NHS Newbury and District Clinical Commissioning Group
NHS North and West Reading Clinical Commissioning Group
NHS South Reading Clinical Commissioning Group
NHS Wokingham Clinical Commissioning Group

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INDIVIDUAL FUNDING REQUEST OPERATIONAL POLICY

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1. Introduction

This document sets out how the process for managing individual funding requests (IFRs) will operate. Appendix 1 is a flowchart version of the process for clinicians to follow.

Since the introduction of the NHS internal market in 1991, and as part of the development of commissioning and contracting procedures in the NHS, Health Authorities, and later their successor Primary Care Trusts (PCTs), have introduced mechanisms for dealing with access to treatments outside the scope of their standard contracts and commissioning policies. With the demise of PCTs from 31/03/13 responsibility for handling requests for such treatments, referred to as IFRs, has transferred to Clinical Commissioning Groups (CCGs) and the NHS Commissioning Board (NHS CB).

This policy has been developed to govern the process for considering individual requests for funding of treatment which are:

(i) Outside the CCG's contractual agreements with providers, and
(ii) Outside the CCG's usual policy on routinely commissioned services.

If Berkshire West CCGs do not normally fund a treatment but an NHS clinician considers that there are clinical grounds for an individual patient to receive that treatment, the IFR process enables the clinician to present a case for funding on his/her patient's behalf and to have it considered by a suitably qualified Case Review Committee of the CCG. This policy provides a framework for the consideration of the patient's clinical circumstances and whether they may provide grounds for individual funding.

2. Definitions and scope

This policy document applies to the population serviced by Berkshire West Clinical Commissioning Groups.

Most of the requests received by Berkshire West CCGs are for treatment of general and acute conditions in primary and secondary care settings.

Elective treatment is routinely commissioned by Berkshire West CCGs from a range of NHS or Independent Sector (IS) providers. Patients usually access this treatment via referral from a General Practitioner (GP) or general Dental Practitioner (GDP), with the ability to choose an appropriate secondary care provider who will assess/treat them (as per the NHS Free Choice policy).

However, referrals for treatment require prior consideration by Berkshire West CCGs if the referral is:

- To a provider which does not have a contract with Berkshire West CCGs **and** is outside the NHS Free Choice network.
- To a Free Choice provider but for a treatment excluded from the contract with that provider.
- To a Free Choice provider but for a procedure excluded from the national PbR (Payment by Results) arrangements.
- To a Free Choice provide but for a procedure not available as an NHS Treatment for other reasons.
- For a treatment or for a condition that Berkshire West CCGs do not routinely commission or that is not routinely available to the rest of the population.
- For a treatment or condition where Berkshire West CCGs have adopted explicit referral criteria that the patient does not appear to meet.
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For many conditions, Berkshire West CCGs have adopted a range of policies on treatments where there is limited evidence of clinical effectiveness. In these cases, there will be a policy statement confirming Berkshire West CCGs' position that the treatment/condition is a procedure of limited clinical value (low priority) for routine commissioning and/or identifying

that there are specific clinical eligibility criteria (Threshold Dependent Procedures) which need to be met.

There may be other treatments that are not routinely available to all patients but where Berkshire West CCGs do not have or have not yet adopted a policy statement. This policy document applies to the consideration of requests for the funding of such treatments, as well as those explicitly covered by a policy statement.

Where the referral is for treatment in any of the circumstances named above, treatment will not automatically be funded by Berkshire West CCGs unless prior consideration is undertaken and advance approval is obtained.

The remainder of this document sets out how Berkshire West CCGs processes individual funding requests (IFRs) via Central Southern Commissioning Support Unit (CSCSU) and how it considers them.

3. General Principles

Berkshire West CCGs have a range of policies in place defining services/treatments that are routinely a procedure of limited clinical value (low priority) for commissioning. These policies are based on evaluation of the clinical effectiveness evidence base and are intended to enable Berkshire West CCGs to discharge its responsibilities for commissioning the most effective range of services for its population in pursuit of its overall aims and objectives.

Berkshire West CCGs uses its Strategic Planning process and annual operating plans to determine the investments it will make in healthcare for the resident population each year. The success of these annual and longer term programmes depends on there being stability of financial control, planning and delivery. Berkshire West CCGs position on services that are not routinely commissioned is part of this overall picture.

Berkshire West CCGs recognise that new information may come to light on the effectiveness of treatments/services – such as the guidance published by the National Institute for Health and Clinical Effectiveness (NICE) – and keeps relevant developments under review, expecting to review and update its policies accordingly.

Berkshire West CCGs are also prepared to consider funding low priority treatments for individual cases demonstrating clinical exceptionality. This policy document explains how decisions on such cases will be taken.

It is important to be clear that Berkshire West CCGs do not expect to introduce new treatments which are relevant (or may be relevant) to groups of patients as an indirect and unplanned consequence of approving individual patients' requests. To do so would risk creating inequity and imbalance in the system, introducing a risk to the planned delivery of strategic developments. There would be a risk that diversion of resources in this way could destabilise other areas of healthcare which have been identified as priorities by Berkshire West CCGs. Individual cases will therefore be considered on their individual merits in accordance with this policy. Usually this will be without prejudice to Berkshire West CCGs' overarching policy on that treatment/service.

Berkshire West CCGs' Individual Funding Request (IFR) process is the means by which an assessment is made as to whether the case for an exception has been established for an individual patient. In order for a patient's case to be deemed exceptional, the case will be considered under Berkshire West CCGs' Exceptionality Policy and guidance.

Consideration of an individual case will always start from the prevailing policy position in place for that condition/treatment at the time. Consideration will then determine whether exceptionality has been established for that patient. Decisions to approve funding for a case may not be made where by so doing a precedent would be set that in effect establishes new policy (e.g. because the patient's circumstances are not, in fact, exceptional, but representative of a group of patients).

Berkshire West CCGs work within the over-arching principles of the Ethical Framework attached at Appendix 2, in relation to its handling of individual funding requests and associated policies.

4. Individual Funding Requests Process: over-arching principles

Applications for Individual Funding Requests (IFR) will only be accepted from the patient's NHS consultant or GP/GDP. "NHS consultant" will be deemed to include Independent Sector (IS) providers providing treatment to the patient as part of the 'NHS Free Choice' policy, when the consultant is providing a service commissioned by the NHS.

Applications may be submitted to Berkshire West CCGs for consideration on the basis that (i) there is a policy that precludes routine commissioning of the treatment or (ii) that there is no policy but the treatment is not one that is routinely available (and therefore requires specific funding approval by Berkshire West CCGs for the individual patient).

In both instances, Berkshire West CCGs will assess the extent to which the individual patient request can be deemed to be clinically exceptional and if so whether Berkshire West CCGs are prepared to fund the treatment in the individual case, using the definition and criteria set out in a later section of this document.

Where there is an existing Berkshire West CCGs policy or other policy guidance that states that the treatment requested is low priority for routine commissioning, the adoption of that policy will have included a review of the basis for that treatment's cost-effectiveness. A case for Berkshire West CCGs to fund such treatment based upon an individual's clinical exceptionality could include evidence that the cost effectiveness for that individual would be greater than for the cohort of patients or the general population on whom Berkshire West CCG's policy is based. This is provided for within Berkshire West CCGs' definition of exceptionality given in a later section of this document.

In order to enable thorough consideration of requests, applications must be accompanied by detailed clinical information. This is the reason for Berkshire West CCGs requiring IFRs to be submitted by the patient's consultant, as defined above.

The obligation to make a comprehensive and coherent argument for the funding of a particular treatment/therapy rests with the clinician making the request not with Berkshire West CCGs. All such applications should demonstrate the case for clinical exceptionality using Berkshire West CCG's definition.

The IFR team within Central Southern Commissioning Support Unit who manage the funding requests will undertake an initial triage of the Individual Funding Request. If further information is required this will be obtained at this point. Once all the information has been received by the IFR team the cases will be collated and considered by the Clinical Triage Panel (CTP). The Clinical Triage Panel will assess the clinical evidence provided by the applicant where required; and make recommendations on Berkshire West CCG's position on the case and make decisions where appropriate.

If a case does not demonstrate the case for exceptionality or include relevant information/evidence related to the individual case; the Requester will be informed and given an opportunity to re-submit (reconsideration) the case with the relevant information.

The IFR team/Clinical Triage Panel (CTP)/Case Review Committee (CRC) will have no obligation to undertake itself a comprehensive search of all available evidence to make its assessment. The CTP/CRC may at its discretion undertake further assessment in addition to the evidence provided by the patient's clinician. The CTP/CRC reserves the right to require the patient's clinician to provide the relevant evidence needed to consider a request. Where a patient's eligibility to access NHS-funded treatment is clear-cut (for example a clear pre-existing Berkshire West CCGs/NHS England or NICE policy statement sets out clinical eligibility criteria which the patient clearly meets), there will be no requirement for the Berkshire West CCGs' Case Review Committee to take a decision. In these cases, the

patient will follow the local pathway for treatment or specialised commissioning pathway for treatment, where applicable.

5. Patient Choice

Patients have the right to be referred to the provider of their choice within the NHS national Free Choice network, subject to the provisos related to prior approval set out in Section 2 of this document. This choice includes a number of Independent Sector (IS) providers, providing care under the NHS brand and for nationally-designated procedures.

In addition to this national provision, Berkshire West CCGs also have contractual arrangements in place for assessment/treatment of patients by certain other IS providers and local primary/community-based service providers for designated conditions. Local referrers are aware of these choices and are able to refer their patients to these services without prior approval as per any referral criteria for each service.

Berkshire West CCGs patients therefore have a wide choice of secondary care providers.

Patients do not have an automatic right to access acute treatment at IS providers who are not included in the Free Choice arrangements or to access non-designated treatments offered by IS Free Choice providers. This stems from the terms of designation for services on the Free Choice menu for IS providers and the price negotiated by the Department of Health for these procedures.

Any requests for treatment at a non-participating IS provider (i.e. an IS provider not providing services as part of the Free Choice arrangements) or for a non-designated treatment would need to be considered by Berkshire West CCGs in advance. This would be viewed as a treatment option not routinely available to all patients in the Berkshire West population and the case would therefore be considered on the grounds of clinical exceptionality. As a matter of principle Berkshire West CCGs would not normally expect to fund a treatment in the Independent Sector when alternative treatment for that condition is available elsewhere via the Free Choice menu: the only circumstances in which Berkshire West CCGs would consider such an application would be where a clear-cut case for clinical exceptionality had been demonstrated**.**

Requests to Continue Funding of Care Commenced Privately

Patients who are entitled to NHS-funded treatment but are receiving care privately have a right to revert to NHS treatment at any point during their private care. In these circumstances Berkshire West CCGs will expect their treatment to follow local NHS treatment pathways. Funding for an individual to continue care in a private facility or to transfer to an NHS provider where the privately consulted clinician has a link will not be routinely authorised. Where individual clinical circumstances may make such funding appropriate, the case will require consideration under the IFR process. Any such requests would be processed by the IFR team on the basis of the NHS vs Private treatment policy and strict assessment of the clinical exceptionality case as defined in this document.

Requests to Continue Funding for Patients Coming off Drugs Trials

Berkshire West CCGs do not expect to provide funding for patients to continue treatments commenced as part of a clinical trial. In line with the Medicines Act 2004 and the Declaration of Helsinki2, the responsibility for ensuring a clear exit strategy from a trial lies with those conducting the trial.

Requests for Referral to a Specialist Provider

The majority of referrals to specialist centres are made by secondary care consultants. Berkshire West CCGs expect consultants to refer patients for tertiary/specialist care using established pathways covered by contract agreements and in line with national guidance on patient choice. Accordingly, requests for referrals to specialist providers for treatment outside the normal patient pathways will usually only be considered after an assessment by an appropriate specialist. Should a consultant decide that a referral outside normal pathways is a priority for a particular patient; the consultant must submit an IFR form for consideration.

Requests for Second Opinion
Patients are entitled to request a second consultant opinion, but this must be for an NHS-funded provider. A resultant treatment plan must be in accordance with treatment options normally available within Berkshire West care pathways or be the subject of an IFR. Further opinions for the same clinical condition will not normally be supported unless there are exceptional circumstances.

Service Developments
The CRC will not consider requests that represent a service development. If there are known to be a number of patients who have apparently similar clinical needs, all requests for their collective treatment must be submitted to Berkshire West CCGs for consideration through the established priority setting and annual commissioning (operational plan) process.

Decisions Inherited from other CCGs/former PCTs
On occasion a patient will move to Berkshire when receiving a package of care or treatment which has been approved by their previous CCG or PCT, but which would not normally be funded for Berkshire patients. Berkshire West CCGs may honour such decisions; providing the care pathway has been initiated (for example an appropriate referral has already been made and approved). In considering applications for funding in these circumstances, Berkshire West CCGs will take account of, and adhere to, national guidance including the principles set out in *Who Pays? Determining Responsibility for Payments to Providers* (NHS Commissioning Board, December 2012).

Patients seeking NHS-funded Hospital Treatment in the European Union, European Economic Area or Switzerland
NHS England has issued guidance with effect from April 2013 on this type of request and will now handle all such requests. More information can be obtained from the IFR team.

6. Exceptionality Policy

Where there is existing NICE guidance or a Berkshire West CCGs' policy stating that a treatment is not routinely commissioned or is not considered effective, requests may be made to Berkshire West CCGs' IFR process.

The first step in consideration of any funding request is to establish if there is an existing policy which applies to the individual case.

Berkshire West CCGs' position is that all requests will be considered on the basis of their clinical exceptionality.

If funding is to be agreed for the proposed treatment, there must be some unusual or unpredictable or unique factor about the patient's clinical circumstances, which suggests that:

- *the presentation/effect of the condition in the patient differs significantly from that found in the general population of patients with the condition*

and, as a result,

- *the patient is likely to gain significantly more clinical benefit from that intervention/ treatment than might be normally expected for patients with that condition (or the patient will be significantly more clinically disadvantaged by not receiving this treatment, than would be normally expected for patients with that condition).*

In addition to this:

- *There should be sufficient evidence of the effectiveness of the treatment in bringing about the expected benefit for the patient.*

Applications may also be submitted on the basis that there is no specific local or national policy related to the treatment but the treatment is not one that is routinely available to other patients in Berkshire West population (and therefore requires specific funding approval through the IFR process for the individual patient). These applications will also be assessed on the basis of clinical exceptionality, given that the treatment is not routinely available to others.

The fact that a treatment is likely to be efficacious for an individual does not make a case exceptional and is not in itself a reason for Berkshire West CCGs to provide funding (see Appendix 3).

7. Process for submitting requests

Any request for funding must be made in writing by a clinician. The request must contain sufficient information to enable the CTP/CRC to make an adequate assessment of the request. The request must demonstrate exceptionality, i.e. the basis for stepping outside the prevailing policy or the usual treatment approach.

There is an IFR application form which should be used by the clinician to submit the relevant information. Clinicians may append additional or supporting information to the application form as necessary. For further information the application form or queries regarding exceptionality, please contact the IFR Team. (Contact details are located in Appendix 4).

The IFR Team reserves the right to return without consideration any requests which do not contain sufficient clinical information about the patient or the proposed treatment to make such a consideration. The IFR Team may request additional information to support consideration of the request.

All Individual Funding Requests for treatments need to be submitted in writing, to the IFR Team. Full details for submitting requests and arrangements for safe transmission of patient-specific data are also set out in Appendix 4 to this document.

All correspondence/information received about an individual patient is treated as highly confidential by the IFR Team and is only shared on a need-to-know basis. If the referral is sent via fax, as detailed in Appendix 4, it will be received into a Safe Haven fax machine.

The receipt of a request will be confirmed in writing within 3 working days of receipt of the request to the requesting clinician, (the GP if they are not the requesting clinician) and the patient (means of communication for acknowledgements will include email where an address has been supplied).

The IFR Team will initiate an assessment of the completeness of the information received, seeking clinical advice as necessary. If further information is required, this will be requested, usually from the referring clinician and usually in writing. Email or telephone requests for further information are also acceptable; all such contacts will be noted in a case file (blueteq database) established for each request and held by the IFR Team.

It is the responsibility of the clinician making a request to ensure that all relevant information is forwarded to the IFR Team. This should include (this is not an exhaustive list of the information required):

a) An outline of the patient's condition (including diagnosis) and the clinical circumstances of the case, including any previous treatment. The latter should include details of the response to treatment.
b) A clear statement of the proposed referral/treatment plan for the patient;
c) Consideration of why the patient's needs cannot be met within existing services/care pathways, e.g. using conventional treatments;
d) A statement of why this treatment, which would not be offered to others with similar clinical need, is a priority in this case, i.e. what are the exceptional clinical circumstances (using the CCGs' definition);

e) Provide evidence of clinical and cost-effectiveness if this is a new treatment not yet funded;
f) The cost of the treatment (together with any relevant comparisons);
g) The health outcomes anticipated if the treatment is provided (with reference to clinical exceptionality definition).

8. Clinical Triage Panel (CTP)

CTP assess each case against the criteria set out in the local priorities policies. If there is no available policy or the case does not meet the criteria outlined in the policy then the case is referred to the Case Review Committee. Cases able to be approved as a result of the patient already being eligible for treatment, in line with current policy will be signed off at this stage, without the need for full panel consideration.

Requests for which no case has been provided (i.e. to justify approval on exceptional grounds) will be returned to the requester clearly stating this. If further satisfactory information is subsequently provided, the case will be reconsidered.

If it is considered that the evidence submitted could demonstrate exceptional clinical circumstances, the request will then be processed by the IFR Team for consideration by the CTP/CRC. However, this will be on the strict basis that the full range of information about the patient, Berkshire West CCGs' exceptionality policy requirements and satisfactory evidence base have been supplied.

Where reconsideration is requested but no new evidence is submitted which supports the reconsideration request, then the case will be handled as follows:

- The case will be assessed by the CTP and a senior manager in the IFR Team as to whether the original decision appears correct.
- If the original decision is upheld, the applicant will be informed of the decision and the next steps open to them, including the appeals process.
- If the basis of the reconsideration is agreed, the case will be taken to CRC for formal review. However reconsiderations can only be approved and cases taken forward provided that there is sufficient evidence supplied to provide the CRC with an exceptionality case to consider

Where reconsideration requests are made with new clinical evidence, the CTP/CRC reserves its right to re-assess the case against the new evidence provided and to process the case from that point in a manner most appropriate to the case and to this policy.

9. Case Review Committee (CRC)

The CRC is the panel established by Berkshire West CCGs to examine individual cases to determine whether there are exceptional circumstances which warrant the funding of treatment, even though it would not be Berkshire West CCGs policy to fund such treatment routinely.

The majority of cases considered by the CRC will relate to existing Berkshire West CCGs policies or prevailing national guidance.

When the decision is taken by the IFR Team/CTP to submit a case to the CRC, the clinician and patient will be informed. This will usually include the expected date that the CRC will consider the case.

The IFR Team will produce the patient's case - will then be presented - anonymised - to the CRC, by a member of the IFR Team.

To ensure the objectivity of the CRC, patients and clinicians should expect to submit any relevant information or evidence in writing. There is no right to appear in person to the CRC or to present a case in person.

The CRC will ensure that all their decisions are based on relevant Berkshire West CCGs' policy (including this document) and are evidence-based and that all appropriate information is taken into account in the decision-making process.

The CRC shall follow the following steps when considering an IFR application:

Stage 1: Where the CRC is required to consider an individual funding request, it will first reach a decision whether the patient has demonstrated exceptional clinical circumstances. If the patient does not demonstrate exceptional clinical circumstances then the application shall be refused.

Stage 2: If the CRC are satisfied that the patient has exceptional clinical circumstances, the CRC has a discretion to determine whether the treatment should be funded or not. The following are factors which the CRC should consider when deciding whether to approve funding:

- Is there sufficient evidence of sufficient quality that the treatment is likely to be clinically effective for this individual patient?
- Is there sufficient evidence of sufficient quality that the treatment is likely to be cost effective for this individual patient?
- Can Berkshire West CCGs afford the treatment?
- Is the investment in this individual patient justifiable given the cost, likelihood of a successful outcome and the opportunity cost to invest the resources in health gain for other patients?

The CRC usually meets monthly and papers are circulated at least three working days in advance. The requesting clinician and the patient (when appropriate) will be advised in writing of the outcome of Committee decisions: in normal circumstances this will be sent within five working days of the decision being made.

Where the decision has been made to approve the individual funding request, the CRC decision letter will detail how the patient meets the criteria. If funding is not approved and there is no evidence of exceptionality, this will be detailed in the CRC decision letter to the clinician and patient.

However in situations where funding is not approved and the clinician and/or patient subsequently provide further information in support of their clinical case, the CRC may at its discretion consider the additional information to review whether the Committee's original decision should be revised.

Membership and Terms of Reference of the Case Review Committee are shown at Appendix 5.

10. Appeals process

If the requesting clinician or patient is dissatisfied with the decision set out in the CRC decision letter, he/she has the right of appeal to Berkshire West CCGs' Appeals Panel. The right to appeal and how to register the appeal is advised within the CRC decision letter. The Appeals Panel consists of members independent of the original decision-making group, but able to access expert evidence when required. Terms of Reference and membership can be seen in Appendix 6.

The Appeals Panel will consider:

- The decision making process and whether the CRC followed the required standards set out in the policy.
- Whether the decision made by the CRC was unreasonable in light of the available evidence and individuals' clinical circumstances.
- Whether the CRC took into consideration immaterial factors.
- Any other relevant factor in relation to the case.

The Appeals Panel will review the information considered by the CRC and determine whether their decision should be upheld. Appeals Panels will be convened as required.

The outcome of Appeals will usually be sent in writing within three working days of the Panel meeting and will include a statement as to the Panel's decision.

Appellants who are unhappy with the outcome of the Appeals process may then take their case through Berkshire West CCGs formal NHS complaints procedure and will be advised of this in the letter advising them of the outcome of the appeal.

Openness and Transparency
Whilst discussions of the Case Review Committee and the Appeals Panel are based on the consideration of anonymised documentation and there is no right of attendance by the requesting clinician, the patient or their representative, it is essential that the process is, nonetheless, both open and transparent.

The CCGs' process enables this to be achieved in the following ways:

- ensuring that relevant information which has been provided and opinions which have been expressed by treating clinicians, their patients and their representatives are considered by the CRC and the AP before a decision is made, and
- providing written explanation of any decision made by the Case Review Committee or the AP and the reasons for it.

11. Short Notice or retrospective requests

It is possible for a clinician to be managing the care of a patient whose proposed treatment is not routinely commissioned (as per the definitions earlier in this policy statement) but where the clinician believes that the proposed treatment is the only appropriate clinical course of action for this patient and holds the view that a delay would adversely affect the patient's outcome.

It is important to note that the vast majority of requests for individual funding will not fall into this category but it is right and proper for Berkshire West CCGs to set out its position with regard to these circumstances. Berkshire West CCGs are committed to processing applications as quickly as possible and will attempt to expedite requests where there is a pressing clinical need for an early response. For these cases the 'virtual' panel will consider the funding application and a decision will be sent out within 48 hours of receipt of the application for funding.

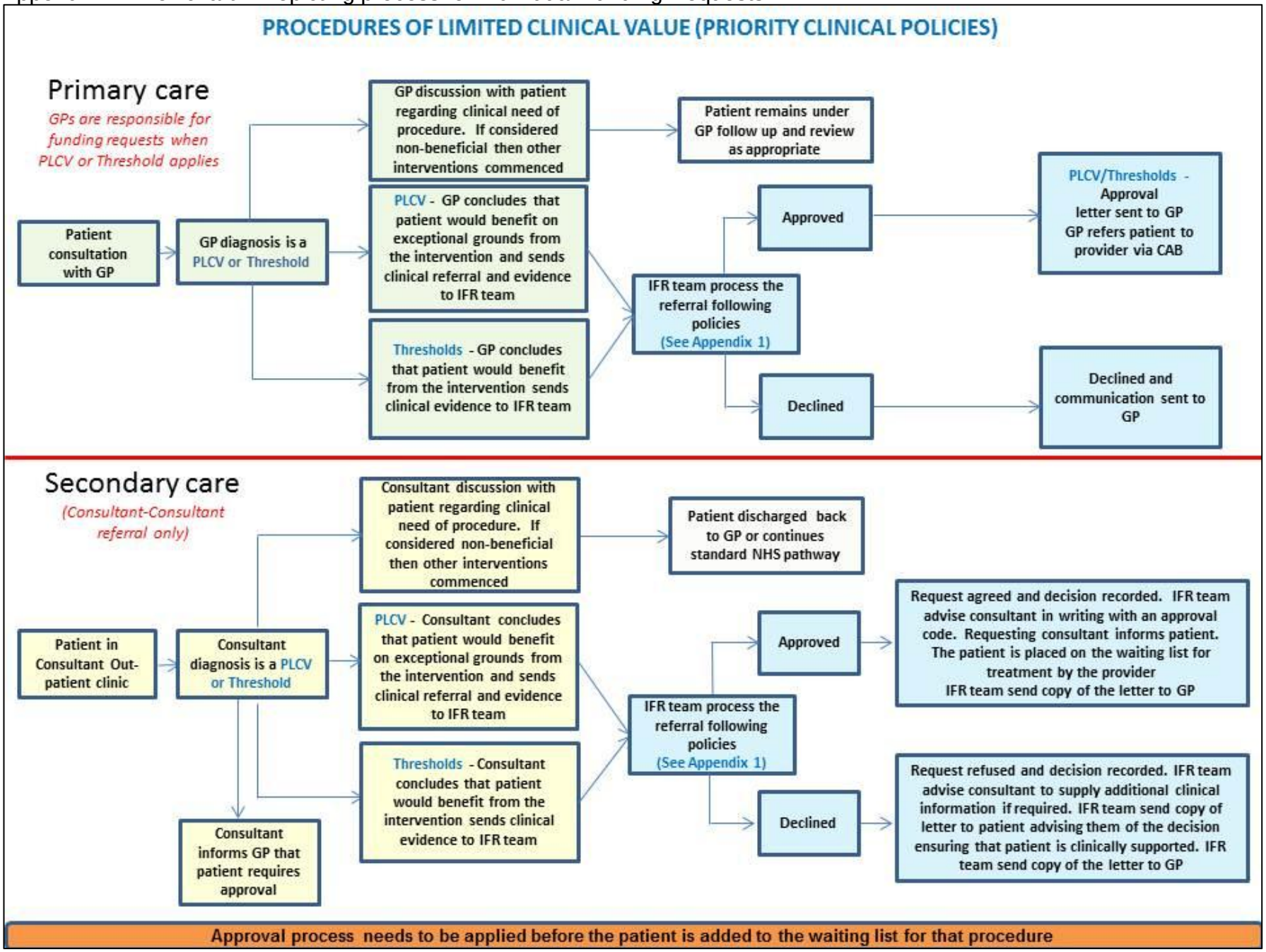
Treating clinicians wishing to initiate treatment within a specific timeframe need to note that this may not be compatible with the time required for the CTP/CRC to thoroughly follow the processes outlined in this paper. Berkshire West CCGs have set out the reasons why it must take a balanced, equitable and evidence-based approach to the consideration of individual funding requests. This document is very clear about the reasons for this position. Berkshire West CCGs have also stated that for these reasons, all requests must follow due process.

If the provider/clinician feels that there is an overriding clinical urgency, the relevant provider organisation must make a decision as to the care to be immediately provided. This is in keeping with the overriding duty of care that the provider and the clinician have to the patient presenting to them.

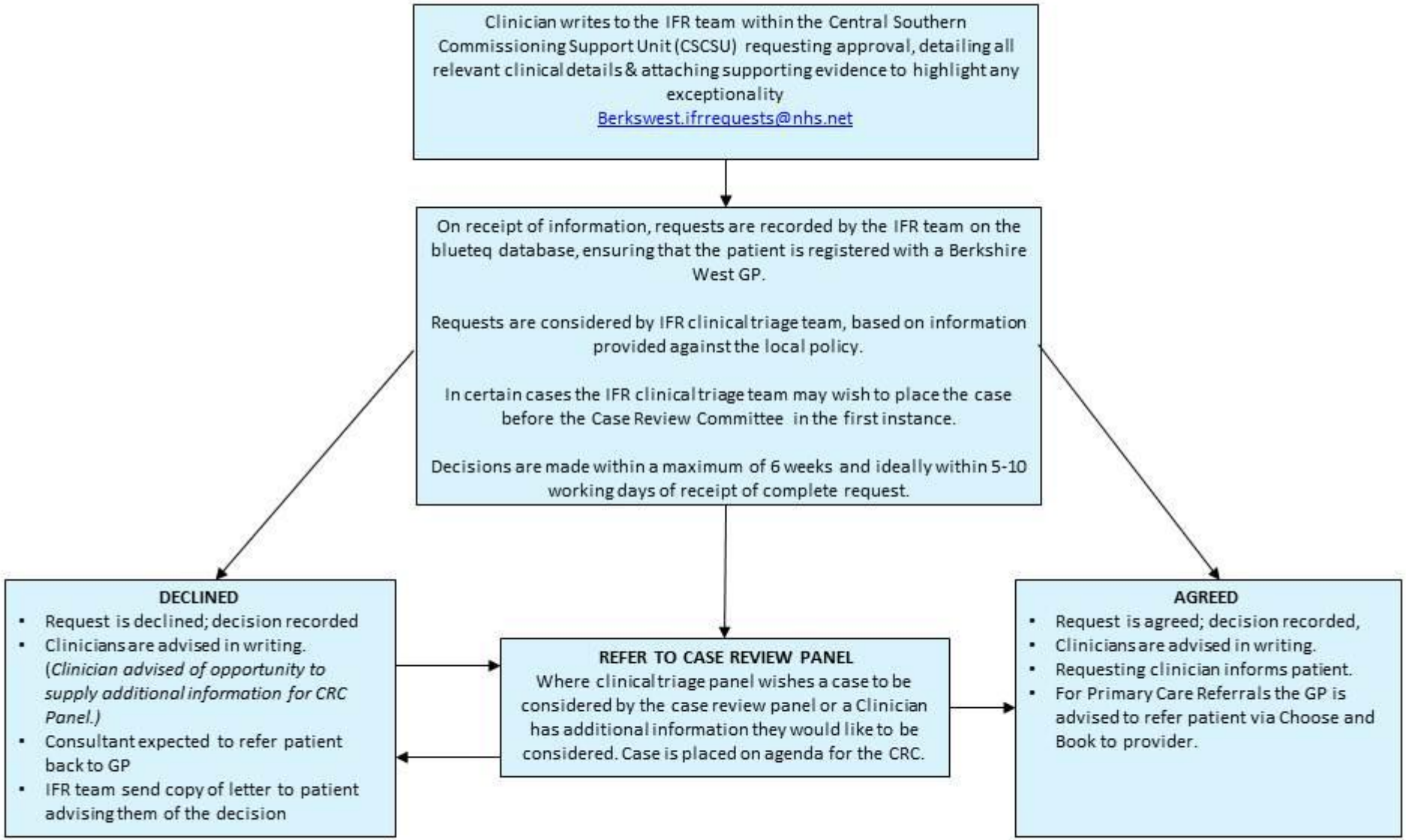
However a decision to proceed with treatment in advance of CTP/CRC consideration will be taken in these circumstances at the risk of the providing organisation and on the strict understanding that Berkshire West CCGs may not ultimately fund the proposed care/treatment/intervention, once due process has been followed.

However in general, retrospective funding will not be made available. All such applications must comply with the requirements of this policy statement and will be assessed in the same way as other applications.

Appendix 1: Flowchart1: Depicting process for Individual Funding Requests



APPENDIX 1- BERKSHIRE WEST PRIOR APPROVAL PROCESS



NHS Aylesbury Vale Clinical Commissioning Group
NHS Bracknell and Ascot Clinical Commissioning Group
NHS Chiltern Clinical Commissioning Group
NHS Newbury and District Clinical Commissioning Group
NHS North and West Reading Clinical Commissioning Group
NHS Oxfordshire Clinical Commissioning Group
NHS South Reading Clinical Commissioning Group
NHS Slough Clinical Commissioning Group
NHS Windsor, Ascot and Maidenhead Clinical Commissioning Group
NHS Wokingham Clinical Commissioning Group

THAMES VALLEY PRIORITIES COMMITTEE
ETHICAL FRAMEWORK

Background

A primary responsibility of the commissioners of NHS health care in England is to make decisions about which treatments and services should be funded for their designated populations. This includes making decisions about the continued funding of currently-commissioned treatments and services, as well as the introduction of new treatments and approaches to the delivery of care.

Commissioners are subject to a statutory duty not to exceed their annual financial allocation. Further, despite an incremental increase in funding, the NHS needs to make substantial financial savings in order to continue to meet increasing demands for care and treatment[1]. As the demand for NHS health care exceeds the financial resources available, commissioners are faced with difficult choices about which services to provide for their local populations.

The Priorities Committee has representatives of the NHS organisations across ten Thames Valley Clinical Commissioning Groups (CCGs) and includes lay members as well as clinicians and managers. The purpose of the Priorities Committee is to make recommendations, in the form of policies, to the local CCGs as to the services and health care interventions that should or should not be funded.

To help in this process, health care commissioners in the Thames Valley region have developed a decision-making tool - the 'Ethical Framework', to facilitate fairness and transparency in the priority-setting process. The Ethical Framework was originally developed in 2004 by the NHS public health organisation Priorities Support Unit (now Solutions for Public Health2) and the Berkshire PCTs. Since then, the Framework has been revised to take account of policy developments in the NHS and changes in the law, and has been adopted more widely.

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[1] *The NHS Belongs to the People – A Call to Action*. NHS England, London, 2013, 15 and The Spending Review settlement for healthcare: Health Select Committee, December 2010 http://www.publications.parliament.uk/pa/cm201011/cmselect/cmhealth/512/51208.htm

[2] http://www.sph.nhs.uk/ebc/about-us

The purpose of the Ethical Framework

The purpose of the ethical framework is to support and underpin the decision making processes of constituent organisations and the Priorities Committee to support consistent commissioning policy through:

- Providing a ***coherent structure*** for the consideration of health care treatments and services to ensure that all important aspects are discussed.
- Promoting fairness and consistency in decision making from meeting to meeting and with regard to different clinical topics, reducing the potential for inequity.
- Ensuring that the principles and legal requirements of the NHS Constitution[3] and the Public Sector Equality Duty [4]are adhered to.
- Providing a transparent means of expressing the reasons behind the decisions made to patients, families, carers, clinicians and the public.
- Supporting and integrating with the development of CCG Commissioning Plans.

Formulating policy recommendations regarding health care priorities involves the exercise of judgment and discretion and there will be room for disagreement both within and outwith the Committee. Although there is no objective measure by which such decisions can be based, the Ethical Framework enables decisions to be made within a consistent setting which respects the needs of individuals and the community.

The following Ethical Framework consists of 8 principles or relevant considerations that will be taken into account in the development of each recommendation. It does not prejudge the weight that any one consideration is given nor does it require that all should be given equal weight.

1. EQUITY

The Committee believes that people should have access to health care on the basis of need. There may also be times when some categories of care are given priority in order to address health inequalities in the community.

However, the Committee will not discriminate, or limit access to NHS care, on grounds of personal characteristics including: age, race, religion, gender or gender identity, sex or sexual orientation, lifestyle, social position, family or financial status, pregnancy, intelligence, disability, physical or cognitive functioning. However, in some circumstances, these factors may be relevant to the clinical effectiveness of an intervention and the capacity of an individual to benefit from the treatment.

[3] The NHS Constitution
http://www.nhs.uk/choiceintheNHS/Rightsandpledges/NHSConstitution/Pages/Overview.aspx
[4] The Public Sector Equality Duty
http://www.equalityhumanrights.com/uploaded_files/EqualityAct/PSED/essential_guide_update.pdf ;
http://www.legislation.gov.uk/uksi/2011/2260/pdfs/uksi_20112260_en.pdf

2. HEALTH CARE NEED AND CAPACITY TO BENEFIT

Health care should be allocated justly and fairly according to need and capacity to benefit. The Committee will consider the health needs of people and populations according to their capacity to benefit from health care interventions. As far as possible, it will respect the wishes of patients to choose between different clinically and cost effective treatment options, subject to the support of the clinical evidence.

This approach leads to three important principles:

- In the absence of evidence of health need, treatment will not generally be given solely because a patient requests it.
- A treatment of little benefit will not be provided simply because it is the only treatment available.
- Treatment which effectively treats “life time” or long term chronic conditions will be considered equally to urgent and life prolonging treatments.

3. EVIDENCE OF CLINICAL EFFECTIVENESS

The Committees will seek to obtain the best available evidence of clinical effectiveness using robust and reproducible methods. Methods to assess clinical and cost effectiveness are well established. The key success factors are the need to search effectively and systematically for relevant evidence, and then to extract, analyse, and present this in a consistent way to support the work of the Committee. Choice of appropriate clinically and patient-defined outcomes need to be given careful consideration, and where possible quality of life measures should be considered.

The Committees will promote treatments and services for which there is good evidence of clinical effectiveness in improving the health status of patients and will not normally recommend treatment and services that cannot be shown to be effective. For example, is the product likely to save lives or significantly improve quality of life? How many patients are likely to benefit? How robust is the clinical evidence that the treatment or service is effective?

When assessing evidence of clinical effectiveness the outcome measures that will be given greatest importance are those considered important to patients’ health status. Patient satisfaction will not necessarily be taken as evidence of clinical effectiveness. Trials of longer duration and clinically relevant outcomes data may be considered more reliable than those of shorter duration with surrogate outcomes. Reliable evidence will often be available from good quality, rigorously appraised studies. Evidence may be available from other sources and this will also be considered. Patients’ evidence of significant clinical benefit is relevant.

The Committee will also take particular account of patient safety. It will consider the reported adverse impacts of treatments and the licence status of medicines and the authorisation of medical devices and diagnostic technologies for NHS use.

4. EVIDENCE OF COST EFFECTIVENESS

The Committees will seek information about cost effectiveness in order to assess whether interventions represent value for money for the NHS. The Committees will compare the cost of a new treatment to the existing care provided and will also compare the cost of the treatment to its overall benefit, both to the individual and the community. The Committee will consider studies that synthesise costs and effectiveness in the form of economic evaluations (e.g. quality adjusted life years, cost-utility, cost-benefit. as they enable the relationship between costs and outcomes of alternative healthcare interventions to be compared, however, these will not by themselves be decisive.

Evidence of cost effectiveness assists understanding whether the NHS can afford to pay for the treatment or service and includes evidence of the costs a new treatment or service may release.

5. COST OF TREATMENT AND OPPORTUNITY COSTS

Because each CCG is duty-bound not to exceed its budget, the cost of a treatment must be considered. A single episode of treatment may be very expensive, or the cost of treating a whole community may be high. This is important because of the overall proportion of the total budget: funds invested in these areas will not be available for other health care interventions.

The Committees will compare the cost of a new treatment to the existing care provided, and consider the cost of the treatment against its overall health benefit, both to the individual and the community. As well as cost information, the Committees will consider the numbers of people in their designation populations who might be treated.

6. NEEDS OF THE COMMUNITY

Public health is an important concern of the Committee and they will seek to make decisions which promote the health of the entire community. Some of these decisions are promoted by the Department of Health (such as the guidance from NICE and Health and Social Care Outcomes Framework). Others are produced locally. The Committee also supports effective policies to promote preventive medicine which help stop people becoming ill in the first place.

Sometimes the needs of the community may conflict with the needs of individuals. Decisions are difficult when expensive treatment produces very little clinical benefit. For example, it may do little to improve the patient's condition, or to stop, or slow the progression of disease. Where it has been decided that a treatment has a low priority and cannot generally be supported, a patient's doctor may still seek to persuade the CCG that there are exceptional circumstances which mean that the patient should receive the treatment.

7. NATIONAL POLICY DIRECTIVES AND GUIDANCE

The Department of Health issues guidance and directions to NHS organisations which may give priority to some categories of patient, or require treatment to be made available within a given period. These may affect the way in which health service resources are allocated by individual CCGs. The Committee operates with these factors in mind and recognise that their discretion may be affected by Health and Social Care Outcomes Frameworks[5], NICE technology appraisal guidance, Secretary of State Directions to the NHS and performance and planning guidance.

Locally, choices about the funding of health care treatments will be informed by the needs of each individual CCG and these will be described in their Local Delivery Plan.

8. EXCEPTIONAL NEED

There will be no blanket bans on treatments since there may be cases in which a patient has special circumstances which present an exceptional need for treatment. Individual cases are considered by each respective CCG. Each case will be considered on its own merits in light of the clinical evidence. CCGs have procedures in place to consider such exceptional cases through their Individual Funding Request Process.

Thames Valley Priorities Committee Working Group

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[5] https://www.gov.uk/government/collections/health-and-social-care-outcomes-frameworks

Appendix 3: Exceptionality Policy and Definitions

Introduction

This appendix includes important information for clinicians submitting cases for funding of individual patients. It provides the definition of exceptionality which all requests should be measured against.

Central to the consideration of exceptionality in the case of individual patients is the question: '*Why should this treatment be provided for this patient when the treatment in question is not routinely funded?'* The clinical circumstances of the patient must therefore be fully established to determine if there is a basis for approving treatment when other patients, who have the same (or a substantively similar) condition, would not be routinely funded.

Definition of exceptionality

For funding to be agreed by Berkshire West CCGs, the following must apply:

- The patient is significantly clinically different to the general population of patients with the condition in question, ***because***
- the patient is likely to gain significantly more clinical benefit from the intervention than might be normally expected for patients with that condition (or the patient will be significantly more clinically disadvantaged by not receiving this treatment, than would be normally expected for patients with that condition)

Applications may also be submitted to the IFR team on the basis that there is no specific local or national policy related to the treatment but the treatment is not one that is routinely available to other patients in the Berkshire West population (and therefore requires specific funding approval by the CTP/CRC for the individual patient). These applications will also be assessed on the basis of clinical exceptionality, given that the treatment is not routinely available to others.

For treatments where there is not an existing policy, a further test will be applied to all applications which will assess the cost-effectiveness of the treatment. In the absence of an existing policy, it is likely that the evidence base demonstrating the clinical effectiveness may not be clear-cut and Berkshire West CCGs reserve the right to assess the extent to which, even if exceptionality is demonstrated, the treatment will generate health outcomes that justify providing NHS funding for the intervention.

Requests which do not meet the clinical exceptionality criteria will not be approved by Berkshire West CCGs. The fact that a treatment is likely to be efficacious for an individual is not in itself a reason for Berkshire West CCGs to provide funding.

It should be noted that social circumstances are unlikely to constitute exceptional clinical circumstances meriting approval by Berkshire West CCGs. The focus of consideration will be *clinical* exceptionality in order to demonstrate that the above criteria are met.

Additional evidence in support of exceptionality

The following is intended to provide further clarification on how clinical exceptionality is to be defined in specific circumstances:

Psychological distress

If psychological distress is cited as a reason for treatment to be funded, the following information should be supplied:

- the extent of psychological distress confirmed in a formal documented diagnosis by the treating psychiatrist. This evidence will need to document the resultant impact on activities of daily living, and
- written confirmation from the treating psychiatrist that the requested treatment will directly resolve the condition being treated by the psychiatrist and how this will be demonstrated in improvement of the patient's daily living. The clinician will be expected to provide evidence for their case.

Mobility

If Mobility is cited as a reason for treatment to be funded, the following information should be supplied:

- assessment by a physiotherapist (+/- Occupational Therapist) documenting the current inability to mobilise as a result of the condition, and
- confirmation by the proposed treatment provider of the expected gains to be made in relation to mobility such that this patient could be considered to be substantially improved by the intervention proposed. The clinician will be expected to provide evidence to support their case.

Activities of Daily Living

If Activities of Daily Living (ADL) is cited as a reason to support funding, the following information should be supplied:

- assessment by an Occupational Therapist (+/-Physiotherapist) documenting the current level of disability in this area as a result of the condition, and
- confirmation by the proposed treatment provider of the expected gains to be made such that this patient could be considered to be substantially improved in relation to ADL as a direct result of the intervention. The clinician will be expected to provide evidence for their case.

Appendix 4: Key Contacts for submission of Individual Funding Requests or Appeals

IFR requests should be submitted to the following:
IFR Team
Central Southern Commissioning Support Unit
57-59 Bath Road
Reading
RG30 2BA
Direct Line: 0118 982 2828
Email: berkswest.ifrrequests@nhs.net

Appeals Panel for IFR requests:
Appeals Panel
Central Southern Commissioning Support Unit
57-59 Bath Road
Reading
RG30 2BA
Direct Line: 0118 982 2828

Requests for individual funding should not be directed to the PALS team. However, the service is available to provide advice for individuals where needed.

Patient Advice and Liaison Service
PALS
Central Southern Commissioning Support Unit
KEVII Hospital
St Leonards Road
Windsor
Direct Line: 01753 636808

Complaints
Complaints Manager
Central Southern Commissioning Support Unit
57-59 Bath Road
Reading
RG30 2BA
Tel: 0118 982 2874 **or** Email:

feedback.wokinghamccg@nhs.net
feedback.newburyccg@nhs.net
feedback.nwreadingccg@nhs.net
feedback.sreadingccg@nhs.net

Appendix 5: Terms of Reference: Case Review Committee

NHS Newbury and District Clinical Commissioning Group
NHS North and West Reading Clinical Commissioning Group
NHS South Reading Clinical Commissioning Group
NHS Wokingham Clinical Commissioning Group

Purpose
Berkshire West CCGs Case Review Committee (CRC) has been established as a committee of the CCG Boards, to deal with funding requests for individual patients.

The circumstances in which cases will be considered by the CRC are set out in the CCG's policy statement related to Individual Funding Requests.

Responsibility
The CRC has delegated responsibility from the CCG Boards for decision making in accordance with this policy and its Terms of Reference where:

a) the evidence base of clinical effectiveness of a particular treatment is low for the general population and therefore it is not routinely commissioned.

b) only patients who meet specific criteria will derive benefit from an intervention.

Membership
The CRC will include (all are voting members of the Committee):

- CCG Lay Member x 2 (one to Chair)
- Consultant in Public Health - Health Care Priorities
- GP representative x 2 nominated by the CCG Boards
- Operations Director
- Member of the medicines Management Team.

Administrative support to the meetings of the CRC will be provided by the CSU, in attendance only with no voting rights. The CRC will be chaired by one of the Lay Members.

Frequency of meetings
CRC will meet at least monthly. Additional meetings may be scheduled more frequently if needed, as indicated by request caseload and at the discretion of the CCGs.

Where necessary for reasons of expediency, virtual meetings will be carried out by telephone, fax or email as necessary. These are not normally a substitute for routine meetings of the CRC but will be used only in unavoidable circumstances so as not to compromise the pace of decision-making for urgent individual cases. In such circumstances a decision will be taken on a consensus view; with the final decision endorsed by the Chair of the CRC and confirmed by the membership for the record.

Training
The Committee members will undertake regular training to ensure they remain up to date with key requirements, policies and general information in relation to good practice with decision-making of IFRs.

New members of the Committee will complete an appropriate induction prior to having voting rights.

Quoracy
In order to be quorate, meetings of the Committee must be attended by a minimum of four of the members. Two of these attendees should have a clinical background and at least one of these should be a GP.

Deputies for members of the committee will not usually be permissible to ensure appropriately trained and experienced personnel are available to make informed decisions.

Voting arrangements
The CRC Chair will have the casting vote in the event of a tied vote.

Role and Key Tasks
The role of the CRC is to:

- To consider individual funding requests put to the Committee in accordance with its terms of reference
- Consider if the CCGs' full requirements for statement of clinical exceptionality – as defined in the policy – have been demonstrated within the case submitted for consideration of funding
- Undertake its decision-making about the IFR in line with the CCGs' Ethical Framework
- Ensure it is consistent in its decision making

Process

- All patient-level information will be dealt with in confidence by members of the CRC. This will entail adhering to strict confidentiality practices in relation to the transmission of data and in the way in which information on cases is handled, both written and verbally.
- Anonymised patients' case summaries will be sent to the CRC members in advance of the meeting.
- The CRC will consider each request in the context of the relevant policy where this exists or as a "treatment not routinely commissioned" where there is no explicit policy.
- The request will be considered on the basis of patients' exceptional clinical circumstances. These are the only circumstances in which decision to fund can be taken.
- Where there appears to be no evidence that the clinical circumstances of the patient's case are exceptional when compared with other patients who have the same or a substantively similar condition, funding will not be approved.
- Information or guidance may be requested by subject experts if appropriate and the decision deferred until the "expert" information has been received.
- Members of CRC who have an interest to declare with regard to a particular patient or clinical condition will identify themselves and will be excluded from the discussion of that case. This will include a personal or professional interest in the case.
- If the requesting clinician or patient is unhappy with the CRC decision they have two options open to them:
    a) If the doctor or patient feels that they have further relevant information available which has not been considered by the CRC, they may ask the CRC to reconsider the case specifically in the light of this further information. This may be undertaken at the CCGs' discretion and depending upon the CCGs Operations Directors / Public Health team agreeing that the additional information is relevant to the exceptionality case.
    b) If the doctor or patient feels that all the relevant information was available to the CRC Panel when the decision was made, but they remain unhappy with the decision, they may ask for it to be reviewed by the Appeals Panel.

- There is no right of attendance by the requesting clinician, the patient or their representative at the CRC.

Outcomes of CRC meetings

The CCGs will communicate CRC decision and the supporting outline reasons in writing to both the referring clinician and the patient, normally within five working days.

Role of the CSU

- The CSU will manage a process for receiving IFRs
- The CSU will maintain a log of all requests, outcomes of the CRC and Appeals Committee and a correspondence log.
- The CSU will prepare papers for the CRC and Appeals Committee, liaising with all relevant parties as required
- The CSU will prepare letters to patients and referring clinicians for signature by the Committee Chair.
- The CSU will provide administrative support to the committee meetings.

Appendix 6: Terms of Reference: Appeals Panel

NHS Newbury and District Clinical Commissioning Group
NHS North and West Reading Clinical Commissioning Group
NHS South Reading Clinical Commissioning Group
NHS Wokingham Clinical Commissioning Group

Purpose
The Appeals Panel has been established by the CCG Boards to consider formal appeals against Case Review Committee (CRC) decisions.

The role of the Appeals Panel is to consider whether:

- The decision making process was followed appropriately and the CRC met the required standards set out in the policy.
- The decision made by the CRC was unreasonable in light of the available evidence and individuals circumstances.
- The CRC took into consideration immaterial factors.
- Any other relevant factor in relation to the case.

Accountability
The Panel is accountable to the Board and has delegated responsibility from the Board to consider Appeals in accordance with the IFR policy and to take decisions accordingly, in line with its Terms of Reference.

Membership
Membership of the Appeals Panel is as follows:

- Nominated CCG Lay Member x 2 (one to Chair)
- Director of Public Health or designated PH consultant
- GP x 2 nominated by the CCG Boards
- Operations Director

Administrative support to the meetings of the CRC will be provided by the CSU and will be in attendance only with no voting rights.

As a matter of principle, none of the above members will simultaneously be members of the Case Review Committee or have taken part in the original decision-making related to cases going to that Appeals Panel. This will ensure that the Appeals Panel is undertaking an objective assessment of the decision-making undertaken for an individual case by the CRC.

Frequency of meetings
The Appeals Panel will be convened when necessary to consider appeals against CRC decisions. The date will usually be set as soon as possible after a request has been received but within maximum of 4 weeks.

Process

- Individuals wishing to appeal against a CRC decision must notify the CSU administrator of their intention, in writing, within three months of the date of the CRC meeting. All appellants will be given information about the Patient Advice Liaison Service (PALS) and the Independent Complaints Advocacy Service (ICAS) for additional support.
- The Appeals Panel will consider whether the original decision of the Case Review Committee followed due process (see below – Role and key tasks).

- The individual requesting the appeal and/or their clinician does not have the right to attend the Appeals Panel meeting in person. All evidence to be considered must be submitted in writing.
- The CSU will provide the Appeals Panel with a case summary and papers from the case file. It is important to note that the Appeals Panel will not consider new information in support of a case. If new information becomes available, the Case Review Committee will be asked to reconsider the case in the light of this.
- Information or guidance may be requested by subject experts if appropriate and the decision deferred until the "expert" information has been received.
- Following the Appeals Panel decision, patients still have the right to complain under the Complaints Procedure.

Role and key tasks
The role of the Panel is to ensure that the CCGs' policy and process has been applied appropriately by the Case Review Committee.

The Appeals Panel will adopt the following approach:

- A review of information considered by the Case Review Committee in reaching their original decision.
- Did the CCGs correctly follow their own procedures and policy?
- Were all relevant facts taken into account when the decision was made?
- Consider the decision of the CRC that exceptionality was not demonstrated.
- Consider whether that decision is consistent with CCGs exceptionality policy and was reasonable on the basis of the information supplied by the appellant in the first instance.
- Consider if there are sufficient grounds for overturning that decision on the basis that clinical exceptionality has been demonstrated.

Quoracy
In order to be quorate, each meeting of the Panel shall be attended by at least three of the members. At least one of these attendees shall be a clinician (primary care or public health).

Deputies may be permitted at the discretion of the Chair.

Training
The committee members will undertake regular training to ensure they remain up to date with key requirements, policies and general information in relation to good practice with decision-making of IFRs.

New members of the committee will complete an appropriate induction prior to having voting rights.

Outcomes of Appeals
If the Panel finds that the decision of the CRC was correct, ie that exceptionality was not demonstrated, they will dismiss the appeal.

If the Panel finds that some aspect of the CCGs' procedure or policy was not followed, the Panel will assess the significance of the procedural breach and decide on the appropriate action. This will not automatically result in the Appeal being upheld.

If the Panel finds that important facts were not taken into account, they may refer the case back to Case Review Committee for re-consideration.

The decision of the Appeals Panel will be recorded, together with the reasons. Appeals Panel decisions will be communicated to the appellants within 5 working days.

Appellants who remain dissatisfied with the outcome of the Appeals process may pursue their case through the formal complaints procedure.

The CSU will submit monthly reports to the CCG Boards, including the updated position on cases approved at Case Review Committee and at Appeals Panel.

Feedback from the Appeals Panel to CRC

Where the Appeals Panel does not uphold a decision made by the Case Review Committee, it is usual for:

- A statement to be made back to the CRC outlining why the original decision was not upheld.
- A note made of any key principle or process that is expected to be applied in the future.