

B/08/056

<b>Report to:</b>	Nottinghamshire County Teaching PCT Board
<b>Date of meeting:</b>	22 May 2008
<b>Title of paper:</b>	Policy on the Management of Named Patient Funding Requests
<p><b>Brief outline of content:</b></p> <p>The Individual Case Review Committee has been operational for approximately 1 year working to the existing terms of reference.</p> <p>The paper comprises a revised policy and procedure for the management of Named Patient Funding Requests and the functioning of the Individual Case Review Committee (ICRC). Processes for asking for a case to be reconsidered and for appeal are also clearly established.</p> <p>The ICRC has spent a good deal of time considering how processes can be more reflective of the patient voice. Improvements to the proposed policy for consideration today include: better and more direct correspondence with the patient following the committee meeting, the consistent use of patient information leaflets, the facility for patients (supported by their clinician) to make an application and, importantly, the inclusion of a new role of 'Lay Assessor' who will be a voting member of the ICRC.</p> <p>Key aspects of the policy (including the schedule of low priority procedures and the PCT decision-making principles) have been consulted upon with three patient involvement groups. The over-riding issue of concern for the involvement groups is that the PCT is seen to be consistent with neighbouring PCTs to guard against the accusation of 'postcode' healthcare.</p> <p>The East Midlands Specialised Commissioning Team will take over responsibility in-year for commissioning some services covered by this policy. The East Midlands Group are currently developing policies on Assisted Conception and Gender Re-assignment, for example. The Board is asked to approve this policy with the appendices A, F and J as interim PCT policies – to be replaced with immediate effect by the East Midlands policies, once these become available, following consultation on an East Midlands-wide basis.</p>	

Legal advice has been sought on the policy and the advice received has been incorporated into the revised policy presented today.

Two NHS Confederation documents on Priority Setting ('Managing Individual Funding Requests' and 'Legal Considerations') have been consulted in the development of this policy.

**Risk management implications (nature and level of risk mitigated and / or assurances provided by the report):**

- The PCT's reputation is at risk if this PCT is seen to be out of step with commissioning policy generally and could be accused of 'postcode healthcare'. This policy – inline with many others across the East Midlands and beyond will mitigate that risk.
- The PCT is at risk of challenge (up to a judicial review) if there are not appropriate policies and procedures in place for the handing of requests by individuals for treatment that the PCT would not normally fund. This policy mitigates that risk and legal advice has been obtained.

**Financial impact of proposals:**

A separate report indicates the financial implications of this area of work.

**Patient & Public Involvement in relation to proposals:**

Three patient involvement groups have been consulted.

**Equality & Diversity impact:**

Equity, Equality and Diversity are considered as a key dimension of each case when deciding whether the case should be funded.

**Related mandatory / statutory requirements / legal issues / previous relevant decisions:**

- The Low Priority Treatments and Procedures policy (July 2007)
- Policy on Assisted Conception (September 2008)
- The ICRC Terms of Reference (November 2007, January 2008)

have previously been considered by the board.

**Future monitoring / review arrangements:**

The Policy will be reviewed in May 2009

<b>Person presenting paper (name / title):</b>	Chris Kerrigan, Director of Commissioning and Performance
<b>Originator of paper (name / title):</b>	Deborah Jaines, Deputy Director, Commissioning and Performance
<p><b>The PCT Board is recommended to:</b></p> <ul style="list-style-type: none"> <li>▪ <b>APPROVE</b> the policy on the Management of Named Patient Funding Requests.</li> <li>▪ <b>APPROVE</b> the appendices A, F and J as interim until the introduction of East Midlands policies, which will replace the above appendices automatically following consultation by EM Specialised Commissioning Team.</li> <li>▪ <b>AGREE</b> to the inclusion of Lay Assessors as members of the ICRC.</li> </ul>	

**POLICY**  
**ON THE MANAGEMENT OF**  
**NAMED PATIENT FUNDING REQUESTS**

<b>Completed:</b> <b>April 2008</b>	<b>Review Date:</b> <b>31 May 2009</b>
<b>Board Approved:</b> <b>22 May 2008</b>	<b>Effective from:</b> <b>1 June 2008</b>

<b>Title of document</b>	Policy on the Management of Named Patient Funding requests
<b>Type of document</b>	Policy
<b>Description</b>	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.
<b>Target audience</b>	Patients, Providers & Primary Care Independent Contractors
<b>Author</b>	Deborah Jaines, Deputy Director, Commissioning and Performance
<b>Directorate</b>	Commissioning and Performance
<b>Approved by</b>	PCT Board
<b>Date of approval</b>	22 May 2008
<b>Next review date</b>	31 May 2009 or before if any new guidance or clinical evidence becomes available. Appendices to be replaced in-year by specific, related East Midlands Specialised Commissioning Group policies (in development)
<b>Related documents</b>	PCT Cosmetic Plastic Surgery Policy PCT Assisted Conception Policy (East Midlands Policy in development) East Midlands Policy on the Management of Gender Dysphoria
<b>Superseded documents</b>	Low Priority Treatment and Procedures Policy July 2007
<b>Required action</b>	Individual Case Review Committee and relevant Commissioning staff to apply the policy and eligibility criteria as appropriate
<b>Internal distribution</b>	Individual Case Review Committee members, Governance Committee, Director of Public Health, Communications, PALS and Complaints Managers
<b>External distribution</b>	Acute Providers, Primary Care Independent Contractors, East Midlands Specialised Commissioning Team, Patient & Public Involvement Groups
<b>Availability</b>	Shared network drive Intranet site (PCT staff)

	Internet site (general public)
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## **POLICY ON THE MANAGEMENT OF NAMED PATIENT FUNDING REQUESTS**

### **(INCLUDING OUT OF AREA TREATMENTS (OATS) AND OTHER TREATMENTS, INTERVENTIONS AND NHS COMMISSIONED CARE, INCLUDING WHERE THE PCT HAS STIPULATED PRIOR APPROVAL IS REQUIRED)**

#### **1. INTRODUCTION**

- 1.1 The NHS exists to serve the needs of all of its patients but also has a statutory duty financially to break even. (National Health Service Act 2006). 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. It is important, therefore, that the PCT has a clear process for commissioning treatments for those patients with rare conditions, those patients for whom treatments of uncertain or unproven medical benefit are sought, or where treatment costs requested may be out of proportion with the benefit to the patient.
- 1.2 Each Primary Care Trust is responsible for the management of Named Patient Funding Requests, which would include requests for aspects of care which are specifically outside service agreements, where cases need assessment against existing policies (e.g requests for 'Low Priority' treatments) and where treatments are proposed that are not considered to be 'mainstream' and already established in Service Level Agreements with providers.
- 1.3 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. The PCT will not make decisions based on personal characteristics, such as age, gender, sexual orientation, race, religion, lifestyle, social position or financial status, intelligence, disability, physical or cognitive functioning. In short, social value judgements will not inform or affect decision-making.
- 1.4 A consistent process and criteria must be adopted across the Primary Care Trust to assess, review and monitor individual Named Patient Funding cases/requests. It is the role of the **Individual Case Review Committee** – a formally constituted committee of the PCT Board – to fulfil this function.

This system should ensure that all patients' needs are considered equitably and a clear process is adhered to.

- 1.5 The term 'Named Patient Funding Requests' (NPFR) will be used to refer to all non-contract treatments, out of area treatments (OATs) and other treatments, interventions and NHS commissioned care where the PCT has stipulated prior approval is required. (The principal treatments that are excluded from contracts, and which the PCT would not normally fund, are set out in the Schedule of Low Priority Treatments – APPENDIX A and the schedule of cosmetic plastic surgery procedures – APPENDIX J).
- 1.6 Increasingly, the East Midlands Specialised Commissioning Team is developing a range of collaborative commissioning policies on behalf of all East Midlands PCTs. Once developed, a number of these will directly relate to some of the services covered by this policy. Once adopted by the East Midlands Specialised Commissioning Board, Nottinghamshire County teaching PCT will adopt the commissioning policies of the East Midlands Specialised Commissioning Board to ensure coherence with neighbouring PCTs and to minimise exposure to claims of 'postcode' healthcare.

## 2. BACKGROUND

2.1 The PCT commissions the majority of treatment, investigations, interventions and care through agreed contracts with providers. (The term 'services' will be used to cover treatment, investigation, intervention and NHS commissioned care). Payment by Results (PBR), 'choice', with national tariff for many services has increased the range of providers accessed by patients. Pre-arranged service agreements are also widely used. However, many services are not included in 'tariff' and PBR or any other pre-arranged service agreements. Also, commissioners have stipulated that some services included in tariff also require prior approval.

2.2 Examples include:

- New, often high cost drugs, some unlicensed. Examples include cancer drugs and disease modifying drugs for auto-immune disorders.
- Existing high cost drugs excluded from tariff (e.g. growth hormone).
- Treatments, usually high cost, excluded from tariff. (These are set out in individual PCT SLAs)
- Devices, usually high cost, either excluded from tariff or for use in the community where tariff does not apply.

## 3. THE PROCESS

As a formally constituted committee of the PCT Board, the Individual Case Review Committee will have ultimate authority to determine whether funding should be provided. The process will be:

### 3.1 General Named Patient Funding Requests

#### New Requests

- a) Requests for funding (which must be supported by an NHS clinician) will be submitted to the Individual Case Review manager, based at Ransom. Requests will be received – usually on the standard application form (APPENDIX B), date stamped and processed by the Individual Case Review manager who will act as the custodian for requests.
- b) The support of the patient's treating clinician should be explicit, as they will be required to act as gatekeepers by informing patients of known policies and procedures currently in place. Therefore, requests will only be accepted from the clinician responsible for managing the proposed treatment being requested.
- c) Any requests received directly from a patient will be acknowledged and a letter will be sent to the patient advising them to contact their clinician to make a request on their behalf. Requests will not be accepted from a private clinician unless they are acting under contract with the NHS.
- d) Clinicians making a request must provide all relevant clinical, evidential and personal information prior to the case being heard by the Individual Case Review Committee, by completing the Nottinghamshire County PCT Request for Named Patient Funding form (APPENDIX B). Incomplete forms will be returned to the referrer.

- e) All requests will be logged onto the Individual Case Review database, which will have restricted access and will be maintained to an agreed standard for logging and updating information on requests.
- f) The Individual Case Review Manager will check the database for previous requests relating to each treatment request. For all new cases a new entry in the database will be made, and a unique case number assigned.
- g) The Individual Case Review Manager will create a new patient file record for the request, or add new details to an existing patient file. File records will be created and maintained and stored to agreed standard ensuring patient confidentiality.
- h) The Individual Case Review Manager will create and log patient details on a new "Decision Record" form.
- i) The Individual Case Review Manager, will ensure that the request form has been fully completed. Incomplete forms will be returned to the referrer for additional information.
- j) The Individual Case Review Manager will check whether there is an existing policy/agreement that covers the treatment requested.
- k) If an agreement exists, the Individual Case Review Manager will check whether the criteria within the agreement can be applied.
- l) Where the criteria require clinical advice to establish eligibility, the Individual Case Review Manager will seek advice of the designated Public Health representative and, if necessary, the relevant senior manager in the Commissioning and Performance Directorate.
- m) If a decision can be made at this point (based on a demonstration of meeting or not meeting the clinical criteria), the decision record should be completed and a letter prepared for a response to be sent to the referrer, together with details of the appeals process in cases where the request is refused. Where appropriate, the decision will also be copied to the patient's GP. Where appropriate, consistent with NHS Guidance on copying letters to patients, the decision will also be copied to the patient.
- n) The database will then be updated and will include costs where agreement for funding is given. **Decisions taken outside of the committee meeting in this way, will be taken for noting to the next meeting of the Individual Case Review Committee meeting.**
- o) Where there is no existing policy/agreement, the Individual Case Review Manager will pass the request to the relevant Commissioning Lead to establish:
  - Whether there is an existing contract/agreement that covers the request.
  - Whether there is a suitable existing alternative local service that covers the request.
  - Gather further information where necessary to inform decision-making.
  - Obtain clinical/public health advice to inform decision-making.
- p) If a decision can be made at this point, the decision record should be completed and a letter prepared for a response to be sent to the referrer, together with details of the appeals process in cases where the request is refused. Where appropriate, the decision will also be copied to the patient's GP. Where appropriate, consistent with NHS Guidance on copying letters to patients, the decision will also be copied to the patient.

- q) The database will then be updated and will include costs where agreement for funding is given. **Decisions taken outside of the committee meeting in this way, will be taken for noting to the next meeting of the Individual Case Review Committee meeting.**

In summary, the Individual Case Review Manager (in consultation with the Deputy Director and Consultant in Public Health) has four possible options for the management of each case:

- to approve on the basis that either the circumstances are so similar to a previous case(s) considered by the ICR Committee that their approval of funding is inevitable, or that the treatment is actually covered by main stream commissioning.
- to refuse funding on the basis again that the circumstances are so similar to a previous case(s) considered by the ICR Committee that their refusal of funding is inevitable, or that existing policy clearly directs that funding would not be granted, or that it is obvious that special circumstances do not exist.
- to determine that insufficient information has been presented within the application to enable a funding decision to be made.
- to refer the application to the ICR Committee

If the Individual Case Review Manager refuses funding, then the clear right of "appeal" to the ICR Committee remains as set out in section 4.2 of this policy

- r) **Where no decision can be made at this point, the request will be referred to the Individual Case Review Committee for a decision.** The Committee will meet on a monthly basis and decisions will be made based either on the PCT individual requests for funding – decision making principles (APPENDIX C) or specific agreed policy where this is available. (Such policy could be obtained either from the East Midlands Clinical Priorities Board or from the East Midlands Specialised Commissioning Team).
- s) Cases referred to the Individual Case Review Committee should, wherever possible be heard at the next scheduled meeting of the Committee from the date the referral was received by the individual Case Review Manager. Due consideration should be given to the clinical urgency of each request and should be processed appropriately. Standard response times are set out in APPENDIX D.
- t) 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 committee) will be dealt with outside of the Committee, if necessary, by the Deputy Director of Commissioning and Performance, the designated public health lead and the Committee Chair. **Decisions taken outside of the committee meeting in this way, will be taken for noting to the next meeting of the Individual Case Review Committee meeting.**
- u) Upon receipt of a request for named patient funding, the Individual Case Review Manager should request a review of the treatment requested by contacting either the designated Public Health lead, the Chief Pharmacist, other staff able to assist with research and by contacting East Midlands specialised commissioning team, as appropriate.
- v) The Individual Case Review manager will check the database for previous cases. Where these exist, a note on the decisions made with reasons for this will be provided to the Individual Case Review Committee.
- w) The PCT Cancer Commissioning Lead will be consulted as part of the assessment process for all requests for cancer treatments. This will ascertain whether the requested treatment has been approved by either the Cancer Network Board or the Chemotherapy sub-group. Where necessary, the Cancer Lead will bring all appropriate requests for decision to the

Individual Case Review Committee for consideration. Where it is likely that an emergent treatment for cancer is likely to be of benefit to a number of patients, the established cancer groups (Cancer Network Board and the Chemotherapy sub-group) will be asked to prioritise and present a business case to the PCT for consideration for funding and, if approved, all affected patients will have an ability to benefit.

- x) The process/flowchart for assessing general requests is outlined in APPENDIX E.

### Monitoring

- a) 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.
- b) For routine cases, where further information is required in order to inform a decision, a reminder letter will be sent where this has not been received after 2 weeks of the first request, a second reminder letter will be sent after 4 weeks and a final letter with a cut off date of 8 weeks from the first request will be sent after 6 weeks. The case will then be closed and notification sent to the referrer.
- c) Information may be requested from the referrer, Public Health, commissioning leads or other sources. Where in-depth research is required which exceeds 8 weeks, cases will be brought to the next meeting of the Individual Case Review Committee for a decision to be taken with the evidence available in order to ensure that patients are not kept waiting for a decision for an unreasonable length of time. **This is for non-urgent requests only.**
- d) 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.
- e) This information will then be passed to the Individual Case Review Manager for review and will be considered at the next meeting of the Individual Case Review Committee, where appropriate.
- f) All communication relating to cases either written or verbal will be fully documented and added to patient case file in chronological order.

### **3.2 Assisted Conception Treatments**

- a) The Individual Case Review manager will receive and assess all requests for assisted conception treatments against the current policy on assisted conception. (APPENDIX F)
- b) The request will be logged onto the appropriate database, which has restricted access. Patient records are filed in a locked filing cabinet.
- c) The decision will be relayed to the referrer. Where appropriate, the decision will be copied to the patient's GP. Where appropriate, the decision will also be copied to the patient.
- d) Where the patient does not fulfil the PCT criteria for funding for assisted conception and the clinician requires the request to be assessed as an exception, or where there is uncertainty, cases will be referred to the Individual Case Review Committee for consideration.

- e) The decision will be relayed to the referrer, together with details of the appeals process in cases where the request is refused. Where appropriate the decision will be copied to the patient's GP. Where appropriate, the decision will also be copied to the patient.

### **3.3 Cosmetic Plastic Surgery Procedures**

This policy should be read in conjunction with the Cosmetic Plastic Surgery Procedures (APPENDIX J) and the description contained within it of the assessment process for eligibility to receive funding for cosmetic plastic surgery.

### **3.4 Reporting**

A process will be put into place to monitor referrals received and decisions made. The Individual Case Review Manager will use the database to produce reports to the Individual Case Review Committee to enable a review to be undertaken and to submit reports and/or recommendations to the PCT Board as required. This will include an annual finance/activity report.

## **4. INDIVIDUAL CASE REVIEW COMMITTEE MEETINGS**

### **4.1 Requests for funding**

- a) The Individual Case Review Manager will agree agenda items with the Deputy Director of Commissioning to include: cases to be considered by the Committee, cases and issues for information/noting and feedback from Appeals.
- b) The Individual Case Review Manager will circulate to members of the Committee the agenda, notes of previous meeting, details of requests including referral letters, decision record sheets and any additional information received 1 week prior to the meeting.
- c) Terms of reference for the Individual Case Review Committee are detailed in APPENDIX G.
- d) The Individual Case Review Committee will assess and evaluate the evidence base for the clinical and cost effectiveness of each intervention and for each patient under discussion and will consider the views of all relevant stakeholders based on all the information made available to the committee at the time the case is being considered. The Committee will apply the agreed decision-making principles (APPENDIX C) in coming to its decision. Primacy of decision-making will be applied to Clinical Effectiveness and Cost Effectiveness.
- e) 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 committee), the Committee will delegate authority to the Public Health Consultant/specialist, the Deputy Director Commissioning and Performance and the Chair of the Committee or their deputy to make decisions. The Committee will be informed of such cases at the next meeting.
- f) The Individual Case Review Manager will record all decisions on the Decision Record proforma, and will produce a response and send to referrer together with details of the appeals process in cases where the request is refused. All outcomes will be notified to the referrer in writing. Where appropriate the decision will be copied to the patient's GP. Where appropriate, consistent with NHS Guidance on copying letters to patients, the decision will also be copied to the patient.

- g) The Individual Case Review Manager will then add the Decision Record proforma and copy letter to the patient's case file. The database will be updated appropriately.
- h) The Individual Case Review Manager will produce suitably detailed notes from the Individual Case Review Committee meetings, which will detail a record of attendees, case numbers discussed and processes and outcomes agreed.
- i) Letters of confirmation will be sent within 3 working days of the date the decision was made, will be in a standard format to include information on the appeals process, will include a copy of the Decision Record for information and will be addressed from the Chairman of the Individual Case Review Committee and signed on the Chair's behalf by the Individual Case Review Manager.

#### **4.2 Reconsiderations**

- a) Where significant new or additional evidence is presented that was not available to the Individual Case Review Committee at the time of the initial consideration of the case, the case will be reconsidered against this evidence by the Individual Case Review Committee.
- b) Requests for reconsiderations will be accepted from the patient's treating clinician acting on behalf of the patient or from the Appeals Panel – usually within 28 days if the letter informing the applicant of the decision not to fund the treatment.
- c) All new or additional evidence presented will be assessed and ratified by the Public Health Consultant and, where agreed to be significant, will be reconsidered at the next meeting of the Individual Case Review Committee.
- d) The Individual Case Review Committee will reconsider a case once only on the grounds of new or additional evidence, in line with the process described in this policy.
- e) Where the new or additional evidence is not considered significant, (for example no additional evidence of clinical effectiveness is provided and/or the patients clinical circumstances have not materially changed) the Individual Case Review Committee will not reconsider the case and the decision will be relayed to the referrer, together with details of the appeals process.
- f) Where the Appeals Panel has heard a case, and a decision is made to refer the matter back to the Individual Case Review Committee for further reconsideration, the case will be reconsidered against the recommendations made by the Individual Case Review Committee at its next meeting..
- g) Any decision taken by the Individual Case Review Committee on cases referred for reconsideration by the Appeals Panel shall be final and no further appeal shall be allowed.

#### **4.2 Appeals**

- a) Where an individual is able to demonstrate that the decision reached by the Individual Case Review Committee was unreasonable (for example, not properly based on the evidence set before the committee, or not all of the available evidence was taken into account in reaching the decision), they have a right to appeal.
- b) The current NHS complaints procedures make it clear that commissioning decisions are not part of the ambit of the complaints procedures.

- c) The appeals procedure is convened by a PCT Officer nominated by the Director of Commissioning and Performance. **The members of the appeal panel must not have had any prior involvement or part in the decision making process.**
- d) The Terms of Reference and procedures for the operation of the Appeals Panel are set out in Appendix H.

## **5. SPECIFIC ISSUES**

### **5.1 Co-funding**

- a) Co-funding – the practice of supplementing the cost of private treatment by using NHS funding is not supported.
- b) Whilst the Department of Health is committed to closer co-operation between the NHS and the private and voluntary health care sectors for the benefit of patients this is on the basis of developing a wider range of health facilities in the locality. The Concordat between the NHS and the Independent Healthcare Association does not relate to individual patient requests for treatment in the private sector.
- c) Individuals remain free to spend their own money as they see fit, but public funds will be devoted solely to NHS patients, and will not be used to subsidise individuals' privately funded healthcare.

### **5.2 Continuation of Private Treatment**

- a) The PCT will not fund the treatment costs of any self funded private patient who subsequently cannot afford further treatment or their private health insurance does not cover treatment costs.
- b) Private patients transferring into the NHS will be subject to standard waiting times and should be managed by the receiving hospitals as a new referral. These patients should be referred to the beginning of an accepted NHS care pathway as an outpatient referral.
- c) Private patients transferring to NHS care will be treated in accordance with the PCTs commissioning policies. If the previously planned treatment is not routinely available in the NHS an alternative mode of conventional treatment should be considered.
- d) The PCT will not provide retrospective funding for any treatment initiated privately – even if the patient is later successful in a funding request from the PCT. If funding is agreed for any treatment, funding will become the responsibility of the PCT from that date of the Individual Case Review Committee meeting at which the request for funding was considered.

### **5.3 Second Opinions**

- a) Patients are entitled to request a second consultant opinion but this must be within an NHS funded clinic. The PCTs Commissioning Team is available to offer advice on preferred providers.
- b) In certain cases, the ICRC may request a second opinion from a specialist to assist in decision-making and before agreeing a request for funding.

### **5.4 Claims for Expenses**

- a) Patients are entitled to request assistance with travel costs in order to undertake treatment in healthcare facilities commissioned by the PCT. In most circumstances the healthcare facilities themselves will re-imburse travel costs in line with national guidance. However, in certain circumstances (e.g where travel outside of England is required) patients may request assistance with travel costs and accommodation costs. Cases will be considered

on a case-by-case basis and will be funded in accordance with national recommendations set out in DoH policy.

- b) Patients who have donated an organ to a named recipient (living donor) are entitled to request reimbursement of reasonable expenses to cover (for example) loss of earnings whilst they recuperate. The PCT will reimburse reasonable expenses – usually in line with the value normally recommended by the renal network in which the operation takes place. Evidence of earnings will be required before reimbursement can take place.

## **5.5 Access to/Requirement for Psychological Assessment**

In certain cases, a psychological assessment will be an expected part of the patient pathway – for example, as part of the gender re-assignment pathways.

## **5.6 Exceptionality**

Where a treatment is not routinely commissioned, but is requested to be considered under exceptional circumstances the definition and criteria for this needs to be clearly established for the benefit of the patient, treating clinician and Individual Case review Committee. APPENDIX B, if properly and fully completed, will indicate patient exceptionality. (Exceptional ability to benefit.)

Cases will be assessed for exceptionality as follows:

- a) The test applied is one of fairness to fund the treatment for one individual in one specific clinical circumstance while declining all others. The focus is on clinical, not social or economic, circumstances. The clinical circumstance must be directly related to the requested treatment for the particular patient.
- b) Patients who have received privately funded treatment will not qualify as 'exceptional' on the basis of their response to treatment.

## **5.7 Support for decision-making**

- a) Some decisions are particularly difficult to make. Reasons for this include:
- There is potential to set a significant precedent
  - Significant uncertainty regarding the case
  - Difficult ethical issues
- b). An expert group may be asked to be convened by the Individual Case Review Committee to advise on a case/decision. The advice of such a group is not binding on the PCT. However, the advice should be made available if there is an appeal made against the PCT's decision.
- c) Where the Individual Case Review Committee considers it necessary to develop interim commissioning policies, the Public Health lead will produce relevant guidelines for consideration by the Committee.
- d) For some treatments or drugs, the PCT may consider there are no circumstances under which they treatments or drugs would be funded (eg where an identical drug exists at a lower cost). The PCT has been advised that 'Blanket bans' of this type are legally permissible.

Policy on the Management of Named Patient Funding Requests  
 APPENDIX A – SCHEDULE OF LOW PRIORITY TREATMENTS  
 Revised May 2008

<b>INTERVENTION</b>	<b>LOW PRIORITY SITUATION</b>
Gastroplasty	For patients meeting the East Midlands Obesity Pathway Criteria, Dietary and pharmacological interventions should already have been undertaken and failed.
Surgery for correction of short sight	Not funded
Autologous Cartilage (chondrocyte) Transplantation	Not funded as routine treatment. All other treatment regimes must have been exhausted
Surgery to address varicose veins	Asymptomatic – not funded. (Where there is no pain or discomfort, or any skin changes) Moderate – not funded. (e.g ankle swelling, feelings of heaviness, swelling, generally only involving superficial veins) Severe – funded where: ulcers/history of ulcers, liposclerosis, varicose eczema, history of phlebitis, history of haemorrhage or significant pain exists.
Hyperbaric oxygen therapy for wound healing	Not funded
Dental Implants	Not funded except post cancer reconstruction, major trauma with bone loss anodontia. Criteria apply
Asymptomatic wisdom tooth removal	Not funded
Prostheses from independent providers	The PCT will not fund prostheses from independent providers as these are available on the NHS
Access to independent providers	Retired NHS clinicians may continue to practice privately. The PCT will not fund patients who wish to continue to see a private consultant where an NHS alternative exists.
Circumcision	Not normally funded in either adults or children unless there are medical indications.
Gender reassignment	Counseling and psychological support funded. Drug therapy and surgery not normally funded
Reversal of male sterilisation	Not funded

Policy on the Management of Named Patient Funding Requests  
APPENDIX A – SCHEDULE OF LOW PRIORITY TREATMENTS  
Revised May 2008

<b>INTERVENTION</b>	<b>LOW PRIORITY SITUATION</b>
Reversal of female sterilization	Not funded
IVF/ICSI/IUI and other forms of assisted conception	Criteria apply. Refer to PCT policy on Assisted Conception
Penile Implants	Not funded except in patients with impotence of organic cause, or for those who have failed to respond to, or are unable to continue with, medical treatment or external devices
Spinal Cord Stimulation for Chronic Pain	Not funded
Pain management programmes using cognitive behavioural approach	Not funded
Residential pain management programmes	Not funded
Acupuncture for pain relief	Funded only where recommended by consultant in pain clinic.
Therapeutic community method for treatment for borderline personality disorder	Not funded
Out of area treatment for chronic Fatigue Syndrome/ME	Not funded. Local pathway in place. Community-based model with access to in-patient care in Derby in severe cases.
Post Traumatic Stress Disorder	Not funded unless referral made by consultant psychiatrist in local Services. Prior Approval required.
Out of Area or referrals to the independent sector for Children with suspected Autism	Referrals to the independent sector or out of area will only be considered where the child's care has been assessed by CAMHS or paediatric services and where there is a recommendation by either or both agencies that such a referral is necessary.
Acupuncture for purposes other than pain relief, including smoking cessation	Not funded
Osteopathy and chiropractic	Not funded unless an agreed care pathway is already in place.
Glucosamine	Not funded
Herbal remedies	Not funded

Policy on the Management of Named Patient Funding Requests  
APPENDIX A – SCHEDULE OF LOW PRIORITY TREATMENTS  
Revised May 2008

<b>INTERVENTION</b>	<b>LOW PRIORITY SITUATION</b>
Homeopathy	Not funded
Chinese medicines	Not funded
Aromatherapy	Not funded although sometimes offered in hospices and other palliative care settings
Massage	Not funded
Reflexology	Not funded
Hypnotherapy	Not funded
All other complementary therapies	Not funded

(Interventions listed in lighter – blue – text indicate a change from the previous (2007) version of the policy. In some cases, these are new additions to what the PCT considers to be low priority in other cases this (2008) version provides greater clarity.

PCT Ref
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## Named Patient Funding Request

Please use this form in the following circumstances to apply for resources from Nottinghamshire County Teaching Primary Care Trust (NCTPCT) for an individual patient where the PCT does not routinely fund the treatment.

**Either** there is an expectation that your patient has an exceptional ability to benefit above that of other similar patients (*we suggest that you read the attached guidance notes*)

**Or** the patient has a rare condition for which the PCT does not have a formal policy.

The nature of the information required to best support an application is usually most thoroughly completed by the specialist who decides the requested intervention may be appropriate.

The form should not be used where the proposed intervention would logically apply to a group of patients without a rare condition. In these circumstances a business case for a service development should be submitted to the PCT using the normal process, through your Trust's commissioning liaison.

Please request an electronic version of this form through your commissioning liaison team. The form will be easier to complete, as boxes will expand to fit your submission. We will start the process on receipt of an electronic copy, but a paper copy should be submitted through your commissioning liaison team complete with the necessary signatures.

### Section A Governance, Patient, Clinician & Trust details

A1 Trust governance confirmation			
<i>The request will be returned unless the governance requirements below are confirmed</i>			
Fully informed consent for the proposed intervention		date patient consented	
Conflict of Interest/Bias statement completed		date	
Provider DTC/Ethics approval	yes / no	date to DTC/Ethics	
Provider Clinical Director support	(signature of clinical director)	date	

Policy on the Management of Named Patient Funding Requests  
 APPENDIX B – REQUEST FOR NAMED PATIENT FUNDING  
 Revised May 2008

A2 Patient details			
Surname		Forename	
DoB		Sex	
NHS Number		Hospital ID	
Address			
Registered GP			
Diagnosis			
Intervention			
Additional costs			
Exceptionality	<i>Is request on grounds of Exceptionality ?</i>		
One off Decisions	<i>Is request on grounds of one off decision ?</i>		
<i>There may be no reference point, the patient does not come from a sizeable group of patients (often they may be unique), nor is there much evidence about the treatment in question</i>			
What is the nature of the condition ?			
What is the nature of the treatment?			
What is the evidence that this treatment might work in this situation? Is there biological plausibility that this treatment might work?			

A3 Requesting clinician details			
Surname and title		Forename	
Specialty		Trust Name	
Address			
Telephone		Fax	

A4 Proposed provider details			
<i>Complete if different to requesting clinician</i>			
Surname		Forename	
Specialty		Trust Name	
Address			
Telephone		Fax	

Policy on the Management of Named Patient Funding Requests  
 APPENDIX B – REQUEST FOR NAMED PATIENT FUNDING  
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<b>A5 Provider commissioning liaison details</b>			
<i>When from a Trust, the request should be forwarded through your commissioning liaison</i>			
Surname		Forename	
Telephone		Fax	
Date forwarded to PCT			
Trust reference			

<b>A6 Tracking</b>			
<b><i>This section is for PCT use</i></b>			
PCT Reference		date received	
<i>Is this patient the responsibility of this PCT (if registration changes so does responsibility)</i>			
Registered at PCT GP	y / n		
<i>PCT commissioning liaison assessment of completeness</i>			
name(s)		date(s)	
<i>Returned to Trust commissioning liaison if unacceptably incomplete</i>			
date(s)			
<i>Commissioning or Pubic Health assessment that case made is one of exceptionalty or rarity (Director of Commissioning or Public Health, Associate Director of commissioning or Consultant in Public Health)</i>			
name(s)		date(s)	
<i>Returned to Trust if request not made on the basis of exceptionalty or rarity</i>			
date(s)			
<i>Withdrawn or not progressed by Trust</i>			
date			
<i>Recheck registered GP (if registration changes so does responsibility)</i>			
Registered at PCT GP	y / n		
<i>Have there been any similar requests to the PCT in the past, and what was the outcome.</i>			
<i>Forwarded to Individual Case Review Committee</i>			
date		date	
<i>Considered by Individual Case Review Committee</i>			
decision		panel date	
<i>Grounds for decision</i>			
Legality	y / n	Safety	y / n
Effective	y / n	Cost Effective	y / n
Equitable	y / n	Accessible	y / n
Affordable	y / n	Exceptional	y / n

## Section B PCT Decision-Making Principles

The PCT has a set of Decision-Making Principles, which it uses to help prioritise the distribution of health care resources. Each of the main points of the policy are addressed in the boxes below

If you are making an application on the grounds of “exceptionality”, we would suggest that you read the attached guidance notes so that you aware what we mean by “exceptionality” before continuing. The majority of applications for Named Patient Treatment Request on the grounds of “exceptionality” we have received in the past have not met the requirements of “exceptionality” and have most often been refused on the grounds that they have essentially been requests for service development because the request would actually have applied to a group of patients.

Similarly, the PCT does not divert resources from other patients solely on the basis of the “rule of rescue”.

<b>B1 Legality</b>
1a. Do you <u>consider</u> the treatment you are recommending to be lawful and comply with human rights act
yes / no

<b>B2 Safety</b>
<i>Standard management options should have been exhausted for this patient</i>
1a. What interventions/management options have already been tried?
1b. What was their outcome
1c. Are there other further interventions available that you or others would normally use which are already funded by the PCT, but have not yet been tried?
1d. If “yes” to 1c, why have these not be tried?
<i>Those proposing to undertake the intervention should be suitably skilled</i>
2a. What evidence is there that the clinician who is to undertake the intervention is appropriately trained and accredited (where and by who)?
2b. What is the experience in the unit of this intervention?
2c. Are there known activity levels that affect positive outcomes and what are these?
2d. If yes to 2c, how do these compare with the activity in the proposed unit

Policy on the Management of Named Patient Funding Requests  
 APPENDIX B – REQUEST FOR NAMED PATIENT FUNDING  
 Revised May 2008

<b>B3 Clinical Effectiveness</b>
<i>The status of the proposed intervention should be clear</i>
1a. If a drug, is it licensed for the proposed use? If an intervention is it usually recommended (and by who)?
1b. Is the intervention still the subject of clinical trials? Please give details.
1c. If resources are made available for this intervention, what ongoing audit programme will outcomes be fed into?
<i>A summary of the evidence base about the intervention should be included. Any assessments by advisory bodies or research papers should accompany the application (preferably electronically). <b>As the requesting clinician it is important to realise that the application may be subject to bias. It is therefore important to fully complete the sections below on evidence. Obvious bias detracts from the strength of an application. Please highlight systematic review, meta-analyses and RCTs</b></i>
2a. What evidence is there to <b>support</b> the use of this intervention in this patient?
2b. What evidence is there that does <b>not support</b> the use of this intervention in this patient?
2c. What <b>gaps</b> are there in evidence for the use of this intervention in this patient?
2d. How generisable to this patient is the evidence you have highlighted?
<i>The proposed intervention should have a high likelihood of producing a demonstrable significant functional improvement, or substantially reduce the risk associated with the standard intervention.</i>
3a. How is it anticipated that the intervention will impact on the patient's functional abilities with, for example, activities of daily living?
3b. What and by how much will risks associated with standard treatment be reduced, and risks associated with the intervention be increased?
3c. Has the information that you have provided above on the evidence and the associated uncertainties for this intervention been discussed with your patient during the process of obtaining informed consent?

Policy on the Management of Named Patient Funding Requests  
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<b>B4 Cost Effectiveness</b>	
<i>It is the PCT's responsibility to establish the cost-effectiveness of the intervention for the individual when weighed against alternative management options and against its responsibility to ensure improved health for all those in the population for which it is responsible. Information on the following will help with the decision on this application</i>	
<i>The funding requirements should be explicit and clear, and should include medium to long term follow-up and other likely future costs of the pathway.</i>	
1a. What is the cost of delivering this intervention?	
Drug/Procedure -	Hospital activity -
1b. What are the future costs associated with this care pathway?	
Drug/Procedure -	Hospital activity -
1c. What costs will not need to be met as a result of not using a standard intervention?	
Drug/Procedure -	Hospital activity -
<i>Intervention aims, monitoring and stopping criteria</i>	
2a. Have clear outcomes (goals of functionally significant change) been set with the patient?	
2b. What level of response will be considered ineffective	
2c. How is the response to the intervention to be monitored	
2d. What is the end point at which the intervention should stop and does your patient understand this and realise that the intervention will then stop?	
2e. What are the longer term follow up arrangement and who is responsible for ensuring that follow up takes place?	
2f. Are additional resources required for follow up?	
<i>National/Independent assessments of cost effectiveness</i>	
3a. Has there been a NIHCE assessment of this intervention? If so what was the outcome and what is the NIHCE reference? <i>You should not leave this blank State none if none</i>	
3b. Has there been a SMC assessment of this intervention? If so what was the outcome and what is the SMC reference? <i>You should not leave this blank State none if none</i>	
3c. If a drug, has there been a DTB, MeReC, NPC or similar review? If so what was the outcome and what is the reference? <i>You should not leave this blank State none if none</i>	

Policy on the Management of Named Patient Funding Requests  
 APPENDIX B – REQUEST FOR NAMED PATIENT FUNDING  
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<b>B5 Equity &amp; Exceptionality</b>
<i>The PCT must ensure that all its patients with similar need are treated in the same way irrespective of clinical picture, social or personal circumstances (unless these should have a direct bearing on clinical outcomes).</i>
1a. How is this patient different to the general patient population with this problem? <i>(if you are applying on the grounds of exceptionality, you will need to identify real and significant differences. Social criteria and presumed previous response do not support an argument of exceptionality – please see attached guidance)</i>
1b. Are you recommending that patients in a similar position have this intervention <i>(this question will rarely apply if the application is on the basis of exceptionality because if there is a group of patients in a similar position an individual patient cannot be an exception)</i>
1c. If your application is based on rarity and the absence of a PCT policy, please indicate the incidence and prevalence of this condition in the general population. <i>(guidelines for our decision are 3 per million per year incidence, and 10 per million prevalence)</i>

<b>B6 Accessibility</b>
<i>The PCT has to ensure that patient choice, including care as close to the patient's home as is feasible, is available where possible.</i>
1a Have the patient been made aware of alternative providers of this intervention?
1b Are there providers of this intervention closer to the patient's home?

<b>B7 Affordability</b>
<i>Applicants should note that Nottinghamshire County teaching PCT will make all its commissioning decisions in the light of the totality of resources available to it. The PCT has a statutory duty to balance its budget.</i>

<b>Abbreviations</b>	
PCT	Primary Care Trust
DTC	Drugs and Therapeutic Committee
NIHCE	National Institute of Health and Clinical Excellence
SCM	Scottish Medicines Consortium
DTB	Drugs and Therapeutic Bulletin
NPC	National Prescribing Centre

Policy on the Management of Named Patient Funding Requests  
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<b>C1 Conflict of Interest</b>		
<p><i>Clinicians may have a variety of interests that arise out of the course of their work or from their personal life that may conflict, or be perceived to conflict, with the advice they give when recommending a particular intervention or policy. The following questions are derived from the NIHCCE code of practice on conflicts of interest. Please refer to this at <a href="http://www.nice.org.uk/niceMedia/pdf/Declarationofinterestpolicy.pdf">http://www.nice.org.uk/niceMedia/pdf/Declarationofinterestpolicy.pdf</a> for a complete description. <b>The application will be returned if this declaration is not completed.</b></i></p> <p><b>Relevant interests are from the last 12 months, or planned for the coming 12 months</b></p>		
<b>A personal pecuniary interest</b>		
<p>A regular payment in cash or in kind, fee paid-work, shareholdings, expenses and hospitality above which you would have had if you had been self financing, from a consultancy, directorship or position in or work for the manufacturer or owner of the product or intervention being recommended (<i>specific interest</i>) or the industry or sector from which the product or intervention comes (<i>non-specific interest</i>)</p>		
Yes or no	If yes, specific or non specific	
Details		
<b>A non personal pecuniary interest</b>		
<p>A payment or other benefit to a department or organisation for which an individual has managerial responsibility that is not received personally. This includes fellowships or grants from a company to run a unit, support staff or commission research. This may relate to the intervention in question (<i>specific interest</i>) or to the manufacture or owner of the intervention but not to the intervention itself (<i>non-specific interest</i>)</p>		
Yes or no	If yes, specific or non specific	
Details		
<b>A personal non pecuniary interest</b>		
<p>This may include, but is not limited to, a clear opinion of the conclusion of research or clinical/cost effectiveness evaluation of a recommended intervention, a public statement where a clear opinion has been expressed that may be interpreted as prejudicial to objective interpretation of evidence, holding office in a profession organisation or advocacy group with an interests in the intervention, or other reputational risk that relates to the intervention</p>		
Yes or no	If yes, then by definition it is specific	
Details		
<b>A personal family interest</b>		
<p>For a family member, a regular payment in cash or in kind, fee paid-work, shareholdings, expenses and hospitality above which they would have had if they had been self financing, from a consultancy, directorship or position in or work for the manufacturer or owner of the product or intervention being recommended (<i>specific interest</i>) or the industry or sector from which the product or intervention comes (<i>non-specific interest</i>)</p>		
Yes or no	If yes, specific or non specific	
Details		
<b>Declaration:</b> I have indicated all my potential conflicts of interest		
<b>Signature</b>	date	

## Individual Case Review Committee

### Guidance notes and clarification of process

#### General

1. PCT policy already states that medicines and interventions that fall outside existing contracts, tariffs or NICE consideration are not normally supported if they require significant additional resources with attached opportunity costs. Within the fixed budget the PCT is provided with, a choice to fund one patient's treatment is also a choice not to fund one or more other patient's treatment. It is a role of the PCT to decide, with consultation, which interventions for which groups of patients are prioritised.
2. Hence, all funding requests for an individual patient to have a treatment that the PCT would not normally provide as a matter of policy must be on the basis of exceptional circumstances. The Individual Case Review Committee (ICRC) is a sub-committee of the PCT board, and will make the decision on whether there is exceptionality and whether the request will be funded.
3. The presence of permission based on licence, Drugs and Therapeutics Committee approval, or previous receipt of the intervention, as part of a trial or privately (whatever the presumed response), is insufficient alone to support an application.

#### Appeals

4. The PCT ICRC appeals process is only to appeal against the ICRC process itself and not the decision. This is in common with Specialised Commissioning Guidance and practice in other ICRCs. Where an appeal is upheld, the ICRC will be asked to repeat their assessment taking into account the appeal panels comments on process. Having done so, the decision reached by the ICRC may not change. If significant additional information to support an application becomes available where there has been a previous decision not to fund, then a new application can be made, and an appeal against the ICRC process is unnecessary. If new information is offered, but its significance is uncertain, the original panel may consider it.

#### Exceptions

5. Exceptionality refers to an individual's exceptional ability to clinically benefit compared with others in a similar position. It does not refer to patients social factors<sup>1</sup>.
6. Exceptions are by definition difficult to define. If sub-groups of patients can be shown from robust evidence and by the nature of certain characteristics to benefit more than others from a particular intervention, then they form a good prognosis group and are not exceptions. Patients in those good prognosis groups may then be considered for funding via the usual LOP process, and the evidence base to support this is likely to be more favorable than for all patients with the same condition. Many NICE decisions already work on this basis. Therefore, if the basis of an application for an individual would in fact apply to a group of patients, there can be no exceptionality, and a business case should be submitted through the normal prioritisation process.

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<sup>1</sup> Social factors include work status, marital status, dependants

7. Patients who present who are clearly individuals who show characteristics of potential exceptional prognosis or response based on good evidence but where no clear evidence that other similar patients exist to justify or anticipate a 'good prognosis group' demand, as in 6 above, may be considered exceptions.
8. If the evidence for particular benefit is present but not strong enough to follow the process outlined in 6 above (eg if it is inferred, observational, not from 'a priori' research, or based on clinical opinion), then such patients, especially if this situation is rare, may be considered exceptions. However, some evidence must be available. An example of the dilemma panels may face is that there may be a clinical argument advanced that a patient is younger and free of co-morbidity and so may promise exceptional survival for a given contested cancer treatment intervention. This would normally have to be backed up with some evidence since some tumours in younger patients may behave more aggressively and the evidence base may not include patients in certain groups. Clinicians should support their advice with evidence and panels are expected to judge the individual arguments.

## Principles of decision-making

9. Blanket bans on potentially effective interventions 'fetter discretion' and so are difficult to justify. All uncertain cases should be progressed via ICRCs.
10. Where the ICRC decides that there is exceptionality, then the existing principles set out in the PCT's Policy on the management of Named Patient Funding Requests will be applied before funding is agreed. These do not currently include the 'rule-of-rescue'.
11. Only clinical benefit for a given demographic profile can be considered as parameters of exceptionality. Social factors<sup>2</sup> must not be used in the consideration.

## Evidence

12. Clinicians applying on behalf of their patients should be open about the level of evidence available to support their request. They should give not just the evidence for the intervention, but also indicate the evidence against it, and where there are gaps in evidence. The presence of obvious bias in the evidence presented detracts from the strength of an application.
13. Most if not all evidence used by the panels will be based on randomized controlled trials. Occasionally high-quality observational data may be appropriate. Good prognosis sub-groups exist in the non-treatment or placebo arm as well as the treatment arms and so the presence of a 'good prognosis sub-group' has to be judged in comparison with its randomized comparator NOT the overall performance of the whole intervention cohort.
14. It is often proposed that patients who might represent exceptions are started on treatment 'to see how they respond', with subsequent funding decisions being based on a report submitted by the clinician at some stage in the future. It is advised that this is not a robust or sound process since many patients in clinical trials may be considered to 'respond', but it is ultimately primary endpoints on which the whole basis of the evidence is predicated, and so treatment decisions should be determined a priori and on an intention-to-treat basis in all cases considered by the panel, whatever the subsequent 'on-the-ground' clinical management that ensues.

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<sup>2</sup> Social factors include work status, marital status, dependants

## Other

15. Applications can be initiated from a patient themselves, or anyone on behalf of a patient. The nature of exceptionality and the necessary collation and assessment of evidence to support an application mean that the vast majority of applications will be from a patient's clinician. If an application is made by anyone else, we will always request their clinician's involvement, including their assessment of exceptionality and the evidence base.
16. Clinicians may disagree with the PCT's existing policy not to fund a particular intervention. The usual Local Operational Plan prioritisation process is the appropriate route to submit proposals for new policies. The ICRC should not be used as a mechanism for this.
17. Given the nature of exceptionality, an individual decision to fund treatment is very unlikely to form a precedent either for future decisions of the ICRC or for the PCT policies.

## Individual requests for funding Decision-Making Principles

1 Legality (*is it lawful?*)

**Nottinghamshire County tPCT will ensure that any decision it takes on the commissioning of new services and treatments is within its legal powers and complies with the principles of the Human Rights Act (which *do not* impose on the PCT a duty to provide health care).**

2 Safety (*'first do no harm'*)

**Nottinghamshire County tPCT will ensure it is not complicit in exposing patients to unsafe healthcare and will look to licensing authorities (especially the MHRA) and other organisations (such as NICE and the BNF) for guidance.**

3 Clinical Effectiveness (*does it work?*)

**Nottinghamshire County tPCT will only commission new services and treatments which are fully accredited and approved and where there is good evidence that a specific benefit will be gained.**

4 Cost Effectiveness (*is it an efficient way of using resources?*)

**Nottinghamshire County tPCT will aim to commission services and treatments, which yield the greatest benefits relative to the cost of providing them. This balances the clinical effectiveness of a service or treatment with its cost. Interventions are not always completely effective all the time and the benefit to the individual needs to be balanced with the greater good.**

5 Equity – Including Equality and Diversity (*is it a fair way of using resources?*)

**Nottinghamshire County tPCT will endeavour to ensure that a service or treatment is available to all those who could benefit from it, taking into account the requirement to balance the needs of the individual and those of the local community**

6 Accessibility (*can people get to the service?*)

**Nottinghamshire County tPCT will, whenever possible and appropriate, commission services and treatments that are accessible to all the people it serves.**

7 Affordability (*do we have the resources to pay for it?*)

**Nottinghamshire County tPCT will make all its commissioning decisions in the light of the totality of resources available to it.**

**Individual Case Review Committee**  
**Schedule of future meetings and Standard response times**

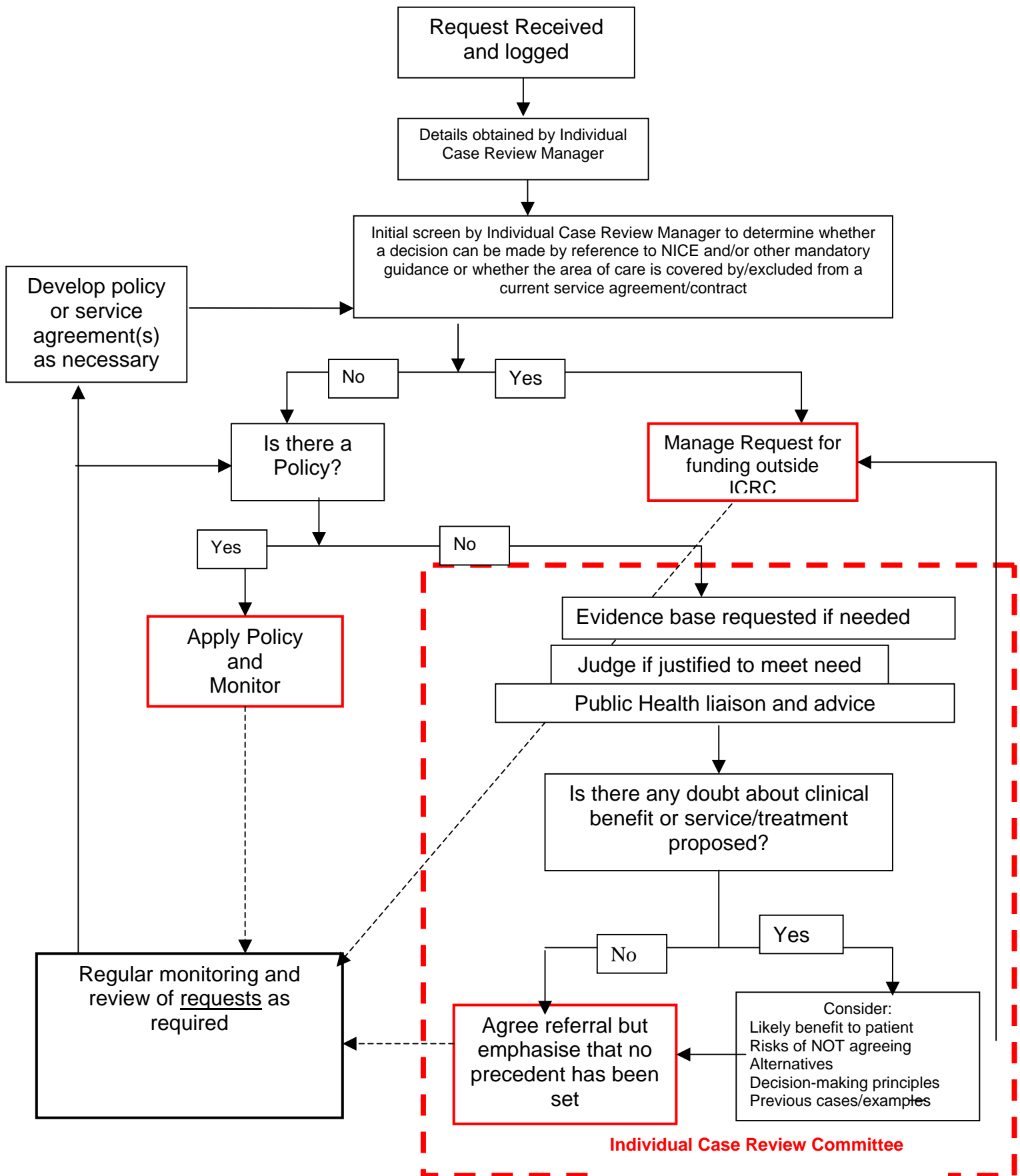
**SCHEDULE OF FUTURE MEETINGS**

<b>12 June 2008</b>
<b>10 July 2008</b>
<b>14 August 2008</b>
<b>11 September 2008</b>
<b>9 October 2008</b>
<b>13 November 2008</b>
<b>11 December 2008</b>
<b>8 January 2009</b>
<b>12 February 2009</b>
<b>12 March 2009</b>
<b>9 April 2009</b>

**STANDARD RESPONSE TIMES FOR CONSIDERATION BY INDIVIDUAL CASE REVIEW COMMITTEE**

Referral received by commissioning directorate (Day 0)
Referral acknowledged within <b>3 working</b> days. Referrer advised how the request is to proceed (if covered by contract, NICE guidance in place, PCT criteria in place, will progress to ICRC case or declined/not fundable.) Referrer advised whether additional information will be required.
If referral is urgent in nature, convene urgent decisions process and advise referrer of the outcome within <b>5 working days</b>
Maximum waiting time for case to be considered by ICRC is <b>30 Calendar days</b> . (Assuming worst case scenario of case being received immediately following a meeting and case needing to be considered by next committee.) Please note that the case cannot proceed without full information required for decision-making. In rare circumstances, the volume of cases may necessitate cases being deferred until next available committee meeting. Clinically urgent cases will take priority.
Following Committee meeting, referrer and patient advised of outcome within <b>3 working days</b>







## **Assisted Conception Policy**

### **NHS Eligibility Criteria for In vitro fertilisation (IVF) Intracytoplasmic sperm injection (ICSI) and Intra- uterine insemination (IUI) treatment for people with infertility in Nottinghamshire County.**

**May 2008**

## Summary

Couples referred for investigation and diagnosis will be eligible for one cycle of NHS funded In vitro fertilisation (IVF) or Intracytoplasmic sperm injection (ICSI) if they meet all of the following criteria (NICE indicates that the criterion is based on NICE guidance):

1. couples who have failed to conceive after regular unprotected sexual intercourse for 3 years; or who have an established cause of infertility. Investigations will begin at 2 years or earlier if there is a history of predisposing factors (NICE).
2. female partner to be aged 23-39 at the start of the treatment cycle (NICE)
3. neither partner has been previously sterilised
4. female partner to have a BMI between 20-29 (NICE)
5. both partners to be childless
6. no more than 2 cycles of IVF already received (regardless of NHS or privately funded) - *couples are only eligible to receive up to a maximum of 3 cycles in a lifetime regardless of NHS or privately funded (NICE advise up to 3 cycles for eligible couples)*
7. the couple's health and/or social circumstances would pose no significant risk to conception, pregnancy or the resultant child
8. the couple are to be registered with a Nottinghamshire County GP
9. written consent to treatment is required from both partners

## Introduction

This paper sets out the criteria for access to NHS funded specialist fertility services for patients who are the responsibility of the Nottinghamshire County Teaching PCT.

It sets out the minimum entitlement and service that will be provided for NHS In vitro fertilisation (IVF) Intracytoplasmic sperm injection (ICSI) and Intra-uterine insemination (IUI) across the health community.

Initial investigation of patients, to be started after two years of infertility (NICE) is usually carried out by a network of specialist gynaecologists at District General Hospitals throughout the Nottinghamshire area.

In any healthcare system there are limits set on what NHS funded care is available and on what people can expect. Primary Care Trusts (PCTs) are required to achieve financial balance; they have a complex task in balancing this with an individual's rights to health care. It is the purpose of the criteria set out here to make the limits on fertility treatment fair, clear and explicit.

Nationally this is undertaken through the work of the National Institute for Clinical Excellence (NICE) and this paper reflects this. The paper should be read in conjunction with the NICE Fertility Guidance available on their web site at [www.nice.org.uk/pdf/CG011niceguideline.pdf.url](http://www.nice.org.uk/pdf/CG011niceguideline.pdf.url).

The NICE Guidance places NHS assisted fertility services firmly in the mainstream of NHS provision, and therefore as a result, patients will expect the NHS to provide this.

Abbreviations used in the document are explained in Appendix A.

Definitions of technical terms are contained in Appendix B.

Appendix C contains some explanatory notes and guidance.

Appendix D is the sub fertility funding assessment sheet. A completed version is required for NHS funding to be considered.

## Eligibility Criteria

### 1 Availability of In vitro fertilisation (IVF), Intracytoplasmic sperm injection (ICSI)

Couples suffering from infertility will be eligible for IVF and ICSI. Infertility is the failure to conceive after regular unprotected sexual intercourse for 3 years. Where there is clear reproductive pathology, couples with infertility of any duration will be considered. This may include couples who cannot achieve full sexual intercourse due to disability.

Any element of surrogacy related infertility treatment would not be eligible for NHS funding.

Any cycle of infertility treatment already undertaken (whether self or NHS funded) will be taken into account when determining NHS funding entitlement.

Since 1<sup>st</sup> April 2005 all women aged between 23 and 39 who met the eligibility criteria have been offered one full cycle of IVF. This has included ovarian stimulation, egg recovery, IVF and embryo transfer. (It has not included further transfers of frozen embryos where the initial procedure did not result in a viable pregnancy.)

Couples who have an appropriately diagnosed cause of infertility of any duration, or unexplained infertility (unexplained infertility includes mild endometriosis and mild semen abnormality) of at least three years duration, and who meet the other criteria should be offered **one** complete full cycle (that is ovarian stimulation, egg recovery, IVF and embryo transfer).

NICE has limited a couple's lifetime access to IVF to a maximum of 3 cycles. A couple who has already had 3 cycles, be they NHS or privately funded (in the UK or abroad) will not be eligible for NHS funding.

### 2 Existing Children

Only couples with no children who fulfil all other criteria will be eligible.

(The definition of childlessness is based solely on parental status, in that it requires neither partner to have any living children. A living child is defined as living offspring regardless of age, which includes adopted children, or children who may have been taken into care, but not foster children.)

### 3 Female age

Assisted reproductive technology will be available to women aged 23 to 39 years at the start of a treatment cycle. A treatment cycle begins with the administration of drugs for IVF, IUI and hormone replacement treatment.

Treatment should be started no later than 12 months from the decision to offer assisted conception. Once treatment is started a women will be entitled to one full cycle, however treatment will cease by the woman's 40<sup>th</sup> birthday.

#### **4 Availability of Intrauterine Insemination (IUI)**

Couples who fail to conceive after 2 years unprotected sexual intercourse and fulfill the eligibility criteria for IVF may be offered intrauterine insemination if clinically appropriate

Couples will normally be offered no more than a maximum of 6 IUI treatments.

Couples who do not conceive after IUI will have a full entitlement to IVF in line with the stated eligibility criteria.

Couples of who choose not to have IUI and progress straight to IVF, will not be permitted to be offered IUI if IVF fails.

#### **5 Obesity**

Women with a body mass index of more than 29 before starting a course of IVF ICSI or IUI will not be eligible.

#### **6 Low Weight**

Women with a body mass index of 19 or under before starting a course of IVF ICSI or IUI will not be eligible<sup>1</sup>.

#### **7 Donor Sperm**

This will be funded only where the male has azoospermia or severe oligospermia or to avoid transmission of inherited disorders to a child where the couple meet the other eligibility criteria.

This would mean up to 6 cycles of donor insemination, in addition to IUI if required, and in addition to IVF entitlement if required.

#### **8 Donor Egg**

This will be available to women who have undergone premature ovarian failure due to an identifiable pathological or iatrogenic cause before the age of 40 or to avoid transmission of inherited disorders to a child where the couple meet the other eligibility criteria.

#### **9 Surrogacy**

Surrogacy, or any assisted conceptions involving surrogacy, are not funded and do not form part of this policy.

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<sup>1</sup> Van der Spuy, Z. M., Steer, P.J., McKusker, M., et al. (1988) Outcome of pregnancy in underweight women after spontaneous and induced ovulation. BMJ 296, 962-967.

## **10 Embryo, Ovarian or Testicular Tissue, Egg and Sperm Storage**

Embryo storage will not be funded by the NHS. Ovarian or testicular tissue storage will not be carried out outside a clinical trial. These are currently experimental. Sperm will be stored according to HFEA Guidance. This includes freezing of sperm for patients undergoing chemotherapy and radiotherapy. Patients whose sperm has been frozen prior to chemotherapy or radiotherapy will be entitled to NHS funded infertility treatment provided they meet the eligibility criteria.

## **11 Sterilisation**

Couples where one partner has been sterilised will not be eligible for treatment, even if a successful reversal has been achieved (reversals are not funded by the NHS).

## **12 Exceptional circumstances**

In the rare or exceptional circumstances where a couple or clinician feel that the couple represent a special case then an application can be made to the PCT's Individual Case Review Committee for consideration of exceptional funding.

## **13 Review**

These treatment criteria will be reviewed in July 2008 or in the light of any new guidance, whichever is the earliest.

September 2007

Appendix A

<b>Abbreviations used</b>	
<b>BMI</b>	<b>Body Mass Index</b>
<b>DI</b>	<b>Donor Insemination</b>
<b>GP</b>	<b>General Practitioner</b>
<b>HFEA</b>	<b>Human Fertilisation and Embryology Authority</b>
<b>ICSI</b>	<b>Intracytoplasmic sperm injection</b>
<b>IUI</b>	<b>Intra-uterine insemination</b>
<b>IVF</b>	<b>In vitro fertilisation</b>
<b>NICE</b>	<b>National Institute of Clinical Excellence</b>
<b>PCT</b>	<b>Primary Care Trust</b>

Appendix B

## Definitions

Term	Definition	Further information
<b>BMI</b>	The healthy weight range is based on a measurement known as the <b>Body Mass Index (BMI)</b> . This can be determined if you know your weight and your height. This calculated as your weight in kilograms divided by the square of your height in metres. In England, people with a body mass index between 25 and 30 are categorised as overweight, and those with an index above 30 are categorised as obese.	BBC Healthy Living <a href="http://www.bbc.co.uk">http://www.bbc.co.uk</a>  NHS Direct <a href="http://www.nhsdirect.nhs.uk">http://www.nhsdirect.nhs.uk</a>
<b>ICSI</b>	<b>Intra Cytoplasmic Sperm Injection (ICSI):</b> In conjunction with IVF, where a single sperm is directly injected, by a recognised practitioner, into the egg. A clinic may also use donor sperm or eggs.	Glossary, HFEA <a href="http://www.hfea.gov.uk">http://www.hfea.gov.uk</a>
<b>IUI</b>	<b>Intra Uterine Insemination (IUI):</b> Insemination of sperm into the uterus of a woman.	As above
<b>IVF</b>	<b>In Vitro Fertilisation (IVF):</b> Patient's eggs and her partner's sperm are collected and mixed together in a laboratory to achieve fertilisation outside the body. The embryos produced may then be transferred into the female patient.	As above
<b>DI</b>	<b>Donor Insemination (DI):</b> The introduction of donor sperm into the vagina, the cervix or womb itself.	As above

Appendix C

**Explanatory Notes and Guidance**

**1 Same-sex couples and single people:**

The NICE Clinical Guidance does not cover same-sex couples and single people. Infertility for the purposes of investigation at 2 years is judged against a recommendation that '*sexual intercourse every 2 to 3 days optimises the chance of pregnancy*'. As this is not typically possible in the case of same-sex couples and single people it would not be possible to distinguish underlying problems from lifestyle choices as the cause of infertility. Furthermore there are intrinsic problems that differentiate the male-male, female-female, single male and single female situations that would make a claim of sexual discrimination difficult to defend, most particularly the non-funding of surrogacy, a necessary requirement for single male or male-male couples.

Should a case be presented where there is a proven cause of infertility, this may need to be considered as an individual case, though the problems of potential discrimination remain.

**2 Previously privately funded treatment**

PCTs have expressed concerns that this policy to fund a cycle even if the couple had had up to 2 cycles funded privately, represented inequality of access (based on equality of effectiveness and cost effectiveness) as success rates decline with each cycle. It was agreed that couples that met the eligibility criteria and had previously funded fewer than 3 cycles should still be offered one NHS funded cycle of IVF/ICSI.

Appendix D

**Sub-Fertility Funding Assessment Sheet**

**Please complete this form for all couples requesting funding for IVF or ICSI.**

Patient Name:  
DOB:  
NHS Number:  
Address:

*Please indicate true or false dependent on agreement with each criteria*

<b>Criteria</b>	<b>True 'T' or False 'F'</b>
Couple has failed to conceive after regular unprotected sexual intercourse for 3 years, or have an established cause of infertility. <i>Therefore will have been a 'couple' for at least 3 years.</i>	
Female partner is aged 23 to 39 at the start of the treatment cycle.	
Neither partner has been previously sterilised.	
Female partner has a 20 and 29	
Both partners are childless - <i>this means that neither partner are to have any living children, this includes adopted children.</i>	
The couple's health and social circumstances would pose no significant risk to conception, pregnancy or the resultant child.	
No more than 2 cycles of IVF already received (regardless of NHS or privately funded) - <i>couples are only eligible to receive up to a maximum of 3 cycles in a lifetime regardless of NHS or privately funded.</i>	
<i>Neither partner has previously received NHS funding for a cycle of IVF or ICSI.</i>	
In addition to couples meeting all of the above criteria, couples will not be eligible for further NHS funded cycles if either partner have previously received one NHS funded IVF or ICSI cycle	
<b>Overall Result (for use by PCT only)</b>	

**If couple are approved for funding please specify patients preferred provider:  
CARE or NURTURE at Queens Medical Centre (*delete as appropriate*)**

Completed by: .....  
Signed: .....

Designation: .....  
Date: .....

**Please return completed forms to:**  
Individual Case Review Committee  
Nottinghamshire County tPCT  
Ransom Hall  
Southwell Road West  
Rainworth

Mansfield NG21 0ER

## TERMS OF REFERENCE FOR THE INDIVIDUAL CASE REVIEW COMMITTEE (ICRC)

- 1. Constitution** The Board of Nottinghamshire County tPCT hereby resolves to establish a sub-committee to be known as the Individual Case Review Committee (ICRC)
- 2. Membership** Membership of the ICRC is as follows:
- 2 Non-Executive Directors of PCT (Chair and Deputy Chair)
  - 3 GPs
  - 2 senior members of PCT Commissioning & Performance Directorate
  - Chief Pharmacist and deputy
  - Director of Nursing and Governance and deputy
  - 2 Public Health Consultants
  - PCT Medical Director
  - Lay assessor(s) (once appointed)
- In attendance: Individual Case Review Manager
- 3. Voting rights** All ICRC members will have the right to vote. If required the Chair will have the casting vote.
- 4. Frequency** The ICRC will meet monthly. If a case needs to be considered urgently between meetings (where the Director of Public Health or nominated deputy considers an urgent clinical decision is to be made, for example), this will be done by telephone, email or fax between the Deputy Director of Commissioning & Performance and the Chair with advice from the Public Health Consultant / Director of Public Health. In this case, decisions taken outside of the meeting will be noted at the next scheduled meeting.
- 5. Authority** The ICRC is authorised by the PCT Board to make decisions on exceptional individual cases only. The ICRC cannot set policy by virtue of setting a precedent.
- 6. Purpose** To decide whether the PCT should fund treatments outwith PCT policy or contracts on the basis of exceptional status.
- 7. Objectives** To apply the values of the PCT by addressing the key issues of:
- Legality
  - Safety
  - Clinical Effectiveness
  - Cost Effectiveness
  - Equity (including equality and diversity)
  - Accessibility
  - Affordability

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## 8. Duties

- Patient information will be dealt with in confidence: no patient identifiable information will be used unless pertinent to the consideration of the request.
- The ICRC will follow the process described in the Policy on the Management of Named Patient Funding Requests May 2008.
- The ICRC will request evidence from the patient's clinician and consider the information received along with supplementary information provided by professionals within the ICRC.
- The ICRC will assess the available evidence on the effectiveness and cost effectiveness of the proposed investigation/treatment.
- The ICRC will co-opt health care practitioners as necessary to advise.
- The ICRC will record clearly and in detail reasons for its decisions.
- The ICRC will produce an annual report for the Board, relating to activity and finance.
- The ICRC will seek information on the outcomes of funded treatments.
- The ICRC will **NOT** agree to fund if, in doing so, a precedent may be set, that establishes new policy (ie the case considered is not exceptional but rather representative of a group of patients). Where the ICRC feels general access to the service should be provided a recommendation should be passed on for consideration through the Local Operational Plan processes, but funding must be refused.
- Where funding is refused and where additional material clinical information is provided that was not previously available the ICRC will re-consider requests for funding. Cases requiring reconsideration will be re-referred to the ICRC at its next available meeting.
- Where funding is refused and no additional clinical information is available, or relevant, the patient may seek to appeal the process and policy that have been applied. In such circumstances an appeal panel will be convened as set out in Appendix H of the Policy on the Management of Named Patient Funding Requests – May 2008.

## 9. Quorum

A minimum of 5, (one Non-Executive Director, one GP, one Pharmacy representative, one Nursing & Governance representative and one Commissioning representative). Exceptionally, the Chair may accept prior assessment and contribution by email in lieu of attendance.

## 10. Attendance

Directors will ensure attendance to achieve the quorum in respect of each department (PCT Chair for Non-Executive Directors).

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**11. Reporting**           The ICRC will report annually to the Board.

**12. Annual Review**   The Terms of Reference for the Individual Case Review Committee will be reviewed in April of each year.

As at 1<sup>st</sup> April 2008, membership of the ICRC is as follows:

<b>Non-Executive Directors</b>	<b>Pharmacy</b>
Dr Patricia Higham (Chair) Stuart Brooke (Deputy Chair)	Cathy Quinn Joe Attewell
<b>Nursing and Governance</b>	<b>GPs</b>
Dr Amanda Sullivan Michelle Bateman	Dr Simon Brenchley (Newark) Dr Gaynor Mountcastle (Mansfield) Dr Khalid Butt (Mansfield Woodhouse)
<b>Public Health</b>	<b>Commissioning and Performance</b>
Dr Chris Kenny Dr Clive Richards	Chris Kerrigan Deborah Jaines
<b>Medical Director</b>	<b>Lay Assessors</b>
Dr Doug Black	To be appointed

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## 1. **TERMS OF REFERENCE OF THE APPEALS PANEL**

- 1.1 To consider and review the process by which the Individual Case Review Committee's (ICRC) decision in relation to the funding or otherwise of an individual's treatment/service was reached. The Appeals Panel can consider whether the evidence that the Individual Case Review Committee had before it supported the decision that was reached and whether there were any circumstances that would have warranted the ICRC coming to a different decision.
- 1.2 In considering the above, the Appeals Panel will use the decision making principles (Appendix C) with reference to:
- i) Local policies together with guidance from the Department of Health; Health Service Circulars; guidance from NICE and other relevant bodies.
  - ii) Oral or written representation from the individual or his or her representative.
  - iii) Such further information and/or evidence which was produced to the ICRC (including the individual's relevant medical records and comments from the treating clinician(s) where provided – subject to provision of the individuals written consent).
- 1.3 Where the appellant has provided new or additional evidence that has not been previously considered by the ICRC, the Appeals Panel shall refer the case back to the ICRC for reconsideration. The Appeals Panel should not consider evidence that has not been subjected to the same rigour and scrutiny that the evidence presented to the ICRC has received. The Appeals Panel will not be permitted to consider a case that is reliant on the presentation of new evidence **if** the case has already been reconsidered by the ICRC previously. Nor will the appeals panel refer this case back to the ICRC for a second reconsideration.
- 1.4 The Appeals Panel's decisions are limited to one of five outcomes outlined in section 2.17 below.
- 1.5 The Appeals Panel will communicate its decision with reasons for its decision to the Chairman of the Primary Care Trust and to the appellant as soon as practicable and within seven working days of the conclusion of the Appeal hearing in any event.

## 2. **APPEALS PROCEDURE**

This procedure relates to cases where a request for funding of a Named Patient Funding Request (NPFR) for an individual has been declined by the PCT's ICRC. It does not relate to commissioning decisions taken by the PCT for groups or cohorts of patients and treatments.

- 2.1 Any individual aggrieved by a decision on services or treatment can appeal against that decision. The decision can be challenged on the grounds that it was unreasonable<sup>1</sup> or not properly based on the evidence set before the ICRC.

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<sup>1</sup> Definition of "unreasonable" for the purposes of this policy is a decision so unreasonable that no reasonable authority could have arrived at it.

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The appellant cannot raise new arguments or present new evidence as a ground of appeal. In the event of new evidence becoming available since the ICRC made its decision, the patient will be requested to invite his or her clinician to submit that evidence to the ICRC so that the case can be duly reconsidered, in accordance with the provisions for reconsideration of the Policy on the management of Named Patient Funding Requests.

- 2.2 The case for which the appeal has been made, must have previously been considered by the ICRC. If this has not occurred, the appeal will be rejected and the case referred to the ICRC for consideration.
- 2.3 The individual (or the treating clinician on his behalf) must notify the PCT's Chief Executive in writing of his / her appeal, including the grounds for the appeal, within twenty-eight working days of the decision of the ICRC being notified to the treating clinician. NB: the ICRC will include the deadline for the appeal in the letter it issues when setting out its decision.
- 2.4 The appeal letter will be subjected to the following tests prior to a decision being taken to set up an oral hearing in front of an Appeal Panel:
- Has the appeal been submitted within the 28 working day limit ? If not, and if the appellant cannot show reasonable grounds for the delay in making the appeal, the appeal will be dismissed as being out of time.
  - Does the appeal raise any new issues that were not part of the original consideration by the ICRC, or present new evidence that the ICRC has not had an opportunity to consider? If so then the appeal will be referred back to the ICRC for reconsideration in accordance with the policy for Named Patient Funding Requests.
  - Does the appeal contain the grounds for the appeal? If not, the appeal will be referred back to the appellant with a request for the grounds to be set out. In this circumstance the appellant will be given a further 14 working days in which to resubmit his appeal in proper form.
  - Does the appeal challenge the decision of the ICRC on the basis that it was unreasonable? If so the appeal will go forward for an oral hearing in front of an Appeals Panel.
  - Does the appeal challenge the validity of the decision in relation to the evidence that was available when the ICRC made its decision? If so, the appeal will go forward for hearing in front of an Appeals Panel.

This screening will be conducted by the Director of Commissioning and Performance or a senior manager nominated to perform this task on his/her behalf.

- 2.5 If, as a result of the above screening, the appeal is to go forward for an oral hearing then, within 5 working days of the decision to convene a panel being taken, the Director of Commissioning and Performance, or his/her nominee will issue a consent form for the appellant to complete and return. This consent form enables the appellant to give his consent for the Appeals Panel to have full access to all relevant information about their case and authorises the Appeals Panel to share

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information on the case with any person nominated by the appellant in the consent form to act on his / her behalf.

The appellant will be asked to return this form within 14 calendar days of receiving it.

2.6 Upon receipt of a properly completed consent form an Appeals Panel will be convened to hear the appeal, and will meet to consider the appeal within 28 days unless further relevant information is awaited by one or both of the parties to the appeal, in which case one extension of a further 28 days will be considered.

2.7 The Chief Executive will nominate a PCT officer to convene (The Convening Officer) the Appeals Panel and undertake collection and distribution of written material for this Panel. The nominated officer will have no prior knowledge of the case.

2.8 The Appeal Panel will comprise:

- One Executive Director of the PCT, who has had no prior involvement in the case being appealed.
- One Non-Executive Director of the PCT, who will Chair the panel, and who has had no prior involvement in the case being appealed.
- The PCT's Medical Director or Chair of the PEC, or other nominated GP who has had no prior involvement in the case being appealed.

The Appeals Panel must not comprise any member who has had any prior involvement in the decision making process.

2.9 The Convening Officer will invite the appellant to submit written information to the Appeals Panel if he / she wishes. This information should be relevant to the grounds of the appeal and should not constitute new or additional evidence not yet heard by the ICRC. If the information is of that nature, the case will be referred back to the ICRC for reconsideration in light of the new or additional evidence. (This will only be possible where no reconsideration has previously been made by the ICRC).

2.10 The Convening Officer will invite the appellant's treating clinician to submit written information to the Appeals Panel if he so wishes (subject to provision of the appellant's written consent). Again, this information should be in support of the grounds for the appeal, and not constitute new or additional evidence.

2.11 The Convening Officer will ask the ICRC's Consultant in Public Health or Specialist (who will work with the relevant PCT Lead Officer) to provide in full the information on the case that was considered at the ICRC meeting.

2.12 The Appeals Panel will be provided, prior to its meeting, with all the written information collected by the Convening Officer.

2.13 The appellant will be entitled to make either oral or written representations to the Appeals Panel and to be accompanied by a representative(s), or a supporter who may make representations on the individual's behalf. The representative/supporter may be the appellant's treating clinician. If the appellant chooses not to be present or be represented at the Appeal Panel hearing, this will not invalidate proceedings

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and the Appeals Panel will be free to consider the appeal with the information it has before it.

- 2.14 The appellant shall not be entitled to legal representation at the hearing of his / her appeal.
- 2.15 The ICRC's Consultant in Public Health / Specialist or other appropriate PCT Officer will attend the Appeals Panel and explain the reasons for the decision made by the ICRC.
- 2.16 In reaching its decision, the Appeals Panel will pay due regard to the PCT's Decision Making Principles (Appendix C of the Policy on the management of Named Patient Funding Requests) and any relevant clinical and commissioning policies in force at the time the request for funding was made.
- 2.17 The decisions available to the Appeals Panel are:
- a. To conclude that the decision of the ICRC was properly, logically and rationally based on the information that the panel had before it, in which case the appeal will be dismissed; and/or
  - b. To conclude that the decision arrived at by the ICRC was made on a reasonable basis, in which case the appeal will be dismissed; or
  - c. To conclude that either the decision of the ICRC was unreasonable (i.e. so unreasonable that no reasonably authority could have arrived at it), or the decision of the ICRC was not properly based upon the evidence set before that Committee, in which case the appeal will be upheld and referred back to the ICRC for reconsideration in accordance with the Policy for Named Patient Funding Requests; or
  - d. To conclude that the appellant has presented new evidence that the ICRC did not have an opportunity to consider, in which case the matter will be referred back to the ICRC for reconsideration in accordance with the Policy for Named Patient Funding Requests; or
  - e. To conclude that in light of the evidence heard by the Appeals Panel there are grounds for upholding the appeal but that further referral back to the ICRC would serve no further purpose, in which case the Appeals Panel will make a recommendation to the PCT Board on the appropriate actions to take.

It should be noted that the Appeals Panel does not have delegated authority to approve expenditure on packages of care and this rests with the ICRC on behalf of the Board. Therefore any final decision on expenditure has to rest with the ICRC or the PCT Board.

- 2.18 Where a case is referred by the Appeals Panel back to the ICRC the decision of the ICRC, after due consideration of the Appeals Panel's recommendations, shall be final and no further appeal shall be allowed. This is to enable appropriate decisions on an individual's care to be taken and implemented. Should the individual remain dissatisfied with the processes by which their case has been handled they have recourse to the PCT's complaints procedure. However, it should be noted that the

PCT's complaints procedure does not have the power or authority to overturn a decision that has properly been considered by the ICRC and the Appeals Panel.

None of the above negates an individual's rights to refer his case to the Healthcare Commission or to the Health Services Ombudsman.

### **3. Proceedings at the Appeal Panel hearing**

The procedure for hearing the appeal will be as follows:

- 3.1 The Panel Chair will determine how the appeal will be conducted within the guidelines set out below.
- 3.2 The Panel Chair will ensure that all parties are introduced.
- 3.3 The Panel Chair will ask the appellant and /or the appellant's representative(s) to explain the reasons for the appeal.
- 3.4 The Panel Chair will ask the Consultant in Public Health / specialist or attending appropriate PCT Officer to explain the ICRC's decision for refusing the request for funding.
- 3.5 The appellant, or his / her representative, may ask the Chair any questions about what has been said.
- 3.6 The Chair and other panel members may ask those attending the appeal hearing any questions about the case and / or what has been said.
- 3.7 The Panel Chair will ask the ICRC's Public Health Consultant / specialist or appropriate PCT Officer to sum up why the ICRC declined to commission (fund) the treatment.
- 3.8 The Panel Chair will end the appeal hearing by inviting the appellant or his representative to sum up the reasons for the appeal against the decision of the ICRC.
- 3.9 All parties other than the Appeals Panel members, will then leave to enable the Appeals Panel to consider the merits of the appeal and come to a decision. Decisions shall be reached by a simple majority of the members of the Appeal Panel present at the hearing. In the event of an equality of votes, the Chair shall have a casting vote.
- 3.10 The Appeals Panel's decision will be notified by letter from the Panel Chair to the appellant within seven working days of the conclusion of the appeal hearing.
- 3.11 The Panel Chair will, whenever possible arrange for the appellant to be informed by telephone of the decision as soon as practicable.

The Chair of the Panel will have the right to vary the above procedure where such variations would assist in ensuring the fairness and equity of the panel's proceedings.

# **COMMISSIONING POLICY**

## **COSMETIC PLASTIC SURGERY PROCEDURES**

**May 2008**

Review date: 31 May 2009

## Introduction

Cosmetic surgery can be defined as any surgery carried out to improve or enhance a person's outward appearance. Although most of the work of plastic surgeons in the NHS is to restore appearance and function following trauma, disease or congenital deformity, surgery can also be carried out to enhance changes in appearance relating to obesity or aging.

The NHS cannot meet all demand for cosmetic surgery within its current resources. As such, the majority of cosmetic surgery procedures are deemed to be 'low-priority' and not normally funded. This policy sets out the eligibility criteria for access to NHS-funded cosmetic surgery procedures.

**Patients requiring reconstructive surgery to restore normal or near normal function or appearance post-trauma or following cancer treatment do not fall within this policy.**

## Background

Although primarily undertaken to enhance outward appearance, many cosmetic surgery procedures have the benefit of improving physical dysfunctions that may be considered 'clinical' in their severity. The circumstances in which cosmetic surgery is deemed to be a priority and funded are as follows;

*Anatomical indications:* - if the purpose of the treatment is to alleviate or improve a physical deformity that most people would recognise as being severely abnormal

*Functional indications:* - if the purpose of the treatment is to substantially alleviate or improve a physical deformity causing significant and/or prolonged functional problems that cannot be resolved effectively by any other appropriate intervention

Eligibility criteria for funding are underpinned by the PCT's decision-making principles of legality, safety, clinical effectiveness, cost effectiveness, equity, accessibility and affordability. Criteria for specific procedures were agreed through consultation with key stakeholders that included patients and public as well as clinical and non-clinical representatives from primary and secondary care organisations in Nottinghamshire County.

It is important to note that a substantial proportion of cosmetic surgery is carried out by specialties other than plastic surgery, including ENT surgery, ophthalmology, maxillofacial surgery, general surgery and dermatology. This policy only concerns procedures carried out in NHS hospitals.

## Referral for cosmetic surgery procedures

Commissioning approval is required for NHS funding of cosmetic surgery procedures. Patients who meet the eligibility criteria set out in this policy should be referred for treatment via the appropriate pathway. Supporting information should be forwarded with each referral, as specified for each procedure in the table below.

**Patients who do not meet the eligibility criteria set out in this policy should NOT be referred for treatment.**

## Relationship with Individual Case Review Committee (ICRC)

Patients who do not meet the eligibility criteria set out in this policy will not be offered NHS funding. If the General Practitioner (GP) and/or patient believe that their case merits funding on an exceptional basis, the General Practitioner will need to;

- demonstrate that the patient is significantly different to the general population of patients with the condition in question, by being likely to gain significantly more benefit from the intervention than might be expected for the average patient with the same clinical condition at the same clinical stage. S
- submit a named patient funding request to the relevant Primary Care Trust's ICRC using the appropriate route

## Appeals mechanism

The appeals mechanism for cosmetic surgery procedures is the same as that for other named patient funding requests. This mechanism exists to provide an opportunity for the GP and/or patient to challenge the way the eligibility criteria have been applied. The appeals mechanism will not be able to reverse a decision on the basis that the GP and/or patient contest the actual criteria for eligibility, which constitutes a formal complaint to the PCT's Chief Executive on commissioning policy. In this case, the formal procedure for written complaints is the appropriate route.

## Monitoring and review

Some aspects of the current policy have changed since the preceding version of the low-priority treatment and procedures policy was approved by the PCT Board. In order to understand the impact of these changes on the number of patients referred, treated and having complications, activity against this policy will be monitored closely following implementation. Procedure codes have been included in Appendix 1 to assist PCTs in identifying hospital activity involving cosmetic surgery procedures. Monitoring will be on a weekly basis initially, then monthly or quarterly as appropriate. The policy, including eligibility criteria, will be reviewed by April 2009 or before if any new guidance or clinical evidence becomes available.

At the time the current policy was reviewed, the Collaborative Commissioning Group of the East Midlands Specialised Commissioning Group identified 'cosmetic surgery' as a

regional priority that required a collaborative approach. On that basis, it is anticipated that a regional cosmetic surgery policy will replace the current local policy at some future date.

## **General Eligibility**

It is the purpose of eligibility criteria to make the limits on NHS-funded cosmetic surgery fair, clear and explicit to patients, providers and commissioners alike.

1. Surgery for patients who are deemed to be within the normal morphological range will be considered purely cosmetic and therefore NOT funded on the NHS.
2. Referrals for the revision of treatments originally performed outside the NHS will NOT normally be supported and patients should be referred back to the practitioner who carried out the original procedure. However there may be unusual or severe complications or circumstances that require the transfer of a patient to the NHS for appropriate management.
3. Patients previously treated within the NHS should be considered for revision surgery based on clinical need and priority.
4. Cosmetic surgery procedures will NOT be funded to alleviate psychological distress or dysfunction. No exceptions to this policy are foreseen. When there is particular concern over psychological well-being, patients should be referred to the appropriate service for psychological assessment and/or support.
5. Surgical outcomes (e.g. wound healing, complications etc) can be adversely affected by smoking. To ensure the best outcomes, patients should have stopped smoking prior to referral. Smoking status may be validated at pre-operative appointment using an appropriate test. Support to stop smoking is available to patients through a range of NHS stop smoking services.
6. All decisions will be taken in the context of the overall financial position of the PCT.

## Eligibility for Specific Procedures

General Surgical Procedures		
<i>Procedure</i>	<i>Eligibility criteria</i>	<i>Information to forward with referral</i>
Abdominoplasty and/or thigh and arm lift surgery (following significant weight loss)	<p>Referral <b>only</b> for patients who;</p> <ul style="list-style-type: none"> <li>• have a BMI between 18 and 27 that has been maintained for at least 2 years AND</li> <li>• have lost a significant amount of weight that is equivalent to at least 10 BMI points AND</li> <li>• are experiencing severe difficulties with daily living e.g. ambulatory or urological restrictions</li> </ul> <p>Surgical outcomes (e.g. wound healing, complications etc) can be adversely affected by smoking. To ensure the best outcomes, patients should have <b>stopped smoking</b> prior to referral. Smoking status may be validated at pre-operative appointment using an appropriate test. Support to stop smoking is available to patients through a range of NHS stop smoking services.</p> <p>BMI should be measured in the NHS. When there is a disabling affect upon daily living, patients may be eligible for contouring at diabetes injections sites (upon recommendation of Diabetologist) or for lymphoedema, thinning of skin flaps or post-gastric partitioning. Female patients planning a family should postpone treatment until after childbirth.</p>	<ul style="list-style-type: none"> <li>• Details of condition</li> <li>• BMI and period maintained</li> <li>• Weight loss in BMI points</li> <li>• Smoking status</li> <li>• Clinical evidence of severe difficulties with daily living</li> <li>• Clinical photographs</li> </ul>
Blepharoplasty (eyelid reduction)	<p>Referral <b>only</b> for patients whose upper eyelid significantly interferes (due to ptosis or excessive skin) with their vision field (as assessed by an Optometrist prior to referral). Lower eyelids are excluded as they do not obscure vision.</p> <p>Surgical outcomes (e.g. wound healing, complications etc) can be adversely affected by smoking. To ensure the best outcomes, patients should have <b>stopped smoking</b> prior to referral. Smoking status may be validated at pre-operative appointment using an appropriate test. Support to stop smoking is available to patients through a range of NHS stop smoking services.</p>	<ul style="list-style-type: none"> <li>• Details of condition</li> <li>• Results of optometry assessment</li> <li>• Smoking status</li> <li>• Clinical photographs</li> </ul>

<i>Procedure</i>	<i>Eligibility criteria</i>	<i>Information to forward with referral</i>
Botulinum toxin injections	<p>Approved for the treatment of the following pathological conditions by appropriate specialists;</p> <ul style="list-style-type: none"> <li>• Axillary hyperhidrosis (refer to Dermatology for consultant assessment)</li> <li>• Blepharospasm (refer to Plastic Surgery for consultant assessment)</li> </ul> <p><b>Not</b> available for the treatment of facial aging or excessive wrinkles.</p> <p>Surgical outcomes (e.g. wound healing, complications etc) can be adversely affected by smoking. To ensure the best outcomes, patients should have <b>stopped smoking</b> prior to referral. Smoking status may be validated at pre-operative appointment using an appropriate test. Support to stop smoking is available to patients through a range of NHS stop smoking services.</p>	<ul style="list-style-type: none"> <li>• Details of condition</li> <li>• Smoking status</li> </ul>
Breast asymmetry	<p>Referral <b>only</b> for patients with gross asymmetry who;</p> <ul style="list-style-type: none"> <li>• are aged 16 years or over AND</li> <li>• have a BMI between 18 and 25 AND where;</li> <li>• there is gross asymmetry equal to or greater than 30% difference in breast volume</li> </ul> <p>Surgical outcomes (e.g. wound healing, complications etc) can be adversely affected by smoking. To ensure the best outcomes, patients should have <b>stopped smoking</b> prior to referral. Smoking status may be validated at pre-operative appointment using an appropriate test. Support to stop smoking is available to patients through a range of NHS stop smoking services.</p> <p>BMI should be measured in the NHS. Patients will be offered a 3D body scan<sup>1</sup> to objectively measure breast volume and the extent of breast asymmetry.</p>	<ul style="list-style-type: none"> <li>• Details of condition</li> <li>• Age</li> <li>• Smoking status</li> <li>• BMI</li> </ul>

<sup>1</sup> Body Aspect Limited provides the 3D body scanning service. Scanning uses white light technology to accurately measure volumes within sections of the body. A female operator will undertake the body scanning. Body Aspect Limited will produce a report of scan results that will be returned to the PCT's pathway co-ordinator and considered against the eligibility criteria along with other information. Scan results will also be used by the surgeon as part of the pre-treatment counselling with the patient and during surgery to assist with the corrective procedure.

<i>Procedure</i>	<i>Eligibility criteria</i>	<i>Information to forward with referral</i>
Breast augmentation	<p><b>Not</b> routinely funded for cosmetic reasons. Breast augmentation may be an appropriate treatment for breast asymmetry in some women (see appropriate criteria).</p> <p>Breast reconstruction is <b>always</b> supported following mastectomy.</p>	See breast asymmetry
Breast mastopexy (surgical fixation of the breast)	<p><b>Not</b> routinely funded for cosmetic reasons (e.g. post-lactation or age-related breast ptosis). Breast mastopexy may be an appropriate treatment for breast asymmetry or breast reduction in some women (see appropriate criteria).</p>	See breast reduction or breast asymmetry
Breast reduction	<p>Referral <b>only</b> for patients with abnormally large breasts who;</p> <ul style="list-style-type: none"> <li>• are aged 16 years or over AND</li> <li>• have a BMI between 18 and 25 AND where;</li> <li>• breast size is equal to or greater than 1000cc per breast AND</li> <li>• the ratio of combined breast volume to adjusted partial torso volume is equal to or greater than 13%</li> </ul> <p>Surgical outcomes (e.g. wound healing, complications etc) can be adversely affected by smoking. To ensure the best outcomes, patients should have <b>stopped smoking</b> prior to referral. Smoking status may be validated at pre-operative appointment using an appropriate test. Support to stop smoking is available to patients through a range of NHS stop smoking services.</p> <p>BMI should be measured in the NHS. Treatment is supported based on the known relationship between large breasts and spinal disorders. Patients will be offered a 3D body scan to objectively measure breast volume.</p>	<ul style="list-style-type: none"> <li>• Details of condition</li> <li>• Age</li> <li>• BMI</li> <li>• Smoking status</li> </ul>

<i>Procedure</i>	<i>Eligibility criteria</i>	<i>Information to forward with referral</i>
Breast reduction (male gynaecomastia)	<p>Referral <b>only</b> for male patients who;</p> <ul style="list-style-type: none"> <li>• are post-pubertal AND</li> <li>• have a BMI between 18 and 25 AND where;</li> <li>• there is excessive breast tissue and the expected reduction to be obtained will be significant and/or there is gross asymmetry</li> </ul> <p>Surgical outcomes (e.g. wound healing, complications etc) can be adversely affected by smoking. To ensure the best outcomes, patients should have <b>stopped smoking</b> prior to referral. Smoking status may be validated at pre-operative appointment using an appropriate test. Support to stop smoking is available to patients through a range of NHS stop smoking services.</p> <p>BMI should be measured in the NHS. In the first instance, patients should be referred for assessment by an Endocrinologist. Patients will <b>not</b> be offered a 3D body scan to objectively measure breast volume as a local trial has shown scanning to be insufficiently sensitive for male gynaecomastia.</p> <p>Individuals who are taking sport performance-enhancing drugs (in whom the gynaecomastia is potentially drug-induced) will be refused surgery and should <b>not</b> be referred.</p>	<ul style="list-style-type: none"> <li>• Details of condition</li> <li>• Pubertal status</li> <li>• Smoking status</li> <li>• BMI</li> <li>• Results of endocrinological assessment</li> <li>• History of sport performance-enhancing drug use</li> <li>• Clinical photographs</li> </ul>
Correction of congenital nipple inversion	<p><b>Not</b> funded for cosmetic reasons. This common condition responds well to non-surgical interventions e.g. Niplette device.</p> <p><b>Note that any recent nipple inversion should be considered as suggestive of breast cancer and requires referral to a breast surgeon.</b></p>	Not funded for cosmetic reasons

<i>Procedure</i>	<i>Eligibility criteria</i>	<i>Information to forward with referral</i>
Dermabrasion	<p>Referral <b>only</b> following trauma, acne, discoid lupus or other scarring facial skin diseases. Patients should be referred to Dermatology. Patients will be jointly assessed by a consultant dermatologist and a consultant plastic surgeon.</p> <p>Surgical outcomes (e.g. wound healing, complications etc) can be adversely affected by smoking. To ensure the best outcomes, patients should have <b>stopped smoking</b> prior to referral. Smoking status may be validated at pre-operative appointment using an appropriate test. Support to stop smoking is available to patients through a range of NHS stop smoking services.</p>	<ul style="list-style-type: none"> <li>• Details of condition</li> <li>• Smoking status</li> <li>• Clinical photographs</li> </ul>
Face or brow lift	<p>Referral <b>only</b> for the surgical correction of facial palsy or deformities following trauma or surgery if other treatments are not appropriate. A consultant will assess the patient and make a clinical decision in each case.</p> <p>Surgical outcomes (e.g. wound healing, complications etc) can be adversely affected by smoking. To ensure the best outcomes, patients should have <b>stopped smoking</b> prior to referral. Smoking status may be validated at pre-operative appointment using an appropriate test. Support to stop smoking is available to patients through a range of NHS stop smoking services.</p>	<ul style="list-style-type: none"> <li>• Details of condition</li> <li>• Smoking status</li> <li>• Clinical photographs</li> </ul>
Hair depilation (for hirsutism, especially in women)	<p>Referral <b>only</b> for patients with excessive and intractable facial hair that;</p> <ul style="list-style-type: none"> <li>• is a recognised component of a clinical condition OR</li> <li>• has been caused by drug therapy OR</li> <li>• is idiopathic and could be considered grossly abnormal</li> </ul> <p>Surgical outcomes (e.g. wound healing, complications etc) can be adversely affected by smoking. To ensure the best outcomes, patients should have <b>stopped smoking</b> prior to referral. Smoking status may be validated at pre-operative appointment using an appropriate test. Support to stop smoking is available to patients through a range of NHS stop smoking services.</p> <p>Patients who have undergone reconstructive skin grafting surgery that has led to abnormally located hair-bearing skin will be treated outside of this policy.</p>	<ul style="list-style-type: none"> <li>• Details of condition</li> <li>• Smoking status</li> <li>• Clinical photographs</li> </ul>

<i>Procedure</i>	<i>Eligibility criteria</i>	<i>Information to forward with referral</i>
Hair transplantation	<p><b>Not</b> funded for cosmetic reasons. Patients requiring reconstruction of the eyebrow following cancer or trauma will be treated outside of this policy.</p> <p>Surgical outcomes (e.g. wound healing, complications etc) can be adversely affected by smoking. To ensure the best outcomes, patients should have <b>stopped smoking</b> prior to referral. Smoking status may be validated at pre-operative appointment using an appropriate test. Support to stop smoking is available to patients through a range of NHS stop smoking services.</p>	Not funded for cosmetic reasons
Liposuction	<p>Liposuction supported <b>only</b> when used in the management of lipodystrophies, large lipomas, fat injuries due to trauma, lymphoedema or as part of other surgery (e.g. thinning of transplanted flap).</p> <p>Surgical outcomes (e.g. wound healing, complications etc) can be adversely affected by smoking. To ensure the best outcomes, patients should have <b>stopped smoking</b> prior to referral. Smoking status may be validated at pre-operative appointment using an appropriate test. Support to stop smoking is available to patients through a range of NHS stop smoking services.</p>	<ul style="list-style-type: none"> <li>• Details of condition</li> <li>• Smoking status</li> </ul>

<i>Procedure</i>	<i>Eligibility criteria</i>	<i>Information to forward with referral</i>
Pinnaplasty (correction of prominent ears)	<p>Referral <b>only</b> for children;</p> <ul style="list-style-type: none"> <li>aged 5 to 18 years at the time of referral AND</li> <li>with very significant ear deformity or asymmetry AND</li> <li>where the child, rather than the parents alone, expresses concern</li> </ul> <p>Surgical outcomes (e.g. wound healing, complications etc) can be adversely affected by smoking. To ensure the best outcomes, patients should have <b>stopped smoking</b> prior to referral. Smoking status may be validated at pre-operative appointment using an appropriate test. Support to stop smoking is available to patients through a range of NHS stop smoking services.</p> <p>Referral of patients over the age of 18 years is considered inappropriate and will <b>not</b> be funded.</p>	<ul style="list-style-type: none"> <li>Details of condition</li> <li>Age</li> <li>Smoking status</li> <li>Clinical photographs</li> </ul>
Removal and replacement of silicone implants (including Capsular contraction following aesthetic augmentation)	<p>Removal of intact or ruptured silicone implants or scar tissue and replacement of silicone implants are <b>not</b> routinely available on the grounds of concern over excess risk of connective tissue disorders<sup>2</sup>.</p> <p><b>All patients will be assessed to rule out any underlying cancers.</b></p> <p>Removal will be offered <b>only</b> if the implants are causing physical problems with everyday life or where the patient has gross deformity. Replacement will be offered <b>only</b> if the implant operation was performed in the NHS (e.g. correction of breast asymmetry or reconstruction following breast cancer) and the patient meets eligibility criteria for augmentation at the time of revision.</p> <p>Surgical outcomes (e.g. wound healing, complications etc) can be adversely affected by smoking. To ensure the best outcomes, patients should have <b>stopped smoking</b> prior to referral. Smoking status may be validated at pre-operative appointment using an appropriate test. Support to stop smoking is available to patients through a range of NHS stop smoking services.</p>	<ul style="list-style-type: none"> <li>Details of condition</li> <li>Clinical evidence of physical problems or gross deformity</li> <li>Responsibility for implant operation</li> <li>Smoking status</li> </ul>

<sup>2</sup> Following the recommendations of the Department of Health's (DH) advisory group (Gott and Tinkler 1994) and Independent Review Group (1998) on silicone gel breast implants and considering the published conclusion that silicone breast implants are not associated with meaningful excess risk of connective tissue disease (Cooper and Dennison 1998, Nyren *et al* 1998)

<i>Procedure</i>	<i>Eligibility criteria</i>	<i>Information to forward with referral</i>
Revision mammoplasty (second surgical alteration of breast size or shape)	<p>Referral <b>only</b> if the;</p> <ul style="list-style-type: none"> <li>implants are causing physical problems with everyday life or where the patient has gross deformity AND</li> <li>implant operation was performed in the NHS (e.g. correction of breast asymmetry or reconstruction following breast cancer)</li> </ul> <p>Surgical outcomes (e.g. wound healing, complications etc) can be adversely affected by smoking. To ensure the best outcomes, patients should have <b>stopped smoking</b> prior to referral. Smoking status may be validated at pre-operative appointment using an appropriate test. Support to stop smoking is available to patients through a range of NHS stop smoking services.</p>	<ul style="list-style-type: none"> <li>Details of condition</li> <li>Clinical evidence of physical problems or gross deformity</li> <li>Responsibility for implant operation</li> <li>Smoking status</li> </ul>
Rhinoplasty	<p>Referral <b>only</b> for patients with;</p> <ul style="list-style-type: none"> <li>congenital (e.g. cleft palate) or post-traumatic deformity (refer to Plastic Surgery for consultant assessment) AND/OR</li> <li>significant airway problems (refer to ENT for consultant assessment)</li> </ul> <p>Surgical outcomes (e.g. wound healing, complications etc) can be adversely affected by smoking. To ensure the best outcomes, patients should have <b>stopped smoking</b> prior to referral. Smoking status may be validated at pre-operative appointment using an appropriate test. Support to stop smoking is available to patients through a range of NHS stop smoking services.</p>	<ul style="list-style-type: none"> <li>Details of condition</li> <li>Clinical evidence of deformity or airway problems</li> <li>Smoking status</li> <li>Clinical photographs</li> </ul>

<i>Procedure</i>	<i>Eligibility criteria</i>	<i>Information to forward with referral</i>
Scar revision	<p>Referral <b>only</b> for treatment of scars, following burns, trauma, keloid formation or post-surgical complications, which interfere with function. The primary concern with this procedure is whether surgery is clinically appropriate and expected to achieve significant benefit.</p> <p>Large lesions that cause extreme facial disfigurement may be eligible if the proposed procedure is assessed as clinically appropriate and expected to achieve significant health benefit. The risks of scarring must be balanced against the appearance of the lesion.</p> <p>Surgical outcomes (e.g. wound healing, complications etc) can be adversely affected by smoking. To ensure the best outcomes, patients should have <b>stopped smoking</b> prior to referral. Smoking status may be validated at pre-operative appointment using an appropriate test. Support to stop smoking is available to patients through a range of NHS stop smoking services.</p>	<ul style="list-style-type: none"> <li>• Details of condition</li> <li>• Smoking status</li> <li>• Clinical photographs</li> </ul>
Tattoo removal	<p>Referral <b>only</b> for patients with tattoos that;</p> <ul style="list-style-type: none"> <li>• are the result of trauma AND/OR</li> <li>• are the source of a significant allergic reaction</li> </ul> <p>Surgical outcomes (e.g. wound healing, complications etc) can be adversely affected by smoking. To ensure the best outcomes, patients should have <b>stopped smoking</b> prior to referral. Smoking status may be validated at pre-operative appointment using an appropriate test. Support to stop smoking is available to patients through a range of NHS stop smoking services.</p>	<ul style="list-style-type: none"> <li>• Details of condition</li> <li>• Smoking status</li> <li>• Clinical photographs</li> </ul>

<b>Excision of Skin Lesions</b>		
<i>Procedure</i>	<i>Eligibility criteria</i>	<i>Information to forward with referral</i>
Benign skin lesions	<p>Treatment of the following benign lesions with no risk of malignancy or infection is considered to be purely cosmetic and should <b>not</b> be referred;</p> <ul style="list-style-type: none"> <li>• Benign naevi</li> <li>• Haemangiomas</li> <li>• Seborrhoeic warts</li> <li>• Skin tags</li> <li>• Spider naevi</li> <li>• Thread veins</li> <li>• Warts (please see specific criteria below)</li> <li>• Xanthelasma</li> </ul> <p>Patient anxiety is not a sufficient reason for referral. For a consultant opinion, refer benign lesions that are symptomatic (e.g. discharging or recurrently infected), problematic (e.g. functionally disabling or subject to trauma) or if there is diagnostic doubt.</p> <p><b>Refer urgently all lesions suspected of malignancy.</b> A copy of the skin clinic letter should be attached that explains to the patient that the lesion will not be treated should it be found to be benign.</p> <p>Large lesions that cause extreme facial disfigurement may be eligible if the proposed procedure is assessed as clinically appropriate and expected to achieve significant health benefit. The risks of scarring must be balanced against the appearance of the lesion.</p> <p>Surgical outcomes (e.g. wound healing, complications etc) can be adversely affected by smoking. To ensure the best outcomes, patients should have <b>stopped smoking</b> prior to referral. Smoking status may be validated at pre-operative appointment using an appropriate test. Support to stop smoking is available to patients through a range of NHS stop smoking services.</p>	<ul style="list-style-type: none"> <li>• Details of condition</li> <li>• For suspect lesions, copy of skin clinic letter</li> <li>• Smoking status</li> <li>• Clinical photographs</li> </ul>

<i>Procedure</i>	<i>Eligibility criteria</i>	<i>Information to forward with referral</i>
Lipomas	<p>Lipomas less than 5cms should be observed only using the soft tissue sarcoma guidelines (SIGN 2003), unless symptomatic (e.g. discharging or recurrently infected) or problematic (e.g. functionally disabling or subject to trauma).  <b>Lipomas located on the body should be referred to the sarcoma clinic if they are over 5cms in diameter or if they are in a sub-fascial position.</b></p> <p>Surgical outcomes (e.g. wound healing, complications etc) can be adversely affected by smoking. To ensure the best outcomes, patients should have <b>stopped smoking</b> prior to referral. Smoking status may be validated at pre-operative appointment using an appropriate test. Support to stop smoking is available to patients through a range of NHS stop smoking services.</p>	<ul style="list-style-type: none"> <li>• Details of condition</li> <li>• Smoking status</li> <li>• Clinical photographs (showing size of lipoma)</li> </ul>
Rhinophyma	<p>The first line treatment of this condition is medical. Referral for surgery or laser treatment <b>only</b> for severe cases that cause extreme facial disfigurement and do not respond to medical treatment.</p> <p>Surgical outcomes (e.g. wound healing, complications etc) can be adversely affected by smoking. To ensure the best outcomes, patients should have <b>stopped smoking</b> prior to referral. Smoking status may be validated at pre-operative appointment using an appropriate test. Support to stop smoking is available to patients through a range of NHS stop smoking services.</p>	<ul style="list-style-type: none"> <li>• Details of condition</li> <li>• Smoking status</li> <li>• Clinical photographs</li> </ul>

<i>Procedure</i>	<i>Eligibility criteria</i>	<i>Information to forward with referral</i>
Sebaceous (epidermal) cysts	<p>An appropriate specialist will treat these lesions. Referral <b>only</b> for patients with cysts;</p> <ul style="list-style-type: none"> <li>• of any size that are symptomatic (e.g. discharging or recurrently infected) or problematic (e.g. functionally disabling or subject to trauma)</li> <li>• over ½ cm on the eyelid (refer to Ocular Plastic Surgeon)</li> <li>• over 1cm on the face</li> <li>• over 2cm on the body</li> <li>• over 1cm prominence on the scalp</li> </ul> <p>Surgical outcomes (e.g. wound healing, complications etc) can be adversely affected by smoking. To ensure the best outcomes, patients should have <b>stopped smoking</b> prior to referral. Smoking status may be validated at pre-operative appointment using an appropriate test. Support to stop smoking is available to patients through a range of NHS stop smoking services.</p>	<ul style="list-style-type: none"> <li>• Details of condition</li> <li>• Smoking status</li> <li>• Clinical photographs (showing size of cyst)</li> </ul>
Warts	<p>Warts should normally be treated in primary care if it is deemed that treatment is needed (warts usually being self-limiting). However, treatment of warts on the margins of the eyelids is problematic and these should be referred to Plastic Surgery for treatment.</p> <p>Surgical outcomes (e.g. wound healing, complications etc) can be adversely affected by smoking. To ensure the best outcomes, patients should have <b>s`topped smoking</b> prior to referral. Smoking status may be validated at pre-operative appointment using an appropriate test. Support to stop smoking is available to patients through a range of NHS stop smoking services.</p>	<ul style="list-style-type: none"> <li>• Details of condition</li> <li>• Smoking status</li> <li>• Clinical photographs</li> </ul>

## References

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**APPENDIX 1. OPCS 4 procedure codes and ICD-10 diagnosis codes for cosmetic surgery procedures (based on mapping by Bedfordshire Heartlands PCT and discussion with the clinical coding team at Nottingham University Hospitals NHS Trust).**

<b>General Surgical Procedures</b>		
<i>Procedure</i>	<i>OPCS 4 procedure codes</i>	<i>ICD-10 diagnosis codes</i>
Abdominoplasty and/or thigh and arm lift surgery (following significant weight loss)	S02.1 Plastic excision of skin of abdominal wall, Abdominoplasty S02.2 Plastic excision of skin of abdominal wall, Abdominolipectomy S03.1 Plastic excision of skin of other site, Buttock lift S03.2 Plastic excision of skin of other site, Thigh lift S03.3 Plastic excision of skin of other site, Excision of redundant skin or fat of arm	
Blepharoplasty (eyelid reduction)	C13.1 Excision of redundant skin of eyelid, Blepharoplasty of both eyelids C13.2 Excision of redundant skin of eyelid, Blepharoplasty of upper eyelid C13.3 Excision of redundant skin of eyelid, Blepharoplasty of lower eyelid C13.4 Excision of redundant skin of eyelid, Blepharoplasty nec C13.8 Excision of redundant skin of eyelid, Other specified C13.9 Excision of redundant skin of eyelid, Unspecified	
Botulinum toxin injections	<i>Specific procedure not known</i>	
Breast asymmetry	<i>Diagnosis. Included within breast augmentation or reduction</i>	
Breast augmentation	B31.2 Other plastic operations on breast, Augmentation mammoplasty B30.1 Prosthesis for breast, Insertion of prosthesis for breast B30.2 Prosthesis for breast, Revision of prosthesis for breast B30.3 Prosthesis for breast, Removal of prosthesis for breast B30.8 Prosthesis for breast, Other specified B30.9 Prosthesis for breast, Unspecified	
Breast mastopexy (surgical fixation of the breast)	<i>B31.3 Other plastic operations on breast, mastopexy</i>	
Breast reduction	B31.1 Other plastic operations on breast, Reduction Mammoplasty	
Breast reduction (male gynaecomastia)	B31.1 Other plastic operations on breast, Reduction Mammoplasty	

<i>Procedure</i>	<i>OPCS 4 procedure codes</i>	<i>ICD-10 diagnosis codes</i>
Correction of congenital nipple inversion	B35.1 Operations on nipple, Transposition of nipple B35.2 Operations on nipple, Excision of nipple B35.3 Operations on nipple, Extirpation of lesion of nipple B35.4 Operations on nipple, Plastic operations on nipple B35.5 Operations on nipple, Biopsy of lesion of nipple B35.6 Operations on nipple, Eversion of nipple B35.8 Operations on nipple, Other specified B35.9 Operations on nipple, Unspecified	
Dermabrasion	S60.1 Dermabrasion of skin of head or neck S60.2 Dermabrasion of skin nec	
Face or brow lift	S01.1 Plastic excision of skin of head or neck, Facelift and tightening of platysma S01.2 Plastic excision of skin of head or neck, Facelift nec S01.3 Plastic excision of skin of head or neck, Submental lipectomy S01.4 Plastic excision of skin of head or neck, Browlift	
Hair depilation (for hirsutism, especially in women)	S10.4 Other destruction of lesion of skin of head or neck, Electrolysis to lesion of skin of head or neck S11.4 Other destruction of lesion of skin of other site, Electrolysis to lesion of skin nec S06.5 Other excision of lesion of skin, Excision of lesion of skin of head or neck nec S06.8 Other excision of lesion of skin, Other specified S06.9 Other excision of lesion of skin, Unspecified	L68* Hirsutism
Hair transplantation	S33 Hair bearing graft of skin to scalp S34 Hair bearing graft of skin to other site	
Liposuction	S62.1 Other operations on subcutaneous tissue, Liposuction of subcutaneous tissue of head or neck S62.2 Other operations on subcutaneous tissue, Liposuction of subcutaneous tissue nec	
Pinnaplasty (correction of prominent ears)	D03.3 Plastic operations on external ear, Pinnaplasty	
Revision mammoplasty (a second surgical alteration of the breast size or shape)	B31.4 Other plastic operations on breast, revision of mammoplasty B30.2 Prosthesis for breast, Revision of prosthesis for breast	
Rhinoplasty	E02.3 Plastic operations on nose, Septorhinoplasty using implant E02.4 Plastic operations on nose, Septorhinoplasty using graft E02.5 Plastic operations on nose, Reduction rhinoplasty E02.6 Plastic operations on nose, Rhinoplasty nec	

<i>Procedure</i>	<i>OPCS 4 procedure codes</i>	<i>ICD-10 diagnosis codes</i>
Scar revision	S60.4 Refashioning of scar NEC	
Tattoo removal	S09.1 Photodestruction of lesion of skin, Laser destruction of lesion of skin of head or neck S09.2 Photodestruction of lesion of skin, Laser destruction of lesion of skin nec S06.5 Other excision of lesion of skin, Excision of lesion of skin of head or neck nec S06.8 Other excision of lesion of skin, Other specified S06.9 Other excision of lesion of skin, Unspecified	L81.8 Other specified disorders of pigmentation

<b>Excision of Skin Lesions</b>		
<i>Procedure</i>	<i>OPCS 4 procedure codes</i>	<i>ICD-10 diagnosis codes</i>
Benign skin lesions	S06.5 Other excision of lesion of skin, Excision of lesion of skin of head or neck nec S06.8 Other excision of lesion of skin, Other specified S06.9 Other excision of lesion of skin, Unspecified S09.1 Photodestruction of lesion of skin, Laser destruction of lesion of skin of head or neck S09.2 Photodestruction of lesion of skin, Laser destruction of lesion of skin nec	<i>Examples (no specific codes)</i> D23* Other benign neoplasms of skin D17* Benign lipomatous neop skin/subcut tis D22* Melanocytic naevi L82.X Seborrheic keratosis H02.6 Xanthelasma of eyelid I78.1 Naevus non-neoplastic I78.8 Other diseases of capillaries
Lipomas	<i>Diagnosis. Specific procedure not known</i>	
Rhinophyma	<i>Diagnosis. Specific procedure not known</i>	
Sebaceous (epidermal) cysts	S06.5 Other excision of lesion of skin, Excision of lesion of skin of head or neck nec S06.8 Other excision of lesion of skin, Other specified S06.9 Other excision of lesion of skin, Unspecified	L72.0 Epidermal cyst
Warts	<i>Diagnosis. Specific procedure not known</i>	