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Principles and Guidance for dealing with Individual Funding Requests Crawley CCG and Horsham and Mid Sussex CCG

September 2017

Crawley Clinical Commissioning Group
Horsham and Mid Sussex Clinical Commissioning Group

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2.0	21 August 2017	Robert Brown		Changes as listed in table 'Changes to previous version'
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Changes to previous version

Description	Reason for change	Author	Date
Any reference to South East Commissioning Support Unit or SECSU changed to NEL Commissioning Support Unit; NELCSU	SECSU transitioned to NELCSU on 1 April 2017	Robert Brown	August 2017
Any reference to 'Associate Partner of IFRs and Clinical Effectiveness' changed to 'Assistant Director – IFR'.	Change of title following transition to NELCSU on 1 April 2017	Robert Brown	August 2017
Paragraph 2.3 Deleted "…draft policy for Prescribed Specialised Services" and replaced with "…Interim Commissioning Policy: Individual Funding Requests (NHSCB/CP/03 April 2013)"	Incorporate updated policy from NHS England	Robert Brown	August 2017
Paragraph 2.5 Deleted reference to PCTs (Primary Care Trusts)	Changed to CCGs (Clinical Commissioning Groups)	Robert Brown	August 2017
Paragraph 3.9; first bullet point Changed the word 'patient' to 'clinician' where it says "… (a) the patient makes a rarity request…or (b) the patient makes an exceptionality request…"	It is the clinician that makes the application not the patient	Robert Brown	October 2017
Paragraph 6.7 IFRs may be submitted by the following NHS personnel: consultant, GP or dental	Clarifies that the request for funding must be led by an NHS practitioner	Robert Brown	August 2017

practitioner, or an equivalent NHS autonomous practitioner where s/he will be responsible for administering the treatment. The person making the request is referred to in this policy as "the requesting clinician". A private practitioner may offer supporting information, but the application must be put forward by the treating NHS clinician. Patients may not make applications directly; applications must be clinically led, with the support of the clinician who is to provide the treatment			
<u>Paragraph 6.11</u> Deleted "…and SECSU in-house Solicitor" and replaced with "…and legal service engaged by NELCSU".	Legal input now sourced by NELCSU from Capsticks Law Firm, London.	Robert Brown	August 2017

1.0 Introduction

1.1 Each CCG has a duty to be able to identify priorities for its population and, for non-prescribed services, decide how health care resources are to be allocated[1].

1.2 This responsibility includes making decisions about funding and commissioning of health care interventions[2].

1.3 The National Health Service Commissioning Board and Clinical Commissioning Groups (Responsibilities and Standing Rules) Regulations 2012, which came into force on 1 April 2013, sets out standing rules for funding and commissioning of drugs and other treatments. The rules provide that "A relevant body must have in place arrangements for making decisions and adopting policies on whether a particular healthcare intervention is to be made available for persons for whom the relevant body has responsibility". These arrangements must "include 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".

1.4 There are several reasons why a CCG may not commission a health care intervention (NHS Confederation 2008):

- "It may not have been aware of the need for this service and so has not incorporated it into the service specification (this can be true for common and uncommon conditions);
- It may have decided to fund the intervention for a limited group of patients that excludes the patient for whom the request is being made;
- It may have decided not to fund the treatment because it does not provide sufficient clinical benefit and/or does not provide value for money;
- It may have accepted the value of the intervention but decided it cannot be afforded in the current year".

[1] From 1 April 2013 Clinical Commissioning Groups (CCGs), established under the Health and Social Care Act 2012, are the statutory bodies responsible for commissioning services for the patients for whom they are responsible.
[2] "healthcare intervention" includes the use of a medicine, medical device, diagnostic technique, surgical procedure or other therapeutic intervention.

1.5 All CCGs are required to have in place arrangements to consider requests to fund a healthcare intervention, which is not commissioned, for an individual patient. These are referred to as Individual Funding Requests (IFRs).

1.6 While decisions about which healthcare interventions should be made available to local people are the responsibility of individual CCGs, it is widely recognised that there are considerable benefits to be gained from an area-wide approach to dealing with IFRs. There are benefits to the general public from greater consistency in decision-making across the area, limiting the potential for "post-code prescribing", and for clinicians in acute trusts. Where CCGs apply the same principles to make IFR decisions, and use a common process, then the procedural maze facing clinicians is reduced. This is entirely positive both in terms of excellence in commissioning practice, as well as with regard to the reputation of the NHS in an area.

2.0 Purpose of this document

2.1 This document outlines the issues and presents a set of principles that underpin the approach by Crawley CCG and Horsham and Mid Sussex CCG to dealing with IFRs. It should be read in conjunction with the Policy and Operating Procedures (POP), which is set out in a separate document.

Development of the principles and guidance

2.2 NELCSU developed an agreed set of principles and guidance to inform the development of IFR policies throughout Crawley CCG and Horsham and Mid Sussex CCG, and developed policy and operating procedures to illustrate the application of these principles.

2.3 The development of these principles and guidance:

- Has been based on current national guidance and Interim Commissioning Policy: Individual Funding Requests (NHSCB/CP/03 April 2013);
- Has benefited from legal advice;
- Defines IFRs and interprets the contributing concepts of exceptionality and rarity;
- Distinguishes IFRs from other individual-level funding decisions.

2.4 The POP sets out how these principles and guidance are applied to produce an IFR process compliant with national guidance and provide a common and consistent decision-making across Crawley, and Horsham and Mid Sussex.

National Guidance

2.5 The way in which CCGs are required to consider IFRs is set out in Regulations issued by the Secretary of State and guided by the NHS constitution, now covered in Directions. There is also extensive Guidance from the National Prescribing Centre[3].

2.6 Relevant national guidance has been taken into account when developing this document. The national guidance includes:

- The National Health Service Commissioning Board and Clinical Commissioning Groups (Responsibilities and Standing Rules) Regulations 2012. (Department of Health 2012);
- NHS Constitution for England. (Department of Health 2009, revised 2012 and 2015);
- Local decision-making competency framework: For groups involved in making local decisions about the funding of medicines and treatments in the NHS. (National Prescribing Centre 2012);
- Directions to Primary Care Trusts and NHS Trusts concerning decisions about drugs and other treatments. (Department of Health 2009);
- Defining guiding principles for processes supporting local decision-making about medicines. Final Report. (National Prescribing Centre/DH 2009);
- Supporting rational local decision-making about medicines (and treatments). A handbook of good practice guidance. (National Prescribing Centre 2009);
- Equity and Excellence: Liberating the NHS (Department of Health 2010);

Definition of an Individual Funding Request

[3] The NPC became part of NICE in April 2011. From 15 May 2012, the team previously delivering the work of the NPC formed the NICE Medicines and Prescribing Centre.

2.7 The following definition of an Individual Funding Request, as set out in the NPC Handbook, has been adopted:

> Individual funding requests (IFR)
>
> "An IFR is a request to fund, for an individual, an episode of healthcare that currently falls outside existing contracts. The funding request may be asking for any type of healthcare: a service, a piece of equipment or aid, a specific treatment or medicine. In contrast to annual prioritisation and in-year service development decisions, appropriate IFRs are considered on an individual patient, rather than population, basis. There are two main categories of appropriate IFR: first, where patients fall outside an existing generic or treatment-specific policy where an unusual circumstance applies to the individual; second, for patients with a very rare clinical condition."
>
> NPC Handbook 2009

3.0 Principles informing the development of IFR policies

3.1 From 1 April 2013 CCGs continued to manage non-prescribed service IFRs on a population basis with cooperation with provider Trusts and stakeholders.

3.2 An IFR is a request to fund a health care intervention, for an individual patient, which falls outside of existing CCG contracts or policy. CCGs should be diligent to ensure that the IFR process is not used by individual patients, groups of patients, or clinicians as a device to bypass usual commissioning processes.

3.3 Clear separation should exist between commissioning procedures which prioritise health care interventions for the whole or a part of the CCG's population, and their agreed process for dealing with individual patients.

3.4 Decisions about treatment for individuals should not be exempted from the requirements of prioritisation. Hence the Ethical Framework underpinning CCG population-level decision-making processes should also apply to the determination of IFRs. The South East Coast (SEC) Ethical Framework for decision-making should be used when making individual-level recommendations (a copy is set out in Appendix A).

3.5 The SEC Ethical Framework requires that the CCG's general approach should be that it would be inequitable to offer a health care intervention to a named individual that would not be offered to all patients with equal clinical need.

Crawley CCG and Horsham and Mid Sussex CCG should therefore ensure individual applications are scrutinised with particular care where there may be a risk of offering a health care intervention to a named individual that would not be offered to all patients with equal clinical need.

3.6 Whether or not a request should be considered as an IFR or as a request for a service development will depend on whether there are one or more other patients within the population served by Crawley CCG and Horsham and Mid Sussex CCG, in the same financial year, who are or are likely to be in the same or similar clinical circumstances as the requesting patient, and who could reasonably be expected to benefit to the same or a similar degree from the requested health care intervention (known as “similar patients”).

3.7 If it is foreseeable that there will be at least one other similar patient within the Crawley CCG and Horsham and Mid Sussex CCG area, then the request should properly 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 rare genetic disease).

3.8 Clinicians are entitled to make a request for an individual (an “individual funding 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 medical condition or clinical presentation which is considered rare, **and** for which the CCG has no policy because the low probability of the condition occurring among the CCG’s population means that an explicit policy is not warranted (“A rarity 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”).

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

- Either (a) the clinician makes a rarity request for funding for treatment in connection with a presenting medical condition for which the CCG has no policy or (b) the clinician 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 the IFR 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 a request for a service development.

3.10 The IFR Panel should 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.

3.11 "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. In making recommendations members of the IFR Panel should not take social or personal circumstances into account for the reasons explained to the High Court and the Court of Appeal in R (Condliff) v North Staffordshire PCT.

4.0 Interface between the IFR policy and other commissioning policies

CCG Commissioning Policy

4.1 The IFR policy is concerned with decisions about the funding of health care interventions for named individuals and should be separate from the proactive processes which each CCG operates as part of its annual commissioning

round or within the year for identifying health care interventions for population decisions and policy development.

4.2 A policy for dealing with IFRs is only one element of a suite of CCG commissioning policies and the IFR policy will not be the only policy concerned with individual level funding for different aspects of the provision of NHS care. It is likely that a CCG will also have policies and processes for dealing with, for example:

- Patients moving into the area;
- NHS pick-up after patients complete clinical trials;
- Retrospective funding requests.

4.3 It is important to bear in mind the interface between the IFR policy and other CCG policies and processes. It is the specific intention of this guidance to enable proper consideration of appropriate IFRs, and to ensure that where the IFR process identifies need for policy development or policy review the topic is raised for consideration through the appropriate process. The guidance makes it clear that making ad hoc policy is not a legitimate role for an IFR Panel.

4.4 In developing this approach to IFRs it has therefore been assumed that the IFR process is one element of a suite of commissioning processes which also includes:

- A separate procedure for considering in-year policy review requests, with the power to take an urgent or interim policy decision;
- The process (or group of processes) dealing with all other circumstances in which consideration of individual level prior approval for funding is required which do not fall within the IFR remit.

4.5 The need for a local funding and commissioning decision about a health care intervention for non-prescribed services will, in general, be addressed as part of the CCG annual planning round. Where the IFR process identifies need for policy development or policy review this will be raised through the appropriate channel. The need for an in-year policy decision may arise where the IFR process has identified urgent need for an interim policy decision; an interim in-year policy decision may be positive or negative and will not set precedent for final policy recommendation pending full review.

4.6 In developing the suite of commissioning policies CCGs will, of course, be concerned to ensure consistency is maintained between the IFR policy and other elements of the suite.

4.7 All related policies should be available to view on the CCG or NELCSU websites.

NHS England Policy

4.8 With effect from 1 April 2013, NHS England (NHS E) has responsibility for IFR process for Prescribed Specialised services. In line with arrangements for the commissioning of prescribed services, IFRs will be managed on a provider rather than a population basis. CCGs will continue to manage non-prescribed service IFRs on a population basis.

4.9 Clinical commissioning policy development for specialised services will be done at a national level so there is one consistent national routine commissioning policy for each treatment/service area covered.

4.10 It is important to consider the interface between CCG IFR policy for non-prescribed service and NHS E IFR policy for prescribed Specialised Services.

4.11 In developing this IFR guidance it has been assumed that both NHS E and CCGs will wish to work together, where necessary, to mitigate the risk of system cross over and confusion, and to ensure that the patient pathway is not fragmented.

5.0 Resourcing

5.1 NHS E expects that CCGs will provide resources to support all commissioning processes, including IFRs, in a timely and efficient manner.

5.2 Suitable and sufficient resources will need to be in place to support IFRs:

- 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 triage of applications for funding and the redirection of requests inappropriate for CCG IFR consideration;
- Timely and efficient communication in appropriate language between everyone involved in the IFR process, including with the relevant CCG, the requesting clinician, the patient and NELCSU;
- The effective working of the IFR Panel and any Appeal Panels;
- Training for everyone involved in the process;
- Monitoring and audit; and
- Secure handling and storage of confidential information.

6.0 How will the IFR process operate?

Overview

6.1 A diagram presenting an overview of the IFR process, and the Appeal process is shown in Figure 1.

6.2 Details of this process are set out in the accompanying Policy and Operating Procedure (POP), which details the steps necessary to comply with the guidance set out in the National Prescribing Centre Handbook.

IFR Process

Appropriate requests

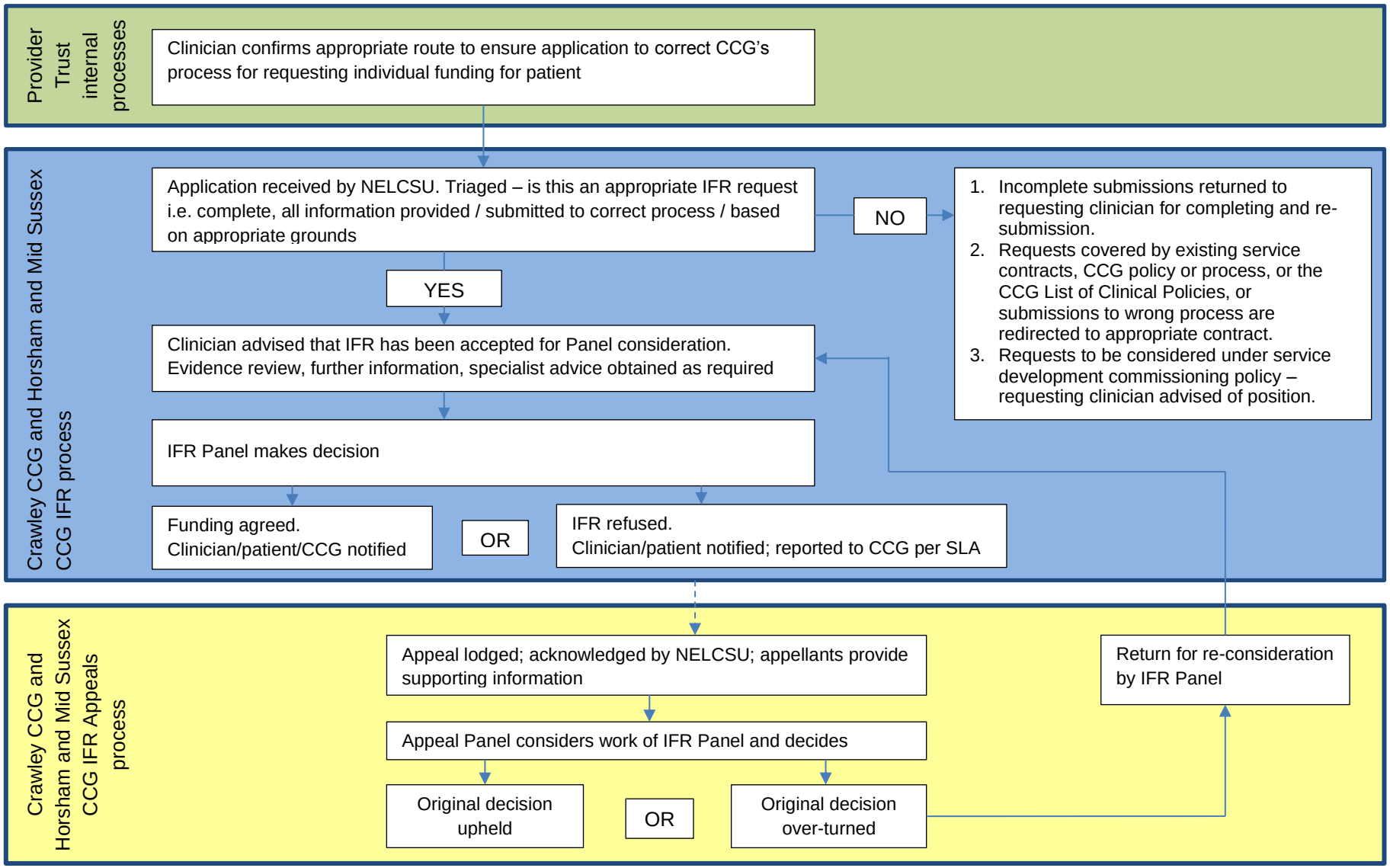
6.3 Only appropriate requests should be considered by the IFR Panel (see section 3 above). In order to be regarded as appropriate, requests must demonstrate a good arguable case that they qualify as either:

- An exceptionality request;
- A rarity request.

6.4 Requests that are not appropriate for consideration by the IFR Panel include:

- Where the treatment in question is funded within an existing commissioning policy;
- Those that fall outside the scope of the IFR process and are covered by another policy/procedure, such as NHS pick up after a clinical trial, patients moving into the area or retrospective funding;
- Where a service development decision is called for because it is foreseeable that there will be similar patients or subgroups of patients, who are likely to benefit from the treatment (e.g. requests relating to a newly licensed drug).

Figure 1: Overview of the IFR and Appeal Processes



6.5 All reasonable attempts will be made by the IFR Team to "sign-post" clinicians and patients to the correct route, as appropriate to the treatment being requested.

6.6 In accordance with national guidance, it is expected that provider Trusts will have processes in place to enable clinicians and managers to identify clearly the appropriate route for applications to CCGs for decisions about the funding of medicines and treatments. Requesting clinicians will be expected to affirm that IFRs have been through the provider Trust's own review systems prior to submission.

Who can submit an IFR?

6.7 IFRs may be submitted by the following NHS personnel: consultant, GP or dental practitioner, or an equivalent NHS autonomous practitioner where s/he will be responsible for administering the treatment. The person making the request is referred to in this policy as "the requesting clinician". A private practitioner may offer supporting information, but the application must be put forward by the treating NHS clinician. Patients may not make applications directly; applications must be clinically led, with the support of the clinician who is to provide the treatment

6.8 The requesting clinician is responsible for ensuring that the patient understands the full implications of submitting an IFR.

6.9 The requesting clinician is responsible, pursuant to the clinician's duty of care to the patient, for providing all necessary supporting information and evidence, and is also responsible for setting out any factors which in his or her view could support a case for exceptional clinical circumstances on behalf of their patient.

The submission process

6.10 Internal documentation is designed to support the South East-wide development of a common submission process and a common submission form, which calls for an equivalent level of information to be provided for all requests. The benefits of standardisation include:

- All requests are considered using comparable quantity and quality of information;

- Panel members become accustomed to the layout of information provided and can quickly find their way around the submission;
- Clinicians have only one form and one process to learn;
- Standard formats permit systems for analysis and transfer of information to be developed efficiently and shared between CCGs;
- Facilitates monitoring, audit and analysis.

Membership of IFR Triage

6.11 The Terms of Reference for IFR Triage can be found at Part II, IFR POP, Appendix E. Membership of Triage will include Crawley CCG and Horsham and Mid Sussex CCG IFR Clinical Lead (Medical Director or delegated GP Clinical Leads), and IFR Team Lead, with input as and when required from Public Health and legal service engaged by NELCSU.

Membership of IFR Panel

6.12 The membership of the IFR Panel will reflect an appropriate mix of suitably qualified and trained members. It is recommended that a Panel should have at least four members, one of whom must be a clinician from the relevant CCG where the patient is registered with a GP practice and one a lay person. The membership and Terms of Reference are detailed in the IFR POP (Part II, Appendix D), and will be drawn from: General Practitioners, medicines management, other healthcare professionals and lay people. All members will receive training on an annual basis.

IFR Panel decisions

6.13 The NELCSU IFR Panel will make individual funding decisions to Crawley CCG and Horsham and Mid Sussex CCG.

6.14 When considering requests the IFR Panel is required to act in accordance with the principles set out in this policy.

6.15 Panel members are entitled to expect the requesting clinician to put the best available evidence before the IFR Panel. The IFR Panel may refuse to

consider a request if the information provided by the requesting clinician falls short of this standard.

6.16 A consensual decision-making process will be adopted (see POP) and used as necessary, directed by the Chair of the Panel.

6.17 A recognised Hierarchy of Evidence will be used, whenever deemed necessary by Panel members and/ or the Chair.

Appeals

6.18 If the IFR Panel declines funding an IFR the requesting clinician or the patient may submit an appeal. The IFR POP defines the Appeals Process.

6.19 The Appeal Panel will review the documentation related to the request for individual funding and the IFR Panel's decision, and consider whether the Appeal Panel is satisfied that the IFR Panel properly considered the application. The review will focus on the process followed by the IFR Panel, the scope and nature of the evidence considered, the factors considered by the IFR Panel and the criteria applied by the IFR Panel in coming to its decision.

6.20 The role of the Appeal Panel is not to reconsider the merits of the request itself. It is part of the CCG corporate governance structure. It is required to decide whether:

- The decision was consistent with the SEC Ethical Framework for decision-making and the principles set out in this policy;
- The IFR Panel acted in accordance with the CCG operating procedures;
- In reaching its decision the IFR Panel took into account and weighed all the relevant factors and did not take into account any irrelevant factors;
- The IFR Panel reached a conclusion that was open to them acting as a reasonable IFR Panel.

6.21 If the Appeal Panel decides that the decision cannot be supported on any of the above grounds, they shall send the case back for re-consideration by the IFR Panel.

6.22 The 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 return the case to the IFR Panel to be reconsidered on the basis of the new evidence, not to appeal the existing decision.

6.23 The IFR Appeal process is clearly separate from the IFR process. It is recommended that the administration of an Appeal respect the clear separation.

6.24 The Appeal Panel should have a different membership from the IFR Panel. The minimum number of Appeal Panel members will be three, to include one CCG Governing Body Member (ideally from but not limited to the commissioning CCG), one clinically-qualified member and one lay member. All members will receive training. Under normal circumstances it is expected that the CCG Governing Body Member will chair the Appeal Panel, but should in exceptional circumstances that not be possible, a senior member of NELCSU will do so. All members will receive training.

6.25 Complaints or appeals about decisions made by the IFR Triage Group will be handled through Customer Services under the CCG Complaints Handling Policy.

Communication

6.26 A patient information leaflet explaining the IFR process and the Appeal process will be available in English. NELCSU may prepare the leaflet in other languages and formats upon request where it is proportionate to do so in accordance with the CCG Equality Impact Assessment.

6.27 A source of information for clinicians, predominantly web-based, is available, including “the policy”, and the suite of accompanying commissioning policies.

Documentation, monitoring and audit of the process

6.28 All stages of the IFR process and the Appeal process will be fully documented and allow the appropriate tracking of all requests. Particular attention will be paid to maintaining the confidentiality of patient information.

6.29 The IFR Panel shall give reasons for all decisions and the reasons will be set out in the minutes of the IFR Panel meeting and in the outcome letter. Both the decision and the reasons for the decision will be clearly communicated to requesting clinicians and patients using appropriate language.

6.30 The reasons for any IFR Triage Group's decisions will be documented.

6.31 Records will also be kept of the number and characteristics of inappropriate submissions to the IFR process so that steps may be taken to provide the necessary information, advice, etc. to clinicians and provider Trusts in order that inappropriate submissions may be reduced to a minimum.

7.0 References

The NHS Confederation. Priority setting: managing individual funding requests. 2008.

Department of Health. The NHS Constitution for England. January 2009; revised 2012 and 2015.

National Prescribing Centre. Defining guiding principles for processes supporting local decision-making about medicines. Final Report. January 2009.

National Prescribing Centre. Supporting rational local decision-making about medicines (and treatments). A handbook of good practice guidance. First Edition. February 2009.

Department of Health. Directions to Primary Care Trusts and NHS trusts concerning decisions about drugs and other treatments 2009. March 2009.

Department of Health. Equity and Excellence: Liberating the NHS. 2010

Specialised Commissioning, NHS England. Standard operating procedure for funding requests for clinically critically urgent treatment outside established policy. June 2015

Appendix A

Ethical Framework for Decision-Making

Introduction

This Ethical Framework is used by commissioners to underpin their approach and application of processes for local decision-making at all levels, including decisions for their population and decisions for individuals.

Purpose

- To establish the key principles that will underpin how CCGs make commissioning decisions on behalf of their populations; including processes operated on their behalf by their commissioning support unit (NELCSU).
- It is important that a CCG can demonstrate that the way it makes decisions is consistent across all levels of commissioning including strategic planning, funding health care interventions, and funding individual treatment requests. It is also important that decision-making is consistent with the requirements of the NHS Constitution, national best practice policy / guidance, and legislation.
- The public will want to know that the CCG takes account of the values of the wider health care community when making its decisions, and to be able to recognise and understand processes for prioritisation and resource allocation.

Context

Each CCG has a duty to be able to identify priorities for its population and, for non-specialised services[4], decide how health care resources are to be allocated[5].

The main mechanism through which investment and disinvestment decisions are taken is through the annual planning round. In undertaking this process of prioritisation, one of the challenges for CCGs is how to strike the right balance between providing services that meet the needs of the population, whilst balancing this with the differing needs of individuals. It is an unavoidable feature of state-funded healthcare systems, such as the NHS, that commissioning bodies have insufficient resources to fund all types of health care that might be requested for their populations.

[4] Specialised services are the commissioning responsibility of NHS England

[5] From 1 April 2013 Clinical Commissioning Groups (CCGs), established under the Health and Social Care Act 2012, are the statutory bodies responsible for commissioning services for the patients for whom they are responsible.

Since April 2009 commissioning bodies have a statutory duty to ensure rational local decision-making, and NHS Trusts have a duty to co-operate. The NHS Constitution, updated in October 2015, sets out a declaration of patients' rights, underpinned by statutory directions, which came into force on 1 April 2009. These provide that patients have the right to expect local decisions on funding of drugs and other treatments to be made rationally following a proper consideration of the evidence.

CCGs will need to take difficult and sensitive decisions about what will be funded and what will not. The way in which decisions are made is fundamental to their democratic acceptability and contributes to whether a decision is judged to be fair or not. A key requirement is for CCGs to demonstrate that decision-making is consistent, takes account of all relevant factors and is underpinned by locally established principles.

Further, CCGs must take account of guidance and principles published by the Secretary of State and in particular the requirement for high standards in the quality and consistency of decision-making, and the need to avoid allegations of post-code lottery.

The Ethical Framework establishes the values based principles that underpin how commissioning decisions are made. The principles can be used to determine the approach to decision-making and the development and application of specific tools and/or criteria to be used in decision-making processes.

It is important to remember the Framework of principles is a guide to inform the way commissioners think about decision-making. It establishes the conditions necessary for fair decision-making. The Framework of principles is not a decision-making tool. It should not be viewed as an algorithm or the process for decision-making. The values based principles which form the Framework should not be used as a checklist or criteria to be satisfied before a decision can be made

Establishing the principles

The values based principles were established through a series of focus groups, held in November and December 2009, involving health colleagues, clinicians, and lay members. Seventy people participated in total and between them generated 580 statements defining the key attributes of decision-making that would assure them that, if applied, a resource allocation decision would be consistent and fair.

The statements generated were analysed by an independent researcher, grouped according to theme, and then sorted by the number of statements coded under each theme. No attempt was made to rank or weight themes in the form of criteria as this is not their purpose.

Six principles for decision-making

Six principles for decision-making have been identified. Key principles are the need for decisions to be rational, socially inclusive, clear and open to scrutiny and take account of economic factors. A further principle is the requirement to allocate health care resources according to health needs, taking care to balance the needs of the individual with the needs of the wider community. The sixth principle is that a wide range of factors and perspectives should be considered when deliberating a decision.

Principle 1: Rational

Decision-making is rational based upon a process of reasoning;

- Ensuring that the decision is based on thoughtful consideration of the available evidence.
- Making a realistic appraisal of the likely benefit to patients.
- Weighing up all the relevant factors, including risks and costs.
- Taking account of the wider political, legal and policy context.
- Ensuring individuals involved in decision-making are appropriately skilled and trained.

Decisions should be made on the basis of a reasonable evaluation of the available evidence, including evidence of efficacy, safety and clinical effectiveness.

A process of inquiry is required to gather the available relevant evidence. The approach to assessing the validity and credibility of evidence should be broad but maintain high standards of critical appraisal. Both qualitative and quantitative evidence will be taken into consideration, with evidence from sources other than large-scale randomised clinical trials given appropriate weight. Expert opinion should be sought.

Decisions should be based on careful consideration of the trade-offs between costs and benefits, both in the short and longer term, but also recognise that complex trade-offs cannot necessarily be reduced to simple cost-benefit calculations.

Rational decisions will weigh up likely outcomes, the wider contexts in which treatments can be provided, the implications for service delivery, clinical pathways, and benefits, costs and risks.

Existing national policy and guidelines must be considered. Decisions should be taken within the political and legal context.

Consideration needs to be given to the people who are responsible for decision-making. The position, qualifications and skills of decision makers should be appropriate to ensure

due deliberation of all the relevant factors and to ensure that appropriate specialist clinical and technical knowledge is available.

Principle 2: Inclusive

Decisions about the allocation of health care resources should be arrived at through a fair and non-discriminatory process:

- Reinforcing the concept of equal opportunity of access to health care
- Ensuring patient and public engagement in decision-making
- Balancing the rights of individuals with the rights of the wider community.

Effort should be made to ensure broad based participation in decision-making groups and committees. Decision-making should be non-partisan and individuals will need to be able to take an objective view of the topic, and maintain an open mind about the evidence. As far as possible consensus decision-making will be used.

Decision-making should not discriminate on characteristics which are irrelevant to health conditions and the efficacy of treatment[6]. Consideration of factors such as age and ethnicity will only be considered where this is clinically relevant.

Decisions should take account of local and societal sensitivities. There should be an active attempt to engage patients, carers and the wider public in the decision-making process to ensure that the perspectives of both health care providers and consumers are fully taken into account.

The aim is to achieve consistent and equitable opportunity of access to health care, between individuals and groups in society, and to promote equity of health outcome.

Principle 3: Clear and open to scrutiny

The process of making decisions about the allocation of health resources should be transparent and easily understood. Patients and the public should have easy access to the processes of decision-making and these processes should be consistently applied.

Both the decisions themselves, and the way they are determined, should be clearly specified, including roles and responsibilities of individuals involved, accountabilities and governance arrangements, and the right of appeal.

[6] NHS organisations have legal duties to eliminate discrimination and promote equalities and good community relations.

Decision-makers will need to provide the rationale for their decisions, any particular factor that has influenced a decision should be clearly stated including, for example, insufficient evidence of effectiveness, or insufficient capacity or resources.

The information provided to decisions-makers should be fully documented. The process of decision-taking should also be documented, to show that it has conformed to the principles agreed and to record the degree of consensus.

Communication throughout a decision-making process is required to be clear and effective, and communication about decisions need to be unambiguous and articulate.

Principle 4: Investment and disinvestment decision within available finite resources.

Resources are finite and must be managed responsibly. Decisions need to be made within the context of available resources. Investment in one area of health care will divert resources away from other areas of potential investment, or existing services.

Factors such as current areas of spend, and the existing care provision must therefore be considered.

Ensuring efficacy and effectiveness of spend are key considerations and a clear understanding of costs and opportunity cost is called for. There is a need to balance cost impact against other factors such as health impact for the population. Impacts need to be considered both in the short and longer term.

Principle 5: Allocation of health care resources according to health needs

Each CCG is required to identify priorities for its population, decide how healthcare resources are to be allocated, and determine the priority to be assigned to a service or a particular health care intervention.

Decisions about the allocation of health care resources should be based on a clear understanding of the health needs of the population whom decisions will affect, and the scale and nature of benefits.

There is requirement to balance the needs of the individual with the needs of the wider community. There may be times when it is appropriate to target some demographic groups or health issues in order to reduce inequalities and promote the well-being of the community as a whole.

Policies which promote health and avoid people becoming ill are considered alongside curative treatments and other interventions.

Principle 6: Promote consideration of a wide range of factors

Decision-making should embrace the concept of ‘broad thinking’, being secular, open to new ways of working and thinking as well as new technologies, and taking account of biological and psychological health outcomes.

The combination of individuals involved in decision-making should provide scope for a good range of perspectives in respect of the detail of the topic and its wider contribution to health care in the area.