

**EVIDENCED BASED INTERVENTIONS APPLICATIONS  
COMMISSIONING POLICY**

<b>Section</b>		<b>Page</b>
	Version Control	1
	Document Change History	2
1	Introduction	2
2	When to Apply the Policy	2
3	Second Opinion Referral	3
4	The Evidenced Based Interventions Application Process	3
5	The Application	3/4
6	Criteria for Decision Making	4/7
7	New Clinical Policies	7
8	Communication of Decisions	8
9	Expert Advice	8
10	New Drugs or Technologies	8/9
11	Re-Consideration of Applications	9
12	Terms of Reference of the EBI Panel	9
13	Appeals	9
14	Reporting on Activity of the EBI Panel	9
15	Co-Operation of NHS Providers	9
16	Urgent Application Decisions	10/11
17	Retrospective, Prospective and Part Funding	11

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V2d	May 2014	Review by the IFRP
V2e	November 17	CEC approved name change to Evidenced Based Interventions Panel (EBI), CCG house styled, inclusion of Head of EBI

## **1 INTRODUCTION**

- 1.1 Somerset Clinical Commissioning Group aims to commission and provide high quality clinical care accessible to the whole population that is equitable and consistently based on clinical need. This is achieved by commissioning clear patient pathways across primary, secondary and sometimes tertiary care.
- 1.2 Somerset Clinical Commissioning Group accepts that there may be individual cases where a patient's needs may not be met through existing care pathways. The Somerset Clinical Commissioning Group has set up an Evidenced Based Interventions Panel to consider these cases.
- 1.3 The role of the Somerset Clinical Commissioning Group Evidenced Based Interventions (EBI) Panel is to consider individual applications from health professionals requesting funding for clinical interventions not routinely commissioned.
- 1.4 Patient confidentiality will be maintained at all times, in accordance with Caldicott guidance. All information considered by the Somerset Clinical Commissioning Group Evidence Based Interventions Panel is strictly confidential and should be sent to the Evidence Based Interventions Panel using the appropriate safe haven contact details.

## **2 WHEN TO APPLY THE POLICY**

- 2.1 This policy applies to any patient where Somerset Clinical Commissioning Group is the responsible Commissioner.
- 2.2 Before an application is put forward every patient should have had a

discussion about treatment options and choice of provider with their General Practitioner or Consultant.

- 2.3 Clinicians or clinical teams on behalf of their patients are entitled to put forward an application (an “Evidence Based Interventions Application”) to the Commissioner for treatment to be funded outside of the Commissioner’s established policies on one of two grounds, namely: The patient is suffering from a presenting medical condition for which treatment is not routinely commissioned and the Commissioner has no policy **or**

The patient is suffering from a presenting medical condition for which the Commissioner has a policy but where the patient’s particular clinical circumstances falls outside the clinical pathway that the Commissioner has agreed to fund.

### **3 Second Opinion Referral**

- 3.1 Patients requiring a second opinion for procedures routinely funded by Somerset CCG do not require approval from the Panel.
- 3.2 Patients need to discuss a second opinion referral with their GP who if they consider it is appropriate may refer their patient to a Provider on the Choice Menu of Choose and Book. The Provider may be one with whom the Somerset Clinical Commissioning Group has a contract with or a non-contractual NHS treatment Provider.
- 3.3 Patients requiring a second opinion for procedures and treatment not routinely funded by the Somerset Clinical Commissioning Group should be referred to the Panel for consideration.
- 3.4 Requests for assessment will normally be authorised for one outpatient appointment only, with subsequent further assessment and/or treatment, subject to authorisation by the Somerset Clinical Commissioning Group Evidenced Based Interventions Panel.
- 3.5 Somerset Clinical Commissioning Group Evidence Based Interventions Panel will not reimburse funding retrospectively for private referrals either to an outpatient clinic or for inpatient treatment. All such referrals must have prior authorisation by the Panel.

### **4 THE EVIDENCED BASED INTERVENTIONS APPLICATION PROCESS**

- 4.1 The flow diagram at **Appendix 1(a)** describes in full the process that each application will take.

### **5 THE APPLICATION**

- 5.1 All applications must be accompanied by written support and evidence provided by the clinical team treating the patient as required in the

Somerset CCG Evidenced Based Interventions Panel Generic Application Form at **Appendix 1 (b)** explaining:

**The clinical circumstance of the patient**

- 5.2 The Clinical Team is required to present a full application to the commissioners which sets out a comprehensive and balanced clinical picture of the history and present state of the patient's medical condition, the nature of the treatment Requested and the anticipated benefits of the treatment.

**The planned treatment and the expected benefits and risks of treatment**

- 5.3 The Clinical Team shall describe the anticipated clinical outcomes for the individual patient of the proposed treatment. This should include the degree of confidence of the Clinical Team that the outcomes will be delivered for this particular patient and any risks associated with the proposed treatment.

**The evidence on which the clinical opinion is based**

- 5.4 The Clinical Team shall refer to, and include, copies of any clinical research material which supports, questions or undermines the case that is being made that the treatment is likely to be clinically effective in the case of the individual patient.

**The costs of treatment**

- 5.5 The Clinical Team shall set out the full attributable costs of and connected to the treatment. The EBI Panel shall be entitled but not obliged to commission its own reports from any duly qualified or experienced clinician or other duly qualified person concerning the full attributable costs of and connected to the treatment.

**Whether or not there are likely to be similar patients either within the Commissioner's area or across the region**

- 5.6 The clinician must also provide the case for treating this patient as exceptional to the cohort of similar patients.

**6 CRITERIA FOR DECISION MAKING**

- 6.1 The Chair of the EBI Panel/ Commissioning Representative shall routinely screen Evidenced Based Interventions to consider whether they represent a service development. The key question used to screen out a service development will be 'are there likely to be other similar patients in the CCG area. If there is evidence the patient is a representative of other similar patients then in these cases, the Evidenced Based Interventions will be sent back to the provider with a request to follow normal procedures for proposal for a service development through the Somerset CCG Clinical Commissioning Policy Forum. It is recognised however, initial applications for a new approach may legitimately be considered by the Panel.

- 6.2 The EBI Panel shall be entitled to approve requests for funding for

treatment for individual patients where the following conditions are met:

- The EBI Panel confirms that there is not an identifiable cohort of similar patients to the requesting patient and that exceptionality is demonstrated.
- Taking into account all relevant considerations, and evidence of likely effectiveness of the requested treatment and benefit to the individual patient, the EBI Panel deem the funding to be appropriate.

### **RELEVANT EBI PANEL CONSIDERATIONS**

6.3 The panel will consider the following areas, if relevant, when making a decision on individual cases:

- Consideration of exceptionality
- Clinical effectiveness and cost effectiveness
- Health needs of the patient and the anticipated impact of the intervention on the patients' health.
- Alternative options that the patient may have and any contraindications to the alternatives.
- Equity
- Absolute affordability

### **CONSIDERATION OF EXCEPTIONALITY**

6.4 The EBI Panel will consider exceptionality in the context of the relevant clinical commissioning policy/policies and guidance notes and in particular the reasons why the intervention is not normally funded or why the particular criteria have been set.

6.5 In determining whether a patient is able to demonstrate exceptional circumstances the EBI Panel shall compare the patient to other patients with the same presenting medical condition at the same stage of progression.

6.6 Are there other factors that need to be considered in making a decision? For exceptional funding to be agreed there must be some unusual or unique clinical factor that suggests that the patient is:

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

6.8 The EBI Panel shall determine, based upon the evidence provided to the panel, whether the patient has demonstrated exceptional circumstances.

6.9 Where a case has been judged as exceptional, the panel shall then consider all other factors including cost effectiveness and clinical effectiveness. When considering cost effectiveness, the panel will consider the appropriate mechanism for doing so. Such an approach should

generally be less restrictive than the case for funding a drug through the business planning cycle.

### **CLINICAL EFFECTIVENESS AND COST EFFECTIVENESS**

- 6.10 There is sufficient evidence from relevant NICE guidance, national sources and research to show that, for the individual patient, the proposed treatment is likely to be clinically effective and cost-effective.
- 6.11 The EBI Panel shall, based on the information before it, take a view on whether the treatment is both effective and cost-effective.
- 6.12 The EBI Panel shall consider but is not required to accept the views expressed by the patient or the clinical team concerning the likely clinical outcomes for the individual patient of the proposed treatment. The EBI Panel is entitled to reach its own views on the likely clinical outcomes for the individual patient of the proposed treatment; and the quality of the evidence to support that decision and/or the degree of confidence that the EBI Panel has about the likelihood of the proposed treatment delivering the proposed clinical outcomes for the individual patient.
- 6.13 The Commissioner does not generally commission treatment for patients under its policies dependent on the patient's social or personal circumstances. Clinical Commissioning Policy is based on identified health need. Accordingly, when making decisions as to whether treatment should be provided to a patient which is not provided to patients generally, the EBI Panel shall adopt the same approach.

### **HEALTH NEEDS OF THE PATIENT AND ANTICIPATED HEALTH BENEFIT OF THE INTERVENTION**

- 6.14 In deciding whether to approve funding, the EBI Panel shall remind itself that the policies of the Commissioner provide that medical treatment is made available to patients generally on the basis of their presenting medical conditions and on the likely benefits and improved health outcome anticipated for a patient from a proposed treatment.

### **EQUITY**

- 6.15 Access to services shall be governed as far as practicable, by the principle of equal access for equal clinical need. Individual patients or groups shall not be unjustifiably advantaged or disadvantaged on the basis of age, gender, sexuality, race, religion, lifestyle, occupation, social position, financial status, or intellect.

### **ABSOLUTE AFFORDABILITY**

- 6.16 The EBI Panel shall have a broad discretion to determine whether the proposed treatment is a justifiable expenditure of the Commissioner's resources.
- 6.17 The EBI panel is however required to bear in mind that the resources requested to support the individual patient will reduce the availability of resources for other investments.

6.18 The EBI Panel shall take care to avoid adopting the approach described as the “the rule of rescue”. The fact that a patient has exhausted all NHS treatment options available for a particular condition is unlikely, of itself, to be sufficient to demonstrate exceptional circumstances. Equally, the fact that the patient is not responding to existing treatments where a recognised proportion of patients with same presenting medical condition at this stage are, to a greater or lesser extent, not responding to existing treatments is unlikely, of itself, to be sufficient to demonstrate exceptional circumstances.

6.19 In reaching a decision the EBI panel must consider the expected clinical outcome and benefit to the patient in the context of the relevant cost and other comparable treatment available.

### **PUBLIC SECTOR EQUALITY DUTY**

6.20 When taking decisions around the care packages, the EBI Panel will always give due consideration to the Public Sector Equality Duty. This requires that it must have due regard to the need to:

- (a) eliminate discrimination, harassment, victimisation and any other conduct that is prohibited by or under the Equality Act;
- (b) advance equality of opportunity between persons who share a relevant protected characteristic and persons who do not share it;
- (c) foster good relations between persons who share a relevant protected characteristic and persons who do not share it.

6.21 Having due regard to the need to advance equality of opportunity between persons who share a relevant protected characteristic and persons who do not share it involves having due regard, in particular, to the need to:

- (a) remove or minimise disadvantages suffered by persons who share a relevant protected characteristic that are connected to that characteristic;
- (b) take steps to meet the needs of persons who share a relevant protected characteristic that are different from the needs of persons who do not share it;
- (c) encourage persons who share a relevant protected characteristic to participate in public life or in any other activity in which participation by such persons is disproportionately low.

## **7 NEW CLINICAL POLICIES**

7.1 Very occasionally an Evidence Based Interventions Application presents a new clinical treatment or approach which needs a substantial piece of work before the Commissioner can reach a conclusion upon its position. This may include wide consultation. Where this occurs the EBI Panel may adjourn a decision on an individual case until that work has been completed.

- 7.2 The EBI panel may in some circumstances decide that an expert opinion is necessary; in these circumstances the panel may appoint their own expert, to provide either a verbal or written opinion. This may impact the timeframe for consideration of the case, and lead to the standard timeframe being exceeded on a small number of occasions.

## **8 COMMUNICATION OF DECISIONS**

- 8.1 The decision will be communicated in writing to the applicant (GP/Consultant), and copied to the patient or parent/guardian when indicated as appropriate on the application form. The decision and the reasons for the decision will be outlined in this letter. The letter will be produced and sent to the applicant within 5 – 10 working days of the panel meeting.
- 8.2 The Commissioner is not obliged to discuss the decision with the applicant, the patient or any other parties prior to the release of the letter of decision; however the Commissioner may release this information at their discretion. The detailed reason for the decision will not be communicated verbally, but will form part of the decision letter.
- 8.3 Minutes of the Panel meetings shall be taken and shall record both the decisions taken and the basis on which these decisions have been reached. The Chair will take minutes of the meeting should administrative support be unavailable.

## **9 EXPERT ADVICE**

- 9.1 The Somerset Clinical Commissioning Group Evidenced Based Interventions Panel will consider whether it requires expert advice on any interventions in question and/or the condition being treated and shall obtain such advice where it considers appropriate. This advice may be in respect of any aspects of the decision including clinical effectiveness, cost effectiveness and exceptionality. It will on occasion request advice from the Somerset Prescribing Forum on the clinical and cost effectiveness of individual pharmaceutical treatments. The Somerset Clinical Commissioning Group Evidenced Based Interventions Panel is not the forum to look at Payment by Results excluded drugs.

## **10 NEW DRUGS OR TECHNOLOGIES**

- 10.1 The Somerset Clinical Commissioning Group does not support the introduction of new drugs or technologies on an ad hoc basis through the funding of individual cases through the Evidence Based Interventions Panel. This risks inequity and may prevent those with equal clinical need from accessing a service.
- 10.2 The Somerset Clinical Commissioning Group would expect the introduction of new drugs or technologies to be considered using the

existing due process of application to local NHS providers drugs and therapeutics committees and the Somerset Prescribing Forum. Under the existing planning framework, after consideration by the appropriate Panels i.e. Somerset Prescribing Forum would consider requests for new drugs where introduction of use would be a service development.

## **11 RE-CONSIDERATION OF APPLICATIONS**

- 11.1 Following a decline of funding outcome an application may be reconsidered by the Panel only where additional information is provided to support the application. The Chair of the Panel will determine if the additional information is additional to the information previously reviewed and considered by the Panel and warrants a re-consideration. Additional information can be put forward by the patients GP/treating consultant or the patient with the support of the patient's clinician

## **12 TERMS OF REFERENCE OF THE Evidenced Based Interventions (EBI) PANEL**

- 12.1 The role of the Evidenced Based Interventions Panel and the makeup of the panel are outlined in ***Appendix 1(c): Terms of Reference of EBI Panel.***

## **13 APPEALS**

- 13.1 The patient shall be entitled to lodge an appeal against the decision of the EBI panel within 28 days of the EBI Panel meeting. The details of the ***Appeals Policy are at Appendix 1(d)***

## **14 REPORTING ON ACTIVITY OF THE EBI PANEL**

- 14.1 The Commissioner will submit a report annually to the Chair of the Evidenced Based Interventions panel which will include:
- Information on the number of applications received and approved
  - The number and type of appeals, and
  - Details of any ad hoc audits

## **15 CO-OPERATION OF NHS PROVIDERS**

- 15.1 The Commissioner requires NHS providers and clinicians to take the commissioning policies into account in the advice and guidance given to patients prior to making the decision to treat a patient, as set out in the NHS Contract.
- 15.2 The Commissioner expects the Management of its NHS providers to have oversight of this process, with accountability resting with the Chief Executive of the provider organisation. The Commissioner would expect every Evidence Based Intervention application to be sanctioned by the NHS provider's management and reserves the right to refer inappropriate

funding requests to the Chief Executive of the relevant NHS provider.

## **16 URGENT APPLICATION DECISIONS**

- 16.1 The Commissioner recognises that there will be occasions when an urgent decision needs to be made to consider approving funding for treatment for an individual patient outside the Commissioner's normal policies. In such circumstances the Commissioner recognises that an urgent decision may have to be made before a panel can be convened. The following provisions apply to such a situation.
- 16.2 An urgent request is one which requires urgent consideration and a decision because the patient faces a substantial risk of significant harm or death if a decision is not made before the next scheduled meeting of the EBI Panel.
- 16.3 Urgency under this policy cannot arise as the result of a failure by the Clinical Team expeditiously to seek funding through the appropriate route and/or where the patient's legitimate expectations have been raised by a commitment being given by the NHS provider to provide a specific treatment to the patient. In such circumstances the Commissioner expects the NHS provider to go ahead with treatment at no cost to the Commissioner.
- 16.4 NHS providers must take all reasonable steps to minimise the need for urgent Requests to be made through the EBI process. If clinicians from any NHS providers are considered by the Commissioner not to be taking all reasonable steps to minimise urgent requests to the EBI process, the Commissioner may refer the matter to the NHS providers Chief Executive.
- 16.5 Where an urgent decision needs to be made to authorise treatment for an individual patient outside the Commissioner's normal policies, and the panel cannot collectively reach a decision in the 5 day timeframe the decision will be made by one of the senior staff delegated to make this decision (the Authorised Officers).
- 16.6 The Authorised officers who have been delegated in the team to make decisions within the team are:
- The Chair of the Evidenced Based Interventions Panel
  - The Deputy Chair of the Evidenced Based Interventions Panel
  - The Director of Quality and Patient Safety
- 16.7 The Authorised Officer shall, as far as possible within the constraints of the urgent situation, follow the policy set out above in making the decision. The Authorised Officer shall consider the nature and severity of the patient's clinical condition and the time period within which the decision needs to be taken. The Authorised Officer shall collect as much information about both the patient's illness and the treatment as is feasible in the time available and shall consider the request for funding in accordance with relevant existing commissioning policies.

The Authorised Officer shall be entitled to reach the view that the decision is not of sufficient urgency or of sufficient importance that a decision needs to be made outside of the usual process.

16.8 The Authorised Officer shall be entitled to reach the view that the request is, properly analysed, and that where a request is for a service development and so should be refused and/or appropriately referred for policy consideration.

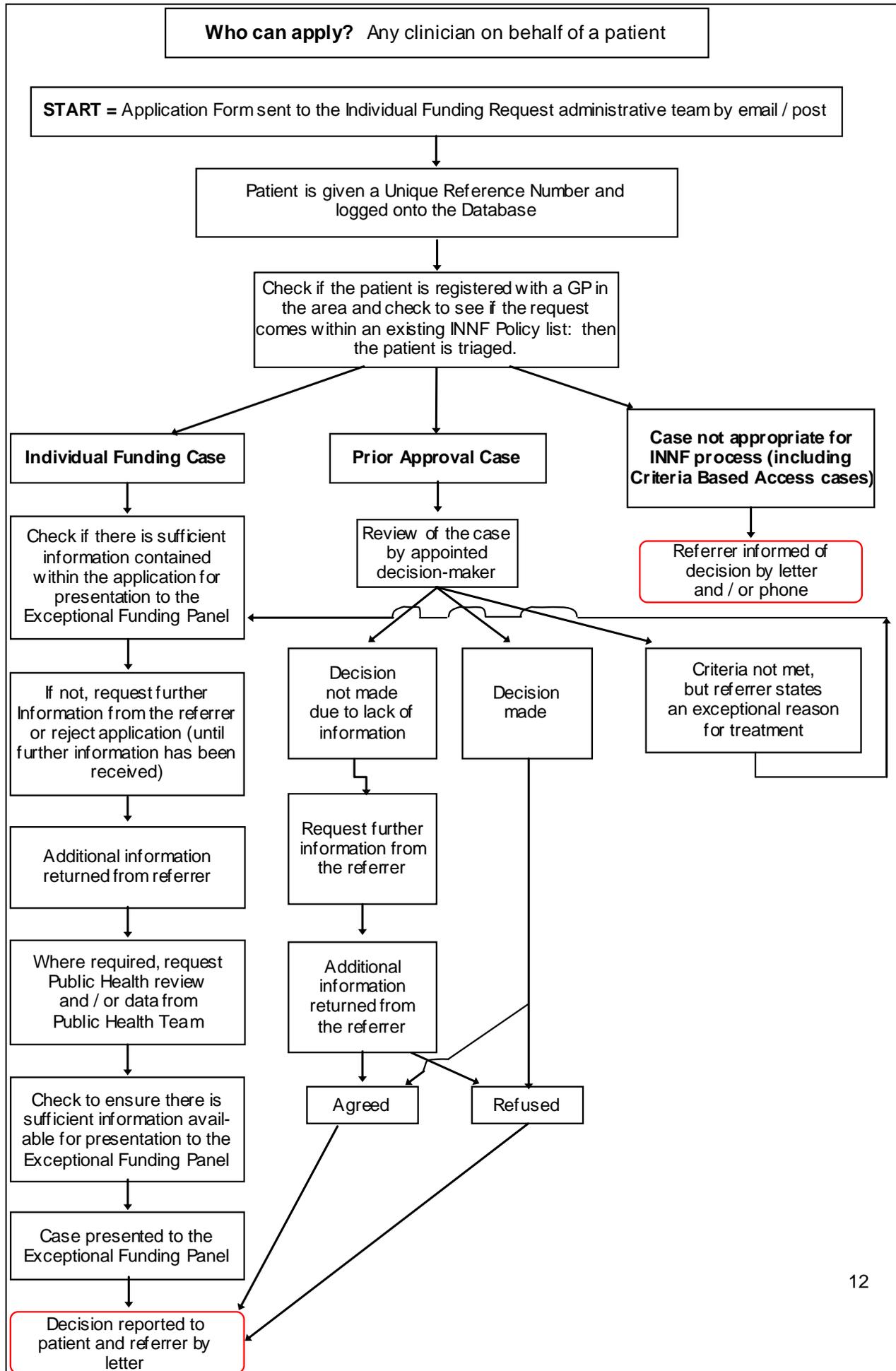
16.9 Where the Authorised Officer considers that there is sufficient time to consult members of the EBI Panel before making an urgent decision, the Authorised Officer shall do so and shall take any views into consideration before making a decision.

16.10 When an 'urgent' decision has been made this will be reported and recorded at the next EBI panel meeting.

## **17 RETROSPECTIVE, PROSPECTIVE AND PART FUNDING**

17.1 The Commissioner does not fund retrospectively or prospectively (where a patient may in future benefit from a treatment that is not currently needed). The Commissioner does not part-fund treatment or fund equipment ordered prior to the panel's approval.

Appendix 1(a)  
**EBI Application Process**



Appendix 1(b)

**GENERIC EVIDENCED BASED INTERVENTIONS (EBI) APPLICATION**

For interventions not funded/commissioned by Somerset CCG or where published criterion is not met  
The completed application form with the supporting evidenced to be emailed to [EBIsomerset@nhs.net](mailto:EBIsomerset@nhs.net)

<b>PATIENT INFORMATION:</b> <i>Failure to complete all sections of this application form could result in a delay whilst the information is being sought from the referrer</i>						
<b>Does this case need to be reviewed urgently due to clinical need?</b> <i>If yes, please explain:</i>		<input type="checkbox"/> YES <input type="checkbox"/> NO	An urgent request is one which requires urgent consideration and a decision because the patient faces a substantial risk of significant harm or death if a decision is not made before the next scheduled <b>monthly</b> meeting of the EBI Panel. What is the window of opportunity and the timescale required for optimum treatment?			
<b>Name</b>			<b>Male</b>	<input type="checkbox"/>	<b>Female</b>	<input type="checkbox"/>
<b>Address</b>			<b>Post Code</b>			
<b>Date of Birth</b>			<b>NHS Number</b>			
I understand that it is a legal requirement for fully informed consent to be obtained from the patient (or a legitimate representative of the patient) prior to disclosure of their personal details for the purpose of a panel/EBI team to decide whether this application will be accepted and treatment funded. By submitting this application form I the referring clinician confirm the patient or patient representative has been informed of the details that will be shared for the aforementioned purpose and consent has been given					<input type="checkbox"/>	
<b>REFERRER'S DETAILS GP/CONSULTANT INFORMATION:</b>						
<b>Name</b>						
<b>Address</b>					<b>Post Code</b>	
<b>Telephone</b>			<b>Email</b>			
<b>GP Details (if not the referrer)</b>						
<b>Name</b>			<b>Practice</b>			
<b>By submitting this form you confirm that the information provided is, to the best of your knowledge, true and complete and you confirm by marking the box(s) that you have:</b>						
<input type="checkbox"/> 1. Referred to the relevant policy prior to completing this EBI application form <input type="checkbox"/> 2. Informed the patient the intervention is only funded where criteria are met or exceptionality demonstrated <input type="checkbox"/> 3. Discussed all alternatives to this intervention with the patient <input type="checkbox"/> 4. Had a conversation with the patient about the most significant benefits and risks of this intervention <input type="checkbox"/> 5. Advised the patient NHS Decision Making Aids are available online should the patient wish to access them at <a href="http://sdm.rightcare.nhs.uk/pda/">http://sdm.rightcare.nhs.uk/pda/</a> <input type="checkbox"/> 6. Discussed with the patient whether any additional communication requirements (e.g. different language, format or limited capacity) are needed (please specify requirements in the box below)						
<b>Clarification/Communication Needs:</b>						
<b>Secondary Care (NHS Providers) to also confirm :</b>						
<input type="checkbox"/> 7. I have informed the patients GP of this application <input type="checkbox"/> 8. <b>I have attached the relevant meeting minutes relating to this application</b> <i>It is essential that appropriate governance systems are in place <b>before</b> an Evidenced Based Intervention Application is made for a new intervention for the <b>requested indication</b>. Providers and Acute Trusts must therefore confirm that this intervention has been considered by their Clinical Effectiveness/ Drugs &amp; Therapeutics Committee (or equivalent) which supports this intervention as appropriate</i>						

**ANY EBI APPLICATION NOT COUNTERSIGNED BY A SENIOR CLINICIAN - A SALARIED PARTNER - LOCUM GP WILL BE REJECTED**

**SIGNED REFERRER:** ..... **DATE:** .....

- GP's to complete Q1–Q6 (& Q15 if appropriate)
- Secondary Care Clinicians (NHS Providers) to complete Q1–Q15

<b>Q1</b>	What intervention are you requesting			
<b>Q2</b>	Expected patient benefit of proposed intervention			
<b>Q3</b> (a)	Brief relevant health history			
(b)	Clinical Need			
<b>Q4</b> (a)	Patient's BMI		Date Recorded by Clinician	
	(b)	Smoking Status		

**Q5 - TREATMENT HISTORY RELEVANT TO THIS CASE - What treatment has the patient tried?**

Date	Intervention	Reason for stopping/Response achieved

**Q6 - EXCEPTIONALITY OF THIS PATIENT** This is the most **IMPORTANT PART** of the EBI application It is crucial that you answer this question comprehensively; Otherwise the panel will be prevented from considering this application fairly

**Exceptionality:**  
 What are the clinical factors over and above those set out which need to be considered and would set this patient out as exceptional?  
 'On what grounds can the CCG's justify funding a particular patient over and above others from the same patient group who are not being funded?'

The fact a treatment is likely to be efficacious for a patient is not, in itself, a basis for exceptionality.  
**In making a case for exceptional consideration, it needs to be demonstrated:**

- the patient is significantly different to the general population of patients with the condition in question
- the patient is likely to gain significantly more benefit than might be normally expected for patients with the same condition

Include relevant clinical information from primary/secondary care and appropriate photograph(s)

<b>Q7</b>	What is the standard care pathway for patient's with this condition		
<b>Q8</b>	Are there alternative interventions/devices available	<input type="checkbox"/> <b>YES</b> <input type="checkbox"/> <b>NO</b>	<i>Describe:</i>
<b>Q9</b>	If yes is the alternative intervention/device commissioned	<input type="checkbox"/> <b>YES</b> <input type="checkbox"/> <b>NO</b>	<i>Why is this alternative not appropriate?</i>
<b>Q10</b>	Please provide details And/or duration of proposed intervention		
<b>Q11</b>	Please provide costs of intervention/device if known, including administration of intervention/device		
<b>Q12</b>	If available the NNT (number needed to treat) for example if the NNT is 20 then 20 patients will need to be treated before one patient will benefit		
<b>Q13</b>	<p>What will be the impact of refusal on the patient</p> <p>How will this be managed if funding is refused</p>		
<b>Q 14 - COHORT</b>			

(a) How many patients with this condition would you expect to see per annum in a population of one million		
(b) Would this cohort of patients all benefit from this intervention/device  <i>Provide details:</i>	<input type="checkbox"/> YES <input type="checkbox"/> NO	
(a) How severe is your patient's condition in relation to this cohort		

#### Q15 - EVIDENCE OF EFFICACY & COST EFFECTIVENESS

<p>Evidence of efficacy, safety &amp; cost effectiveness of the intervention/device:</p> <p>(e.g. NICE/Scottish Medicines Consortium/ASW Cancer Forum/All Wales Medicines Strategy/London New Drugs/ journals/publications) (attach additional sheet(s) if necessary) please attached PDF versions of articles if available</p>	<p><i>Please list below and attach full journal articles or NICE guidance;</i></p>
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- Somerset CCG published Policies be can accessed the SCCG website:  
<http://www.somersetccg.nhs.uk/about-us/how-we-do-things/individual-funding-requests/>
- Upon receipt of a completed and signed application form with all the supporting evidence attached Somerset CCG EBI Team aims to review within 6 weeks of receipt
- If you have any queries please contact the EBI Administrator on 01935 384001
- The completed application form with supporting information should be emailed to  
[ebisomerset@nhs.net](mailto:ebisomerset@nhs.net)

**Evidenced Based Interventions Panel Terms of Reference**

<b>Section</b>		<b>Page</b>
	Version Control	1
	Document Change History	1
1	Objective/Purpose	2
2	Accountability	2
3	Membership of the Panel	2
4	Quoracy and Frequency of Meetings	2/3
5	Urgent Application Decisions	3/4
6	Responsibilities	4/5
7	Guiding Principles	5
<b>VERSION CONTROL</b>		
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V2d	May 2014	Review by the IFRP
V2e	April 2016	Review by the IFRP
V2f	September 2017	Review by the IFRP
V2g	November 2017	CEC approved name change to Evidenced Based Interventions Panel (EBI), CCG house styled, inclusion of Head of EBI

**1 OBJECTIVE/PURPOSE**

- 1.1 The Evidence Based Interventions Panel is a permanent sub-group of the Clinical Commissioning Group Boards. They have been created in recognition that consideration may need to be given to individual cases when treatment is not routinely funded by the NHS locally.
- 1.2 Collectively these treatments are known as Interventions that are Not

Normally Funded (INNF).

- 1.3 The Panels support the process which has been established to ensure that applications to the Commissioner for funding of INNF are considered by a fair and consistent method that is open to scrutiny.

## **2 ACCOUNTABILITY**

- 2.1 The Panels are accountable through the Chair of the Evidence Based Interventions Panel to the Board of the Clinical Commissioning Groups.

## **3 MEMBERSHIP OF THE PANEL**

- 3.1 The Panel (all voting) will consist of:
- Two general practitioners, one of whom will be the Chair
  - A consultant in Public Health
  - A Medicines Management representative
  - Director of Finance and Acute Commissioning/ nominated representative
  - Lay representative from the Governing Body/delegated representative
  - Head of Evidence Based Interventions
  - Director of Quality and Safety/nominated representative
  - When appropriate an expert in a specialist area
  - Administrative Support (non-voting)
- 3.2 One of the GPs will normally chair the meetings and will have a nominated deputy if unavailable. The panel retains the right to seek specialist advice where appropriate.
- 3.3 Patients and their representatives are not invited to attend these meetings, but are able to present their case by providing a letter, photographs or other supporting information.

## **4 QUORACY AND FREQUENCY OF MEETINGS**

- 4.1 For a Panel meeting to be quorate, a GP and at least three other members would need to be present.
- 4.2 The Panel will meet regularly, normally once per month, but at least every 2 months. These meetings will be arranged in advance at the beginning of each calendar year.
- 4.3 The Chair and the Evidence Based Interventions Deputy will draw up the Agenda. Agendas and papers will be circulated at least 3 working days in advance of each meeting.
- 4.4 Minutes of the Panel meetings shall be taken and shall record both the decisions taken and the basis on which these decisions have been reached. The Chair will take minutes of the meeting should administrative

support be unavailable.

## **5 URGENT APPLICATION DECISIONS**

- 5.1 The Commissioner recognises that there will be occasions when an urgent decision needs to be made to consider approving funding for treatment for an individual patient outside the Commissioner's normal policies. In such circumstances the Commissioner recognises that an urgent decision may have to be made before a panel can be convened. The following provisions apply to such a situation.
- 5.2 An urgent request is one which requires urgent consideration and a decision because the patient faces a substantial risk of significant harm or death if a decision is not made before the next scheduled meeting of the EBI Panel.
- 5.3 Urgency under this policy cannot arise as the result of a failure by the Clinical Team expeditiously to seek funding through the appropriate route and/or where the patient's legitimate expectations have been raised by a commitment being given by the NHS provider to provide a specific treatment to the patient. In such circumstances the Commissioner expects the NHS provider to go ahead with treatment at no cost to the Commissioner.
- 5.4 NHS providers must take all reasonable steps to minimise the need for urgent requests to be made through the EBI process. If clinicians from any NHS provider are considered by the Commissioner not to be taking all reasonable steps to minimise urgent requests to the EBI process, the Commissioner may refer the matter to the NHS provider Chief Executive.
- 5.6 Where an urgent decision needs to be made to authorise treatment for an individual patient outside the Commissioner's normal policies, and the panel cannot collectively reach a decision in the 5 day timeframe the decision will be made by one of the senior staff delegated to make this decision (the Authorised Officers).
- 5.7 The Authorised officers who have been delegated in the team to make decisions within the team are:
- The Chair of the Evidence Based Interventions Panel
  - The Deputy Chair of the Evidence Based Interventions Panel
  - The Director of Quality and Safety
  - Head of Evidence Based Interventions
- 5.8 The Authorised Officer shall, as far as possible within the constraints of the urgent situation, follow the policy set out above in making the decision. The Authorised Officer shall consider the nature and severity of the patient's clinical condition and the time period within which the decision needs to be taken. The Authorised Officer shall collect as much information about both the patient's illness and the treatment as is feasible in the time available and shall consider the request for funding in

accordance with relevant existing commissioning policies.

- 5.9 The Authorised Officer shall be entitled to reach the view that the decision is not of sufficient urgency or of sufficient importance that a decision needs to be made outside of the usual process.
- 5.10 The Authorised Officer shall be entitled to reach the view that the request is, properly analysed, and that where a request is for a service development and so should be refused and/or appropriately referred for policy consideration.
- 5.11 Where the Authorised Officer considers that there is sufficient time to consult members of the EBI Panel before making an urgent decision, the Authorised Officer shall do so and shall take any views into consideration before making a decision.
- 5.12 When an 'urgent' decision has been made this will be reported and recorded at the next Evidence Based Interventions panel meeting.

## **6 RESPONSIBILITIES**

- 6.1 To consider and determine clinically-supported applications for Evidence Based Interventions funding based on evidence of exceptionality, in line with the Commissioner's Evidence Based Interventions Policy.
- 6.2 To ensure a consistent and equitable approach to Evidence Based Interventions requests.
- 6.3 To build up an overall understanding of cases that are being considered and that may collectively represent a potential need for policy updates to be made, e.g. potential changes to access criteria, areas of potential need that may need to be considered as new service developments in the annual Prioritisation of Resources Process.
- 6.4 To attend Evidence Based Interventions Appeal Panels to provide details of the basis of decisions made, on behalf of the panel (usually undertaken by the public health or commissioning representatives)

## **7 GUIDING PRINCIPLES**

- 7.1 All members must commit to regular attendance of the Panel, as continuity and balance of input to decision making is important. Suitably briefed nominated deputies should be identified where possible to ensure that the group is always quorate. Any substitutions need to be agreed by the panel as appropriate.
- 7.2 All Panel Members should declare any conflicts of interest, in line with appropriate CCG Policies. Any panel member with a conflict of interest will not be involved in the decision making in this case.

- 7.3 As a general rule, individual cases should be considered by the panel within six weeks of receiving full supporting evidence.
- 7.4 Meetings should encourage open, honest, and challenging debate. Decisions should be reached by consensus where possible. Where there is a difference of opinion, a majority decision will be made and this will be recorded in the minutes. In circumstances where there is no majority, the Chair shall have one additional casting vote.

Appendix 1(d)

**POLICY FOR APPEALS AGAINST DECISIONS  
TAKEN UNDER THE EVIDENCE BASED INTERVENTIONS POLICY**

<b>Section</b>		<b>Page</b>
	Version Control	2
	Document Change History	2
1	Purpose	2
2	Background	2
3	Terms of Reference for the Appeal Panel	2/3
4	Authority	3
5	Membership	3
6	Independence	3
7	Access to External Advice	4
8	Quoracy	4
9	Frequency of Meetings	4
10	Appeal Process	4
11	Disclosure of Information	5
12	Arrangements for the hearing	5/6
13	General Communication	6
14	Confidentiality	6
15	Reporting Procedures	6
16	Media	6
17	Right of Redress	6
Appendix 1	The EBI Appeals Process Chart	7

<b>VERSION CONTROL</b>	
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<b>DOCUMENT CHANGE HISTORY</b>		
<b>Version</b>	<b>Date</b>	<b>Comments</b>
V2d	March 2014	CEC approved name change to Evidenced Based Interventions Panel (EBI), CCG house styled

## **1 PURPOSE**

To set out the process by which appeals against EBI Panel decisions made by the Commissioner are considered.

## **2 BACKGROUND**

- 2.1 The Commissioner has an agreed policy by which individual patient funding decisions are made for treatments falling outside of locally or nationally agreed commissioning policies. Such requests are considered by the Evidence Based Interventions Panel (EBIP).
- 2.2 Provided that the Commissioner is satisfied that the referring practitioner and the relevant specialist have provided adequate information on all the issues identified in the policy, it will consider individual requests for care that is not normally funded through its Evidence Based Interventions Panel.
- 2.3 Where the Commissioner, through the EBIP, has decided not to fund a particular procedure or treatment for an individual, it is open to the individual and/or their referring practitioner to request an appeal, where grounds for appeal exist.
- 2.4 This document sets out the process for handling appeals.

## **3 TERMS OF REFERENCE FOR THE APPEAL PANEL**

### **PURPOSE**

- 3.1 The purpose of the appeal process is to review decisions made by the EBIP where it might reasonably be argued that the decision was not made in accordance with the EBI Policy. The EBI Appeals Committee may overturn the decision of the EBIP if it can be demonstrated that the EBIP:
  - Failed in a material way to follow its own procedures; and/or
  - Failed in a material way to consider the evidence presented to it

- (e.g. by failing to take account of a material fact; and/or
- Made a decision that no reasonable EBIP could have reached on the evidence before the panel

- 3.2 The EBI Appeal Committee shall have the following options:
- Uphold all or part of the appeal, but consider that funding the intervention is not appropriate
  - Uphold the patient's appeal, and if appropriate authorise funding for the requested intervention
  - Dismiss the appeal, and uphold the decision on the EBI Panel

- 3.3 The Appeal Panel is constituted to review the circumstances surrounding an individual case and is not authorised to review or formulate routine commissioning policy. Individuals who wish to raise concerns about a Commissioning Policy may approach the Patient Advice and Liaison Service (PALS) or formally pursue a complaint through the NHS Complaints process by writing directly to the Commissioner.

#### **4 AUTHORITY**

The appeal panel is the final arbiter of a decision for the Commissioner and acts as a sub-committee of the Clinical Commissioning Group's Board. This does not remove a patient's right to access the NHS complaints procedure and the Ombudsman in order to seek further redress.

#### **5 MEMBERSHIP**

Membership of the panel will comprise of (none of whom will have been Involved in the case previously);

- Chief Officer / Chief Operating Office (or a nominated deputy) in the Chair
- A Lay Member of the Clinical Commissioning Group Board
- A Lead GP from the Governing Body

#### **6 INDEPENDENCE**

The panel should not include any member who took part in the original funding decision. If any member of the panel believes from the information provided, that they may have personal knowledge of the individual they should declare this to the Chair of the appeals panel who will then seek to replace them on the panel.

#### **7 ACCESS TO EXTERNAL ADVICE**

Panel members are not required to have specialist expertise in the clinical area covered by the funding request, but should have the opportunity to commission external expertise if this is relevant. For example, if there is an instrumental dispute of the facts presented the panel should be able to seek the advice of a separate independent 'expert' advisor or panel.

#### **8 QUORACY**

All members of the Panel or suitable nominated deputies must be present.

## **9 FREQUENCY OF MEETINGS**

The Panel will meet as required and will hear appeals within two months of the request being received unless there are mitigating circumstances e.g., restricted availability of an independent expert where this is considered material to the decision making process. In the latter scenarios the appellant will be informed, in writing, of the delay and the reason for the delay and given an estimated timescale for their appeal being heard. In any event the appeal will be heard within a maximum of six months of the request, unless there are extenuating circumstances.

## **10 APPEAL PROCESS**

### **Who may Appeal**

- 10.1 Requests to appeal a decision of the EBIP may be made by the individual's GP or managing consultant and/or by the individual directly (or their responsible parent, guardian or main carer where applicable; in the case of an adult with capacity, their consent will be required).

### **METHOD OF MAKING AN APPEAL**

- 10.2 Communication of a re-consideration decision by the EBIP not to fund a procedure/treatment will include advice to the individual of their right to appeal. The letter will set out clearly the grounds upon which such an appeal will be considered and the process through which an appeal should be lodged.
- 10.3 Appeals should be made in writing to the Commissioner, clearly stating the grounds for the appeal and should be made within 28 days of the original decision of the EBIP.
- 10.4 On receipt of a request for an appeal to be heard, the case will be referred to the Chief Officer / Chief Operating Officer (or nominated deputy) who has not previously been involved in the case and the appellant will be advised within 28 days of receipt of the appeal letter whether an appeal has been granted.

### **GROUNDINGS FOR APPEAL**

- 10.5 The Chief Officer / Chief Operating Officer (or nominated deputy) who has not previously been involved in the case will review all requests for an appeal to determine whether grounds for an appeal exist. In determining whether grounds for appeal are present the process will take into account whether the EBIP;
- Failed in a material way to follow its own procedures; and/or
  - Failed in a material way to consider the evidence presented to it (e.g. by failing to take account of a material fact; and/or
  - Came to a decision that no reasonable EBIP could have reached on the evidence before the panel.
- 10.6 In circumstances where during the appeal process new, relevant information that the Chief Officer / Chief Operating Officer (or nominated deputy) considers may have materially affected the decision of the EBI

panel is presented the case can be re-considered by the EBIP at the request of the Chief Officer / Chief Operating Officer (or nominated deputy) considering the appeal, or an appeal panel can be established to consider the new information. If the new information in the opinion of the Chief Officer / Chief Operating Officer (or nominated deputy) would not have affected the decision of the panel and no grounds for an appeal are identified the appeal will be rejected.

## **11 DISCLOSURE OF INFORMATION**

- 11.1 The patient and /or the referring practitioner will be given access to all information used by the Commissioner to make the decision. This will be provided prior to the appeal hearing
- 11.2 Disclosure of information will only be withheld if disclosure is likely to be of harm to the recipient a result of the disclosure. The decision on whether to withhold information will be made by the Chair of the Appeals Panel. Information may be given to the panel orally where a written account may be considered inappropriate.

## **12 ARRANGEMENTS FOR THE HEARING**

- 12.1 Patients are given the opportunity to make representations to the Appeal Panel either in person or in writing. Attendance at panel is at the discretion of the individual. Patients are welcome to use advocacy services to assist in the presentation of their case, if they wish though this excludes legal representatives acting in their professional capacity.
- 12.2 A member of the original EBIP may be invited to attend the Panel hearing to outline to the Panel and Appellant what information was considered and to clarify the decision reached. The EBIP representative will be then asked to leave the Panel meeting, and will not be included in the decision making process, which will be undertaken by Appeal Panel members only.
- 12.3 After hearing all relevant presentations and having considered all relevant information made available to the panel, the Panel will retire in private to make their decision in accordance with their terms of reference.
- 14.4 A decision will be made by a majority vote of the Appeals Panel. If there is a tied vote, the Chair will have a further casting vote.
- 12.5 The Appeals Panel will inform the patient, their GP and/or any relevant Consultant (in writing) of the decision of the appeal panel within 7 working days of the appeal being heard.

## **13 GENERAL - COMMUNICATION**

The commissioner is committed to robust and effective communication. All decisions will be communicated in writing to the appellant.

## **14 CONFIDENTIALITY**

- 14.1 Information will only be shared amongst the panel members, invited experts and the commissioning team involved in preparation of panel materials.
- 14.2 All information presented to either the Evidence Based Interventions Panel or Appeal Panel will be presented in such a way as to ensure confidentiality.

## **15 REPORTING PROCEDURES**

- 15.1 Decisions of the Evidence Based Interventions Panel and Appeal Panel will be presented to the Board via an annual report.
- 15.2 All information presented to either the Board from the EBIP or Appeal Panel will be presented in such a way as to ensure confidentiality.

## **16 MEDIA**

Media contact will be handled within the Commissioners communications policy.

## **17 RIGHT OF REDRESS**

The Appeal Panel is the final arbiter of a decision for the Commissioner. Any further redress requested by the appellant would be through the NHS Complaints process and or the Parliamentary Health Service Ombudsman

**Appendix 1 (e): The EBI Appeals Process**  
 (following EBIP consideration and/or reconsideration)

