NHS
Bromley
Clinical Commissioning Group

# INDIVIDUAL FUNDING REQUESTS PROCEDURE

Issued by:

**Director of Commissioning**

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# BROMLEY CLINICAL COMMISSIONING GROUP
# PROCEDURE FOR INDIVIDUAL FUNDING REQUESTS

**Document control**

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**Governance**

This procedure is aligned to the SL Individual Funding Request Policy. It supersedes all pre-existing policies and procedures. It has been adopted by NHS Bromley CCG.

This procedure applies to all staff working on behalf of NHS Bromley CCG. The procedure applies to all hosted bodies and those working on behalf of NHS Bromley CCG.

**Version Control**

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|---|---|---|
| 0.1 | Integrated Governance Committee | 09/10/2014 |
| 1.0 | Integrated Governance Committee | |
| | | |

# BROMLEY CLINICAL COMMISSIONING GROUP
# PROCEDURE FOR INDIVIDUAL FUNDING REQUESTS

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**DEFINITIONS**

**Individual Funding Requests (IFRs) –** an IFR is a request to fund, for an individual, an episode of healthcare that currently falls outside the existing commissioning arrangements or contracts entered into by Bromley Clinical Commissioning Group (Bromley CCG)

**Appropriate IFR –**

- Where a patient's treatment falls outside an existing generic or treatment-specific policy where an unusual circumstance applies to the individual
- For patients with a very rare clinical condition or intervention*

**The CCG –** Bromley Clinical Commissioning Group

- Rare condition/intervention – so rare that CCGs would be unlikely to get another request in the foreseeable future. In addition, there are no current arrangements for this condition or intervention

## PROCEDURE STATEMENT

The purpose of this Procedure is to ensure effective implementation of the SL IFR Policy on Individual Funding Requests. It sets out the way in which the Bromley CCG deals with requests from patients for treatments or diagnostic procedures that fall outside the usual commissioning arrangements and contracts entered into by Bromley CCG.

This Procedure is underpinned by the principles set out in the SL IFR Policy, and is based on the organisational elements established within it.

## THE SCOPE OF THIS PROCEDURE

The Procedure applies to all written application for individual funding requests, submitted by an NHS Consultant, GP or clinician.

The lead for the administration of this Policy is the Head of Contracts.

Secretariat support for the process will be provided by the Contract Support Manager.

Secretariat support for the appeals process will be provided by the Head for Corporate Affairs.

## DUTIES AND RESPONSIBILITIES

It is the responsibility of the Head of Contracts to ensure that this procedure is followed and that it is reviewed in line with relevant CCG protocols.

It is the responsibility of the Contract Support Manager, on behalf of the CCG, to receive and acknowledge all requests for exceptional treatments or diagnostic procedures submitted to the CCG and to co-ordinate the process of assessment and consideration by the CCG's Individual Funding Request (IFR) Panel in line with the agreed CCG Procedure. The Contract Support Manager will also pass all appeals made against decisions of the IFR Panel to the Head for Corporate Affairs, who will convene and act as Secretary to the CCG's Individual Funding Request Appeals Panel (IFRAP).

It is the responsibility of the IFR Triage Panel to assess all requests prior to submission to the CCG for consideration.

It is the responsibility of the Public Health Consultant to assess the evidence of effectiveness of any non-drug requests and the responsibility of the CCG Pharmacist to assess all drug requests.

## ORGANISATIONAL ARRANGEMENTS

### 1. Receipt of a Request for Individual Funding

1.1. The Contract Support Manager with designated reasonability of management of the Individual Funding Requests procedure ("the IFR Manager") shall be the contact person and the central point for receiving the written requests. He/she, on receipt of a request, will confirm that:

- the patient is registered with a GP attached to Bromley CCG
- Explicit written consent has been obtained by the referring applicant (GP or Consultant).
- the request is for an individual treatment or diagnostic procedure i.e. one not covered by the usual/normal commissioning arrangements or contracts or where approval is being sought in advance for a particular treatment. Retrospective funding is not available.
- the patient is sponsored by an NHS GP and/or Consultant.

If any of the above is **not confirmed** a letter will be sent to the applicant advising on why a request cannot be pursued and suggesting a more appropriate course of action, if appropriate.

Alternatively if a query has been raised

- If the above is confirmed, but a form not yet completed, a letter and application form will be sent to the referring GP/Consultant (see Appendix A – IFR Drug application or Appendix B non-drug application, whichever is applicable)
-

1.2. If the conditions at 1.1 **are confirmed and an application form received,** the details of the request will be entered on a confidential database and the following actions will be taken:

1.2.1 An acknowledgement will be sent to the applicant (and patient if details known) with a further explanation of the next stage in Individual Funding Request process.

1.2.2 They will also be required to provide all relevant information and respond to additional questions/requests for information in time to take the request to the next available meeting. The IFR Panel will make a decision based on the information available at the time. The IFR Panel will only proceed with consideration of the request if all members agree that they have sufficient information upon which to make a decision.

### Timescales

1.3 Bromley CCG will aim to process all requests within 4-6 weeks of receiving the completed application, together with all relevant supporting documentation and evidence, at their registered address. Completed urgent requests are to be reviewed within 10 working days. The Panel can only review such applications when they have sufficient information upon which to base a decision.

1.3.1. In the case of an emergency, where there is clinical decision that treatment or intervention is required within less than 10 working days or if insufficient information is

provided for the decision to be taken within 10 working days, providers will have to provide treatment or intervention at their own cost. The decision whether to provide funding will be considered subsequently by the CCG upon the receipt of all necessary information.

1.3.2. Delay at any stage of the process should be communicated by the IFR Manager to the referring applicant (and patient if details known) and an explanation provided.

## 2. Assessment of the Request

2.1. When an application is received, the IFR Manager will check that the form is fully and correctly completed and explicit consent received. If that is not the case, a letter will go to the referring clinician explaining that the request cannot proceed and be considered by Bromley CCG until all the necessary information and clarification has been received.

2.2. On receipt of a correctly completed application, the details of the request will be entered on a confidential database.

2.3. On receipt of a full completed and correct application form, the request will be assessed by the IFR Triage Panel (Terms of Reference – see Appendix C) The following options are then open to them:

- To request any further information they think is necessary
- To refer the request to the IFR Panel
- To agree the request without reference to the IFR Panel
- To refuse the request without reference to the IFR Panel

2.4. The IFR Triage Panel may only agree to fund a request at this stage where they agree that;

2.4.1 The patient fully meets the relevant criteria as set out within the appropriate section of the South East London Treatment Access Policy, or

2.4.2 where there is compelling evidence of exceptionality and significant evidence of clinical effectiveness**.**

2.5. The IFR Triage Panel can only refuse to fund a request at this point based on the assessors' view that the patient does not fulfil the relevant criteria as set out within the appropriate South East London Treatment Access Policy and there is no evidence that the patient would constitute a clinical exception. These patients have the right of appeal to Bromley CCG Appeals Panel

2.6. Where there is uncertainty, the IFR Triage Panel should refer the case to the IFR Panel. A peer-review audit of 5% of these cases will be conducted annually.

## 3. Consideration by the Individual Funding Requests Panel ("IFR Panel")

3.1. The terms of reference and membership of the IFR Panel are set out in (Appendix D) and form part of the SL IFR Policy. The Panel will consider all cases referred to it by applying the principles set out within the SL IFR Policy.

3.2. The IFR Manager will ensure that the request is prepared for consideration by the IFR Panel and that the following is available:

- A fully completed application form (dependent on type of request) Appendices A & B, together with any further relevant information received with the request
- Evidence of clinical effectiveness
- Evidence of cost effectiveness (if available)
- Details of any exceptional individual circumstances

All paperwork should be fully anonymised

It will be the responsibility of the Bromley CCG pharmacist and for the Public Health Consultant to assess the requests and prepare evidence for the consideration of the IFR Panel, as appropriate.

3.3. Every request for funding considered at a meeting of the IFR Panel shall be determined by a majority of the votes of members present and voting on the request. In the case of an equal vote, the Chair shall have a casting vote. At the discretion of the Chair, all requests put to the vote shall be determined by oral expression or by a show of hands, unless the Chair directs otherwise, or it is proposed, seconded and carried that a vote be taken by paper ballot.

3.4 The IFR Panel's decision will take into account the impact of the following:-

3.4.1 Relevant Aspect of the Human Rights Act 1988 (Appendix F)
Bromley CCG's definition of clinical and cost effectiveness (Appendix G)
Ethical Decision-Making Framework for Individual Funding Requests (Appendix H)

3.5 A full and detailed account of the proceedings should be recorded in the minutes which should be agreed with IFR Panel members at their next meeting.

3.6 The IFR Manager on behalf of the IFR Panel should communicate the decision to the referring NHS GP or Consultant/clinician and patient (if details are known)

3.7 Where the request is refused, a clear, accurate and comprehensive explanation must be given. The letter should state that the case could be reconsidered by the IFR Panel if new and material evidence becomes available.

3.8 Where the request is agreed, the letter may request that a report is provided on the patient's progress, to determine whether treatment is effective. The CCG may use this information to consider the continuation of treatment.

3.9. The refusal notification must include advice to the referring applicant about the terms on which they can make an appeal to the IFRP Appeals Panel. For patients where the CCG does not have patient details, it is the duty of the referring applicant to inform the patient about the appeals process.

3.10. The IFR Manager should keep a secure database with the following minimum information:

- Patient details: name, date of birth,
- GP details
- Details of requested treatment
- Date request received at the CCG
- Date of the IFRP decision
- Nature of decision
- Cost of treatment (if known)

## 4 Monitoring of the Individual Funding Request Process

4.1. The Individual Funding Request Process should be monitored on a regular basis by the following methods:

- An Annual Report from the IFR Manager to the CCGs Integrated Governance Committee.
- An annual audit of the assessments undertaken by the IFR Triage Panel (5% sample of the decisions) to be conducted by the full IFR Panel.
- Peer review audit of an individual case with the SL CSU IFR Team

## 5 The Process of Appeal

5.1. In all cases where the request has been refused by the IFR Panel, the referring applicant must be advised in writing of their right to have the IFR Panel's decision considered by an Appeals Panel (See Appendix E). The refusal notification letter should include the following guidance:-

- Applicants wishing to submit an appeal must provide a signed statement setting out their grounds for appeal to the Chair of the Appeals Panel within 30 days of receipt of the letter notifying refusal.
- Effective grounds of appeal will need to demonstrate that there was a shortcoming in the process of consideration of the request by Bromley CCG, and/or that new and material evidence has come to light that was not available for consideration previously in the process.

5.2. The Secretary to the Appeals Panel will acknowledge receipt of a letter of appeal within five working days of receipt. The acknowledgement letter will advise the applicant that an Appeals Panel will only be set up to consider the request if it is the view of the Chair that:-

- the appeal submission constitutes permissible grounds of appeal which are that there was a shortcoming in the process of consideration of the request by the CCG, and/or that new and material evidence has come to light that was not available for consideration previously in the process, and

- there is no further action that can be taken short of calling a meeting of the IFR Appeals Panel to resolve the issue.

5.3. The Secretary to the Appeals Panel will forward a complete set of case papers provided by the IFR Panel to the Panel Chair as soon as possible, and seek further specialist advice if necessary.

5.4. Having considered the documentation the Chair will decide whether to convene an Appeals Panel and will take into consideration:-

- the grounds of appeal presented by the applicant
- whether any further action can be taken to resolve the issue, other than by convening an Appeals Panel.
- whether further expert advice is needed
- what value convening an Appeals Panel would add to the process

5.5 The Secretary to the Appeals Panel should inform the patient about the decision to convene or not to convene an Appeals Panel. Where the decision is to convene a Panel, an indication of the timing of the Appeals Panel hearing and notification of the decision should be given. This should be within ten working days of the notification of the decision to convene an Appeals Panel. When the request to convene an Appeals Panel is turned down the reasons and proposals for any alternative action must be clearly stated.

5.6 Where it is decided to convene a Panel members of the Appeals Panel should be provided with full details of the case including all correspondence, evidence of clinical and cost effectiveness, full documentation of the discussion and outcome.

5.7 Appeals Panel members will not have been a member of the Committee involved in the original IFR Panel decision

5.8. The Appeal Panel will need to consider whether, in the light of the patient's statement:-

- the IFR Panel decision-making process was robust and had been followed correctly and fairly in line with the criteria (this should include resolution of any disputed aspects if appropriate).
- sufficient advice and information was sought by the IFR Panel.
- the decision of the IFR Panel was reasonable, lawful and based on all relevant factors and not on irrelevant factors

5.9. In coming to a decision the Appeals Panel should:-

- review all relevant evidence
- consider the claims and views of the patient
- obtain additional expert opinion where necessary
- take a decision that takes fair and reasonable account of the patient's circumstances as well as the CCG's statutory duties and obligations towards its local population.

5.10. The Appeals Panel should consider and decide the case on the basis of the papers and would not hear evidence from, or be addressed by, the patient in person, or a representative of Bromley CCG.

5.11. The possible outcomes of the Appeals Panel will be to:-

5.11.1 uphold the decision of the IFR Panel, in which case the applicant will be reminded of their right to invoke the NHS complaints procedure, or to

5.11.2 refer the case back to the IFR Panel for further consideration (in particular the Panel may at its discretion choose to take this course following receipt of significant additional information not previously considered by the IFR Panel).

5.12. In the event of disagreement within the membership of the IFR Appeals Panel, the decision shall be determined by a majority vote. In the event of a tied vote, the Chair shall have a second, casting vote. A member co-opted by the Chair shall not have a vote.

5.13. Decisions of the IFR Appeals Panel must be fully documented. The Chair of the IFR Appeals Panel should ensure that the outcome of the Appeal is communicated to the applicant and the clinician patient (if details known) concerned, as well as to the Chair of the IFR Panel.

5.14. The Panel should make clear its reasons for referring the request back to the IFR Panel, including identifying any shortcomings in the process and any new evidence that needs to be taken into consideration.

5.15. The findings of the Panel should be clearly stated in terms which include:

5.15.1 Shortcomings in the process and at which stage/element of the IFR process was found inadequate (for example, on receipt; assessment or consideration by the IFR Panel).

5.15.2 New evidence with details of new and relevant evidence submitted.

5.16. The Secretary of the Panel will also communicate to the Chair of the IFR Panel any concerns about the relevant Polices and Procedures arising from the appeal process.

5.17 Information regarding number of Appeals received and the outcomes will be included in the IFR annual Report

5.18. The Appeals Panel will try to meet within four weeks of receipt of a written request and aim to ensure that those concerned are informed of its decision within one week of the hearing.

5.19. The applicant or patient has the right at any stage to seek to invoke the statutory NHS Complaints Procedure. However, an applicant or patient who is dissatisfied with the decision of the IFR Panel would be encouraged first to exercise their right to appeal to the CCG's Appeals Panel.

5.20. If the request is referred back to the IFR Panel by the Appeals Panel, they will re-consider the case at the next available meeting. The request will be reconsidered anew, taking into account the findings of the Appeals panel

## 6 High Value Requests

6.1. In exceptional circumstances, requests for individual treatment may be received that do not fall within delegated limits of financial responsibility of the Executive Directors of Bromley CCG.

6.2. Where only the CCG Board has the power to take a decision, it will be for the Chief Officer and the Executive Team to present a report, based on the advice given by both the IFR Panel and the Integrated Governance Committee, which will make a recommendation to the CCG Board.

6.3. Being mindful of the possible urgency of some requests made under the terms of the Individual Funding Requests Panel, the chairman will take action on behalf of the CCG Board.

6.4. Where the decision is taken by the CCG Board, or the chairman acting on behalf of the Board, that decision will be conveyed to the patient and referring clinician in a letter from the Secretary to the CCG Board.

## APPENDIX A


# INDIVIDUAL FUNDING REQUEST (IFR) APPLICATION FORM 2017-18 – DRUG REQUESTS

Please tick or select the corresponding CCG that the patient is registered to:

| | | |
|---|---|---|
| **Croydon CCG** ☐ | **Kingston CCG** ☐ | **Merton CCG** ☐ |
| **Sutton CCG** ☐ | **Richmond CCG** ☐ | **Wandsworth CCG** ☐ |

| | | |
|---|---|---|
| **Bexley CCG** ☐ | **Greenwich CCG** ☐ | **Lambeth CCG** ☐ |
| **Lewisham CCG** ☐ | **Southwark CCG** ☐ | **Bromley CCG** ☐ |

**All fields must be completed (or n/a stated where filed is not applicable). Incomplete mandatory fields will result in the form being returned and may cause delays to consideration for funding.**

***Anonymity – Please ensure that, in order to protect patient's identity that apart from Section A, the patient is not referred to by name or initials within the application form. PLEASE REFER TO SECTION H REGARDING GAINING EXPLICIT CONSENT FROM PATIENT BEFORE APPLYING.***

| ***SECTION A: CONTACT INFORMATION*** | | |
|---|---|---|
| **1. NHS Approved Provider Name** | | |
| **2. Address** | | |
| **3. Applicant Details**<br>*The applicant should have clinical responsibility for this intervention for this patient for this specific clinical indication.*<br>*Please ensure the declaration is signed and dated (Section H)* | **Name:** | |
| | **Designation:** | |
| | **Tel:** | |
| | **nhs.net address - No other email accepted** | |
| **4. Patient Details** | **Initials:** | |

| | | |
|---|---|---|
| | **NHS Number:** | |
| | **Hospital ID number:** | |
| | **DoB:** | |
| | **Registered Consultant:** | |
| | **Registered GP name:** | |
| | **GP practice code:** | |
| | **Date of referral:** | |

| **SECTION B: INTERVENTION REQUESTED**<br>(NB: Intervention refers to requested treatment, investigation, etc) | | |
|---|---|---|
| **5. Patient Diagnosis or condition** (for which intervention is requested) | | |
| **6. Do you consider this condition to be rare?** If so please state UK **prevalence** and quote the source/reference | Delete as appropriate: **Yes / No**<br><br>UK **prevalence:** Ref: | |
| **7. Other relevant diagnosis or co-morbidities** | | |
| **8. Details of intervention** (for which funding is requested).<br><br>**If the intervention forms part of a drug regimen, please document the full regimen** (e.g. Drug X as part of regimen Y (consisting of drug V, drug W, drug X and drug Z). | **Name** of intervention: | |
| | Type of Intervention: | ☐ Drug ☐ Procedure ☐ Device ☐ Other |
| | Planned duration of intervention:<br>**(please do not use abbreviations)** | |
| | Dose and frequency of drug: | |
| | Route of administration of drug: | |
| **9. Anticipated start date** | **Your request will be acknowledged within 5 working days of receipt. A funding decision usually takes the CSU up to 4 weeks from the date of receipt of a full & accurately completed application with copies of supporting clinical papers and completion of section I..** | |
| **Clinical Urgency**<br>The decision to treat in the | **Is the case more urgent than this?** | |

| | | | |
|---|---|---|---|
| event of immediate or life-threatening circumstances must be made in accordance with NHS Approved Provider (Trust) governance mechanisms. | **Yes** | **No** | **If 'YES' please state why** |
| **10. Is requested intervention part of a clinical trial?** | Delete as appropriate: **Yes / No**<br><br>If **Yes**, **then STOP HERE.** This funding route is not appropriate.<br>Please speak to your Trust Chief Pharmacist for drug trials.<br>There is no need to complete the rest of this proforma. | | |

| **SECTION C: COMPARISON WITH STANDARD COMMISSIONED INTERVENTION** | |
|---|---|
| 11. (a) What would be the standard intervention / management at this stage? | |
| (b) What would be the expected outcome from the standard intervention? | |
| (c) What are the patient specific reasons that make the standard intervention inappropriate for this patient? | |

| **SECTION D: CURRENT STATUS OF PATIENT** | | |
|---|---|---|
| 12. (a) for **all conditions** | Please summarise the current status of the patient in terms of quality of life, symptoms etc including any recognised condition-specific QoL / status scores. | |
| | What is the patient's current clinical severity?<br>Please use standard scoring systems e.g. WHO, DAS28, 6MW, cardiac index or those applicable to the patients clinical diagnosis. Please include interpretation of the score | |
| (b) In case of intervention for **cancer**: | Please indicate whether the intervention is for:<br>-adjuvant / neoadjuvant<br>-1st line relapse (or metastatic)<br>-2nd line relapse<br>-Other (please specify) | |

| | | |
|---|---|---|
| | What is the WHO performance status? Or other recognised status/score | |
| | How advanced is the cancer? (stage) | |
| | Describe any metastases: | |

| **SECTION E: PREVIOUS TREATMENT/INTERVENTIONS** | | | | |
|---|---|---|---|---|
| **13. Summary of previous intervention(s) this patient has received for the condition.**<br>* Reasons for stopping may include:<br>▪ Course completed<br>▪ No or poor response<br>▪ Disease progression<br>▪ Adverse effects/poorly tolerated (please detail nature of adverse effect/intolerance) | **Start Date:** | **Stop Date:** | **Name of Intervention**<br>**(for drugs include name, dose and frequency of use)** | **Reason for stopping* / Response achieved or indicate if still continuing** |
| | | | | |
| | | | | |
| | | | | |
| | | | | |
| **14.** Has a previous application been submitted on behalf of this patient? | | | Delete as appropriate: **Yes / No** | |

| **SECTION F: EVIDENCE FOR EFFECTIVENESS OF INTERVENTION REQUESTED** | | |
|---|---|---|
| **15.** Is the requested intervention licensed for the requested indication in the UK? | | Delete as appropriate: **Yes / No** |
| **16. Governance**<br>Has the Approved NHS Provider approved the requested intervention for use through its recognised clinical governance arrangements? | Drugs- Has the trust Drugs and Therapeutics Committee (DTC) or equivalent approved the requested intervention for use? | Delete as appropriate: **Yes / No**<br>If **No, then STOP HERE.**<br>The application requires DTC approval<br>Evidence **MUST** be supplied e.g. DTC minutes, a letter from the DTC Chairman, if Chairman's action has been taken |
| | Medical devices & interventions- has the device/ intervention been approved in accordance with Approved NHS Provider clinical | Delete as appropriate: **Yes / No**<br>If **No, then STOP HERE.**<br>The application requires approval<br>Evidence **MUST** be supplied e.g. meeting minutes |

| | | |
|---|---|---|
| | governance arrangements | where approval was given |
| **17. Evidence**<br>**It is the applicant's responsibility to provide robust*, relevant and valid evidence to support the use of the intervention in this patient.** | All relevant evidence should be provided. Give details of national or local guidelines/ recommendations (e.g. NICE, Scottish Medicines Consortium, London (Cancer) New Drugs Group etc) and/or full published papers (rather than abstracts) supporting the use of the requested intervention for this condition, unless the application relates to the use of an intervention in a rare disease. Please include any available data on the use of this treatment by your unit including audits<br>Copies of key references **MUST** be provided | |
| **Hierarchy of Evidence (Taken from NPC 'Supporting rational local decision-making about medicines (and treatments) Feb 2009)*<br>*1. Well-conducted meta-analysis of several, similar, large, well-designed RCTs 2. Large well-designed RCT*<br>*3. Meta-analysis of smaller RCTs 4. Case-control and cohort studies 5. Case reports and case series*<br>*6. Consensus from expert panels 7. Individual opinion* | | |
| **18. Outcomes**<br>(a) What would you consider to be a successful outcome for this intervention in this patient? – include details of the parameters you intend to measure | | |
| (b) How and how frequently will you monitor this? | | |
| (c) What is the minimum timeframe/course of treatment at which a clinical response can be assessed? | | |
| (d) What stopping criteria will be used to decide when the intervention is no longer effective? | | |
| (e) Detail the current status of the patient according to these measures. | | |
| 19. What are the anticipated adverse effects and potential risks of the intervention for this patient? | | |
| 20. How do the benefits outweigh the risks? | | |
| **21. Please confirm that the patient,** (or in the case of a minor or | | Delete as appropriate: **Yes / No** |

| | |
|---|---|
| vulnerable adult the parent / legal guardian/ carer**) has been appraised of the benefits/risks and has consented to the proposed treatment** | |

| **SECTION G: STATEMENT OF EXCEPTIONALITY OR RARITY** | |
|---|---|
| **22. On which basis are you making this request?** | ☐ Exceptional clinical circumstances<br>☐ Rarity of condition or presentation |
| **23. If exceptionality, please describe why the patient's clinical circumstances are exceptional**<br>*Give specific information to indicate how this patient is significantly different from the cohort of other patients with the same clinical condition* | |
| **24. If rarity, please describe why this patient's condition or clinical presentation is so unusual that there is no relevant commissioning arrangement in place** | |
| **25. How many patients with the same condition or presentation as this patient do you expect to see in the next 12 months?** | |

| **SECTION H: APPLICANT'S DECLARATION** | | |
|---|---|---|
| **22. Declaration**<br>I declare that this application is complete and accurate and that all necessary supporting information and evidence has been provided on this form (& attachments). | | Delete as appropriate: **Yes / No** |
| **23. Patient Consent**<br>I confirm that this Individual Funding Request (IFR) has been discussed in full with the patient (or in the case of a minor or vulnerable adult with the parent / legal guardian/ carer). They are aware that through the submission of this form they are consenting for CCG & CSU staff involved in the preparation, consideration and funding of their case to access confidential clinical information about them including their NHS no. to enable full consideration of this request and payment of invoices. | | Delete as appropriate: **Yes / No**<br><br>**Patient Signature**: |
| **24.Correspondence and Contact**<br>The IFR team will copy the patient into correspondence concerning progress and outcome of their application. If you do not want the patient to be contacted or to receive correspondence please indicate this. | | **Please copy the patient into correspondence.**<br><br>Delete as appropriate: **Yes / No** |
| **Responsible Clinician Name:** | **Signature or email confirmation:** | **Date:**<br>**DD/MM/YY** |

| **SECTION I: COSTS and REVIEW** | |
|---|---|
| If the application is for a drug, the completed form must be sent to the Trust Chief Pharmacist, for completion of Part A. If the application is for a medical device or other intervention, the completed form must be sent to the Trust Service Manager (or equivalent) for completion of Part B. Part C needs to be completed for both drug and non drug applications by the service manager. | |
| **PART A – DRUG INTERVENTIONS** ( to be completed by approved NHS provider Chief Pharmacist) | |
| **24.** Total Acquisition cost (inc VAT) for duration of treatment being applied for (or annual cost if treatment for longer than year), | |

| | |
|---|---|
| **25.** State the value of any offset costs | |
| **26.** Please benchmark these costs against London Procurement Prices | |
| **27.** Application reviewed by Chief Pharmacist or nominated authorised deputy | **Name:**<br>**Signature or email confirmation:** |
| **PART B - NON-DRUG INTERVENTIONS** ( to be completed by approved NHS provider service manager ) | |
| **28.** Total Acquisition cost (inc VAT) for duration of treatment being applied for (or annual cost if treatment for longer than one year), | |
| **29.** State the value of any offset costs | |
| **30.** Please benchmark these costs against London Procurement Prices | |
| **PART C- ALL INTERVENTIONS** ( to be completed by approved NHS provider service manager ) | |
| **31.** Application reviewed by Service Manager or nominated authorised deputy | **Name:**<br>**Signature or email confirmation:** |

Forward application to the IFR team (via Trust Service Agreements Department or equivalent, if applicable).

**Forms for the CCGs of Croydon, Kingston, Merton, Sutton, Richmond and Wandsworth should be submitted to: slcsu.ifrswlondon@nhs.net**

**Forms for the CCGs of Lewisham, Bexley, Greenwich, Southwark and Lambeth should be submitted to: slcsu.selifr@nhs.net**

**Forms for BROMLEY CCG should be submitted to: broccg.ifr@nhs.net**

## APPENDIX B

NHS Bromley Clinical Commissioning Group

**INDIVIDUAL FUNDING REQUEST (IFR) FORM**
**(Please ensure that all forms are typed)**

**Declaration (to be completed by the referring clinician)**
I declare that this application is complete and accurate and that all necessary supporting information and evidence has been provided with this form (including supporting documentation).

Responsible Clinician Name:

Signature or email confirmation:

Date:

**Consent Declaration (to be completed by the patient/service user)**
I confirm that the Individual Funding Request (IFR) application and decision making process has been discussed in full with me (or in the case of a minor or vulnerable adult with my parent / legal guardian/ carer), and this has included the Bromley Clinical Commissioning Group Patient Information Leaflet.

I give my agreement to NHS Bromley Clinical Commissioning Group and IFR support organisations to collect and use my clinically related health information to enable preparation, consideration and decision making regarding my request and NHS financial processes.

**Patient Signature: …… Date ……**

**(1) Patient's details**

Name …….. NHS Number ……..

Address ……..

…….

Dob …….

GP & Surgery address ……..

…….

Referring Clinician ……

Name of Facility Providing Treatment ……

(2) **Medical Condition**

Please provide a full **relevant** medical history (with dates) including **evidence that the standard NHS treatments have been exhausted or that the patient is clinically unable to have the standard treatment.**

**(3) Proposed Intervention / Treatment / Diagnostic Procedure**

Type of Intervention/procedure

Supporting evidence of effectiveness (if new treatment). If appropriate, please add attach further documentation in support.

**(4) Approximate Price of Treatment / Drug / Procedure if known:**

**(5) Where continuation of treatment, drug, procedure is being requested, please confirm how treatment has previously been funded.**

**(6) Exceptional Clinical Circumstances & Other Special Individual Circumstances you wish the IFR Panel to take into consideration (please note that the IFRP are unable to assess issues of a personal or social nature)**

**You must provide information to confirm that your patient has an unusual or unique clinical factor about them that suggests that they are:**

- **Significantly different to the general population of patients with the condition in question AND**
- **Likely to gain significantly more benefit from the intervention than might be expected from the average patient with the condition.**

**Please return to: Kiran Bhatoa, Contract Support Manager, Bromley CCG, 1st Floor, Beckenham Beacon, 379 Croydon Road, Beckenham, Kent BR3 3QL or email broccg.ifr@nhs.net or Tel: 01689 866539**

# APPENDIX C
# IFR Triage Meeting: Terms of Reference

## 1. Governance Arrangements

1.1 The Individual Funding Request (IFR) Triage meeting is a clinically led professional meeting responsible for determining that an IFR application is eligible for consideration by the IFR Panel.

1.2 The IFR Triage Meeting is accountable to the IFR Panel, so will act as a sub-committee of the IFR Panel. The IFR Panel is accountable to the Clinical Commissioning Group (CCG) Governing Board via its committee structure.

## 2. The IFR Triage Process

2.1 The IFR Panel will only consider requests as defined within the CCG(s) IFR policy so the IFR Triage process is undertaken in order to reduce inappropriate requests.

2.2 Once an application has been administratively triaged, it will be submitted to the next triage meeting to determine whether the IFR is eligible for consideration by the IFR panel, from a clinical perspective, or whether funding can be agreed by the Triage panel prior to this under section 3.3 below.

## 3. Duties and Responsibilities

3.1 The purpose of the Triage Meeting is to determine that an IFR is eligible for consideration by the IFR Panel. The triage meeting will consider the following options for each IFR requests:

- Is the treatment requested funded within an existing commissioning policy?
- Is the treatment requested covered by another CCG policy or process?
- Is the treatment an obvious Service Development (i.e. a request pertaining to a cohort of patients and not reflective of an individual's clinical circumstances)?
- Is the submission lacking sufficient information to support the individual's clinical exceptionality?
- Is an additional evidence review required?
- Is the request an appeal or resubmission of a previous case?

3.2 Triage has the authority to close cases when further information has not been received in the given timescales or a repeat application containing no new or additional information has been received.

3.3 Triage has the authority to make decisions to approve or decline funding under the Treatment Access Policy (TAP), assessing submissions against TAP criteria.

## 4. Membership & Quorum

4.1 IFR Triage will be made up of a membership comprising of either:

- Senior Prescribing Adviser (or their delegate)

  or

- Consultant in Public Health (or their delegate)

  And

  Senior Commissioning Manager

4.2 The meeting will be considered quorate if one medically qualified member is present. If a drug case is to be considered, a pharmacist must be present.

## 5. Frequency of Triage Meetings

5.1 The frequency of triage meetings depends on volume of IFR applications received. A minimum of one triage meeting a month is required to meet the timeline of IFR referrals to be responded within 20 working days.

## 6. Confidentiality

6.1 Anonymity is essential for two reasons:

- In order to protect patient's identity, for this reason the requesting clinician is asked to not refer to the patient by name or initials within the rest of the application form.
- For equity of decision making, to ensure that the panel decisions do not take into account personal details such as age or sex

6.2 Depending upon individual clinical circumstances it may be necessary to re-introduce information on the patient's age and/or sex for consideration. When cases are considered which require access to confidential clinical information through triage, implied consent to disclosure of such information to all members of the IFR Triage Panel will be assumed. This will be indicated to patients by the referring clinician and be confirmed in IFR publicity material.

## 7. Review

7.1 The IFR Triage Meeting Terms of Reference will be reviewed annually or in light of any changes in legislation, practice or local/national guidance.

# APPENDIX D
# IFR Panel: Terms of Reference

## 1. Governance Arrangements

1.0.1 The Individual Funding Request (IFR) Panel is a multi-professional group responsible for the management of all IFRs within its remit (see section 2 below). The IFR Panel will be responsible for approving deciding on funding for treatment requests for exceptional cases or for rare conditions.

1.0.2 The IFR Panel will be accountable to the Clinical Commissioning Group (CCG) Governing Body via its committee structure. Each CCG will be required to confirm its governance arrangements to ensure that the IFR Panel is held accountable to the CCG Body.

1.0.3 Members of the IFR Panel will be appointed by the CCG's Chief Officer. The IFR Panel will operate within the limits of delegated authority as determined by the CGG's Director of Finance and within the CCG's Standing Financial Code of Practice.

1.0.4 The IFR Panel will be supported administratively by the IFR service to discharge its responsibilities.

1.0.5 The IFR panel will participate in the regular peer review process which will be agreed with other IFR panels across South London.

## 2. Duties and Responsibilities

2.0.1 The IFR Panel will consider IFR requests as defined within the South London IFR policy.

2.0.2 The IFR Panel have a duty to consider IFRs and make funding decisions based on the ethical decision making framework.

2.0.3 The IFR Panel has delegated the preliminary assessment and triage of IFR requests to a clinically led triage panel. The details of the triage process and triage panel are set out in the IFR Policy.

2.0.4 The IFR Panel will be required to consider IFRs for both high cost drugs and other interventions and to review decisions made for IFR submissions where new information is available.

2.0.5 The IFR Panel will also consider Planned Treatment Abroad if IFR Panel approval is required.

2.0.6 The IFR Panel will advise the CCG on the programme of care pathways and policy development as they affect patients with exceptional care needs to inform future CCG's commissioning strategies.

2.0.7 The IFR Panel will be required to produce an Annual Report with the support from the IFR service.

## 3. Constitution

### 3.1 Meetings

3.1.1 The IFR Panel will adopt the consensus method of decision making where a unanimous view cannot be reached on an individual case. In the case of an equal vote, the Chair shall have a second and casting vote. At the discretion of the Chair all requests put to the vote shall be determined verbally or by a show of hands, unless the Chair directs otherwise.

3.1.2 Panel meetings will be held in private. Requesting clinicians and patients will not be invited to attend.

### 3.2 Membership

3.2.1 The IFR Panel will be made up of a multi-professional membership comprising:

- a GP
- a lay representative
- a public health consultant delegated from the relevant CCG(s) or their delegate
- a head of medicines management or their delegate
- a senior acute commissioner (this role can be covered by the GP member in their clinical commissioning role).

3.2.2 Other Specialist Advisors can be invited to attend by the Chair to address specific patient issues including senior acute contracting, dental advisors, etc.

3.2.3 Members are expected to send suitable representation for the meetings they are unable to attend.

3.2.4 A register of attendance at the Panel meeting will be maintained and reviewed by the Panel on a 6 monthly basis to ensure that attendance at the panel is representative of the membership

3.2.5 IFR Panel members are required to declare any interests before serving on an IFR Panel. Any conflicts of interest must be declared as a standing item at the commencement of every meeting and the Chair will decide the appropriate action, including requesting that members withdraw from the meeting.

### 3.3 Chair

3.3.1 The Panel can be chaired by any of the members provided that s/he has sat as an IFR Panel member at least 4 times. The Chair must be identified in advance of the meeting, and must be available to approve the minutes/letters and fulfil and any other obligations within the specified time frame.

### 3.4 Quorum Arrangements

3.4.1 At least 3 members of the Panel must be present for IFR Panel to proceed.

- 2 must be clinically qualified
- At least 1 medically qualified.

3.4.2 Where CCGs have chosen to have joint Panel arrangements, each constituent CCG must have a minimum of 1 representative if there is an IFR case being discussed for a patient belonging to that respective CCG. In the event that no IFR cases are being discussed for a particular CCG, an IFR Panel representative from that respective CCG is not required to attend but may attend to ensure quoracy of members.

### 3.5 Training of IFR Panel Members

3.5.1 Members of the IFR Panel will be provided with training and must be fully familiar with the IFR Policy and Ethical Decision Making Framework for dealing with IFRs and process before sitting on a panel. Good practice suggest that Panel members should attend a training session at least once every 2 years and partake in IFR Panels regularly to retain their specialist expertise and knowledge.

### 3.6 Frequency of Meetings

3.6.1 IFR Panels shall be held as required in order to ensure that there is a timely response to all funding requests, but within a maximum of four – six weeks of a completed IFR request being made. Good practice suggests that the IFR Panel meets at least once a month. However changes to this arrangement may be made in order to cover annual leave or other absence.

### 3.7 Urgent Decisions

3.7.1 In clinically urgent situations a request may be considered in advance of a formal IFR Panel meeting. An urgent IFR will be considered by a specially convened group acting as a sub-committee of the next scheduled IFR panel under delegated powers. The group will comprise of at least 3 members of the IFR panel membership and must include the following:

- 2 must be clinically qualified
- At least 1 medically qualified.

3.7.2 The decision will be reported at the next IFR Panel meeting and formally ratified.

### 3.8 Reporting

3.8.1 The minutes of the meetings shall be recorded by the relevant IFR Manager/Officer and approved by the Chair of the Panel.

### 3.9 Venues of Meetings

3.9.1 The Chair of the IFR Panel will determine the venue of meetings in discussion with the members of IFR Panel.

### 3.10 Joint IFR Panels

3.10.1 Some CCGs may choose to have joint Panel arrangements. The Chief Officer of the CCG will determine whether Joint IFR Panels are an effective means of executing the IFR Panels responsibilities. See paragraph 3.4.2 for quoracy of joint Panel.

## 4. Confidentiality

4.0.1 Anonymity is essential for two reasons:

- In order to protect patient's identity, for this reason the requesting clinician is asked to not refer to the patient by name or initials within the rest of the application form.
- For equity of decision making, to ensure that the panel decisions do not take into account personal details such as age or sex

4.0.2 Depending upon individual clinical circumstances it may be necessary to re-introduce information on the patient's age and/or sex for consideration. When cases are considered which require access to confidential clinical information through triage, implied consent to disclosure of such information to all members of the IFR Panel will be assumed. This will be indicated to patients by the referring clinician and be confirmed in IFR publicity material.

## 5. Review

5.0.1 The IFR Panel's Terms of Reference will be reviewed annually or in light of any changes in legislation, practice or local/national guidance.

# BROMLEY CLINICAL COMMISSIONING GROUP
# PROCEDURE FOR INDIVIDUAL FUNDING REQUESTS

## APPENDIX E
## IFR Appeal Panel: Terms of Reference

### 1. Governance Arrangements

1.0.1 The IFR Appeals Panel will be accountable to the Clinical Commissioning Group (CCG) Governing Body via its committee structure. Each CCG will be required to confirm its governance arrangements to ensure that the IFR Appeals Panel is held accountable to the CCG Governing Body.

1.0.2 Members of the IFR Appeals Panel will be appointed by the CCG's Chief Officer.

1.0.3 The IFR Appeals Panel will be supported to discharge its responsibilities administratively by the IFR service

### 2. Duties and Responsibilities

2.0.1 On behalf of the CCG, the IFR service will receive and acknowledge the letter of appeal. The IFR triage meeting will be responsible for undertaking the preliminary assessment of the appeal request to determine whether new evidence has been received and if the case should be sent back to panel. If no new evidence has been received, the case should be passed to an IFR Appeal Panel.

2.0.2 Where it is decided to convene a Panel, members of the Appeals Panel should be provided with full details of the case including all correspondence, evidence of clinical and cost effectiveness, full documentation of the discussion and outcome.

2.0.3 The Appeals Panel will need to consider whether there are grounds for appeal:

- 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: Whether the decision was irrational in light of the information available to the Panel.

2.0.4 An IFR Appeal Panel will not consider new evidence. New evidence must be considered as an IFR resubmission.

2.0.5 If the Appeal Panel upholds the original IFR Panel's decision, the appellant will be advised that if they wish to take the matter further this must be done through the NHS Complaints process.

2.0.6 If the Appeals Panel consider that the IFR panel did not consider all the evidence provided the application can be directed back to the IFR panel for re-consideration

## 3. Constitution

### 3.1 Meetings

3.1.1 IFR Appeal Panel meetings will be held in private. Patients and their representatives will not be permitted to attend the panel discussions to put forward their case verbally. All appeal cases must be submitted in writing to the Panel.

3.1.2 The IFR Appeal Panel will adopt the consensus method of decision making where a unanimous view cannot be reached on an individual case. In the case of an equal vote, the Chair shall have a second and casting vote.

### 3.2 Membership

3.2.1 IFR Appeal Panel will include the following members:

- A clinician/GP
- A representative of the Constituent CCG(s)
- Lay Member

3.2.2 All IFR Appeal Panel members must be independent of any of the original decision making processes and not have been a member of the IFR Panel involved in the original decision. The member must have received appropriate training (see section 3.4) and must be familiar with all relevant policies and procedures.

3.2.3 IFR Appeal Panel members are required to declare their interests before serving on an IFR Appeal Panel. Any conflicts of interest must be declared as a standing item at the commencement of every meeting and the Chair will decide the appropriate action, including requesting that members withdraw from the meeting.

### 3.3 Chair

3.3.1 Any member of the Appeal Panel may chair the meeting provided that s/he has received appropriate training.

3.3.2 The Chair must be identified in advance of the meeting, and must be available to approve the minutes and relevant correspondence and fulfil and any other obligations within the specified time frame**.**

### 3.4 Training

3.4.1 IFR Appeal Panel members must have attended training to ensure that they are fully familiar with the IFR Policy and National guidance for dealing with IFRs and process before sitting on the IFR Appeals panel. Best practice suggests that Appeal Panel Members should attend a training session at least once every 2 years to retain their specialist expertise and knowledge.

### 3.5 Frequency of Appeals Panels

3.5.1 The numbers of appeals that may be received are difficult to predict and therefore arrangements for Appeal Panel meetings will be flexible, and will be arranged to ensure that appeals are considered within 20 working days of an appeal being received by IFR Team.

3.5.2 If a matter is exceptionally urgent the Chair shall have the power to call an IFR Appeal Panel at any other time.

### 3.6 Quorum Arrangements

3.6.1 The IFR Appeal Panel may not proceed unless at least two members are present, including the Chair.

### 3.7 Joint IFR Appeals Panels

3.7.1 Some CCGs may choose to have joint Appeal Panel arrangements. The Chief Officer of the CCG will determine whether Joint IFR Appeal Panels are an effective means of executing the IFR Panels responsibilities.

### 3.8 Reporting

3.8.1 The minutes of the meetings shall be recorded by the relevant IFR Manager/Officer and approved by the Chair of the Appeal Panel.

3.8.2 Copies of minutes will not be distributed to IFR Appeals panel members for their retention and will not be placed in the public domain in order to preserve patient confidentiality.

## 4. Confidentiality

4.1 Anonymity is essential for two reasons:

- In order to protect patient's identity, for this reason the requesting clinician is asked to not refer to the patient by name or initials within the rest of the application form.
- For equity of decision making, to ensure that the panel decisions do not take into account personal details such as age or sex

4.2 Depending upon individual clinical circumstances it may be necessary to re-introduce information on the patient's age and/or sex for consideration. When cases are considered which require access to confidential clinical information through triage, implied consent to disclosure of such information to all members of the IFR Appeal Panel will be assumed. This will be indicated to patients by the referring clinician and be confirmed in IFR publicity material.

## 5. Review

5.0.1 The IFR Appeal Panel's Terms of Reference will be reviewed annually or in light of any changes in legislation, practice or local/national guidance.

# APPENDIX F

**HUMAN RIGHTS ACT 1998**

This Act incorporates the rights and freedoms guaranteed under the European Convention of Human Rights. The rights are referred to as they appear within the Convention itself as Articles. The ETG will review the various rights below and assess the impact of its decision on the patient in this context.

- Article 1: The protection of property
- Article 2: The right to life
- Article 3: Prohibition of torture
- Article 4: Prohibition of slavery and forced labour
- Article 5: Right to liberty and security
- Article 6: Right to a fair trial
- Article 7: No punishment without law
- Article 8: Right to respect for private and family life
- Article 9: Freedom of thought, conscience and religion
- Article 10: Freedom of expression
- Article 11: Freedom of assembly and association
- Article 12: Right to marry
- Article 14: Prohibition of discrimination
- Article 16: Restrictions on political activity of aliens
- Article 17: Prohibition of abuse of rights
- Article 18: Limitation on use of restrictions on rights

# APPENDIX G

## Definition of Clinical and Cost Effectiveness

1.2. Clinical effectiveness

Clinical effectiveness is the extent to which specific clinical interventions do what they are intended to do – that is, maintain or improve health, and secure the greatest possible health gain.

The CCG will not ordinarily support the use of interventions for which evidence of clinical effectiveness is either absent, or too weak for reasonable conclusions about efficacy to be reached.

The CCG will not ordinarily support the use of interventions which are deemed to be experimental.

As well as strength of evidence for a particular intervention, the CCG will also take into account the likely magnitude of benefit and issues of harm and safety.

The relevance of the evidence for a particular patient will be an important factor when assessing the extent to which that patient's circumstances match those of the studied population.

1.3. Cost-effectiveness

Cost-effectiveness is the balance of a given outcome against the financial cost involved.

Cost-effectiveness analysis is conducted by specialists in health economics, such as the National Institute for Clinical Excellence (NICE), Scottish Medicines Consortium (SMC) or Academic Institutions. The PCTs do not have the range and levels of expertise required to conduct these types of analyses but will use published analyses when available.

# APPENDIX H

## Ethical Decision-Making Framework for Individual Funding Requests (IFRs) v1.1

### 1. Introduction

1.1 This Ethical Framework sets out the values that South London IFR Panels and South London CCGs will apply in making decisions on IFRs. South London CCGs will use it in all decisions, ranging from those which may affect a cohort of patients reviewed at the IFR Triage meeting to those that affect individuals heard at IFR Panels. This framework should be used in conjunction with the South London IFR Policy for dealing with IFRs

### 2. Purpose of the Ethical Framework

2.1 Public bodies are required to be transparent about their decision- making processes, accountable to their service users and should be able to demonstrate that these are reasonable. South London CCGs have to demonstrate that their decisions about health policies and IFRs are based on sound principles and have been made after careful consideration of all the relevant factors, with reference to local conditions, and with a conscious intent to avoid discrimination.

2.2 CCG's have 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 as fair.

2.3 This framework is designed to provide guidance to decision makers to help them make fair and consistent decisions which respect the needs of individuals and the community.

2.4 The purpose of an ethical framework is to:

- to demonstrate that decisions about health policies and IFRs are based on sound principles and have been made after careful consideration of all the relevant factors, with reference to local conditions, and with a conscious intent to avoid discrimination
- Provide a coherent structure and framework for decision-making that ensures all the important aspects of each issue are considered.
- Promote fairness and consistency in decision-making
- Ensure that the reasons behind decisions that have been taken are clear and comprehensive.
- Provide transparency and support CCG to

### 3. Legal Duties

3.1 South London CCGs have certain legal duties as public bodies and their decisions and actions should be able to withstand scrutiny with regards to:

- Meeting statutory duties
- Legality

- Reasonableness
- Proportionality
- Procedural Propriety
- Legitimate expectations
- Equality and non-discrimination

## 4. Equality Statement

4.1 South London CCGs and the SLCSU have a duty to have regard to reduce health inequalities in access to health services and health outcomes achieved as enshrined in the Health and Social Care Act 2012.

4.2 South London CCGs and the SLCSU are committed to ensuring equality of access and non-discrimination, irrespective of age, gender, disability (including learning disability), gender reassignment, marriage and civil partnership, pregnancy and maternity, race, religion or belief, sex (gender) or sexual orientation. In carrying out their functions, South London CCGs and the SLCSU will have due regard to the different needs of protected equality groups, in line with the Equality Act 2010.

4.3 This document is compliant with the NHS Constitution and the Human Rights Act 1998. This applies to all activities for which they are responsible, including policy development, review and implementation.

## 5. Five core principles for decision-making

5.1 In line with the legal and ethical duties to CCG populations, it is expected that the following key principles will be applied to all decisions.

5.2 These key principles are the need for decisions to be

- rational;
- socially inclusive;
- clear and open to scrutiny;
- take economic factor into account , and
- themselves must promote health for both individuals and the community

### Principle 1: Rational

5.3 South London CCGs have a responsibility to make rational decisions and to act fairly in balancing competing claims on resources between different patient groups and individuals.

5.4 Aspects of this principle include:

- Ensuring that the decision is based on evidence of clinical effectiveness
- Being logical in reasoning towards a decision
- Making a realistic appraisal of the likely benefit to patients
- Weighing up all the relevant factors, including risks and costs
- Taking into account the wider political, legal and policy context
- Ensuring individuals involved in decision making are appropriately trained

5.5 Where available, existing national standards, policy and authoritative guidelines must be considered; such as national directives, guidance from the National Institute of Health & Clinical Excellence, Department of Health directives etc. Local factors, including existing provisions must also be considered. Decisions should be taken within the political and legal context.

5.6 South London CCGs are committed to evidence-based healthcare. Decisions should therefore be made on the basis of a reasonable evaluation of the available evidence of clinical effectiveness. Those involved in decision-making have an obligation to seek out the best evidence of clinical effectiveness to inform their decisions.

5.7 The approach to accessing the validity and credibility of evidence should be broad but maintain high standards of critical appraisal. South London CCGs will follow the well-developed scientific approach to hierarchy of evidence. Where appropriate, both qualitative and quantitative evidence will be taken into consideration.

5.8 Outcome measures should be considered in terms of their importance to the patients. This is particularity significant in the treatment of illness where no cure can be expected, in palliative care, and the care of people who are terminally ill. Rational decisions will weigh up likely outcomes, the wider contexts in which treatments can be provided, the implications for service delivery, clinical pathways, and the scale and nature of benefits, costs and risks.

5.9 The position, qualifications and skills of decision makers will be appropriate to ensure due deliberation of all the relevant factors.

**Principle 2: Inclusive**

5.10 The term inclusivity may be interpreted as including:

- 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 to achieve equitable and consistent resource allocation between individuals and groups in society.

5.11 There are proven links between social inequalities and inequalities in health, health needs and access to healthcare. Access to funding of services should be governed, as far as practicable, by the principle of equal access for equal clinical need. Individual patients or groups should not be unjustifiably advantaged or disadvantaged on the basis of age, gender, sexuality, race, religion, lifestyle, occupation, social position, financial status, family status (including responsibility for dependants), intellectual / cognitive function or physical functions.

5.12 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.

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

5.14 Decisions should take account of local and societal sensitivities.

5.15 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.

5.16 The aim is to achieve consistent and equitable opportunity of access to health care, between individuals and groups in society, and to avoid the kind of arbitrary discrimination sometimes referred to with the term 'postcode' as in 'postcode lottery' (of health service provision).

5.17 Policies should work in favour of patient choice at the individual level, respecting the individual's preferences, in particular, the ethical framework calls for sensitivity to the patient's perspective and the individual nature of choices based on quality of life.

5.18 South London CCGs will respect patient choice about where an IFR treatment, if agreed to be funded, is delivered, as far as this is compatible with IFR Panel's judgments as to the clinical and cost effectiveness, against costs quoted that were presented for their decision making, and having regard to whether proposed providers have been commissioned by the NHS for the treatments in question.

**Principle 3: Clarity, consistency and transparency**

5.19 The values and principles at all levels of decision-making must be consistent. IFR decisions and the way they are determined, will be clearly specified, consistent, easy to understand, and open to public scrutiny.

5.20 This should also be the case with the roles and responsibilities of individual's involved in the process, accountabilities, governance arrangements, and the patient's right of appeal.

5.21 The formal process set out for the identification, prioritisation and review of policy issues has been designed with the need for clarity and scrutiny. However, IFR Panel members undertaking decision-making have a responsibility to work towards achieving these goals. Decision makers will provide the rationale for their decisions; and all facts that have influenced a decision will be clearly stated in the records of meetings.

5.22 The process of decision-taking will also be carefully documented, to show that it has conformed to the agreed process and to record 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: Taking into account economic factors**

5.23 South London CCGs must ensure that the decisions they take demonstrate value for money and an appropriate use of NHS funding based on the needs of the population it serves. Given the finite resources available to CCG's, their budgets must be managed responsibly so the cost of an intervention must be considered alongside the evidence of effectiveness.

5.24 Investing in one area of healthcare inevitably diverts resources from other areas. Decisions will 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.

5.25 South London CCGs will consider the extent to which the individual or patient group will gain a benefit from the treatment. They will also balance the needs of each individual against the benefit which could be gained by alternative investment possibilities to meet the needs of the community.

South London CCGs should only invest in treatments and services which are of proven cost-effectiveness unless it does so in the context of well-designed and properly conducted clinical trials that will enable the NHS to assess the effectiveness and/or value for money of a treatment or other healthcare intervention. In general, low-cost treatments with high effectiveness will be preferred, whereas high cost treatments with low effectiveness are to be discouraged.

**Principle 5: Promote health for both individuals and the community**

5.26 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.

5.27 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- health needs assessment and JSNA. There is a requirement to balance the needs of the individual with the needs of the wider community.

5.28 Policies which promote health and avoid people becoming ill are considered alongside curative treatments and other interventions. 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. Priority may be given to health services targeting the needs of sub-groups of the population who currently have poorer than average health outcomes (including morbidity and mortality) or poorer access to services.

## 6. Considerations

6.1 South London CCGs seek to achieve a balance between the ethical principles and to meet the legal duties of public bodies. When making resource allocation decisions, the following considerations should be taken into account:

- The standard treatment options available to the patient.
- The clinical needs of the patient, and the nature of the intervention including the clinician's treatment plan
- The scientific evidence of clinical effectiveness of the proposed intervention and where in doubt, normative practice
- The cost effectiveness of the intervention
- The balance of risk and benefit for the patient and the capacity to benefit
- The impact of provision of this treatment on South London CCG resources and whether needs can be met with an alternative provider
- Consistency in decision-making and the impact of providing similar treatment to other patients with similar needs
- The impact of the funding decision on other services or interventions for which money is then not available
- Patient views
- Potential human rights considerations and proportionality

- Procedural propriety in decision-making, transparency and probity
- The legality of the funding decision

## 7. References

7.1 In constructing this ethical framework, a number of existing ethical policy documents have been referred to, including:

- NHS South West London *Ethical Decision Making Framework for Individual Funding Requests*
- NHS North West London *Ethical Framework for decision-making*
- NHS Commissioning Board *Ethical Framework for priority setting and resource allocation*
- NHS Kent and Medway *Ethical Framework*
- NHS Brighton and Hove *Ethical Framework*