of all committee members and should be maintained at all times.

## **9. Reporting arrangements to the Governing Body**

The IFR committee will report any significant issues and risks arising to the executive team via the IFR bi-yearly report.

## **10. Annual review of the IFR committee**

10.1 The IFR committee will undertake a bi-yearly self-assessment to:

- Review that these Terms of Reference have been complied with and whether they remain fit for purpose;
- Determine whether its planned activities and responsibilities for the previous year have been sufficiently discharged; and,
- Recommend any changes and / or actions it considers necessary, in respect of the above.
- Provide the Governing Body with an annual report, which details the outcome of the annual review.

## **11. Committee servicing**

11.1 The IFR committee shall be supported administratively by the IFR team (or other nominated representative), whose duties in this respect will include:

- Prepare clinical cases for the meeting.
- The IFR Manager will seek agreement of the Agenda with the Head of IFR and collation of papers in-line with the IFR Policy.
- Taking the minutes and keeping a record of matters arising and issues to be carried forward;
- Producing a single document to track the panels agreed actions and report progress to the committee;
- Producing draft notes with which to inform the decision letters for approval within five working days of the meeting.

## Appendix 2

**THIS PAGE MUST BE COMPLETED FOR ALL REQUESTS**

**STRICTLY PRIVATE AND CONFIDENTIAL APPLICATION FOR  
EXCEPTIONAL FUNDING:**

**Nature of proposed treatment or  
intervention:**

### A. Patient Information

<b>Name</b>		Male	<input type="checkbox"/>	Female	<input type="checkbox"/>
<b>Address</b>					
<b>Post Code</b>					
<b>Date of Birth</b>		<b>NHS Number</b>			

### B. Referrer's Details (GP/Consultant/Clinician)

<b>Name</b>					
<b>Address</b>					
<b>Post Code</b>					
<b>Telephone</b>		<b>Email</b>			

### GP Details (if not referrer)

<b>Name</b>		<b>Practice</b>			
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By submitting this form you confirm that the information provided is, to the best of your knowledge, true and complete and that you have:

- Discussed all alternatives to this intervention with the patient
- Had a conversation with the patient about the most significant benefits and risks of this intervention
- Informed the patient that this intervention is only funded where criteria are met or exceptionality demonstrated
- Checked that the patient is happy to receive postal correspondence concerning their application where appropriate, or clarified alternative needs
- Checked that the patient understands spoken and written English, or clarified required needs

I understand that it is a legal requirement for fully informed consent to be obtained from the patient (or a legitimate representative of the patient) prior to disclosure of their personal details for the purpose of a panel/IFR team to decide whether this application will be accepted and treatment funded. By submitting this form I confirm that the patient/representative has been informed of the details that will be shared for the aforementioned purpose and consent has been given.

**Signed Referrer:** ..... **Please also print name:** .....

**Date:** .....

### Submission

The completed form(s) should be sent electronically (from a nhs.net email address) in confidence with any other supporting documents to [WCCG.IFR@nhs.net](mailto:WCCG.IFR@nhs.net)

**In order to comply with information governance standards, emails containing identifiable patient data should only be sent securely, i.e. from an nhs.net account.**

**THIS PAGE MUST BE COMPLETED FOR ALL REQUESTS**

**C. Treatment requested**

Nature of proposed treatment or intervention:
Brief history, including the patient's current health status and any other health care problems:
Why do you consider this patient to have exceptional clinical circumstances:
Is there any other relevant information that should be considered? (e.g. clinical factors/co-morbidities/relevant personal circumstances)
What are the anticipated clinical benefits in this individual case of the particular treatment requested over other available options:
How will the benefits of the procedure/treatment be measured? What are the intended outcomes and how will these be determined? What 'stopping' criteria will be in place if the treatment is ineffective? NHS Wiltshire CCG will require regular feedback on the outcome if the treatment is approved:

D. Costs

<p>Cost of treatment requested:  (for drug therapy – cycle and annual cost)</p>	
<p>Details of any long-term cost implications and resultant needs that may be acquired from the proposed treatment:</p>	

E. Alternative Treatment Options

<p>Provide a full list of treatments for condition that have been tried or considered, please include dates:</p>		
<p>Date:</p>	<p>Intervention drug/surgery:</p>	<p>Reason for stopping/response achieved:</p>

F. Clinical Evidence

<p>List of written supporting information – to include all relevant clinical details and copies of correspondence: For example: GP Medical history record, extracts from Medical Records.</p>

## Appendix 3

### IFR Appeal Panel: Terms of Reference

#### 1. Governance Arrangements

- 1.1.1 The IFR Appeals Panel will be accountable to the Clinical Commissioning Group (CCG) Governing Body via its committee structure.
- 1.1.2 Members of the IFR Appeals Panel will be appointed by the CCG's Chief Officer
- 1.1.3 The IFR Appeals Panel will be supported to discharge its responsibilities administratively by the IFR service

#### 2. Duties and Responsibilities

- 2.1.1 The IFR team will receive and acknowledge the letter of appeal. The IFR triage meeting will be responsible for undertaking the preliminary assessment of the appeal request to determine whether new evidence has been received and if the case should be sent back to panel. If no new evidence has been received, the case should be passed to an IFR Appeal Panel.
- 2.1.2 Where it is decided to convene a Panel, members of the Appeals Panel should be provided with full details of the case including all correspondence, evidence of clinical and cost effectiveness, full documentation of the discussion and outcome.
- 2.1.3 The Appeals Panel will need to consider whether there are grounds for appeal:
  - Illegality: the refusal of the request was not an option that could lawfully have been taken by the IFR panel.
  - Procedural impropriety: There were substantial and/or serious procedural errors in the way in which the IFR Process was conducted.
  - Irrationality: Whether the decision was irrational in light of the information available to the Panel.
- 2.1.4 An IFR Appeal Panel will not consider new evidence. New evidence must be considered as an IFR resubmission.
- 2.1.5 If the Appeal Panel upholds the original IFR Panel's decision, the appellant will be advised that if they wish to take the matter further this must be done through the NHS Complaints process.
- 2.1.6 If the Appeals Panel consider that the IFR panel did not consider all the evidence provided the application can be directed back to the IFR panel for re-consideration.

#### 3. Constitution

##### 3.1 Meetings

- 3.1.1 IFR Appeal Panel meetings will be held in private. Patients and their representatives will not be permitted to attend the panel discussions to put forward their case verbally. All appeal cases must be submitted in writing to the Panel.
- 3.1.2 The IFR Appeal Panel will adopt the consensus method of decision making where a unanimous view cannot be reached on an individual case. In the case of an equal vote, the Chair shall have a second and casting vote

## 3.2 **Membership**

3.2.1 IFR Appeal Panel will include the following members:

- A clinician/GP
- A representative of the Constituent CCG(s)
- Lay Member

3.2.2 All IFR Appeal Panel members must be independent of any of the original decision making processes and not have been a member of the IFR Panel involved in the original decision. The member must be familiar with all relevant policies and procedures.

3.2.3 IFR Appeal Panel members are required to declare their interests before serving on an IFR Appeal Panel. Any conflicts of interest must be declared as a standing item at the commencement of every meeting and the Chair will decide the appropriate action, including requesting that members withdraw from the meeting.

## 3.3 **Chair**

3.3.2 The Chair must be identified in advance of the meeting, and must be available to approve the minutes and relevant correspondence and fulfill any other obligations within the specified time frame.

## 3.4 **Frequency of Appeals Panels**

3.4.2 The numbers of appeals that may be received are difficult to predict and therefore arrangements for Appeal Panel meetings will be flexible, and will be arranged to ensure that appeals are considered within 20 working days of an appeal being received by IFR Team.

3.4.3 If a matter is exceptionally urgent the Chair shall have the power to call an IFR Appeal Panel at any other time.

## 3.5 **Quorum Arrangements**

3.5.2 The IFR Appeal Panel may not proceed unless at least two members are present, including the Chair.

## 3.6 **Joint IFR Appeals Panels**

3.6.2 Going forward we may choose to have joint Appeal Panel arrangements across the three constituent CCGs within the STP, specifically BaNES CCG, Swindon CCG and Wiltshire CCG.

## 3.7 **Reporting**

3.7.2 The minutes of the meetings shall be recorded by the relevant IFR Manager/Officer and approved by the Chair of the Appeal Panel.

3.7.3 Copies of minutes will not be distributed to IFR Appeals panel members for their retention and will not be placed in the public domain in order to preserve patient confidentiality.

#### 4. **Confidentiality**

4.1 Anonymity is essential for two reasons:

- In order to protect patient's identity, for this reason the requesting clinician is asked to not refer to the patient by name or initials within the rest of the application form.
- For equity of decision making, to ensure that the panel decisions do not take into account personal details such as age or sex.

4.2 Depending upon individual clinical circumstances it may be necessary to re-introduce information on the patient's age and/or sex for consideration. When cases are considered which require access to confidential clinical information through triage, implied consent to disclosure of such information to all members of the IFR Appeal Panel will be assumed. This will be indicated to patients by the referring clinician and be confirmed in IFR publicity material.

#### 5. **Review**

5.1 The IFR Appeal Panel's Terms of Reference will be reviewed annually or in light of any changes in legislation, practice or local/national guidance.

**Next review date April 2019.**