INDIVIDUAL FUNDING & EXCEPTIONAL CASE PANEL
(Including consideration of Individual Funding Requests)

Terms of Reference
and
Ethical Decision Making Framework

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Purpose
1. The NHS exists to serve the needs of all of its patients but also has a statutory duty financially to break even. Primary Care Trusts (PCTs) have a responsibility to provide health benefit for the whole of their population whilst commissioning appropriate care to meet the clinical needs of individual patients.

2. This policy sets out the eligibility criteria for patients to receive NHS funding for services for which there is no established Service Level Agreement or where a treatment is considered to be ‘Low Priority’ for funding (including out of area treatments, interventions and NHS commissioned care, and where the PCT has stipulated prior approval is required). The Exceptional Case Panel will take decisions on both individual funding requests and exceptional cases.

3. It is important to distinguish between an exceptional case and an individual funding request. In an exceptional case, a patient seeks to show that he or she is an ‘exception to the rule or policy’ and so may have access to an intervention that is not routinely commissioned for that condition.

4. For partially excluded procedures additional guidance on the circumstances that might be considered as “exceptional” is provided in the Clinical Priorities Policy recommendations.

5. In contrast, an individual funding request arises when a treatment is requested for which the PCT has no policy. This may be because:
   - it is a treatment for a very rare condition for which the PCT has not previously needed to make provision or
   - there is only limited evidence for the use of the treatment in the requested application or
   - the treatment has not been considered by the PCT before because it is a new way of treating a more common condition.

In this last instance, when this relates to a cohort of patients, this should prompt the development of a policy/business case on the treatment in question rather than an individual funding request, unless there is grave clinical urgency. The PCT does not expect to introduce new drugs/technologies on an ad hoc basis through the mechanism of the Exceptional Case Panel. Consideration of new treatments (drugs or technologies) should take place within the existing planning framework overseen by the Commissioning Board. Please contact Jennifer Melville, Commissioning Manager, on Jennifer.Melville@midessexpct.nhs for further information about this process.

In instances in which a patient is part of a cohort for whom there is no current commissioning decision and the patient is experiencing rapid...
deterioration in their condition that could result in either permanent disability or death, the following process will be followed:

- Undertake an urgent communication with the applicant clinician to determine the degree of clinical deterioration/severity.
- ECP will reconsider the case as urgent if necessary if new indication of exceptionality provided.
- If not exceptional, the case will be brought to the attention of the Director of Commissioning immediately to determine the appropriate corporate course of action on the individual case in light of the clinical information provided and the stage in the commissioning decision making process for the cohort.

6. Many of the requests for individual treatments that fall outside of the scope of existing contracting arrangements will, by their nature, be difficult to resolve. In reaching a decision, the PCT needs to take into account the rights and needs of the individual, the duties and responsibilities of the NHS, and to ensure that decisions are made in a consistent, fair and transparent manner.

7. The PCT does not have an allocated fixed budget for exceptional cases and individual treatment requests. These are funded from the general commissioning budget.

8. The purpose of the ethical framework is to support and underpin the decision making processes through:
   - Providing a coherent structure for discussion, ensuring all important aspects of each issue are considered;
   - Promoting fairness and consistency in decision making from meeting to meeting and with regard to different clinical topics, reducing the potential for inequity;
   - Providing a means of expressing the reasons behind the decisions made;
   - Reducing risk of judicial review by implementation of robust decision-making processes that are based on evidence of clinical and cost effectiveness and an ethical framework;
   - Supporting and integrating with the development of PCT Commissioning Plans.

Applications
9. A detailed explanation of the process for making an application, and each subsequent stage in the application process, is detailed in Appendix 1.

10. The Panel will receive requests for funding treatment by the referring clinician completing in full the PCT’s Request for Exceptional Funding form. This form must be completed **in full** and can be accompanied by a
referral letter and/or any other relevant clinical information. Applications should be submitted electronically to ifr.me-pct.nhs.net or by marked PRIVATE & CONFIDENTIAL by post to the:

Exceptional Cases Manager c/o NHS Mid Essex, Swift House, Hedgerows Business Centre, Colchester Road, Chelmsford, CM2 5PF

11. Referrals will be accepted from:
- The patient’s GP
- A relevant NHS consultant

The appropriate referring clinician will usually be the person with clinical responsibility for the treatment being proposed. Where an application is for non NHS provision, an NHS clinician should have assessed the patient’s need, the treatment, and local provision.

12. The Panel cannot accept applications directly from a patient. If the Exceptional Case Team do receive an application directly from a patient, the ECP Administrator will write to the patient explaining that s/he need to contact his/her GP/Consultant to discuss the possibility of making an application. The patient will also be provided with details of the NHS Mid Essex Patient Experience Team in the event that they require any extra support at this stage of the process. The application then needs to be submitted directly from the referring GP / NHS Consultant with supporting evidence.

Delegated Levels of Decision Making
13. Level 1: Exceptional Cases Commissioning Manager

Cases submitted for consideration by the Panel will be subject to initial review by the Commissioning Manager with appropriate clinical support as needed. If the request is able to be resolved by the Commissioning Lead, the outcome will be communicated to the patient’s clinician. The Commissioning Manager has authority to approve applications of the following nature:

- Where prior approval is needed against explicit criteria as set out in the Clinical Priorities Policy or other similar PCT approved pathway.
- Within existing SLAs.

If the request is unable to be resolved through existing service agreements or alternative arrangements, the Commissioning Manager will present the application to the Clinical Review Group.

14. Level 2: Clinical Review Group (CRG)
The Clinical Review Group will screen applications with a view to support the Commissioning Manager decide whether the application can be agreed without recourse to the Exceptional Cases Panel or to propose that further information is required before the application can be presented. The CRG will be composed of the Commissioning Manager, a GP and a Consultant in Public Health; depending on the application it may also include the Chief Pharmacist.

15. The CRG can make decisions in the following circumstances:

- Applying discretion as per the Clinical Priorities Policy
  Where the CRG can not make a unanimous decision the application will automatically be referred to the Exceptional Cases Panel.
- The CRG will screen out Individual Funding Requests which refer to a cohort of patients (see above paragraph 5) and reply to the referring clinician asking that they submit a business case for consideration in the planning process for the Commissioning Board.

16. **Level 3: Exceptional Cases Panel**

Membership
- PCT Director of Commissioning (Chair)
- PCT Non Executive Director
- 2 Doctors
- A Nurse/Therapist
- Public Health Consultant
- PCT Commissioning Manager
- PCT Chief Pharmacist
- PCT finance Lead
- PCT Governance representative
- A patient representative

A quorate meeting will include 5 members which must include the non-executive member, a governance lead, a doctor and a commissioner. Where members are unable to attend, they will endeavour to provide a nominated attendee. Panel members will declare any vested interest.

17. Patients or their advocates may not attend the Panel meeting but may make representations in writing to the Panel as part of the case to be considered by the Panel. Applicant clinicians will be invited to advocate on their patients behalf at the Panel meetings through teleconference.

18. The purpose of the Panel will be:

- To make decisions on individual cases using the Clinical Priorities Policy recommendations as a guide but exercising discretion following a consideration of more detailed information on each case;
To make decisions about provision of equipment and related treatment in individual cases exercising discretion following a consideration of detailed information in each such case;  
To receive quarterly reports on expenditure from a member of the Finance Department; and  
To undertake appeal reviews on behalf of NHS West Essex.

19. As a formally constituted sub-committee of the PCT Board, the Exceptional Case Panel will have ultimate authority to determine whether funding should be provided.

20. In making its decisions, the Panel will have reference to a continuous record of previous decisions to ensure consistency.

**Decision making criteria – Individual Funding Requests**

21. The Panel will take into account when considering Individual Funding Requests:

   i. Does the intervention work (clinical effectiveness)?
   ii. Is it safe?
   iii. What is the broad balance of costs and benefits? (cost effectiveness)
   iv. What are the alternatives available to the patient? What is the usual/standard treatment pathway?
   v. What is the impact of this treatment on the PCT’s resources?
   vi. How is this patient significantly different from the population of patients with similar clinical circumstances who would not normally be offered this treatment? Is this patient likely to gain significantly more benefit from this treatment than would be expected from other patients with the same condition who are not currently offered it?
   vii. For treatments for which a trial period is indicated, is the patient willing to co-operate in having his or her condition regularly assessed to determine whether the treatment is effective and thus whether it should be continued.

22. The panel will also take into account the ethical considerations of autonomy (respect for individual choice), beneficence (duty to promote good which includes balancing benefits and risks), non-malfeasance (duty to do no harm) and justice (both distributive justice, and fair access / non discriminatory principles) where not already explicit within the criteria noted in paragraph 20. The panel will also take into account the impact of the Human Rights Act 1998 and the relevant Articles referred to therein but these will be balanced against proportionality and the statutory responsibilities of the PCT. Appendix 1 details the Articles referred to within the Act to assist the Panel in this process.

23. The panel will not take into account irrelevant considerations in evaluating each case. The Panel will seek to uphold the basic tenet of the NHS that people with equal need should be treated equally.
Decision Making Criteria – Exceptional Cases

24. Exceptionality is difficult to pre-define, however, it is the responsibility of the applicant clinician to differentiate clearly between the majority of patients for whom the treatment is not available and the patient in question.

- The Panel will have regard for:

  How is this patient significantly different from the population of patients with similar clinical circumstances who would not normally be offered this treatment?

  Is this patient likely to gain significantly more benefit from this treatment than would be expected from other patients who are not currently offered it?

Responsibility for demonstrating exceptionality lies with the applicant clinician.

25. When considering Exceptional Cases, the Panel will also have regard for paragraphs 22 and 23 above.

Urgent requests

26. For clinically urgent requests (where a patient’s health may be seriously adversely affected if a decision is not taken before the next scheduled meeting of the Panel), the Exceptional Cases Panel delegates its authority to the Clinical Review Group. The Panel will be informed of such cases at the next scheduled meeting.

27. Urgent requests are expected to come in the form of an urgent clinical letter or a phone call from the responsible consultant to the Consultant in Public Health, GP Representative or Chief Pharmacist who will be advised by the remaining members of the CRG providing their advice can be sought in a timely manner. The request will be assessed as to whether the funding request is because of clinical urgency or administrative urgency.

CONTACT DETAILS:
Exceptional Case Manager, Jane Christy, 01245 398740
Exceptional Case Administrator, Rachel Anderson, 01245 459472
Consultant in Public Health, Maggie Pacini, 01245 459425

28. Administrative urgency is defined as a funding request which has now become urgent because the provider has failed to seek funding approval in advance of any arrangement to treat the patient. The provider trust, having given a commitment to treat the patient, is expected to go ahead with treatment and bear the costs itself, pending the outcome of the Exceptional Case Panel decision making process.
29. Clinical emergency is where there is a genuine unplanned and urgent clinical need which requires an urgent decision. These decisions are delegated to nominated officers of the PCT as indicated in paragraph 26. The nominated officer will aim to establish:
- The nature and severity of the patient’s clinical condition.
- The window of opportunity for treatment and subsequently agree a time with the clinician the deadline for decision making.
- As much information about both the patient illness and the treatment as is feasibly in the time available possible.
- Identify any commissioning policy/policies which are engaged in this situation.

30. A decision will be made on the basis of the above information. Urgent decisions are not precedent setting.

31. The appeals process for decisions on urgent cases is set out in Appendix 1, Section E.

Confidentiality
32. Patient sensitive/patient identifiable information passed to the Panel will be handled in a sensitive and lawful manner in line with the Data Protection Act 1998. An application identity code will be used in place of names; where names have been included on documentation it will be redacted. In line with Caldicott Principles, patient identifiable information will only be used by the Panel if:-
- there is a justified purpose for the confidential information being seen
- the use of the information is absolutely necessary to the discussion
- the minimum data of the purpose is used
- there is a need to know, and
- all members of the Panel understand their responsibilities in regard to patient confidentiality.

Reconsideration
33. Requests for reconsideration based on new or additional relevant information should be submitted within 42 days of the letter informing the applicant of the decision not to fund the treatment.

34. All new or additional information submitted for reconsideration will be assessed by the Clinical Review Group. When the Group agrees that the new information is relevant, the case will then be reconsidered at the next meeting of the Exceptional Cases Panel.

35. Where the new or additional information is not considered relevant, (for example no additional evidence of clinical effectiveness is provided and/or the patient’s clinical circumstances have not materially changed,) the Exceptional Cases Panel will not reconsider the case and the decision will be relayed to the applicant. The applicant still has right to
seek appeal (and will be provided with details of the appeals process) in the circumstances listed below.

**Appeals**

36. In cases where ECP funding is denied, the letter sent to the applicant clinician will also include details of the process by which a decision can be appealed. Where a patient/clinician wishes to appeal, they should give notice of their intention to do so in writing within 42 days of being notified of the decision. Appeals should be sent to the Exceptional Cases Manager electronically or in writing (details as per paragraph 10). The reasons proposing the appeal (see paragraph 36) should be clearly set out in writing. For a detailed explanation of the Appeals Process please see Appendix 1, Section E.

37. An appeals panel will be convened only if the applicant (clinician or patient):

- Believes a matter of process (as detailed in this Appendix) was not adhered to, or
- Believes not all of the available evidence was taken into account in reaching the decision), or
- is able to demonstrate that the decision reached by the Exceptional Cases Panel was unreasonable (for example, not properly based on the evidence set before the committee).

Disagreeing with the Panel’s original decision alone is insufficient grounds for appeal. The Appeals Panel does not reconsider the merits of the original application, but evaluates whether or not the original decision followed procedure, considered all the available evidence and was reasonable. If the grounds for appeal are upheld the ECP will reconsider the application on those specified grounds only.

38. The PCT will not entertain appeals outside the 42 day time limit, unless the applicant can show that it was not possible to apply within that time limit.

39. Appeals of an Exceptional Cases Panel decision by West Essex PCT will not be heard in public and the patient is unable to make personal representations.

40. The patient has the right to make a complaint to NHS Mid Essex regarding the administration of the appeal process using the PCT’s Complaints Procedure.

41. Thereafter the patient may have recourse to the Care Quality Commission.
42. Appeals for urgent applications will be heard by the Director of Commissioning or Chief Executive.

Communication with Patients
43. The Exceptional Cases Team members will always seek to be timely and informative in their contact with all parties with regards to the processing of the application in question.

44. All patient initiated contact with the Exceptional Case Panel Administrative Team will be in writing to ensure that the correct information is available to be presented to the Panel. Patients are asked to discuss any specific issues/concerns that they may have with their application with their referring clinician.

45. In situations in which there are concerns about patient safety or provider performance, telephone contact directly with a patient may be initiated at the discretion of the Exceptional Case Manager.

46. The Exceptional Case Team will not discuss the outcome of cases with patients on the telephone. This is to ensure that patients receive accurate information from a clinically trained professional who can also offer the appropriate support if necessary.

Monitoring and Reporting
47. An Annual report will be produced for the Panel and presented to the Acute Transformational Delivery Board.
   - Number of applications reviewed
   - Budget areas or speciality of treatments being requested
   - Decision outcome
   - Time to decision made
   - Number and outcomes of appeals
   - Indicative expenditure for approved applications
   - Trends/Gap Analysis
   - Outcomes of interventions agreed

Quarterly reports on expenditure will be present to the Panel and to the appropriate commissioners against whose budget applications are funded.

Other Relevant Policies
48. The policy should be read in conjunction with the following:
   - Managed introduction of new medicines
   - Top up – draft
   - Post trial
   - Treatment abroad - draft
Review
49. The policy and its processes will be reviewed annually and signed-off by the PCT Board.

Publication and dissemination
50. The policy will be published on the NHS Mid Essex.
APPENDIX 1

Exceptional Case Process and Systems

A. Applications

1. All requests for exceptional funding must be submitted directly by the referring clinician (see below paragraph 2). In order for a request to be considered, the referring clinician must complete in full the Exceptional Funding Request form (see attached Appendix 2). This form can be accompanied by a referral letter and any other relevant clinical information. Applications can be submitted electronically to email address or by post to the Exceptional Cases Manager c/o NHS Mid Essex.

2. Referrals will be accepted from:
   - The patient’s GP
   - A relevant NHS consultant

The appropriate referring clinician will usually be the person with clinical responsibility for the treatment being proposed. Where an application is for non NHS provision, a local NHS clinician should have assessed the patient's need, the treatment, and local provision.

If the request is for an out-of-area NHS service, we ask that a relevant local NHS clinician write in support of the application and clarify why the service cannot be provided locally. This is not relevant in situations in which Patient Choice applies.

3. The Panel cannot accept applications directly from a patient. If the Exceptional Case Team do receive an application directly from a patient, the ECP Administrator will write to the patient explaining that s/he need to contact his/her GP/Consultant to discuss the possibility of making an application. The patient will also be provided with details of the NHS Mid Essex Patient Experience Team in the event that they require any extra support at this stage of the process. The application then needs to be submitted directly from the referring GP / NHS Consultant with supporting evidence.

B. Preparation of Applications within Exceptional Case Process

4. The Exceptional Case Manager will coordinate (with support from Commissioning Manager and the Clinical Review Group when needed) the gathering of any necessary supporting evidence. All information must be in written format; verbal exchange between clinician and PCT staff is will not be included in the application, but should be followed up with written or electronic summary of key points discussed. In some circumstances a second clinical opinion may be required before the application is decided.
5. For routine cases, where further information has been requested in order to inform a decision, reminder letters will be sent where this has not been received after 2 weeks, 4 weeks and 6 weeks. The case will be closed and notification sent to the applicant clinician if, after 8 weeks from the original request for additional information, the Exceptional Case Team have not received this information. After this point, a new application will have to be made.

C. Decision Making – Delegated Authority

Level 1 Delegated Decision Making: Commissioning Manager

6. Cases for consideration in the Exceptional Cases Process will be subject to initial review by the Commissioning Manager with appropriate clinical support as needed. If the request is able to be resolved by the commissioning lead, the outcome will be communicated to the patient’s clinician. The Commissioning Manager has authority to approve applications of the following nature:

- Where prior approval is needed against explicit criteria as set out in the Clinical Priorities Policy or other similar PCT approved pathway
- Within existing SLAs

7. If the request is unable to be resolved through existing service agreements or alternative arrangements, the Commissioning Manager will present the application to the Clinical Review Group.

8. A holding letter will be dispatched, by the Exceptional Cases Administrator, to the patient’s referring clinician with information about the next steps together with information about how the outcome of the Panel’s deliberations will be communicated.

Level 2 Delegated Decision Making: Clinical Review Group

9. The Commissioning Manager will present cases for consideration to the Clinical Review Group.

10. A summary of cases will be circulated to Group members whenever possible 48 hours prior to the meeting.

11. The Clinical Review Group (CRG) will screen applications and advise the Commissioning Manager whether the application can be agreed without recourse to the Exceptional Cases Panel or whether further information is required before the application can be presented. The CRG will be composed of the Commissioning Manager, a GP and a Consultant in Public Health; depending on the application it may also include the Chief Pharmacist.

12. The CRP can make decisions in the following circumstances:
- Applying discretion as per the Clinical Priorities Policy
• Screening out individual funding requests for new drugs/treatments for which there can be an anticipated cohort of patients with the same clinical need to be considered as part of the general planning process for commissioning priorities (see above main document, paragraph 5).

13. Where the CRG can not make a unanimous decision the application will automatically be referred to the Exceptional Cases Panel.

A holding letter will be written by the Exceptional Cases Administrator to the patient’s clinician with information about the next steps together with information about how the outcomes of the Exceptional Case Panel will be communicated.

14. If an application has been refused by the Clinical Review Group a letter will be sent by the Exceptional Cases Administrator within 48 hours of the meeting. The applicant clinician is invited to provide additional relevant clinical information supporting the exceptionality of the patient in order that the case may be reconsidered within 28 days of the date of refusal. After this point, a new application will be required.

15. The Exceptional Cases Administrator will keep a record of the outcomes of the Clinical Review Group meetings with notes providing information on the decision making process.

**Level 3 Delegated Decision Making: Exceptional Case Panel**

16. The purpose of the Panel is to:

- To make decision on individual requests for treatment (medicines and/or packages of care) using appropriate National Guidance and the Mid Essex Clinical Priorities Policy recommendations as a guide but exercising discretion following a consideration of more detailed information on each case
- To make decisions about provision of equipment and related treatment in individual cases exercising discretion following a consideration of detailed information in each case
- To undertake appeal reviews on behalf of NHS West Essex.
- To receive quarterly reports on expenditure from a member of the Finance Department

17. Membership

- PCT Director of Commissioning (Chair)
- PCT Non Executive Director
- A Doctor
- A Nurse/Therapist
- Public Health Consultant
- PCT Commissioning Manager
- PCT Chief Pharmacist
• PCT Governance representative
• A patient representative

A quorate meeting will include 5 members which must include the non-executive member, a governance lead, a doctor and a commissioner. Where members are unable to attend, they will endeavour to provide a nominated attendee. Panel members will declare any vested interest or conflict of interest.

18. The Panel aims to make a decision on all applications within 6 weeks of a completed application being received (see paragraphs F) for urgent applications) providing all pertinent information is received. If the application is incomplete or further information is required prior to presenting the application (Section B: Preparation of Applications), then the application will be heard within four weeks of all information being received.

D. ECP Meetings
19. The Panel will meet on a monthly basis. The Panel may establish time limited sub-groups with professional and managerial expertise appropriate to the issue under review to support its work.

20. In making its decisions, the Panel will have reference to a continuous record of previous decisions to ensure consistency.

21. An agenda and all supporting documents will be circulated one week before the Panel meeting. Papers will not usually be tabled at meetings in order to ensure that all decision makers have had an opportunity to read and comprehend all pertinent information. Any application that is not complete one week prior to the meeting date will be deferred to the next meeting.

22. Patients or their advocates may not attend the Panel meeting but may make representations in writing to the Panel as part of the case to be considered by the Panel.

23. The Exceptional Cases Manager will produce suitably detailed minutes/notes from the Exceptional Cases Panel meetings, which will detail a record of attendees, case numbers discussed and processes and outcomes agreed.

24. Following the Panel meeting, the outcome will be communicated, by the Exceptional Cases Manager to the applicant clinician. A letter indicating the outcome of the Panel’s deliberation will be sent to the referring clinician within 48 hours. The outcome will not normally be directly communicated to the patient; this is to ensure that the patient’s
applicant clinician can inform and support their patient appropriately following the decision.

25. Outcome letters will be in a standard format to include information on the appeals process, a copy of the Decision Record for information and will be addressed from the Chairman of the Exceptional Cases Panel and signed on the Chair’s behalf by the Exceptional Cases Manager.

E. Appeals (Non-clinically Urgent Cases)

26. In cases where ECP funding is denied, the letter sent to the applicant clinician will also include details of the process by which a decision can be appealed. Where a patient wishes to appeal they should give notice of their intention to do so in writing within 42 days of being notified of the decision. Appeals should be sent to the Exceptional Cases Manager electronically or in writing (details as per paragraph 7). The reasons proposing the appeal (see paragraph 27) should be clearly set out in writing.

27. An appeals panel will be convened only if the applicant clinician believes:

1. A matter of process (as detailed in this Appendix) was not adhered to, or

2. Not all of the available evidence was taken into account in reaching the decision), or

3. Where an individual is able to demonstrate that the decision reached by the Exceptional Cases Panel was unreasonable (for example, not properly based on the evidence set before the committee).

Disagreeing with the decision alone is insufficient grounds for appeal. The Appeals Panel does not reconsider the merits of the original application, but evaluates whether or not the original decision followed procedure, considered all the available evidence and was reasonable.

28. Appeals will only be entertained in circumstances where the applicant clinician supports it and submits the appeal.

29. The PCT will not entertain appeals outside the 42 - day time limit, unless the applicant clinician can show that it was not possible to apply within that time limit.

30. Upon receiving an appeal request, NHS Mid Essex will remit the appeal to NHS West Essex. Depending on the nature of the application, the appeal will be considered by either the Exceptional Case Panel. Patients will be sent a holding letter informing them of the date of their appeal.
31. The Exceptional Cases Manager will prepare the following papers for consideration by the NHS West Essex Service Restriction Appeals Panel:
- the papers presented to the Exceptional Cases Panel together with their decision (as minuted & including details of panel attendance)
- a chronological statement of events
- the letter requesting the appeal from the applicant clinician.
- any further material submitted by the patient (a statement of grounds for appeal)

32. West Essex PCT will consider the original reports and the process undertaken and will not make a decision on the merits of the application itself. If it concludes that any of the steps outlined in this paragraph were not followed then it will direct the Exceptional Cases Panel to reconsider that specific point(s) only.

Appeals of an Exceptional Cases Panel decision by West Essex PCT will not be heard in public and the patient is unable to make personal representations.

33. The patient will receive a written response informing them of the outcome of their appeal within 7 days of the final decision by West Essex PCT.

34. The patient has the right to make a complaint to NHS Mid Essex regarding the administration of the appeal process using the PCT’s Complaints Procedure.

35. Thereafter the patient may have recourse to the Health Care Commission.

36. Appeals for urgent applications will be heard by the Director of Commissioning

F. Urgent Requests

37. For clinically urgent requests (where a patient’s health may be seriously adversely affected if a decision is not taken before the next scheduled meeting of the Panel), the Exceptional Cases Panel delegates its authority to the Clinical Review Group. The Panel will be informed of such cases at the next scheduled meeting.

38. Urgent requests are expected to come in the form of an urgent clinical letter or a phone call from the responsible consultant to the Consultant in Public Health, Chief Pharmacist or Clinical Review Group GP, who will be advised by the remaining members of the CRG providing their advice can be sought in a timely manner. The request will be assessed as to whether the funding request is because of clinical urgency or administrative urgency.
39. Urgent requests are required to be sanctioned by the provider trust during normal working hours.

40. A contact name and number of the applicant clinician should be provided to enable the PCT to gather further information if needed.

41. Administrative urgency is defined as a funding request which has now become urgent because the provider has failed to seek funding approval in advance of any arrangement to treat the patient. Funding will not be approved. The provider trust, having given a commitment to treat the patient, is expected to go ahead with treatment and bear the costs itself.

42. Clinical emergency is where a genuine unplanned and urgent clinical need requires an urgent decision. These decisions are delegated to nominated officers of the PCT as indicated in paragraph 31. The nominated officer will aim to establish:
   - The nature and severity of the patient’s clinical condition.
   - The window of opportunity for treatment and subsequently agree with the clinician the deadline for decision making.
   - As much information about both the patient’s illness and the treatment as feasible in the available time scale.
   - Identify any commissioning policy/policies which are engaged in this situation.

43. A decision will be made on the basis of the above information. Urgent decisions are not precedent setting. There may be times when the decision needs to be escalated up beyond delegate duties as set out here.

44. The appeals process for decisions on urgent cases is set out in paragraph E.11.

G. Information Systems to support Exceptional Case Panel
45. The Exceptional Case Team will maintain a database containing the following minimum dataset:

   - Application identifier
   - Referring clinician
   - Date ECF received
   - Date of consideration by ECP
   - Date of decision
   - Decision
   - Reconsideration (date and decision)
   - Appeal (date and decision)
   - Cost
   - Date of trial period if required

46. A process for monitoring cases will be established to
ensure that further information is pursued on a timely basis, and where this is not forthcoming, that cases are closed and referrers are informed.

47. Any further information on existing cases that is requested and received will be updated on the database, and a file note entered into the patient’s record. All communication relating to cases either written or verbal will be fully documented and added to patient case file in chronological order.

48. Quarterly reports on performance will be provided with respect to timeliness and outcomes of case load managed in that period.

49. All hardcopy ECP files will be kept in locked cupboards.

50. All electronic ECP files/information will be kept in a designated and protected folder on the M-drive. All electronic files relating to the ECP must be kept exclusively in this folder. Access to this folder will be limited to members of the ECP Team.

G. Communication with Patients

51. The Exceptional Cases Team members will always seek to be timely, polite and informative in their contact with all parties with regards to the processing of the application in question.

52. All patient initiated contact with the Exceptional Case Panel Administrative Team will be in writing to ensure that the correct information is available to be presented to the Panel. Patients are asked to discuss any specific issues/concerns that they may have with their application with their referring clinician.

53. In situations in which there are concerns about patient safety or provider performance, telephone contact directly with a patient may be initiated at the discretion of the Exceptional Case Manager.

54. The Exceptional Case Team will not discuss the outcome of cases with patients on the telephone. This is to ensure that patients receive accurate information from a clinically trained professional who can also offer the appropriate support if necessary.
F. EXCEPTIONAL CASE APPLICATION PROCESS (Non-Clinically Urgent Cases)

Application for Exceptional Funding Submitted

- Letter of Acknowledgement of receipt of application will be sent within 24 hours by the Exceptional Case Administrator

Level 1: Decision Making
Commissioning Manager assesses application

- Decided applications: Letter written to applicant clinician indicating whether or not funded within 7 days
- Undecided applications: Letter written to applicant clinician indicating application to be considered at next Clinical Review Group within 7 days

If further clinical information is required the Exceptional Case Manager will write to the relevant clinician asking for further supporting information.

Level 2: Decision Making
Application reviewed by Clinical Review Group

- Decided applications: Letter written to applicant clinician indicating whether or not funded within 7 days
- Undecided applications: Letter written to applicant clinician indicating application to be considered by Exceptional Case Panel (If application has all information required, will be taken to next monthly meeting. If awaiting further information, will be taken to meeting following provision of additional information.)

If further clinical information is required the Exceptional Case Manager will write to the relevant clinician asking for further supporting information.

Level 3: Decision Making
Application considered by the Exceptional Case Panel

- The Exceptional Case Panel decision will be communicated by letter to the applicant clinician within 48 hours of the meeting.

Funding Supported OR Funding Refused (If new clinical evidence demonstrating exceptionality is provided the application will be reconsidered).

Undecided Panel has requested further clinical information

Funding Supported OR Funding Refused (If new clinical evidence demonstrating exceptionality is provided the application will be reconsidered).

Decided

Funding Supported

Funding Refused: Please see information on Appeals Process
APPENDIX 2

HUMAN RIGHTS ACT 1998

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

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