**Appendix 3**

**Standard Operating Procedure for the management of**

**Individual Funding Requests**

**January 2016**

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# Introduction

1.1 This document sets out the principles and process for individual funding requests i.e. requests for treatments that fall outside the usual (CCG) commissioning contracts and service level agreements. The CCG’s Individual Funding Request (IFR) Panel is established to consider these exceptional funding requests and to ensure that decisions made are equitable, represent value for money and are in the interest of the whole population.

1.2 A key element of this will be consideration of the cases on the basis of evidence of effectiveness, cost effectiveness, impact on health and affordability, ensuring that the CCG has a robust process in place to ensure compliance with the NHS Constitution, CQC Regulations Essential Standards of Quality and Safety and other statutory regulations.

1.3 The purpose of this procedure is to:

* Set out the process for handling individual funding requests.
* Clarify the decision making criteria against which requests are judged.
* Set out the appeals process that can be invoked as necessary.

1.4 This procedure applies to all written individual funding requests for treatments for the registered population of Gloucestershire, provided through primary care (General Practitioner services), secondary care (hospital services), tertiary (specialist) care and community services

1.5 This document should be read in conjunction with the following policies and documents:

* Ethical Framework Policy
* Experimental and Unproven Treatments Policy
* Individual Funding Request Policy
* Terms of Reference for the Individual Funding Request Panel
* Standard Operating Procedure for Prior Approval Funding Requests
* The Effective Clinical Commissioning Policies list
* Appeals Procedure

1.6 All relevant documents are available on the NHS Gloucestershire CCG website - <http://www.gloucestershireccg.nhs.uk/about-us/funding-treatment/interventions-not-normally-funded/>

# Managing Individual Funding Requests: The IFR Process

This section sets out the procedure for managing IFR requests.

# 2.1 Submitting an IFR

2.1.1 The managing clinician must first consult the CCG’s current commissioning policy statements to establish that the patient’s treatment does not fall within current treatment policies and commissioning responsibilities.

2.1.2 If the treatment is not normally funded the clinician needs to submit an individual funding request application to the Panel in liaison with the patient. Applications will only be accepted from clinicians or other health care professionals involved in the care of the patient.

2.1.3 Individual funding requests must be submitted on the standard application form to ensure that the Individual Funding Request Panel receive all the relevant information in order to make a decision. The application needs to be submitted electronically to ensure legibility. The same application form is used for requests for equipment, drugs, surgery or other treatments that fall outside of existing commissioning contracts.

2.1.4 The information required includes the following:

* Clinical circumstances of the patient
* Treatment/intervention requested, expected benefits and risks of treatment
* Reasons why the patient’s clinical circumstances are ‘exceptional’ or should otherwise lead to the CCG agreeing to an intervention outside of normal commissioning arrangements
* Evidence on which the clinical opinion is based
* The cost of treatment (if available/known) and length of treatment (number of treatment episodes, length of in-patient stay, etc)
* Whether there are likely to be similar patients within the CCG population

2.1.5 It is the responsibility of the referring clinician to provide sufficient clinical evidence in the form of hard copies of research papers or other documentary evidence to support the application. Where appropriate, supporting letters from the patient, clinical specialists or other health or social care professionals involved in the patients’ care should also be included.

2.1.6 Completed applications should be e-mailed to the address specified on the application form.

# 2.2 Administration

2.2.1 On receipt of an IFR application key information about the application, including the date of receipt, patient information, referring clinician and treatment requested, is entered onto the CCG IFR database by the IFR administrator.

2.2.2 All decisions will be fully documented and all communications from the IFR team will be confirmed by email/letter.

2.2.3 Records will be retained and processed in accordance with appropriate NHS policies regarding confidentiality and retention and disposal or records.

# 2.3 Timescales for managing an IFR

2.3.1 The standard response time for dealing with an IFR request is 40 working days from the date of receipt of the completed IFR application form to the date of the letter from the CCG informing the requesting clinician of the funding decision. This will exclude any days where the IFR team is awaiting information sought from the referring clinician or other external source. If there is a delay for any other reasons the referring clinician will be notified.

# 2.4 Initial assessment of an IFR application

2.4.1 All funding applications are considered via a Triage Panel. The Triage Panel is made up of the IFR Manager (or nominated deputy) and a medical advisor (usually a GP). Where appropriate advice will be sought from relevant commissioning leads to inform the triage process. In these circumstances the commissioning lead’s role is purely advisory and the final decision on how to manage the application will be made by the Triage Panel. The Triage Panel is authorised to make the following decisions:

* Return the application if the CCG does not have a responsibility for commissioning the care requested for the individual patient.
* Return the application if the treatment is covered by an existing contract with a provider or covered by a Criteria Based Access policy where the patient meets the criteria, with an explanation that funding approval is not required.
* Reject the application if other standard treatments are commissioned for the condition that have not yet been tried.
* Reject the application if there is a cohort of patients (as defined within Appendix 5 of the IFR Policy) as this should be treated as a service development proposal.
* Request further information in order to give the referring clinician every opportunity to describe any circumstances that may indicate that the patient is an exception to the CCG policy
* Reject the application if it does not demonstrate sufficient clinically exceptional circumstances to be considered by the Panel as an IFR.
* Refer the case to the IFR panel for a decision on exceptionality

2.4.2 Where there is uncertainty or doubt about the application of the IFR policy, the case will be referred to the IFR Panel.

2.4.3 All decisions made by the Triage Panel will be recorded on the IFR database. The IFR Manager will produce a bi-monthly report on Triage Panel decisions that will be presented to the IFR Panel for review to provide assurance that intra-IFR panel decision making is consistent and fair.

2.4.4 If further information is requested from the referring clinician or other external source to support the case, the 40 working day timeline for responding to the IFR is suspended until that information is received. The referring clinician will be informed that the clock has been suspended.

2.4.5 The decisions of the Triage Panel will be communicated directly to the referring clinician and/or the patient’s GP (if this is not the same person). The patient/guardian/carer will be copied in to the response letter, unless the clinician making the request has indicated that it is not clinically appropriate to do so.

2.4.6 If a request is declined by the Triage Panel the IFR policy does not provide a right of appeal to the IFR Panel. The Triage Panel will always review a case should more clinical information be presented by the referring clinician. If the patient disagrees with the commissioning policy he/she has a right to make a complaint under the NHS Complaints Procedure.

# 2.5 The IFR Panel

2.5.1 The IFR Panel will meet a minimum of ten times a year. The Panel acts as a formal sub-committee of the Integrated Governance and Quality Committee. It has the authority to make exceptions to the Commissioning Policies of the CCG and thus commit financial resources within the frameworks agreed. The Panel will report its decisions to the Integrated Governance and Quality Committee on an annual basis or earlier if significant risk issues identified. The terms of reference for the panel are attached at appendix 1.

# 2.6 Membership of the Panel

2.6.1 Membership will consist of the following:

* Lay worker (Chair)
* Lay worker
* Two from the following list of clinically qualified members
  + Chair of Gloucestershire Clinical Commissioning Group Board or their nominated deputy
  + Executive Nurse & Quality Lead or nominated deputy [clinical]
* Chief Finance Officer, Director of Integration or Director of Commissioning Implementation or their nominated deputy
* Public Health Consultant or nominated deputy
* IFR Manager (non-voting member)
  + 1. The Panel will be quorate if 3 members are present and with at least:
* One Lay worker
* One Director or nominated deputy from Commissioning Implementation, Integration or Finance
* One clinically qualified member
  + 1. The Chair of the Panel is approved by the CCG Board. One of the members will be appointed Vice Chair by the Panel. Expert advisors may be invited as necessary to advise the Panel but will not have a role in the decision making.
    2. Decisions are made by consensus. If consensus cannot be reached, decisions are made by simple majority voting, with each Panel member having one vote and the Chair having the casting vote.

# 2.7 Patient representation at the IFR Panel

2.7.1 Where the application is to be considered by the IFR Panel, the patient will have a choice in how to be represented. A patient may choose to represent themselves or be represented by their clinician or another chosen person (although not a legal representative acting in a professional capacity). Patients may be accompanied, but not by someone acting in a legal capacity. Patients may also choose not to be represented.

2.7.2 If a patient chooses to be represented, they are to be advised that the IFR panel meets on set dates and these cannot be changed to suit attendance. If a patient or their representative is unable to attend on the allocated panel date, the patient can choose to delay their hearing until the next panel date or to allow the hearing to go ahead on the allocated date without representation.

2.7.3 A patient or representative will be allocated ten minutes at the panel meeting to present their case to the panel followed by an opportunity for the panel to ask any questions. There will be no opportunity for the patient to question the panel during the meeting.

2.7.4 Patients will have an identified point of contact throughout the application process.

# 2.8 Format of meetings

2.8.1 Panel meetings will be scheduled on a rolling programme at least 6 months in advance. The IFR Manager will book cases onto the next available meeting date and contact the referring clinician to ask if they wish to submit any further information. The IFR Manager will also contact the patient to inform them of the panel date and determine whether they wish to attend in person.

2.8.2 The IFR Manager will ensure that case files are prepared for the Panel meeting, providing all the documentation that has been received regarding the request in an anonymised form to protect confidentiality.

2.8.3 When relevant, the Panel will receive and consider a briefing of the evidence-base supporting the requested treatment or intervention, prepared by the public health team.

# 2.9 Urgent IFR decisions

2.9.1 It is recognised that occasionally urgent decisions are required. In such instances, the IFR Panel will consider cases outside of scheduled meetings, using fax/email/telephone conference facilities as necessary, as set out in the Individual Funding Request Policy. Despite urgent circumstances, no members of the Individual Funding Request Panel can normally make decisions on their own, and it is recommended that urgent decisions are delegated by the Chair of the Individual Funding Request Panel to, as a minimum, an Executive Director or a designated deputy, medically qualified representative of the Panel and a Lay worker.

2.9.2 In exceptional circumstances an executive director of the CCG can make a decision on an urgent request as set out in the Individual Funding Request Policy.

# 2.10 Decision making

2.10.1 The IFR Panel will be guided by the the summarised decision making check list (Appendix 2). The IFR Panel shall be entitled to approve requests for funding for treatment for individual patients where the following conditions (1-5 and either 6 or 7) are met:

1. The IFR Panel concludes that there are likely to be no similar patients to the requesting patient.
2. There is sufficient evidence (see appendix 3 for levels of evidence) to show that, for the individual patient, the proposed treatment is likely to be clinically and cost-effective (taking note of any possible harm).
3. Treating the patient is higher priority than other unfunded developments (see CCG commissioning strategy and list of low priority interventions) and the treatment can be afforded.
4. The IFR Panel is guided by the Ethical framework as set out in the Ethical Framework Policy.
5. The Panel has adequate information upon which to base its decisions provided through the standard application form.
6. **Individual Requests** - The IFR Panel will apply paragraphs 2.5, 2.6, 2.7 and 2.8 of the Experimental and Unproven Treatments Policy when considering individual requests for off-licensed or unlicensed use of a drug or other unproven treatments for the clinical condition under consideration.
7. **Exceptional Requests** - Exceptional clinical circumstances refers to 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 the same stage of progression as the patient

2.10.2 The IFR Panel will consider exceptionality in the context of the relevant commissioning policy statements and policies.

2.10.3 The IFR Panel will apply the guidance on exceptional clinical circumstances as defined in the Individual Funding Request Policy.

# 2.11 Outcome of the IFR Panel

2.11.1 The Individual Funding Request Panel can make one of four different decisions regarding individual funding requests:

1. Support the application for funding.
2. Defer a decision pending further information/investigation.
3. Decline to support the application.
4. Decline to support the application as an individual request due to the likely existence of ‘Similar Patients’ but refer to be considered as a service development/in-year service development as part of the normal commissioning process.

Whenever possible the panel will seek to make a decision on the day the panel sits (unless there is a need to request supplementary information).

2.11.2 The referring clinician will be informed of the Panel’s decision within 15 working days.

2.11.3 The decisions of the Panel will be communicated directly to the referring clinician and/or the patient’s GP (if this is not the same person). The patient/guardian/carer will be sent a separate letter with advice to contact their GP to discuss the recommendation of the Panel; unless the clinician making the request has indicated that it is not clinically appropriate to do so.

2.11.4 If funding is agreed the CCG will expect a mechanism to be in place for the referring clinician to monitor the clinical outcome of the treatment in order to determine whether it has resulted in benefit for the patient. An appropriate review date will be determined by the panel and the referring clinician will be informed of this date. The IFR Manager will ensure that feedback on outcomes is requested in line with this timescale and reported back to the IFR Panel. Provider trusts and clinicians are expected to comply with such requests for information on the outcome for their patient. If this information is not available on request it may affect future funding decisions for the continuation of treatment.

2.11.5 In line with the NHS constitution, it is expected that agreed treatment will normally start within 18 weeks of the application being supported. There may be legitimate clinical or patient choice factors which may require that the planned treatment does not start within 18 weeks. For this reason, the Panel decision is valid for the treatment to commence within a 12 month period from the decision. If for any reason the treatment is not started within 12 months from decision, the applicant will be required to seek re-authorisation of funding from the Panel.

# 2.12 Re-submission of an application

2.12.1 If the request for funding has been refused by the Panel, the referring clinician can re-submit the case if new information of a material nature is available to the panel. If this information is deemed ‘new evidence’ by the triage meeting it will be considered at the next available meeting of the Panel. Re-submissions with additional new evidence are accepted within six months of the original application. Otherwise a new application for the panel is necessary

# 2.13 Appeals

2.13.1 In the event that the referring clinician and/or patient wish to appeal against a decision made by the Individual Funding Request Panel, then the Appeals Procedure will be followed. Information on how to invoke the appeals process is included in all reply letters to the applicant in ‘not supported’ cases, and is available from the Individual Funding Request Panel administrator.

2.13.2 A patient and /or clinician wishing to appeal against the Panel decision must notify the IFR Panel administrator within one month of the date of the original decision giving reasons for the appeal. This notification will be forwarded to the Appeals Panel and a meeting will be convened within the established protocol.

2.13.3 If the client/applicant is unhappy with the outcome of the Appeals process, the CCG Complaints Procedure can be followed, information for which is available from the Patient Advice Liaison Service (PALS).

# 3.0 Availability

3.1 All the documents related to the Individual Funding requests are available on the CCG website and G-Care. If a different format of this procedure is required it can requested from the IFR Panel secretary.

# 4.0 Monitoring

4.1 Performance against expected service standards will be monitored throughout the year and reported to the Integrated Governance and Quality Committee as part of the IFR annual report. The key standards for the IFR process are as follows:

* Time from receipt of an IFR application to date of letter confirming the CCGs funding decision should not exceed 40 working days (excluding any time when the clock is suspended pending further information that has been requested from the referring clinician or other source) – Service standard 100%

4.2 The Panel will provide evidence of adherence to the NHS Constitution through its annual effectiveness review and audit against national good practice guidance. An annual effectiveness review will take place at the end of each financial year.

# 5.0 References

Defining Guiding Principles for Processes supporting Local Decision Making about Medicines (2009) Available from: <http://www.npc.co.uk/policy/resources/guiding_principles.pdf>

Supporting rational local decision-making about medicines (and treatments) A handbook of good practice guidance (2009). Available from: <http://www.npc.co.uk/policy/local/constitution_handbook.htm>

**Appendix 1**

**Individual Funding Request Panel Terms of Reference**

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| **1** | **Overview** |
| 1.1 | These terms of reference reflect the core standards of conduct as defined in the Code of Conduct for NHS managers. |
| 1.2 | The Panel adheres to the national good practice guidance in supporting rational local decision making about medicines and treatments1,2, therefore ensuring compliance with the NHS Constitution. These terms of reference reflect the role of the Panel in developing the individual funding process and ensuring that the use of resources and performance of the committee contributes towards putting national policy into practice and delivering targets. This includes compliance with the Care Quality Commission Essential Standard for Quality and Safety, Diversity and Equality and Information Governance standards.  1 Supporting rational local decision making about medicines and treatments; A handbook of good practice guidance. February 2009. National Prescribing Centre.  2 Defining guiding principles for processes supporting local decision making about medicines. January 2009. National prescribing Centre, commissioned by DoH |
| **2** | **Purpose of the Panel** |
| 2.1 | The primary role of the Individual Funding Request Panel is to provide assurance to the CCG board that resource allocation to all individual or exceptional funding requests, which do not fall under existing contracts, are equitable, represent value for money and are in the interests of the whole population, thereby supporting the delivery of the organisational objectives. |
| 2.2 | A key element of this will be consideration of the cases on the basis of evidence of effectiveness, safety, cost effectiveness, impact on health and affordability, ensuring that the CCG has a robust process in place to ensure compliance with the NHS Constitution, Standards for Better Health (CQC Regulations) and other statutory regulations. |
| 2.3 | The Individual Funding Request Panel has the delegated authority to make exceptions to the commissioning policies and healthcare contracts of the CCG and commit financial resources within the frameworks agreed. |
| 2.4 | The Panel also has a delegated responsibility for ensuring compliance with the core values of the NHS Constitution and contributing evidence towards elements of the Guiding Principles identified in the NHS Constitution Framework. |
| **3** | **Accountability** |
| 3.1 | The Individual Funding Request Panel operates as a formal sub-committee of the Integrated Governance and Quality Committee and this is reflected in the CCG Internal Controls framework. |
| 3.2 | The Individual Funding Request Panel operates in accordance with the CCG Standing Financial Instructions/Standing Orders and the Detailed Scheme of Delegation. |
| 3.3 | The Panel is authorised by the Board to investigate any activity within its terms of reference. It is authorised to seek any information it requires from any employee and all employees are directed to co-operate with any request made by the Panel. The Panel is authorised by the Board to obtain outside legal or other independent professional advice and to secure the attendance of outsiders with relevant experience and expertise if it considers this necessary. |
| 3.4 | The Individual Funding Request Panel Chair is directly accountable to CCG Chair. |
| **4** | **Membership and Quoracy** |
| 4.1 | Membership will consist of the following:   * Lay worker (Chair) * Lay worker * Two from the following list of clinically qualified members   + Chair of Gloucestershire Clinical Commissioning Group Board or their nominated deputy   + Executive Nurse & Quality Lead or nominated deputy * Chief Finance Officer, Director of Integration or Director of Commissioning Implementation or their nominated deputy * Public Health Consultant or nominated deputy * IFR Manager (non voting member) or nominated deputy |
| 4.2 | The Panel will be quorate if 3 members are present and with at least   * One Lay worker * One Director [Finance, Integration or Commissioning Implementation] or nominated deputy * One clinically/medically qualified member |
|  |  |
| 4.3 | The Chair of the Panel is approved by the CCG Board. One of the members will be appointed Vice Chair by the Panel. Expert advisors (e.g. on medicines, public health, clinical effectiveness, cost effectiveness) may be invited as necessary to advise the Panel but will not have a role in the decision making. |
| **5** | **Responsibilities and Duties** |
| 5.1 | The principal duty of the Panel is to make decisions on individual funding requests. Patients or their clinicians are entitled to make a request to the IFR Panel for treatment to be funded by the CCG outside of its established policies on one of two grounds, namely:   * The patient is suffering from a presenting medical condition for which the CCG has no policy (**“an individual request”),** or * The patient is suffering from a presenting medical condition for which the CCG has a policy but where the patient’s particular clinical circumstances are perceived by the referring clinician to fall outside that policy **(“an exceptionality request”**). |
| **6** | Decision making |
| 6.1 | The IFR Panel shall be entitled to approve requests for funding for treatment for individual patients where the following conditions (1-5 and either 6 or 7) are met: |
| 6.2 | 1. The IFR Panel concludes that there are likely to be no similar patients to the requesting patient. |
| 6.3 | 1. There is sufficient evidence to show that, for the individual patient, the proposed treatment is likely to be clinically and cost-effective (taking note of any possible harm). |
| 6.4 | 1. Treating the patient is higher priority than other unfunded developments (see CCG commissioning strategy and list of low priority interventions) and the treatment can be afforded |
| 6.5 | 1. The IFR Panel is guided by the Ethical framework as set out in the Ethical Framework Policy (Appendix 1). |
| 6.6 | 1. The Panel has adequate information upon which to base its decisions provided through the standard application form. |
| 6.7 | 6. Individual requests  The IFR Panel will apply paragraphs 2.5, 2.6, 2.7 and 2.8 of the Experimental and Unproven Treatments Policy when considering individual requests for off-licensed or unlicensed use of a drug or other unproven treatments for the clinical condition under consideration. |
| 6.8 | 7. Exceptional requests  Exceptional clinical circumstances refers to 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 the same stage of progression as the patient |
| 6.9 | The IFR Panel will consider exceptionality in the context of the relevant commissioning policy statements and policies. |
| 6.10 | The IFR Panel will apply the guidance on exceptional clinical circumstances as defined in the Individual Funding Request Policy. |
| 6.11 | The panel will share within and across CCG’s the experience gained in dealing with requests for individual patients. |
| 6.12 | The Panel will provide evidence of adherence to the NHS Constitution through its annual effectiveness review and audit against national good practice guidance. |
| **7** | **Patient representation at the IFR Panel** |
| 7.1 | Where the application is to be considered by the IFR Panel, the patient will have a choice in how to be represented. A patient may choose to represent themselves or be represented by their clinician or another chosen person (although not a legal representative acting in a professional capacity). Patients may be accompanied, but not by someone acting in a legal capacity. Patients may also choose not to be represented. |
| 7.2 | If a patient chooses to be represented, they are to be advised that the IFR panel meets on set dates and these cannot be changed to suit attendance. If a patient or their representative is unable to attend on the allocated panel date, the patient can choose to delay their hearing until the next panel date or to allow the hearing to go ahead on the allocated date without representation. |
| 7.3 | A patient or representative will be allocated ten minutes at the panel meeting to present their case to the panel followed by an opportunity for the panel to ask any questions. There will be no opportunity for the patient to question the panel during the meeting. The patient or representative will be asked to leave while the panel conducts its deliberations. |

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| 7.4 | Patients will have an identified point of contact throughout the application process. |
| **8** | **Corporate Governance and Risk Management** |
| 8.1 | The Panel will adhere to all the appropriate CCG corporate governance and risk management arrangements including the development, implementation and monitoring of agreed strategies, policies and procedures. |
| 8.2 | The Panel will also contribute towards the CCG meeting the requirements of the appropriate inspection agencies including the Care Quality Commission, the NHS Litigation Authority and the Health and Safety Executive. |
| 8.3 | The Panel should also ensure the CCG Board is provided with the appropriate information in relation to the compliance with all of the inspection agencies. |
| **9** | **Frequency of Meetings and Reporting Framework** |
| 9.1 | The Individual Funding Request Panel will meet at least ten times a year. |
| 9.2 | The servicing, administrative and appropriate support to the Chair and members of the Panel will be provided by a nominated administrator. |
| 9.3 | Where requested by the patient, the patient will be entitled to receive a copy of all written evidence that is presented to the IFR Panel (except in rare circumstances where this is considered by the patient’s clinician to be detrimental to the patient’s wellbeing). |
| 9.4 | A patient or representative will be allocated ten minutes at the panel meeting to present their case to the panel followed by an opportunity for the panel to ask any questions. There will be no opportunity for the patient to question the panel during the meeting. |
| 9.5 | The decisions of the Panel will be conveyed in writing to the referring clinician. |
| 9.6 | The Chair of the Panel shall draw to the attention of the Integrated Governance and Quality Committee any issues that may require disclosure to the Board, or require executive action. |
| 9.7 | The Individual Funding Request Panel will report on its work to the Integrated Governance and Quality Committee on an annual basis on the cases considered and on its compliance on NHS Constitution core principles. |
| **10** | **Urgent Decisions** |
| 10.1 | It is recognised that occasionally urgent decisions are required.  Where circumstances dictate that a request cannot wait until the next meeting and where the referring clinician makes a case for urgent request based on clinical need and comprehensive background information is available, an urgent panel can be constituted. |
| 10.2 | In such instances, the Individual Funding Request Panel will consider cases outside of scheduled meetings, using fax/e-mail/telephone conference facilities as necessary. However, despite urgent circumstances, no member of the Individual Funding Request Panel can normally make decisions on their own, and it is recommended that urgent decisions are delegated by the Chair of the Individual Funding Request Panel to, as a minimum, an Executive Director or a designated deputy, medically qualified representative of the Panel and a Lay worker. |
| 10.3 | In exceptional circumstances an executive director of the CCG can make a decision on an urgent request as set out in the Individual Funding Request Policy. |
| 10.4 | The record of decisions made on an urgent basis should be relayed to the next formal Panel meeting for ratification. |
| **11** | **Review Arrangements** |
| 11.1 | The Chair of the Individual Funding Request Panel will lead the annual effectiveness review which will be undertaken by the end of the financial year. |

**Appendix 2**

**Summarised decision making check-list**

|  |  |
| --- | --- |
| Background information | Is all the required information available? |
| Exceptional clinical circumstances to current  CCG policy  OR | Are the patient’sclinical circumstances outside the range of clinical circumstances, presented by patients with the same medical condition and at the same stage of progression? |
| Individual request  The CCG will give consideration to supporting experimental treatment or off label use for rare clinical situations for which good quality clinical trials are considered impossible. | Points to consider:   * the potential benefit and risks of the treatment * the biological plausibility of benefit based on other evidence * an assessment of value for money * the priority of the patient’s needs vis-à-vis other competing demands |
| Similar patients | Are there likely to be no other similar patients?  Is this a potential service development? |
| Health care need and capacity benefit | What is the expected health gain?  Does the likely clinical benefit outweigh treatment risks?  Does the treatment meet the patient’s needs? |
| Evidence of clinical and cost effectiveness | Is the treatment of proven benefit?  What is the level of evidence available?  Is the treatment safe?  The NHS should only invest in treatments and services which are of proven effectiveness unless it does so in the context of well designed, sufficiently powered and properly conducted clinical trials. |
| Affordability | Do we have the resources to pay for this and are we using NHS resources wisely?  What are the range and location of local services, relevant to the patient’s clinical need, available within existing SLAs? |
| Equity | Is this patient or patient subgroup being treated fairly?  Is there consistency with previous decisions?  Would this decision set a precedent? |
| Quality and safety | Has the treatment been requested from a provider with an established reputation for safety, audit and clinical governance e.g. comply with the ‘NHS standards for Better Health’ |
| Final check; is this decision | * **Legal** (within CCG duties and human rights) * **Rational and reasonable** (considered relevant factors and excluded irrelevant factors) * **Followed procedural propriety** |

**Levels of evidence Appendix 3**

**Hierarchical systems for levels of evidence and recommendations2,3**

* The hierarchy of evidence and the recommendation grading relates to the strength of the literature and not necessarily to clinical importance.

|  |  |  |  |
| --- | --- | --- | --- |
| Hierarchy of evidence | | Grading recommendations | |
| Level | Type of evidence | Level | Type of evidence |
| 1a | Evidence from systematic reviews or meta-analysis of randomised controlled trials. | A | Based on hierarchy 1 evidence. |
| 1b | Evidence from at least one randomised controlled trial. |
| 2a | Evidence from at least one well-designed controlled study without randomisation. | B | Based on hierarchy 2 evidence or extrapolated from hierarchy 1 evidence. |
| 2b | Evidence from at least other type of quasi experimental study. |
| 3 | Well-designed non-experimental descriptive studies, such as comparative studies, correlation studies, case–control studies and case series. | C | Based on hierarchy 3 evidence or extrapolated from hierarchy1 or 2 evidence. |
| 4 | Expert committee reports, opinions and/or clinical experience of respected authorities | D | Directly based on hierarchy 4 evidence or extrapolated from hierarchy 1,2 or 3 evidence. |

2 <http://www,cebm.net/?o=1025>

<http://www.nice.org.uk/niceMedia/pdf/GDM_Chapter7_0305.pdf>

3 National Public Health Service for Wales Evidence-based advice to inform commissioning decisions on ‘Interventions not normally funded’ 2007, Dr Arif Mahmood and Dr Mary Webb