Appendix 1: Standard Operating Procedure for the management of Individual Funding Requests

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# Introduction

1.1 This document sets out the process for managing Individual Funding Requests as defined within the IFR policy. The intended audience is those responsible for the operation of the IFR process and decision making, but it may be of interest to those making funding applications under the IFR policy and so is published accordingly. The Standard Operating Procedure (SOP) should be read in conjunction with the IFR policy and appendices, the ICB Ethical Framework, and the Effective Clinical Commissioning Policies list.

1.2 Specifically the procedure sets out:

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

1.3 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 care and community services, where Gloucestershire ICB is the responsible commissioner. Applications for services where NHS England is the responsible commissioner (such as specialised commissioning and military health) should be made to NHS England in accordance with NHS England’s published policies and procedures.

# 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 ICB’s current commissioning policy statements to establish that the patient’s treatment does not fall within current treatment policies and commissioning arrangements.

2.1.2 Where a treatment is not normally funded by the ICB 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. The ICB does not accept applications from patients or their non-clinical representatives, however the process does provide an opportunity for patients to attend panel to present their case, or to submit a supporting written statement.

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. All sections of the form must be fully completed in order for the application to be accepted. The application needs to be submitted in typeface to ensure legibility. Handwritten applications will be returned to the requester for amendment and will not be considered further until resubmitted in typeface. 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 ICB 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 ICB population

2.1.5 It is the responsibility of the referring clinician to make a clear and compelling case to support the application. The application should include 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 patient’s 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 basic checks will be undertaken by the IFR team to ensure that:

* the patient falls within the commissioning responsibility of the ICB
* that the treatment would not be covered by existing commissioned services or policies
* that the application has been adequately completed to progress to the next stage of the process (including being completed in typeface).

If the application fails to pass these initial checks it will be returned to the requester with guidance on next steps (such additional information that is required in order to progress the application), and will not be considered further unless resubmitted.

2.2.2 Where the application passes the initial basic checks key information about the application, including the date of receipt, patient information, referring clinician and treatment requested, is entered onto the ICB IFR database by the IFR administrator.

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

2.2.4 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 fully completed IFR application form to the date of the letter from the ICB 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 appropriately completed funding applications are considered via a Triage GP. The purpose of the triage GP is to determine if the application should properly be considered an IFR, that is confirm that the treatment is not covered by other arrangements, that there is not a cohort that requires a service development, and that the requester appears to have presented an arguable case for clinical exceptionality that justifies consideration by the IFR panel.

2.4.2 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 GP. The Triage GP is authorised to make the following decisions:

* Return the application if the ICB does not have responsibility for commissioning the care requested for the individual patient (where this was not addressed through the initial administrative checks).
* 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 (where this was not addressed through the initial administrative checks).
* Reject the application if other standard treatments are commissioned for the condition that have not yet been tried or clearly ruled out on other clinical grounds.
* Reject the application if there is a cohort of patients (as defined within Appendix 5 of the IFR Policy) and there is no evidence of the individual patient being exceptional to that cohort. This should be treated as a service development proposal.
* Reject the application if there is insufficient information submitted for a decision to be reached. The ICB will reconsider the application if more information is provided.
* Reject the application if it does not demonstrate an arguable case for clinically exceptional circumstances that would justify consideration by the IFR panel.
* Refer the case to the IFR panel for a decision where there appears to be an arguable case for clinical exceptionality.

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

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

2.4.5 If the application is rejected on the grounds of insufficient information or failure to demonstrate an arguable case for exceptionality, but is later resubmitted with new information/clinical arguments this will be treated as a new funding request that will start a new 40 day response time clock.

2.4.6 The decisions of the Triage GP will be communicated directly to the referring clinician and/or the patient’s GP (if this is not the same person). It is the requesting clinician’s responsibility to inform the patient of the outcome.

2.4.7 If a request is declined by the Triage GP the IFR policy does not provide a right of appeal to the IFR Panel. The Triage GP will always re-consider 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.

2.4.8 Any application resubmitted will be considered following the same process as a new IFR funding application to assess if the new information

# 2.5 The IFR Panel

2.5.1 IFR Panel meetings are scheduled in advance and take place on a monthly basis. The Panel acts as a formal sub-committee of the System Quality Committee. It has the authority to make exceptions to the Commissioning Policies of the ICB and thus commit financial resources within the frameworks agreed. The Panel will report its decisions to the System Quality Committee on an annual basis or earlier if significant risk issues are 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
	+ Medical Director or their nominated deputies
	+ Chief Nursing Officer or nominated deputies [clinical]
* Chief Finance Officer, Director of Integration or Executive Director of Operational Planning and Performance or their nominated deputies
* Public Health Consultant or nominated deputies
* IFR Assistant 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 Operational Planning and Performance, Integration or Finance
* One clinically qualified member
	+ 1. The Chair of the Panel is approved by the Board of the ICB. 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. If the patient chooses not to be represented they may choose to submit an additional written statement to support their case.

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 information that they wish to share with the panel to support their case. This will be 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 or submit a written statement.

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. The IFR manager will also provide summary details of any similar cases previously considered by panel and the outcome to support consistent decision making.

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 ICB 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 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 are met:

1. The application sets out a clear and compelling case to demonstrate clinical exceptionality in line with the definitions and principles set out in the IFR policy.
2. The IFR Panel concludes that there is not a cohort of similar patients (see appendix 3 of the IFR policy for further guidance on cohorts and service developments).
3. There is sufficient evidence to show that, for the individual patient, the proposed treatment is likely to be clinically effective and cost-effective (taking note of any possible harm).
4. There is sufficient evidence to suggest that the intervention is likely to be cost-effective, and treating the patient is a higher priority than other unfunded developments and can be afforded. The IFR Panel will be 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.

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 where a clear and compelling case for exceptionality has been demonstrated.
2. Defer a decision pending further information/investigation.
3. Decline to support the application where a clear and compelling case has not been demonstrated.
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 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 the requesting clinician to discuss the recommendation of the Panel; unless the clinician making the request has indicated that it is not clinically appropriate to do so. The responsibility for explaining the reasons for the decision (based on the information provided by the ICB) and answering any questions the patient may have about their request or their clinical options rests with the requesting clinician. The clinician should contact the patient to discuss the outcome and any next steps.

2.11.4 If funding is agreed upon (outcome 1) the ICB 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 patients. 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 the decision, the applicant will be required to seek an extension from the ICB and this may require re-authorisation of funding from the Panel. The ICB may at its discretion extend this 12 month period to allow for unforeseen circumstances.

# 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 ICB 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 ICB website and G-Care. If a different format of this procedure is required it can be requested from the IFR Manager.

# 4.0 Monitoring

4.1 Performance against expected service standards will be monitored throughout the year and reported to the System 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 the date of the letter confirming the ICB’s 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 another source) – Service standard 100%

**Appendix 1**

**Individual Funding Request Panel Terms of Reference**

|  |  |
| --- | --- |
| **1** | **Purpose of the IFR Panel** |
| 1.1 | The primary role of the Individual Funding Request Panel is to provide assurance to the ICB Board that resource allocation to all individual 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. |
| 1.2 | The Individual Funding Request Panel has the delegated authority to make exceptions to the commissioning policies and healthcare contracts of the ICB and commit financial resources in line with the principles and processes set out in the IFR policy. |
| **2** | **Accountability** |
| 2.1 | The Individual Funding Request Panel operates as a formal sub-committee of the System Quality Committee and this is reflected in the ICB Internal Controls framework. |
| 2.2 | The Individual Funding Request Panel operates in accordance with the ICB 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. |
| 2.3 | The Individual Funding Request Panel Chair is directly accountable to the ICB Chair. |
| **3** | **Membership and Quoracy** |
| 3.1 | Membership will consist of the following:* Lay worker (Chair)
* Lay worker
* Two from the following list of clinically qualified members
	+ Medical Director or their nominated deputy
	+ Chief Nursing Officer or nominated deputy [clinical]
* Chief Finance Officer, Director of Integration or Executive Director of Operational Planning and Performance or their nominated deputy
* Public Health Consultant or nominated deputy
* IFR Assistant Manager (non-voting member)
 |
| 3.2 | The Panel will be quorate if 3 members are present and with at least * One Lay worker
* One Director [Finance, Integration or Operational Planning and Performance] or nominated deputy
* One clinically/medically qualified member
 |
| 3.3 | The Chair of the Panel is approved by the ICB 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. |
| **4** | **Responsibilities and Duties** |
| 4.1 | 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 ICB outside of its established policies where the patient presents with exceptional clinical circumstances, that is:*The ICB has no explicit policy in place for the management of the patient’s condition because the patient is suffering from a medical condition or clinical presentation that is rare or unusual to the extent that they cannot be considered part of a defined group of patients in the same or similar clinical circumstances.*OR*The patient is suffering from a presenting medical condition for which the ICB has a policy, but where the patient's particular clinical circumstances mean that they do not qualify for treatment under that policy. However, the clinician believes that the patient is in a substantially different clinical circumstance when compared to the typical patient population with the same condition, and because of this, they are likely to receive material additional clinical benefits from treatment than other patients with the same condition, which justifies giving them access to an intervention that is not available to others.* |
| **5** | Decision making |
| 5.1 | The IFR Panel shall be entitled to approve requests for funding for treatment in line with the decision-making guidance in section 4 of the IFR policy. |
| 5.2 | The panel will share within and across ICB’s the experience gained in dealing with requests for individual patients.  |
| **6** | **Patient representation at the IFR Panel** |
| 6.1 | The IFR panel will ensure that patients are given the opportunity to present their cases to the panel in line with the requirements set out in section 5 of the IFR policy. |
| **7** | **Frequency of Meetings and Reporting Framework**  |
| 7.1 | The Individual Funding Request Panel will meet on a monthly basis provided that there are cases to be heard.  |
| 7.2 | The servicing, administrative and appropriate support to the Chair and members of the Panel will be provided by the IFR Manager or nominated deputy following the processes set out in the IFR policy and Standard Operating Procedure.  |
| 7.3 | 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).  |
| 7.4 | The decisions of the Panel will be conveyed in writing to the referring clinician.  |
| 7.5 | The Chair of the Panel shall draw to the attention of the System Quality Committee any issues that may require disclosure to the Board, or require executive action. |
| 7.6 | The Individual Funding Request Panel will report on its work to the System Quality Committee on an annual basis on the cases considered and on its compliance with the NHS Constitution’s core principles. |
| **8** | **Urgent Decisions** |
| 8.1 | It is recognised that occasionally urgent decisions are required. Where circumstances dictate that a request cannot wait until the next meeting decisions will be taken in line with section 6 of the IFR policy which describes the process for managing urgent decisions. |
| 8.2 | The record of decisions made on an urgent basis will be reported to the next IFR panel for information. |
| **9** | **Training** |
| 9.1 | Panel members must take part in induction training and ensure that they are fully familiar with the IFR policy and associated procedures before sitting on a panel. Members should sit on a panel at least twice per year in order to retain their competence to serve on the panel.  |

**Appendix 2**

**Summarised decision making check-list**

|  |  |
| --- | --- |
| Background information | Is all the required information available? |
| Is there a clear and compelling case to demonstrate clinical exceptionality | *The ICB has no explicit policy in place for the management of the patient’s condition because patient is suffering from a medical condition or clinical presentation that is rare or unusual to the extent that they cannot be considered part of a defined group of patients in the same or similar clinical circumstances.***OR***The patient is suffering from a presenting medical condition for which the ICB has a policy, but where the patient's particular clinical circumstances mean that they do not qualify for treatment under that policy. However, the clinician believes that the patient is in a substantially different clinical circumstance when compared to the typical patient population with the same condition, and because of this they are likely to receive material additional clinical benefit from treatment than other patients with the same condition, which justifies giving them access to an intervention that is not available to others.* |
| 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 ICB duties and human rights)
* **Rational and reasonable** (considered relevant factors and excluded irrelevant factors)
* **Followed procedural propriety**
 |