

Individual Funding Request Policy

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1.0 INTRODUCTION

- 1.1 The policy has been produced by the Staffordshire and Stoke-on-Trent Integrated Care Board to govern the Individual Funding Request (IFR) process.
- 1.2 Throughout the policy reference is made to “the ICB” which means the Integrated Care Board for which the patient request under consideration is the responsible commissioner.

2.0 PURPOSE

- 2.1 The ICB recognises that there may be individual cases where a patient’s needs cannot be met through existing care pathways and therapies.
- 2.2 This Policy sets out the principles and process to be adopted when the ICB is considering any request for treatment that falls outside of national, regional, or local commissioning arrangements or service level agreements
- 2.3 All requests falling within 2.1 and 2.2 will only be considered for funding on an exceptional basis.
- 2.4 This Policy is not intended to be applied to cases where the failure of a provider to provide adequate care and treatment has precipitated the need for the intervention for which funding is sought. Funding for any such intervention will be the responsibility of the provider concerned.

3.0 GOVERNANCE ARRANGEMENTS

3.1 Legal Framework

- 3.1.1 The ICB is a public, statutory NHS body, with delegated responsibility from the Secretary of State for Health for commissioning healthcare for its patients and for protecting and improving the health of its population.
- 3.1.2 The National Health Service Act 2006 sets out a general duty to provide services to support the prevention, diagnosis, and treatment of illness.¹ This is a target duty, rather than a specific legal duty owed to each and every individual in the ICB’s population. In consequence, the provision of healthcare services is legitimately subject to a decision as to what is considered appropriate and affordable within the overall annual prioritisation of healthcare interventions.
- 3.1.3 The ICB has a statutory responsibility to maintain financial balance² and, as part of discharging this obligation, has to decide how and where finite local resources are allocated.

¹ National Health Service Act 2006, Section 3

² National Health Service Act 2006, Section 229 & 230

3.2 Responsibility

- 3.2.1 The ICB is responsible for ensuring that the necessary processes are in place to underpin the delivery of the IFR process (see Appendix I - IFR process) in accordance with this Policy.

3.3 Accountability & Reporting

- 3.3.1 The IFR Committee will act as a formal sub-committee on behalf of the Finance & Performance (F&P) Committee, to exercise their individual statutory IFR commissioning function.
- 3.3.2 IFR Funding decisions taken by the IFR Committee will be presented to the F&P Committee ('for information only') as and when they reach the IFR Panel Stage – Decision on exceptionality.
- 3.3.3 The IFR Panel will report its activity to the IFR Policy Review Group (see Appendix II - Terms of Reference) which will meet 6 monthly and report to the F&P Committee on an annual basis.

4.0 POLICY PRINCIPLES

4.1 Basic Principles

- 4.1.1 Wherever possible, patients will be referred to services covered by an existing service level agreement and prescribing should, wherever possible, be in line with existing local and national prescribing guidelines, including guidance from the National Institute for Health and Clinical Excellence.
- 4.1.2 Where a particular treatment or procedure is not part of an agreed pathway or existing commissioned service, it will not be routinely funded. The patient's request for funding for such a treatment or procedure will be considered under the terms of this Policy.
- 4.1.3 This Policy is intended to govern the consideration of IFRs where, following an initial determination stage and screening stage there is deemed to be prima facie evidence of exceptionality as defined at 4.2.
- 4.1.4 The IFR process is not a mechanism to endorse, implement or introduce new therapies, procedures or services in-year that are not routinely commissioned. These will be treated as new service developments and considered through the ICB's annual prioritisation process. To do otherwise would risk destabilising previously identified funding priorities and would impair the responsibility for ensuring that treatments and services are offered in an equitable and consistent manner.
- 4.1.5 Where a patient moves into the ICB area, having already commenced treatment approved by their previous CCG or ICB, the

ICB will honour the funding decision of the originating commissioner, even where the ICB, had it been the recipient of the original funding request, may have decided that funding was not appropriate in the particular clinical circumstances.

- 4.1.6 The provisions of paragraph 4.1.5 only apply under this policy for those treatments and services for which the ICB is considered the responsible commissioner. The ICB will, under no circumstance consider funding treatments and services which fall under the responsibility of the NHS England Specialised Commissioning or Local Authority.

4.2 Exceptionality

- 4.2.1 Where the ICB considers that the IFR submitted is supported by prima facie evidence of exceptionality, the request will be further considered under the terms of this Policy and via the supporting process.
- 4.2.2 The request is legally that of the patient, who should provide his or her explicit consent in line with GDPR 2018 to the involvement in the IFR Process, at the outset. Although the patient may submit the request themselves, the ICB acknowledges that in most cases the IFR will be formally made, and supporting evidence provided, by the clinician who is recommending the treatment. Indeed, the ICB recommends this approach. Responsibility for completing the request should not be delegated to another clinician from a different provider organisation unless otherwise agreed. The individual submitting the collated IFR information is referred to within the Policy as 'the Requester'. Where the patient lacks capacity, the Requester must disclose whether or not a best interest's assessment has been undertaken. The ICB will not process the application, in such cases, until a positive confirmation has been provided that the treatment for which funding is sought is in the patient's best interests.
- 4.2.3 The ICB will respond by way of correspondence to the Requester. Where the Requester is not the patient, the correspondence will be copied to the patient unless the Clinician has advised on the IFR application that direct correspondence with the patient would not be in his or her best interests for clinical reasons. Other than in such cases, the patient will receive with the copy correspondence and a leaflet intended as a patient's guide to the process.
- 4.2.4 Satisfaction of each of the following three criteria is one way in which exceptionality might be demonstrated:
- i. That the application does not, in fact, seek to introduce a new treatment for a definable group (however small). Such cases constitute service developments and should be introduced via the ICB's annual prioritisation process.

- i. That the patient is significantly different from the general population of patients with the condition in question, at the same stage of progression, who are currently excluded from funding, or not part of a group of patients with the same condition, however small, in the local population.
- iii. That the patient is likely to gain significantly more benefit from the intervention than the average patient with the condition, at the same stage of progression.

Although this should not be regarded as the only way in which exceptional clinical circumstances can be made out and the IFR Panel will consider each case on its merits.

- 4.2.5 Non-clinical social factors (for example, but not limited to, age, gender, ethnicity, employment status, parental status, marital status, carer status, religious/cultural factors) will not be taken into account in determining whether exceptionality has been established.
- 4.2.6 The onus is on the Requester to set out clearly for the IFR Panel ('the Panel') the ground on which it is said that the patient is exceptional. Further guidance can be found in Appendix III - Guidance for panels. This guidance is not intended to be exhaustive but provides more detailed information and assistance to those making and adjudicating upon IFR applications.
- 4.2.7 If prima facie evidence of exceptionality has been provided, the case will be referred to the next IFR Panel.

4.3 Framework for Decision Making

- 4.3.0 To ensure consistency in approach, all decisions on funding taken under this Policy will be made against a common framework of commissioning standards, as detailed below:

4.3.1 Evidence – clinical and cost effectiveness

The decision to fund any intervention or treatment may be taken only after the Panel has satisfied itself that there is a sound evidence base for the likely clinical effectiveness and cost-effectiveness of the proposed treatment. Appendix III provides further information in respect of the evidence required to support a request for individual funding in accordance with this Policy.

4.3.2 Affordability

The ICB has a statutory duty to achieve financial balance despite the infinite demands placed on its finite resources. The affordability of treatment is therefore an inevitable and important consideration, when the ICB decides what specific aspects of health care it will commission for its patient population. This means that some treatments will not be routinely provided, whilst the cost of

supporting one funding request may mean no funding being available for another request. Within these financial constraints, the ICB seeks to commission healthcare equitably amongst its population.

4.3.3 Equity

The ICB is continually seeking to deliver improved healthcare outcomes to its population and to promote the health of the wider community. With finite resources, however, the ICB needs to reach decisions to ensure that those resources are utilised to provide the greatest overall health benefits for patients. The needs of the community may therefore conflict with the needs of the individual patient; and treatment will not generally be commissioned solely because an individual patient requests it.

4.4 Right to Appeal

4.4.1 If the patient or Requester is not satisfied that the correct process has been followed by the IFR Panel in reaching a decision on a funding request, the patient or Requester may ask for the matter to be considered by an Appeal Panel. (See 6.1 below).

4.4.2 The Appeal Panel will consider whether the procedure under this Policy was correctly applied in the IFR Panel's consideration of the request. If the Appeal Panel identifies a failure in process, the Appeal Panel will return the case to an appropriately constituted IFR Panel for reassessment (see 6.1.8).

4.5 Right to Complain

4.5.1 This Policy expressly preserves the right of any requester under the IFR process to make a complaint, at any stage in the process, via the ICBs Patient Advice and Liaison Service.

4.5.2 Any complaint should normally be made within twelve months of the conclusion of the process, but this time limit may be extended at the discretion of the ICB Chief Executive Officer

4.5.3 If a patient remains dissatisfied with the way the complaint is handled within the ICB, they may pursue the matter further via the Health Service Ombudsman.

4.6 Triggers for Service Development

4.6.1 All requests for treatments that are not routinely commissioned, where the patient fails to establish exceptionality, will be treated as potential service developments, and assessed through the prioritisation process. They will not be funded in-year unless there are compelling reasons, in terms of safety, clinical effectiveness and cost effectiveness, to consider them outside of the ICB's annual prioritisation process.

- 4.6.2 If multiple IFRs are received, on behalf of different patients, for the same treatment, the IFR Panel will notify the ICB's prioritisation group. The ICB will then review the need for a commissioning policy, in the usual way, but such requests cannot be considered exceptional and cannot be dealt with under this policy.

4.7 Emergency Decisions

- 4.7.1 Where, in the opinion of the Clinician supporting the request, an immediate decision needs to be made for emergency treatment purposes, the ICB will support the principle that treatment should be provided, and agreement then reached with the Provider on who is responsible for the costs involved.
- 4.7.2 If a case is deemed urgent, but not an emergency, the Requester should email the request form to the ICB's IFR team, using the confidential email address ifrteam@nhs.net and then follow this up with a telephone call to the IFR Administrator, in the first instance, to discuss and agree a reasonable timetable for the ICB to consider this request and make a decision. If appropriate, an Extraordinary Panel will be convened or a Virtual Panel if this is not possible.
- 4.7.3 For the purposes of this paragraph 4.7.2 and the operation of the Policy, "emergency" means "immediately life-threatening". A case is deemed "urgent" if a decision needs to be reached more expeditiously than normal circumstances and process would allow, even though the patient's condition is not immediately life-threatening.

4.8 Support for Patients

- 4.8.1 The IFR Administrator can be accessed by patients and their representatives to provide general information and guidance prior to submission of a funding request.
- 4.8.2 If a patient is notified that their IFR will be considered by a Panel on a specific date, the notification letter will provide the name of an IFR Administrator to whom all future enquiries about the request should be directed.
- 4.8.3 The patient, Requester or the Clinician can contact the named IFR Administrator at any stage throughout the process. However, the named IFR Administrator will be unable to advise of the Panel decision or enter into discussions regarding the decision over the telephone with the patient, the Requester, or the Clinician, other than such cases as described in 4.7.1 and 4.7.2 when any delay may compromise the care of the patient.

4.9 Requests to Continue the Funding of Care Commenced Privately

4.9.1 Patients have a right to revert to NHS care and funding at any point during their treatment. However, if they wish to exercise this right, the ICB will expect their care to be transferred to local pathways. Funding for the patient to continue to receive care in a private facility, or to transfer to an NHS provider with which a clinician consulted privately has a link, will not routinely be authorised and the patient would have to demonstrate that they were exceptional within the terms of this Policy for such funding to be considered appropriate. Private treatment is not funded retrospectively.

4.10 Trial Pickup

4.10.1 ICB will not consider funding requests through this Policy where a patient has been part of a drug trial and requests that the ICB continues to fund that treatment once the trial ends (trial pickup). The companies that initiate drug trials, not the ICB, are responsible for any post-trial funding of patients.

4.10.2 This position is supported by the Helsinki Declaration. Full details on [The Medicines for Human Use \(Clinical Trials\) \(Amendment\) \(EU Exit\) Regulations 2019 \(legislation.gov.uk\)](#)

5.0 THE REQUEST PROCESS

5.1 Initial Determination Stage

5.1.1 Each IFR will be considered and decided on its own merits.

5.1.2 All requests for funding will be considered in the first instance by the IFR/Commissioning Support Manager or the IFR Administrator and where appropriate a Medicines Optimisation Representative.

5.1.3 Any incomplete applications will be returned to the Requester at this stage for completion.

5.1.4 The aim of the initial determination stage is to establish whether the funding request is properly categorised as an IFR, or whether it should be dealt with more appropriately through other channels (e.g., a request for prior approval). To this end, the IFR / Commissioning Support Manager and/or the IFR Administrator and/or Medicines Optimisation Representative will seek advice from one or more senior colleagues in Commissioning as appropriate. This stage will also determine whether the request should be dealt with by the Specialised Commissioning Directorate at NHS England and Improvement or Local Authority and will be signposted to that responsible commissioner.

5.1.5 A request for an effective intervention needed for a population of patients (however small) should be referred as a service development for potential inclusion in the prioritisation process and

not couched in the form of an IFR application.

- 5.1.6 Once the IFR/Commissioning Support Manager and/or the IFR Administrator is satisfied that the request is properly categorised as an IFR, the following steps will be taken

5.2 The Screening Stage (Stage 1 review)

- 5.2.4 The Senior IFR/Improvement Manager, together with one or more senior colleagues in, Public Health and/or Medicines Optimisation, as appropriate, will establish whether prima facie evidence of exceptionality has been provided. The outcome of the screening process, and the reasoning on which the decision reached was based, will be documented.
- 5.2.5 The Stage 1 review form will be completed by each reviewer and returned to the IFR Administrator.
- 5.2.6 If prima facie evidence of exceptionality has not been provided, the request will be refused and the IFR Administrator will write to the Requester to give him/her the opportunity to provide such evidence. Such requests will not proceed through the IFR process but will instead be designated as service developments and treated as such unless and until prima facie evidence of exceptionality is provided.

5.3 The IFR Panel Stage – decision on Exceptionality

- 5.3.0 Where prima facie evidence of clinical exceptionality has been provided by or on behalf of the patient, the request will be submitted for consideration under this Policy by the IFR Panel. Key elements of the discussion and the decision reached will be documented. Unless there are extenuating circumstances, the Panel will meet as often as required. See paragraph 4.7.1 and 4.7.2 for the procedure relating to urgent and emergency decisions

5.4 IFR Panel - Membership

- 5.4.1 An IFR Panel will consist of five principal members or deputies of which must be present for the Panel to be quorate. (see Appendix IV – IFR Panel Terms of Reference)
- i. Non-Executive Director of the Integrated Care Board as nominated by the group - **Chair** (voting)
 - ii. Head of Transformation (voting)
 - iii. Two ICB clinicians not responsible for the care of the individual for who the IFR application is made (voting)
 - iv. Public Health Consultant (voting)
 - v. A senior representative from Medicines Optimisation (voting)
- Members of the IFR team will join the Panel specifically to document

the Panel meeting only and will not be able to vote on any decision. Other professionals and advisors may be invited to attend, as relevant, to support and advise on discussions. They will not be entitled to vote on any decision.

5.5 IFR Panel - Role

- 5.5.1 All evidence supporting a claim to exceptionality should be submitted in appropriate documentary form, in advance of the Panel meeting, for the consideration of the Panel members. Neither Patients nor their Clinicians will be invited to attend Panel meetings and therefore the Requester should ensure that the Panel has all the documentation necessary for an informed consideration of the case. Patients may, however, submit a personal statement for the Panel's consideration, if they so wish, provided that this relies upon and refers only to their clinical circumstances and not to non-clinical social factors. The Panel will make its determination after careful scrutiny and discussion of the documentary evidence.
- 5.5.2 If the view of the voting members of the Panel is not unanimous, the decision will be carried by a majority vote. In the event of a tied vote, the Chair will have a casting vote.
- 5.5.3 The Panel must:
- i. Confirm that there is no existing service level agreement or commissioning policy under which the treatment sought could be funded.
 - ii. Take into account all the relevant information submitted to it by the Requester.
 - iii. Consistently apply the decision-making framework in considering applications, to ensure that all cases are dealt with fairly and equitably.
 - iv. Give proper consideration to the expressed needs of the patient, as described, and evidenced by the Clinician and the patient themselves.
 - v. Take into account all relevant factors, including the clinical effectiveness and cost- effectiveness of the requested treatment.
 - vi. Ensure that any issues and concerns, identified either by the Panel or by the Requester, which are outside the remit of this Policy, are noted and passed through to the appropriate area of the ICB for further consideration and response.
 - vii. Set out its decision and the reasons for that decision in writing to the Requester and the patient (unless such communication is contra-indicated by the Clinician - see section 4.2.3 above).

- 5.5.4 Any conflicts of interest or potential conflicts should be identified and declared to the Chair or the Senior IFR/Improvement Manager at the earliest opportunity once the paperwork has been sent to the members so that a substitute member may be found as soon as possible, to avoid postponement of consideration of the case. Where the conflict or potential conflict only becomes apparent at the start of or during the course of the Panel discussions, the member should declare it immediately and a decision will be taken as to whether the conflict requires the withdrawal of that Panel member, in which case consideration of the case is likely to have to be postponed.

5.6 The Virtual Panel

- 5.6.1 It is anticipated that, in normal circumstances, the Panel will meet face to face (this includes Microsoft Teams). When circumstances require an urgent decision and a face-to-face meeting cannot be convened, a virtual meeting may be held, whereby discussions take place by telephone and/or by email (as the nature of the discussions require), with all nominated members of the Panel contributing to the discussions.
- 5.6.2 Any Virtual Panel will be expected to ensure that auditable standards of documentation supporting the discussions are maintained and that its meeting is conducted in accordance with the following procedure:
- 5.6.3 Procedure
- i. All paperwork concerning the matter for decision will be emailed or posted (and clearly marked CONFIDENTIAL AND HIGH PRIORITY) to all members, together with any supporting documentation.
 - ii. The treatment upon which a decision is sought from the Panel will be clearly stated.
 - iii. All queries, comments and discussion points will be shared with the members via email, or by telephone conferencing.
 - iv. A clear deadline for the decision will be identified.
 - v. The Chair of the Panel will normally be a non-executive director of the ICB as nominated by the group
 - vi. Any conflicts of interest or potential conflicts should be declared to the Chair or the Senior IFR/Improvement Manager, at the earliest opportunity once the paperwork has been sent to the members or, where the conflict or potential conflict only becomes apparent during the course of the virtual discussions, as soon as the Virtual Panel member becomes aware of it.

- vii. If the view of the Virtual Panel is not unanimous, the decision will be carried by majority vote. In the event of a tied vote the Chair will have a casting vote.
- viii. The outcome of the Virtual Panel meeting will be advised formally in writing to all members of the Panel. The decision and the reasons for that decision will be set out in writing to the Requester and the patient (unless this is contra-indicated by the Clinician -see section 4.2.3 above).
- ix. Given the confidential nature of the material to be considered under this virtual process, all emails will be marked as CONFIDENTIAL and HIGH PRIORITY and documents will be protected in line with the following ICB policies: (the list will be updated to reflect ICB's equivalents):

<https://www.cannockchaseccg.nhs.uk/about-us/policies/information-governance/521-staffordshire-ccgs-code-of-conduct-2018-19>

<https://www.cannockchaseccg.nhs.uk/about-us/policies/information-governance/272-information-governance-policy-1>

<https://eaststaffsccg.nhs.uk/publications/policies/corporate/information-governance/665-2018-19-staffordshire-ccg-codeof-conduct/file>

<https://eaststaffsccg.nhs.uk/publications/policies/corporate/information-governance/666-2018-staffordshire-ccgs-ig-data-security-and-protection-policies/file>

<https://www.northstaffsccg.nhs.uk/your-ccg-stoke/sot-publications/generic-publications-2/governance-1/1428-2018-19-staffordshire-ccg-code-of-conduct-v0-2-1/file>

<https://www.northstaffsccg.nhs.uk/governance/policies/information-policies/960-5-8-information-governance-policy-north-staffs-and-stoke-on-trent-2017-18-v4-0-september18/file>

<https://sesandspccg.nhs.uk/news-and-information/publications/policy-and-procedures/information-governance/466-staffordshire-ccgs-code-of-conduct-2018-19>

<https://sesandspccg.nhs.uk/news-and-information/publications/policy-and-procedures/information-governance/134-information-governance-policy>

<https://www.staffordsurroundsccg.nhs.uk/about-us/our-policies/information-governance/625-staffordshire-ccg-code-of-conduct/file>

<https://www.staffordsurroundsccg.nhs.uk/about-us/our-policies/information-governance/366-information-governance-policy/file>

<https://www.stokeccg.nhs.uk/publications-library/governance/1425-2018-19-staffordshire-ccg-code-of-conduct-v0-2/file>

<https://www.stokeccg.nhs.uk/stoke-governance/policies/information-policies/960-5-8-information-governance-policy-north-staffs-and-stoke-on-trent-2017-18-v4-0-september18/file>

5.7 Fresh evidence

- 5.7.1 Where a request for funding for a particular treatment has been refused by a Panel or Virtual Panel, the case will nonetheless remain on file. In the event that fresh evidence subsequently comes to light which may, potentially, be capable of demonstrating exceptional clinical circumstances, the Requester may submit this, in appropriate documentary form, to the IFR/Improvement Manager. The new material will be examined and screened in accordance with Paragraphs 5.1 and 5.2 above. If it is considered to demonstrate prima facie evidence of exceptionality, it will go before the next IFR Panel for consideration. The IFR Panel will consider the fresh evidence in the context of the original evidence submitted rather than in isolation i.e. it will consider the totality of the evidence, old and new.
- 5.7.2 The submission of fresh evidence should not be confused with an appeal. Where fresh evidence is submitted but the request for reconsideration is incorrectly couched as a request for an “appeal”, it will be dealt with in accordance with Paragraph 5.7.1

6.0 THE APPEAL PROCESS

6.1 Appeal Panel - Function

- 6.1.1 If the Requester or patient is not satisfied that the correct process has been followed by the Panel in reaching a decision on a funding request, the patient or requester may ask for the matter to be considered by an Appeal Panel. This is the only ground on which an appeal may be requested.
- 6.1.2 If an IFR has been refused in accordance with the screening criteria (at 5.2 above), because no prima facie evidence of exceptionality has been submitted, an appeal cannot be requested. Instead, the Requester will be given the opportunity to provide such evidence.
- 6.1.3 The Requester should submit a request for an appeal, in writing to the Chief Transformation Officer within three months of receipt of the notification letter detailing the outcome of the decision of the initial IFR Panel. The Chief Transformation Officer may agree to consider an appeal received outside of this timescale, if it considers that the Requester has good reasons for failing to observe the three-month time limit for submission of an appeal.

The decision to consider, or to decline to consider, an appeal submitted out of time is entirely within the Chief Transformation Officer's discretion and will be reached after consideration of the particular circumstances.

- 6.1.4 The sole purpose of the Appeal Panel will be to consider whether, having regard to the appeal papers submitted by or on behalf of the patient, the decision of the initial Panel was valid, having regard to the process followed, the factors and information considered, and the criteria applied.
- 6.1.5 It is not appropriate for an appeal to be requested solely on the grounds that an individual disagrees with the decision made by the IFR Panel. The decision itself will not be reviewed; only the process which the Panel followed in order to reach that decision. Patients who merely disagree with the decision made will be advised of their right to pursue the matter via the NHS Complaints system and thence, if appropriate, the Parliamentary and Health Service Ombudsman.
- 6.1.6 Given that the sole purpose of the Appeal Panel, as outlined at 6.1.4 above, is to consider whether the decision of the initial Panel is valid, having regard to the process followed, the factors and information considered and the criteria applied, patients, Requesters and their Clinicians will not routinely be invited to attend Appeal Panel hearings.
- 6.1.7 In deciding an Appeal, the Appeal Panel will consider whether:
- i. The decision was consistent with the "Policy Principles" set out at section 4.0 above
 - ii. The decision was consistent with previous analogous decisions
 - iii. In reaching the decision, the Panel had taken into account and weighed all the relevant evidence given proper consideration to the claims of the patient and accorded proper weight to their claims against those of other groups competing for scarce resources
 - iv. Taken into account only material factors
 - v. Acted in utmost good faith
 - vi. Reached a decision that is in every sense reasonable
- 6.1.8 If the Appeal Panel concludes that there was a failing in the original decision-making process, it will return the case to an appropriately constituted IFR Panel for reassessment, having outlined the areas in which the panel is deemed to have failed to follow process.
- 6.1.9 Any conflicts of interest or potential conflicts should be identified and declared to the IFR/Improvement Manager or Chair, at the earliest opportunity once the paperwork has been sent to the Appeal Panel

members so that a substitute member may be found as soon as possible, to avoid postponement of consideration of the case. Where the conflict or potential conflict only becomes apparent at the start of or during the course of the Appeal Panel discussions, the member should declare it immediately and a decision will be taken as to whether the conflict requires the withdrawal of that Panel member, in which case consideration of the case is likely to have to be postponed.

6.2 Appeal Panel - Structure

6.2.1 Appeal Panels will consist of six principle members or nominated deputies, all of which must be present for the appeal panel to be quorate (see Appendix V – IFR Appeal Panel Terms of Reference)

- i. Chief Transformation Officer (Appeal Panel Chair)
- ii. A non-executive director/nominated patient representative (voting)
- iii. Senior Commissioning Manager (not previously involved in the case) (voting)
- iv. Public Health Specialist (not previously involved in the case) (voting)
- v. Senior Representative from Medicines Optimisation (not previously involved in the case) (voting)
- vi. ICB Clinician or nominated Clinical Director (not previously involved in the case) (voting)

6.2.2 If the view of the Appeal Panel is not unanimous, the decision will be carried by a majority vote. In the event of a tie, the Chair will have the casting vote.

6.2.3 The decision of the Appeal Panel will be final.

6.2.4 If the patient or Requester remains dissatisfied with the Appeal Panel's decision, it is open to them to pursue the matter through the NHS Complaints process and subsequently, if appropriate, with the Parliamentary and Health Service Ombudsman.

6.2.5 All Appeals Panel decisions will be reported promptly to the joint Staffordshire and Stoke-on-Trent SFP Committee.

7.0 TIMESCALES

7.1 All requests for the consideration of an IFR or an appeal will be acknowledged within 3 working days of receipt.

7.2 The outcome of the screening process will be notified to the Requester within 15 working days of receipt of the initial application. Where the request has been refused, the Requester will be offered the opportunity to submit further evidence.

7.3 Where the screening process determines that prima facie evidence of exceptionality has been provided, the case will usually be considered by

the next scheduled Panel (panels are usually scheduled to meet monthly). The Requester will be notified in writing of the Panel's decision within 5 working days of the Panel meeting. ICB staff will not enter into verbal or written correspondence with the patient or their Clinician during this 5 working day period, with the exception of urgent requests where delayed communication may compromise the patients care.

7.4 The Appeal Panel will meet as and when required. The Appeal Panel will be convened within 30 days of receipt of an appeal.

7.5 The IFR Administrator will notify the Requester of the decision of the Appeal Panel within 5 working days of the Appeal Panel meeting.

8.0 MANAGING INFORMATION

8.1 Patient Confidentiality

8.1.1 All information received and considered under this Policy remains confidential and will be managed in accordance with GDPR/the Data Protection Act 2018 and will be held, processed, and shared only as required for the purposes of delivering services in accordance with the principles of the Policy.

8.1.2 A patient who has mental capacity must consent to all relevant information being shared with the IFR Panel. The IFR application form requires the Requester to confirm that the patient has consented to an IFR application being made and processed. Written permission will be obtained from the patient at any time that the sharing of identifiable data, beyond the ICB or requesting team involved in handling the request, is envisaged.

8.1.3 Where the patient lacks mental capacity, the Clinician will be asked to confirm on the application form that a best interest's assessment has been undertaken. The Clinician must be able to supply documentary evidence of the assessment and the resulting decision, should the ICB request this, although this should not be submitted with the application.

8.1.4 All patient identifiable data will be transmitted in accordance with the ICB's policy on the handling of sensitive personal data as set out in the following policies (the list will be updated to reflect ICB's equivalents):

<https://www.cannockchaseccg.nhs.uk/about-us/policies/information-governance/521-staffordshire-ccgs-code-of-conduct-2018-19>

<https://eaststaffsccg.nhs.uk/publications/policies/corporate/information-governance/665-2018-19-staffordshire-ccg-code-of-conduct/file>

<https://www.northstaffsccg.nhs.uk/your-ccg-stoke/sot-publications/generic-publications-2/governance-1/1428-2018-19-staffordshire-ccg-code-of-conduct-v0-2-1/file>

<https://sesandspccg.nhs.uk/news-and-information/publications/policy-and-procedures/information-governance/466-staffordshire-ccgs-code-of-conduct-2018-19>

<https://www.staffordsurroundsccg.nhs.uk/about-us/ourpolicies/information-governance/625-staffordshire-ccg-code-of-conduct/file>

<https://www.stokeccg.nhs.uk/publicationslibrary/governance/1425-2018-19-staffordshire-ccg-code-of-conduct-v0-2/file>

8.2 Communicating Decisions

8.1.1 The ICB will provide the Requester and the patient (unless this is contra-indicated by the Clinician, or Requester - see 4.2.3) with an explanation of the reason(s) for any decision not to fund the treatment sought.

8.1.2 Where the Panel declines a request for funding, the Requester and patient (unless contra-indicated) will be clearly advised of the grounds on which an appeal may be lodged.

8.3 Responsible Commissioner

8.3.1 Where the ICB receives a request for treatment that falls within a service area not directly managed by the ICB, the request will be referred to the relevant host organisation for review and consideration under their local policy and procedures.

8.4 Other Matters Identified

8.4.1 Where the Panel or Appeal Panel, in the course of considering a funding request, identifies issues which lie outside the purpose and remit of the IFR process, the Panel or Appeal Panel will formally note the concern or issue for follow up with the relevant team within the ICB.

9.0 EVALUATION & REVIEW

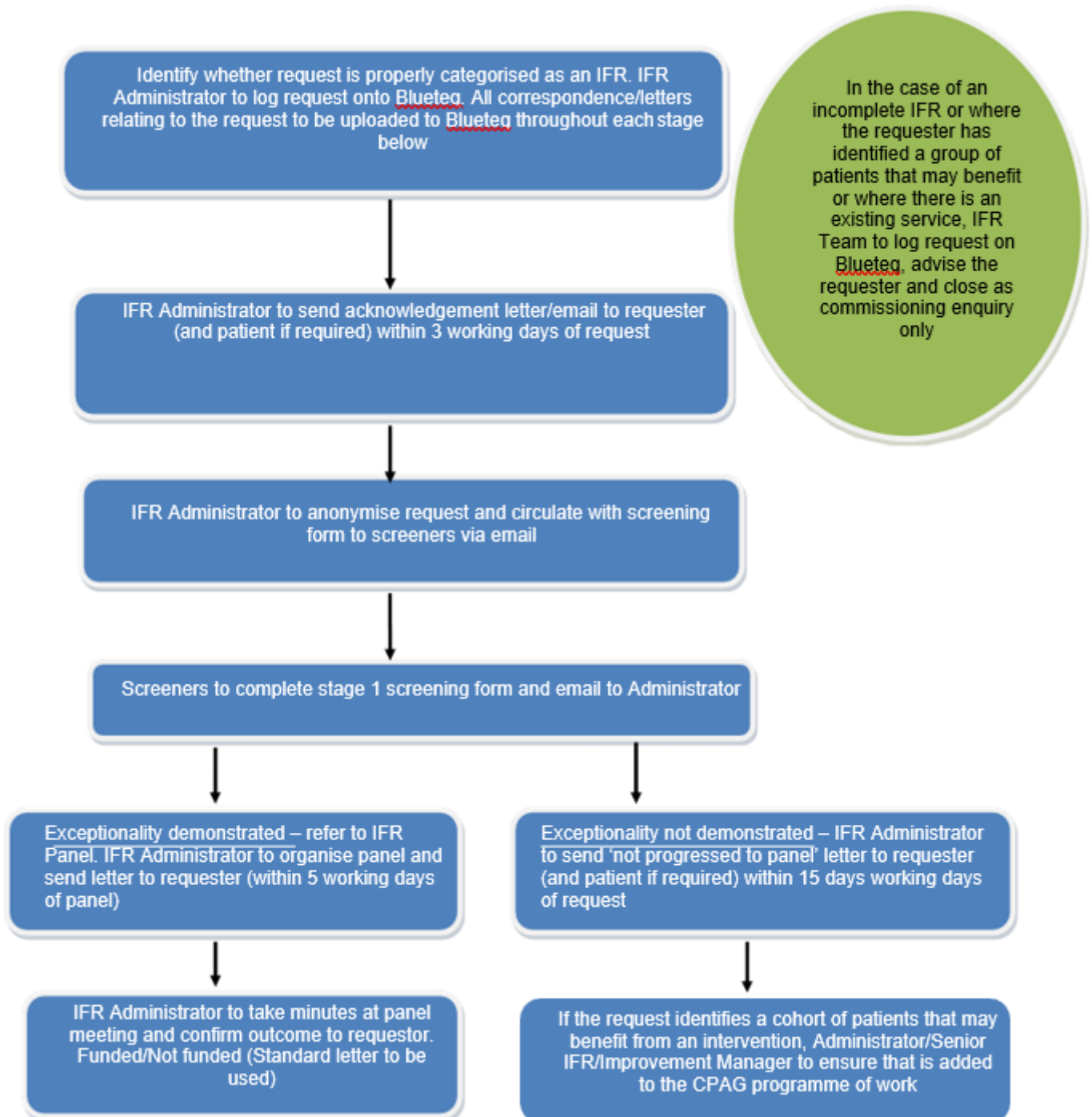
9.1 This Policy will be reviewed every three years unless circumstances suggest that earlier review is appropriate.

9.2 The review will include an equality analysis and an audit of decisions made, to ensure that the Policy has been applied consistently and to identify any changes required to the process, in the light of existing practice and other factors such as developing legislation, reform and case law.

10.0 TRAINING SUPPORT

10.1 Training to support members of the Panels and Appeal Panels will be provided, to ensure that respective roles are understood and to provide members with the necessary skills to fulfil their role as a Panel member.

Appendix I – IFR Process



Appendix II – Individual Funding Request (IFR) Policy Review Group – Terms of Reference

1.0 Main Objectives of the Review Group

The purpose of the Committee is to monitor the process of IFRs according to policy.

2.0 Frequency of Meetings

Six Monthly

3.0 Authority

The IFR Policy Review Group has authority to advise on IFR policy, review lessons learned from the process and support any review as a result of changes in legislation to ensure that the Staffordshire and Stoke-on-Trent ICB is delivering in its responsibilities in respect of IFRs. The IFR policy review group will make recommendations to the SFP Committee

4.0 Membership

(Nominated Deputies – Members will ensure a deputy familiar with the IFR process is present if unable to attend in person)

- i. Head of Transformation
- ii. Public Health Specialist
- iii. Medical Director or Clinical Director
- iv. Head of Medicines Optimisation
- v. IFR Panel Clinicians
- vi. Senior IFR / Improvement Manager
- vii. Non-executive director or nominated Patient Representative
- viii. IFR Administrator (Minute Taker)

4.1 Quoracy

- i. Head of Transformation
- ii. Public Health Specialist
- iii. 2 ICB Clinicians
- iv. Patient Representative
- v. Senior IFR/Improvement Manager
- vi. IFR Administrator (Minute Taker)

5.0 Reporting

Report to Staffordshire and Stoke-on-Trent SFP Committee

6.0 Duties

6.1 Review the IFR policy and advise on policy development, taking into consideration recommendations from any Equality or Quality Impact Assessments undertaken.

6.2 Review methods of communication in respect of patient, public and clinical feedback

- 6.3** Review IFR Management and panel activity within the ICB prior to presentation to the SFP Committee.
- 6.4** Assure itself that the active audit cycle is carried out to review the panel case summaries. Highlight any inconsistencies identified in the process and report where appropriate.
- 6.5** Review and advise on the infrastructure in place within the ICB in respect of the resources required to support the IFR process including:
- Departmental structure
 - Job Descriptions
 - IT resources
 - Training
- 6.6** Review any publications relating to the IFR process including material available on the website.
- 6.7** Seek assurance that in sensitive cases, for example with media and / or MP involvement, that all correspondence is appropriate. Identify relevant spokesperson if required.
- 6.8** Review and advise on all documentation utilised in the process at each stage and assure itself that the documentation is robust, captures all relevant data and can be evidenced appropriately as an audit trail to the process.
- 6.9** Consider its own membership including patient/public representation.
- 6.10** Assure itself that in service developments identified by IFRs are dealt with through the Clinical Priorities Advisory Group (CPAG) as part of wider prioritisation process in a timely way.

7.0 Administration

Papers will be circulated prior to the meeting (with 5 working days' notice) minutes will be taken.

8.0 Review Date & Monitoring

These Terms of Reference will be reviewed as part of the IFR Policy review

Appendix III - Guidance for Panels

A) The determination of exceptionality

Funding will only be provided for a patient outside the ICB's annual prioritisation process if the Requester is able to demonstrate that the patient's clinical circumstances are exceptional.

B) What is meant by "exceptional" circumstances?

There can be no exhaustive definition of the conditions which are likely to come within the definition of an exceptional individual case. The word "exception" means "a person, thing or case to which the general rule is not applicable"³. The Panel should bear in mind that, whilst everyone's individual circumstances are, by definition, unique, very few patients have circumstances which are exceptional, so as to justify funding for treatment for that patient which is not available to other patients. The following points constitute general guidance to assist the Panel. However, the overriding question which the Panel needs to ask itself remains "Has it been demonstrated that this patient's clinical circumstances are exceptional?"

- It may be possible to demonstrate exceptionality where the patient has a medical condition which is so rare that the result of the ICB's annual prioritisation process provides no established treatment care pathway for that condition.
- If a patient has a condition for which there is an established care pathway, the Panel may find it helpful to ask itself whether the clinical circumstances of the patient are such that they are exceptional as compared with the relevant subset of patients with that medical condition at the same stage of progression of the condition.
- The fact that a patient failed to respond to, or is unable to be provided with, one or more treatments usually provided to a patient with his or her medical condition (either because of a generic other medical condition or because the patient cannot tolerate the side effects of the "usual" treatment) *may* be a basis upon which a Panel could find that a patient is exceptional.

However, the Panel would normally need to be satisfied that the patient's inability to respond to, or be provided with, the "usual" treatment was a genuinely exceptional circumstance. For example:

- If the "usual" treatment is only effective for a proportion of patients (even a high proportion), this leaves a proportion of patients for whom the "usual" treatment is not available or is not clinically effective. If there is likely to be a significant number of patients for whom the "usual" treatment is not clinically effective or not otherwise appropriate (for any reason), the fact that the requesting patient falls into that group is unlikely to be a proper ground on which to base a claim that the requesting patient is exceptional.
- If the "usual" treatment cannot be given because of a pre-existing co-morbidity which could not itself be described as exceptional in this patient group, the fact of the co-morbidity and its impact on treatment options for the requesting patient is unlikely to make the patient exceptional.

³ Definition in the Short Oxford English Dictionary

a) Non-clinical factors:

Patients often seek to support an application for individual funding on the grounds that their personal circumstances are exceptional. This assertion can include details about the extent to which other persons rely on the patient, or the degree to which the patient has contributed, or is continuing to contribute, to society. The ICB understands that everyone's life is different and that such factors may seem to be of vital importance to patients in justifying investment for them in their individual case. However, including such non-clinical, social factors in any decision-making raises at least three significant problems for the ICB:

- Across the population of patients who make such applications, the ICB is unable to make an objective assessment of material put before it relating to non-clinical factors. This makes it very difficult for the Panel to be confident of dealing in a fair and even-handed manner in comparable cases.
- The essence of an individual funding application is that the ICB is making funding available on a one-off basis to a patient where other patients with similar conditions would not get such funding. If non-clinical factors are included in the decision-making process, the ICB does not know whether it is being fair to other patients who are denied such treatment and whose social factors are entirely unknown.
- The ICB is committed to a policy of non-discrimination in the provision of medical treatment. If, for example, treatment were provided which had the effect of keeping someone in paid work, this would tend to discriminate in favour of those of working age and against the retired. If a treatment were provided differentially to patients who were carers, this would tend to favour treatment for women over men. If treatment were provided, in part, on the basis that a medical condition had affected a person at a younger age than that at which the condition normally presents, this would constitute direct age discrimination.

Generally, the NHS does not take into account social factors in deciding what treatment to provide. It does not seek to deny treatment to smokers on the grounds that they may have caused or contributed to their own illnesses through smoking, nor does it deny treatment to those injured in dangerous sports in which they were voluntary participants.

In general, the NHS treats the presenting medical condition and does not inquire into the background factors which led to the condition. The policy of the ICB is that it should continue to apply these broad principles in individual applications for funding approval. The ICB will therefore seek to commission treatment based on the presenting clinical condition of the patient and not based on the patient's non-clinical social circumstances.

In reaching a decision as to whether a patient's circumstances are exceptional, the Panel is required to follow the principle that non-clinical or social factors including social value judgments about the underlying medical condition or the patient's circumstances are never relevant. Patients and referring clinicians are asked to bear this policy in mind and not to refer to social or non-clinical factors to seek to support the application for individual funding.

b) Proving the case that the patient's circumstances are exceptional

The onus is on the Requester to set out the grounds clearly for the Panel on which it is said that this patient is exceptional. The grounds will usually arise out of an exceptional clinical manifestation of the medical condition, as compared to the general population of patients with the medical condition which the patient has.

Grounds must be set out on the form provided by the ICBs and should clearly set out any factors that the patient invites the Panel to consider as constituting a case of exceptional circumstances. If, for example, it is said that the patient cannot tolerate the "usual" treatment because of the side effects of another treatment, the patient, or the referring clinician (who is often the expert with detailed knowledge) must explain how unusual it is for patients with this condition not to be able to be provided with the "usual" treatment.

If a clear case as to why the patient's circumstances are said to be exceptional is not made out, then the Panel is obliged to refuse the application. The Panel recognises that the patient's referring clinician is often in the best position to provide information about the patient's clinical condition as compared to a subset of patients with that condition. The ICB therefore requires the referring clinician, as part of their duty of care to the patient, to explain why the patient's circumstances are said to be exceptional.

The policy of the ICB is that there is no duty on the Panel to carry out its own investigations about the patient's circumstances in order to try to find a ground upon which the patient may be considered to be exceptional nor to make assumptions in favour of the patient if one or more matters are not made clear in the application. Therefore, if a clear case of exceptionality is not made out by the Requester, the Panel is obliged to turn down the application.

c) Multiple claimed grounds of exceptionality

There may be cases where patients seek to rely on multiple grounds to show their case is exceptional. In such cases the Panel should look at each factor individually to determine (a) whether the factor was capable of making the case exceptional and (b) whether it did in fact make the patient's case exceptional. The Panel may conclude, for example, that a factor was incapable of supporting a case of exceptionality and should therefore be ignored. That is a judgment within the discretion of the Panel.

If the Panel is of the view that none of the individual factors on their own make the patient's circumstances exceptional, the Panel should then look at the combined effect of those factors which are, in the Panel's judgment, capable of supporting a finding of exceptionality. The Panel should consider whether, in the round, these combined factors prove that the patient's circumstances are exceptional. In reaching that decision the Panel should remind itself of the difference between individually distinct circumstances and exceptional circumstances.

d) The determination of clinical effectiveness

It is the responsibility of the Requester to explain to the Panel the basis upon which it is said that the requested treatment would be likely to be clinically effective for that individual patient. Details should be provided of the anticipated benefits for the patient, the level of confidence that the referring clinician has that the benefits will be shown and the likely duration of any benefit.

Reference should be made to published material including Random Controlled Trials (RCTs), NICE or other Guidance, recommendations of specialist medical bodies and any other materials relied upon.

The Panel is entitled but not obliged to seek its own specialist advice about whether a treatment is likely to be clinically effective. A case which comes before the Panel for approval for individual funding will be subject to the same principles of assessing clinical effectiveness as treatments where a population-wide approach is taken (as far as that is possible given the inherent difficulties in an individual case).

No treatment will be approved for funding by the ICB unless the Panel is satisfied that the treatment is likely to be clinically effective. If the Panel is not provided with sufficient material so that it can be reasonably confident that the treatment is likely to be clinically effective, then it must refuse the application.

e) The determination of cost-effectiveness

It is the responsibility of the Requester to explain to the Panel the basis upon which it is said that the requested treatment is likely to be cost-effective for the individual patient.

Reference should be made to published Incremental Cost-Effectiveness Ratio/Quality Adjusted Life Year (“ICER/QALY”) material or other guidance, recommendations of specialist medical bodies and any other materials relied upon. If the referring Clinician is aware of any material relating to cost-effectiveness, including any adverse observations on the cost-effectiveness of the requested treatment, he or she is required to put this material before the Panel.

The Panel is entitled but not obliged to seek its own specialist advice about whether a treatment is likely to be cost-effective. However, the ICB recognises that good estimates on cost-effectiveness may not be available and the panel may consider the opportunity cost as an alternative in such cases

Appendix IV – Individual Funding Request Panel (IFRP) – Terms of Reference

1.0 Authority & Reporting

The IFR Committee is a formal sub-committee of the Finance and Performance Committee for this area of decision-making, i.e. exceptional individual cases. It will report its activity to the Committee on an annual basis unless, exceptionally, the Panel considers that the decision reached requires the endorsement of the Committee. Decisions for which it might be appropriate to seek formal endorsement include those:

- which will create significant media or MP interest
- of particular public sensitivity
- of significant financial value and risk

The IFR Administrator will take notes of key discussion points and the decision and record this for the patient's file, and for reference for activity reports to SFP Committee.

2.0 Purpose

To decide whether the ICB should fund treatments outside of ICB policy or contracts on the basis of exceptional individual status within a decision-making framework detailed at section 4, policy principles within this Policy, including:

- the exceptionality criteria
- evidence of clinical and cost effectiveness
- affordability
- equity
- national standards

3.0 Exceptions

The IFR policy specifically excludes an IFR Panel from considering requests where:

- the patient has been a part of a drug trial and wants the ICB to pick up funding
- the patient seeks retrospective funding for private healthcare already received
- the case for exceptionality is based on non-health factors (e.g., social factors)

4.0 Membership

An IFR Panel will consist of up to six principal members or deputies, of which five must be present for the Panel to be quorate.

- i. Non-executive Director of the Integrated Care Board as nominated by the group – **Chair** (voting)
- ii. Head of Transformation or nominated deputy (voting)
- iii. Two ICB clinicians not responsible for the care of the individual for who the IFR application is made. (voting)
- iv. Public Health – (voting)
- v. Senior representative from Medicines Optimisation (voting)

Members of the IFR Team will join the panel to document the Panel meeting only and will not be able to vote. Other professionals and advisors may be invited to attend, as relevant, to support and advise on discussions. They will not be entitled to vote on any decision.

5.0 Frequency and Style

The IFR Panel will meet monthly. In normal circumstances, the Panel will meet face to face. (includes Microsoft Teams). When circumstances require an urgent decision and a face-to-face meeting cannot be convened, a “virtual” meeting may be held, whereby discussions take place by telephone and/or by email (as the nature of the discussions require), with all nominated members of the Panel contributing to the discussions.

6.0 Role of the Panel

All evidence supporting a claim to exceptionality should be submitted in the appropriate documentary form, in advance of the Panel meeting, for the consideration of the Panel members. The Panel will make its determination after careful scrutiny and discussion of the documentary evidence. If the view of the Panel is not unanimous, the decision will be carried by a majority vote. In the event of a tied vote, the Chair will have a casting vote. The Panel has the discretion to re-consider cases if genuinely new evidence is presented demonstrating that the patient is exceptional. The Panel must:

- i. Confirm that there is no existing service level agreement or commissioning policy under which the treatment sought could be funded.
- ii. Take into account all the relevant information submitted by the Requester
- iii. Consistently apply the decision framework in considering applications to ensure that all cases are dealt with fairly and equitably
- iv. Give proper consideration to the expressed needs of the patient, as described, and evidenced by the clinician and the patient themselves
- v. Take into account all relevant factors, including the clinical effectiveness and cost effectiveness of the requested treatment
- vi. Ensure that any issues and concerns, identified either by the Panel or by the Requester, which are outside the remit of this policy, are noted and passed through to the appropriate area of the ICB for further consideration and response
- vii. Set out its decision and the reasons for that decision in writing to the Requester and the patient (unless such communication is contra-indicated by the Requester)

7.0 Attendance

The Head of Transformation will ensure attendance to achieve the quorum in respect of each department

8.0 Review

These Terms of Reference will be reviewed as part of the IFR Policy review.

Appendix V – Individual Funding Request Appeal Panel – Terms of Reference

1.0 Right to Appeal

If the Requester or the patient is not satisfied the correct process has been followed by the Panel in reaching a decision on a funding request, the patient or the Requester may ask for the matter to be considered by an Appeal Panel. This is the only ground on which an appeal may be requested.

If an IFR has been refused in accordance with the screening criteria (*section 5.2 in the IFR Policy*) because no prima facie evidence of exceptionality has been submitted, an appeal cannot be requested. (*Refer to section 6 of the IFR Policy*)

If an IFR has progressed through an IFR Panel and the patient is not satisfied that the correct process has been followed by the Panel in reaching a decision, the Requester or the patient may ask for the matter to be considered by an Appeal Panel. This should be done in writing to the Chief Transformation Officer within three months of being advised of the IFR panel decision, but the ICB may consider appeals outside of this timescale.

2.0 Role of the IFR Appeal Panel (IFRAP)

The sole purpose of the IFRAP is to consider whether the decision of the initial Panel was valid with regard to the process followed, the factors and information considered, and the criteria applied. It does not (re)consider the actual decision and therefore the Requester and/or patients are not routinely invited to attend.

2.1 In deciding an Appeal, the Appeal Panel will consider whether:

- i. the decision was consistent with the “Policy Principles” (including decision making framework) set out at section 4.0 of the IFR Policy
- ii. the decision was consistent with previous analogous decisions
- iii. in reaching the decision, the Panel had taken into account and weighed all the relevant evidence, given proper consideration to the claims of the patient and accorded proper weight to their claims against those of other groups competing for scarce resources
- iv. taken into account only material factors
- v. acted in utmost good faith
- vi. reached a decision that is in every sense reasonable

2.2 If the Appeal Panel concludes that there was a failing in the original decision-making process, it will return the case to an appropriately constituted IFR Panel for reassessment, having outlined the areas in which the panel is deemed to have failed to follow process.

2.3 In such instances, the majority of Panel members must not have been involved in the original assessment.

In particular, the following must be different:

1. One of the two ICB clinicians and/or independent contractor clinicians
2. Panel Chair

3.0 IFRAP Structure

Appeal Panels will consist of six principle members or nominated deputies, all of which must be present for the appeal panel to be quorate.

- i. Chief Transformation Officer (Appeal Panel Chair) (voting)
- ii. Non-executive director of the ICB (voting)
- iii. Senior Commissioning Manager (not previously involved in case) (voting)
- iv. Public Health Specialist (not previously involved in the case) (voting)
- v. Senior Representative from Medicines Optimisation (not previously involved in the case) (voting)
- vi. ICB clinician or nominated Clinical Director (not previously involved in the case) (voting)

4.0 The Appeal Panel will be advised on

- Process and legality by the Head of Governance
- Clinical matters by the Public Health Clinician (or, where they were previously involved in the case, an alternative senior ICB clinician)
- Commissioning policy by the relevant commissioning managers (not previously involved in the case)

The advice received, in documentary form, will be presented to the Appeal Panel with the appeal papers received from or on behalf of the patient.

Those providing this advice will be in attendance, as required, to discuss the advice further with the Appeal Panel.

5.0 Decision

If the view of the Appeal Panel is not unanimous, the decision will be carried by a majority vote. In the event of a tie, the Chair will have the casting vote.

The decision of the Appeal Panel will be final but does not preclude the right of the patient to lodge a complaint about the decision and/or the process through the ICB's Complaints Procedure.

If the patient remains dissatisfied with the ICB's decision, it is open to them to pursue the matter with the complaints process and/or Parliamentary and Health Service Ombudsman.

6.0 Timeline

The IFRAP will meet as and when required. The ICB will notify the Requester and/or the patient of the outcome within 5 working days of the decision.

7.0 Review

These Terms of Reference will be reviewed as part of the IFR Policy review.