NHS South East Essex
and NHS South West Essex

# INDIVIDUAL FUNDING REQUESTS POLICY

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| **Version:** | 001 |
| **Ratified by:** | Exercise of Emergency Powers<br>PCT Chair and Chief Executive |
| **Date Ratified:** | December 2011 |
| **Name of originator/author** | Andrew Stride, Head of Governance, Risk & Customer Services |
| **Date Issued:** | 1st December 2011 |
| **Review Date:** | 1st June 2012 |
| **Target Audience:** | PCT staff, patients and the public, primary and secondary care providers |

## Contents

## 1. Introduction

This document is the policy of NHS South East Essex & NHS South West Essex (hereafter referred to as "the PCT Cluster") for managing individual funding requests (IFRs) in a manner which complies with the Directions to Primary Care Trusts and NHS Trusts concerning decisions about drugs and other treatments 2009, the NHS Constitution for England (2009), the National Health Service (Reimbursement of the Cost of EEA Treatment) Regulations 2010 and associated guidance on good practice (see Appendix A)

## 2. Purpose

This policy ensures that the PCT Cluster makes decisions on IFRs in a fair, reasonable, transparent and consistent manner in accordance with principles of governance and probity, having regard to the need for PCTs to strike the correct balance between commissioning services that meet the needs of the majority of the population and accommodating the differing needs of individual patients.

The policy makes an explicit link between the IFR process and the PCT's mechanisms for commissioning decisions. Information gained from the IFR process will be used to inform commissioners of potential gaps in commissioned services or unintended consequences of commissioning policies.

## 3. Definitions

### Individual Funding Request

An IFR is a request to a PCT to fund healthcare for an individual who falls outside the range of services and treatments that the PCT has agreed to commission (NHS Confederation 2008).

### Exceptionality

This policy adopts the generally accepted definition of Dr Henrietta Ewart of Warwickshire PCT which is also recommended by the NHS Confederation and Department of Health.

This states that in making a case for special consideration, it needs to be demonstrated that :

- The patient is significantly different to the general population of patients with the condition in question; and
- As a result of that difference, the patient is likely to gain significantly more benefit from the intervention than might be normally expected for patients with that condition.

However this is a threshold and the IFR Panel will still consider clinical and cost effectiveness of treatments requested.

## 4. Roles and Responsibilities

### Individual Funding Requests Service

The IFR Service, provided by the Head of Governance, Risk & Customer Services & the IFR Administrator, is responsible for receiving and handling all IFRs submitted to the PCT Cluster. The Service is responsible for handling all IFRs in accordance with this policy and will act as the first point of contact for all IFRs received by the PCT.

### Head of Governance, Risk & Customer Services

The Head of Governance, Risk & Customer Services is responsible for managing the IFR Service for the PCT.

### Directors of Public Health and Associate Directors, Community Pharmacy & Medicines Management

These senior postholders (or their nominated deputies) are responsible for providing clinical advice to the IFR Service during the screening process.

### Chief Operating Officers

The Chief Operating Officers (COOs) of the PCT's arms length organisations (East of England Specialist Commissioning Group and the Clinical Commissioning Groups) will ensure that this policy is implemented within their organisations.

### All Employees

All members of PCT staff have a responsibility to appraise themselves of the correct action to take in the event that they receive an IFR or wish to make such a request on behalf of a patient / client.

### IFR Panel

The IFR Panel is responsible for considering IFRs which have been assessed through the PCT's screening process as falling outside approved policy and where no precedent can be established as a basis for approving funding.

The IFR Panel does not make policy decisions for the PCT. Potential service gaps and commissioning issues that may arise through the work of the Panel will be raised with the Commissioning Directorate Senior Management Team as they arise.

## 5. Policy Procedural Requirements

### 5.1. When do IFRs arise ?

Generally IFRs fall into one of three categories :

- The PCT may not have been aware of the need for this service and so has not incorporated it into the service specification (this can be true for common and uncommon conditions)

- The PCT (or the East of England Specialist Commissioning Group on the PCT's behalf) may have decided to fund the intervention for a limited group of patients by setting eligibility criteria that exclude the person making the request

- The PCT may have decided not to provide a particular treatment because it does not provide sufficient clinical benefit and/or does not provide value for money (see Appendix A)

### 5.2. Who can make an IFR ?

IFRs can originate from a variety of sources. Most will be submitted by clinicians such as GPs and Hospital Consultants although overseas treatment requests are most likely to be submitted by patients directly wishing to exercise their rights under European Law.

Any IFRs received directly from patients will require support from a clinician involved in the patient's treatment before they can be considered.

### 5.3. Receiving IFRs

All IFRs will be submitted to the IFR Service where they will be logged and appropriate action co-ordinated.

Providers will be encouraged to submit all IFRs in writing to the IFR Administrator at Phoenix Place, by safe haven fax to (01268) 705005 or by email to fundingrequests.south@nhs.net.

### 5.4. Screening Process

Upon receipt, all IFRs will undergo a screening process by the IFR Service. This screening will determine the most appropriate means of progressing the request with the aim of expediting access to the most clinically appropriate treatment for the individual and minimising unnecessary bureaucratic and process-based delays.

Appendix B summarises the screening process to be followed.

### 5.5. Consent

The provision of information is central to the consent process. Before patients can reach a decision about treatment, they need comprehensive information about their condition and possible treatments.

Where an IFR is received directly from a patient, no approach will be made to the GP or other health and social care professionals without first obtaining the written consent of the patient to do so.

The IFR Service will ensure that consent is obtained as appropriate to each individual case and will follow the PCT's Consent Policy in this regard.

## 6. Monitoring Compliance

This Policy will be reviewed by the Head of Governance, Risk & Customer Services every six months in the first instance and then every two years thereafter.

If only minor revisions are made then the policy can be approved by the Integrated Governance Committee and the version number for the policy will be updated by ".1" e.g. from version 1.0 to 1.1.

If significant amendments need to be made then the policy will need to be approved by the PCT Board. In this case the version number would increase to the next whole number e.g. from version 1.1 to 2.

Responsibility for the operational monitoring of this policy will rest with the Head of Governance, Risk & Customer Services.

The operational performance of the IFR Service will be monitored on an ongoing basis through the Customer Services Performance Framework which will include quality assurance questionnaires to applicants submitting IFRs and regular audits. Six monthly reports on performance against this framework will be received regularly by the Integrated Governance Committee.

The Director who has overall responsibility for monitoring this policy is the Director of Finance & Performance.

## 7. Associated Documentation

NHS South East Essex Care & Resource Utilisation Policies
NHS South West Essex Service Restriction Policy

## 8. List of Stakeholders Consulted

| Date Sent | Name of individual Or Group | Designation | Were comments received, considered and incorporated<br><br>Yes/No |
|---|---|---|---|
| 10/10/11 | Meeting of members of previous SWE and SEE panels, attendance as below: | | **Yes** |
| | Beryl Furr | NED and SEE IFR Panel Chair | |
| | Barbara Hallows | SWE IFR Panel Lay Chair | |
| | Jane Foster-Taylor | Nurse Representative – SEE Panel | |
| | Nikki Livermore | Commissioning Representative – SEE Panel | |
| | Tom Abell | Director of Commissioning | |
| | Dawn Scrafield | Director of Finance & Performance | |
| | Lorraine Lockwood | Commissioning Representative – SWE Panel | |
| | Dr Nick Tressider | Assistant Medical Director | |
| | Bill Sandhu | Associate Director, Medicines Management | |
| | Simon Williams | Associate Director, Medicines Management | |
| | Buddug Jones-Bennett | Commissioning Representative – SWE Panel | |
| | Viv Barnes | Associate Director, Corporate Services & Communications | |
| | Andrew Stride | Head of Governance, Risk & Customer Services | |
| | Kaye Lawson | IFR Administrator | |
| | Dr Danny Showell | Consultant in Public Health Medicine – SEE Panel | |
| | Dr Andrea Atherton | Director of Public Health (South East) | |

## 9. Equality Impact Assessment

The PCT Cluster is committed to carrying out a systematic review of all its existing and proposed policies to determine whether there are any equality implications.

This policy has been assessed using the PCT Cluster's Equality Impact Assessment framework and identified as having the following impact/s upon equality and diversity issues:

| Age | Disability | Gender & Pregnancy | Race | Sexuality | Religion | Marital Status | Human Rights | Total Points | Impact |
|---|---|---|---|---|---|---|---|---|---|
| 0 | 0 | 0 | 0 | 0 | 0 | 0 | 2 | 2 | Medium |

The IFR Policy has a medium relevance to Human Rights given that the policy, by definition, sets out how decisions around eligibility for NHS funded treatment will be made. There is a Human Right to Life which could be impacted upon by decisions to withhold life-prolonging drugs or fertility treatment.

| 10 | VERSION CONTROL | | | |
|---|---|---|---|---|
| | **Version** | **Author: Name & Title** | **Date Policy Issued** | **Date Policy Due to be Reviewed** |
| | **1.0.** | **Andrew Stride, Head of Governance, Risk & Customer Services** | **1st December 2011** | **1st June 2012** |
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## Appendices

A – National and local policy drivers relevant to IFRs
Bi & ii– Screening process for all IFRs
Ci & ii– Special Case Review Process and Terms of Reference for Special Care Review Panel
D – Process for handling requests from patients for treatment in countries of the European Economic Area

## Strategic Drivers for the Development of a Policy on Individual Funding Requests

### *Overview*

Individual Funding Requests (IFRs) have been subject to significant national interest from the Department of Health and the media in recent years as the result of a perception of a "postcode lottery" when individual PCTs make funding decisions based upon local priorities that may be different from those made by neighbouring PCTs. Individual funding decisions are particularly emotive and controversial when they involve treatment for patients with life-threatening conditions such as cancer.

All PCTs are now required to have an IFR Policy. The outcome should be to produce a process which is fair and transparent to individual patients in the context of the right of individual PCTs to set local priorities for use of resources.

The main strategic drivers behind the IFR Policy are set out below:

### Improving access to medicines for NHS patients: a report for the Secretary of State for Health' By Professor Mike Richards (Richards Review – DH, November 2008)[1]

The report set out 12 recommendations which were all accepted by the Secretary of State on 4th November 2008.

The report stated that "Clinicians should exhaust all reasonable avenues for securing NHS funding before a patient considers whether to purchase additional drugs. Patients should be able to receive additional private drugs as long as these are delivered separately from the NHS elements of their care".

The onus is upon acute providers to ensure they have the mechanisms in place to deliver this separation.

It is also recognised that an IFR policy should provide a clear structure on how to deal with the difficulties faced by PCTs in instances where drugs are not routinely available on the basis that they have not yet been approved by the National Institute for Clinical Excellence (NICE), or where NICE has assessed them as not being clinically cost-effective for NHS use.

There is also a recommendation that there should be increased communication and collaborative working between PCTs in terms of the development of evidence-based policies on the commissioning of new drugs and the grounds for making special case decisions where funding is approved outside these policies. There is an aim to promote consistency in decision-making and avoid the perception of a 'postcode lottery' in the NHS.

The Richards Review also recognises that there is a role for PCTs in determining local funding policies, even when NICE has approved a drug and for considering special cases against these local polices.

**The Handbook to the NHS Constitution for England[1] (DH, January 2009)**

The NHS Constitution states that patients have a right to drugs and treatments that have been recommended by NICE for use in the NHS, if clinically appropriate for the patient.

Both NICE and the Constitution highlight this as a key issue. It is therefore a necessary requirement to outline a clear and comprehensive policy by which patients' IFRs are managed in a fair, transparent and robust manner.

The NHS Constitution also gives patients the right under certain circumstances to obtain treatment in EEA countries at the expense of the NHS (see April 2010 regulations below).

**Priority Setting: Managing Individual Funding Requests (NHS Confederation, 2008)[2]**

This document highlighted a requirement to have a protocol and policy-based decision making framework for IFRs that is robust. The key areas that should be included are that of a logging and tracking system, a screening system and leaflets appropriate for patients as well as one for clinicians on the definition of exceptionality adopted by the PCT.

The NHS Confederation recognised that the consideration of personal and social factors as part of the IFR decision-making process can be justifiably included or excluded. The law relating to priority setting is not at all clear about the factors that PCTs should use and what they can rule out. Case law presents an inconsistent picture as to the acceptability of personal and social factors. Greater certainty will only be reached over time as more cases are considered through the courts.

It is evident, however, that IFR policies must clarify whether personal and social factors will be taken into account by the PCT in question. IFR decisions will then be open to challenge through the courts in the event that the approved PCT policy is not followed, irrespective of whether said policy includes or excludes personal and social factors.

It was recommended that PCTs must have a definition which will clearly identify what is meant by exceptionality as well as providing a consistent approach across England. The NHS Confederation recommended Dr Henrietta Ewart's definition.

[1] http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_093421

[2] http://www.nhsconfed.org/Publications/prioritysetting/Pages/Prioritysettingfunding.aspx

**Directions to primary care trusts and NHS trusts concerning decisions about drugs and other treatments 2009[3] (DH, January 2009)**

This document goes further than the Confederation guidance to set out additional requirements which this IFR Policy addresses.

It must be evidenced that an IFR policy provides its PCT with arrangements for decision making, as well as adopting a policy on whether particular healthcare interventions are made available.

There is also a requirement that PCTs have a clear and consistent approach founded out of a clearly structured processing arrangement for IFR requests.

The IFR policy must provide a procedure that ensures written records are kept and explanations given to patients and referring clinicians to clearly state the rationale behind each IFR decision if requested.

**East of England Specialist Commissioning Group Policy on Individual Funding Requests (EOESCG, March 2009)**

This document sets out the process for handling IFRs by the East of England Specialist Commissioning Group (EOESCG). The SCG policy centres upon the principle that where a patient falls outside criteria set by SCG, or where a requested treatment or provider is not commissioned by SCG, the IFR decision will be handled by each local PCT's IFR policy.

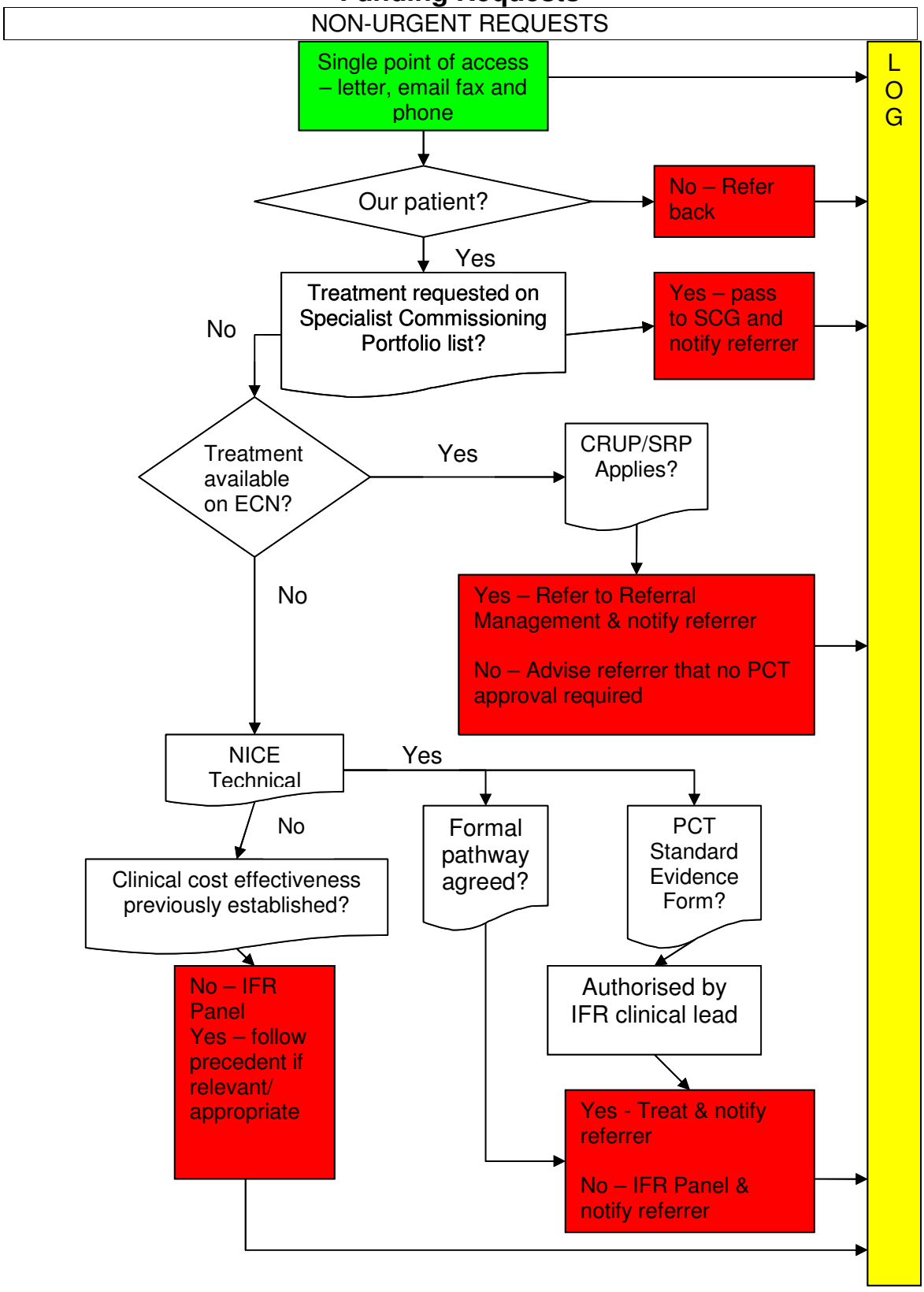
**National Health Service (Reimbursement of the Cost of EEA Treatment) Regulations 2010 (DH, April 2010)[4]**

These regulations set out the obligations of PCTs in England in relation to claims for reimbursement of treatment costs and applications from patients who seek prior authorisation from the PCT for the receipt of healthcare in another EEA state. The regulations also provide guidance on the exercise of these functions by PCTs. A more detailed account of these Regulations can be found in Appendix D.

[3] http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsLegislation/DH_096067

[4] http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_115256

# Funding Requests



## URGENT REQUESTS

Authorised by **any two** of Director of Public Health (or nominated representative), Associate Director Medicines Management, Medical Director or Deputy Medical Director - Treat without prejudice to precedent.

# Appendix Bii

Screening Process

The Screening Process will be conducted by the Head of Governance, Risk & Customer Services and IFR Administrator with input as required from the Director of Public Health and the Associate Director, Community Pharmacy & Medicines Management, or their clinically qualified deputies.

All IFRs will follow the process in Appendix Bi.

- All requests will be reviewed against current formally agreed local policy, past precedent or national policy and guidance.
- The IFR Service can

A) decide if approval can be given based on information received or request further information
B) Decline the request based on current policy or past precedent and on the lack of any indication of exceptionality within the information supplied by the patient and treating clinician

Or, if the request falls outside of any approved policy and no relevant or appropriate past precedent can be established, the IFR will be referred to the IFR Panel.

These decisions are formally recorded (including the rationale and policy basis for the decision) and then communicated to the referring clinician by letter and copied to the patient.

When cases are referred to the IFR Panel, the IFR Service will complete a pro-forma setting out the basis for that decision which will be considered as part of the background evidence presented to the Panel.

The guiding ethos of the IFR Service during the screening process will be to ease the access of the patient to the correct service and to support clinicians by advising on the range of services available under the NHS. This will involve a casework approach liaising with the patient, the PCT commissioning team, the customer services team, specialist commissioning and providers as necessary.

If the IFR Team send a letter of approval to the referring clinician, responsibility for progressing the treatment rests entirely with the clinician concerned.

On an ongoing basis, the IFR Service will monitor trends in the number and nature of IFRs received and will advise the Commissioning Directorate Senior Management Team of any possible contradictions in policies or gaps in commissioned services. This will enable the identification of opportunities for in year service developments and provide evidence for annual commissioning decisions

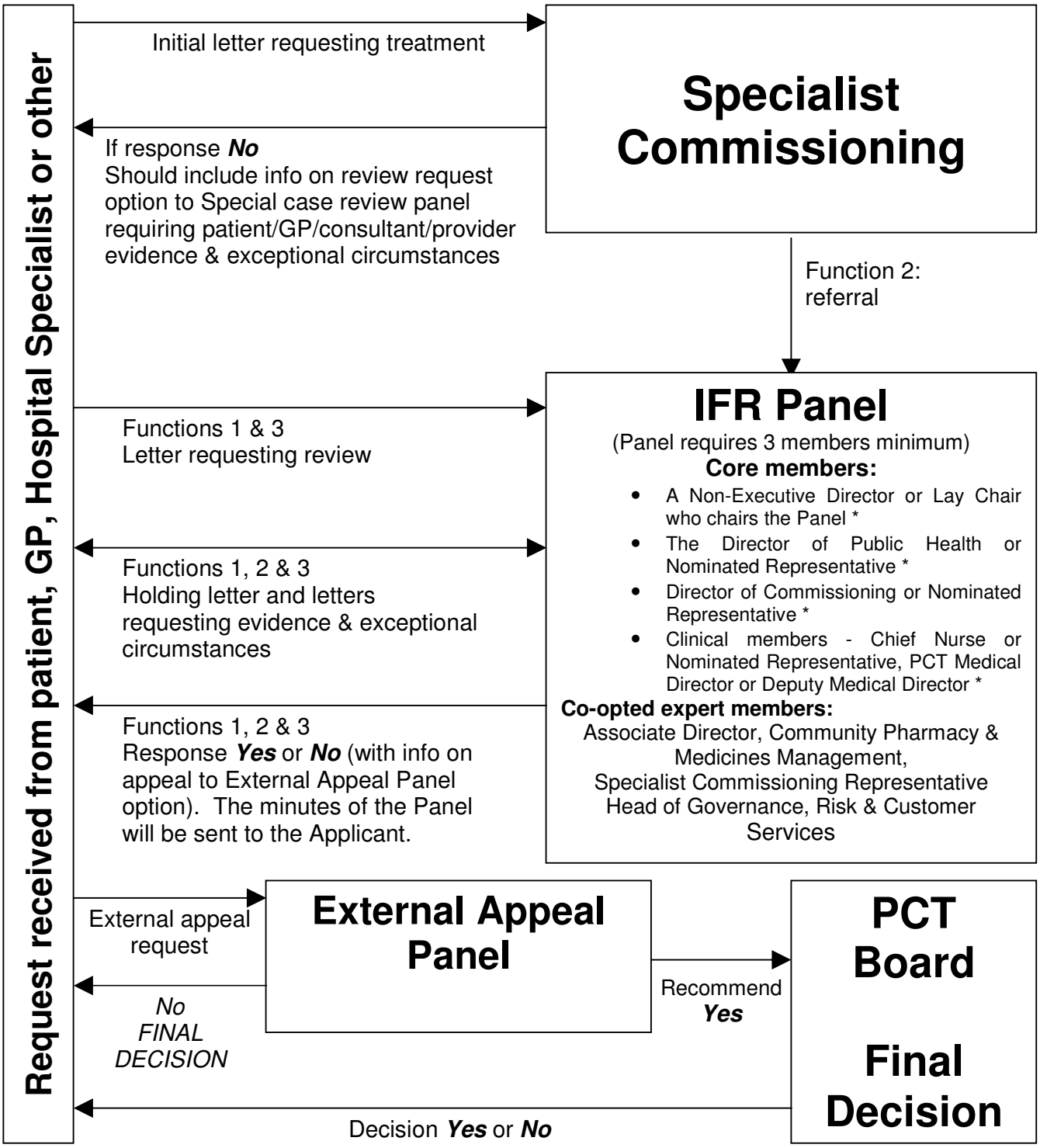
**IFR Panel Process**

**Functions of the Panel:**

Function 1 Review after refusal by Specialist Commissioning or RMC
Function 2 Special advice to Specialist Commissioning
Function 3 Non-standard treatments/providers

**Bases for case consideration:**

A With regard to what might be considered exceptional circumstances
B With reference to previous cases to ensure equity


Request received from patient, GP, Hospital Specialist or other
Initial letter requesting treatment
Specialist Commissioning
If response No
Should include info on review request option to Special case review panel requiring patient/GP/consultant/provider evidence & exceptional circumstances
Function 2: referral
IFR Panel
(Panel requires 3 members minimum)
Core members:
A Non-Executive Director or Lay Chair who chairs the Panel *
The Director of Public Health or Nominated Representative *
Director of Commissioning or Nominated Representative *
Clinical members - Chief Nurse or Nominated Representative, PCT Medical Director or Deputy Medical Director *
Co-opted expert members:
Associate Director, Community Pharmacy & Medicines Management,
Specialist Commissioning Representative
Head of Governance, Risk & Customer Services
Functions 1 & 3
Letter requesting review
Functions 1, 2 & 3
Holding letter and letters requesting evidence & exceptional circumstances
Functions 1, 2 & 3
Response Yes or No (with info on appeal to External Appeal Panel option). The minutes of the Panel will be sent to the Applicant.
External appeal request
External Appeal Panel
No
FINAL DECISION
Recommend Yes
PCT Board
Final Decision
Decision Yes or No

# NHS SOUTH EAST ESSEX & NHS SOUTH WEST ESSEX
# IFR PANEL GUIDELINES

1 Functions of the IFR Panel

The PCT Cluster is required to commission healthcare on behalf of the local population within the resources available. To ensure that resources are used effectively some restrictions exist limiting access to certain procedures considered to be of low priority. In addition individual decisions need to be made about commissioning certain non-standard treatments and this is the function of this panel.

**The IFR Panel exists to ensure decisions are made about commissioning treatments that are:**

- Based on the best available clinical evidence

and to:

- Consider as much as is reasonable of the available evidence
- Consider the views of the patient and the referring clinician, including inviting patients to give evidence in person to the panel if they wish
- Make best use of the resources available for healthcare within the PCT Cluster area

The panel in all its functions should ensure that it considers cases on the following bases:

A With regard to what might be considered exceptional and extenuating circumstances

B With reference to previous decisions made by the Panel to ensure equity.

## FUNCTION 1 - Review

The IFR Panel offers a review process open to patients and referring clinicians if a refusal to treat decision is made by the SCG or by the PCT's Referral Management Centre (RMC). The SCG and RMC base their decisions to treat on the criteria and policies determined by the SCG Board and the PCT's Service Restriction Policy/Care & Resource Utilisation Policies (CRUP) respectively . In these circumstances the IFR Panel would normally deal directly with the referring clinician or patient. In any event, the panel would not consider a request without written support of a clinician.

An individual who believes that a restriction policy has not been correctly applied or that their case is exceptional may ask for a review by the panel, but this will only be granted if the information supplied by the patient and clinician contains any indication that exceptionality may exist. That exceptionality will then be tested at panel.

In these instances, the panel will assess the individual case against the definition of exceptionality referred to in Section 4 of this policy.

If a patient and/or his or her treating clinician remains dissatisfied they may appeal to the External Review Panel

*Sources of referral: patient, GP, service provider, SCG.*

## FUNCTION 2 – Special advice

The IFR PANEL offers decision making support to the Specialist Commissioning Team in circumstances where there is ambiguity surrounding a request for treatment that is covered by the Restrictions to Treatment Policy. The Specialist Commissioning Team would liaise with the referring clinician and patient. If the patient is refused after this review, they will then be offered the opportunity to appeal to an External Appeal Panel.

Sources of referral: Specialist Commissioning

## FUNCTION 3 – Non-standard treatments/providers

The IFR Panel considers requests for treatment not normally provided in the mainstream NHS.

In addition patients and their treating doctor may request NHS treatment from a provider with whom the PCT Cluster does not have an SLA.

When considering cases of this nature, the Public Health Department with support from the IFR Service will conduct a literature review to establish the evidence-base for the treatment and come to a recommendation to the panel based upon evidence of clinical cost-effectiveness.

If the treatment is declined by the IFR Panel, patients will be offered the opportunity to appeal to an External Appeal Panel.

The IFR Panel will consider requests from the public to go to certain other European countries for treatment which in the UK is provided in hospitals, in line with the National Health Service (Reimbursement of the Cost of EEA Treatment) Regulations 2010 and associated guidance :

http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_115256

Sources of referral: Patients, GP, their treating clinician

**Target Timescales**

The PCT Cluster will aim to achieve a case completion time of **two months** from receipt of the initial request/application through to communication of a decision following a Panel Hearing (where such a hearing is appropriate).

It is recognised that the organisation's response time is highly dependent upon the receipt of information and evidence from other parties, such as the patient, his or her GP and Hospital clinicians.

For this reason, the PCT Cluster will aim to comply with this timescale in **80%** of cases. In cases where the two month target is exceeded due to lack of crucial evidence, a Panel will be convened within one month of all the necessary evidence being received.

For urgent / fast track cases, the target for a decision to be made and communicated to the provider or patient as appropriate is **five working days** from receipt of the request. However as with regular panels, this is highly dependent on the provision of information and evidence from providers.

Particular attention will be paid to the requirement within the 2010 Overseas Treatment Directions to reach a decision on these cases within 20 working days of receipt. This will still be contingent upon sufficient clinical information being received to enable a proper consideration of the request, but the fast-track / virtual panel provisions set out below may be used to comply with the 20 working day timescale in the Directions.

**Fast-Track Process**

Some cases will require consideration on a shorter timescale than that detailed above. For example, where a patient has limited life expectancy or a treatment is required in circumstances of urgent clinical need. These will often be requests directly from providers for the funding of high-cost drugs for conditions such as cancer.

The Head of Governance, Risk & Customer Services is responsible for screening applications received through the IFR process. If in his or her opinion a case requires an urgent decision, this postholder is able to fast-track that case ahead of others and convene a panel at short notice if required.

In these circumstances, it may not be practical or in the interests of the patient to follow the normal process for panel hearings such as inviting patients to the hearing.

In these instances, the IFR Service will liaise directly with the supporting clinician (e.g., hospital oncologist) to obtain details of any exceptional circumstances which may apply.

Fast-track panels will also have different quoracy arrangements to facilitate convening hearings at short notice.

Patients (or supporting clinicians on their behalf) will have full access to the External Review Process as with non fast-track cases.

## 2 Structure & membership of the Panel

The panel consists of:

- A Non-Executive Director or Lay Chair who chairs the Panel *
- The Director of Public Health or Nominated Representative *
- Director of Commissioning or Nominated Representative *
- Clinical members - Chief Nurse or Nominated Representative, PCT Medical Director or Deputy Medical Director *

In order for regular panels to be quorate, each of the asterisked members must be present. For clarity, the quorum requires **any one** of the postholders in the fourth bullet point, i.e., a panel will be quorate if either the Chief Nurse or representative or the Medical or Deputy Medical Director to be in attendance.

The Chair may co-opt pharmacy, specialist commissioning, primary care and governance support if required.

Panels that are convened to consider cases defined as urgent / fast track have a reduced quorum to facilitate quick decision-making. In such cases, any **two** of the following members will be required :

- Director of Public Health or Nominated Representative
- Associate Director, Medicines Management
- Medical Director or Deputy Medical Director

The panel will receive relevant information on individual cases provided as appropriate by:

- the patient (patient evidence required within time limit in order to consider case)
- the GP (GP evidence required within time limit in order to consider case)
- any relevant local consultants
- the provider of the requested service
- a review of the evidence relating to the effectiveness of the treatment requested where this is an issue i.e. whether the treatment is likely to work

When evidence is requested for the panel, it should be made clear that decisions are considered on the basis of:

A With regard to what might be considered exceptional and extenuating circumstances

B With reference to previous cases and the CRUP/SRP policies to ensure equity.

## 3 Making decisions - guidelines

Panels will have regard to the precedent set by Panels in previous cases within the PCT Cluster when reaching their decisions to promote consistency and equity. This will be achieved by a briefing paper for each case summarising relevant previous decisions. However previous decisions are not strictly binding on panels and are for guidance only.

In making their decision, the IFR Panel can take account of personal and social factors as well as information which are clearly clinical in nature. This is in keeping with the World Health Organisation concept of health which takes into account personal, social and environmental factors as a determination of wellbeing. However the Panel will be mindful of the risk of decisions being influenced by the emotional response of the Panel members and/or the applicant and the attendant risk of making subjective inequitable decisions and unintentionally setting precedents. In taking account of personal and social factors, the Panel will require evidence of such factors to constitute exceptionality by the same definition and to the same standard of exceptionality as clinical factors.

Members will have regard to culture or religious factors pertaining to the individual which may warrant funding for treatment not ordinarily provided under the NHS.

**FUNCTION 1:**

Evidence of the efficacy and priority of this treatment will have been considered when the restriction policies were developed.

The panel needs to consider whether the policies have been correctly applied and then, if appropriate, whether the case is exceptional.

The IFR Panel bases its decision on the Ewart definition of exceptionality as set out in Section 4 of this policy.

However this is a threshold and the Panel will still consider clinical and cost effectiveness of treatments requested.

**FUNCTION 2:**

The IFR Panel need to support and advise the SCG in circumstances where it is not clear if a patient is outside of the terms of the Restriction to Treatment Policy.

**FUNCTION 3:**

New treatments are continually being developed and some treatments are so unusual that they may not be covered within the service level agreements that exist with secondary and tertiary care centres. The IFR Panel need to consider a variety of factors before reaching a decision:

What clinical evidence supports the treatment being requested? This should come from the main provider backed up by the PCT's own or Public Health Network search. Consideration should be given however to treatments without supporting evidence as in some circumstances for example Appendectomy there is no RCT data.

What is the quality of the available evidence? The IFR Panel must be able to demonstrate that they have looked at the available evidence and reached a decision that is consistent with other cases.

The existence of academic/research papers supporting treatment may not be proof of efficacy. Also there could be some indication of success associated with a treatment where there is no statistical significance in the available evidence.

The success of a treatment in one area does not infer success in another for instance:

There is some good physiological evidence why acupuncture works on pain. However pain gate theory does not explain or support the treatment of addiction with acupuncture.

# 4 Process

- Patients and the referring clinician will be sent an acknowledgement letter outlining the process involved in their case.

- Patients will also be sent an information leaflet about the panel

- Patients will be explicitly invited to attend the relevant Panel Hearing if they wish to do so

- Clinicians requesting a panel hearing will be asked for evidence:
    - That the intervention sort is likely to be effective and cost-effective for the particular patient and
    - That the patient has exceptional circumstances.

The Director of Public Health (or nominated representative) will advise the IFR Service as to whether the content of support letters from clinicians contain sufficient evidence of exceptionality to warrant consideration by the IFR Panel. If there is no such evidence, the IFR will not proceed to the IFR Panel and the referrer will be advised accordingly.

- Following a panel meeting patients and treating clinicians will be sent written confirmation that treatment can proceed or a refusal letter outlining the External Review Process, along with minutes of the meeting with the Panel. The minutes of the Panel meeting will be approved by the senior clinician in attendance at the Panel and the decision letter will be signed by or on behalf of the Panel Chairman.

- In line with the recommendations of the Richards Review (DH, 2008) which were accepted by the Department of Health in November 2008, in cases where funding for a particular treatment or drug has been declined by the PCT, the patient and referring clinician will be reminded of the patient's right to purchase additional drugs privately losing their entitlement to NHS care if they are able to afford to do so without. The contractual obligation will be upon the provider to ensure that the facility is available to individual patients to separate NHS and private care in this way.

**The following circumstances will not be considered by the IFR Panel:**

- The IFR Panel will not normally accept direct referrals that should have gone to the Specialist Commissioning Group, except those relating to treatments or providers clearly not provided for under existing SLAs. These will be returned to the sender informing them of the correct process.

- The IFR Panel will not normally accept requests for treatment without the support of a relevant clinician including an indication that the patient may have exceptional circumstances. In the event that the Director of Public Health and Head of Governance, Risk & Customer Services agree that supporting letters do not contain this information, clarification will be sought from the referring clinician. Ultimately if the referrer is unable to provide this indication then cases will not proceed to a panel.

- The IFR Panel will not normally accept referrals for treatment under function 3 commenced in the private sector without prior support of the PCT

- The IFR Panel will not consider requests for funding to meet the cost of statutory NHS charges for primary care services such as prescription, optical and dental charges and travel to hospital. Applicants will instead be advised by the IFR Service of the process for applying for financial assistance under the Low Income Scheme.

## 5 External Review Process

When a patient is informed of a decision not to fund treatment by the IFR Panel, the patient will also be informed in writing within the decision letter about the external review process. Until the North Essex PCTs clustering process has been completed, South Essex appeals will be considered by the IFR Panel of NHS Mid Essex.

If the patient wishes to exercise his or her right to request a review of the decision, they must do so within 28 days of the letter notifying them of the decision not to fund treatment.

Cases will only be accepted for appeal if, in the view of the Head of Governance, Risk & Customer Services, there is any indication at all within the appeal letter that the appeal is based on a flaw in the process followed by the panel. Appeals based purely on a disagreement with the panel's decision will not be permitted to proceed to appeal.

The full set of papers considered by the original panel will be sent to NHS Mid Essex, together with a copy of the panel minutes and the decision letter that was sent to the patient.

The External Review Panel will follow the following process :

- It will examine whether the original IFR Panel correctly applied its own stated IFR policy in reaching its decision

- It will not consider any new evidence or information which was not considered by the original panel

- Patients will not be invited to attend the External Review Panel but they will be made aware of the date when their case will be considered

- The letter notifying patients of the arrangements for the External Review Panel will also advise them that if any new information has come to light or if there has been any significant change in circumstances since their case was originally considered, then the patient should bring this to the attention of their own PCT.

- In the event that such new information does come to light after the original panel has declined funding in a particular case, a request can be made for the case to be considered afresh. This will be considered a new case and will be dealt with under PCT's IFR Policy as such (i.e., not as an External Review).

- The decision as to whether to permit a case to be reconsidered under this provision will be made by the Head of Governance, Risk & Customer Services, a Panel Chairman and the Director of Public Health acting together.

## 6. Terms of Reference for South Essex PCTs Cluster IFR Panel

The Terms of Reference for the IFR Panel form Appendix Cii and will be reviewed at the same time as the IFR Policy overall.

**INDIVIDUAL FUNDING REQUESTS PANEL**
**TERMS OF REFERENCE**

## 1. ROLE

**Purpose:**
To ensure decisions are made about commissioning treatments that are based on the best available evidence and have a positive outcome for the patient. To review requests for treatment not routinely funded by the local NHS.

**Objectives:**
To review and make decisions whether treatment should be commissioned in the following circumstances:

- Cases where a refusal to treat decision has been made by the Specialist Commissioning team or Referral Management Centre on the basis that the patient does not meet the agreed criteria
- Cases where special advice is requested by the Specialist Commissioning Group;
- Cases where a request has been made for treatment not normally provided in the mainstream NHS.

## 2. ACCOUNTABILITY

**Accountable to:**
Integrated Governance Committee

**Key Relationships:**
PCT Commissioning Teams
East of England Specialist Commissioning Group
Referral Management Centre
External Review Panel

## 3. DECISION MAKING

The IFR Panel has delegated authority to decide whether treatment should be commissioned in respect of individual cases referred to it for consideration.

## 4. PRIORITIES

To consider each case individually, while making the best and fairest use of resources available for healthcare within the South Essex PCTs Cluster area

## 5. MONITORING AND REPORTING

**Monitoring:**
The Panel will monitor itself against its objectives and undertake a review of its performance annually. This review will be led by one of the Non Executive Director Panel Chairs and will involve all panel members and the Head of Governance, Risk & Customer Services. An annual report from the panel will be submitted each year to the Integrated Governance Committee.

**Reporting:**

IFR Panel cases will normally only be reported to the Board where an appeal has been submitted and considered by the External Appeal Panel and where the Appeal Panel have disagreed with the original decision.

In cases where the Appeal Panel uphold the decision of the original Panel, that will be the final decision and there will be no recourse to the PCT Board.

## 6. MEMBERSHIP

**Core members:**

- A Non-Executive Director or Lay Chair who chairs the Panel *
- The Director of Public Health or Nominated Representative *
- Director of Commissioning or Nominated Representative *
- Clinical members - Chief Nurse or Nominated Representative, PCT Medical Director or Deputy Medical Director *

There shall be no more than 4 voting members at any Panel. In the event that two members from the same category, e.g., both the Director of Public Health and Consultant in Public Health are present, there shall be only one vote placed by the more senior of the two.

In the event of a tied vote, the Chair will have the casting vote.

**Co-opted members:**
Associate Director, Community Pharmacy & Medicines Management
Specialist Commissioning Group Representative
Head of Governance, Risk & Customer Services

## 7. QUORUM

The Panel will be considered quorate when at least three members are present, including those asterisked above, except in the case of urgent panels which require Panels that are convened to consider cases defined as urgent / fast track have a reduced quorum to facilitate quick decision-making. In such cases, any **two** of the following members will be required :

- Director of Public Health or Nominated Representative
- Associate Director, Medicines Management
- Medical Director or Deputy Medical Director

## 8. VOTING RIGHTS

Only the core members have a vote.

In the event of a tied vote, the Panel Chairman has an extra casting vote.

## 9. FREQUENCY OF MEETINGS

The Panel will meet as frequently as required by its caseload

## 9. REVIEW OF TERMS OF REFERENCE

To be reviewed at the same time as the IFR Policy overall is reviewed.
To be agreed by the Panel and ratified by the Integrated Governance Committee.

# Appendix D

Process for handling requests from or on behalf of patients for treatment in countries of the European Economic Area

The law governing the right to obtain state-funded treatment overseas is highly complex, deriving from case law established by the European Court of Justice.

There are two potential routes for patients to receive planned care in another Member State at the expense of the NHS.

- The long-established route under Articles 20 and 27(3) of Regulation (EC) 883/2004 whereby the Secretary of State issues to a patient a form E112. This is hereafter referred to as "the E112 route", and

- Article 56 of the Treaty on the Functioning of the European Union (TFEU). This is hereafter referred to as "the Article 56 route"

The key difference is that the E112 route relates only to state-provided treatment and costs are dealt with directly between Member States. The Article 56 route enables reimbursement of healthcare costs both within the state sector and the private sector of the country in question.

The E112 Route

The PCT has a role in deciding whether to authorise planned treatment in another Member State. The E112 route can only be used in advance of treatment being undertaken. No retrospective reimbursement of fees incurred for treatment abroad will be available under the E112 route.

All applications under E112 route for patients registered with a GP in South East Essex will be considered by the IFR PANEL on a case-by-case basis.

In making their decision, the IFR Panel will decide whether to authorise treatment, based upon :

- A clinical assessment of the patient's specific needs
- Confirmation that the treatment is not experimental or a drug trial
- Confirmation that the treatment is available under the other country's state health scheme, and
- That the patient would be entitled to the proposed treatment under the NHS, if they were to be treated in the UK (e.g., if a patient would not be entitled to plastic surgery under the South East Essex criteria, they would not be entitled to obtain this overseas at the expense of the PCT)

The key factor, having satisfied the above, will be whether or not the treatment can be provided by the NHS in the UK within a timescale that is clinically acceptable. Where it is established that the treatment cannot be provided in the UK in a clinically acceptable timescale, authorisation must be given.

Article 56 Route

Article 56 confers a fundamental right to healthcare services across borders for all EEA citizens. Under this route, patients can access any healthcare service in another Member State that is the same or equivalent to a service that would have been provided to the patient under the patient's home healthcare system. The patient then has a right to claim reimbursement up to the amount that the same or equivalent treatment would cost had the patient obtained that treatment under their home healthcare system.

The Article 56 route allows the patient to seek retrospective reimbursement for state-provided treatment **and** services provided in the private sector of a Member State, upon returning to the UK.

The regulations permit PCTs to insist on a patient obtaining prior authorisation only where this is justified, provided that the system for making an application and the criteria for agreeing it are publicly available, robust and transparent. **The circumstances where it is reasonable to request prior authorisation are essentially where hospital inpatient care is received**. Such treatment is known as "special services" within the 2010 Regulations and include the following :

- A service that involves a stay in hospital accommodation for at least one night
- Medical treatment that involves general anaesthesia, epidural anaesthesia or intravenously administered sedation
- Dental treatment that involves general anaesthesia or intravenously administered sedation or
- A service whose provision involves the use of specialised or cost-intensive medical infrastructure or medical equipment

For treatments that fall outside this definition, patients are not required to obtain prior authorisation but are encouraged to do so to ensure they do not incur treatment fees overseas which are not reimbursable in the UK. Such advice can be given by the PCT's IFR Service.

In determining whether to authorise overseas treatment under Article 56, the IFR PANEL will use the same criteria as listed under the E112 route.

The Guidance around the Article 56 Route states that patients will ordinarily be expected to pay for overseas treatment from their own resources, even when it has been approved by the PCT, and then reclaim the cost from the PCT upon their return. In order to prevent undue hardship preventing a patient from exercising their rights to EEA treatment, the IFR Panel may consider making a direct commissioning arrangement with an overseas provider which would involve direct payment to the provider by the PCT.

Right of Appeal

All applicants under either the E112 or the Article 56 route have the right to request that their case be considered by the External Appeal Panel under the same process as outlined on pages 22-23.