Coastal West Sussex
Clinical Commissioning Group

Coastal West Clinical Commissioning Group

Policy for Dealing with

Individual Funding Requests

May 2015 V3

The Coastal West Clinical Commissioning Group policy on individual funding requests (IFRs) is based on National Guidance. The relevant documents are referenced.

Table of Contents

1. Introduction

1.1 NHS commissioning organisations, including Coastal West Clinical commissioning Group ("the CCG"), are provided with a limited budget by the Department of Health (via NHS England) and must therefore make decisions about how to use NHS money in the best way to meet the health and social care needs for the population served by the CCG. To do this the CCG has to identify priorities for spending NHS money to benefit its patient population and, because there is never enough money to provide every patient with a comprehensive service in all areas, the CCG must identify areas of healthcare expenditure that have a lower level of priority.

1.2 The money provided to the CCG is substantial but is fixed in each financial year. The CCG will always be faced with difficult and sensitive decisions about apportioning healthcare resources. The CCG Governing Body prepares its Annual Commissioning Plan which explains the commissioning decisions that have been made by the CCG. That plan is supported by general commissioning policies which identify the services that will be funded for clinically defined groups of patients served by the CCG. Clinicians working for the CCG only have delegated authority to charge the CCG for providing services to NHS patients where the service is (a) approved by reference to a current CCG policy or (b) the subject of an IFR decision made under this policy.

1.3 Coastal West Clinical Commissioning Group recognises there may be individual cases where a patient's need for healthcare services cannot be met through existing commissioned services. There are several reasons why the CCG may not commission a healthcare intervention for an individual patient. These can include the following reasons:

- The proposed service may be a new medical technology which has not yet been assessed by the CCG and so is not included in the CCG's Annual Commissioning Plan or its existing policies. Clinically effective services are constantly being developed for both common and uncommon conditions but they cannot become part of NHS funded treatment until the CCG has made a positive decision to adopt a policy which defines that the service is to be funded for a specific group of patients.
- The CCG may have decided to fund the intervention for a limited group of patients, possibly within a clinical trial, but the group excludes the person making the request
- The CCG may have decided not to fund the treatment for all patients or only for a group patients which excludes the patient making the request because the CCG considers there is insufficient evidence that the treatment is clinically effective (or is only clinically effective for a narrow group or that the proposed treatment does not provide value for money
- The CCG may have agreed that the proposed treatment is both clinically effective and cost effective but decided that, given the priorities for investment decided by the CCG, the proposed treatment cannot be afforded in the current financial year.

1.4 The CCG is required by Regulation 34(1) of the National Health Service Commissioning Board and Clinical Commissioning Groups (Responsibilities and Standing Rules) Regulations 2012 ("the 2012 Regulations") to have "*arrangements for making decisions and adopting policies on whether a particular health care intervention is to be made available for persons for whom the relevant body has responsibility*". That decision making process will inevitably result in decisions being made that some patients cannot have NHS funded treatment to meet their healthcare needs under CCG polices.

1.5 Regulation 34(2)(b) of the National Health Service Commissioning Board and Clinical Commissioning Groups (Responsibilities and Standing Rules) Regulations 2012 requires the CCG to have "arrangements for the determination of any request for the funding of a health care intervention for a person, where there is no relevant NICE recommendation and the relevant body's general policy is not to fund that intervention". This policy constitutes the CCG's arrangements to comply with this legal obligation.

1.6 This policy has also been influenced by the documents listed in the Appendix.

2. Principles Informing the Development of IFR Policies

2.1 In general, decisions made about the funding of medicines and treatments will be taken on a population basis by CCG with cooperation with provider trusts and stakeholders.

2.2 An IFR is a request to fund a treatment or medicine for an individual patient who falls outside of existing CCG contracts or policy.

2.3 There will be a clear separation between commissioning procedures which prioritises treatments for the whole or a part of the CCG population, including policies which only apply to a small number of patients, and CCG processes dealing with individual patients.

2.4 Decisions about treatment for individuals will not be exempted from the requirements of prioritisation. The ethical framework underpinning CCG population-level decision-making processes will also apply to the determination of IFRs. The Ethical Framework for decision-making will be used by the CCG when making individual-level decisions (a copy is set out in Appendix 1).

2.5 The CCG's general approach is that it would be inequitable to offer treatment to a named individual that would not be offered to all patients with equal clinical need. The CCG will therefore scrutinise individual applications with particular care where there may be a risk of offering treatment to a named individual that would not be offered to other patients in like clinical circumstances or with equal clinical need.

2.6 Clinicians can make a request (an "Individual Funding Request") to the IFR Panel for treatment to be funded by the CCG outside its established policies on one of two grounds, namely:

- The patient is suffering from a medical condition or clinical presentation for which the CCG has no policy or established treatment path which defines which treatment is funded for such patients ("A no policy request"), or
- The patient is suffering from a presenting medical condition for which the CCG has a policy, but where the requested treatment has not been agreed to be funded under the policy ("An exceptionality request").

2.7 The CCG may have no policy for funding an intervention for a variety of reasons including where the condition has low probability of occurring among the CCG's population which means that an explicit policy is not warranted. Alternatively the treatment may be recently developed, or may be novel or experimental so that the CCG has not yet developed a policy on whether it should be offered to any patient as part of NHS funded treatment.

2.8 The IFR Panel will take care to avoid adopting the approach described as "the rule of rescue". The fact that a patient has exhausted all NHS treatment options available for a particular condition is unlikely, of itself, to be sufficient to demonstrate exceptional clinical circumstances. Equally, the fact that the patient is refractory to existing treatments where a recognised proportion of patients with same presenting medical condition at the same stage are, to a greater or lesser extent, refractory to existing treatments is unlikely, of itself, to be sufficient to demonstrate exceptional clinical circumstances.

2.9 "Clinical circumstances" means the clinical features of the named patient's medical condition or the progression of the named patient's condition as opposed to the named patient's social or personal circumstances.

3. Interface between the IFR policy and other Commissioning Policies

3.1 The IFR policy is concerned with decisions about the funding of treatments for named individuals. This decision making process is separate from the proactive processes which CCGs operate as part of the process leading to the development of the CCG annual commissioning plan or service development processes within the year for identifying medicines and treatments for population decisions and policy development.

3.2 **Service Developments:** An in-year service development is any change in the level of investment by the CCG outside the annual commissioning round which affects or may affect multiple patients. This includes all new services, new treatments (including medicines) and changes to treatment thresholds. It includes quality improvements such as reduced waiting times. It also refers to other types of investment that existing services might need, such as pump-priming to establish new models of care, training

to meet anticipated manpower shortages and implementing legal reforms. If the CCG considers that a cohort of patients within the population served by the CCG are or are likely to be in the same or similar clinical circumstances as the requesting patient in the same financial year, and who could reasonably be expected to benefit to the same or a similar degree from the requested treatment (known as “similar patients”) then an application will be treated as a request for a service development

3.3 If it foreseeable that the request represents a cohort of patients, then the request will be considered as a request for a service development except in the circumstances where all the similar patients are expected to be from the same family group; a situation which may arise in the context of a genetic disease.

3.4 The CCG will also have policies and processes dealing with, for example:

- Patients requesting retrospective funding.
- Patients moving into the area and seeking funding to continue NHS funded treatment commenced elsewhere
- NHS pick-up after patients complete clinical trials
- Cross border funding requests – as per NHSE Guidance

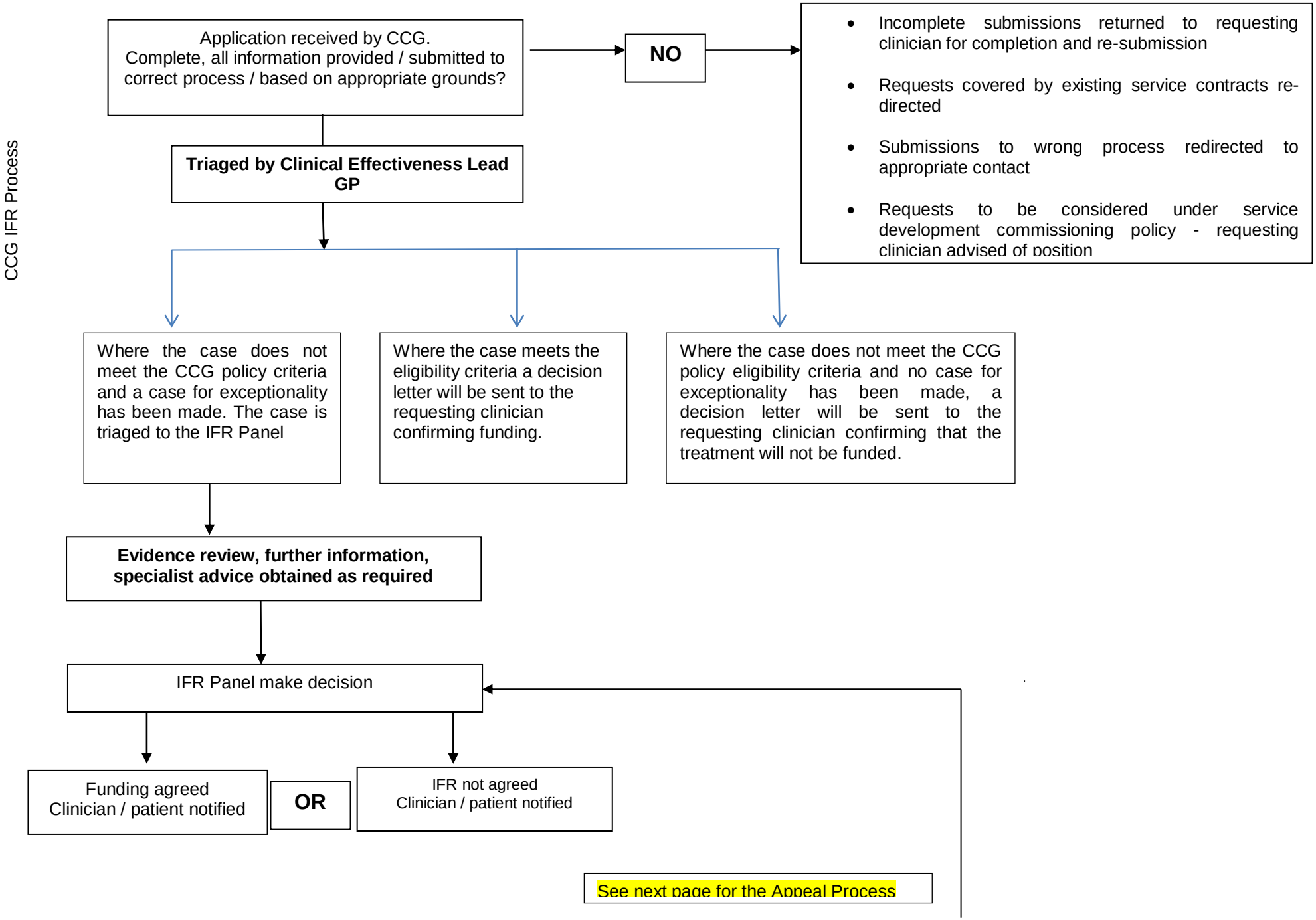
3.5 The IFR process is one part of the CCG decision making processes. The CCG also makes decisions about funding for treatment for patients through the following processes:

- The Annual Commissioning Plan process.
- The procedure for considering in-year service developments, including the power to take an urgent or interim policy decision.

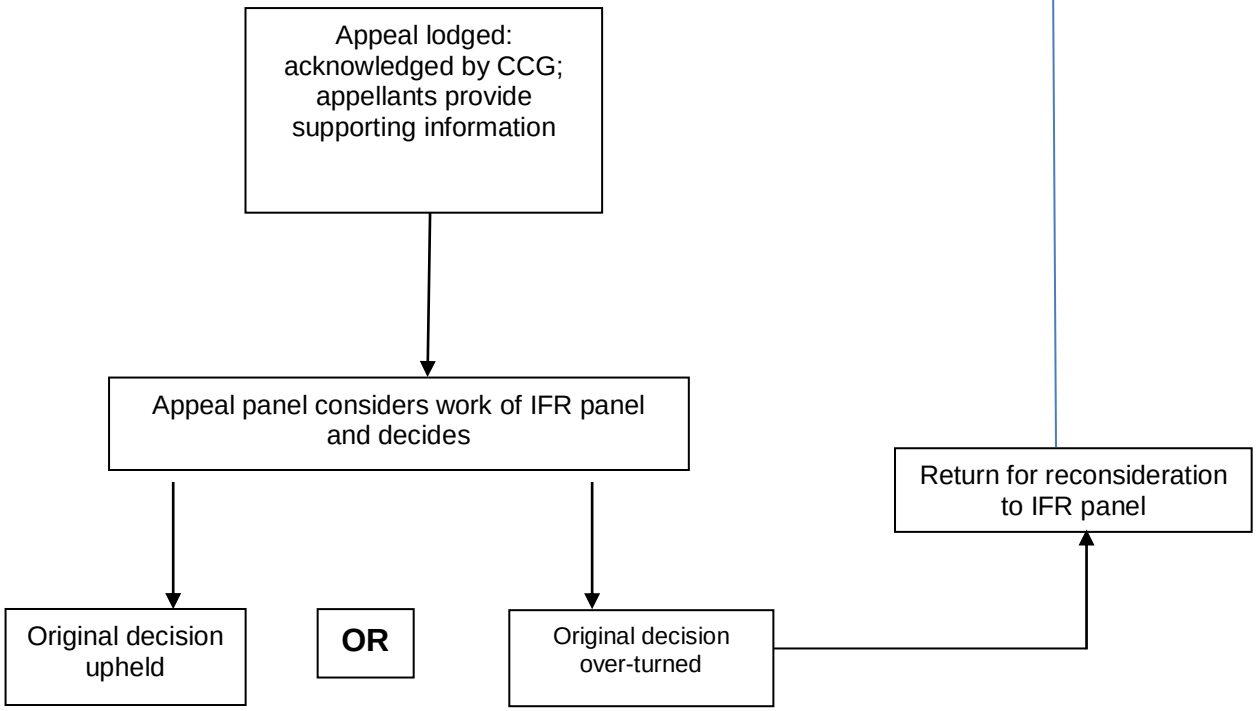
4. IFR Process

4.1 The diagram below provides an overview of the IFR and Appeal Processes

CCG IFR Process



CCG IFR Appeals process



Who can submit an IFR?

4.2 IFRs may be submitted by an NHS consultant, a GP or dental practitioner, or an equivalent autonomous practitioner where he/she will be responsible for administering the treatment. Patients may not make applications directly.

4.3 The requesting clinician is responsible for ensuring that the patient understands the full implications of submitting an IFR and required to affirm that s/he has discussed the proposed treatment with the patient (or has offered such a discussion) before the application is made for funding on his/her behalf.

4.4 The requesting clinician must make the patient aware of the implications of embarking on this process, particularly that it may take some time before the request can be decided and, if the patient is considering privately funding the requested treatment while the IFR is being considered that no retrospective funding is available; even if the IFR is approved.

4.5 It is the responsibility of the requesting clinician to ensure that all the required information is submitted.

Screening of Potential IFRs before Submission to the CCG

4.6 The CCG works with their provider Trusts and GP practices to ensure that personnel are aware of the various processes by which applications for funding may be made to the CCG and to ensure that clinicians only submit IFRs when this is the correct process to use.

4.7 When an IFR is submitted by an NHS consultant or equivalent practitioner, the national guidance requires the submission to be approved by the designated representative of the provider Trust. In the case of an IFR for a drug, this is likely to be the Chief Pharmacist. For other treatments, it may be the business manager of the department where the treatment will be provided.

4.8 When an IFR is submitted by a GP or dental practitioner, it is expected that s/he will have fully considered whether this is the correct process to use.

Submission of IFRs and Triaging

4.9 Submissions, providing all the required information, will be triaged by the CCG Clinical Effectiveness Lead GP

4.9.1 Where the case meets the eligibility criteria a decision letter will be sent to the requesting clinician confirming funding.

4.9.2 Where the case does not meet the CCG policy eligibility criteria and a case for exceptionality has not been made, a decision letter will be sent to the requesting clinician confirming that the treatment will not be funded.

4.9.3 Where the case does not meet the CCG policy criteria and a case for exception has been made. The case is triaged to the IFR Panel

Fast-Tracking Urgent IFRs

4.11 IFRs will only be fast-tracked where there is a clear clinical reason why the patient's health will be significantly compromised by waiting until the next scheduled IFR panel meeting for a decision to be made. It is expected that only a small minority of IFRs will be dealt with in this way and these will usually involve life-threatening conditions. IFRs will not be fast-tracked on the basis that waiting until the next IFR panel is inconvenient or problematic for the patient or requesting clinician. The clinician submitting the funding application will need to state the clinical reason for the need fast-track a case.

4.12 A fast-tracked IFR should be considered under delegated powers by a specially-convened group acting as a sub-committee of the next scheduled IFR panel.

4.13 This group will be composed of three members of the IFR panel member pool and will include one lay member, one person qualified to chair and one member who are clinically-qualified. The group may confer by email as well as in person. The IFR Lead is responsible for managing communications and the distribution of information/evidence among the sub-group.

4.14 The decisions of the sub-group will be ratified by the IFR panel during its next scheduled meeting. The decisions available to a fast-track panel are:

- the request will be funded **without conditions**
- the request will be **funded with conditions** attached
- the request will **not** be **funded**

4.15 The group may also decide that it is not appropriate for them to make a decision on the request, in which case they must refer the request to the next meeting of the IFR panel, stating the reasons why they could not make a decision

4.16 The IFR Lead will communicate the fast-track decision to the requesting clinician (and the patient, if appropriate) in writing by a secure means. S/He will also be responsible for documenting the decision, the reasons behind the decision and the consensus achieved, and passing all relevant information to the Administration team for inclusion in the papers for the next scheduled panel meeting.

4.17 All cases going before the panel for consideration will be anonymised.

4.18 Panel meetings will be held in private. Requesting clinicians or patients will not be invited to make representations in person. The IFR Lead will attend the meetings to provide advice or information, but may not be a voting member of the panel.

4.19 Each IFR will be considered on its own merits. Decisions will be taken using consensus decision-making.

4.20 The IFR Panel shall be entitled to approve requests for funding for treatment for a named patient where all four of the following conditions are met:

- Either (a) the patient makes a "no policy" request for funding for treatment in connection with a presenting medical condition for which the CCG has no policy which describes what treatment will be funded for patients with the patient's presenting condition or existing treatment pathway for patients with the patient's presenting condition, or (b) the patient makes an exceptionality request for funding for treatment in connection with a medical condition for which the CCG has a policy and where the patient has demonstrated exceptional clinical circumstances.
- There is sufficient evidence to show that, for the named patient, the proposed treatment is likely to be clinically effective.
- Applying the approach that the CCG takes to the assessments of costs for other treatments outside this policy, the cost to the CCG of providing funding to support the requested treatment is justified in the light of the benefits likely to be delivered for the named patient by the requested treatment.
- The request for this patient is not deemed to be a request for a service development

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

4.22 Whether a patient can demonstrate "exceptional clinical circumstances" depends on the precise clinical facts of each individual case and whether those can genuinely be described as exceptional. A patient is highly unlikely to be able to demonstrate exceptional clinical circumstances unless the patient can present with clinical features which show that he or she is significantly different from the general population of patients with the condition in question at that stage of development of the condition. Further, in order to show that this is a genuinely individual case, the patient is likely to have to show that, as a result of that difference or differences, the

patient is likely to gain significantly more benefit from the requested intervention than might normally be expected for patients with that condition.

4.23 **The fact that a patient has exhausted all NHS treatment options available for a particular condition is unlikely, of itself, to be sufficient to demonstrate exceptional circumstances**. Equally, the fact that the patient is refractory to existing treatments where a recognised proportion of patients with the same presenting medical condition at the same stage are, to a greater or lesser extent, refractory to existing treatments is unlikely, of itself, to be sufficient to demonstrate exceptional circumstances.

Decisions Available to the Panel

4.24 When considering a new submission, the panel may decide as follows:

- the request will be funded **without conditions**
- the request will be **funded with conditions** attached
- the request will **not** be **funded**
- the submission cannot be decided at this meeting because more evidence/ information is required and is therefore **deferred**

4.25 The IFR Panel may decide to defer a decision because information called for by the IFR Lead before the meeting is not yet available, or because the panel members decide at the meeting that they need more information.

Recording of Panel Meetings and Confidentiality

4.26 All discussion during a meeting of the IFR panel will be confidential. Notes of an IFR panel meeting will be taken by a designated individual.

4.27 The panel's decision will always be communicated in writing by a secure means within 5 days of the Panel meetings.

Membership of IFR Panel

4.28 The IFR Panel will be charged with deciding whether IFR should be funded or not. The membership of the panel will reflect an appropriate mix of medically-qualified and lay members. The panel will have at least five members, two of whom will be clinically qualified, and one a lay person.

4.29. The membership of the IFR panel will be drawn from a pool comprising: - GPs, hospital consultants, CCG finance/commissioning, lay people and other healthcare professionals. All members will receive training before sitting on the panel.

4.30 Members of an IFR Panel will serve as individuals, not as representatives of any particular organisation or interest group. Indemnity will be proved by the CCG. Lay members of IFR panels will have had Disclosure and Barring Service (DBS) checks.

4.31 The IFR panel may call for specialist clinical, legal, financial, or other advice as appropriate.

4.32 Conflict of interest means any activity, commitment or interest that may adversely affect, compromise, or be incompatible with the obligations of a panel member. It includes, but is not limited to, situations where a significant financial or other interest could affect a panel member's judgement.

4.33 Members should be required to declare their interests in a register of members' interests before joining the panel pool. The IFR Lead will be in a position to bear these in mind when organising panels. As an additional safeguard, at the beginning of every meeting there should be a declaration of interests, so that anybody who has any link with any of the IFRs under review can withdraw from the discussion.

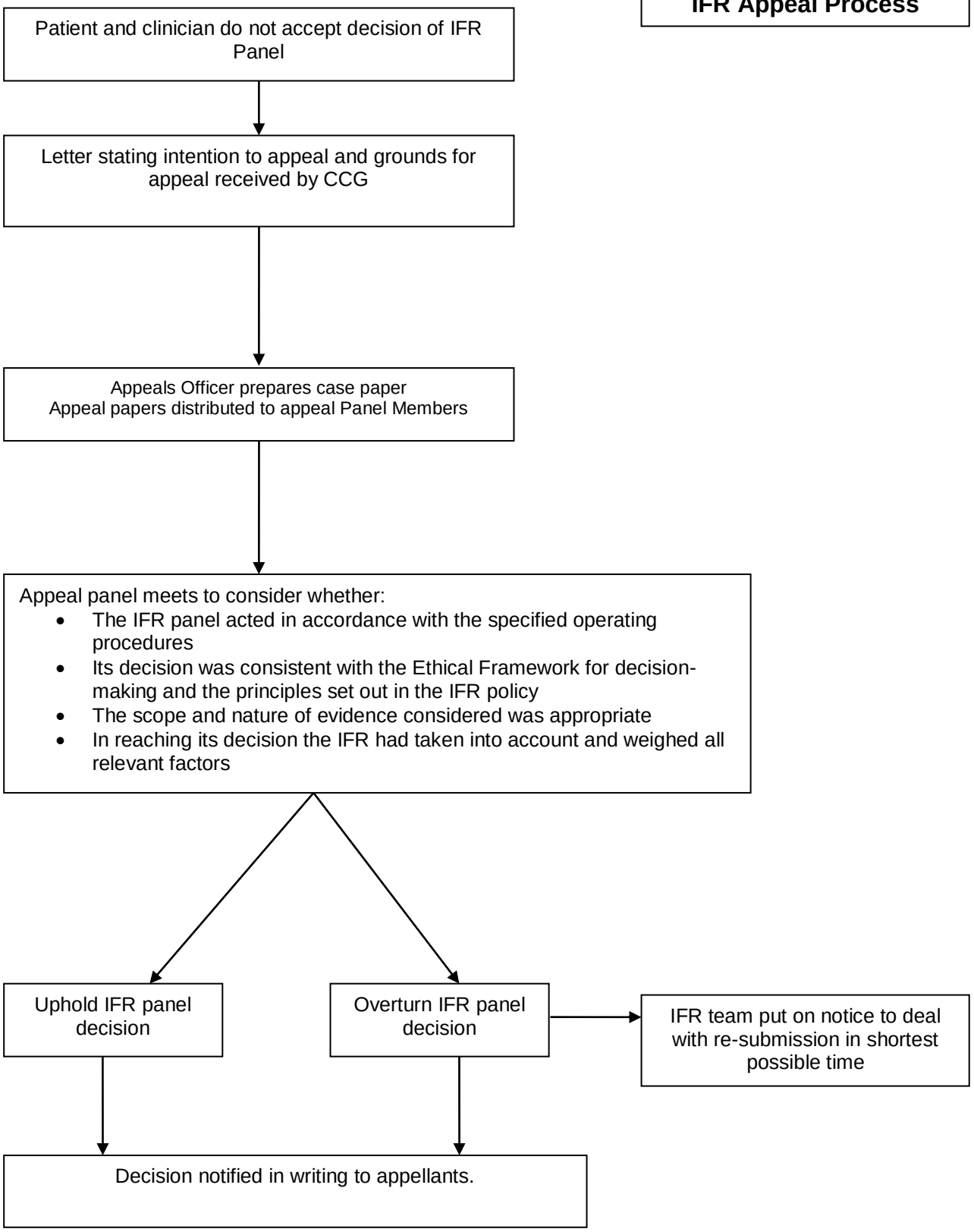
5. The IFR Appeal Process

5.1 The IFR Appeal process allows patients and their clinicians to appeal against the decision made by an IFR panel. The appeal process will be independent of the IFR process.

5.2 An IFR Appeal panel will not consider new evidence. If new evidence becomes available after a decision not to fund has been made by an IFR panel, then the correct procedure is to submit a new IFR supported by the new evidence, not to appeal the existing decision.

The diagram below provides an overview of the Appeal process

5.4
IFR Appeal Process



Remit of the Appeal Panel

5.3 The role of the Appeal panel is not to reconsider the merits of the request itself. The Appeal panel will review all documents relating to the original IFR submission and the IFR's decision and decide whether:-

- The IFR panel acted in accordance with the operating procedures adopted by the CCG
- In reaching its decision the IFR took into account and weighed all the relevant factors and did not take into account irrelevant factors
- The IFR panel reached a decision that was open to them acting as a reasonable IFR panel.

Grounds for Appeal

5.5 The decision of an IFR panel can be appealed on the grounds of:

- Illegality: The refusal of the request was not an option that could lawfully have been taken by the IFR panel
- Procedural impropriety: There were substantial and/or serious procedural errors in the way in which the IFR process was conducted
- Irrationality: The decision to refuse funding for the requested treatment was a decision which no reasonable IFR panel could have reached on the evidence before the panel

5.6 The Appeal panel will not consider new evidence of clinical or cost effectiveness in support of an IFR. If new evidence becomes available, or the patient's clinical condition changes, the case will be referred back to the IFR panel for reconsideration.

5.7 The Appeal panel will have a different membership from the IFR panel.

Membership of the Appeal Panel

5.8 The Appeal panel will comprise a minimum of three members, to include: a clinically qualified member and a lay member.

5.9 Panel members will be fully familiar with the CCG's IFR policy and process and have been trained.

5.10 Members of an IFR Appeal panel will serve as individuals, not as representatives of any particular organisation or interest group. Indemnity will be provided by the CCG.

5.11 The IFR Appeal panel may call for specialist legal or other advice as appropriate.

Lodging an Appeal

5.12 The appeal can be lodged by:

- The clinician who submitted the IFR
- The patient
- The legal guardian where the patient is a child under 18 years of age
- A person appointed with lasting power of attorney if the patient lacks the mental capacity to lodge an appeal themselves
- A third party (e.g. friend or relative) with the documented consent of the patient

5.13 If the clinician lodges the appeal he/she is required to affirm that he/she has discussed the appeal process fully with the patient and is acting with his/her consent. If the patient or his/her representative lodges the appeal, they should have the support of the clinician who requested the IFR.

5.14 The person lodging the appeal should write to the CCG stating that they wish to appeal and the grounds on which the appeal is being made, confirming that they have the consent of the other party, and providing as much information/evidence as possible in support.

5.15 The appeal panel will meet in private and the patient or his/her clinician will not be invited to attend.

5.16 The patient and his/her clinician will be invited to submit appropriate material in support of an appeal. Information may be provided by the clinician and the patient and on behalf of the patient by guardians, representatives, family members, carers and so on.

5.17 Information provided by the clinician should be in English and in writing or a conventional clinical medium such as x-ray or scan results, provided these are accompanied by a report on their interpretation from the appropriate consultant.

5.18 Information provided by the patient, or on the patient's behalf by non-clinicians, may be in other languages, or other media, including video recording, audio recording or Braille. If necessary, translation services should be provided by the CCG.

5.19 All discussion during the Appeal panel meeting will be confidential. Decisions will be taken using the consensus decision-making process. The principles of the Ethical Framework will be considered throughout.

5.20 The Appeal panel may uphold or overturn the decision of the IFR panel. **A decision to overturn does not mean that the request will be funded: it means that the request will be considered again by the IFR panel.**

5.21 The Appeal panel may not defer its decision.

Communicating the Decision

5.22 The decision of the Appeal panel will be notified in writing and sent by secure means to the appellant within 5 working days of the meeting.

5.23 If the Appeal panel upheld the IFR panel's decision, the appellant will be advised that no further considerations can be made by the CCG through the IFR process and their next recourse must be to the NHS Complaints process.

5.24 **If the Appeal panel overturned the IFR panel's decision, the patient and his/her clinician will be advised that their IFR application will be reconsidered by the IFR panel, which will take account of any additional evidence which has become available in the meantime. In this situation, the IFR Lead will ensure that the new IFR submission is dealt with in the shortest possible time.**

6. Training of IFR & Appeal Panel Members

6.1 Training will be provided for IFR and Appeal Panel members. The training will cover:

- IFR policy and process, confidentiality, and the requirements of the Data Protection Act and the Freedom of Information Act
- Legal aspects in considering Individual funding requests
- IFR Appeals – Procedural Impropriety, Irrationality and Illegality
- CCG accountability for Public funds in relation to Individual funding Requests
- Principles in evaluating clinical evidence for decision making.
- How to evaluate clinical and cost effectiveness

7 Administration of IFRs

7.1 Suitable and sufficient resources will be provided by the CCG to support the IFR process as follows:

- Triage of applications for funding and the redirection of requests
- Administrative services dedicated to the IFR process and the Appeal process
- A named, senior manager, to take the role of IFR lead
- Suitably qualified IFR panel members, and Appeal panel members, sufficient to allow panels to sit at appropriate intervals
- Timely and efficient communication in appropriate language between everyone involved in the IFR process both within the CCG and with the requesting clinician and patient
- The effective working of the IFR panel and any Appeal panels

- Training for everyone involved in the process
- Monitoring and audit
- Secure handling and storage of confidential information

Role of the IFR Lead

7.2 The IFR Lead is responsible for coordinating, managing and developing the IFR process, and the work of the IFR panels.

Key elements of the IFR Lead's role will be:

- Managing the work of the Administration team
- Establishing the protocols for communicating and liaising with patients and clinicians
- Triaging submissions to the IFR process, identifying service development requirements, and redirecting inappropriate submission as required
- Deciding which submissions should be fast-tracked
- Determining the additional information, specialist advice and reviews of evidence necessary to inform the panel's decision
- Attending IFR panel meetings in the role of advisor
- Organising the recruitment and training of panel members
- Contributing to the continuing development of the IFR process
- Liaising within the CCG with the directorate responsible for priority-setting and policy development to deal with situations where there is a lack of existing policy

7.3 S/He will be responsible for ensuring there is a single point of contact for patients and clinicians involved in the IFR and Appeal processes.

Responsibilities of the IFR Administration Team

8.5 The Administration team will be responsible for:

- Administering the paperwork, ensuring the efficient handling and documentation of submissions, from first receipt through to archiving
- Maintaining patient confidentiality and data security in accordance with the standards set by the Records Management Code of Practice
- Organising the IFR panel meetings, and acting as Secretary to the meetings
- Correspondence
- Progress chasing

8. Reporting, Quality Assurance and Archiving

8.1 The IFR team function will be reviewed by the CCG's internal auditors to provide assurance to the Board.

8.2 The Administration team will be responsible for the final task of ensuring that:

- All documentation relating to each submission is properly identified, controlled and filed
- Quality assurance checks are completed
- Files are updated, closed and securely stored
- Electronic data are properly documented, secured and stored
- Information likely to be required for audit is available in suitable format

8.4 In keeping with the requirement of *Records Management: Code or Practice* (DH 2006), IFR files will be kept in archive for a minimum of 6 years

9. References

1. The NHS confederation. Priority setting: managing individual funding requests - 2008
2. National Prescribing Centre. Defining guiding principles for process supporting local decision-making about medicines. Final Report - January 2009
3. National Prescribing Centre. Supporting rational local decision-making about medicines (and treatments). A handbook of good practice guidance. First edition - February 2009.
4. Department of Health. Directions to primary care trusts and NHS trusts concerning decisions about drugs and other treatments 2009 - March 2009.
5. Department of Health. The NHS Constitution for England - January 2009

Background - Purpose of the Ethical Framework

The purpose of the ethical framework is to support and underpin the decision making processes of the Coastal West Sussex Clinical Commissioning Group (CCG) to support consistent commissioning policy through:

- Providing a coherent structure for discussion, ensuring all important aspects of each issue are considered
- Promoting fairness and consistency in decision making from meeting to meeting and with regard to different clinical topics, reducing the potential for inequity
- Providing a means of expressing the rationale behind the decisions made
- Reducing risk of judicial review by implementation of robust decision-making processes that are based on evidence of clinical and cost effectiveness and an ethical framework

Formulating policy recommendations regarding health care priorities involves the exercise of judgment and discretion and there will be room for disagreement both within and without the CCG.

Although there is no objective or infallible 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 Framework incorporates the principles developed by the courts in the judicial review cases and the *NHS Constitution* to create an over-arching mechanism for developing treatment-specific commissioning policies within the CCG.

Principles of the Ethical Framework

1. **Evidence of Clinical and Cost Effectiveness**

The CCG will seek to obtain the best available evidence of clinical and cost effectiveness using robust and reproducible methods. Relevant evidence should be consistently and systematically found, extracted, analysed, and presented to support the CCG's work. Both clinically- and patient-defined outcome must be considered, alongside quality-of-life measures and cost utility analyses where possible.

The CCG will promote treatments for which there is good evidence of clinical effectiveness and will not normally recommend treatment that is shown to be ineffective. The outcome measures viewed as most important to assessing evidence of clinical effectiveness should be those related to patients' health status. Reliable evidence will often be available from good-quality, rigorously appraised studies, and patients' evidence of significant clinical benefit is also relevant.

The CCG 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. They will consider technical cost-benefit calculations, but these will not by themselves be decisive. The ethical framework may be used to guide context-specific judgements about the relative priority that should be given to each topic.

2. **Equity**

The CCG believe that people should have access to health care on the basis of need. It may also be necessary to prioritise some categories of care in order to address health inequalities

within the community. The CCG will not discriminate on grounds of protected characteristics as defined by Disability Discrimination Act. These factors, however, may be relevant to the clinical effectiveness of an intervention and the capacity of an individual to benefit from the treatment.

3. Health Care Need and Capacity to Benefit

Health care should be allocated justly and fairly according to need and capacity to benefit, such that the health of the population is maximised within the resources available. The CCG will consider the health needs of people and populations according to their capacity to benefit from health care interventions. So far as possible, the CCG will respect the wishes of patients to choose between different clinically and cost-effective options. 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 solely because it is the only treatment available
- Treatment which effectively treats long term chronic conditions will be considered equally to urgent and life-prolonging treatments.

4. Cost of Treatment and Opportunity Costs

Because the CCG has a duty not to exceed its budget, the cost of treatment must be considered. The cost of treatment is significant because investing in one area of health care inevitably diverts resources from other uses. This is known as opportunity costs and is defined as the value of the opportunities lost which would accrue by investing the same resources in the best alternative way.

5. Needs of the Community

Public health is an important concern of the CCG and they will seek to make decisions to promote the health of the entire community. Some decisions are promoted by the Department of health; some are produced locally. The CCG also supports effective policies to promote preventive medicine.

Sometimes the needs of the community may conflict with the needs of individuals. Decisions are difficult when expensive treatment produces very little clinical benefit. However, even when a treatment cannot generally be supported, a patient's doctor may still seek to persuade the CCG that there are exceptional circumstances in that patient's case.

6. Policy Drivers

The Department of Health issues guidance and directions to NHS organisations which may affect the way in which health service resources are allocated by individual CCGs. The discretion of the CCG can also be affected by the guiding bodies described above. Locally, choices about the funding of health care treatments will be informed by the needs of the CCG, as described in their Commissioning Intentions and Delivery Plans.

7. Exceptional Need

There will be no blanket bans on treatment since there may be cases in which a patient has special circumstances which present an exceptional need for treatment. Each case of this sort will be considered on its own merits in light of the clinical evidence. The CCG has procedures in place to consider such exceptional cases on their merits.