Individual Funding Request Commissioning Principles and Process Framework
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This document should be read in conjunction with

The NHS Constitution for England
Supporting rational local decision-making about medicines and (treatments), National Prescribing Centre

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PURPOSE

1. The purpose of this document is to establish a prioritisation framework for the commissioning of health services for individual cases. The framework includes how the Primary Care Trust is to make prioritisation decisions in respect of healthcare interventions for individual cases and the Ethical Framework (Appendix 1) and Commissioning Principles (Appendix 2) that underpin the making of these decisions.

INTRODUCTION

2. The principles that underlie the making of commissioning decisions apply to both decisions about services and treatments for the whole population (or segments of it) through the corporate business planning process and to decisions about services or treatments for individual patients.

3. These principles provide a clear public statement about the factors to be taken into account when decisions are made about which services and treatments are to be given priority

4. The policy includes the revised policy for considering requests for treatments for individual patients outside of existing commissioned services.

5. Prioritisation decisions require careful deliberation and input from the public and healthcare specialists to make decisions that are evidence-based and broadly supported. This requires the Primary Care Trust to have transparent and coherent decision making processes embedded in the governance structure.

BACKGROUND – PRIMARY CARE DUTIES

6. A Primary Care Trust is under a statutory duty ‘to promote comprehensive healthcare within the resources available’. However a Primary Care Trust is not under an absolute obligation to provide every treatment that a patient, or group of patients, may demand.

7. A Primary Care Trust may develop processes to prioritise treatments and is entitled to take into account the resources available to it and the competing demands on those resources. The precise allocation of resources and the process for prioritising those resources is a matter of judgement for individual Primary Care Trusts.

8. Primary Care Trusts must therefore be able to demonstrate that they have clear mechanisms in place for making decisions about relative priorities both at a strategic and an individual case level, including a mechanism by which individuals that might be an exception to a commissioning policy can be considered.
THE ANNUAL OPERATIONAL PLAN

9. All prioritisation decisions about services and treatments are made through the annual operational planning process to ensure their relative priority is weighed against each other to determine the overall priority for funding. The annual operating planning process is the primary vehicle for determining what services and treatments should be funded and where services need to be developed or redesigned.

10. The annual operational planning process considers service developments including new treatments and new indications for existing treatments that will have potential financial implications for the Primary Care Trust.

11. All service developments are scored using the PCT’s prioritisation framework. The criterion used in the scoring are: needs, (links to priority from robust needs assessment); local public opinion; population health gain; percentage of population affected by condition; health gain and cost of health gain as well as national policy (achievement of national strategic aims or targets); NICE guidance; whether a service development links to the PCT’s strategic aims, and the risk of not investing in the service.

12. The annual operational planning process also reviews the existing commissioning portfolio to ensure that resources already committed are achieving maximum possible health gain. Programme budgeting information and other comparative information on resource usage is used as a guide to determine whether the Primary Care Trust is investing too much or too little in a specific care programme.

13. As a general rule, the Primary Care Trust will use the methodology of programme budgeting i.e. invest in programmes that are underfunded; disinvest in programmes that are overfunded, and promote financial investments in new treatments through disinvestment elsewhere in the same programme.

14. Service developments will be considered by the Executive Directors, advised by the MT and CCEC, outside the annual operational planning process only on the following grounds. These are:

   a) There is a serious clinical governance issue or threat to the viability of a core service requiring urgent interim support measures.

   b) A treatment has been recommended by NICE Technology Appraisal requiring implementation within the 3 month statutory period.

   c) A new highly cost-effective treatment is made available (ie cost per QALY would usually be well below £10,000) and is for a serious illness and will have a major health impact for those patients who are affected.
d) A service is considered either cost neutral or cost saving, does not need pump priming and investment will not therefore distort other priorities.

ETHICAL FRAMEWORK

15. The Ethical Framework to support and underpin the decision making processes of the Primary Care Trust is in Appendix A. Although there is no objective or infallible measure by which such decisions can be based, the Framework enables decisions to be made within a consistent setting which respects the needs of individuals and the community.

16. NHS Central Lancashire recognises that its discretion may be affected by National Service Frameworks, National Institute for Health and Clinical Excellence (NICE) technology appraisal guidance and Secretary of State Directions to the NHS.

17. The Commissioning Principles devised by a Pan Lancashire Group provides more details to strengthen the existing Ethical Framework and describes the types of category for procedures and treatments. The principles are set out in Appendix B.

TYPES OF PRIORITISATION DECISIONS

18. NHS Central Lancashire has to make choices around priorities on a number of different levels. These are:

   a) The goals of the overall Commissioning Strategy.

   b) The portfolio of ‘service line programmes’ to deliver the outcomes specified in the Strategy.

   c) The programme of ‘change projects’ within each programme to be identified within the operational plan.

   d) The programme of investments and disinvestments to be identified within the corporate business planning process in respect of its resource allocation.

   e) The development of commissioning policies of low clinical priority.

   f) The funding of care for individual patients outside of existing commissioned services.

The Ethical Framework set out in Appendix A needs to underpin all these type of prioritisation decisions.
MAKING PRIORITISATION DECISIONS

19. The table below outlines the body responsible for making decisions on priorities and what groups will advise.

<table>
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<th>Types of choices</th>
<th>Who makes decision</th>
<th>Who advises</th>
<th>How</th>
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<tr>
<td>Strategic Goals</td>
<td>Primary Care Trust Board</td>
<td>Service Lines, Clinical Groups, Practice Based Commissioners, Staff, partners and public</td>
<td>Using JSNA &amp; other intelligence together with local engagement exercises</td>
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<td>Portfolio of Change Programmes</td>
<td>Executive Directors</td>
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<td>CCEC, Quality and Strategy Group</td>
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<td>Funding of care of individual patients</td>
<td>Individual funding request panel</td>
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<td>Using exception criteria and Primary Care Trust commissioning policies</td>
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DECISION-MAKING FOR NON-COMMISSIONED TREATMENTS FOR INDIVIDUAL PATIENTS

20. NHS Central Lancashire expects the vast majority of care to be part of established care pathways provided under existing commissioned services.

21. Services which are not prioritised and funded as part of the corporate business planning process will not normally be funded by the PCT.

22. However, NHS Central Lancashire will receive requests for treatment for specific patients where these are not currently commissioned.
23. The policy and process for considering these requests is outlined in Appendix C.

24. Normally the Primary Care Trust does not expect to introduce new treatments through the process of individual patient requests. To do so risks inequity as the treatments may not be offered openly and equally to all with equal clinical need. There is also the risk that diversification of resources in this way will destabilise other areas of healthcare which have been identified as priorities by the Primary Care Trust.

25. The PCT will consider that a requested treatment is a “new treatment” which amounts to a service development if there is one or more patients within the population served by the PCT who is or is likely to be in the same or similar clinical circumstances as the requesting patient in the same financial year, and who could reasonably be expected to benefit to the same or a similar degree from the requested treatment.

DECISION MAKING FOR EXISTING COMMISSIONING POLICIES WHERE APPROVAL IS REQUIRED

26. The PCT will consider a request from a referring clinician against a commissioning policy. The clinician should be familiar with the requirements of the particular policy and the submitting clinical evidence set out in the individual request form should clearly demonstrate this. The PCT’s decision will be made on the evidence submitted.

REQUESTS FOR TREATMENTS OUTSIDE OF EXISTING COMMISSIONED SERVICES

27. NHS Central Lancashire receives a fixed budget from central government with which to commission the health care required by its population and has a statutory duty to ‘promote comprehensive healthcare within the resources available.’ However, given the finite resources available, NHS Central Lancashire has limited funds to support all types of healthcare that might potentially be available or requested for its population.

28. In law a Primary Care Trust has the powers to exercise discretion to set health priorities within national guidelines and to allocate resources accordingly.

29. Each Primary Care Trust has to make choices about which health care interventions to commission [within national guidance] and to develop processes to prioritise treatments. NHS Central Lancashire makes these prioritisation decisions as part of the corporate business planning process as mentioned earlier in the document.

30. Through this process the Primary Care Trust decides which services, treatments and interventions are local priorities for investment based on local

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1 The term treatment used throughout this document includes all health technologies and interventions, including drugs, surgical procedures, diagnostics tests, other investigative procedures, rehabilitation, immunisations and screening.

Individual funding request/Commissioning principles and process framework - April 2011
needs assessments. On occasions, the discretion of the Primary Care Trust may be influenced or overridden by National Service Frameworks, guidance from the National Institute for Health and Clinical Excellence and NHS Directions.

31. Services which are not prioritised and funded as part of the Operational Plan will not normally be funded by the Primary Care Trust.

32. The Primary Care Trust will not normally take investment decisions outside of the corporate business planning process. Ad hoc decision making would introduce additional financial risks which may destabilise previously identified priorities.

33. The Primary Care Trust does receive requests for treatments which are not currently commissioned. The process for considering these requests and the principles on which decisions will be made are outlined in this policy.

TYPES OF REQUEST FOR NON-COMMISSIONED TREATMENTS

34. There are occasions when clinicians may wish to request funding for a treatment for a specific patient which NHS Central Lancashire does not currently commission. This may occur in the following circumstances:

35. When the Primary Care Trust has a policy for the patient’s presenting condition which does not currently fund the treatment in question. This may be because:

   (a) The Primary Care Trust has considered the available evidence and has reached the decision that the requested treatment does not support a conclusion that the treatment is a sufficiently high priority that it can be afforded within the available Primary Care Trust resources. This is usually because the treatment falls below commonly accepted thresholds of clinical effectiveness or cost effectiveness or a combination of both.

   or

   (b) The Primary Care Trust believes that the treatment is a low priority for NHS resources when compared to the other health needs of the population.

   and

   c) The requesting clinician still believes that there is/are exceptional clinical circumstance/s which may make the treatment more effective for the patient in question.

36. The Primary Care Trust has not yet considered the available evidence and so has not yet made a decision as to whether the requested treatment should be made available and included in a Primary Care Trust policy. This is usually because the case to support the requested treatment has not been made to the Primary Care Trust within its corporate business planning process.

37. When the treatment is new or has not yet been considered by the Primary Care Trust and may affect one or more patients a year, the request will be considered as a service development and will be referred to the corporate business planning process in line with Primary Care Trust policy.
38. When the request is made on behalf of a patient in a clinically urgent situation, the Primary Care Trust will make an emergency decision in line with the process detailed below. Emergency approval may be given to fund a one-off treatment; where ongoing treatment is required this may be approved in the first instance by emergency decision prior to fuller consideration by the Commissioning Request Panel.

39. The Primary Care Trust will not expect to introduce new treatments through the process of individual patient requests. To do so risks inequity as the treatment may not be offered openly and equally to all with equal clinical need. There is also the risk that diversification of resources in this way will destabilise other areas of healthcare which have been identified as priorities by the Primary Care Trust.

TREATMENTS OF LOW CLINICAL PRIORITY

40. In line with its requirements to ensure that resources are used effectively, NHS Central Lancashire has identified a number of treatments which have a lower clinical benefit and therefore are not routinely commissioned.

41. These include, but are not limited to, cosmetic procedures. These treatments will only be funded for individual patients who are clinically exceptional, these cases will be considered by the Commissioning Request Panel.

42. The portfolio of approved commissioning policies is set out in Appendix H.

OTHER TYPES OF REQUEST

43. The Primary Care Trust will not normally consider requests for funding in the following circumstances:

   (a) Requests to continue funding of care commenced privately
   Patients have a right to revert to NHS treatment at any point during their care. However the Primary Care Trust will expect their treatment to follow local pathways. Where individual clinical circumstances make funding alternative pathways appropriate the case will be considered by the Commissioning Request Panel.

   (b) Requests to continue funding for patients coming off drugs trials
   The Primary Care Trust does not expect to provide funding for patients to continue treatment commenced as part of a clinical trial. This is in line with the Medicines Act 2004 and the Declaration of Helsinki which stipulates that the responsibility for ensuring a clear exit strategy from a trial, and that those benefiting from treatment will have ongoing access to it, lies with those conducting the trial.

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2 For the purpose of this policy the definition of clinically urgent is; a significant chance that a life threatening event or major function failure will occur if the case waits until the meeting of the next Commissioning Request Panel meeting. It will be for the requesting clinician to clearly demonstrate the likelihood of this event occurring and the severity of its impact.
(c) Requests for referral to a specialist provider

The majority of referrals to specialist centres are made by secondary care consultants. The Primary Care Trust expects consultants to refer patients for tertiary/specialist care using established pathways covered by Service Level Agreements and in line with national guidance on Patient Choice. Accordingly, requests for referrals to specialist providers, outside existing pathways, will usually only be considered after an assessment by appropriate specialists within the existing pathway.

Should a local consultant decide that a referral outside existing pathways is a priority for a particular patient, the consultant shall ask for the case to be considered by the Commissioning Request Panel.

(d) Decisions inherited by other Primary Care Trusts

Occasionally patients move in to the area when a package of care or treatment option has already been approved by their previous Primary Care Trust. NHS Central Lancashire may honour such decisions, providing the care pathway has already been initiated (for example an appropriate referral has already been made and approved).

(e) Requests for NHS Continuing Healthcare

All requests for Continuing Healthcare (CHC) are dealt with in accordance with the “National Framework For NHS Continuing Healthcare and NHS-Funded Nursing Care” (DH Oct 2007, revised July 2009. Gateway reference 11509 ). The process is set out in the NHS Central Lancashire CHC Operating Framework.

(f) Retrospective funding of treatment already commenced

It is the responsibility of the requesting clinician to ensure that requests for funding are made prior to treatment commencing, funding will not normally be approved retrospectively. If a non-commissioned treatment has been started prior to approval for funding being given (for example, in a clinical emergency), the risk for funding this treatment sits solely with the providing organisation. Retrospective funding requests for patients who have already funded private treatment will not be considered.

EXCEPTIONAL CLINICAL CIRCUMSTANCES

44. In order for a patient to be considered as exceptional, the Commissioning Request Panel must be persuaded that the patient has a clinical picture that is significantly different to the general population of patients with that condition at the stage of progression of the condition as the requesting patient and as a result of that difference, the patient is likely to derive greater benefit from the intervention than might normally be expected for a patient with that condition.

45. The key question that the Panel will consider is one of equity: “why should funding be made available to the patient in question when the treatment is unavailable to others with the same condition?”
46. NHS Central Lancashire will consider exceptionality on purely clinical grounds. To consider social and other non-clinical factors, including those which cause unhappiness rather than ill health, would imply that some patients have a higher intrinsic social worth than others with the same condition. To do so would be in conflict with the principles that guide the NHS as stated in the NHS Constitution, 2009.
APPENDIX A  ETHICAL FRAMEWORK

The Ethical Framework is the tool that underpins decision making in priority setting, both for policy-making and when considering individual patients’ requests for funding of treatments ‘not normally funded’ by the Primary Care Trust.

EVIDENCE OF CLINICAL AND COST EFFECTIVENESS

1. The Primary Care Trust will seek to obtain the best available evidence of clinical and cost effectiveness using robust and reproducible methods.

2. Methods to assess clinical and cost effectiveness are well established. The key success factors are the need to search effectively and systematically for relevant evidence, and then to extract, analyse, and present this in a consistent way.

3. Choice of appropriate clinically and patient-defined outcome needs to be given careful consideration, and where possible quality of life measures and cost utility analysis should be considered.

4. The Primary Care Trust will promote treatments for which there is good evidence of clinical effectiveness in improving the health status of patients and does not normally commission a treatment unless it has been shown to be clinically effective.

5. Issues such as safety and drug licensing will also be carefully considered. When assessing evidence of clinical effectiveness the outcome measures that will be given greatest importance are those considered important to patients’ health status. Patient satisfaction will not necessarily be taken as evidence of clinical effectiveness.

6. Trials of longer duration and clinically relevant outcomes data may be considered more reliable than those of shorter duration with surrogate outcomes. Reliable evidence will often be available from good quality, rigorously appraised studies. Evidence may be available from other sources and this will also be considered.

7. Patients’ evidence of significant clinical benefit is relevant.

8. When weighing the relative priority of different treatments, NHS Central Lancashire will consider the strength of health benefit; the size of any potential health benefit (deaths prevented, quality of life years gained); the probability of health benefit.

9. NHS Central Lancashire will compare the cost of a new treatment to the existing care provided and will also compare the cost of the treatment to its overall benefit, both to the individual and the community. They will also consider technical cost-benefit calculations (e.g. quality adjusted life years), but these will not by themselves be decisive. NHS Central Lancashire may use the Ethical Framework to guide context-specific judgements about the relative priority that should be given to each topic.
10. In considering very high cost interventions, NHS Central Lancashire may conclude that an intervention is not cost effective even if it is proven to be clinically effective in saving or extending the lives of patients. Where a decision is made that a high cost intervention is not to be routinely funded, NHS Central Lancashire will always consider the exceptional circumstances of an individual request for a high cost intervention.

EQUITY

11. NHS Central Lancashire believes that people should have access to health care on the basis of need. There may also be times when some categories of care are given priority in order to address health inequalities in the community.

12. NHS Central Lancashire will not discriminate on the grounds of personal characteristics, such as age, gender, sexual orientation, gender identity, race, religion, lifestyle, social position, family or financial status, intelligence, disability, physical or cognitive functioning.

13. In some circumstances the above factors may be relevant to the clinical effectiveness of a proposed treatment or the cost effectiveness of an intervention. These factors, along with other medical conditions from which a patient is suffering, may affect the capacity of an individual or groups within the population to benefit from the treatment. In such circumstances, as an exception to the above policy, the PCT is entitled to limit access to defined treatments by reference to some of the above factors.

HEALTH CARE NEED AND CAPACITY TO BENEFIT

14. Health care should be allocated justly and fairly according to need and capacity to benefit, such that the health of the population is maximised within the resources available. NHS Central Lancashire will consider the health needs of people and populations according to their capacity to benefit from health care interventions. So far as possible, it will respect the wishes of patients to choose between different clinically and cost effective treatment options, subject to the support of clinical evidence. This approach leads to three important principles:

- In the absence of evidence of health need, treatment will not generally be given solely because a patient requests it.
- A treatment of little benefit will not be provided simply because it is only treatment available.
- Treatment which effectively treats ‘life-time’ or long-term conditions will be considered equally to urgent and life prolonging treatments.

COST OF TREATMENT AND OPPORTUNITY COSTS

15. The Primary Care Trust is required by the National Health Service Act 2006 not to exceed its annual budget. The PCT therefore has a legal duty to take account of the cost of treatment. The cost of treatment is significant because investing in one area of health care inevitably diverts resources from other
uses. This is known as opportunity costs and is defined as benefit foregone, or value opportunities lost, that would accrue from the notion of scarcity of resources.

16. Prioritisation decisions must be taken with full consideration of the consequences for funding other priorities.

NEEDS OF THE COMMUNITY

17. One of the NHS Central Lancashire’s key objectives is to make decisions to improve the health of its population and reduce health inequalities. Some of these decisions are promoted by the Department of Health through National Service Frameworks and NICE. Others are produced locally and should be made with reference to our local Joint Strategic Needs Assessment and local public engagement processes.

18. Sometimes the needs of the community may conflict with the needs of individuals. There can be difficult decisions where an individual patient needs a considerable investment to support their health but where the same money could be used to greater overall effect for a group of patients, and the Primary Care Trust cannot afford both sets of treatment.

POLICY DRIVERS

19. The Department of Health issues guidance and directions to NHS organisations. These Directions require the Primary Care Trust to give priority to some categories of treatment for some patients. The Primary Care Trust is legally required to consider (but not necessarily implement in full) Department of Health Guidance. Both Directions and Guidance may affect the way in which health service resources are allocated by the Primary Care Trust.

EXCEPTIONAL NEED

20. NHS Central Lancashire is not permitted to impose a blanket ban on any treatment as a result of the “Directions to Primary Care Trusts and NHS Trusts Concerning Decisions about Drugs and Other Treatments” (Secretary of State for Health, 2009). It recognises that there may be cases in which a patient has exceptional clinical circumstances which may justify funding for treatment that is denied to other patients. Each case of this sort will be considered on its own merits in the light of the clinical evidence.

21. NHS Central Lancashire has procedures in place to consider such exceptional cases on their merits through the CRP. This process is outlined in Appendix C.
APPENDIX B - COMMISSIONING PRINCIPLES

1. A Commissioning Organisation will only commission interventions which fulfil all of the following criteria:
   - Appropriate
   - Effective
   - Cost effective
   - Ethical

**Appropriate**

2. A Commissioning Organisation defines an appropriate intervention as
   - One which has the intended outcome of preventing, diagnosing or treating a medical condition. The Commissioning Organisation defines a medical condition as any illness, injury or impairment in which there is an abnormality in the structure or function of the body.
   - One which ensures dignity at the time of death.
   - One which has the intended outcome of preventing unwanted pregnancy.
   - One which has the intended outcome of managing a normal pregnancy

3. A Commissioning Organisation categorises appropriate interventions as follows:
   - Those which are appropriate for current commissioning – this includes any intervention for which the intended outcome is to
     - preserve life, or
     - prevent or relieve pain, disability or physical discomfort, or
     - directly address the distress or disability associated with a diagnosed mental health condition, or
     - maintain dignity at the time of death
   - Those which are appropriate for aspirational commissioning – this includes interventions which are by definition appropriate for commissioning but have an intended outcome which is other than those listed in 2.2 above

4. A Commissioning Organisation will only consider commissioning interventions which are in the aspirational subcategory if its financial position permits.

5. Any new procedure for which there is no budgetary provision in the current financial year may be placed in the aspirational category until such time as the budget can be prioritised.
Effective

• The Commissioning Organisation defines an effective intervention as one which is capable of achieving its intended outcome as demonstrated by research evidence and of doing so without causing undue harm.

• In assessing whether an intervention is effective the Commissioning Organisation will normally consider the content and quality of the available research and evidence.

• A treatment of little benefit will not be provided simply because it is the only treatment available.

• The Commissioning Organisation will not normally commission an intervention for which evidence of effectiveness is unavailable unless it is delivered as part of high quality research which complies with the Commissioning Organisation’s Research Governance Framework (See separate policy on Commissioning within Research).

Cost effective

• The Commissioning Organisation defines a cost effective intervention as one which represents good value for money in comparison with other possible uses of that money.

• The Commissioning Organisation will not normally commission any intervention which does not meet the National Institute for Health and Clinical Excellence’s criteria for cost effectiveness.

Ethical

• The Commissioning Organisation defines ethical healthcare as that which is provided justly and fairly according to need such that the health of the population is maximised within the resources available.

• The Commissioning Organisation will commission interventions based on the health and healthcare needs of its resident population, as assessed by the Commissioning Organisation. In doing so it will seek to reduce health inequalities within the population.

• The Commissioning Organisation commissioning policies will not discriminate on the basis of age, gender, sexual orientation, race, religion, lifestyle, occupation, social position, financial status, family status (including responsibility for dependants), intelligence, disability, physical or cognitive functioning. However if there is robust evidence that these factors affect the effectiveness of an intervention, the Commissioning Organisation may take this into account in its commissioning policy.

• The Commissioning Organisation will not commission a service simply because that service is commissioned by another Commissioning Organisation or Commissioning Organisations.

• The Commissioning Organisation will not commission for one patient an intervention which cannot be afforded for all patients with the same clinical need.

• In the absence of evidence of health need, treatment will not generally be given solely because a patient requests it.
• The Commissioning Organisation will not continue or retrospectively fund any intervention which it does normally commission and which has been commenced outside the NHS, irrespective of the apparent benefits. This includes interventions received as part of research trials and interventions commenced through self funded treatment in the private sector.

• The Commissioning Organisation respects the rights of individuals to determine the course of their own lives, including the right to be fully involved in decisions concerning their healthcare. However this has to be balanced against the Commissioning Organisations responsibility to ensure equitable and consistent access to quality healthcare for all the population.
APPENDIX C - THREE STAGE PROCESS - FUNDING REQUESTS

Stage 1 – Triage against existing policies and referral criteria:

1. This will be carried out by the Contracting Officer (who manages the individual request process) and the Medical Director who has executive responsibility for the process. In the case of annual leave or sickness absence this process can be carried out by any Director plus any manager with knowledge of the policies and process.

2. At the first stage, following validation that the patient is registered with an NHS Central Lancashire general practitioner, the request will be considered against any existing commissioning policies and/or protocols or clinical criteria that have been previously agreed. The Officer and Director can action the following outcomes:

- If the request clearly meets the funding criteria in a commissioning policy, the request will be approved.

- If the request does not meet the criteria in an existing policy the request will be turned down, in line with the specified policy.

- If the request is claiming exceptionality or if there is any uncertainty as to whether the circumstances of the request meet the criteria outlined in a commissioning policy, then an appropriate clinical opinion will be sought.

- If the request is for a medicine which is being requested outside its normal use or contrary to NICE guidance, advice will be sought from the Medicines Management Team.

- If the request is for an unusual treatment which is for a variation on the normal clinical pathway, advice will be sought from the Consultant in Public Health or the North West Specialised Commissioning Team.

- If the request is for a new treatment, not previously considered by the Primary Care Trust, it may be identified as a service development and will be deferred to the corporate business planning process. In this instance funding for the patient in question will rarely be approved prior to the completion of this process unless there is substantial evidence of the exceptional clinical circumstances.

- If the request fulfils the Continuing Healthcare criteria, Chairs Action can be taken for fast track cases and other cases by the Associate Director and ratified at the next Panel.

3. If there is any uncertainty over any of these decisions at this stage, the Officer and Director shall refer to the Commissioning Request Panel.

4. Where it is possible to make a decision at this stage, either a signed proforma or a letter will be sent to the requesting clinician authorising the treatment. Where the decision is one not to fund, the letter will give a detailed
explanation as to why the decision not to fund has been made and include any relevant policies.

Stage 2 – Presentation of IFR to Commissioning Request Panel

1. The Commissioning Request Panel meets bi-monthly and provide quarterly reports on its decisions to the Clinical Executive Committee and six monthly reports on the governance issues to the Quality and Strategy Committee.

2. The Terms of Reference for the committee are included at Appendix E

3. The membership of the Commissioning Request Panel are approved by the Primary Care Trust Board and the Clinical Commissioning Executive Committee. The membership includes the Director with executive responsibility for the process, Clinical Executive clinicians, public health professionals, and representatives from community provider, social services, commissioning, public health and continuing healthcare professionals will support the Commissioning Request Panel as required. Quoracy is set out in the Terms of Reference.

4. Where the application raises particular technical issues, the Commissioning Request Panel may call on expert/s to enhance its understanding of the relevant issues.

5. Following submissions from the clinicians supporting the case (if in attendance) and any expert who has been called upon to advise the Panel, the Commissioning Request Panel shall retire to make a decision on the application. Attendees at the Panel who have been invited, will be asked to leave prior to discussion of the application by the Panel Members.

6. The Commissioning Request Panel shall be entitled to approve requests for funding for treatment for individual patients where all four conditions are met. These are:

   • Either (a) the request for funding is for a treatment in connection with a presenting medical condition for which the PCT has no policy or (b) the clinician makes an exceptionality request for funding for treatment in connection with a medical condition for which the PCT has a policy and where the patient has demonstrated exceptional clinical circumstances; and
   
   • There is sufficient evidence to show that, for the individual patient, the proposed treatment is likely to be clinically effective; and
   
   • Applying the approach that the PCT takes to the assessments of costs for other treatments outside this policy, the cost to the PCT of providing funding to support the requested treatment is justified in the light of the benefits likely to be delivered for the individual patient by the requested treatment; and
• The Panel concludes that there are likely to be no similar patients to the patient in question presenting in the current financial year (in which case the request is properly characterised as a service development and should be considered as such).

7. The Panel shall reach a decision based on consensus. Where the Panel finds it difficult to reach a decision on the basis of consensus, the chair shall inform the Panel that a decision on a majority basis shall be taken. If required the chair shall have a casting vote.

8. The decision of the panel will be notified to the requesting clinician in writing within 10 working days of the panel meeting. Where the decision is one not to fund the letter will give a detailed explanation as to why the decision not to fund has been made and include any relevant policies.

9. When the Commissioning Request Panel makes a decision to fund a treatment, regular reports will be submitted to the Clinical Commissioning Executive Committee to advise them of the types of activity and compliance with the best practice timelines for handling requests.

10. The CCEC will then consider whether an in year policy is required to commission the service. This decision will be based on examination against wider priorities and pressures within the organisation and will be processed via the Primary Care Trust’s corporate business planning process.

**Emergency Decisions**

11. In clinically urgent situations (definition of clinically urgent is included in footnote,) a request may be considered before the next Panel meeting. Emergency decisions will be made by any three of the following four: Director with executive responsibility for the process, Chief Executive, Medical Director, Public Health Specialist, Associate Director Contracting.

12. Deliberations may take place via email and a formal meeting might not take place. Records of all correspondence and conversations will be kept, dated and filed with the case.

13. In urgent cases the Primary Care Trust will notify the requesting clinician of a decision as soon as possible, depending on the nature of the clinical urgency.

**Stage 3 – Appeals against decisions**

1. Clinicians and patients, provided they are supported by the referring clinician, will be entitled to appeal against the process to reach decisions, made by either the Commissioning Request Panel or through Chair’s Action. When a decision is made not to fund a treatment, the letter outlining this decision will include details of the appeals process.

2. Challenges against continuing healthcare decisions follow the National Service Framework pathway recommendations which is separate to this process.
2. Appeals must be made in writing to the Chief Executive within two months of the original decision. The Primary Care Trust will provide clarification of the appeals process to appellants if required.

3. Appeals will be considered by the IFR Review Panel (IFRRP). The Review Panel membership will consist of: Non Executive Director, two Executive Directors, one of whom should be a senior clinician from the Primary Care Trust. The Director with executive responsibility for either the bespoke care or continuing healthcare processes should not be involved in the IFRRP process.

4. The IFRRP consider:

   • Whether there is any new evidence relevant to the case, which was not available to the original decision makers. If this is the case the Review Panel will ask the Commissioning Request Panel or Director to reconsider the case in light of this new evidence,

   • Whether the Primary Care Trust followed the correct defined procedure and principles for considering the case. If the correct process was not followed, or if principles were wrongfully applied the IFRRP may ask the Commissioning Request Panel or Director to reconsider the case with guidance on the correct procedure and principles to be followed.

   • Was this a decision which was within the reasonable range of decisions that a reasonable Commissioning Request Panel could have reached.

5. The IFRRP cannot overturn a decision made by the Commissioning Request Panel or Director. It can uphold the decision not to fund.

6. The requesting clinician and/or patient can attend the IFRRP to give additional evidence. The Panel can invite appropriate experts to give additional evidence if required.

7. Following presentation of this evidence the IFRRP will retire to carry out its deliberations. Attendees at the IFRRP who have been invited will be asked to leave prior to discussion of the appeal by the Panel members.

8. The IFRRP shall reach its decision on the basis of consensus. In the unlikely event that this is not possible, the chair shall put the decision to a vote with all members of the Panel having one vote each.

9. The decision of the IFRRP will be communicated to the appellant within 10 working days of the meeting.

10. The policy and procedures for the IFRRP is set out in Appendix F.
APPENDIX D  THE FUNDING REQUEST PROCESS

1. It is important that this process is not allowed to destabilise or circumvent the corporate business planning process.

2. Requests should only be made where there are genuine grounds for clinical exceptionality, or a medical condition where the Primary Care Trust does not yet have a commissioning policy. All requests will be considered in light of the policy context and background (Annex 1) and the ethical framework included in the Commissioning Principles Framework.

Making a request

3. It is the responsibility of the requesting clinician to submit a request for funding prior to the treatment taking place. Requests should be made on our Commissioning Request Form (Annex ). Requests can only be received from clinicians as we cannot receive requests directly from patients as full clinical evidence is required.

4. Completed forms should be sent to:

   Contracting Officer  
   NHS Central Lancashire  
   Jubilee House, Centurion Way  
   Leyland, Lancashire  
   PR26 6TR  tel: (01772 644405)       fax (01772 227024)

   Email: 

5. It is important that applications for funding are completed in full and that all supporting evidence is fully referenced and appended. The request will not be considered until all relevant information has been provided, including a quote for the costs of the treatment.

6. When making a case for exceptionality from any of our existing policies, it is for the requesting clinician to make explicit the case for clinical exceptionality and outline the justification for this case (including any supporting information).

Response Times

7. Acknowledgement of the clinician’s request within 5 working days where this is appropriate (some requests can be managed with one or two days)

   with either a decision if request fulfills policy, protocol or clinical criteria for treatment or

   setting out course of action that will happen i.e. referral to public health team, medicines management team, specialised commissioning team, commissioning panel.

8. NHS Central Lancashire aims to decide on all cases within 25 working days of receipt of the detailed request including all of the relevant supporting information.

9. The start date for the request will run from the date that all the requisite information has been received the by Primary Care Trust.

10. A written response will be sent from Panel within 10 working days.

11. The signed Chairs Action sheet will be copied to the Continuing Care Teams.
12. Where the request is particularly complex, or further information from the applicant is needed, we may not be able to make a decision in this time scale. If this is the case the Primary Care Trust will write to the requesting clinician within the first 28 days outlining the reason for the delay. A letter will be sent to the patient enclosing a copy of the letter sent to the referer.
## APPENDIX E

### NHS Central Lancashire

### Individual Funding Request Form

<table>
<thead>
<tr>
<th>Question</th>
<th>Response</th>
</tr>
</thead>
<tbody>
<tr>
<td>1  Patient’s NHS number</td>
<td></td>
</tr>
<tr>
<td>2  <strong>Patient’s details</strong> <em>(please include date of birth and gender as a minimum)</em></td>
<td></td>
</tr>
<tr>
<td>3  <strong>GP Details</strong> <em>(include GP name and surgery)</em></td>
<td></td>
</tr>
<tr>
<td>4  <strong>Referring clinician name and contact details</strong></td>
<td></td>
</tr>
<tr>
<td>5  <strong>Treatment or intervention requested</strong> <em>(e.g. is it for a second opinion; procedure; or new treatment?)</em> Please give as much detail as possible on the nature and duration of treatment</td>
<td></td>
</tr>
<tr>
<td>6  <strong>Brief summary of clinical condition</strong> <em>(Please supply as much detail as possible about: severity, duration and prognosis)</em></td>
<td></td>
</tr>
<tr>
<td>7  <strong>Previous treatment(s)</strong> <em>(Please list all previous treatments and whether they were ineffective or not tolerated.</em></td>
<td></td>
</tr>
<tr>
<td>8  <strong>Relevant past medical history</strong></td>
<td></td>
</tr>
<tr>
<td>9  <strong>What is the standard treatment and why is this not appropriate?</strong></td>
<td></td>
</tr>
<tr>
<td>10 <strong>Why is this particular treatment being considered now?</strong></td>
<td></td>
</tr>
<tr>
<td>11 <strong>Who will provide this treatment/intervention?</strong></td>
<td></td>
</tr>
<tr>
<td>12 <strong>What is the evidence of effectiveness of this treatment in</strong></td>
<td></td>
</tr>
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<td></td>
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<tr>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td>13</td>
<td><strong>What will the treatment cost and what other costs will be avoided?</strong> Is this in addition or instead of current treatment?</td>
</tr>
<tr>
<td>14</td>
<td><strong>What benefit would you expect the patient to derive from this treatment/ intervention?</strong> This should be expressed as a patient orientated outcome e.g. improvement in pain score, increased functionality, rather than a disease orientated outcome e.g. physiological marker</td>
</tr>
<tr>
<td>15</td>
<td><strong>How will the response be measured?</strong> Please provide details, including time frame, for assessing whether the intervention is effective</td>
</tr>
<tr>
<td>16</td>
<td><strong>What could be the consequences of not having this treatment?</strong> Please give details of any alternative treatments</td>
</tr>
<tr>
<td>17</td>
<td><strong>What is the licensing status of the treatment?</strong> e.g. is this a licensed treatment used in its licensed indication, or outside its licensed indication, or an unlicensed treatment?</td>
</tr>
<tr>
<td>18</td>
<td><strong>Is the treatment being used as part of a clinical trial?</strong> If so, please provide information on how ethical approval was obtained and details of post-trial funding arrangements.</td>
</tr>
<tr>
<td>19</td>
<td><strong>Has the patient been informed of any clinical risks?</strong> Please outline the risks discussed with the patient</td>
</tr>
<tr>
<td>20</td>
<td><strong>Has the treatment been considered by the Trust Drug &amp; Therapeutic Committee or other processes?</strong> If so, please give details. <strong>N.B.</strong> Trust approval does not mean that the request will be automatically approved</td>
</tr>
<tr>
<td>21</td>
<td><strong>Has the patient given consent for</strong></td>
</tr>
<tr>
<td>all information relating to their case to be shared with the Panel?</td>
<td></td>
</tr>
<tr>
<td>-------------------------------------------------</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>22</th>
<th>For panel use only</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Funding approved – yes/no</td>
</tr>
<tr>
<td></td>
<td>Reason(s) for approval/non-approval</td>
</tr>
<tr>
<td></td>
<td>Further action/information required</td>
</tr>
</tbody>
</table>

Signature of requesting clinician

Date

Please send the completed form to:

Contracting Officer  
NHS Central Lancashire  
Jubilee House, Centurion Way  
Leyland, Lancashire  
PR26 6TR  
tel: (01772 644405)  
fax (01772 227024)  
Email:
APPENDIX F

COMMISSIONING REQUEST PANEL

TERMS OF REFERENCE

CONSTITUTION

1. The Quality and Strategy Committee has approved the establishment of the Commissioning Request Panel in respect of governance reporting and the Panel will report its clinical decisions to the Clinical Executive Committee. Any changes to these Terms of Reference must be approved by the Quality and Strategy Committee.

MEMBERSHIP

2. The Panel shall include the following members:

   a) Medical Director (Chair)
   b) CCEC GP representative
   c) Associate Director – Acute Contracting or Associate Director Community/Primary Care
   d) Associate Director, Medicines Management or deputy
   e) 2 nominated senior clinicians from NHS Central Lancashire Provider Community Care Team
   f) Consultant In Public Health
   f) Contracting – Specialised Services Lead

   All members to have nominated deputies

ATTENDANCE

3. A Contracting Manager will be in attendance.

4. The Panel may also extend invitations to other personnel with relevant skills, experience or expertise as necessary to deal with the business on the agenda. Such personnel will be in attendance and will have no voting rights.

QUORUM

5. A meeting will be quorate if at least three members are in attendance, including:

   a) Medical Director or nominated Deputy
FREQUENCY OF MEETINGS

6. As a minimum, meetings will be held on the first Thursday of each month with the dates and times to be determined by the Panel. The Chair may also convene a meeting should he/she be of the opinion that a view needs to be taken on an urgent application /matter.

AUTHORITY

7. The Commissioning Request Panel is authorised by the Quality and Strategy Committee and the Clinical Commissioning Executive Committee
   a) to investigate any activity within its terms of reference;
   b) to be responsible for ensuring compliance with financial, governance and World Class Commissioning arrangements when undertaking its terms of reference;
   c) To make funding decisions in accordance with the delegated limits as outlined in the Corporate Governance Manual.

DUTIES

8. In particular the Commissioning Request Panel will
   a) consider and, if appropriate, approve applications from eligible patients for funding intervention/s or treatment/s which fall under the category of non contractual activity.
   b) ensure that, when considering the said applications, the Panel acts in line with relevant existing Primary Care Trust and national policy.
   c) consider and determine defined cases of NHS Continuing Healthcare referred to it by the patient and/or her/his representatives.
   d) ensure that, when considering the said applications, the Panel considers and if appropriate follows any existing good practice guidance.
   e) ensure [where practicable] that it reaches its decisions in a timely manner.
   f) ensure that the decisions of the Panel are transparent and easy to understand by the public.
   g) ensure that the business of the Panel is conducted with appropriate degree and level of confidentiality.

REPORTING

9. The Panel will have the following reporting responsibilities:

3 The Panel shall reach a decision concerning the appropriate package of care to be provided to a patient who is eligible for as to NHS Continuing Healthcare.

30 Individual funding request /Commissioning principles and process framework - April 2011
a) to ensure that the anonymised minutes of its meetings are formally recorded.
b) any items of specific concern will be reported to the Clinical Commissioning Executive Committee;
c) to provide exception reports to the Clinical Commissioning Executive Committee highlighting reasons in respect of complex cases that required longer timescales to manage the request.

REPORTING GROUPS

10. The Commissioning Request Panel will be required to submit the following information to the Quality and Strategy Group

a) Terms of Reference for formal approval and review;

and to the Clinical Commissioning Executive Committee

b) Quarterly reports

RESPONSIBILITY OF PANEL MEMBERS AND ATTENDEES

11. Members of the Panel have a responsibility to:

- Undertake IFR training
- Make a declaration of interest
- attend meetings, having read all papers beforehand;
- ensure that any decisions made are in line with the relevant Primary Care Trust policy
- ensure that they declare any interest in a case under consideration prior to the commencement of the deliberations The chair shall then determine whether such an interest amounts to an interest which could deemed to a “conflict of interest”. If so, the Chair shall take the appropriate action.

ADMINISTRATIVE ARRANGEMENTS

12. The responsible Director will ensure the correct minutes are taken, and once agreed by the Chair, within 10 working days, distributing minutes to the members. The minutes must include:

- Declaration of Interests
- Background to the application
- The key points of the application
- The issues raised by the referring clinician including an accurate description of the issues.
- The Panel’s response to the issues raised by the referring clinician
- Main issues which emerged in the course of the discussion
- Reference to relevant Primary Care Trust policies.
- The reasons for a decision where a decision is reached by consensus or the reasons for individual members of the Panel where a vote is held.
• the decision of the Panel is communicated to the requesting clinician within the timescales determined by the relevant Primary Care Trust policy.
• producing an action list following each meeting and ensuring any outstanding action is carried forward on the action list until complete;
• providing appropriate support to the Chair and Panel members
• agreeing the agenda with the Chair prior to sending papers to members no later than four working days before the meeting;
• the papers of the Panel are filed in accordance with the Primary Care Trust’s policies and procedures.

REVIEW

13. Terms of Reference will normally be reviewed annually.

AGENDA

14. The agenda will be divided up into sections relating to the different types of cases whilst there is one panel for all cases.

   a) Individual Funding Requests
   b) Treatments, Procedures, Drugs
   c) Continuing Care Cases
   d) Complex Cases children
   e) Mental Health cases
   f) Chairs Action list
ANNEX G - IFR REVIEW PANEL POLICY AND PROCEDURE

Introduction

1. There is no statutory requirement for primary care organisations to hold appeals but in line with best practice, NHS Central Lancashire does allow appeals to be made against the process that was followed to arrive at a decision.

Background

2. The IFR Review Panel is the group NHS Central Lancashire has formally appointed to receive and determine all appeals concerning commissioning decisions made by the Commissioning Panel.

Scope

3. Membership of the IFR Review Panel will consist of NHS Central Lancashire Executive and Non Executive Directors

   A Non Executive PCT Director
   Two Executive Directors
   Chair of Clinical commissioning Executive

   Assisted and advised, as required by

   Relevant clinical advisor and/or
   Relevant independent clinical expert
   PCT legal advisor

Principles

4. NHS Central Lancashire operates the IFR Review Panel (IFRRP) to consider any appeals to commissioning decisions made by the Commissioning Panel.

5. The appeals policy provides a review mechanism to ensure that all the agreed processes required to reach a decision for an individual funding request, were followed. The IFRRP has a role to review the process to reach the decision and not to change the actual decision.

6. The IFRRP will meet to consider whether:

   • The Commissioning Request Panel acted in accordance with the specified operating procedures
   • Its decision was consistent with the Ethical Framework for decision making and the principles set out in the IFR policy
   • The scope and nature of evidence considered was appropriate
   • In reaching its decision the IFR had taken into account and weighed all relevant factors
7. If the appeal request appears to provide substantially fresh evidence which was not apparently available to the Commissioning Panel, the IFRRP may remit the matter back to the original Commissioning Panel for fresh determination.

8. The decision of an IFR commissioning panel can be appealed on the grounds of:

- **Illegality**: The refusal of the request was not an option that could lawfully have been taken by the IFR Panel.

- **Procedural impropriety**: There were substantial and/or serious procedural errors in the way in which the IFR Process was conducted.

- **Irrationality**: The decision to refuse funding for the requested treatment was a decision which no reasonable IFR Panel could have reached on the evidence before the panel.

**Implementation**

**Making an appeal**

9. Appeals to the Review Panel (IFRRP) should be made in writing, addressed to the Chief Executive of NHS Central Lancashire and be made on behalf of the patient by the referring clinician and set out the basis of the appeal.

10. Where the patient is challenging the decision and the process, a letter will be sent to them advising the proposed course of action i.e. referral back to Commissioning Panel or to establish a Review Panel.

11. In order to maintain separation between the IFR process and the Appeal process, the IFR team should not be involved in any of the administration surrounding an Appeal.

12. The clinician and or the patient should be advised that at the hearing, they can attend alone and / or in the company of a friend or Advocate (clinical or non-clinical). They also may prefer to send a written supporting statement.

13. A minimum of five working days notice of the date of the hearing must be given to allow the patient to make domestic arrangements and also prepare for the appeal. This may be extended by mutual consent. The following items must be included in the letter.

- the date, timed and venue of the hearing
- the names and post titles of the Panel member
- the reason for the appeal
- copies of any reports, statement for information that will be relied on or referred to at the hearing
- copies of correspondence relating to the case
- clinical guidance or relevant policy
Appeal Panel arrangements

14. Prior to the Hearing, the IFRRP will read and consider the papers relating to the original Panel decision and all documents submitted by or on behalf of the patient.

15. The nominated Chair of the Panel will identify whether any medical expertise or legal support is appropriate for the hearing. This may not become apparent until the hearing has commenced.

16. The venue should be appropriate for the client/patient involved and able to accommodate both parties, plus the Review Panel members.

17. There should be separate waiting rooms, from which either party can be called into the hearing. Ideally, Boardroom 1 should be reserved for Review Panels.

At the start of the hearing

18. The IFRRP members will convene to consider the request and have had time to consider the papers before them.

19. A representative of the IFRRP will set out, orally, the process that was followed and the rationale for the decision.

20. The Review Panel may also ask questions of that representative.

21. The patient or their friend/advocate may then set out orally the basis of the Appeal and any other relevant factors which the patient wishes the IFRRP to take into account. [A patient may choose not to speak but to rely upon written submissions.]

22. The Review Panel may ask questions of the patient or advocate.

23. The members of the IFRRP will then adjourn the hearing to make their decision.

At the end of the hearing

24. The decision of the IFRRP will be communicated in writing to the parties within 10 working days of it being made and the decision shall provide reasons.

25. At any stage of the hearing, members of the IFRRP may seek advice from the Panel’s chosen clinical expert. At any stage during the hearing or during the decision making process the Panel may instruct its Legal Advisor to provide legal advice or assistance.

26. The decision of the Chair of the IFRRP regarding process and relevance shall be final.
Appendix H - Training for Panel Members

It is proposed that training should cover the following areas for new members and that a regular update session should be held annually.

- IFR policy and process, including Appeals
- Legal aspects of the work of IFR panels
- Healthcare ethics and applying the SEC Ethical Framework to decision-making
- Consensus decision-making
- Commissioning practice and PCT funding decisions
- Critical appraisal skills
- Methods of assessment of clinical and cost effectiveness
- Confidentiality, data security, Caldicott principles and the requirements of the Data Protection Act and the Freedom of Information Act
- The work of PALS and the NHS Complaints process
- Media handling and coverage
Appendix I - Communication Strategy

1. Copies of the Commissioning Principles Framework and its associated supporting documents will be available on the NHS Central Lancashire’s website, together with the Commissioning Policies.

2. The communication link at all times will be through the referring clinician and with copied correspondence to the patient’s general practitioner. A copy of the response letter to the clinician will be sent to the patient.

3. Copies of the Individual Funding Request leaflets will be available in all GP practices and copies will be circulated to local Trusts. The leaflet is intended to help patients and clinicians to understand the process that is followed to reach decisions.

4. Awareness raising of the IFR process will be undertaken with GPs and clinicians on annual basis.
Appendix J - COMMISSIONING POLICIES (available on PCT website)

- Acupuncture
- Alternative/complementary therapy
- Bariatric surgery services policy
- Cosmetic breast procedures
- Cosmetic facial procedures policy
- Cosmetic procedures for hair, skin and subcutaneous lesions policy
- Cosmetic procedures for body contouring
- Cosmetic facial procedures policy
- Ethical Framework
- Fertility Services
- Homeopathy policy
- NHS continuing healthcare retrospective review policy
- Patient access procedure
- Reversal of sterilisation
- Treatment of varicose veins
APPENDIX K

Going to a European Economic Area country or Switzerland in order to get treatment

1. Under European Union Regulations, a system exists for referral to another European Economic Area country or Switzerland specifically for medical care.

2. Two systems are in operation:
   - the E112 referral system which covers maternity care and referrals for specific medical treatment; and
   - the Direct Purchase Method where under some (limited) circumstances patients may arrange and pay for hospital treatment abroad and reclaim some of the costs from their UK health care provider.

3. The difference between the two systems is that the E112 arrangements provide treatment on the terms of the scheme in the country where treatment is provided (which may include a patient contribution to the costs) and the NHS pays the provider directly.

4. The direct purchase method provides care up to the financial limits applying in the home state. This is an evolving area of European legislation and practice in the United Kingdom. The Primary Care Trust would therefore be strongly advised to seek advice from the Department of Health on the latest position.

The E112 system

5. The Department of Health, or its equivalent in Northern Ireland, is responsible for authorising the treatment abroad and, if appropriate, for issuing an E112, basing its decision on recommendations made by local health commissioners. E112s are not issued automatically or on a ‘just in case’ basis. There must be a clear need for treatment.

6. In deciding whether to recommend to the Department of Health, or its equivalent in Northern Ireland, that a patient is given an E112, the local health commissioner [Primary Care Trust] will need to be satisfied that:

   • a UK NHS doctor - usually a hospital consultant - recommends that a patient be treated in the other country, and that a full clinical assessment has been carried out to demonstrate that the treatment will meet a patient’s needs;

   • the costs of sending the patient abroad for treatment are justified against the local health commissioner’s responsibilities for spending money efficiently and fairly in the interests of all the patients it looks after;

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4 There is a Directive going through the European Commission and European Parliament at present which will amend these provisions. This advice will need to be revised once the details are known.
• the treatment is available under the other country’s state health insurance scheme; and the patient is entitled to a European Health Insurance Card.

Rights to treatment under the E112 scheme

7. In some circumstances a local health commissioner must recommend that a patient is given an E112.

8. This is a situation where a patient cannot obtain the treatment in the UK without undue delay and where the treatment is of a kind provided by the NHS and is justified. In considering what constitutes undue delay, the local health commissioner will take into account all the circumstances of the case, including, if appropriate, the degree of pain or the nature of your disability and whether this affects, for example, a patient’s ability to do carry out her/his job.

Refusals to recommend treatment under the E112 system in another European Economic Area country or Switzerland

9. The local health commissioner [Primary Care Trust] will decide whether to recommend [but not decide] that a patient be treated abroad at public expense under the E112 system.

10. If a patient believes that she/he has the right to go abroad because of undue delay in her/his treatment and does not agree with the decision of the local health commissioner, she/he can apply direct to the Department of Health. The Department will consider whether to authorise the treatment and issue the E112, even though the local health commissioner has not recommended it.

11. The Department will not judge the medical facts of the case: the patient will need to ask the local health commissioner for a second NHS medical opinion if she/he is unhappy with the first one opinion. The Department will normally deal with direct applications within 20 working days of receiving the patient’s application.
ANNEX 1 - POLICY CONTEXT AND BACKGROUND

The NHS Constitution\(^5\) published in January 2009 is Guidance to the PCT. It confirms the existing right for patients to receive certain approved treatments, drugs and programmes:

- **You have the right** to drugs and treatments that have been recommended by NICE for use in the NHS, if your doctor says they are clinically appropriate for you.

- **You have the right** to expect local decisions on funding of other drugs and treatments to be made rationally following a proper consideration of the evidence. If the local NHS decides not to fund a drug or treatment you and your doctor feel would be right for you, they will explain that decision to you.

The National Prescribing Centre Supporting rational local decision-making about medicines (and treatments); a handbook of good practice guidance\(^6\) was published in February. The handbook is being used by the Primary Care Trust to undertake a comprehensive review of our arrangements that will inform any further revisions that are considered necessary.

In law, the Primary Care Trust has the powers to exercise discretion to set health priorities within national guidelines and allocate resources accordingly to meet the set priorities.

When exercising its discretion the Primary Care Trust is required to be aware of needs of its population and in establishing priorities [comparing the respective needs of patients suffering from different illness and determining the respective strengths of their claims to treatments], in law the Primary Care Trust would be required to at least (a) accurately to assess the nature and seriousness of each type to illness; (b) to determine the effectiveness of various forms of treatment for it; and (c) to give proper effect to that assessment and that determination in the formulation and the individual application of its policy.

When exercising its discretion in relation to designated NHS Continuing Healthcare, the Primary Care Trust shall have regard to the contents of Annex 3

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\(^6\) Supporting rational local decision-making about medicines (and treatments), National Prescribing Centre http://www.npc.co.uk
PATIENT CHOICE

Patients are entitled to choose clinically appropriate options from the national choice menu and to get the support and information they need to do so. GP practices are expected to discuss the clinically appropriate options available with their patients.

THE RELEVANT LAW

In law the Primary Care Trust is a public body [due to the fact it was created on a statutory basis]. It is subject to scrutiny by the courts and would be expected to conduct its business in line with the requirements of the Human Rights Act 1998.

The National Health Service Act 2006

The Act\(^7\) places a duty to the Secretary of State to: continue the promotion in England and Wales of a comprehensive health service designed to secure improvement: (a) in the physical and mental health of the people of those countries, and (b) in the prevention, diagnosis and treatment of illness and, for that purpose, to provide or secure effective provision of services in accordance with this Act.

It should be noted that above does not place a duty on the Secretary of State to provide a comprehensive health service. His duty is to “continue to promote” such a service. In addition, the services which he is required to provide have to be provided “in accordance with this Act”

The Secretary of State has a duty to provide a range of healthcare services including hospital and primary care “to such extent as he considers necessary to meet all reasonable requirements” and to do any other thing whatsoever which is calculated to facilitate, or is conducive or incidental to, the discharge of such a duty.

The duties under section 3 are not absolute. The Court of Appeal has held that the section imposes a duty to provide services in general but the NHS can choose which services it can afford to provide. The Secretary of State, and thus the PCT, is entitled to have regard to the resources made available to the NHS under current government economic policy in making those choices.

Delegation of the powers of the Secretary of State

Regulation 3 of the National Health Service (Functions of Strategic Health Authorities and Primary Care Trusts and Administration Arrangements) (England) Regulations 2002, SI/2002/2375, delegates the general duties of

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\(^7\) Which replaced the National Health Service Act 1977, which in turn replaced the National Health Service Act 1946.
the Secretary of State found in section 2 of the 1977 Act to Primary Care Trusts (Primary Care Trust’s) and Strategic Health Authorities as from 1 October 2002 for defined groups of patients, who are mainly the patients of GPs in the PCT’s area.

Sections 7 and 8 of the 2006 Act enable the Secretary of State to give directions to Primary Care Trusts which they must follow. By section 2 of the 2006 Act the Secretary of State also has power to issue guidance. PCTs and NHS trusts must have regard to such guidance.

The Primary Care Trust’s and, directions and guidance from Secretary of State

If the Secretary of State issues formal guidance [which is usually in a form of a circular or letter, rather than expressing views in a speech, press release or comments to a Select Committee], The Courts have said that “in the case of guidance, albeit in strong terms, then the only duty placed upon health authorities [Primary Care Trust’s] was to take it into account in the discharge of their functions. They would be susceptible to challenge only on Wednesbury\(^8\) principles if they failed to consider the circular, or if they misconstrued or misapplied it whether deliberately or negligently”.

If the Secretary of State issues Directions (which are usually separate documents titled “Directions”), then the PCT has an absolute duty to comply.

The courts have said they would be “slow to construe a document as a direction in the absence of clear words that, that is what it is intended to be. [“The language of the circular is very far from clearly demonstrating an intention to give directions. It is, of course, important to examine substance rather than form. The substance here is to be found in the language of the circular”- a quote from the litigation in relation to Herceptin]

COMMON LAW IN PRINCIPLES IN JUDICIAL REVIEW PROCEEDINGS

Human rights

The court may not interfere with the exercise of an administrative discretion on substantive grounds save where the court is satisfied that the decision is unreasonable in the sense that it is beyond the range of responses open to a reasonable decision-maker. But in judging whether the decision-maker has exceeded this margin of appreciation the human rights context is important. The more substantial is the interference with human rights, the more the court will require by way of justification before it is satisfied that the decision is reasonable.

Challenge under the Human Rights Act 1998


\(^8\) Wednesbury principles: The principles which the court use to decide whether the decisions taken by a public body are lawful.
incorporation is that the UK citizens can bring a claim against a public body in the UK court alleging breach of his or her rights under the Convention.

The Convention is made up of a number articles and protocols which confer legal rights to citizens of the UK. Most of the articles confer qualified rights, whereas a small number of articles confer absolute rights.

In relation to healthcare, the following articles 2 [right to life], 3 [inhuman and degrading treatment] and 8 [right to private and family life] have been raised in legal proceedings against NHS organisations.

**Article 2**
The right to life, while fundamental, is nevertheless not an absolute or unqualified right. While the Convention imposes a positive obligation on a signatory state to safeguard the lives of its subjects, it is highly unlikely that a domestic or the European Court of Human Rights would require an NHS body to fund a treatment irrespective of availability of resources or the other demands on those resources.

**Articles 3 and 8**
The decided cases indicate that the courts are reluctant to hold that article 3 should be engaged where there was a challenge to an NHS body’s allocation of finite resources between competing demands as illustrated by the quote in a judgment: “The Convention does not give the applicants rights to free healthcare in general, or to gender reassignment in particular. Even if the applicants had such a right it would be qualified by the respondent’s right to determine priorities in the light of its limited resources”. The Court of Appeal also held that article 8 imposes no positive obligations to provide medical treatment.

In a case involving the funding for bilateral hip replacement it was argued that [the patient argued that the Primary Care Trust in question should fund her treatment overseas when the treatment was not available promptly in the UK], the patient’s rights under articles 3 and 8 were breached. It was held that article 8 imposed no positive obligation to provide treatment and that article 3 was concerned with positive conduct with a high degree of seriousness and therefore did not apply to mere policy decisions on resource allocations.

**Resource allocation decisions**
The domestic courts recognise that resources in the health service are limited and that difficult decisions have to be made by Primary Care Trusts, as illustrated by this quote from a judgment by the Court of Appeal:

“I have no doubt that in a perfect world any treatment which a patient, or a patient's family, sought would be provided if doctors were willing to give it, no matter how much the cost, particularly when a life is potentially at stake. It would however, in my view, be shutting one's eyes to the real world if the court were to proceed on the basis that we do live in such a world. It is common knowledge that health authorities of all kinds are constantly pressed
to make ends meet ... Difficult and agonising judgments have to be made as to how a limited budget is best allocated to the maximum advantage of the maximum number of patients. That is not a judgment which the court can make. In my judgment, it is not something that a health authority such as this authority can be fairly criticised for not advancing before the court."

Another quote from the Court of Appeal supporting the view of finite resources:

“it is an unhappy but unavoidable feature of state funded health care that regional health authorities have to establish certain priorities in funding different treatments from their finite resources”.

The discretion available to Primary Care Trust’s when making resource allocations decisions

The courts recognise that Primary Care Trust’s do need to have discretion on allocation of resources in their localities [because of their local knowledge and varying health needs of their populations]. This recognition is illustrated in the following quote from a Court of Appeal judgment:

“It is natural that each authority, in establishing its own priorities, will give greater priority to life-threatening and other grave illnesses than to others obviously less demanding of medical intervention. The precise allocation and weighting of priorities is clearly a matter of judgment for each authority, keeping well in mind its statutory obligations to meet the reasonable requirements of all those within its area for which it is responsible. It makes sense to have a policy for the purpose - indeed, it might well be irrational not to have one - and it makes sense too that, in settling on such a policy, an authority would normally place treatment of transsexualism lower in its scale of priorities than, say, cancer or heart disease or kidney failure. Authorities might reasonably differ as to precisely where in the scale transsexualism should be placed and as to the criteria for determining the appropriateness and need for treatment of it in individual cases. It is proper for an authority to adopt a general policy for the exercise of such an administrative discretion, to allow for exceptions from it in 'exceptional circumstances' and to leave those circumstances undefined”

Further “In my view, a policy to place transsexualism low in an order of priorities of illnesses for treatment and to deny it treatment, save in exceptional circumstances such as overriding clinical need, is not in principle irrational [unlawful], provided that the policy genuinely recognises the possibility of there being an overriding clinical need and requires each request for treatment to be considered on its individual merits”.

Comment: The above quotes clearly indicate that an allocation policy which resulted in a “post code lottery” would not in principle be unlawful. However the key lawfulness of the policy would be judged on its merits and not on whether it resulted in led to a “post code lottery”.
Individual cases and exceptional circumstances

The decided cases suggest the following:

- that a policy on resource allocation, which stipulates a total ban on certain conditions/treatments or a group of conditions/treatments may be deemed to be unlawful;

- that for a policy which rules out funding for certain conditions/treatments can be lawful provided it makes provision by meaningful consideration of individual cases which may be exceptions to the policy;

- that where a policy states that individual cases may be funded in exceptional circumstances, then in general it should be possible to contemplate the type of circumstances which may be held to be exceptional. For instance in the above case on transsexualism, it was held that policy not to provide transgender surgery save in exceptional circumstances was potentially lawful. However if a PCT had a policy not fund an unlicensed drug except in exceptional individual circumstances, that is potentially lawful provided the restrictions are based on the allocation of resources. The court held where a patient met the clinical criteria for being able to benefit from treatment [based on clinical trial evidence], if the Primary Care Trust did not take resources into consideration it would not be able to distinguish between eligible patients on an individual basis and therefore take account of exceptional circumstances. The court took the view that the effect of the policy was that the Primary Care Trust would be able to say that it would not fund any case.

National Institute for Health and Clinical Excellence

Since January 2002, NHS organisations in England and Wales are required to provide funding for medicines and treatments recommended by National Institute for Health and Clinical Excellence in its technology appraisal guidance.

The NHS normally has three months from the date of the publication of each technology appraisal guidance to provide funding and resources.

Local NHS organisations are expected to meet the costs of medicines and treatments recommended by National Institute for Health and Clinical Excellence out of their general annual budgets.

If a drug or device is being appraised by National Institute for Health and Clinical Excellence, the NHS organisations should make decisions on its use locally using their usual arrangements, until the National Institute for Health and Clinical Excellence guidance is published.

Directions now mean that the PCT is obliged to have arrangements to consider individual cases outside established commissioning decisions.