Report to Merton Clinical Commissioning Group
Governing Body

Date of Meeting: 25 September 2014

Agenda No: 7.2
Attachment: 07

<table>
<thead>
<tr>
<th>Title of Document:</th>
<th>Purpose of Report:</th>
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<td>2014/15 South West London Effective Commissioning Initiative</td>
<td>For Approval</td>
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<tr>
<th>Report Author:</th>
<th>Lead Director:</th>
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<tr>
<td>ECI Group</td>
<td>Lynn Street, Director of Quality</td>
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<tr>
<th>Contact details:</th>
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<tbody>
<tr>
<td><a href="mailto:Lynn.street@mertonccg.nhs.uk">Lynn.street@mertonccg.nhs.uk</a></td>
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**Executive Summary:**
The development of the South West London Effective Commissioning Initiative 2013/14 was led by the Public Health Department of Croydon PCT. In February 2013, Croydon PCT ceased the co-ordination role and no receiving organisation was identified to carry on this role. In October 2013 the constituent CCGs (Croydon, Kingston, Merton, Sutton, Richmond, and Wandsworth) agreed to fund the CSU to take on the co-ordination role on behalf of the CCGs. In the interim, an extension of the ECI 2013/14 policy was agreed by the CCGs from April 2014 until September 2014 with the expectation that a refreshed ECI Policy would be approved in August 2014.

The SWL ECI Review Group met on 02/09/13, 02/12/13, 30/01/14, 05/03/14, 28/05/14 and 09/07/14.

The ECI Policy was amended to include necessary updates and NICE recommendations. The Policy was agreed by the ECI Group on 28/05/14. Following this agreement, the policy was circulated to local providers for clinical consultation. The results of the clinical consultation showed limited or no clinically-relevant resistance to the policy changes.

The ECI 2014/15 Policy is now ready for formal CCG approval so that the policy can be published and included within Acute Contracts.

Work has commenced to begin the review for 2015/16. Review of the policy requires the identification of capacity, resources and clinical engagement to continue this workstream.
Key sections for particular note (paragraph/page), areas of concern etc:
ECI 2013/14:
The 2013/14 policy has been updated for 2014/15 with a number of changes - see brief summary of changes below. The attached summary of changes document provides further detail and rational of all changes. All changes are also captured within a tracked changed version of the ECI policy:

- Revised policies:
  - Varicose Veins: Policy developed in line with NICE guidance. The new policy would effectively lower the current thresholds for access to surgical treatment. Due to these changes, it is predicted that there may be an initial increase in activity levels.
  - Manual Lymphatic Drainage (MLD): Minimal changes to policy. An additional reference for best practice has been included as guidance in the appendix section.
  - Circumcision: Minimal changes to policy. One new criteria inserted to include an additional clinical condition where the procedure may be indicated. Clause inserted to clarify that circumcisions will be considered for funding on medical grounds where clinically indicated.
  - Open MRI: Criteria clarified and extended to capture a cohort of patients who cannot fit safely into conventional MRIs due to other clinical conditions.
  - Pinnaplasty: Criteria inserted to include reference to patient age for clinical suitability. Criteria inserted to clarify appropriate degree of angle of external ear from head.
  - CCGs’ IVF Policies updated follow review of new NICE guidance. Merton CCGs IVF policy has been added in Appendix G (p.116)

- Clarification of unclear policies: Minimal changes to wording of several policies to remove ambiguity
- Removal of outdated CCG prior approval/funding routes table in Appendix A - pending revised version
- CCG prior approval process updated to include referral management centre arrangements
- Removal of policies now commissioned by NHS England – policy list provided as an appendix.
- Revised IFR Application Form inserted

ECI 2015/16:
The ECI is a rolling document requiring on-going review to ensure specific policy areas are updated and new policies developed in accordance with new local and national clinical guidance. Continual updating of the ECI Policy will require consideration of the following:

- Resources for the CSU team to run the administration of the process.
- Capacity and resources for Public Health and/or alternative post-holder (new role) to conduct policy reviews on behalf of CCGs.
- A revision to the Terms of Reference for the ECI group to make clear that it is advisory to CCG Boards/Governing Bodies.
- Oversight by the SW London Directors of Commissioning group to ensure that progress can be made across CCGs in SW London.
**Recommendation(s):**
The Governing Body is asked to:
- Approve the amendments so that the ECI 2014/15 policy can be published and included within Acute Contracts.
- Approve the ECI 2014/15 policy on the caveat that the CCG reserves the right to make in-year changes to the policy should there be a significant financial impact due to the changes.
- Consider future input into the policy review for 2015/16.

**Committees which have previously discussed/agreed the report:**
ECI Policy Group
Executive Management Team
Financial Implications:

1. Varicose Veins Policy:
The revised policy has been developed in line with NICE guidance. The new policy would effectively lower the current thresholds for access to surgical treatment. Due to these changes, it is predicted that there may be an initial increase in activity levels.

NICE produced a cost template to help ascertain the implications for moving towards the recommended guidelines. This cost template estimated an increase in referrals of 25%. However, based on NICE guidance, the proposed policy should offer financial savings where new and emerging technologies associated with varicose vein treatment are offered and more cost-effective.

The NICE costing template produced to support the guidance enables organisations in England, Wales and Northern Ireland to estimate the impact locally. A sample calculation using this template showed a cost of £1,200 for a population of 100,000.

Using this template, the estimated increase in resource to meet the demand across the South West London CCGs is as follows (based on the over 18 year-old population with a 25% varicose vein prevalence):

<table>
<thead>
<tr>
<th>CCG</th>
<th>Net Resource Impact</th>
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<tbody>
<tr>
<td>Croydon</td>
<td>£4,437</td>
</tr>
<tr>
<td>Kingston</td>
<td>£2,296</td>
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<tr>
<td>Merton</td>
<td>£2,578</td>
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<tr>
<td>Richmond</td>
<td>£2,361</td>
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<tr>
<td>Sutton</td>
<td>£2,197</td>
</tr>
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<td>Wandsworth</td>
<td>£4,418</td>
</tr>
<tr>
<td>SWL CCGs</td>
<td>£18,288</td>
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It is recommended that approval of the ECI policy should be made with the caveat that the CCG reserves the right to make in-year changes to the policy should there be a significant financial impact due to changes (such as the new varicose veins policy).

2. Failure to approve ECI Policy
Failing to review and agree revision of policy due to updated evidence and NICE guidance results in the policies being out of date and no longer evidence-based. This leaves CCGs vulnerable to policy challenge, inequitable access to treatment and associated financial implications (such as legal, financial or reputational and failure to realise financial savings through effective commissioning).

3. Resourcing 2015/16 Policy Review
Continual updating of the ECI Policy will require consideration of:
- Resources for the CSU team to run the administration of the process.
- Capacity and resources for Public Health and/or alternative post-holder (new role) to conduct policy reviews on behalf of CCGs.
Other Implications: (including patient and public involvement/Legal/Governance/ Risk/ Diversity/ Staffing)
Reputation: Clarity on access to treatment interventions maintains CCG reputation.
Performance: The availability of an ECI policy improves equity, consistency and speeds up time to patient treatment.
Governance: The ECI policy is evidence based and prevents interventions where they are not cost-effective or clinically appropriate.

How has the Patient voice been considered in development of this paper:
The South West London Effective Commissioning Initiative (SWL ECI) was established in 2006. Membership of the group is made up of representatives from Public Health, the SW London Acute Commissioning Unit and a Patient/Lay Representative.

Equality Analysis:
As part of the IFR Policy, ECI policies were considered within the EA assessment

Information Privacy Issues:
None

Communication Plan: (including any implications under the Freedom of Information Act or NHS Constitution)
For Governing Body approval and publication on the website.
The changes will be communicated to GP practices along with the updated policy.
2014/15 South West London Effective Commissioning Initiative
### Version Control:

<table>
<thead>
<tr>
<th>Version</th>
<th>Description of Change(s)</th>
<th>Reason for Change</th>
<th>Author</th>
<th>Date</th>
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<tr>
<td>1.0</td>
<td>NHSE Policies removed from 2013-14 Policy</td>
<td>Updated as per NHSE commissioning arrangements</td>
<td>SL CSU</td>
<td>February 2014</td>
</tr>
<tr>
<td>1.1</td>
<td>Document formatted</td>
<td>Policies numbered and text formatted to create a user-friendly, readable document.</td>
<td>SL CSU</td>
<td>February 2014</td>
</tr>
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</table>
| 1.2     | • Amended to 2014-15 date  
• Version control added  
• Revised draft policies added; MLD, Varicose Veins, Circumcision and Open MRI  
• AS edit of clarifying ambiguous policies  
• ECI form deleted to be replaced with current IFR form (in progress)  
• Contact details updated  
• Governance section revised  
• Contents page updated and appendices aligned | Updating to a 2014/15 document to take into account contact changes, clarifying unclear policy wording and including 4 revised policies as agreed by CCG ECI Working Group | SL CSU     | February 2014 |
| 1.3     | Changes reflecting discussion at ECI Group Meeting held on 05.03.14:  
• Revised policies: MLD, Varicose Veins, Circumcision, Open MRI, Dupuytren’s Contracture, Autologous Chondrocyte, Carpal Tunnel  
• Clarification of unclear policies  
• Removal of outdated prior approval table in Appendix A  
• Croydon CCG prior approval process updated  
• Insertion of table of policies now commissioned by NHS England  
• Insertion of Wandsworth CCG IVF criteria  
• Revised IFR Application Form inserted (v2.1) | Changes agreed at ECI Group Meeting held on 05.03.14 and resulting virtual discussion. | SL CSU     | March 2014 |
| 1.4     | Changes reflecting virtual discussions by ECI Group on changes to v1.3                  | Changes reflecting virtual discussions by ECI Group on changes to v1.3                                       | SL CSU     | March 2014 |
| 1.5     | Changes reflecting discussion by ECI Group Meeting held on 28.05.14:  
• Revised policies agreed: MLD, Varicose Veins, Circumcision, Open MRI and Pinnaplasty.  
• Policy reviews and updates removed for 14/15 ECI: | Changes agreed by ECI Group Meeting held on 28.05.14                                                        | SL CSU     | May 2014   |
<table>
<thead>
<tr>
<th></th>
<th>Dupuytren’s Contracture, Autologous Chondrocyte, Carpal Tunnel</th>
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| 1.6 | • Revised IFR Application Form inserted (v2.2)  
• Sutton IVF Policy updated  
• Merton IVF Policy updated  
• Kingston IVF Policy updated  
• Richmond IVF Policy updated  
• St George’s Hospital deviation from Dupuytren’s and Carpal Tunnel policy clause inserted |
|  | Appendices updated  
SL CSU  
Jul 2014 |
| 1.6.1 | • Croydon IVF Policy updated  
• Merton IVF Policy updated |
|  | Appendices updated  
SL CSU  
Aug 2014 |
| 1.7 | • Fertility Preservation Policy updated  
• Croydon CCG deviation from Varicose Veins Policy included |
|  | Policy wording clarified following response to clinical consultation  
SL CSU  
Aug 2014 |
| 1.7.1 | • Merton IVF Policy updated |
|  | Appendices updated  
SL CSU  
Sep 2014 |
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9.2 Grommets in older children (12 and above) and adults (ventilation tubes) (Insertion of)

9.3 Grommets in children under 12 (ventilation tubes) (Insertion of)

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10.2 Brow lift

10.3 Cataract surgery

11. Minor Skin Lesions (Treatment of)

12. Obstructive sleep apnoea in adults

13. Obstetrics, Gynaecology & Reproduction

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13.2 Female genital prolapse/stress incontinence (assessment of)

13.3 Fertility preservation techniques
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Introduction

This document describes the South West London Effective Commissioning Initiative (SWL ECI). It provides a set of patient criteria to inform the commissioning of clinical interventions in South West London. They have been developed by the South West London Public Health Network. For some procedures, such as dental implants and aesthetics, all cases need to be reviewed through an individual application as per local agreement (this may be Individual Funding Request (IFR) including Exceptional Circumstances application or other prior approval process e.g. referral review via a Clinical Assessment Service (CAS)). See Appendix A for local processes.

Aesthetic surgery for cosmetic purposes will not normally be funded by CCGs.

For other procedures, such as hip replacement, specific criteria must be met before it can be carried out. In such cases it will be up to individual CCGs to decide how adherence to these criteria is monitored (e.g. prior approval, audits, notification only).

The criteria for the following procedures have been added since the Document 2012/2013: Acupuncture for non-specific low back pain, deep brain stimulation (DBS) for Parkinson’s disease, (ENT) grommets in adults, fertility preservation techniques and sacral nerve stimulation (SNS) for faecal incontinence.

Amendments to/clarification of criteria, have been made to procedures already in the 2012/2013 Document as follows: aesthetic surgery, bariatric surgery, ENT (adeno)tonsillectomy, bone anchored hearing aids (BAHA’s), cochlear implants and grommets in children, minor skin lesions, discectomy for lumbar disc prolapse, Dupuytren’s contracture, epidural injections for lumbar back pain, ganglia, therapeutic facet joint injections/media branch blocks, thermal radiofrequency denervation of lumbar and cervical facet joints and trigger finger.

It should be noted that procedures that have been the subject of NICE Technology Appraisals will be amended without going through the usual consultation period. A list of those procedures amended will be published as they occur.

This document includes the criteria (with rationale/supporting evidence) that are required to be met in order to receive approval for funding.

In order for funding to be agreed for an ECI procedure outside of the criteria (or for procedures where no specific criteria are given), the applicant must make a case for exceptional circumstances by demonstrating that there is some unusual clinical factor about the patient that suggests that they are:

- Significantly different to the general population of patients with the condition in question.
- Likely to gain significantly more benefit from the intervention than might be normally expected for the average patient with the condition.

The fact that the treatment is likely to be efficacious for a patient is not, in itself, a basis for exceptionality. Also the patient’s social circumstances including family or work-related factors are not taken into consideration by the Individual Funding Request panel, which will consider the evidence and decide upon funding. The IFR form is available as an appendix to this Document (Appendix B).
The SWL ECI Group Principles and Processes for Decision Making are attached as Appendix C.

Applications for funding should be made on behalf of the patient by primary or secondary care clinicians.

The South West London Effective Commissioning Initiative (SWL ECI) was established in 2006 and consists of representatives from all six SW London Cluster Borough Teams. Membership of the group is made up of representatives from Public Health, the SW London Acute Commissioning Unit and a Patient/Lay Representative.

The SWL ECI provides a set of patient criteria to inform the commissioning of clinical interventions in South West London.

The SWL ECI is driven by the need to ensure that NHS funded treatments are effective and evidence-based and that access to treatment throughout the SWL area is equal for patients with similar need. It also attempts to define more clearly and openly the limits of NHS funding for procedures with social but not physical benefits cosmetic procedures. Although not the main driving force, it is also linked to the need to ensure that the NHS provides value for money and achieves financial balance.

The current procedures included in the ECI document can broadly be classified into four groups:

- Procedures with limited evidence of effectiveness.
- Procedures where initial conservative therapy is possible.
- Effective procedures where a threshold for intervention may be appropriate.
- Procedures where NHS provision may be inappropriate.

Criteria for funding of procedures included in the SWL ECI document are developed on the basis of current evidence of best practice and in consultation with local clinical teams.

A rolling programme is in place to ensure that criteria for procedures are up to date, are based on best available evidence, and that new procedures are added to the document.

Homeopathic/Complementary therapies

These therapies are not funded by the NHS (Appendix D).

Procedures with limited evidence of benefit

This includes grommet insertion and tonsillectomy. For these procedures, the available evidence suggests limited benefit and significant risks.

Procedures where initial conservative therapy is effective

This includes procedures such as hysterectomy for heavy menstrual bleeding where surgical treatment may be considered but conservative therapy is effective and can avoid the risks associated with surgery.

Procedures where a threshold for intervention may be appropriate

This includes cataract surgery. For these procedures, it is possible to select patient groups who are unlikely to benefit from treatment.

Procedures where NHS provision may be inappropriate

This includes all cosmetic surgery and removal of some minor skin lesions. They are procedures for which the primary purpose is to improve appearance and the evidence for other benefits, including...
psychological, is limited.

**Aesthetic Surgery**

**Definition**

In this guidance aesthetic or cosmetic surgery is defined as surgery undertaken to improve one’s appearance or reshape normal body parts to improve appearance. This differs from reconstructive surgery which is undertaken to reshape abnormal structures of the body, from accidents, injuries, infections, cancers or other diseases, as well as congenital deformities.

Aesthetic surgery for cosmetic purposes will not normally be funded by the CCG. All proposals need to be approved as per local agreement (this may be Individual Funding Request (IFR) (See appendix B) including Exceptional Circumstances application or other prior approval process e.g. referral review via a Clinical Assessment Service (CAS)).

Note: Minor skin lesions are covered in a separate section of this document.

National Aesthetic Surgery Guidelines were published in Action on Plastic Surgery ‘Information for Commissioners of Plastic Surgery Services. Referrals and Guidelines in Plastic Surgery’. The SWL Public Health ECI network reviewed these guidelines, existing NHS policies and evidence of effectiveness for individual procedures to produce a set of guidelines/criteria. Where the group found no robust evidence, the guidelines/criteria in the table below represent a consensus view of who might be considered appropriate for surgery and the actions which need to be taken before sending a proposal to the IFR/exceptions/prior approvals panel. The table below describes the criteria/guidelines for aesthetic procedures and should be considered against requests for procedures as indicated in this policy document.

**General Principles**

1. Patients should be at least 18 years of age for most procedures (where this is the case the procedure is annotated with "**"). It should be demonstrated that the conservative treatments/options had been exhausted.

2. CCGs will not generally fund cosmetic procedures solely to improve appearance in the absence of the following:
   - Disease, eg recurrent infection;
   - Congenital deformity (this does not include normal variation);
   - Limitation of function;
   - Impaired ability to perform activities of daily living.

3. Psychological distress alone will normally not be accepted as a reason to fund surgery.

4. In exceptional circumstances psychological distress alone may be considered as a reason for cosmetic surgery if it may alleviate severe and enduring psychological dysfunction. In these cases a NHS psychiatrist or psychologist must provide demonstrable evidence of treatment(s) used to alleviate/improve the patient’s psychological wellbeing, including impact and duration of treatment(s). Patients should be currently engaged or have undergone appropriate psychological or psychiatric treatment. Patients should NOT be referred into mental health services specifically to support an application for aesthetic surgery.
5. Clinicians are requested to refer to NICE CG31 Obsessive-compulsive disorder (OCD): Core interventions in the treatment of obsessive-compulsive disorder and body dysmorphic disorder¹ prior to referring on psychological grounds alone.

6. For patients with anxiety or depression, clinicians should consider a referral to the local Improving Access to Psychological Therapies service before requesting cosmetic surgery.

References:

1. National Institute for Health & Clinical Excellence (NICE) CG31 Obsessive-Compulsive Disorder (OCD) and Body Dysmorphic Syndrome (BDS), Nov 2005
1. **Breast Procedures**

These criteria do not apply to cosmetic surgery following breast cancer treatment as this is covered by cancer network commissioning policies and pathways.

1.1 **Reduction mammoplasty**  
** (Female breast reduction)

Funding may be considered in the following circumstances:

<table>
<thead>
<tr>
<th>Criteria</th>
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<tbody>
<tr>
<td>The patient should be 18 or over at the time of application.</td>
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<tr>
<td>AND</td>
</tr>
<tr>
<td>Gross asymmetry of at least 2 cup sizes* difference between the breasts.</td>
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<tr>
<td>OR</td>
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<tr>
<td>BMI equal to or below 27:</td>
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<tr>
<td>AND</td>
</tr>
<tr>
<td>The patient has a bra cup size of F or more or requires at least 500g of tissue to be removed from each breast**;</td>
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<tr>
<td>AND</td>
</tr>
<tr>
<td>If the patient has at least TWO of the following for at least one year (and documented evidence of GP visits for these problems) ¹:</td>
</tr>
<tr>
<td>• Pain in the neck</td>
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<tr>
<td>• Pain in the upper back</td>
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<tr>
<td>• Pain in shoulders</td>
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<tr>
<td>• Pain / discomfort / ulceration from bra straps cutting into shoulders;</td>
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<tr>
<td>AND</td>
</tr>
<tr>
<td>Pain symptoms persist as documented by the physician despite a 6-month trial of therapeutic measures including all of the following:</td>
</tr>
<tr>
<td>• Supportive devices (e.g., appropriate bra/support bra fitted by a trained bra fitter, wide bra straps).</td>
</tr>
<tr>
<td>• Analgesic / non-steroidal anti-inflammatory drugs (NSAIDs) interventions.</td>
</tr>
<tr>
<td>• Physical therapy / exercises / posturing</td>
</tr>
</tbody>
</table>
• manoeuvres.

Chronic intertrigo, eczema or dermatitis alone will not be considered as grounds for this procedure unless all of the above are met and the patient has failed to respond to 6 months of conservative treatment.

*AA, A, B, C, D, DD, E, F, FF, G, GG, H, HH, J, JJ, K, L

** 500g estimates to a 4 cup size reduction in patients with chest sizes 30 to 34 or 2 cup size reduction in patients with wider chests 34-40+.

http://www.aetna.com/cpb/medical/data/1_99/0017.html

1.2 Gynaecomastia

** (Male breast reduction for gynaecomastia) (liposuction may form part of the treatment plan for this condition)

It is important that male breast cancer is not mistaken for gynaecomastia and, if there is any doubt, an urgent consultation with an appropriate specialist should be obtained.

The patient should meet the following criteria:

<table>
<thead>
<tr>
<th>Criteria</th>
</tr>
</thead>
<tbody>
<tr>
<td>The patient should be 18 or over at the time of application;</td>
</tr>
<tr>
<td>AND</td>
</tr>
<tr>
<td>BMI of equal to or below 27;</td>
</tr>
<tr>
<td>AND</td>
</tr>
<tr>
<td>Have gynaecomastia of Grade III * i.e. Gross breast enlargement with skin redundancy and ptosis so as to simulate a pendulous female breast;</td>
</tr>
<tr>
<td>AND</td>
</tr>
<tr>
<td>Have been screened for endocrinological or drug related causes.</td>
</tr>
</tbody>
</table>

Notes:
*Simon’s classification for gynaecomastia
I Minor but visible breast enlargement without skin redundancy. Ila Moderate breast enlargement without skin redundancy
Iib Moderate breast enlargement with minor skin redundancy
III Gross breast enlargement with skin redundancy and ptosis so as to simulate a pendulous female breast.


1.3 Augmentation/ Mammoplasty

** (Breast enlargement)

Criteria

<table>
<thead>
<tr>
<th>Criteria</th>
</tr>
</thead>
<tbody>
<tr>
<td>The patient should be 18 or over at the time of application;</td>
</tr>
</tbody>
</table>
AND

Has significant asymmetry. (Significant asymmetry will be defined as a difference of at least 2 full cup sizes*) to the extent that they cannot get a bra to fit;

OR

There is complete absence of breast tissue unilaterally or bilaterally.

*AA, A, B, C, D, DD, E, F, FF, G, GG, H, HH, J, JJ, K, L

1.4 Revision of breast augmentation

Criteria

The patient should be 18 or over at the time of application.

AND

Removal of implants will be considered, but not replacement, if at least one of the following criteria are met:

- Rupture of silicone-filled implant.
- Implants complicated by recurrent infections.
- Extrusion of implant through skin.
- Implants with Baker Class IV contracture associated with severe pain.
- Implants with severe contracture that
- Interferes with mammography.

Replacement of implants will be considered, for clinical reasons, if the original implants were funded by the NHS for non-cosmetic reasons.

1.5 Mastopexy

(Breast lift)

The patient should be 18 or over at the time of application.

Mastopexy (Breast lift) will not be funded for purely cosmetic/aesthetic purposes such as post-lactational ptosis.

NB for asymmetry see breast augmentation, for back pain as a result of breast size, see breast reduction.

1.6 Surgical correction of nipple inversion

(Breast lift)
1.5 The patient should be 18 or over at the time of application.
See General Principles above.
Nipple inversion may occur as a result of an underlying breast malignancy and it is essential that this be excluded.

2. Facial Procedures

2.1 Rhytidectomy
** (Face lifts)

The patient should be 18 or over at the time of application.
See General Principles Above

2.2 Rhinoplasty
(Surgery to reshape the nose)

Nasal airway obstruction causing significant symptoms (e.g., chronic rhinosinusitis, difficulty breathing).

OR

Obstructive symptoms persist despite conservative management for three months or greater, which includes, where appropriate, nasal steroids or immunotherapy.

OR

Correction of complex congenital conditions unless covered by specialised commissioning arrangements.

Prior ENT consultation should take place for patients with isolated airway problems (in the absence of visible nasal deformity).
2.3 Pinnaplasty/Otoplasty
(Correction of prominent ears)

Patients should be aged less than 18 years of age at the time of application.

See General Principles above.

The following criteria should be referred to by the IFR Panel when considering funding on an exceptional basis:

1. The patient should be between 5 and 18 years of age (surgery under 5 should only be considered for children who require a hearing aid and where this will be better supported following a correction of ear prominence)
2. The angle between the side of the head and the external ear should be more than 35 degrees. (Normal angle is between 20 to 35 degrees).
3. The level of psychological distress felt by the patient - The child rather than the parents are concerned about prominent ears.

References:

3. http://www.patient.co.uk/doctor/Prominent-Ears.htm

2.4 Repair of external ear lobes
(Lobules)

Consideration will be given to completely split ear lobes as a result of direct trauma.

Note: If a previously repaired earlobe is pierced and the split recurs, no further treatment will be offered.

If approved, Panels will agree funding for one episode of repair only

2.5 Hair replacement techniques to correct hair loss
(e.g. due alopecia or male pattern baldness)

This procedure is not routinely funded by the NHS. If clinical exceptional circumstances exist, applications for funding can be made in the form of an individual application (such as an Individual Funding Request (IFR)).

In certain circumstances wigs may be considered clinically appropriate. Some patients, depending on their social circumstances may be eligible for a NHS funded wig (see Appendix E).
3. Body Contouring Procedures

3.1 Apronectomy or Abdominoplasty
** (Tummy tuck)

The patient should be 18 or over at the time of application.

AND

At the time of the application the patient should have a BMI of between 18 and equal or less than 27 kg/m² and must have maintained a BMI in this range for at least 24 months.

OR

Further consideration may be given to people who have had very significant weight loss post bariatric surgery who should have lost at least 50% of their original excess weight and maintained this weight for at least 6 months, and be at least 18 months post-surgery.

AND

Have severe functional problems which should include at least one of the following:

- Severe difficulties with daily living i.e. ambulatory restrictions.
- Documented record of recurrent intertrigo beneath the skin folds that recurs or fails to respond despite appropriate medical therapy for at least 6 months

* Percentage of excess weight lost =  \( \frac{\text{initial weight} - \text{current weight}}{\text{initial weight} - (25 \times \text{height})} \times 100 \)

(NB where weight is in kilos and height is in metres)

3.2 Body contouring
** (Other skin excision for contour e.g. buttock lift, thigh lift, arm lift (brachioplasty)

(For apronectomy/abdominoplasty in respect of body contouring see criteria for apronectomy/abdominoplasty above)

The patient should be 18 or over at the time of application;

AND

At the time of the application the patient must have a BMI of equal to or below 27 kg/m² and must have maintained a BMI in this range for at least 18 months;

AND

Have severe functional problems which may include:
3.3 Liposuction

Liposuction will not be routinely funded to correct the distribution of fat. If clinical exceptional circumstances exist, applications for funding can be made in the form of an individual application (such as an Individual Funding Request (IFR)).

4. Skin and Subcutaneous Lesions

4.1 Facial skin procedures

Skin resurfacing and other surgical interventions for scarring, including laser, dermabrasion and chemical peels)

Skin resurfacing procedures for cosmetic purposes or purely to improve appearance will not be routinely funded.

Individual requests will be considered on an exceptional basis where there is evidence that the procedure will improve clinically significant signs and symptoms.

4.2 Tattoo removal

See General Principles above.

4.3 Treatment of skin hyperpigmentation

(including laser therapy, chemical peels etc.)

See General Principles above.

4.4 Treatment of vascular lesions
See General Principles above.

Individual requests will be considered on an exceptional basis which may include evidence that facial lesions cause significant disfigurement or obstructive symptoms.

Small, benign, acquired, vascular lesions such as thread veins and spider naevi would not normally be treated.

5. Miscellaneous

5.1 Injection of facial botulinum toxin for cosmetic indications

Botulinum toxin is not routinely funded for the treatment of facial ageing or excessive wrinkles. If clinical exceptional circumstances exist, applications for funding can be made in the form of an individual application (such as an Individual Funding Request (IFR)).

Botulinum toxin is available for the treatment of pathological conditions by appropriate specialists in cases such as Frey's syndrome-gustatory sweating after parotid surgery; Botox A injection is recommended as a first line treatment for Frey's syndrome and can be used in conjunction with or instead of oral anticholinergic medication.

5.2 Hair depilation

(Hair removal by electrolysis and/or laser)

Treatment of severe hirsutism on the facial, neck and/or chest area will be considered if standard treatments have failed and exceptionality is demonstrated.

The methods of hair removal used should be diathermy electrolysis performed by a registered electrologist or, if appropriate, laser in the following circumstances and after all standard treatments have been tried:

- Abnormally located hair-bearing skin following reconstructive surgery.
- Treatment for pilonidal sinuses to reduce recurrence.

Funding will be agreed for a course of treatment after which a review of effectiveness will be required prior to any further funding being agreed.

5.3 Cosmetic genital surgery

See General Principles above

5.4 Keloidectomy

If the keloid:

Results in significant functional impairment.
6. Asymptomatic gallstones

CCGs will not routinely fund cholecystectomy for asymptomatic gallstones. Applications for funding should be made in the form of an individual application via an Individual Funding Request (IFR).

Asymptomatic gallstones are gallstones detected incidentally in patients who do not have any abdominal symptoms or have symptoms that are not thought to be due to gallstones \(^1\).

Rationale

- The natural history of asymptomatic gallstones is that serious symptoms and complications only develop in 1-2% of patients annually \(^2\ 3\ 4\).
- The cumulative risk of requiring treatment in the first 5 years after the detection of asymptomatic gallstones is 7.6% \(^3\ 4\ 5\).
- The World Gastroenterology Organisation (WGO) Practice Guidelines do not recommend cholecystectomy in patients with asymptomatic gallstones \(^6\).

Evidence

A Cochrane review concluded that only patients with symptomatic gallstones should be treated due to the complication rates for elective cholecystectomy \(^5\).

References:

Panels will take into consideration the number of previous surgeries.

If approved, Panels will agree funding for one repair only and for steroid and/or radiotherapy as clinically indicated.


7. Circumcision

Circumcision is an effective operative procedure with a range of medical indications. This statement refers to circumcision (the surgical removal of the penile foreskin) in males only. Female circumcision is prohibited by law (The Prohibition of Female Circumcision Act 1995).

Circumcision will be considered on medical grounds where clinically indicated.

Criteria:

CCGs will fund circumcisions for the following indications:

- Suspected cancer or balanitis xerotica obliterans.
- OR
- Congenital urological abnormalities when skin is required for grafting.
- OR
- Interference with normal sexual activity in adult males
- OR
- Phimosis seriously interfering with urine flow and/or associated with significant recurrent infections.
- OR
- Symptomatic cases of paraphimosis.
- OR
- Symptomatic cases of minor hypospadias.
- OR
- Recurrent balanoposthitis resistant to antibiotic treatment
Rationale

• The foreskin is still in the process of developing at birth and is often non-retractable up to the age of three years. The process of separation is spontaneous and does not require any manipulation or intervention. By 3 years of age 90% of boys will have a retractable foreskin. By the age of 16 only 1% of boys will have an unretractile foreskin.

• Pathological phimosis (scarring of the foreskin making it non-retractable) is unusual under 5 years of age.

• Paraphimosis can usually be reduced under anaesthetic and the chance of recurrence reduced by avoiding forcibly retracting the foreskin. Paraphimosis is not a routine indication for circumcision.

Evidence

• As with other types of surgery circumcision carries potential anaesthetic risks, and the short term risk of bleeding and infection. Longer term potential complications include pain on erection, penile disfigurement, and psychological problems. There is some evidence that the procedure can also reduce local sensitivity

• Balanoposthitis can be successfully treated using antibiotics. Most people do not have further infections. Circumcision is usually recommended only in adults in rare cases where someone has repeated infections.

References:


3. The law and ethics of male circumcision – guidance for doctors. BMA June 2006


7. NCL guidance [check reference]

8. NHS North West London Circumcision 5/11/10


10. ONEL Acute Commissioning Unit April 2010


8. Diagnostic

8.1 Open magnetic resonance imaging (MRI)

Prior approval should be sought from the CCG.

CCGs will fund:

- Low field MRI for interventional and intraoperative procedures only.
- Fund Open MRI of greater than >0.5T as an alternative to conventional MRI in the following circumstances:

<table>
<thead>
<tr>
<th>Patients who suffer from claustrophobia where taking an oral prescription sedative(^1) to support conventional MRI has been tried and was not effective.</th>
</tr>
</thead>
<tbody>
<tr>
<td>OR</td>
</tr>
<tr>
<td>Patients who cannot fit safely or comfortably in a conventional MRI, due to obesity or to some other confirmed clinical condition.</td>
</tr>
</tbody>
</table>

1. GPs should prescribe an oral sedative before referring for an Open MRI
2. Standard MRI has a 60 cm bore and can tolerate a maximum weight of 250 kg. Latest Standard MRI machines have an 80cm bore and are able to scan obese patients. Please check before referring for an Open MRI.

CCGs will not routinely fund:

Standing, Weight-Bearing, Positional, or Upright MRI except on an exceptional basis via the IFR route.

Introduction

MRI is a widely used diagnostic imaging technology and is particularly useful in detecting soft tissue damage and disease. The patient undergoing imaging is placed in a gradient magnetic field delivering radiofrequency pulses to the patient and processing the resulting electromagnetic signals emitted from the region being examined.\(^1\) (CADTH) The standard (closed/high-field) method of MRI requires the patient to be in a supine or recumbent position. The orientation of standard MRIs requires the patient to be horizontal and stationary. (Washington State) Magnetic resonance (MR) imaging (MRI) is particularly useful in detecting soft tissue damage or disease.

For most scanners, the patient examination table is positioned in a long, narrow tube. Some patients may experience claustrophobic reactions which might be effectively controlled by sedation or anaesthesia. Obese individuals may not fit into the tube.

Open MRIs in which patients lie, sit or stand between two plates overcome these difficulties. They are also used for intraoperative imaging or image-guided interventions where easy access to the patient is required.

The technology

The quality of MRI images is partly dependent on the field strength of the magnet which is measured in Tesla (above 1 Tesla (T) is considered high). Closed MRIs have magnet field strengths of >1.5 tesla whereas open MRIs have medium strengths magnets of 0.5-1.0T. The lower field strength of open MRIs results in poorer quality images in comparison to closed MRIs, with lower signal-to-noise ratios and more motion artefacts. The length of time required to obtain an image is also longer.

Generally low field strength is below 0.5T, mid-field strength is 0.5 T, up to 0.9 T or 1 T; and high-field
strength is at/and or above 1 T. High-field devices are usually closed-bore magnets due to the fact that the stronger magnetic fields (1–3 T) require more robust shielding and gradient structure to maintain field homogeneity. The open magnet’s field strength usually varies from 0.2–1.0 T.

Evidence

- MRI studies reported in the literature are generally based on intermediate- or high-field MRI. There is insufficient evidence in the published peer-reviewed literature to support the use of low-field strength MRI for any diagnostic indication including but not limited to the following: breast (Paakko, et al., 2005); cardiac (Klein, et al., 2007; Rupprecht, et al., 2002); cerebral/stroke (Terada, et al., 2006; Mehdizade, et al., 2003); pulmonary (Abolmaali, et al., 2004; Wagner, et al., 2001); renal (Stecco, et al., 2007; Kajander, et al., 2000); multiple sclerosis (Ertl-Wagner, et al., 2001) and retrocochlear disorders (Dubrulle, et al., 2002).

- An evidence review performed by the Canadian Agency for Drugs and Technologies in Health (CADTH) found several non-randomised trials which compared high and low field MRIs.

- In a prospective study comparing a 0.2 T open scanner and a 1.5 T highfield system were used to examine 401 patients. There was no significant difference in the diagnostic accuracy of the two types of scanners in examinations for patients with diseases of the kidney (n=78), shoulder (n=122), or spine (n=105), using surgical or clinical follow-up as the reference finding. In cerebral examinations (n=96), the high-field system had a statistically significant advantage in accuracy (p=0.01). The authors suggest that limitations due to field strength are relevant only in a small number of cases that warrant high-field examination.

- In a study on MRI arthrography of the shoulder, a 0.2 T open MRI and a 1.5 T high-field system were used to examine 38 patients. Correlation of surgical and MRI findings was available for 27 patients (71%). The high-field MRI produced better image quality and fewer motion artefacts than the open low-field MRI, but diagnostic accuracy in the cases with surgical correlation was the same for both systems. The authors conclude that low-field MRI compares favourably to high-field MRI in detecting major abnormalities of the shoulder, but has disadvantages because of the duration of the examination, and the increased risk of reduced image quality due to motion artefacts.

- Michel et al. compared patients’ acceptance of MRI pelvimetry that was done using open 0.5 T and closed 1.5 T systems. Of 30 women referred for pelvimetry, 60% preferred the open system, 7% the closed system, and 33% had no preference. The image quality was adequate in both systems. In a British study, 47 of 50 patients (94%) who had failed to complete a scan in a conventional machine underwent successful MRI in a 0.5 T open system.

- Enders et al. (2011), a randomised controlled trial was carried out to investigate whether an open panoramic MR scanner is superior to a short-bore MR scanner in reducing the occurrence of claustrophobic events. A total of 174 were enrolled, 87 in the short-bore MR group and 87 in the open MRI group. With 33 claustrophobic events in the short-bore group (39% [95% confidence interval [CI] 28% to 50%]) versus 23 in the open scanner group (26% [95% CI 18% to 37%]; P = 0.08) the difference was not significant. Enders and colleagues noted that the most problematic phases of the scan were patient positioning and entry into the exam suite. The researchers also noted that the claustrophobic event rates remained consistent—at more than 25 percent—regardless of patient characteristics and the anatomical region being scanned. The conclusions were that even recent MR cannot prevent claustrophobia suggesting that further developments to create a more patient-centered MR scanner environment were needed. The claustrophobia screening tool, CLQ may be a useful tool to detect patients at risk before claustrophobia occurs.

Interventional and Intraoperative

The use of MRI in guiding interventional and intraoperative procedures has become widely accepted as standard of care in equipped facilities. There are limited comparative studies between this and
conventional approaches but there are several small, observational studies which indicate that MRI can be used safely and effectively.2

Low-field MRI

There is insufficient evidence in the published peer-reviewed literature to support the use of low-field strength MRI for any indication other than intervention guidance. There is a lack of data: clarifying the impact of treatment decisions—based upon low-field interpretation—on patient outcomes; addressing accuracy and impact of interpretation of low-field MR images outside the hospital setting (i.e., non-radiologist interpretation); addressing any value of dynamic or positional low-field MRI compared to conventional MRI, or impact to patient outcomes; and clarifying what role low-field imaging should hold in the diagnostic algorithm of joint conditions. Due to insufficient evidence, it remains unknown if substituting low-field strength MRI in place of conventional MRI causes a negative impact to diagnostic accuracy, treatment planning and overall patient outcomes. The limited evidence fails to prove that the use of low-field strength MRI in place of conventional MRI improves diagnostic accuracy, treatment planning and overall patient outcomes.2

Open and Semi-Open MRI

Open (i.e., extremity, upright, positional) MRI allows for imaging without the patient being placed within an enclosed space. Open and semi-open MRI systems have a variety of configurations wherein the patient is not completely surrounded by the magnet. Instead of a tunnel as with standard MRI, common configurations are open along the sides and/or consist of a shorter tunnel such that only the portion of the body being imaged is surrounded by the magnet. Some designs have flared ends or two large discs separated by a pillar. Both are open on the sides, allowing for imaging in different patient positions and for axial loading.1 Open-design has become the standard of care when conventional design is contraindicated. Specifically, this includes patients with pulmonary and/or cerebrovascular disease as well as patients who would require sedation for a conventional MRI such as severely claustrophobic or paediatric patients.

Standing, Weight-Bearing, Positional, or Upright MRI

Upright, standing or positional MRI (uMRI) is a type of vertically open MRI that has been developed in recent years. Such systems are open at the front and top, with the magnetic poles placed on either side of the patient and allow for vertical (upright, weight bearing), horizontal (recumbent) positioning, and dynamic kinetic flexion and extension maneuvers. Current uMRI scanners generally use medium field magnets of 0.5T (e.g., GE Signa™ SP/i) or 0.6T (e.g., FONAR Upright™MRI).

Washington State published a Health Technology Assessment on Standing, Weight-Bearing, Positional, or Upright MRI (2006). Some conclusions included 1:

- There is limited scientific data available on the accuracy and diagnostic utility of standing, upright, weight-bearing or positional MRI.
- There is no evidence from well-designed clinical trials demonstrating the accuracy or effectiveness of weight-bearing MRI for specific conditions or patient populations.
- Due to the lack of evidence addressing diagnostic accuracy or diagnostic utility, standing, weight-bearing, positional MRI is considered investigational and experimental.

References:

2. CIGNA. Magnetic Resonance Imaging- low field. CIGNA coverage policy 0444
18. Washington State Department of Labor and Industries, Office of the Medical Director. Standing,weight-bearing, positional or upright MRI. Health Technology Assessment. Olympia Washington State Department of Labor and Industries; May 31 2006
8.2 Wireless capsule endoscopy and double balloon enteroscopy in obscure gastrointestinal bleeding

Criteria

CCGs will fund wireless capsule endoscopy or double balloon enteroscopy for obscure gastrointestinal bleeding when:

<table>
<thead>
<tr>
<th>Patients with gastrointestinal bleeding have undergone a gastroscopy and/or endoscopy and results are negative then</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Capsule endoscopy for investigation</td>
</tr>
<tr>
<td>A) If wireless capsule endoscopy identifies source of bleeding in small bowel then</td>
</tr>
<tr>
<td>• Where indicated, double balloon enteroscopy for treatment</td>
</tr>
<tr>
<td>B) If results of wireless capsule endoscopy are normal but there is persistent bleeding then</td>
</tr>
<tr>
<td>• Consider second look wireless capsule endoscopy</td>
</tr>
<tr>
<td>OR</td>
</tr>
<tr>
<td>• Double balloon enteroscopy for investigation and treatment where appropriate</td>
</tr>
</tbody>
</table>

Rationale

- The evidence available shows that WCE and DBE are safe and effective diagnostic procedures for the detection of OGIB. Both have a higher diagnostic yield than conventional methods.
- CE and DBE have common indications but different features. CE can cover the whole GI tract, requires no sedation and is better tolerated by patients. Its major limitations are the inability to obtain a biopsy, precisely localise a lesion, or perform therapeutic endoscopy. DBE has the advantage of being controllable and enabling therapeutic treatment to take place simultaneously. The procedure is invasive and not as well tolerated as CE, requiring additional staff, typically two physicians or an additional specialist nurse.
- Cost-effectiveness modelling suggests that that CE-guided DBE may be associated with better long-term outcomes because of the potential for fewer complications and decreased utilisation of endoscopic resources.

Evidence

- NICE produced interventional procedure guidance on WCE in 2004 ¹.
• Guidelines produced by British Society of Gastroenterologists in 2008, state DBE should be used complementary to WCE, particularly in the context of therapeutic intervention beyond the reach of push enteroscopy.

References:

8.3 Wireless capsule endoscopy and double balloon enteroscopy in Crohn’s disease

Criteria

CCGs will fund wireless capsule endoscopy or double balloon enteroscopy for Crohn’s disease when:

Following inconclusive ileocolonoscopy and/or small bowel radiology clinical suspicion of Crohn’s disease remains then:

A) If pain is not a significant feature or where pain is a significant feature and there is no evidence of strictures on small bowel radiography.
   - Wireless capsule endoscopy for diagnosis

B) If pain is significant feature and there is evidence of strictures on small bowel radiography or wireless capsule endoscopy results are inconclusive.
   - Double balloon enteroscopy to obtain histology

Rationale

- The evidence available shows that WCE is a safe and effective diagnostic procedure for the detection of Crohn’s disease. WCE has a higher diagnostic yield than push enteroscopy and other conventional methods. The results suggest that it is superior to conventional radiological procedures in the detection of lesions in patients with Crohn’s disease. However, the high number of patients with strictures limits its use as a first line diagnostic test in patients previously diagnosed.

- Capsule retention remains a risk in patients with Crohn’s disease with significant strictures. The risk is greater in patients with established Crohn’s disease compared to patients suspected to have Crohn’s disease.

Evidence

- NICE produced interventional procedures guidance on WCE in 2004.

Guidelines produced by British Society of Gastroenterologists in 2008, state DBE should be used complementary to WCE, particularly in the context of therapeutic intervention beyond the reach of push enteroscopy.

References:

9. ENT

9.1 (Adeno)Tonsillectomy

These criteria refer to tonsillectomies with or without adenoidectomies. Adenoidectomies, for clinical reasons, are routinely funded.

Criteria

If there is suspicion of malignancy funding need not be requested in advance of surgery.

Recurrent sore throat where the majority of episodes required antibiotic treatment and have been adequately treated and who meet all of the criteria within one of the following groups:

**Group 1**
- Sore throat is due to diagnosed tonsillitis

  AND

- 5 or more episodes in the last year, OR 4 or more episodes in each of the last two successive years, OR 3 or more episodes in each of the last 3 years;

  AND

- There has been significant severe impact on quality of life indicated by at least one of the following:
  i) Documented evidence of absence from school, work or playgroup;
  OR
  ii) Failure to thrive.

OR

**Group 2**

Documented evidence of 2 or more episodes of tonsillitis or quinsy (peri-tonsillar abscess) requiring admission to hospital.

OR

**Group 3**

Severe halitosis (evaluated using a recognised grading scheme) due to tonsil crypt debris following conservative management in primary care.

OR

**Group 4**
The CCG will only consider funding for (adenoid) tonsillectomy as a treatment for sleep apnoea syndrome in children who meet the criteria in one of the following Groups.

**Group 1**
The patient must meet two out of the three following criteria:
- Witnessed episodes of apnoea (breathing pause of 10 seconds or longer)
- Choking episodes during sleep
- Daytime neurobehavioural abnormalities or sleepiness

**OR**

**Group 2**
If the patient has habitual snoring with laboured breathing and falls into one of the following complex high risk category for sleep apnoea:
- Down’s syndrome
- Cerebral palsy
- Craniofacial disorders
- Chronic lung disease
- Sickle cell disease
- Neuromuscular disorders
- Genetic/metabolic/storage disease
- Central hyperventilation syndromes

Applications for funding are more likely to be approved where there is documented supporting evidence such as attendance at general practice or other health care settings, sleep studies, growth charts, letters from GPs and letters from employers, school or playgroup in respect of time off work, school or playgroup which may be considered as evidence of an episode of tonsillitis.

For tonsillectomy in adults for sleep apnoea please see surgical treatment of ‘sleep apnoea in adults’ guidance.

**Rationale**
- The natural history of tonsillitis is for the episodes to get less frequent with time.
- Watchful waiting is more appropriate than tonsillectomy in children with mild sore throats.
- Exposure to second hand smoke in children leads to an increased risk of respiratory tract infections including tonsillitis and otitis media\(^5\).
The frequency of sore throat episodes and upper respiratory infections reduces with time whether or not tonsillectomy has been performed. Tonsillectomy offers relatively small clinical benefits compared with non-surgical treatment.

Tonsillectomy probably gives an additional, but small, reduction of sore throat episodes, days of sore throat associated school absence, and upper respiratory infections compared to watchful waiting.

The benefit in the year after the operation is roughly 2.8 less days off school.

This benefit needs to be weighted against the risk of mortality (estimated to be between 1/8,000 - 1/35,000) and other surgical complications.

Evidence

A Cochrane systemic review\(^1\) concluded that, “There is no evidence from randomised controlled trials to guide the clinician in formulating the indications for surgery in adults or children”.

References:


9.2 Grommets in older children (12 and above) and adults (ventilation tubes) (Insertion of)

These criteria apply to children aged 12 and above and adults.

These criteria do not apply for grommet insertion as part of a procedure for the diagnosis or management of head and neck cancer and/or its complications.

The CCG will fund treatment with grommets for older children and adults with:

- A middle ear effusion causing measured conductive hearing loss of 26–40\(^1\) dB or worse averaged at 0.5, 1, 2 and 4 kHz, and resistant to medical treatments.

- OR

- Persistent Eustachian tube dysfunction resulting in pain (e.g. due to air pressure changes when flying)

- OR

- As one possible treatment for Meniere’s disease.
Severe retraction of the tympanic membrane if the clinician feels this may be reversible and reversing it may help avoid erosion of the ossicular chain or the development of cholesteatoma.

Rationale

Although the outcome of otitis media with effusion (OME) in children is generally good, it is less clear in adults. Watchful waiting is often not appropriate. Many patients with adult-onset OME have underlying pathology that could lead to recurrence of OME following ventilation tube extrusion. In addition, the underlying pathology needs investigation to exclude atopy or malignancy.

These criteria have been adapted from the NHS Surrey and NHS Brighton and Hove criteria for grommets in adults.

References:

2. NHS Institute for Innovation and Improvement. NHS Better Care, Better Value Indicators: Surgical thresholds indicators. 10 October 2007 At http://www.productivity.nhs.uk/Definitions.aspx Accessed 26.3.08

9.3 Grommets in children under 12 (ventilation tubes) (Insertion of)

Criteria

These criteria apply to children aged under 12 years only.

The CCG will fund treatment with grommets for children with persistent otitis media with effusion (OME)\(^1\) where:

Persistent bilateral OME has been documented over a period of 3 months with a hearing level in the **better ear** of 25–30 dBHL or worse averaged at 0.5, 1, 2 and 4 kHz (or equivalent dBA where dBHL not available).

OR

Persistent bilateral OME with a hearing loss less than 25–30 dBHL where the impact of the hearing loss on a child’s developmental, social or educational status is judged to be significant.

In children with additional disabilities such as Down’s Syndrome or cleft palate, involvement of a multidisciplinary team with expertise in assessing and treating OME in these children is essential\(^1\).

Rationale
• The reduced risk of serious complications of anaesthesia and surgery must be balanced against the increased hearing loss and episodes of infection requiring antibiotic treatment and time off school or playgroup. The evidence of effectiveness is limited.

• Restricting access to grommets is not a new phenomenon. A 1995 survey revealed that 23 of the 129 health authorities in England, Scotland and Wales had excluded grommets. The key points are summarised below:

  ➢ Surgery may resolve glue ear and improve hearing in the short term compared with non-surgical treatment, but there is less certainty about long-term outcomes and large variation in effect between children.

  ➢ There continues to be debate about how best to select children for surgery. This issue is complicated by the high rate of resolution of glue ear, particularly in younger children.³

  ➢ The timing of surgery may not be critical². An initial period of watchful waiting is recommended for most children.⁴ If watchful waiting is being considered, the child should undergo audiometry to exclude a more serious degree of hearing loss.

  ➢ The benefits of surgery have to be balanced against possible harms. One third of children who have grommets have complications. Tympanosclerosis frequently occurs after grommet insertion, infection may occur, and there is a slightly increased incidence of chronic perforation.
Evidence

- Cochrane review\(^2\) showed that the benefits of grommets in children are small compared with myringotomy or non-surgical treatment. The effect of grommets on hearing diminished during the first year. It recommends an initial period of watchful waiting for most children with OME.

- A 1999 trial\(^4\) compared 9 months 'watchful waiting' with immediate surgery and found outcomes to be similar to 18 months. However, by this time, 85% of children in the watchful waiting group had been treated with grommets.

References:

1. National Institute for Health & Clinical Excellence (NICE) CG60 Surgical Management of otitis media with effusion in children, Feb 2008
2. Cochrane review: Grommets for hearing loss associated with otitis media with effusion. January 2005
3. Cochrane review: Grommets (ventilation tubes) for recurrent acute otitis media in children. October 2008, assessed as up-to-date January 2011
6. Adjuvant adenoidectomy in persistent bilateral otitis media with effusion: hearing and revision surgery outcomes through 2 years in the TARGET randomised trial
7. MRC Multicentre Otitis Media Study Group Article first published online: 19 APR 2012 DOI: 10.1111/j.1749-4486.2012.02469.x
10. Eyes

10.1 Blepharoplasty (surgery on the upper & lower lid)

This procedure is not routinely funded by the NHS but may be funded through the local prior approval process. Applications can be made in the form of an individual application as per local agreement (this may be Individual Funding Request (IFR) including Exceptional Circumstances application or other prior approval process e.g. referral review via a Clinical Assessment Service (CAS)) in the following situations.

- To relieve entropion or ectropion.
- OR
- To remove lesions of the eyelid skin or lid margin in the following situations:
  - 1. Impairment of vision by lid as evidenced by photographs.
  - OR
  - 2. Impairment of the visual field by lid as evidenced by visual field test.
- OR
- Other demonstrated complications, e.g. disruptions of the tear film, evidence of chronic compensation of ptosis through elevation of the brow.

10.2 Brow lift

This procedure is not routinely funded by the NHS but may be funded through the local prior approval process. Applications can be made in the form of an individual application as per local agreement (this may be Individual Funding Request (IFR) including Exceptional Circumstances application or other prior approval process e.g. referral review via a Clinical Assessment Service (CAS)) in the following situations.

- Impairment of vision by lid as evidenced by photographs.
- OR
- To correct impairment of the visual field by lid as evidenced by visual field test.

10.3 Cataract surgery

Criteria

The CCG will only fund elective cataract surgery where the following apply:
The best corrected visual acuity is 6/9 or worse in either the first or second eye; AND

The patient has impairment in lifestyle such as substantial effect on activities of daily living, leisure activities, and risk of falls.

OR

Surgery is indicated for management of ocular co-morbidities such as control of glaucoma, view of diabetic retinopathy etc. OR

Patients with cataract having visual acuity better than 6/9 where there is a clear clinical indication or symptoms affecting lifestyle. For example, the patient with a visual acuity of 6/6 and symptomatic posterior subcapsular cataract, affecting activities of daily living and driving.

Rationale

- Visually impairing cataract is common in persons of 65 years and over.
- The effectiveness of cataract surgery (first and second eye) is established.
- Up to one third of cataract operations are for second eye surgery.
- Delay in second eye surgery is associated with poorer quality of life and functioning.

Evidence

- Cost utility studies based on a prospective cohort study determined a cost utility value of £1000/QALY\(^1\) for first eye and around £1300/QALY for second eye surgery\(^1\).
- A recent cost benefit analysis used the English Longitudinal Survey of Ageing (ELSA) to explore the self-reported effect of cataract operations on eyesight. The survey did not distinguish first and second eyes. The average expected welfare gain from surgery is valued at £1,110 in the year after surgery costing £672\(^2\).

References:

11. Minor Skin Lesions (Treatment of)

Minor skin lesions include benign pigmented moles, comedones, corn/callus, lipoma, milia, molluscum contagiosum, sebaceous cysts (epidermoid or pilar cysts), seborrhoeic keratoses (basal cell papillomata), skin tags including anal tags, spider naevi (telangiectasia), warts, xanthelasma and neurofibromata.

This policy applies to treatment of minor skin lesions in primary and secondary care.

<table>
<thead>
<tr>
<th>Suspcion of malignancy</th>
</tr>
</thead>
<tbody>
<tr>
<td>If there is any suspicion of malignancy, patients should be referred immediately to an appropriate service as described in the NICE improving outcomes guidance.</td>
</tr>
</tbody>
</table>

Criteria for Surgical excision:

- Obstruction of an orifice or vision.
- Functional limitation on movement or activity.
- Moderate to large facial lesions causing disfigurement.
- Recurrent bleeding / infection / inflammation, or marked itching, or severe pain which fails to respond to pharmacological treatment.
- The lesion is located in an anatomic area subject to recurrent trauma.

Rationale

- There is limited evidence that surgery on these lesions for aesthetic reasons offers benefit to patients.
- Where there is no suspicion of malignancy or complications, benign skin lesions may be self-limiting, respond to conservative measures and have no long-term health consequences for patients.
- There is a wide clinical consensus on the list of lesions included, and similar policies have been adopted by a number of CCGs.

Evidence

- This approach is consistent with the national aesthetic surgery guidelines².
References:

12. Obstructive sleep apnoea in adults
(surgical treatment of)

Note: Surgery for obstructive sleep apnoea will only be funded through a prior approval route. Applications for funding can be made in the form of an individual application as per local agreement. This may be Individual Funding Request (IFR) including Exceptional Circumstances application or other prior approval process e.g. referral review via a Clinical Assessment Service (CAS).

Criteria

<table>
<thead>
<tr>
<th>Criteria</th>
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<tbody>
<tr>
<td>Patient has moderate to severe symptoms (measured for example by the Epworth Sleepiness Score: 15-18= moderate, &gt;18 = severe);</td>
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<tr>
<td>OR</td>
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<tr>
<td>Patient is sleepy in dangerous situations such as driving (regardless of Epworth Sleepiness Score) Appendix F;</td>
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<tr>
<td>AND</td>
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<tr>
<td>Patient has significant sleep disordered breathing (as measured during a sleep study, usually by the Apnoea/Hypopnoea Index: 15-30/hr = moderate, &gt;30/hr = severe);</td>
</tr>
<tr>
<td>AND</td>
</tr>
<tr>
<td>Patient has already tried continuous positive airways pressure (CPAP) unsuccessfully for 6 months prior to being considered for surgery OR patient had major side effects to CPAP such as significant nosebleeds;</td>
</tr>
<tr>
<td>AND</td>
</tr>
<tr>
<td>Patient has already tried an intra-oral device, with monitoring to allow device adjustment and assessment of symptom control, unsuccessfully for 3 months OR patient has been unable to tolerate intra-oral device due to recurrent dislodgement of the device during sleep or temporomandibular pain;</td>
</tr>
<tr>
<td>AND</td>
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<tr>
<td>A specialist believes the individual patient will benefit€;</td>
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<tr>
<td>AND</td>
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<tr>
<td>The patient is fully informed as to the limited effectiveness of procedures, the lack of</td>
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</table>

Note: € indicates the requirement for a separate funding request for each patient.
long term outcomes and likely adverse effects including pain following surgery.

Note: Please refer to Appendix F for Epworth Sleepiness Score.

This guidance does not make detailed recommendations on the use of individual surgical procedures, although studies have shown varying levels of effectiveness in terms of outcomes and adverse effects between the different surgical procedures. However, exceptional circumstances/prior approval panels should take account of the fact that palatal surgery, such as UPPP and LAUP is not recommended by SIGN (2003) and it may compromise the patient’s subsequent ability to use nasal CPAP, although the extent of this risk is not known. Current evidence on soft-palate implants for obstructive sleep apnoea (OSA) raises no major safety concerns, but there is inadequate evidence that the procedure is efficacious in the treatment of this potentially serious condition for which other treatments exist. Therefore, soft-palate implants should not be used in the treatment of this condition.

Rationale

• The prevalence of obstructive sleep apnoea/hypopnoea syndrome (OSAHS) in men is estimated between 0.3% and 4%, and in women between 0.5% and 1%.
• Untreated OSAHS can affect daily function and quality of life. Resultant excessive daytime sleepiness and impaired concentration is estimated to cause a 1-2 fold increased risk of accidents. Sleepiness at the wheel is estimated to cause 20% of road accidents, with high mortality rates due to the lack of avoidance reactions when the patient falls asleep.
• Continuous positive airways pressure (CPAP) is recommended as the first choice therapy in patients with moderate to severe OSAHS who are sufficiently symptomatic to require intervention. Minor side effects are common and intensive support may be needed to increase uptake and compliance.
• Intra-oral devices including mandibular advancement devices are recommended for patients with mild OSAHS and normal daytime sleepiness, or for patients unable to tolerate CPAP.
• Weight loss may benefit some patients according to uncontrolled studies although a Cochrane review was unable to identify any research of good enough quality to quantify the effectiveness of weight loss on sleep apnoea. Failure to lose weight should not delay the institution of other therapies of proven effectiveness such as CPAP.
• Exercise is primarily to aid weight loss and may benefit some patients, although a Cochrane review (see below) was unable to identify any research of good enough quality to quantify the effectiveness of exercise on sleep apnoea.
• Pharmacological therapies should not be used as first line treatments for OSAHS.
• ‘Sleep hygiene’ includes using a comfortable bed in a warm, dark, quiet room, mentally winding down and avoidance of evening alcohol, caffeine and hypnotics. A Cochrane review (see below) was unable to identify any research of good enough quality to quantify the effectiveness of sleep hygiene on sleep apnoea.
• The place of surgery for OSAHS is controversial.

Choice of procedure

The main surgical procedures might include:

• Tracheostomy.
• Radiofrequency tissue ablation.
• Tonsillectomy and adenoidectomy, most usually in children.
- Maxillo-mandibular osteotomy and advancement.
- Removal of local specific obstructing pathologies.

This is not a definitive list.

**Evidence**

A Cochrane Review on Surgery for Obstructive Sleep Apnoea and the SIGN Guidelines on the Management of Obstructive Sleep Apnoea/Hypopnoea Syndrome in Adults (2003, last confirmed as up to date 2009) have been used as the basis for this guidance. The Cochrane review states that the place of surgery for OSAHS is controversial and that most studies recommending a particular surgery are based on evidence from case series. The review found eight randomised controlled trials of mixed quality. The trials found an inconsistent impact on subjective and objective markers of OSAHS in patients. The individual trials do not support the widespread use of surgery as a means of improving sleep quality over other therapeutic options available. Surgery potentially offers a ‘one-off treatment’ to alleviate signs and symptoms of OSAHS, but long terms benefits are not known. It is unknown if the long terms risk of cardiovascular disease and other events are reduced by surgery, due to lack of follow up.

**References:**


a According to available literature the subgroups in which surgical intervention may be effective are currently not known
13. Obstetrics, Gynaecology & Reproduction

13.1 Dilatation & curettage (D&C)

Funding will NOT be routinely provided for the following indications: investigation and/or treatment of menorrhagia; investigation of dysfunctional uterine bleeding or post-menopausal bleeding; treatment of irregular periods; treatment of endometrial hyperplasia; removing unwanted tissue, endometrial polyps or benign tumours of the womb; removing an IUD that has become embedded in the wall of the womb. Referral for D&C for evacuation of retained products of conception or removal of a molar pregnancy should only be considered if vacuum aspiration/suction curettage is contraindicated.

Criteria

D&C for the investigation of abnormal uterine bleeding should only be considered if:

- Transvaginal ultrasound with Pipelle endometrial aspirate has failed due to cervical stenosis or pain and facilities for a hysteroscopy with targeted biopsy are unavailable.
- Hysteroscopy with targeted biopsy has failed/is not possible due to cervical stenosis, pain or inability to dilate the cervix.
- Transvaginal ultrasound has demonstrated focal pathology and facilities for a hysteroscopy with targeted biopsy are unavailable.

Evidence

- D&C is no longer recommended as a diagnostic tool in heavy menstrual bleeding (HMB). To detect histological abnormalities in HMB endometrial sampling or hysteroscopy with directed biopsy have superseded D&C for obtaining endometrial tissue.
- Limited evidence is available on the therapeutic use of D&C for HMB. The NICE recommendation that D&C should not be used as a treatment for HMB was based on clinical expert opinion.
- Evacuation of retained products of conception after incomplete miscarriage or delivery has been recommended in order to reduce potential complications such as haemorrhage or infection. Surgical evacuation has been considered the most effective method by D&C or vacuum aspiration/suction curettage. A Cochrane review found that vacuum aspiration/suction curettage was safe, quick and easy to perform, and less painful than D&C. In most developed countries vacuum aspiration/suction curettage has replaced D&C for surgical evacuation of the uterus in incomplete miscarriage.
- Vacuum aspiration/suction curettage (rather than D&C/sharp metal curettage) is the preferred method of evacuation irrespective of uterine size in patients with hydatidiform mole who want to preserve fertility.

References:


13.2 Female genital prolapse/stress incontinence (assessment of)

Initially patients should be assessed and managed conservatively. Continent women with prolapse should be offered a trial of a ring pessary with a discussion of the potential benefits and risks. Evidence of this discussion should be documented in the primary and secondary care notes.

Surgical treatment is not funded for asymptomatic prolapse 1.

Surgical treatment of severe symptoms of prolapse/incontinence will be funded following assessment 12.

Criteria

Referral for specialist assessment is indicated for:

- Assessment and fitting of pessary only if this cannot be undertaken in primary care.

  OR

- Prolapse combined with urinary or faecal incontinence.

  OR

- Moderate to severe symptoms of prolapse.

  OR

- Failure of pessary.

Rationale

- Symptoms of prolapse can be classified as mechanical, sexual, lower urinary tract or bowel. Mechanical symptoms include tissue protruding from the vagina, having to manually reduce the bulge to urinate or defecate, spotting from ulceration of the protrusion and vaginal pain/discomfort. Sexual symptoms include dyspareunia, decreased sexual satisfaction and incontinence/prolapse during intercourse. Lower urinary tract symptoms include stress incontinence and urge incontinence. Bowel symptoms include faecal and flatus incontinence 3 4 5 6.
Four main POP grading systems are currently in use – quantitative POP (POPQ), vaginal profile, grading system and severity. Pelvic organ prolapse (POP) is common and many women with POP are asymptomatic. POP is not always chronic and progressive. Although prolapse can be associated with varied symptoms few are specific to prolapse. The extent of prolapse does not correlate well with symptoms.

Evidence

- A Cochrane review in 2004 found that there were no RCTs of pessary use in women with POP and no consensus on type or use of devices. Expert opinion is that pessaries are effective and should be considered before surgery in women with symptomatic POP at any level of severity. Pessaries can be used for short term relief before surgery or as a long term non surgical option. They can also be used to predict surgical outcomes or unmask occult urodynamic stress incontinence pre-operatively.

- The POPPY multicentre trial pilot study suggested that pelvic floor muscle training delivered by a physiotherapist to symptomatic women could reduce the severity of prolapse. A Cochrane review on the role of pelvic floor muscle exercises in the management of POP concluded that the evidence from the 3 RCTs included were insufficient to judge their use in the conservative management of POP and that further trials were needed.

- A Cochrane review on the use of vaginal oestrogen creams found limited evidence of their effectiveness in reducing or preventing the symptoms of prolapse.

References:

10. Machana t. Ring pessary for all pelvic organ prolapse. Arch Gynecol Obstet. 2010 Sep 17


13.3 Fertility preservation techniques

This policy is not applicable to Kingston CCG – Refer to Kingston CCG’s Assisted Conception Guidelines for cryopreservation & cryostorage policy.

The following preservation techniques: semen cryostorage, oocyte cryostorage, embryo cryostorage, will be routinely funded by SWL CCGs in the following circumstances:

- Where a man or a woman requires medical or surgical treatment that is likely to have a permanent harmful effect on subsequent sperm or egg production. Such treatment includes radiotherapy or chemotherapy for malignant disease.

- OR

- Where a man or a woman requires ongoing medical treatment that, whilst on treatment, causes harmful effects on sperm or egg production, impotence or has possible teratogenic effects, and in whom stopping treatment for a prolonged period of time to enable conception is not an option.

It is important to note that the eggs are extracted for cryostorage using drugs and procedures of egg collection normally used for assisted conception; therefore the funding includes assisted conception drugs and procedures as well as the storage costs. This will not progress to IVF/ICSI or any other assisted conception procedures to form an embryo in these cases, unless this is sought separately later through the assisted conception pathway.

Note:

- Women should be offered oocyte or embryo cryostorage (without simultaneous assisted conception treatment) as appropriate if they are well enough to undergo ovarian stimulation and egg collection, provided this will not worsen their condition and that sufficient time is available.

- Women preparing for medical treatment that is likely to make them infertile should be informed that oocyte cryostorage has very limited success, and that cryopreservation of ovarian tissue is still in an early stage of development.

Storage

- If agreed, will be funded for five (5) years. The HFEA would grant a license to cryostore oocytes for ten years. The further extension up to ten years can still be offered to the patient but as a self funded process.

- Will not be available where a man or woman chooses to undergo medical or surgical treatment whose primary purpose is that it will render her infertile, such as sterilisation.

- Will not be available where a man or woman requests cryostorage for personal lifestyle reasons, such as wishing to delay trying to conceive.

Post-storage Treatment

Funding of assisted conception treatments would be made available on the same basis as other patients who have not undergone such storage.

Self-funding following cessation of NHS funding

Once the period of NHS funding ceases, patients can elect to self-fund for a further period, not to exceed appropriate HFEA regulations on length of storage.

Embryo Cryostorage after NHS funded assisted conception
Suitable embryo's that are not transferred in IVF/ICSI cycle - Storage will be funded for a minimum period of one (1) year.
### 13.4 Hysterectomy for heavy menstrual bleeding

**Criteria:**

CCGs will fund hysterectomy for heavy menstrual bleeding only when:

<table>
<thead>
<tr>
<th>There has been an unsuccessful trial (of at least 6 cycles) with a levonorgestrel intrauterine system (e.g. Mirena®) unless medically contraindicated</th>
<th>(1st line pharmaceutical treatment)</th>
</tr>
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<tbody>
<tr>
<td>AND</td>
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<tr>
<td>A second pharmaceutical treatment (unless contraindicated) has been tried and has also failed. These pharmaceutical treatments include:</td>
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<tr>
<td>• Tranexamic acid (2nd line pharmaceutical treatment)</td>
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<tr>
<td>• Non-steroidal anti-inflammatory drugs (NSAIDs) (2nd line pharmaceutical treatment)</td>
<td></td>
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<tr>
<td>• Combined oral contraceptives (2nd line pharmaceutical treatment)</td>
<td></td>
</tr>
<tr>
<td>• Oral progesterone ((3rd line pharmaceutical treatment))</td>
<td></td>
</tr>
<tr>
<td>• Injected progesterone (3rd line pharmaceutical treatment)</td>
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<tr>
<td>AND</td>
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<tr>
<td>Endometrial ablation has been tried (unless the patient has fibroids &gt;3cm, an abnormal uterus or other contraindications)</td>
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</tr>
<tr>
<td>Note: endometrial ablation is suitable for women who do not want to conceive in the future and should only be offered after full discussion of risks and benefits and other treatment options</td>
<td></td>
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</tbody>
</table>

Hysterectomy should not be used as a first-line treatment solely for HMB. Hysterectomy should only be considered when:

- other pharmaceutical, surgical and radiological treatment options have failed, are contraindicated or are declined by the woman
- there is severe impact on quality of life
- fibroids (if present) are >3cm in diameter
- there is structural/histological abnormality of the uterus
- the woman no longer wishes to retain her uterus and fertility

**Rationale**

- The levonorgestrel intrauterine system is effective in the treatment of heavy menstrual bleeding and is considerably cheaper than performing a hysterectomy, even if required for many years, and fertility of the woman may be maintained.
- A number of effective conservative treatments are available as second line treatments after failure of Mirena or where it is contra-indicated.
Evidence

- NICE released guidelines on heavy menstrual bleeding in January 2007\(^2\) and these form the basis of these proposals.
- A Cochrane systemic review concluded that levonorgestrel intrauterine system improved the quality of life of women with menorrhagia as effectively as hysterectomy.
- In a NICE study of long-acting reversible contraception\(^3\), the average annual cost of Mirena was estimated at £70. This compares to the average cost to the CCG of performing a hysterectomy of £2,362.

References:

1. *Contraindications to the levonorgestrel intrauterine system are severe anaemia, unresponsive to transfusion or other treatment, distorted or small uterine cavity, genital malignancy, active trophoblastic disease, pelvic inflammatory disease, established or marked immunosuppression.*

2. *National Institute for Health & Clinical Excellence (NICE) CG44 Heavy menstrual bleeding, Jan 2007*

### 13.5 IVF

See Appendix G for individual CCG variations

<table>
<thead>
<tr>
<th>Criteria</th>
<th>Rationale</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Duration of subfertility</strong></td>
<td>Couples will be eligible for referral for treatment if they have experienced thirty six months of unexplained infertility or have an identified cause of infertility. 84% of women will conceive within one year of regular unprotected sexual intercourse, this increases to 92% after 2 years and 93% after 3 years.</td>
</tr>
<tr>
<td><strong>Age of woman at start of treatment cycle</strong></td>
<td>The age range will be a local CCG (Borough) decision. The likelihood of a live birth following assisted conception declines with age. Chances of a live birth per IVF cycle are: &gt;20% for women aged 23-35 15% for women aged 36-38 10% for women aged 39 years 6% for women aged 40 years and over.</td>
</tr>
<tr>
<td><strong>Body mass index of woman</strong></td>
<td>19 – 30 kg/m²: weight to be maintained for the last 6 months prior to application. Higher body mass index reduces the probability of success associated with assisted conception techniques.</td>
</tr>
<tr>
<td><strong>Smoking status of couple</strong></td>
<td>Both partners should have been non-smokers for at least six months prior to commencement of treatment. Smoking can adversely affect the success rates of assisted reproductive techniques.</td>
</tr>
<tr>
<td><strong>Previous cycles</strong></td>
<td>The number of NHS funded cycles including the number of frozen embryo transfers and duration of storage of frozen embryos will be a local CCG decision. The probability of a live birth following the IVF is consistent for the first three cycles but effectiveness of subsequent cycles is uncertain.</td>
</tr>
<tr>
<td><strong>Childlessness</strong></td>
<td>Neither partner must have any living children from this or previous relationships (including adopted children). As funding for assisted conception is limited, priority will be given to couples with the greatest need.</td>
</tr>
<tr>
<td><strong>Sterilisation</strong></td>
<td>Treatments will not be available if either partner has undergone previous sterilisation. Sterilisation is offered as an irreversible method of contraception and individuals on the NHS are made aware of this at the time of the procedure.</td>
</tr>
<tr>
<td><strong>HFEA Code of Practice</strong></td>
<td>Couples must comply to a Welfare of the Child assessment. Human Fertilisation and Embryology (HFE) Act 1990 (as amended) states: Section 13 (5): A woman shall not be provided with treatment services unless account has been taken of the welfare of any child who may be born as a result of the treatment (including the need of that child for supportive parenting), and of any other child who may be affected by the birth. Section 2 (1) “treatment services” means medical, surgical or obstetric services provided... for the purpose of assisting women to carry children.</td>
</tr>
<tr>
<td><strong>Women in same sex couples/ and women not in a partnership</strong></td>
<td>Sub-fertility treatment will be funded for women in same sex couples or women not in a partnership if those seeking treatment are demonstrably. This section was copied from the South Central criteria to ensure equality of access to the service.</td>
</tr>
</tbody>
</table>
In the case of women in same sex couples in which only one partner is sub fertile, clinicians should discuss the possibility of the other partner receiving treatment before proceeding to interventions involving the sub fertile partner. NHS funding will not be available for access to insemination facilities for fertile women who are part of a same sex partnership or those not in a partnership.

In circumstances in which women in a same sex partnership or individuals are eligible for sub fertility treatment, the other criteria for eligibility for sub fertility treatments will also apply. Women in same sex couples and women not in a partnership should have access to professional experts in reproductive medicine to obtain advice on the options available to enable them to proceed along this route if they so wish.

| FSH | The level of FSH would be a local CCG (Borough) decision. |

CCGs may wish to add additional criteria to this list based on local circumstances

References:


13.6 Uterine fibroids (minimally invasive surgery for)

Criteria

The CCGs will only fund the following procedures1, 2, & 3 for uterine fibroids via the prior approval route. Applications for funding can be made in the form of an individual application as per local agreement (this may be Individual Funding Request (IFR) including Exceptional Circumstances application or other prior approval process e.g. referral review via a Clinical Assessment Service (CAS)).

- MRI-guided percutaneous laser ablation
- Laparoscopic laser myomectomy
- MRI-guided focused ultrasound ablation

CCGs will fund uterine artery embolisation when the following criteria are met:

| The fibroid is greater than 3 cm in diameter; | AND |
| The fibroid is causing other symptoms that have a severe impact on the woman’s quality of life such as heavy or painful menstrual bleeding, problems with fertility or pressure symptoms; | AND |
| The woman wants to avoid surgery and / or retain uterus. |

Rationale

- Uterine fibroids or leiomyomata are benign tumours that occur in the uterus. They are the most common type of female tumour and their aetiology is not fully understood. They are found anchored to the uterine wall and can vary in size from the size of the grape to large masses that can be palpated through the uterine wall4.

- Current evidence5, 6 on UAE suggests that it is safe enough for routine use and there are symptomatic benefits in the majority of patients in the short term. However more evidence is required on the degree and duration of the benefits and of its effects on fertility.

- Evidence review commissioned by NICE showed that3 Laparoscopic Laser Myomectomy may be suitable for small fibroids, most of which are asymptomatic, and therefore the Specialist Advisors to NICE questioned the clinical value of the procedure.

- The NICE clinical guideline on heavy menstrual bleeding7 (HMB) states that when surgery for fibroid-related HMB is felt necessary, UAE, myomectomy and hysterectomy must all be considered discussed and documented. UAE should be considered in women with HMB associated with fibroids who want to retain their uterus and /or avoid surgery.

Evidence

- NICE commissioned a review of the evidence of UAE5 and found that the procedure was efficacious in reducing mean fibroid volume from between 40- 70% but the reduction in volume
did not correlate with changes in symptoms. Improvement in symptoms was reported in between 62-95% of women.

- NICE issued 'Interventional procedure guidance' in September 2007 which advised that MRgFUS should only be used with special arrangements for consent and for audit and research.
- Evidence on the safety and efficacy of MRI-guided percutaneous laser ablation of uterine fibroids is insufficient to support its use without special arrangements for consent, audit and research.
- Current evidence on the safety and efficacy of laparoscopic laser myomectomy does not appear adequate to support the use of this procedure without special arrangements for consent, audit or research.

References:
2. NICE MRI-guided transcutaneous focused ultrasound ablation for uterine fibroids—IPG 231 (2007)
7. NICE Heavy Menstrual Bleeding Clinical Guideline 44 July 2007
14. Orthopaedic & Pain Management

14.1 Acupuncture for Non-Specific Low Back Pain (LBP)

CCGs will only fund acupuncture if all of the following criteria are met under the following circumstances.

A maximum of 10 sessions should be offered over a period of 12 weeks as a one-off treatment. Any additional treatments sessions will require prior approval for funding. Acupuncture is more effective if it is offered as an adjunct to other conventional treatments. The treatment may be offered in primary care.

Criteria

<table>
<thead>
<tr>
<th>LBP exists for more than 6 months;</th>
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<td>AND</td>
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<td>LBP is severe as assessed by one of the grading systems e.g. RMDQ;</td>
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<td>AND</td>
</tr>
<tr>
<td>All other conventional treatments such as exercise, pharmacological management, physiotherapy etc. have been tried without any improvement in symptoms for a minimum of 6 months;</td>
</tr>
<tr>
<td>AND</td>
</tr>
<tr>
<td>Acupuncture is used in conjunction with other conventional treatments as part of a pain management programme.</td>
</tr>
</tbody>
</table>

Rationale

- Acupuncture is more effective for pain relief than no treatment or sham treatment, in measurements taken up to three months. The results also show that for chronic low-back pain, acupuncture is more effective for improving function than no treatment, in the short-term. Acupuncture is not more effective than other conventional and “alternative” treatments. When acupuncture is added to other conventional therapies, it relieves pain and improves function better than the conventional therapies alone.

- There is evidence that acupuncture provides a short-term clinically relevant effect when compared with a waiting list control or when acupuncture is added to another intervention.

- Traditional acupuncture care delivered in a primary care setting was safe and acceptable to patients with non-specific low back pain.

- A study showed a statistically significant difference in pain scores between the acupuncture and no acupuncture groups (P <0.001 at 8 weeks). However, no significant difference in pain between the acupuncture and minimal acupuncture groups was found at 8, 26 and 52 weeks (the acupuncture group did have slightly better outcomes than the minimal acupuncture group).

- Estimates of the prevalence of low back pain vary considerably between studies - up to 33% for point prevalence, 65% for 1-year prevalence, and 84% for lifetime prevalence.
- A study reported that 1 in 4 people can get localised erythema due to acupuncture as a side-effect 8.

- The QALY gain for the acupuncture group over 24 months was 1.453 (0.248) compared to a mean of 1.426 (0.191) for the usual care group. The mean incremental health gain from Low Back Pain acupuncture at 24 months was 0.027 QALYs, leading to a base case estimate of £4241 per QALY gained 9.

References:


4. Sidney M. Rubinstein • Marienke van Middelkoop • Ton Kuijpers • Raymond Ostelo • Arianne P. Verhagen • Michiel R. de Boer • Bart W. Koes • Maurits W. van Tulder A systematic review on the effectiveness of complementary and alternative medicine for chronic non-specific low-back pain. European Spine Journal, August 2010, vol./is. 19/8(1213-1228), 0940-6719 (August 2010)

5. KJ Thomas, H MacPherson, J Ratcliffe, L Thorpe, J Brazier, M Campbell, M Fitter, M Roman, S Walters and JP Nicholl Longer term clinical and economic benefits of offering acupuncture care to patients with chronic low back pain Health Technology Assessment 2005; Vol. 9: No. 32


14.2 Autologous chondrocyte implantation

NICE has produced technical guidance on the use of autologous chondrocyte implantation (ACI)

Criteria:

\[
\text{ACI is NOT recommended for the treatment of articular cartilage defects except in the context of ongoing or new clinical studies that are designed to generate robust and relevant outcome data.}
\]

SWL CCGs will not routinely fund health care interventions that NICE has recommended should only be undertaken in the context of research. Clinicians wishing to undertake such procedures should ensure they fulfil the normal requirements for undertaking research.

Rationale

- If trials are undertaken patients should be fully informed of the uncertainties about the long-term effectiveness and potential adverse effects of this procedure.

- Any outcome data from trials should include measurement of health related quality of life and long-term follow up.

Evidence

NICE assessed a number of trials but found inconsistent evidence of the clinical effectiveness of ACI. The studies were heterogeneous in terms of the patients recruited, the ACI technique used and the measures used to assess outcome. In addition, comparative trial follow-up was limited to 1–2 years. The longer term case series showed similar benefits under most modes of treatment. There were no trials comparing ACI (or any of the other interventions in the studies reviewed) with conservative management.

References:

14.3 Carpal tunnel syndrome (surgical treatment of)

This policy is not applicable to St George's Hospital - Refer to the 'St. George’s Hospital Carpal Tunnel Management Guidelines & Referral Protocol'.

All referrals should be through an agreed pathway to optimise access to conservative treatment.

Criteria

The CCG will fund carpal tunnel surgery where:

<table>
<thead>
<tr>
<th>Symptoms persist for more than three months after conservative therapy with oral/local corticosteroid injections and/or splinting.</th>
</tr>
</thead>
</table>

OR

<table>
<thead>
<tr>
<th>There is neurological deficit or median nerve denervation for example sensory blunting, muscle wasting or weakness of thenar abduction.</th>
</tr>
</thead>
</table>

OR

<table>
<thead>
<tr>
<th>Severe symptoms significantly interfering with daily activities.</th>
</tr>
</thead>
</table>

Rationale

- Carpal Tunnel Syndrome (CTS) presents with symptoms ranging in severity and should be recognised before permanent deficits develop. Risk of nerve damage is low for most patients and the relationship between symptoms and nerve conduction study results is not strong.
- Conservative treatment offers short-term benefit (0-3 months) and symptom severity can be seen to improve after 2-7 weeks of initial treatment.
- Conservative treatment offers the opportunity to avoid surgery and have the advantage of being relatively inexpensive and without serious adverse side effects.
- Steroids (oral and local injection) and nocturnal splinting in the neutral position are considered the most effective conservative therapies.
- In the mid and longer term (3-18 months), surgery is more effective than conservative treatment.
- Open carpal tunnel release/decompression is the most common surgical treatment performed. The choice of endoscopic or open technique is usually guided by surgeon's experience and patient's preference.

Evidence

- This approach is supported by evidence from several recent systematic reviews, randomized control trials, guidelines (including American Academy of Orthopaedic Surgeons 2009) and recommendations1-8.
- Studies have shown that provocative physical tests such as Phalen's sign and Tinel's sign range in sensitivity (8-100%) and specificity (55-87%) and are less reliable in advanced CTS7.
- There is moderate evidence that splints are effective in decreasing symptom severity and two reviews suggests neutral position is more effective than wrist cock-up splint1,3,5,6
- Two systematic reviews suggest strong evidence of effectiveness of oral steroids compared to placebo, but there is no evidence of difference in effectiveness of dosage3,5.
- In the short term (0-3months), there is strong evidence of the effectiveness of steroid injections in providing symptom relief and moderate evidence local steroid injections are more effective than either oral steroids or systemic corticosteroids injections1,3,5. There is no evidence in effectiveness of short acting compared to long-acting corticosteriod injection in the
short term\(^3\).
- Other non-surgical treatments, such as non-steroidal anti-inflammatories, diuretics, botulinum toxin, therapeutic exercises, vitamin B6 and physical treatments (e.g. ultrasound, low power laser) have limited or no evidence that they are effective in the short term\(^3, 5, 6\).
- In the literature, conservative treatment is given preference in mild to moderate cases and surgical treatment is mainly applied in severe cases including nerve denervation. Surgical treatment is also indicated in cases in which initial conservative management fails\(^4\).
- Evidence suggests that surgical treatment is more effective than splinting and hand function in midterm and long term (3-18 months), but evidence is conflicting when comparing conservative treatment to surgery in the short term\(^3, 4\). An RCT in 2009, showed outcomes were better in terms of hand function and symptoms at 3 months and one year compared to a control group\(^1\).
- No RCTs published at present explore the optimal timing strategy for surgery\(^4\). There is no validated evidence to identify which patients should undergo surgery as initial treatment\(^1\).
- One study found that 75% of patients surveyed (n=4000) having surgery under usual NHS conditions found the operation an unqualified success about two years after surgery\(^7\).
- There is no unequivocal evidence that suggest one surgical treatment is more effective than the other\(^1, 4\).

References:
8. BSSH Evidence for Surgical Treatment Carpal Tunnel Syndrome (CTS) http://www.bssh.ac.uk/education/guidelines/carpal_tunnel_syndrome.pdf
14.4 Discectomy for lumbar disc prolapse (elective)

Criteria

<table>
<thead>
<tr>
<th>The patient must be 18 years or older;</th>
</tr>
</thead>
<tbody>
<tr>
<td>AND</td>
</tr>
<tr>
<td>The patient has had magnetic resonance imaging, showing disc herniation (protrusion, extrusion, or sequestered fragment) at a level and side corresponding to the clinical symptoms;</td>
</tr>
<tr>
<td>AND</td>
</tr>
<tr>
<td>The patient has radicular pain (below the knee for lower lumbar herniation, into the anterior thigh for upper lumbar herniation) consistent with the level of spinal involvement.</td>
</tr>
</tbody>
</table>

OR

<table>
<thead>
<tr>
<th>There is evidence of nerve-root irritation with a positive nerve-root tension sign (straight leg raise–positive between 30° and 70° or positive femoral tension sign);</th>
</tr>
</thead>
<tbody>
<tr>
<td>AND</td>
</tr>
<tr>
<td>Symptoms persist despite some non-operative treatment for at least 6 weeks (e.g. analgesia, physical therapy, bed rest etc.) provided that analgesia is adequate and there is no imminent risk of neurological deficit.</td>
</tr>
</tbody>
</table>

Rationale

- Herniated lumbar discs account for less than 5% of lower back pain but are responsible for most cases of sciatica (nerve root pain). Ninety per cent of cases of sciatica resolve with conservative management.
- The primary aim of surgery is to provide relief of symptoms in those patients who have failed to respond to conservative treatment.
- A Cochrane review concluded that surgical discectomy for carefully selected patients with sciatica due to lumbar disc prolapse, provides faster relief from an acute attack than conservative management although any positive and negative effects on the lifetime natural history of the disease are unclear.
- In the absence of clear indications for surgery, postponing surgery to further assess progress may delay recovery but does not produce long-term harm.
- There is little evidence on the optimal timing of surgery.
- Microdiscectomy is broadly as effective as open/macro discectomy. Microdiscectomy is a longer procedure than open discectomy but there are no differences in peri-operative bleeding, length of hospitalisation or formation of scar tissue.
- Discectomy is cost effective with a willingness to pay 40,000 Euros per QALY.

Evidence

- A 2008 Cochrane review concluded that surgical discectomy for carefully selected patients with sciatica due to lumbar disc prolapse provides faster relief from the acute attack than
conservative management. They also concluded that open and microdiscectomy are more effective than chemonucleolysis. They also concluded that open and microdiscectomy are more effective than chemonucleolysis.

- There are several low quality RCTs that have compared discectomy with conservative management (including epidural injection, physiotherapy and education). They conclude that discectomy provides better clinical outcomes than conservative management and it is more effective than conservative management at one year. Systematic reviews undertaken in 2008 and 2009 also agreed with these findings. No significant differences were found between surgery and usual conservative care in any of the clinical outcomes after 1 and 2 years.

- The evidence for minimally invasive techniques for discectomy remains unclear. One systematic review on the effectiveness of nucleoplasty procedure concluded that nucleoplasty is potentially effective in patients with symptomatic disc herniation who are refractory to conservative treatment, but higher quality evidence is necessary to confirm efficacy and risks.

References:


4. Jordan J, Konstantinou K, O'Dowd J. Herniated Lumbar Disc Clinical Evidence 2009;03:1118

14.5 Dupuytren’s contracture (fasciotomy/fasciectomy)  
(surgical treatment of)

This policy is not applicable to St George’s Hospital - Refer to the ‘St. George’s Hospital Dupuytren’s Contracture Guidelines & Referral Checklist’.

Criteria for surgical treatment

<table>
<thead>
<tr>
<th>Metacarpophalangeal joint contracture or proximal interphalangeal joint contracture of 30 degrees or more at least in one joint (inability to put hand flat on table)</th>
</tr>
</thead>
<tbody>
<tr>
<td>OR</td>
</tr>
<tr>
<td>Patient has at least 10 degrees loss of extension in 2 or more joints</td>
</tr>
<tr>
<td>OR</td>
</tr>
<tr>
<td>Metacarpophalangeal joint contracture or proximal interphalangeal joint contracture is less than 30 degrees at least in one joint</td>
</tr>
<tr>
<td>AND</td>
</tr>
<tr>
<td>All additional risk factors for aggressive progression are present, specifically - bilateral disease, family history of condition, ectopic lesions, age under 50 and male gender</td>
</tr>
<tr>
<td>AND</td>
</tr>
<tr>
<td>There is significant threat to hand function</td>
</tr>
</tbody>
</table>

Evidence

- Symptoms of Dupuytren’s contracture are often mild and painless and do not require treatment. Disease progression is unpredictable; where the contractures themselves are not functionally limiting management should compose of reassurance and observation.
- Surgery should not be considered a cure and patients should be advised of the risks of recurrence when deciding whether to consider surgical intervention.
- As the condition progresses it can become difficult to fully extend the finger(s) affected, eventually becoming permanently fixed in a flexed (bent) position affecting activities of daily living.
- Treatment seeks to restore hand function and prevent progression, however the underlying disease will remain. Recurrence following surgical intervention is common, ranging from 30-40% following open partial fasciectomy to 60% following needle aponeurotomy/fasciectomy.
- Evidence is lacking on the effectiveness of non-surgical treatments for Dupuytren’s contracture such as vitamin E cream ultrasonic therapy and radiation therapy. Radiation therapy should only be used with special arrangements for clinical governance, consent and audit or research.
- There is a lack of evidence on the long-term efficacy of collagenase injections.
- Clinical consensus suggests surgical intervention is recommended when metacarpophalangeal joint contracture or proximal interphalangeal joint contracture reaches 30 degrees.
- Dupuytren’s contracture has a greater tendency for aggressive progression and recurrence.
after surgical treatment in the presence of 5 factors - bilateral disease, family history of condition, ectopic lesions, age under 50 and male gender.

References:

14.6 Epidural injections for lumbar back pain

CCGs will fund lumbar interlaminar, transforaminal and caudal epidural injections for patients with radicular pain due to herniated disc (sciatica) when the following criteria have been met.

Criteria

<table>
<thead>
<tr>
<th>The patient must be 18 years or above;</th>
</tr>
</thead>
<tbody>
<tr>
<td>AND</td>
</tr>
<tr>
<td>The patient has radicular pain (below the knee for lower lumbar herniation, into the anterior thigh for upper lumbar herniation) consistent with the level of spinal involvement.</td>
</tr>
<tr>
<td>OR</td>
</tr>
<tr>
<td>There is evidence of nerve-root irritation with a positive nerve-root tension sign (straight leg raise—positive between 30° and 70° or positive femoral tension sign).</td>
</tr>
<tr>
<td>AND</td>
</tr>
<tr>
<td>Symptoms persist despite some non-operative treatment for at least 3 weeks (e.g. analgesia, physical therapy, bed rest etc.).</td>
</tr>
</tbody>
</table>

Epidural injections beyond the first three injections are provided as part of a comprehensive pain management programme.

Patients may receive up to six injections 2-3 months apart provided there has been >50% reduction in symptoms for six weeks.

Evidence

- Epidural injection for the management of spinal pain is one of the commonest interventions performed in many countries although there is still some uncertainty regarding their effectiveness and safety\(^1\). Spinal pain is a common cause of chronic pain with lifetime prevalence 54-80%. Annual prevalence of chronic low back pain ranges from 15-45%.

- A number of systematic reviews\(^2, 3\) concluded that for sciatica or prolapsed lumbar disc with radiculopathy, there is fair evidence that epidural steroid injection is moderately effective for short-term (but not long term) symptom relief. They found insufficient evidence to determine the optimal route of administration.

- Another systematic review, by Manchikanti et al\(^4\), looked at the epidural administration by the caudal, interlaminal and transforaminal routes separately. They found strong evidence of the effectiveness of the caudal route in the short and long term, and moderate evidence for the effectiveness of the transforaminal and interlaminal approaches in the short and long term.

Complications

The most common type of complications are related to needle placement and drug administration including dural puncture, spinal cord trauma, subdural injections and abscess formation.

References:
14.7 Ganglia (Excision of ganglia)

Criteria for surgical removal

<table>
<thead>
<tr>
<th>The ganglia are painful seed ganglia¹.</th>
</tr>
</thead>
<tbody>
<tr>
<td>OR</td>
</tr>
<tr>
<td>The ganglia are mucoid cysts arising at the distal interphalangeal joint and disturbing nail growth or discharging².</td>
</tr>
<tr>
<td>OR</td>
</tr>
<tr>
<td>The ganglion is causing significant functional impairment and/or pain¹.</td>
</tr>
</tbody>
</table>

Clinicians could consider aspiration as an alternative to excision due to its lower complication rates. The higher recurrence rates for treatment with aspiration should be considered in this assessment (20% for aspiration vs. 10% for surgical)³.

If aspiration has not been attempted, referrals may be redirected to a GP with Special Interest (GPwSI) in minor surgery for aspiration where available. Ganglia on the feet should be referred to a GPwSI in Podiatry where available².

Rationale

- Most ganglia are symptom free, but some give pain, weakness, mobility disorders or pressure neuropathy².
- The recurrence rate after excision of wrist ganglia is between 10-45%¹, ².

Evidence

The Trent regional audit (which reviewed the progress of 729 ganglions up to 10 years from attendance) indicated that 33% of dorsal ganglions and 45% of volar-wrist ganglia would resolve spontaneously in six years².
References:


14.8 Hip replacement surgery (primary)

Criteria

The CCG will agree to fund elective surgery when any one of the following sets of criteria have been completely met:

<table>
<thead>
<tr>
<th>Group 1</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adults where the patient’s Oxford Hip score (Appendix H) is ≤ 26 on the 0 to 48 system; or ≥ 34 on the 60 to 12 system</td>
</tr>
</tbody>
</table>

OR

<table>
<thead>
<tr>
<th>Group 2</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patient complains of severe joint pain (as defined in Appendix H);</td>
</tr>
</tbody>
</table>

AND

Has severe functional limitation despite the use of an extended course of non-surgical treatments such as adequate doses of appropriate analgesia (see Appendix H), weight control treatments and physical therapies;

AND

Has radiographic evidence of joint damage (e.g. loss of joint space, marginal osteophytes).

OR

<table>
<thead>
<tr>
<th>Group 3</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patient complains of severe joint pain (as defined in Appendix H);</td>
</tr>
</tbody>
</table>

AND

Patient has minor to moderate functional limitation, despite the use of an extended course of non-surgical treatments such as adequate doses of appropriate analgesia (see Appendix H), weight control treatments and physical therapies.
Has **radiographic evidence** of joint damage\(^3\) (e.g. loss of joint space, marginal osteophytes)\(^3,4\).

OR

**Group 4**

Patient complains of **mild to moderate** joint pain (as defined in Appendix H)\(^5\);

AND

Has **severe** functional limitation, despite the use of an extended course of non-surgical treatments such as adequate doses of appropriate analgesia (see Appendix I), weight control treatments and physical therapies.

AND

Has **radiographic evidence** of joint damage (e.g. loss of joint space, marginal osteophytes)

**Note:** Please refer to Appendix H for classifications of the pain levels and functional limitations.

**Prior to referral**

Any other pre-existing medical conditions have been investigated and optimised\(^6\).

If appropriate the patient should have been advised to reduce their BMI to less than 30 and all reasonable attempts made to reduce their weight to this level prior to surgery\(^7\). Exceptions include patients whose pain is so severe and/or mobility so compromised that they are in immediate danger of losing their independence and where joint replacement would relieve this threat. An exception would also be patients in whom destruction of the joint is of such severity that delaying surgical correction would increase the technical difficulty of the procedure.

**Initial management of osteoarthritis**

Evidence from the Musculoskeletal National Service Framework (NSF), NICE, the GP Training Network and the National Institute of Health (NIH) Consensus Panel\(^8\) suggests that management of common musculoskeletal problems, including hip pain, should ideally be undertaken in primary care. Patients should be referred for a specialist opinion on total joint replacement when prolonged use of all conservative means has failed to alleviate the patient's pain and disability. This initial non-surgical management of hip pain due to osteoarthritis (OA) may include (as appropriate for the individual patient) weight reduction, activity modification, patient specific exercise programmes, adequate doses of NSAIDS and analgesics, joint injection, walking aids, home adaptations, curtailment of inappropriate activities and other forms of physical therapies.

**Note on Hip Resurfacing**

NICE guidance for metal on metal (MoM) hip-resurfacing\(^9,10\) states that “MoM hip resurfacing arthroplasty is recommended as one option for people with advanced hip disease who would otherwise receive and are likely to outlive a conventional primary total hip replacement”. In considering hip resurfacing arthroplasty, it is recommended that surgeons take into account activity levels of potential recipients and bear in mind that the current evidence for the clinical and cost-effectiveness of
MoM hip resurfacing arthroplasty is principally in individuals less than 65 years of age. This guidance indicates that resurfacing is recommended for younger patients in order to avoid future revision surgery. However, there is uncertainty over the long-term reliability of hip resurfacing.

MoM hip resurfacing should only be performed by a surgeon with specific training in this technique. As part of the consent process patients should be made aware of the medium to long term safety and reliability of MoM devices and the likely outcome of revision surgery compared to conventional total hip replacement.

References:
# 14.9 Knee arthroscopy

Assessment of knee pathology should include a competent clinical examination (or MRI scans if there is diagnostic uncertainty or red flag signs/symptoms/conditions). If examination and/or MRI have demonstrated clear evidence of an internal joint derangement and conservative treatment has failed, or it is clear that conservative treatment will not be effective, knee arthroscopy should be considered.

Arthroscopy will NOT be routinely funded as primary diagnostic tool.

## Criteria

CCGs will only fund arthroscopy of the knee for the following **diagnostic** indications:

- Patients with medial knee pain with suspected Plica syndrome
- Suspected chondromalacia patellae
- When information is required on the degree and distribution of joint damage to inform the type of knee replacement that should be performed

CCGs will only fund arthroscopy of the knee for the following **therapeutic** indications:

- Removal of loose body causing mechanical symptoms
- Meniscal surgery (repair or resection)
- Ligament repair or reconstruction (including lateral release)
- Synovectomy
- Treatment of articular defects e.g. microfracture
- Debridement of arthritis in younger patients (i.e. under 60 years of age) delaying need for total knee replacement

## Rationale

- Knee arthroscopy should not be considered a primary diagnostic tool. MRI should be used where there is diagnostic uncertainty. In the majority of cases clinical assessment (history and examination) by an experienced clinician will provide a diagnosis and demonstrate if internal joint derangement is present.
• Red flag symptoms: recent trauma, constant progressive non-mechanical pain (particularly at night), previous history of cancer, long term oral steroid use, history of drug abuse or HIV, fever, being systemically unwell, recent unexplained weight loss, persisting severe restriction of joint movement, widespread neurological changes and structural deformity

• Red flag conditions: infection, carcinoma, nerve root impingement, bone fracture, avascular necrosis

Evidence

NICE guidance states that arthroscopic lavage and debridement alone should not be used as a treatment for osteoarthritis unless the patient has knee osteoarthritis with a clear history of mechanical locking NOT swelling, giving way or X-ray evidence of loose bodies because it cannot demonstrate clinically useful benefit in the short or long term.

References:
2. IPG230 Arthroscopic knee washout, with or without debridement, for the treatment of osteoarthritis. National Institute of Health & Clinical Excellence August 2007
14.10 Knee replacement surgery (primary)

Criteria

The CCG will agree to fund elective surgery when any one of the following sets of criteria has been completely met:

**Group 1**
When the patient's Oxford Knee score (Appendix I) is $\leq 20$ on the 0 to 48 system; or
$\geq 40$ on the 60 to 12 system

**Group 2**
Where the patient's complains of intense or severe symptomatology (see Appendix I) not adequately relieved by an extended course of non-surgical management such as adequate doses of appropriate analgesia (see Appendix I), weight control treatments and physical therapies

AND

Has radiological features of severe disease;

AND

Has demonstrated disease within all three compartments of the knee (tricompartmental) or localised to one compartment.

**Group 3**
Where the patients complains of intense or severe symptomatology (see Appendix I) not adequately relieved by an extended course of non-surgical management such as adequate doses of appropriate analgesia (see Appendix I), weight control treatments and physical therapies

AND

Has radiological features of moderate disease;

AND

Is troubled by limited mobility or instability of the knee joint.

**Group 4**
The patient complains of severe symptomatology (see Appendix I) not adequately relieved by an extended course of non-surgical management such as adequate doses of appropriate analgesia (see Appendix I), weight control treatments and physical therapies;

AND

Has radiological features of slight disease;

AND
Is troubled by limited mobility or stability of the knee joint.

Note: Please refer to the Appendix I for the classifications of symptoms, radiology and localisation

Prior to referral

Any other pre-existing medical conditions have been investigated and optimised

If appropriate the patient should have been advised to reduce their BMI to less than 30 and all reasonable attempts made to reduce their weight to this level prior to surgery. Exceptions include patients whose pain is so severe and/or mobility so compromised that they are in immediate danger of losing their independence and where joint replacement would relieve this threat. An exception would also be patients in whom destruction of the joint is of such severity that delaying surgical correction would increase the technical difficulty of the procedure.

Initial management of osteoarthritis

Evidence from the Musculoskeletal National Service Framework (NSF), NICE, the GP Training Network and the National Institute of Health (NIH) Consensus Panel suggests that management of common musculoskeletal problems, including knee pain, should ideally be undertaken in primary care. Patients should be referred for a specialist opinion on total joint replacement when prolonged use of all conservative means has failed to alleviate the patient's pain and disability. This initial non-surgical management of knee pain due to osteoarthritis (OA) may include (as appropriate for the individual patient) weight reduction, activity modification, patient specific exercise programmes, adequate doses of NSAIDS and analgesics, joint injection, walking aids, home adaptations, curtailment of inappropriate activities and other forms of physical therapies.

References:

1. Total knee replacement – Ontario Health Technology Assessment Series 2005; vol5, no.9
14.11 Knee washout (in patients with knee osteoarthritis)

Criteria

CCGs will only fund arthroscopic lavage and debridement in patients with knee osteoarthritis for the following indication:

| Patients with a clear history of true mechanical locking |

NICE guidance states that arthroscopic lavage and debridement alone should not be used as a treatment for osteoarthritis unless the patient has knee osteoarthritis with a clear history of mechanical locking NOT gelling, giving way or X-ray evidence of loose bodies because it cannot demonstrate clinically useful benefit in the short or long term.

References:
2. IPG230 Arthroscopic knee washout, with or without debridement, for the treatment of osteoarthritis. National Institute of Health & Clinical Excellence August 2007

14.12 Therapeutic facet joint injections/medial branch blocks

These criteria do not relate to cancer related pain.

CCGs will fund medial branch blocks for the management of cervical, thoracic and lumbar back pain as specified below.

CCGs will fund medial branch blocks when all the following criteria are met:

| The pain has lasted for more than one year; |
| AND |
| The pain has resulted in moderate to significant impact on daily functioning; |
| AND |
| All conservative management options (bed rest, exercise, pharmacotherapy including analgesia and muscle relaxants) have been tried and failed. |

Clinical practice

Prior to the administration of the medial branch blocks facet joint pain should be confirmed by controlled diagnostic local anaesthetic block. In the diagnostic phase the patient may receive up to 3 injections 1-2 weeks apart, in the therapeutic phase, up to six injections 2-3 months apart provided there has been >50% reduction in symptoms for six weeks. Medial branch blocks beyond the first three injections should be provided as part of a comprehensive pain management programme.
Evidence

Medial Branch Blocks

Injection of a local anaesthetic, steroid or other agents around the primary nerve innervating the facet joint (the medial branch of the posterior primary ramus) is termed a medial branch block. It can be used as a diagnostic procedure intended to establish whether pain originates from the facet joint, and it may also be used as a therapeutic procedure.

Manchikanti et al. ² identified four randomized trials that assessed medial branch block using an active control design, demonstrating strong evidence of both short and long term pain relief in the cervical, thoracic and lumbar spine. However Chou et al. ¹ found no randomized control trials that compared efficacy of therapeutic medial branch block versus sham or placebo injection, and concluded that there is insufficient evidence to reach reliable conclusions regarding the effectiveness of therapeutic median nerve block.

Intra-articular facet joint injections

Intra-articular facet joint injections will not normally be funded as there is good evidence from randomised control trials that facet joint injections are not effective¹, ².

The UK RCGP guidelines found that facet joint injection do not produce pain relief or global improvement, with neither the type of agent injected nor the site of injection making a significant difference to outcomes ³. This is supported by American Pain Society Guidelines ¹ and other evidence reviews².

NICE guidance⁴, relating only to treatment of back pain of less than 1 year’s duration states: “Do not offer injections of therapeutic substances into the back for non-specific back pain.”

Diagnostic facet joint blocks

Diagnostic facet joint blocks have a specificity of 8% and sensitivity varying from 27-63% for cervical spine, 42-58% thoracic spine and 17-50% in the lumbar spine. The positive predictive value has been estimated at 31% and the diagnostic effect may be confounded by leakage into the peri-articular tissues.

The European COST guidelines recommend against facet joint blocks for the diagnosis of facet joint pain³.

Complications

The most common complications are related to needle placement and drug administration e.g. dural puncture, spinal cord trauma, infection, intra-arterial and intravenous injection, spinal anaesthesia, chemical meningitis etc.

References:


14.13 Thermal radiofrequency denervation of lumbar & cervical facet joints

These criteria do not relate to cancer related pain.

Criteria

CCGs will fund thermal radiofrequency controlled denervation of the medial branch of the dorsal rami of the lumbar and cervical facet joints (medial branch neurotomy) in the following circumstances:

- The patient must be aged over 18 or above.

- Non-radicular lumbar (all levels) or cervical (C3-4 and below) facet joint pain.

- Failure of one year of non-invasive therapy, such as medication and physiotherapy and bed rest.

- Radiological imaging to rule out any correctable structural lesion e.g. MRI.

- At least 2 anaesthetic diagnostic blocks, one of which must be of the medial branch of the dorsal ramus innervating the target facet joint with at least 80% reduction in pain following each block during the activities that normally generate pain\(^1\). The pain relief must be consistent with the expected duration of the anaesthetic block.

- All procedures must be performed under fluoroscopy (x-ray guidance).

Thermal radiofrequency denervation is provided as part of a comprehensive pain management programme.

CCGs **will not fund** cryoneurolysis or laser denervation.

CCGs **will fund** up to three facet denervations on one occasion.

CCGs **will not** fund re-treatment at the same location unless at least six months have elapsed since prior treatment.

Evidence of the effectiveness of the treatment of facet joint pain associated with a neurological deficit, radiculopathy or overt disc herniation, metastatic diseases, patients awaiting back surgery or patients with multiple, focal or chronic pain syndromes is limited.

Background

Facet or zygapophysial joints are innervated by the medial branches of the dorsal rami. Facet joint pain is responsible for spinal pain in 15-45% of patients with low back pain, 36-67% of people with neck pain and 34-48% of people with thoracic pain.

The procedure
Radiofrequency denervation is the destruction of nerves using heat generated by a radiofrequency current. It involves the placement of a catheter or electrode near or in the target nerve. Once the position of the catheter is confirmed by fluoroscopy, a radiofrequency current is applied in order to heat and coagulate adjacent tissues, including the target nerve.

**Complications**

The most common complications are related to the placement of the catheter or electrode near to or in the target nerve.

**Evidence**

- Chou et al.\(^1\) found insufficient evidence from nine randomized trials to reach reliable conclusions regarding the use of radiofrequency denervation for chronic back pain, due to conflicting results from the RCTs.

- Manchikanti et al.\(^2\) identified nine randomised control trials, but only considered two of sufficient quality. On this basis they concluded that there is evidence of short term effectiveness at the lumbar level, and short and long- term effectiveness at the cervical level.

- NICE guidance\(^3\), relating only to treatment of back pain of less than 1 year's duration recommends not referring people for radiofrequency facet joint denervation.

- The European COST guidelines found insufficient evidence to recommend radiofrequency denervation of dorsal root ganglion for chronic low back pain\(^4\).

**References:**


14.14 Trigger Finger

Criteria for surgical treatment

<table>
<thead>
<tr>
<th>Initial conservative treatment (e.g. activity modification, non-steroidal anti-inflammatory drugs for pain control, joint immobilisation (splinting)) has been unsuccessful;</th>
</tr>
</thead>
<tbody>
<tr>
<td>AND</td>
</tr>
<tr>
<td>The patient has failed to respond or experiences recurrence of triggering following one corticosteroid injection.</td>
</tr>
</tbody>
</table>

OR

| The patient has a fixed contracture. |

Rationale

- Spontaneous recovery has been reported in up to 29% of cases.
- Initial treatment should be conservative involving activity modification, non-steroidal anti-inflammatory drugs for pain control, joint immobilisation (splinting) and corticosteroid injection.
- Splinting has been shown to have a 55 - 73% success rate.
- An RCT comparing corticosteroid injection with surgical interventions indicated success rates following a single corticosteroid injection are 57%. Success rates as high as 97% have been reported for patients with mild trigger finger.
- Corticosteroid injection is associated with low morbidity and is a less painful method of treating trigger finger than surgery.
- Some patient groups are less likely to benefit from corticosteroid injections; these include diabetic patients, those with multiple digit involvement and those with symptom duration ≥6 months. However corticosteroid injection should still form the first line of treatment for these patients as it still offers the opportunity for the avoidance of surgery.

References:

1. Local clinical consensus developed via email, April 2012
15. Vascular

15.1 Manual lymphatic drainage (MLD)

CCGs will not routinely fund MLD as part of the Decongestive Lymphoedema Treatment (DLT) \(^1\) or on its own. It can only be considered through the prior approval route. Applications for funding can be made in the form of an individual application (such as an Individual Funding Request (IFR)).

The panels may consider referral criteria, staging (at appendix J) and guidelines contained in the Best Practice for the management of Lymphoedema (Lymphoedema Framework 2006) to determine exceptionality. In all circumstances, MLD should not be funded on its own but in combination with DLT.

Rationale

- The components of DLT are:
  - Manual lymphatic drainage (MLD) - a specialised massage technique designed to stimulate the flow of fluid and reduce swelling,
  - Multilayer lymphoedema bandaging (MLLB) - MLLB uses elastic compression bandages and compression garments to support muscles to encourage the movement of fluid out of the affected limb.
  - Remedial exercises - designed to strengthen the muscle in the limb in order to improve lymph circulation, and skin care - required to prevent infection

- There is good evidence that other components of DLT work well except for MLD.\(^1,2,3,4\)
- A crossover study of MLD followed by self administered massage versus no treatment concluded that improvements in both groups were attributable to the use of compression sleeves and that MLD provided no extra benefit.\(^1\)
- The Cochrane review concluded that more research is needed in order to evaluate the effectiveness of massage in the treatment of lymphoedema.\(^1\)
- Multilayer bandaging as an initial phase of treatment for lymphedema patients followed by hosiery achieves greater and more sustained limb volume reduction than hosiery alone.\(^2\)
- International consensus guidelines acknowledge the limited amount of research data to conclusively support the use of MLD. The guidelines state that “although there is a wealth of clinical opinion advocating the benefits of MLD, there are little research data to conclusively support its use. The most appropriate techniques, optimal frequency and indications for MLD, as well as the benefits of treatment, all remain to be clarified.\(^3\)
- There is moderate evidence that compression bandages decreased lymphoedema but pneumatic pumps had no effect on lymphoedema. No conclusions could be drawn regarding other interventions, such as manual lymphatic drainage due to poor quality of studies.\(^4\)
- High level evidence indicates that the addition of MLD to compression and exercise therapy for the treatment of secondary lymphoedema is unlikely to produce a significant reduction in the volume. Although individual studies reported advantages associated with MLD.\(^11\). Therefore, the referral criteria and guidelines included in the Best Practice for the management of Lymphoedema 2006 guidelines should be considered.
Evidence

- There are two systematic reviews (one of very poor quality), several low quality RCTs, some case series and prospective trials available that have reviewed MLD along with other conservative treatments. They concluded that there was a need of large scale clinical trial in this area. The Cochrane review carried out in 2008 agreed with these findings.

- Cochrane review (carried out in 2008) concluded that more research is needed in order to evaluate the effectiveness of massage in the treatment of lymphoedema. The review aimed to assess the effect of physical treatment programmes on the volume, shape, condition and long term control of oedema in lymphoedematous limbs. Three RCTs were included involving 150 patients were included. Only one considered MLD. This crossover study of MLD followed by self administered massage versus no treatment concluded that improvements in both groups were attributable to the use of compression sleeves and that MLD provided no extra benefit.

References

15.2 Varicose veins

This policy is not applicable to Croydon CCG – Croydon CCG will continue to apply the ECI 2013/14 Policy for Varicose Veins.

This guidance applies to each leg individually. Patients with varicose veins that are exacerbated by pregnancy are excluded from this guideline, and should be managed conservatively except in exceptional circumstances\(^1\),\(^2\).

Criteria\(^1,\)\(^2\)

Only symptomatic patients should be referred to a vascular service. Aesthetic surgery for cosmetic purposes will not normally be funded by CCGs.

CCGs will normally fund interventions for varicose veins if they are confirmed with duplex ultrasound and truncal reflex is present. Patients should only be referred for vascular review if they are affected by one or more of the following complications:

- Primary or recurrent varicose veins in association with lower limb symptoms (typically pain, aching, discomfort, swelling, heaviness or itching) severely affecting the patient's quality of life as evidenced by a full account of their symptoms.

- OR

- Superficial vein thrombosis (characterised by the appearance of hard, painful veins) and suspected venous incompetence.

- OR

- Lower-limb skin changes, such as pigmentation or eczema, thought to be caused by chronic venous insufficiency.

- OR

- A venous leg ulcer (a break in the skin below the knee that has not healed within 2 weeks).

- OR

- A healed venous leg ulcer.

Background

The number of procedures undertaken for varicose veins in the NHS means there is a considerable financial cost and impact on workload attributable to the condition. There had previously been no established framework within the NHS for the diagnosis and management of varicose veins, which led to considerable regional variation in the management of varicose veins in the UK. The aim of the National Institute for Health and Care Excellence (NICE) Guideline published in 2013 was to give healthcare professionals guidance on the diagnosis and management of varicose veins in the leg, in order to improve patient care and minimize such disparities in care across the UK\(^1\). These SWL ECI guidelines have therefore been modified substantially to reflect the new NICE recommendations.

Management

The techniques that are normally approved are the endovenous techniques, endovenous laser ablation (EVLA) and radiofrequency ablation (RFA). They provide minimally invasive alternatives to
surgical ligation and stripping of the great saphenous vein.

Foam sclerotherapy will not normally be funded unless endothermal ablation is unsuitable. Open surgery (ligation and stripping) is reserved for cases where minimally invasive options are inappropriate. Compression hosiery should only be offered if interventional treatment is not suitable or declined by the patient.

Rationale

- Varicose veins are common in the adult population, and the majority of patients do not experience complications or symptoms.
- Conservative methods such as compression hosiery (support stockings or tights) reduce patient ratings of ankle swelling, cramps and the feeling of tired/heavy legs, but these reductions are small. There is insufficient evidence to determine whether or not compression stockings are effective as the sole and initial treatment of symptomatic varicose veins in people without healed or active venous ulceration.
- A cost-utility analysis of management options was undertaken for the purposes of NICE guideline development. Endothermal ablation was found to dominate surgery and conservative care, with more QALYs gained at less cost.
- There is little to choose between the minimally invasive techniques in terms of efficacy or cost, and each offers a viable, clinically effective alternative to stripping.
- Although endothermal treatment is more expensive than foam sclerotherapy, it is also more effective. The NICE model found endothermal treatment to be the most cost-effective treatment strategy.

Evidence

Referral Thresholds

NICE identified eleven studies that provided evidence for risk factors for disease progression or that predict increased benefits or harms from interventional treatment. These studies ranged in quality from moderate to very low quality. Factors which predict prognosis and those most likely to benefit from treatment were unclear.

In the absence of any clear indicators of referral, NICE based their recommendations on the limited evidence and expert consensus. Given that interventional treatments were found to be highly cost effective, and superior to conservative strategies, they felt that evaluation of all symptomatic patients by a vascular service is warranted to ensure clinician and patient decisions are fully informed. This should include specialist clinical and duplex Doppler ultrasound assessment.

Compression stockings

NICE found there was currently no evidence for improvement of health related quality of life for compression stocking treatment versus no treatment or lifestyle advice. The evidence base, however, showed their use resulted in small improvements in patient ratings of ankle swelling, cramps and the feeling of tired/heavy legs. There was a clinical benefit in terms of reduced complaints in the group with compression. Results for other outcomes such as pain relief and overall body image satisfaction were less conclusive. A Cochrane review published in December 2013 studied the evidence from eleven studies involving 356 participants with varicose veins without healed or active venous ulceration. They found insufficient high quality evidence to determine whether or not compression stockings are effective as the sole and initial treatment of varicose veins in this group.

NICE found no convincing evidence for using or not using compression therapy post operatively so did not recommend their long term use. A meta-analysis of 4 RCTs published since found no benefits to long-term compression therapy after varicose vein surgery of the great saphenous vein.
Interventional management

During the development of the NICE guideline the evidence comparing clinical benefits and harms of traditional stripping surgery, endovascular surgery and foam sclerotherapy was reviewed. Each option was compared to the others in turn. Overall, the quality of evidence was considered to be of low to very low quality. Generally the reviewers found insufficient evidence to suggest a large clinical benefit of one treatment modality over another, however did conclude that endothermal ablation was the only treatment judged to have any clinical advantage over the others.

A search of The Cochrane Library, PubMed and Trip Database on the 24th of January 2014 for relevant research published since the NICE literature review found four new RCTs comparing two or more of these treatment modalities. In two studies foam sclerotherapy was found to be associated with a higher recurrence of venous reflux than endovenous ablation and conventional surgery, and in another endovenous ablation was more effective in reducing venous reflux and was associated with less periprocedural morbidity compared to conventional surgery. However, none of the four found significant symptomatic benefit of one intervention over another at follow-up periods ranging from 15 months to 5 years. The literature search also found one meta-analysis published in 2013 comparing conventional surgery with endovenous ablation in a total of a total of 2245 lower limbs. Duplex-detected and clinical recurrence rates were similar between the two interventions after one and two years. Evidence published since the NICE review generally supports the finding that there is no large clinical benefit for one interventional management approach over another.

Choice of treatment

NICE recommendations for choice of interventional management and Royal College of Surgeons commissioning guidelines were largely based on an economic model developed by NICE to combine best available evidence on the efficacy of the various interventional treatments and conservative care for varicose veins. Endothermal ablation was found to dominate surgery and conservative care, with more QALYs gained at less cost. It was cost-effective in 71% of model simulations. Although endothermal treatment is more expensive than foam sclerotherapy, it is also more effective. The model found endothermal treatment to be the cost-effective treatment strategy, with foam sclerotherapy ranked second, and surgery third. The model was robust to all sensitivity analyses surrounding key assumptions and data used to inform the model. No more recent economic evidence was found in the development of these SWL ECI guidelines.

References:


Appendix A: Local funding application processes SWL ECI
Application/Funding process

Croydon CCG Funding request pathway:

- **GP** * determines that patient fulfils Effective Commissioning Initiative criteria
  - GP completes Prior Approvals form and sends to CReSS
  - CReSS confirms funding approved and GP advised.
    - CReSS process referral
  - If GP receives rejection through Prior Approval process but GP believes patient is exceptional then an IFR application is completed
    - In rare circumstances specialist confirms exceptionality or appropriate for effective commissioning criteria and completes IFR form
    - IFR Panel considers application and GP/specialist advised of decision

* NB: ECI Applications completed by an Acute Trust/Provider, where there is no formal triage function, as opposed to a GP, should be submitted to the IFR Team.

IFR Team contact details:

**South West London IFR Team**
South London CSU
120 The Broadway
Wimbledon
London
SW19 1RH

Email: slcsu.IFRswlondon@nhs.net
Phone: 020 3668 1222

NB: This pathway is subject to change.
Kingston CCG Funding request process:

Applications are sent to KCAS (GP referrals through Choose & Book) and are then triaged.

Three routes – approved, rejected or returned to GP for further information.

Following receipt of further information (if requested), three routes – approved, rejected, sent to IFR/EC Panel.

Administrator advises clinician of decision.

Address for IFR applications:

South West London IFR Team
South London CSU
120 The Broadway
Wimbledon
London
SW19 1RH

Email: slcsu.IFRswlondon@nhs.net
Phone: 020 3668 1222
Merton CCG Individual Funding Request (IFR) Pathway

GP determines that patient fulfils effective commissioning criteria or exceptionality exists

GP completes IFR form

IFR Panel confirms funding request and informs GP

GP undertakes referral to

The GP is uncertain that patient fulfils effective commissioning criteria or exceptionality exists

GP refers patient to specialist to clarify the above

Specialist confirms exceptionality or appropriate for effective commissioning criteria

The specialist undertakes completion of the IFR form

IFR Panel confirms funding request and informs the specialist

Consultant in rare circumstances is uncertain that patient fulfils effective commissioning criteria or exceptionality exists

Address for IFR applications:

South West London IFR Team
South London CSU
120 The Broadway
Wimbledon
London
SW19 1RH

Email: slcsu.IFRswlondon@nhs.net
Phone: 020 3668 1222
Richmond CCG Funding Request Process

GP referrals are sent to RCAS (GP referrals through Choose & Book) and are then triaged. Not including exclusions such as Cancer 2WW.

Three routes – approved, returned to GP for further information or rejected as inappropriate referral or RCAS GP Assessor would like public health input, e.g. second opinion, evidence search etc.

Following PH input or further information received, three routes – approved, rejected, Referrer asked to complete IFR as does not meet SWLECI/Local guidance etc and should therefore be exceptional.

Decision conveyed via C&B Practice managing their work list etc.

Address for IFR applications:

South West London IFR Team
South London CSU
120 The Broadway
Wimbledon
London
SW19 1RH

Email: slcsu.IFRswlondon@nhs.net
Phone: 020 3668 1222
Sutton CCG Process Individual Funding Request (IFR) Pathway

- GP determines that patient fulfils effective commissioning criteria or exceptionality exists
  - GP completes IFR form
    - IFR Panel confirms funding request and informs GP
      - GP undertakes referral to

- The GP is uncertain that patient fulfils effective commissioning criteria or exceptionality exists
  - GP refers patient to specialist to clarify the above
    - Specialist confirms exceptionality or appropriate for effective commissioning criteria
      - The specialist undertakes completion of the IFR form
        - IFR Panel confirms funding request and informs the specialist

- Consultant in rare circumstances is uncertain that patient fulfils effective commissioning criteria or exceptionality exists

Applications should be sent to:

South West London IFR Team
South London CSU
120 The Broadway
Wimbledon
London
SW19 1RH

Email: slcsu.IFRswlondon@nhs.net
Phone: 020 3668 1222
Wandsworth CCG Funding Request Process

GP determines that patient fulfils effective commissioning criteria or exceptionality exists

The GP is uncertain that patient fulfils effective commissioning criteria or exceptionality exists

GP completes IFR form

GP refers patient to specialist to clarify the above

Specialist confirms exceptionality or appropriate for effective commissioning criteria

The specialist undertakes completion of the IFR form

IFR Panel confirms funding request and informs the specialist

Consultant in rare circumstances is uncertain that patient fulfils effective commissioning criteria or exceptionality exists

Applications should be sent to:

South West London IFR Team
South London CSU
120 The Broadway
Wimbledon
London
SW19 1RH

Email: slcsu.IFRswlondon@nhs.net
Phone: 020 3668 1222
## Appendix B: Individual Funding Request Application Form

**INDIVIDUAL FUNDING REQUEST (IFR) APPLICATION FORM**

Please tick or select the corresponding CCG that the patient is registered to:

<table>
<thead>
<tr>
<th>Croydon CCG</th>
<th>Kingston CCG</th>
<th>Merton CCG</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sutton CCG</td>
<td>Richmond CCG</td>
<td>Wandsworth CCG</td>
</tr>
<tr>
<td>Bexley CCG</td>
<td>Greenwich CCG</td>
<td>Lambeth CCG</td>
</tr>
<tr>
<td>Lewisham CCG</td>
<td>Southwark CCG</td>
<td></td>
</tr>
</tbody>
</table>

All forms must be typed and all fields must be completed (or n/a stated where field is not applicable). Incomplete mandatory fields and hand-written forms will result in the form being returned and may cause delays to consideration for funding.

Anonymity – Please ensure that in order to protect patient’s identity, apart from Section A, the patient is not referred to by name or initials within the application form.

* Mandatory field for all requests  
** Mandatory field for drug requests  
*** Mandatory fields for non-drug requests

### SECTION A: CONTACT INFORMATION

3. Applicant Details  
The applicant should have clinical responsibility for this intervention for this patient for this specific clinical indication. Please ensure the declaration is signed and dated (Section H)  

<table>
<thead>
<tr>
<th>Name: *</th>
<th>Designation: *</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tel: *</td>
<td>nhs.net address - No other email accepted *</td>
</tr>
</tbody>
</table>

4. Patient Details  

<table>
<thead>
<tr>
<th>Initials: *</th>
<th>NHS Number: *</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hospital ID number:</td>
<td>DoB: *</td>
</tr>
<tr>
<td>Patient Address: *</td>
<td></td>
</tr>
<tr>
<td>Registered Consultant:</td>
<td></td>
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<td>-----------------------</td>
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<tr>
<td>Registered GP name: *</td>
<td></td>
</tr>
<tr>
<td>GP practice code: *</td>
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<tr>
<td>Date of referral: *</td>
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</tbody>
</table>

### SECTION B: INTERVENTION REQUESTED
(NB: Intervention refers to requested treatment, investigation, etc)

5. **Patient Diagnosis or condition** (for which intervention is requested) *

6. **Do you consider this condition to be rare?** If so please state UK prevalence and quote the source/reference *
   - Yes [ ] No [ ]
   - UK prevalence: [ ] Ref: [ ]

7. **Other relevant diagnosis or co-morbidities**

8. **Details of intervention** (for which funding is requested).
   - **Name of intervention:** *
   - **Type of Intervention:** *
     - Drug [ ] Procedure [ ] Device [ ] Other [ ]
   - **Planned duration of intervention:** *(please do not use abbreviations)*
   - **Dose and frequency of drug:**
   - **Route of administration of drug:**

9. **Anticipated start date**
   - **Clinical Urgency**
     - The decision to treat in the event of immediate or life-threatening circumstances must be made in accordance with NHS Approved Provider (Trust) governance mechanisms.
     - **Is the case more urgent than this?** *
       - Yes [ ] No [ ]
       - If ‘Yes’ please state why

10. **Is requested intervention part of a clinical trial?**
    - Yes [ ] No [ ]
    - If Yes, then STOP HERE. This funding route is not appropriate. Please speak to your Trust Chief Pharmacist for drug trials. There is no need to complete the rest of this proforma.

11. **NHS Approved Provider Name**

12. **Address**

---

Date Approved: August 2014  Review Date: March 2015  Version 1.7.1
13. Does the intervention requested fall under a TAP or ECI procedure?  
If yes and this application is being submitted by a GP, please check whether your CCG provides a referral management/clinical assessment service which processes TAP and ECI requests before submitting this to the IFR Team  

| Yes | No |

14. If yes, has this request already been declined by a referral management/clinical assessment centre?  

| Yes | No |

---

### SECTION C: COMPARISON WITH STANDARD COMMISSIONED INTERVENTION

15. (a) What would be the standard intervention/management at this stage?  

(b) What would be the expected outcome from the standard intervention?  

(c) What are the patient specific reasons that make the standard intervention inappropriate for this patient?  

---

### SECTION D: CURRENT STATUS OF PATIENT

16. For all conditions  
Please summarise the current status of the patient in terms of quality of life, symptoms etc including any recognised condition-specific QoL/status scores.  

What is the patient’s current clinical severity?  
Please use standard scoring systems e.g. WHO, DAS28, 6MW, cardiac index or those applicable to the patient’s clinical diagnosis. Please include interpretation of the score  

---

### SECTION E: PREVIOUS TREATMENT/INTERVENTIONS

17. Summary of previous intervention(s) this patient has received for the condition.  
* Reasons for stopping may include:  
  - Course completed  
  - No or poor response  
  - Disease progression  
  - Adverse effects/poorly tolerated (please detail nature of adverse effect/intolerance)  

<table>
<thead>
<tr>
<th>Start Date:</th>
<th>Stop Date:</th>
<th>Name of Intervention (for drugs include name, dose and frequency of use)</th>
<th>Reason for stopping* / Response achieved or indicate if still continuing</th>
</tr>
</thead>
<tbody>
<tr>
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</table>

18. Has a previous application been submitted on behalf of this patient?  

| Yes | No |

---

Date Approved: August 2014 | Review Date: March 2015 | Version 1.7.1
**SECTION F: EVIDENCE FOR EFFECTIVENESS OF INTERVENTION REQUESTED**

<table>
<thead>
<tr>
<th></th>
<th></th>
<th><strong>Yes</strong></th>
<th><strong>No</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>19.</td>
<td>Is the requested intervention licensed for the requested indication in the UK?</td>
<td></td>
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</tr>
<tr>
<td>20. Governance</td>
<td>Has the Approved NHS Provider approved the requested intervention for use through its recognised clinical governance arrangements?</td>
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</tr>
<tr>
<td></td>
<td>Drugs- Has the trust Drugs and Therapeutics Committee (DTC) or equivalent approved the requested intervention for use?</td>
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<td></td>
<td>Medical devices &amp; interventions- has the device/ intervention been approved in accordance with Approved NHS Provider clinical governance arrangements</td>
<td></td>
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</tr>
<tr>
<td>21. Evidence</td>
<td>It is the applicant’s responsibility to provide robust*, relevant and valid evidence to support the use of the intervention in this patient.</td>
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<tr>
<td></td>
<td>All relevant evidence should be provided. Give details of national or local guidelines/ recommendations (e.g. NICE, Scottish Medicines Consortium, London (Cancer) New Drugs Group etc) and/or full published papers (rather than abstracts) supporting the use of the requested intervention for this condition, unless the application relates to the use of an intervention in a rare disease. Please include any available data on the use of this treatment by your unit including audits Copies of key references MUST be provided</td>
<td></td>
<td></td>
</tr>
<tr>
<td>22. Outcomes</td>
<td>(a) What would you consider to be a successful outcome for this intervention in this patient? – include details of the parameters you intend to measure</td>
<td></td>
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</tr>
<tr>
<td></td>
<td>(b) How will you monitor this and how frequently will you monitor this?</td>
<td></td>
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<tr>
<td></td>
<td>(c) What is the minimum timeframe/course of treatment at which a clinical response can be assessed?</td>
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<tr>
<td></td>
<td>(d) What stopping criteria will be used to decide when the intervention is no longer effective?</td>
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</tr>
</tbody>
</table>

*Hierarchy of Evidence (Taken from NPC ‘Supporting rational local decision-making about medicines (and treatments) Feb 2009)
1. Well-conducted meta-analysis of several, similar, large, well-designed RCTs
2. Large well-designed RCT
3. Meta-analysis of smaller RCTs
4. Case-control and cohort studies
5. Case reports and case series
6. Consensus from expert panels
7. Individual opinion
(e) Detail the current status of the patient according to these measures.

| 23. What are the anticipated adverse effects and potential risks of the intervention for this patient? * |
| 24. How do the benefits outweigh the risks? |

### SECTION G: STATEMENT OF EXCEPTIONALITY OR RARITY

| 25. On which basis are you making this request? * |
| ☐ Exceptional clinical circumstances |
| ☐ Rarity of condition or presentation |

| 26. If exceptionality, please describe why the patient’s clinical circumstances are exceptional * |
| Give specific information to indicate how this patient is significantly different from the cohort of other patients with the same clinical condition |

| 27. If rarity, please describe why this patient’s condition or clinical presentation is so unusual that there is no relevant commissioning arrangement in place |

| 28. How many patients with the same condition or presentation as this patient do you expect to see in the next 12 months? * |

### SECTION H: COSTS and REVIEW

If the application is for a drug, the completed form must be sent to the Trust Chief Pharmacist, for completion of Part A. If the application is for a medical device or other intervention, the completed form must be sent to the Trust Service Manager (or equivalent) for completion of Part B. Part C needs to be completed for both drug and non-drug applications by the service manager.

**PART A – DRUG INTERVENTIONS** (to be completed by approved NHS provider Chief Pharmacist)**

| 29. Total Acquisition cost (inc VAT) for duration of treatment being applied for (or annual cost if treatment for longer than year), |
| 30. State the value of any offset costs |
| 31. Please benchmark these costs against London Procurement Prices |

| 32. Application reviewed by Chief Pharmacist or nominated authorised deputy |
| Name: |
| Signature or email confirmation: |

**PART B - NON-DRUG INTERVENTIONS** (to be completed by approved NHS provider service manager)***

| 33. Total Acquisition cost (inc VAT) for duration of treatment being applied for (or annual cost if treatment for longer than one year), |
34. State the value of any offset costs

35. Please benchmark these costs against London Procurement Prices

**PART C- ALL INTERVENTIONS** (to be completed by approved NHS provider service manager)

36. Application reviewed by Service Manager or nominated authorised deputy

<table>
<thead>
<tr>
<th>Name:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Signature or email confirmation:</td>
</tr>
</tbody>
</table>

**SECTION I: APPLICANT’S DECLARATION**

29. Declaration *
   I declare that this application is complete and accurate and that all necessary supporting information and evidence has been provided on this form (& attachments).

30. Patient Consent *
   I confirm that this IFR has been discussed in full with the patient, including an appraisal of the benefits/risks of the intervention and they have consented to the proposed treatment. I confirm the patient has consented to CCG & CSU staff involved in the preparation, consideration and funding of their case to access confidential clinical information about them (including their NHS no.) to enable full consideration of this request and payment of invoices. In the case of a minor or vulnerable adult I confirm I have complied with the relevant legislation guidance including the Children Act 2004 and Mental Capacity Act 2005.

28. Correspondence and Contact *
   The IFR team will copy the patient into correspondence concerning progress and outcome of their application. If you do not want the patient to be contacted or to receive correspondence please indicate this.

<table>
<thead>
<tr>
<th>Responsible Clinician Name:</th>
<th>Signature or email confirmation:</th>
<th>Date:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>* DD/MM/YY</td>
</tr>
</tbody>
</table>

Forward application to the IFR team (via Trust Service Agreements Department or equivalent, if applicable).

**For SW London CCGs:** Croydon, Kingston, Merton, Sutton, Richmond and Wandsworth Forms should be submitted to slcsu.ifrswlondon@nhs.net Tel. enquiries: 020 3668 1222

**For SE London CCGs:** Lewisham, Bexley, Greenwich, Southwark and Lambeth Forms should be submitted to: slcsu.selifr@nhs.net Tel. enquiries: 020 3049 4154
Patient Equality Monitoring Data *  
This section is for data monitoring purposes only and will be removed from the application prior to consideration by the IFR Panel.

Information unavailable □  
Prefer not to disclose □

<table>
<thead>
<tr>
<th>1 Ethnic Origin</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>White</strong></td>
</tr>
<tr>
<td>British □</td>
</tr>
<tr>
<td>Irish □</td>
</tr>
<tr>
<td>Any other White background □</td>
</tr>
<tr>
<td><strong>Mixed</strong></td>
</tr>
<tr>
<td>White and Black Caribbean □</td>
</tr>
<tr>
<td>White and Black African □</td>
</tr>
<tr>
<td>White and Asian □</td>
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<tr>
<td><strong>Asian or Asian British</strong></td>
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<td>Indian □</td>
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<tr>
<td>Pakistani □</td>
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<tr>
<td>Bangladeshi □</td>
</tr>
<tr>
<td>Any other Asian background □</td>
</tr>
<tr>
<td><strong>Black or Black British</strong></td>
</tr>
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<td>Caribbean □</td>
</tr>
<tr>
<td>African □</td>
</tr>
<tr>
<td>Any other Black background □</td>
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<tr>
<td><strong>Other Ethnic Groups</strong></td>
</tr>
<tr>
<td>Chinese □</td>
</tr>
<tr>
<td>Any other ethnic group □</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
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</tr>
</thead>
<tbody>
<tr>
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</tr>
<tr>
<td>Female □</td>
</tr>
<tr>
<td>Transgender □</td>
</tr>
<tr>
<td>Not disclosed □</td>
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</table>

<table>
<thead>
<tr>
<th>3 Sexuality</th>
</tr>
</thead>
<tbody>
<tr>
<td>Heterosexual □</td>
</tr>
<tr>
<td>Bisexual □</td>
</tr>
<tr>
<td>Gay □</td>
</tr>
<tr>
<td>Lesbian □</td>
</tr>
<tr>
<td>Not disclosed □</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>4 Age Group</th>
</tr>
</thead>
<tbody>
<tr>
<td>16-25 □</td>
</tr>
<tr>
<td>26-35 □</td>
</tr>
<tr>
<td>36-45 □</td>
</tr>
<tr>
<td>46-55 □</td>
</tr>
<tr>
<td>56-65 □</td>
</tr>
<tr>
<td>66+ □</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>5 Do you consider yourself to have a disability?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Registered disabled □</td>
</tr>
<tr>
<td>Unregistered disabled □</td>
</tr>
<tr>
<td>Not disabled □</td>
</tr>
</tbody>
</table>

**Nature of disability**

| Hearing impairment □ |
| Speech impairment □ |
| Mobility Impairment □ |
| Age related impairment □ |
| Visual impairment □ |
| Learning disability □ |
| Mental health □ |
| Other □ |

<table>
<thead>
<tr>
<th>6 Religion</th>
</tr>
</thead>
<tbody>
<tr>
<td>No religion □</td>
</tr>
<tr>
<td>Christian □</td>
</tr>
<tr>
<td>Buddhist □</td>
</tr>
<tr>
<td>Other □</td>
</tr>
<tr>
<td>Hindu □</td>
</tr>
<tr>
<td>Jewish □</td>
</tr>
<tr>
<td>Muslim □</td>
</tr>
</tbody>
</table>
Appendix C: Principles and processes for decision making for the SWL Effective Commissioning Initiative (ECI)

Introduction

The South West London Effective Commissioning Initiative (SWL ECI) provides a set of patient criteria to inform the commissioning of clinical interventions in South West London.

The ECI is driven by the need to ensure that NHS funded treatments are effective and evidence-based. The initiative aims to provide equal access to treatment for patients with similar levels of need throughout South West London. It also attempts to define more clearly and openly the limits of NHS funding for procedures with social but not physical benefits e.g. cosmetic procedures. Although not the main driving force, it is also linked to the need to ensure that the NHS provides value for money and achieves financial balance.

The current proposals can broadly be classified into four groups:

- Procedures with limited evidence of effectiveness.
- Procedures where initial conservative therapy is possible.
- Effective procedures where a threshold for intervention may be appropriate.
- Procedures where NHS provision may be inappropriate

This principles and processes document sets out the values that the SWL ECI group applies in developing the SWL ECI document. The ECI group will use the principles as laid out in this document across the full range of its work and decision making.

The need for principles and processes document

The NHS constitution states that the one of the key principles of the NHS is that it should make ‘the most effective, fair and sustainable use of finite resources’. The CCGs in South West London are duty bound to promote the health of the local community but they also receive a fixed budget from central government with which to fund health care for their populations. Therefore CCGs have an obligation to ensure that resources are used wisely, in general to provide the greatest health benefit. Factors such as an ageing population, developments in technology and new drugs mean that the demand for health care outstrips funding. Therefore decisions will be required regarding relative priorities for allocating funding.

These decisions must take account of national directives, guidance from the National Institute of Health & Clinical Excellence and the Department of Health as well as local factors relating to the availability of resources and facilities.

The way in which these difficult, complex and sensitive decisions are made is extremely important and as public bodies the CCGs are accountable for these decisions. A key requirement is for the SWL ECI group, on behalf of all 6 CCGs, to demonstrate that their decision-making is reasonable, consistent, takes account of all relevant factors, is underpinned by locally established principles and is defensible and open to external scrutiny.
There is no purely objective or value-free method by which health policy decisions can be reached. Making decisions will involve the exercise of judgement and discretion and there will be differences of opinion on the outcomes. This principles and processes document is designed to provide guidance to those decision-makers to help them make fair and consistent decisions which respects the needs of individuals and the community and ensure that all relevant factors have been considered in the light of key principles, with reference to local conditions and with a conscious intent to avoid discrimination. This document outlines these principles and should be read in conjunction with the SWL ECI document and the SWL ECI group terms of reference.

The SWL ECI group will assess implementation of the principles and processes through an annual review process.

**Principles for decision making**

In line with the legal and ethical duties to CCG populations the following four key groups of values will be applied to all decisions:

- **Rationality**
- **Affordability**
- **Inclusivity**
- **Clarity, consistency and transparency**

1. **Rationality**

Aspects of this principle include:

- Being logical in reasoning towards a decision
- Ensuring that the decision is based on evidence of clinical effectiveness
- Making a realistic appraisal of the likely benefit to patients.
- Weighing up all the relevant factors, including risks and costs.
- Taking into account the wider political, legal and policy context.
- Ensuring individuals involved in decision-making are appropriately trained.

Decisions will be made on the basis of a reasonable evaluation of the available evidence of efficacy, safety and clinical effectiveness. Those involved in decision making will seek to gather the best evidence of clinical effectiveness available and consider the views of local providers and commissioners. Where available, existing national standards and guidelines will be considered. Local factors, including existing provision, may also be considered. The approach to assessing the validity and credibility of evidence should be broad but maintain high standards of critical appraisal. The SWL ECI group will follow a well developed scientific approach to hierarchy of evidence. Both qualitative and quantitative evidence will be taken into consideration, where appropriate. Outcome measures will be considered in terms of their importance to patients.

Rational decisions will weigh up likely outcomes, the wider contexts in which treatments can be provided, the implications for service delivery, clinical pathways, and benefits, costs and risks.
The position, qualifications and skills of decision makers will be appropriate to ensure due deliberation of all the relevant factors.
2. Affordability

Given the finite resources available to CCGs their budgets must be managed responsibly so the cost of an intervention must be considered alongside the evidence of effectiveness. This is important as investing in one area of healthcare inevitably diverts resources from other areas. Decisions will be based on careful consideration of the trade-offs between costs and benefits, both in the short and longer term, but also recognise that complex trade-offs cannot necessarily be reduced to simple cost-benefit calculations.

Ensuring efficacy and effectiveness of spend are key considerations and a clear understanding of costs and opportunity cost is required. There is a need to balance cost impact against other factors such as health impact for the population. Impacts need to be considered both in the short and longer term.

3. Inclusivity

The term inclusivity may be interpreted as including:

- Reinforcing the concept of equal opportunity of access to health care.
- Ensuring patient and public engagement in decision-making.
- Balancing the rights of individuals with the rights of the wider community. The aim of this principle is to achieve equitable and consistent resource allocation
- between individuals and groups in society.

The SWL ECI group considers each individual within its population to be of equal value.

Commissioning and provision of health care services is based on clinical need, within the resources made available. CCGs will uphold their public equality duty to eliminate unlawful discrimination, advance equality and opportunity and foster good relations. They will not discriminate on age, disability, pregnancy and maternity, gender reassignment, race, religion (including the lack thereof), sex and sexual orientation.

Decision-making will not discriminate on characteristics which are irrelevant to health conditions and the efficacy of treatment. Consideration of factors such as age and ethnicity will only be considered where this is clinically relevant.

Decision-making will be non-partisan and individuals will need to be able to take an objective view of the topic, and maintain an open mind about the evidence. As far as possible consensus decision-making will be used.

4. Clarity, consistency and transparency

The SWL ECI document itself, the way that it is produced and the process of making decisions about its contents will be clearly specified, consistent, easy to understand and transparent. Patients and the public should have easy access to the processes of decision-making and these processes should be consistently applied.

Both the decisions themselves, and the way they are determined, will be clearly specified, including roles and responsibilities of individuals involved, accountabilities and governance arrangements. Decision-makers will provide the rationale for their decisions, any particular factor that has influenced a decision will be clearly stated.
This document has used content from the ethical frameworks used by NHS SWL IFR decision making framework, NHS Kingston, Surrey & Sussex Health Priorities Support Unit, Berkshire Priorities Committee and Oxford Priorities Forum. It has also referenced the NHS constitution: http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/@dh/@en/document}s/digitalasset/dh_132958.pdf.
Appendix D: Policy on alternative/homeopathic/ complementary therapies

The literature on the effectiveness of alternative (complementary) therapies is notable by the lack of good quality studies. That much more rigorous evidence is demanded for complementary therapies compared to other areas of medical practice is an argument often advanced but this is not true. All new developments/ innovations are to be backed up by evidence of effectiveness. South West London CCGs have accepted the effectiveness agenda and attempting to introduce unevaluated therapies would be a departure from this, more so since alternative therapies are not without side effects and complications, and this is especially so for spinal manipulation.

There is absolute lack of well-conducted systematic reviews that permits any basic analyses of these therapies. The only procedure that seems to have any effect is acupressure on pre- and postoperative nausea and vomiting, as explained below.

For the rest of the procedures:

**Homeopathy:** There is very little, if any, evidence of effectiveness of homeopathy and, even when it is claimed to exist (such as for asthma), it is inconclusive and based on poorly designed studies. Although some CCGs have a clear policy denying the commissioning of homeopathy, the present system for dealing with homeopathic referrals allows again the patient’s GP to justify the referral. This justification is hardly ever based on scientific grounds but on social need, failure of traditional methods or pressure on the part of the patient. It is, therefore, recommended that funding homeopathy for any procedure should cease completely in any form or through any possible referral route, be it from Primary Care or be it through consultant to consultant referral. This policy should also be extended to palliative patients, as there is no evidence whatsoever that homeopathy benefits in any way to these patients.

**Acupuncture:** Acupuncture appears to be effective for chemotherapy-related and postoperative and nausea and vomiting in adults and that related mainly to acupressure. It is also effective for low back pain for a cohort of patients who fulfil the criteria for Low Back Pain included in this document. It should not be funded for any other indications (like obesity or smoking cessation, etc), other than the mentioned above.

**Osteopathy and Spinal Manipulation:** The present state of evidence is such that the effectiveness of spinal manipulation has been shown only for acute low back pain. Spinal manipulation is of different types (osteopathy, chiropractor, physiotherapy) and it is not clear which of these are effective. There is no data on cost-effectiveness. In view of this, SWL CCGs should not commission osteopathy services.

**Clinical Ecology:** Multiple Chemical Sensibilities and all the treatments attached to this, including rotation diet, avoidance, antifungal treatment for candidiasis, and provocation-neutralisation procedure, lack of sound scientific evidence to support their use. EPD and other forms of allergy immunotherapy it should be considered investigational.

**Other Alternative Therapies:** No sound evidence of the effectiveness of aromatherapy, Chinese medicines, chiropractice therapy, herbal remedies, hydrotherapy, hypnotherapy, massage or reflexology has been found.
Appendix E – Eligibility for NHS funded wigs

Any patient recommended by a dermatologist for wigs may have to be paid for in part by the patient.

Patients can get free wigs and fabric supports if they:*

- are under 16
- are aged 16, 17 or 18 in full-time education
- are a hospital in-patient
- are a war pensioner and the wig or fabric support is for them accepted
- disablement and they have a valid war pension exemption certificate
- are getting or their partner gets:
  - Income Support
  - Income-based Jobseeker’s Allowance (Incapacity Benefit or Disability Living Allowance do not count as they are not income related.)
  - Pension Credit Guarantee Credit
- are entitled to, or named on, a valid NHS tax credit exemption certificate
- are named on a valid HC2 certificate.

Partial help: if they are named on a valid HC3 certificate they might get some help.

## Appendix F: Epworth Sleepiness Scale

How likely are you to doze off or fall asleep in the following situations, in contrast to feeling just tired? This refers to your usual way of life in recent times. Even if you have not done some of these things recently try to work out how they would have affected you. Use the following scale to choose the most appropriate number for each situation:

0 = no chance of dozing  
1 = slight chance of dozing  
2 = moderate chance of dozing  
3 = high chance of dozing

<table>
<thead>
<tr>
<th>Situation</th>
<th>Chance of dozing</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sitting and reading.</td>
<td></td>
</tr>
<tr>
<td>Watching TV.</td>
<td></td>
</tr>
<tr>
<td>Sitting inactive in a public place (e.g. a theatre or a meeting).</td>
<td></td>
</tr>
<tr>
<td>As a passenger in a car for an hour without a break.</td>
<td></td>
</tr>
<tr>
<td>Lying down to rest in the afternoon when circumstances permit.</td>
<td></td>
</tr>
<tr>
<td>Sitting and talking to someone.</td>
<td></td>
</tr>
<tr>
<td>Sitting quietly after a lunch without alcohol.</td>
<td></td>
</tr>
<tr>
<td>In a car, while stopped for a few minutes in traffic.</td>
<td></td>
</tr>
</tbody>
</table>

### References

### Appendix G: Local CCG variations to IVF criteria

#### CROYDON CCG - IVF criteria 2014/2015

<table>
<thead>
<tr>
<th>Criteria</th>
<th>Rationale</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Duration of subfertility</strong></td>
<td>Couples will be eligible for referral for treatment if they have experienced thirty six months of unexplained infertility or have an identified cause of infertility. 84% of women will conceive within one year of regular unprotected sexual intercourse, this increases to 92% after 2 years and 93% after 3 years.</td>
</tr>
</tbody>
</table>
| **Age of woman at start of treatment cycle** | The patient should be 39 or younger at the time of application. (nb treatment, if approved, should be started within six months of the application) The likelihood of a live birth following assisted conception declines with age. Chances of live birth per IVF cycle are:  
- >20% for women aged 23-35  
- 15% for women aged 36-38  
- 10% for women aged 39 years  
- 6% for women aged 40 years and over |
| **Body mass index of woman** | 19 – 30 kg/m², weight to be maintained for the last 6 months prior to application. Higher body mass index reduces the probability of success associated with assisted conception techniques. |
| **Smoking status of couple** | Both partners should have been non-smokers for at least six months prior to commencement of treatment. Smoking can adversely affect the success rates of assisted reproductive techniques. |
| **Previous cycles** | Couples will be eligible for one NHS funded cycle and a maximum of two un-stimulated frozen cycles. The storage cost for frozen embryos for up to three years or a live birth (whichever is sooner) would be paid for by the PCT’s. Where couples have self-funded previous cycles, these must not exceed TWO. The probability of a live birth following the IVF is consistent for the first three cycles but effectiveness of subsequent cycles is uncertain. |
| **Childlessness** | Neither partner must have any living children from this or previous relationships (including adopted children). As funding for assisted conception is limited, priority will be given to couples with the greatest need. |
| **Sterilisation** | Treatments will not be available if either partner has undergone previous sterilisation. Sterilisation is offered as an irreversible method of contraception and individuals on the NHS are made aware of this at the time of the procedure. |
| **HFEA Code of Practice** | Couples must comply to a *Welfare of the Child* assessment. *Human Fertilisation and Embryology (HFE) Act 1990* (as amended) states:  
Section 13 (5): A woman shall not be provided with treatment services unless account has been taken of the welfare of any child who may be born as a result of the treatment (including the need of that child for supportive parenting), and of any other child. |
who may be affected by the birth.

Section 2 (1) … “treatment services” means medical, surgical or obstetric services provided … for the purpose of assisting women to carry children.

| **Women in same sex couples/ and women not in a partnership** | Sub fertility treatment will be funded for women in same sex couples or women not in a partnership if those seeking treatment are demonstrably sub fertile. In the case of women in same sex couples in which only one partner is sub fertile, clinicians should discuss the possibility of the other partner receiving treatment before proceeding to interventions involving the sub fertile partner. NHS funding will not be available for access to insemination facilities for fertile women who are part of a same sex partnership or those not in a partnership. In circumstances in which women in a same sex partnership or individuals are eligible for sub fertility treatment, the other criteria for eligibility for sub fertility treatments will also apply. Women in same sex couples and women not in a partnership should have access to professional experts in reproductive medicine to obtain advice on the options available to enable them to proceed along this route if they so wish. | This section was copied from the South Central criteria to ensure equality of access to the service. |

**References**

KINGSTON CCG – Assisted Conception Guidelines 2014/2015

Assisted Conception Commissioning Guidelines
Kingston Clinical Commissioning Group

Principles

When commissioning healthcare for its population, Kingston CCG, in line with the RCGP Ethical Commissioning Guidance 2011, aims to ‘use limited resources to do as much good as possible whilst being fair.’

With respect to assisted conception, Kingston CCG aims to:

- Treat subfertility secondary to disease processes
- Follow NICE guidance as far as it is compatible with the CCG’s resources to treat its population
- Treat any couple with no existing children (from either party, including adopted children), or woman with no existing children.
- Limit treatment to one live birth per couple.

Equality Statement

“This document demonstrates Kingston CCG’s commitment to create a positive culture of respect for all individuals, including staff, patients, their families and carers as well as community partners. The intention is, as required by the Equality Act 2010, to identify, remove or minimise discriminatory practice in the nine named protected characteristics of age, disability, sex, gender reassignment, pregnancy and maternity, race, sexual orientation, religion or belief, and marriage and civil partnership. It is also intended to use the Human Rights Act 1998 and to promote positive practice and value the diversity of all individuals and communities”.

Engagement

Kingston CCG’s previous In Vitro Fertilization (IVF) guidelines were developed by the South West London Effective Commissioning Group with lay representation from the South West London.

The working group responsible for updating local IVF guidelines included representation from Kingston CCG (lead GP), Royal Borough of Kingston (Public Health consultant and senior registrar) and Kingston Hospital NHS Foundation Trust (two Consultant Gynaecologist Leads from the Assisted Conception Unit and a service manager). Kingston Hospital NHS Foundation Trust representatives provided a clinical perspective and they also provided the working group with the views of their service users.

The final draft of the updated KCCG guidelines was shared with Kingston Healthwatch. It was also discussed at Kingston Governing Body Seminars and presented to the Kingston Integrated Governance Committee before approval was granted by the Kingston Governing Body.
Kingston CCG Assisted Conception Pathway

Note to Kingston GPs about the timing of referrals to secondary care

Assessment and management of fertility problems involves several stages (see diagram) so it is imperative that referrals for further investigation are timely.

- Refer for further clinical assessment and investigation, with her partner,
  - a woman of reproductive age who has not conceived after 1 year of unprotected vaginal sexual intercourse (or six cycles of artificial insemination) in the absence of any known cause of infertility

- Offer an earlier referral when:
  - the woman is aged 36 years or over (please note that if IVF is considered a possible treatment option, referral should be by the 42nd birthday to allow sufficient time for investigation and expectant management)
  - there is a known cause of infertility or a history of predisposing factors of infertility.

Even if patients do not meet the criteria set out in the guidelines for assisted conception treatments, patients who demonstrate subfertility can still be referred to the Fertility Clinic for further investigations (subject to agreement by the GP and patient and approval by KCAS).

The Fertility Clinic consultant will decide if assisted conception is indicated and if so forward the names of the couple to the Assisted Conception Unit (ACU) at Kingston Hospital NHS

Date Approved: August 2014  Review Date: March 2015  Version 1.7.1
Policy statement 1: IVF

Kingston CCG will fund 1 fresh IVF cycle (cycle starts once ovarian stimulation has been commenced) and 2 frozen embryo transfer (FET) cycles with embryos generated from the fresh cycle\(^1\), with or without ICSI, for the following groups of women:

<table>
<thead>
<tr>
<th>Group 1:</th>
<th>Age at treatment(^{iii}): up to 40(^{th}) birthday AND Have had a maximum of two previous self-funded cycles</th>
</tr>
</thead>
</table>

OR

<table>
<thead>
<tr>
<th>Group 2:</th>
<th>Age at treatment(^{iii}): 40 up to 43(^{rd}) birthday AND No previous self-funded cycles(^{iv})</th>
</tr>
</thead>
</table>

who also meet the additional criteria outlined below:

<table>
<thead>
<tr>
<th>Criteria</th>
<th>Rationale</th>
</tr>
</thead>
<tbody>
<tr>
<td>Duration of subfertility</td>
<td>Couples will be eligible for referral for treatment if they have not conceived after 2 years of regular unprotected intercourse or up to 12 cycles of intrauterine insemination. OR where investigations show there is no chance of pregnancy with expectant management and where IVF is the only effective treatment (for example women with apparently occluded fallopian tubes or severe endometriosis, or obstructive azoospermia).</td>
</tr>
</tbody>
</table>

1 The storage cost for frozen embryos for up to three years or a live birth (whichever is sooner) would be paid for KCCG. Requests for funding for storage beyond three years should be made via an Individual Funding Request.

iii this is defined as age at egg collection.

iv this is in line with NICE recommendations stating that, due to the lower chance of successful IVF in this age-group, IVF is only cost-effective when offered to women who have not had any previous cycles.
<table>
<thead>
<tr>
<th><strong>Body mass index of woman</strong></th>
<th>19 – 30 kg/m² weight to be maintained for the last 6 months prior to application.</th>
<th>Female BMI outside this range reduces the probability of success associated with assisted conception techniques.</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Smoking status of couple</strong></td>
<td>Both partners should have been non-smokers for at least six months prior to commencement of treatment.</td>
<td>Smoking can adversely affect the success rates of assisted reproductive techniques.</td>
</tr>
<tr>
<td><strong>Childlessness</strong></td>
<td>Neither partner must have any living children from this or previous relationships (including adopted children)</td>
<td>As funding for assisted conception is limited, priority will be given to couples with the greatest need.</td>
</tr>
<tr>
<td><strong>Sterilisation</strong></td>
<td>Treatments will not be available if either partner has undergone previous sterilisation.</td>
<td>Sterilisation is offered as an irreversible method of contraception and individuals on the NHS are made aware of this at the time of the procedure.</td>
</tr>
<tr>
<td><strong>Same sex couples and women not in a partnership</strong></td>
<td>IVF treatment will be funded for same sex couples or women not in a partnership if those seeking treatment are demonstrably subfertile and have undergone a period of expectant management. They would first need to demonstrate subfertility through 6 self-funded attempts at artificial insemination using donor sperm in a clinical setting, and undergo a period of expectant management involving up to a further 6 cycles of self or NHS-funded donor intra-uterine insemination (see policy statement 4). Note: Men in same-sex relationships wanting a baby can either adopt or use some form of surrogacy. The CCG will not fund surrogacy arrangements. However, when a pregnancy does not occur through surrogacy after 6 cycles of self-funded intra-uterine insemination in a clinical setting there is an increased risk of some underlying problem. In those circumstances, the man whose sperm is being used and the surrogate partner would be eligible to be referred for further clinical assessment and possible treatment.</td>
<td>Same-sex couples should have access to IVF on equivalent grounds to heterosexual couples. In this respect, failure to conceive after six cycles of self-funded artificial insemination has been deemed an equivalent indicator of sub-fertility, given clinical and practical considerations. Further NHS-funded cycles of intra-uterine insemination (up to six) constitutes the period of expectant management required prior to being eligible for IVF, during which pregnancy may be achieved (based on NICE recommendation and advice of local clinicians).</td>
</tr>
</tbody>
</table>
In the case of same sex couples where only one partner is sub fertile, clinicians should discuss the possibility of the other partner receiving treatment before proceeding to interventions involving the sub fertile partner.

The other criteria for eligibility for IVF will also apply.

All same sex couples and women not in a partnership should have access to professional experts in reproductive medicine to obtain advice on the options available to them.

<table>
<thead>
<tr>
<th>FSH</th>
<th>Women aged 40 up to 43rd birthday only: There is no evidence of low ovarian reserve when assessed in accordance with the treatment provider’s protocol.</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>In this age group, falling ovarian reserve is the commonest cause of infertility. The use of ovarian reserve testing allows IVF to be targeted to women with a demonstrable chance of success.</td>
</tr>
</tbody>
</table>

**Rationale**

The likelihood of a live birth following assisted conception declines with age. Chances of live birth per IVF cycle are:

- 32.2% for women aged 18-34
- 27.7% for women aged 35-37
- 20.8% for women aged 38-39
- 13.6% for women aged 40-42
- 5.0% for women aged 43-44

The overall chance of a live birth following IVF treatment also falls as the number of unsuccessful cycles increases. Model-based evidence for cost-effectiveness of treatment for women aged 40 years and over is based on the assumption they have not previously attempted IVF.
Policy statement 2: Cryopreservation & cryostorage for pre-cancer treatment

Criteria

Kingston CCG will fund cryopreservation in the following circumstances:

<table>
<thead>
<tr>
<th>Sperm cryopreservation to men and adolescent boys who are preparing for medical treatment for cancer that is likely to make them infertile. OR Oocyte or embryo cryopreservation as appropriate to women of reproductive age (including adolescent girls) who are preparing for medical treatment for cancer that is likely to make them infertile if:</th>
</tr>
</thead>
<tbody>
<tr>
<td>• they are well enough to undergo ovarian stimulation and egg collection and • this will not worsen their condition and • enough time is available before the start of their cancer treatment</td>
</tr>
</tbody>
</table>

Storage

- Will be funded up until one of the following (whichever is soonest)
  - 10 years after the collection
  - [For oocytes or embryos] the woman’s 43rd birthday
  - a live birth.
- Requests for storage beyond 10 years should be assessed on a case by case basis via an individual funding request (IFR).

Post storage treatments

- Will be made available on the same basis as other patients who have not undergone such storage (see criteria for IVF). There is thus the potential for individuals to meet the criteria for cryopreservation and not to meet the criteria for infertility treatments at a later date, which should be explained to them.

Egg preservation for delayed conception in other (non-medical) circumstances

- This will not be funded on the NHS

Rationale

- Cryopreservation of sperm, oocytes and embryos is an effective method of achieving future clinical pregnancies or live births to people undergoing treatment for cancer which has the potential to affect fertility³.
Policy statement 3: Intrauterine Insemination

3.1 Using partner sperm

Criteria
Kingston CCG will fund up to 6 cycles of unstimulated intrauterine insemination (IUI) in the following groups as an alternative to vaginal intercourse:

- Couples who are unable to, or would find it very difficult to, have vaginal intercourse because of a clinically diagnosed physical disability or psychosexual problem
- Couples with conditions that require specific consideration in relation to methods of conception (for example after sperm washing where the man is HIV positive)

Intra-uterine insemination should not be offered routinely to people with unexplained fertility, mild endometriosis or mild male factor infertility.

Rationale
- The NICE guideline\(^3\) states that for these groups, where vaginal sex is inappropriate or not possible, that IUI without stimulation with sperm from a male partner or donor would be the first-line approach.

3.2 Using donor sperm (donor insemination)

Criteria
Kingston CCG will fund up to 6 cycles of unstimulated donor insemination (including donor sperm), without ovarian stimulation, for

1. obstructive azoospermia
2. non-obstructive azoospermia
3. severe deficits in semen quality in couples who do not wish to undergo ICSI
4. couples in a same-sex relationship who can demonstrate subfertility through failure to conceive following 6 self-funded cycles of intra-uterine insemination within a clinical setting.

Donor insemination should be considered in conditions such as:

5. where there is a high risk of transmitting a genetic disorder to the offspring
6. where there is a high risk of transmitting infectious disease to the offspring or woman from the man
7. severe rhesus isoimmunisation.
Rationale
Donor insemination is an effective treatment option for male factor infertility, although in some men with azoospermia, semen can be surgically extracted and be used in intracytoplasmic sperm injection (ICSI) procedures

Donor insemination is also indicated where the male partner is likely to pass on an inheritable genetic condition, an infection such as HIV or if severe rhesus incompatibility has been a problem because of the male partner's homozygous status

Up to six cycles of donor insemination for subfertile same-sex couples constitutes the period of expectant management required prior to being eligible for IVF, during which pregnancy may be achieved

Donor insemination is specified since this provides a number of benefits: (i) donor screening and cryopreservation of sperm to protect against transmission of sexually transmitted infections, (ii) optimisation of timing of insemination to maximise chance of conception, and (iii) early identification of sub-fertility.

Policy statement 4: Surgical Sperm Retrieval

Criteria
Surgical sperm retrieval as part of ICSI will be commissioned in appropriately selected patients provided the azoospermia is not the result of a sterilisation procedure or the proven absence of sperm and the couple meets all other criteria for ICSI.

Cryopreservation of remaining sperm will be funded for up to 1 year or a live birth, whichever is sooner.

Rationale
Spermatozoa can be retrieved from both the epididymis and the testis using a variety of techniques with the intention of achieving pregnancies for couples where the male partner has obstructive or non-obstructive azoospermia. Sperm recovery is also used in ejaculatory failure and where only non-motile spermatozoa are present in the ejaculate. Surgically collected sperm in azoospermia are immature (because they have not traversed the epididymus) and have low fertilising ability with standard IVF. It is therefore necessary to use ICSI.
Policy statement 5: Ovulation Induction

Criteria
Kingston CCG will fund up to 3 cycles of ovulation induction using pulsatile administration of gonadotrophin-releasing hormone or gonadotrophins with luteinising hormone activity, for women with WHO Group I ovulation disorders (hypothalamic pituitary failure), to be used with timed intercourse. Couples may proceed to IVF if they meet the criteria outlined in that policy should ovulation induction fail.

Rationale
Evidence from case series studies have demonstrated that pulsatile GnRH induces ovulation, achieving cumulative pregnancy rates of up to 82% in women with hypogonadotrophic hypogonadism and 95% in women with weight-related amenorrhoea after 12 cycles. The corresponding figures for live birth rates were 65% and 85%, respectively [Evidence level 3].

References:
(3) NICE Clinical guideline 156 (2013). Fertility; Assessment and treatment for people with fertility problems.
(5) HFEA, Fertility treatment in 2011: Trends and Figures (www.hfea.gov.uk/104.html)
1. Introduction

1.1 This policy describes circumstances in which Merton CCG will fund treatment for assisted conception as defined in appendix 1.

1.2 The objective of treatment for subfertility is to achieve a successful pregnancy quickly and safely with the least intervention required and the delivery of a healthy child.

1.3 The criteria set out in this policy apply irrespective of where the residents of Merton CCG have their treatment. A Merton CCG patient is defined as someone registered with a GP practice which is part of Merton CCG.

1.4 This policy has drawn on guidance issued by the Department of Health, Infertility Network UK and the revised NICE guidance (CG 156) published in February 2013.


http://guidance.nice.org.uk/CG156 (summary guidance)


2. Defining infertility

2.1 Infertility is a disease of the reproductive system defined by the failure to achieve a clinical pregnancy after 12 months or more of regular unprotected sexual intercourse.

3. Types of infertility treatment

3.1 There are three main types of infertility treatment –

- medical management (such as drugs for ovulation induction),
- surgical treatment (i.e. to correct a physical cause for infertility such as blocked fallopian tubes)
- assisted conception

3.2 Assisted conception is a collective name for treatments designed to lead to conception by means other than sexual intercourse where gametes are manipulated. Assisted conception techniques include intrauterine insemination (IUI), in vitro fertilisation (IVF), donor insemination (DI), intracytoplasmic sperm injection (ICSI) and cryopreservation (of sperm, oocytes and embryos).

4. Pathway and provider arrangements for assisted conception (IUI, IVF, ICSI)

4.1 Merton CCG will have a waiting list for assisted conception at three providers:
5. Commissioning policy

5.1 In Vitro Fertilisation (IVF) / Intracytoplasmic sperm injection (ICSI):

5.1.1 Definition:

In Vitro Fertilisation (IVF) is a technique by which eggs are collected from a woman and fertilised with a man’s sperm outside the body. Usually one or two resulting embryos are then transferred to the womb. If one of them attaches successfully, it results in a pregnancy. Intracytoplasmic sperm injection (ICSI) is a variation of IVF in which a single sperm is injected into an egg.

5.1.2 Policy statement:

Merton CCG will fund one (1) fresh cycle of IVF or ICSI for patients who meet all of the criteria in Appendix 1.

Where the couple produces more than one good quality embryo and have an elective single embryo transfer, the PCT will fund 12 months of cryopreservation of the remaining embryos. If the initial embryo transfer does not result in a live birth, the CCG will then fund a single unstimulated frozen embryo transfer.

It is expected that the majority of patients receiving Merton CCG funded IVF/ICSI will undergo single embryo transfer. This will reduce the number of multiple pregnancies within Merton CCG and falls within HFEA guidance. The IVF providers will be expected to have in place a “Minimisation of Multiple Birth Strategy” which gives precise details of those couples who will be required to have single embryo transfer.

More information is available at www.oneatatime.org.uk

5.2 Intrauterine insemination (IUI)

5.2.1 Definition:

Intra-uterine insemination (IUI) is a technique to place sperm into a woman’s womb through the cervix.

5.2.2 Policy statement

Merton CCG will fund three (3) cycles of intrauterine insemination for couples undergoing insemination for the following conditions:

- Obstructive azoospermia (i.e. where the man has no sperm in his semen)
- Where there is a high risk of transmitting a genetic disorder to the offspring
- Where there is high risk of transmitting an infectious disease from the man to the woman or to the offspring
- Severe rhesus isoimmunisation
5.3 Pre-implantation genetic diagnosis

5.3.1 Definition:
Pre-implantation genetic diagnosis can be used when one partner is known to have a faulty gene. It involves having in-vitro fertilization (IVF) treatment, then genetically testing the embryo in a laboratory to see if it has the faulty gene. The embryo will only be placed inside the woman if it does not have the faulty gene.

5.3.2 Policy statement
Merton CCG will consider funding up to one fresh cycle of IVF or ICSI for couples who have had this recommended by the Pre-implantation Genetic Diagnosis (PGD) Clinical Advisory Group.

5.3.3 Rationale
The Pre-implantation Genetic Diagnosis (PGD) Clinical Advisory Group has been set up by the Genetics Consortium to consider individual requests for funding and make recommendations to commissioners of member CCGs on the clinical appropriateness to fund individual PGD cases.
Couples wishing to access PGD will therefore not be treated in the same way as couples requesting assisted conception. As such they will not be limited by the requirements of this policy (e.g. joining the centrally managed list, other aspects of the clinical criteria). However, each case will need to receive specific prior approval for funding from the CCG which will then act on the recommendations of the PGD Clinical Advisory Group. Funding for PGD does not fall within the financial allocation for assisted conception.

5.4 Egg Donation

5.4.1 Definition:
Egg donation is the process by which a fertile woman donates her eggs for use in the treatment of other women.

5.4.2 Policy statement
Merton CCG will fund one cycle of IVF/ICSI using egg donation for women with:

- Premature ovarian failure
- Gonadal dysgenesis including Turner’s syndrome
- Bilateral oophorectomy
- Ovarian failure following chemotherapy or radiotherapy

Women must meet all of the criteria in Appendix 1.

Eggs must be donated through an altruistic donor, egg sharing schemes or sourcing eggs from overseas will not be funded.

5.4.3 Rationale:
Some women cannot produce eggs, usually because their ovaries are not functioning, have been removed or they have a chromosomal abnormality.

5.5 Donor insemination

5.5.1 Definition:
This form of treatment involves using sperm donated anonymously by another man.
5.5.2 Policy statement
Merton CCG will fund donor insemination using IUI for the following conditions if appropriate:

- Non-obstructive azoospermia
- Where there is a high risk of transmitting a genetic disorder to the offspring
- Where there is high risk of transmitting an infectious disease from the man to the woman or to the offspring
- Severe rhesus isoimmunisation

5.6 Surrogacy

5.6.1 Definition:
Surrogacy is a way for a childless couple to become parents, with a surrogate mother carrying their child. In traditional surrogacy, the surrogate may be the child's genetic mother i.e. her egg is fertilized using sperm from the man who wishes to raise the child. In gestational surrogacy, the pregnant woman is not biologically related to the baby.

5.6.2 Policy statement
Merton CCG does not fund any element of surrogacy arrangements or associated fertility treatments and procedures.

5.6.3 Rationale:
The funding of surrogacy arrangements and associated fertility treatments raises numerous legal and ethical issues which present significant risk to commissioners. These risks arise from the complexities associated with surrogate arrangements including: issues relating to the parentage of the child; change of mind by any of the parties involved in the surrogate arrangement (including termination of pregnancy or refusal to surrender child); problems arising from “unwanted baby” or genetic or congenital defects. Given that these are either unresolved and that the legal position on many of these aspects are presently unclear, the legal advice to CCGs is not to fund any element of surrogacy procedures.

5.7 Private/Self Funding Patients

5.7.1 Policy statement
Patients who are undergoing treatment outside of an NHS pathway will not be funded or reimbursed for drugs or additional tests incurred as a result of self-funded/private treatment.

5.8 In vitro maturation

5.8.1 Definition:
In vitro maturation involves removing immature eggs that have yet to complete their growth, and subsequently maturing these eggs in the laboratory.

5.8.2 Policy statement
In vitro maturation will only be funded in exceptional circumstances.

5.8.3 Rationale
There is limited evidence for the effectiveness of in vitro maturation of eggs.
5.9 HIV infection and sperm washing

5.9.1 Definition:
Sperm washing is a process in which individual sperm are removed from the semen then used in IUI or IVF. Its use in reducing male to female HIV transmission is based on the observation that HIV is found in the seminal fluid rather than the sperm cells.

5.9.2 Policy statement
Funding of Sperm washing for the prevention of transmission HIV will be considered on an individual patient basis.

5.9.3 Rationale:
Where the man is HIV positive, the risk of HIV transmission through unprotected sexual intercourse is negligible when all of the following criteria are met:

- the man is complying with highly active antiretroviral therapy (HAART)
- the man has a plasma viral load of less than 50 copies/ml
- there are no other infections present
- unprotected intercourse is limited to the time of ovulation

If all of the criteria above are met, sperm washing may not further reduce the risk of infection and may actually reduce the likelihood of pregnancy. In addition, sperm washing reduces, but does not eliminate, the risk of HIV transmission.

5.10 Cryopreservation and cryostorage

5.10.1 Definition
Cryopreservation entails freezing of eggs, sperm and/or embryos that may be thawed for use in future IVF treatment cycles. Cryostorage entails storage of frozen eggs, sperm and/or embryos that may be thawed for use in future IVF treatment cycles.

5.10.2 Policy statement
i) Merton CCG will fund sperm cryostorage, egg cryostorage and embryo cryostorage in the following circumstances:

- Medical or surgical treatment that is likely to have a permanent harmful effect on subsequent sperm or egg production. Such treatment includes radiotherapy or chemotherapy for malignant disease.
- Ongoing medical treatment that, whilst on treatment, causes harmful effects on sperm or egg production or has possible teratogenic effects, and in whom stopping treatment for a prolonged period of time to enable conception is not an option.

ii) Commencement of cryostorage does not entitle people to assisted conception treatments. In this circumstance and individual funding request can be applied.

iii) Storage:
- May not exceed five (10) years.
- Will not be available where a man or woman chooses to undergo medical or surgical treatment whose primary purpose is infertility, such as sterilisation;
- Will not be available where a man or woman requests cryostorage for personal lifestyle reasons, such as wishing to delay trying to conceive.

iv) Post-storage Treatment
- Funding of assisted conception treatments would be made available on the same basis as other patients who have not undergone such storage.
5.11 Surgical sperm retrieval/recovery

5.11.1 Definition:
A surgical procedure to obtain sperm from the testicles in men who cannot ejaculate or have a blockage in the flow of sperm from their testicles.

5.11.2 Policy statement
Surgical sperm retrieval will be commissioned in appropriately selected patients provided the azoospermia is not the result of a sterilisation procedure or the absence of sperm and the couple meets all other criteria.

5.11.3 Rationale
Spermatozoa can be retrieved from both the epididymis and the testis using a variety of techniques with the intention of achieving pregnancies for couples where the male partner has obstructive or non-obstructive azoospermia. Sperm recovery is also used in ejaculatory failure and where only non-motile spermatozoa are present in the ejaculate. Surgically collected sperm in azoospermia are immature (because they have not traversed the epididymus) and have low fertilising ability with standard IVF. It is therefore necessary to use ICSI.
### Appendix 1: Merton CCG Criteria for Access to Intrauterine Insemination (IUI), In Vitro Fertilisation (IVF), Intracytoplasmic Sperm Injection (ICSI)

<table>
<thead>
<tr>
<th>Title</th>
<th>Criteria</th>
<th>Rationale</th>
</tr>
</thead>
<tbody>
<tr>
<td>Duration of subfertility</td>
<td>• Couples will be eligible for referral for treatment if they have experienced twenty four months of unexplained infertility or have an identified cause of infertility</td>
<td>• 84% of women will conceive within one year of regular unprotected sexual intercourse, this increases to 92% after 2 years and 93% after 3 years</td>
</tr>
</tbody>
</table>
| Age of woman at start of treatment cycle | • Woman is aged 23 – 42 at the time of treatment i.e she has not had her 43rd birthday  
• Couples will not be able to be referred from secondary to tertiary care where the women is aged over 42.5 years. This is because treatment must take place before her 43rd birthday and clinics will be operating an 18 week pathway. The lower age limit will not apply to women accessing treatment due to clinical care that is likely to result in long-term infertility | The likelihood of a live birth following assisted conception declines with age. Chances of live birth per IVF cycle are:  
• >20% for women aged 23-35  
• 15% for women aged 36-38  
• 10% for women aged 39 years  
• 6% for women aged 40 years and over |
| Body mass index of woman      | • 19 – 30 kg/m², weight to be maintained for the last 6 months prior to application. | Higher body mass index reduces the probability of success associated with assisted conception techniques                                                                                                     |
| Smoking status of couple      | • Both partners should have been non-smokers for at least six months prior to commencement of treatment. | Smoking can adversely affect the success rates of assisted reproductive techniques.                                                                                                                        |
| Previous cycles               | • Couples will be eligible for NHS funding of one fresh cycle of IVF or ICSI. Where the couple produces more than one good quality embryo and have an elective single embryo transfer, the PCT will fund 12 months of cryopreservation of the remaining embryos. If the initial embryo transfer does not result in a live birth, Merton CCG will then fund a single unstimulated frozen embryo transfer  
• Where couples have self-funded previous cycles, these must not exceed one. | The probability of a live birth following the IVF is consistent for the first three cycles but effectiveness of subsequent cycles is uncertain.                                                                 |
| **Couples will not be eligible for treatment if they have received any previous NHS funded treatment**  
| Women who are aged over 40 at the time of treatment will be entitled to one cycle of IVF/ICSI treatment provided that they have not undergone any previous self-funded or NHS IVF/ICSI treatment previously |
| **As funding for assisted conception is limited, priority will be given to couples with the greatest need.** |
| **Childlessness**  
| Neither partner will have any living children from this or previous relationships (including adopted children) |
| **Sterilisation**  
| Treatments will not be available if either partner has undergone sterilisation. |
| **Sterilisation is offered as an irreversible method of contraception and individuals on the NHS are made aware of this at the time of the procedure** |
| **HFEA Code of Practice**  
| Couples must comply to a *Welfare of the Child* assessment |
| **Human Fertilisation and Embryology (HFE) Act 1990 (as amended) states:**  
| Section 13 (5): A woman shall not be provided with treatment services unless account has been taken of the welfare of any child who may be born as a result of the treatment (including the need of that child for supportive parenting), and of any other child who may be affected by the birth. |
| **Same sex couples and women not in a partnership**  
| IVF treatment will be funded for same sex couples or women not in a partnership if those seeking treatment are demonstrably subfertile and have undergone a period of expectant management. They would first need to demonstrate subfertility through 6 self-funded attempts at artificial insemination using donor sperm in a clinical setting, and undergo a period of expectant management involving up to a further 6 cycles of self or NHS-funded donor intra-uterine insemination (see policy statement 4). |
| **Same-sex couples should have access to IVF on equivalent grounds to heterosexual couples.**  
| In this respect, failure to conceive after six cycles of self-funded artificial insemination has been deemed an equivalent indicator of subfertility, given clinical and practical considerations³. |

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Review Date: March 2015  
Version 1.7.1*
Note: Men in same-sex relationships wanting a baby can either adopt or use some form of surrogacy. The CCG will not fund surrogacy arrangements. However, when a pregnancy does not occur through surrogacy after 6 cycles of self-funded intra-uterine insemination in a clinical setting there is an increased risk of some underlying problem. In those circumstances, the man whose sperm is being used and the surrogate partner would be eligible to be referred for further clinical assessment and possible treatment.

In the case of same sex couples where only one partner is sub fertile, clinicians should discuss the possibility of the other partner receiving treatment before proceeding to interventions involving the sub fertile partner.

The other criteria for eligibility for IVF will also apply.

- All same sex couples and women not in a partnership should have access to professional experts in reproductive medicine to obtain advice on the options available

Further NHS-funded cycles of intra-uterine insemination (up to six) constitutes the period of expectant management required prior to being eligible for IVF, during which pregnancy may be achieved (based on NICE recommendation and advice of local clinicians).

•

FSH

- FSH levels should be checked between day 2 and 4 of the menstrual cycle, where day 1 is the first full day of menstrual bleeding, with Oestradiol level. Only women whose FSH has never exceeded a level of 11.9 iu/L or less when an oestradiol level checked on the same day is 249 pmol/l or less will be eligible for treatment with the sample timed within 6 months of date of treatment. For those with no periods the sample can be timed at any date but the same maximum levels apply. The clinic will be expected to repeat the FSH blood test if the level was checked more than 6 months prior to treatment and treatment will be withdrawn if the repeated level exceeds 11.9iu/L

Investigations

- The couple must have been appropriately investigated within a recognised NHS fertility clinic in secondary care. The couple can only be referred for assisted conception once all of these investigations have been completed and a proforma referral document completed. The referring clinic will check to ensure that the couple fulfil the relevant criteria and at that point will start an 18 week clock. Couples must NOT be referred for assisted conception until all other relevant procedures have been completed and the patient discharged from secondary care.
RICHMOND CCG – IVF criteria 2014/2015

Sub-fertility Investigations and Assisted Conception Policy

Summary

This summary should be read with

- Appendix A-Decision tree for subfertility investigations and treatment
- Appendix B-Criteria for Subfertility Investigations
- Appendix C-Criteria for Assisted Conception including IVF, ICSI and IUI
- Appendix D-South West London Effective Commissioning (SWLECI)criteria on Fertility Preservation techniques

1. Richmond CCG will only fund fertility investigations and related drugs (Appendix B) for:
   a. women 45 years of age or below; and
   b. who are childless or have only one living child (including adopted children) either from this or previous relationship and
   c. who are in a current long term relationship (atleast one year)

2. Please refer to the appendices regarding which investigations should be carried out in general practice. Subfertility investigations and treatment criteria are attached at appendix A, B and C. Patient choice exists for subfertility investigation but not for Assisted Conception i.e. IUI, IVF and ICSI. When referring patients for investigations please consider this to avoid duplication of investigation. Please note that the ACU at KH will always repeat the semen analysis before any assisted conception.

3. Primary Care investigations include
   - BMI - if >30 refer to LiveWell Richmond weight management programme.
   - Routine bloods – Rubella, FSH/LH (day 2 – 4) and Progesterone (day 21).
   - If indicated, conduct smear.
   - If amenorrhoea or oligomenorrhea, conduct Prolactin and TFT.
   - Semen analysis – if abnormal repeat after 6 – 8 weeks.

4. Specialist investigations include Hep B, HIV, and ovarian reserve; tubal and uterine abnormalities.

5. Please do not carry out specialist investigations in Primary care (Please note this also applies to Private clinics)

6. The referral letter to secondary care should include the following information regarding patient’s
   - BMI
   - Smoking status
   - Duration of trying
   - Relationship status
   - Existing children

7. Assisted Conception i.e. IUI/IVF and ICSI is only commissioned at Assisted Conception Unit based at Kingston Hospital.
8. Richmond CCG will only fund **one fresh cycle of IVF and two frozen cycles** for women between **23 to 42 years of age** and who fulfil the criteria set out in **appendix C**

9. Richmond CCG will **only fund IUI cycles (upto a maximum of 6 cycles)** for people (Appendix C);
   
   a. who are unable to, or would find it very difficult to, have vaginal intercourse because of a clinically diagnosed physical disability or psychosexual problem  
   who are using partner or donor sperm  
   
people with conditions that require specific consideration in relation to methods of conception (for example, after sperm washing where the man is HIV positive)
Appendix A: Management of Subfertility

Appendix A: MANAGEMENT OF SUBFERTILITY*

*Developed using NICE 2013 sub fertility guidance

Is the individual due to undergo medical or surgical treatment that will have a harmful effect on fertility?

Yes

No

START:

• Patient <46 years;
• has no more than one living child from this or previous relationship; and
• is currently in a long-term relationship; and
• is concerned about fertility. (Appendix B)

Is the patient having regular unprotected vaginal intercourse?

Yes

No

Is there a known physical reason? (Appendix C)

Yes

No

Same sex couple: (women)?

Yes

No

Have 6 cycles of non-NHS artificial insemination been completed unsuccessfully? (Appendix C)

Yes

No

Refer for specialist fertility investigation.

Refer for specialist consultation

Has the woman been trying to conceive for ≥ 1 yr, or is she ≥ 35 years of age and has been trying to conceive for ≥ 6 months. (Appendix B)

Yes

No

Is the reason for infertility known?

Yes

No

Provide advice on: chance of conception, frequency and timing of intercourse, alcohol, smoking, obesity, low body weight, occupation, drug use, folic acid.

Contains a referral to NHS Stop Smoking and Livewell Richmond for Lifestyle Services. If BMI > 30 refer to Livewell Richmond for weight management services.

Infertility unknown: GP refers for specialist fertility investigation.

Specialist investigations: Hep B, HIV, ovarian reserve; tubal and uterine abnormalities.

Treat in line with NICE fertility recommendations 2013 and local policies.

Treatment successful?

Yes

No

Has the patient been trying to conceive for ≥ 2 yrs? (Appendix C)

Offer up to 6 cycles of intrauterine insemination.

If eligible, provide IUI/IVF/ICSI at Kingston ACU

Livewell Richmond and Gynaecology and/or urology

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### Annex B: RICHMOND CCG – Subfertility Investigations- 2014/2015

<table>
<thead>
<tr>
<th>Criteria</th>
<th>Rationale</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Duration of subfertility</strong></td>
<td>Couples will be eligible for subfertility investigations* who have tried to conceive for 12 months or where the woman is over the age of 36, have been trying to conceive for 6 months or an identified cause of infertility¹</td>
</tr>
<tr>
<td><strong>Age of woman at the time of referral</strong></td>
<td>The maximum age of the woman should be less than 46 years of age i.e. 45 years or below²</td>
</tr>
<tr>
<td><strong>Body mass index of woman</strong></td>
<td>19 – 30 kg/m² weight to be maintained for the last 6 months prior to referral³</td>
</tr>
<tr>
<td><strong>Smoking status of couple</strong></td>
<td>Both partners should have been non-smokers for at least 6 months³</td>
</tr>
<tr>
<td><strong>Childlessness</strong></td>
<td>Neither partner should have more than one living child from this or previous relationships (including adopted children)</td>
</tr>
<tr>
<td><strong>Women in same sex couples/ and women not in a partnership</strong></td>
<td>Sub fertility investigations will be funded for women in same sex couples if those seeking treatment are demonstrably sub-fertile. (This requires that same-sex female couples complete 6 cycles of artificial insemination successfully (Not NHS-funded) before being eligible for NHS sub-fertility assessment and treatment)</td>
</tr>
<tr>
<td></td>
<td><strong>In the case of women in same sex couples in which only one partner is sub-fertile, clinicians should discuss the possibility of the other partner receiving treatment before proceeding to interventions involving the sub-fertile partner.</strong></td>
</tr>
<tr>
<td></td>
<td><strong>NHS funding will not be available for access to insemination facilities for fertile women who are part of a same sex partnership or those not in a partnership.</strong></td>
</tr>
<tr>
<td></td>
<td><strong>In circumstances in which women in a same sex partnership are eligible for sub-fertility treatment, the other criteria for eligibility for sub-fertility treatments will also apply.</strong></td>
</tr>
<tr>
<td></td>
<td><strong>Women in same sex couples and women not in a partnership should have access to professional experts in reproductive medicine to obtain advice on the options available to enable them to proceed along this route if they so wish.</strong></td>
</tr>
</tbody>
</table>

*All Assisted conception (IUI/IVF and ICSI) should only be carried out at Kingston Hospital.*

**References:**

Date Approved: August 2014  |  Review Date: March 2015  |  Version 1.7.1

Richmond CCG criteria for Access to Assisted Conception, including, In Vitro Fertilisation (IVF), Intracytoplasmic Sperm Injection (ICSI) and Intrauterine Insemination (IUI)

<table>
<thead>
<tr>
<th>Criteria</th>
<th>Rationale</th>
</tr>
</thead>
</table>
| Duration of subfertility                    | Couples will be eligible for referral for treatment if they have experienced twenty four months of unexplained infertility* (this can include upto twelve months before their fertility investigations)  
• or an identified cause of infertility.                                                                                                                   |
|                                              | 84% of women will conceive within one year of regular unprotected sexual intercourse, this increases to 92% after 2 years and 93% after 3 years.                                                        |
| Age of woman at start of treatment cycle    | The age range will be between 23-39 years as per NICE Guidance. If the woman reaches the age of 40 during treatment, complete the current full cycle but do not offer further full cycles  
• Women aged between 40-42 who have experienced twenty four months of unexplained infertility*, where the following criteria are fulfilled:  
  o They have never previously had IVF treatment  
  o There is no evidence of low ovarian reserve  
  o There has been a discussion of the additional implications of IVF and pregnancy at this stage  
|                                              | The likelihood of a live birth following assisted conception declines with age. Chances of live birth per IVF cycle are:  
•  >20% for women aged 23-35  
•  15% for women aged 36-38  
•  10% for women aged 39 years  
•  6% for women aged 40 years and over  |
| Body mass index of woman                     | 19 – 30 kg/m² weight to be maintained for the last 6 months prior to application.                                                                                                                             |
|                                              | Higher body mass index reduces the probability of fertility and the success associated with assisted conception techniques.                                                                                         |
| Smoking status of couple                     | Both partners should have been non-smokers for at least six months prior to commencement of treatment.                                                                                                           |
|                                              | Smoking can adversely affect the success rates of assisted reproductive techniques.                                                                                                                                 |
| IVF** Cycles and ICSI                        | Couples (Women 23-39 years of age) will be eligible for one fresh and a maximum of two un-stimulated frozen cycles with or without ICSI. The storage cost for frozen embryos for up to one year or until a live birth ( whichever is sooner ) would be paid for by the CCG. (Criteria at Appendix D)  
• Couples ( Women 40-42) will be eligible for only one NHS funded IVF cycle with or without ICSI.                                                                 |
|                                              | The probability of a live birth following the IVF is consistent for the first three cycles but effectiveness of subsequent cycles is uncertain.                                                                       |

NICE Guidance 2013.
| **IUI Cycles** | Offer IUI cycles (upto a maximum of 6 cycles) to:  
- people who are unable to, or would find it very difficult to, have vaginal intercourse because of a clinically diagnosed physical disability or psychosexual problem who are using partner or donor sperm  
- people with conditions that require specific consideration in relation to methods of conception (for example, after sperm washing where the man is HIV positive) | NICE Guidance 2013. |
| **Childlessness** | Neither partner must have any living children from this or previous relationships (including adopted children). | As funding for assisted conception is limited, priority will be given to couples with the greatest need. |
| **Sterilisation** | Treatments will not be available if either partner has undergone previous sterilisation. | Sterilisation is offered as an irreversible method of contraception and individuals on the NHS are made aware of this at the time of the procedure. |
| **HFEA Code of Practice** | Couples must comply to a Welfare of the Child assessment. | Human Fertilisation and Embryology (HFE) Act 1990 (as amended) states: Section 13 (5): A woman shall not be provided with treatment services unless account has been taken of the welfare of any child who may be born as a result of the treatment (including the need of that child for supportive parenting), and of any other child who may be affected by the birth. Section 2 (1)... “treatment services” means medical, surgical or obstetric services provided... for the purpose of assisting women to carry children. |
| **Women in same sex couples/ and women not in a partnership** | Sub fertility treatment will be funded for women in same sex couples if those seeking treatment are demonstrably sub fertile. (This requires that same-sex female couples complete 6 cycles of artificial insemination successfully before being eligible for NHS sub-fertility assessment and treatment)  
- In the case of women in same sex couples in which only one partner is sub fertile, clinicians should discuss the possibility of the other partner receiving treatment before proceeding to interventions involving the sub fertile partner.  
- NHS funding will not be available for access to insemination facilities for fertile women who are part of a same sex partnership or those not in a partnership.  
- In circumstances in which women in a same sex partnership or individuals are eligible for sub fertility treatment, the other criteria for eligibility for sub fertility treatments will also apply.  
- Women in same sex couples and women | This section was copied from the South Central criteria to ensure equality of access to the service. |
not in a partnership should have access to professional experts in reproductive medicine to obtain advice on the options available to enable them to proceed along this route if they so wish2.

FSH
- FSH levels should be checked between day 1 and 4 of the menstrual cycle with an LH and Oestradiol level. Only women whose FSH has never exceeded a level of 11.9 iu/l or less when an oestradiol level checked on the same day is 249 pmol/l or less will be eligible for treatment with the sample timed within 6 months of date of referral. For those with no periods the sample can be timed at any date but the same maximum levels apply4

*women who have not conceived after 24 months of regular unprotected intercourse or 12 cycles of artificial insemination (where 6 or more are by intrauterine insemination). This period may be known as 'expectant management' or 'watchful waiting'.

**All Assisted conception i.e. IUI, IVF and ICSI should only be carried out at Kingston Hospital

References:
5. South West London Effective Commissioning Initiative Criteria 2013/14;Criteria for IVF
6. South West London Effective Commissioning Initiative Criteria 2013/14; Criteria on Fertility Preservation Techniques
7. Wandsworth CCG IVF Criteria 2012

Appendix D: Fertility preservation techniques (SWLECI Criteria 2013/14)

The following preservation techniques: semen cryostorage, oocyte cryostorage, embryo cryostorage, will be routinely funded by SWL CCGs in the following circumstances:

Where a man or a woman requires medical or surgical treatment that is likely to have a permanent harmful effect on subsequent sperm or egg production. Such treatment includes radiotherapy or chemotherapy for malignant disease.

OR

Where a man or a woman requires ongoing medical treatment that, whilst on treatment, causes harmful effects on sperm or egg production, impotence or has possible teratogenic effects, and in whom stopping treatment for a prolonged period of time to enable conception is not an option.

It is important to note that the eggs are extracted for cryostorage using drugs and procedures of egg collection normally used for assisted conception;
therefore the funding includes assisted conception drugs and procedures as well as the storage costs. This will not progress to IVF/ICSI or any other assisted conception procedures to form an embryo in these cases, unless this is sought separately later through the assisted conception pathway.

**Note:**

- Women should be offered oocyte or embryo cryostorage (without simultaneous assisted conception treatment) as appropriate if they are well enough to undergo ovarian stimulation and egg collection, provided this will not worsen their condition and that sufficient time is available.
- Women preparing for medical treatment that is likely to make them infertile should be informed that oocyte cryostorage has very limited success, and that cryopreservation of ovarian tissue is still in an early stage of development.

**Storage**

- If agreed, will be funded for five (5) years. The HFEA would grant a license to cryostore oocytes for ten years. The further extension up to ten years can still be offered to the patient but as a self-funded process.
- Will not be available where a man or woman chooses to undergo medical or surgical treatment whose primary purpose is that it will render her infertile, such as sterilisation.
- Will not be available where a man or woman requests cryostorage for personal lifestyle reasons, such as wishing to delay trying to conceive.

**Post-storage Treatment**

Funding of assisted conception treatments would be made available on the same basis as other patients who have not undergone such storage.

**Self-funding following cessation of NHS funding**

Once the period of NHS funding ceases, patients can elect to self-fund for a further period, not to exceed appropriate HFEA regulations on length of storage.

**Embryo Cryostorage after NHS funded assisted conception**

Suitable embryo’s that are not transferred in IVF/ICSI cycle - Storage will be funded for a period of one (1) year.
SUTTON CCG – IVF criteria 2014/2015

Sutton CCG does not routinely commission Assisted Conception, however, this policy is currently being reviewed and any changes will be updated as appropriate.
WANDSWORTH CCG - IVF criteria 2013/2015

<table>
<thead>
<tr>
<th>Title</th>
<th>Criteria</th>
<th>Rationale</th>
</tr>
</thead>
</table>
| Duration of subfertility | • Couples will be eligible for referral for treatment if they have experienced twenty four months of unexplained infertility* (this can include up to twelve months before their fertility investigations)  
• or have an identified cause of infertility | 84% of women will conceive within one year of regular unprotected sexual intercourse, this increases to 92% after 2 years and 93% after 3 years |
| Age of woman at start of treatment cycle | • Woman is aged 23 – 39 years at the time of treatment  
• The lower age limit will not apply to women accessing treatment due to clinical care that is likely to result in long-term infertility  
• Women aged 40 – 42 who have experienced twenty four months of unexplained infertility*, where the following criteria are fulfilled:  
  - They have never previously had IVF treatment  
  - There is no evidence of low ovarian reserve  
  - There has been a discussion of the additional implications of IVF and pregnancy at this age | The likelihood of a live birth following assisted conception declines with age. Chances of live birth per IVF cycle are:  
• >20% for women aged 23-35  
• 15% for women aged 36-38  
• 10% for women aged 39 years  
• 6% for women aged 40 years and over |
| Body mass index of woman | • 19 – 30 kg/m², weight to be maintained for the last 6 months prior to application. | Higher body mass index reduces the probability of success associated with assisted conception techniques |
| Smoking status of couple | • Both partners should have been non-smokers for at least six months prior to commencement of treatment. | Smoking can adversely affect the success rates of assisted reproductive techniques |
| Previous cycles | • Couples will be eligible for NHS funding of one fresh cycle of IVF or ICSI. Where the couple produces more than one good quality embryo and have an elective single embryo transfer, the CCG will fund 12 months of cryopreservation of the remaining embryos. If the initial embryo transfer does not result in a live birth, the CCG will then fund a single unstimulated frozen embryo transfer  
• Where couples have self-funded previous cycles, these must not exceed TWO. | The probability of a live birth following the IVF is consistent for the first three cycles but effectiveness of subsequent cycles is uncertain. |
| Childlessness | • Neither partner must have any living children from this or previous relationships (including adopted children) | As funding for assisted conception is limited, priority will be given to couples with the greatest need. |
| Sterilisation | • Treatments will not be available if either partner has undergone previous sterilisation. | Sterilisation is offered as an irreversible method of contraception and individuals on the NHS are made aware of this at the time of the procedure |
| HFEA Code of Practice | Couples must comply to a Welfare of the Child assessment as described in the Human Fertilisation and Embryology Authority Code of Practice | Human Fertilisation and Embryology (HFE) Act 1990 (as amended) states:  
Section 13 (5): A woman shall not be provided with treatment services unless account has been taken of the welfare of any child who may be born as a result of the treatment (including the need of that child for supportive parenting), and of any other child who may be affected by the birth. |
| Women in same sex couples/ and women not in a partnership | • Sub fertility treatment will be funded for women in same sex couples or women not in a partnership if those seeking treatment are demonstrably sub fertile.  
• In the case of women in same sex couples in which only one partner is sub fertile, clinicians should discuss the possibility of the other partner receiving treatment before proceeding to interventions involving the sub fertile partner.  
• NHS funding will not be available for access to insemination facilities for fertile women who are part of a same sex partnership or those not in a partnership.  
• In circumstances in which women in a same sex partnership or individuals are eligible for sub fertility treatment, the other criteria for eligibility for sub fertility treatments will also apply.  
• Women in same sex couples and women not in a partnership should have access to professional experts in reproductive medicine to obtain advice on the options available to enable them | To ensure equality of access to the service. |
<table>
<thead>
<tr>
<th>Title</th>
<th>Criteria</th>
<th>Rationale</th>
</tr>
</thead>
<tbody>
<tr>
<td>FSH</td>
<td>FSH levels should be checked between day 1 and 4 of the menstrual cycle with an LH and Oestradiol level. Only women whose FSH has never exceeded a level of 11.9 iu/l or less when an oestradiol level checked on the same day is 249 pmol/l or less will be eligible for treatment with the sample timed within 6 months of date of referral. For those with no periods the sample can be timed at any date but the same maximum levels apply.</td>
<td></td>
</tr>
</tbody>
</table>

*women who have not conceived after 24 months of regular unprotected intercourse or 12 cycles of artificial insemination (where 6 or more are by intrauterine insemination). This period may be known as 'expectant management' or 'watchful waiting'.

The content should demonstrably comply with all relevant legal and statutory requirements, NHS guidance and policy in force at the time of writing or reviewing the document. It should include Consultation and Equality Analysis results and any required changes to the document.
### Appendix H: Classification of Pain Levels and Functional Limitations Table for Primary Hip Replacement and Oxford Hip Score

<table>
<thead>
<tr>
<th>Variable</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Pain Level</strong></td>
<td></td>
</tr>
<tr>
<td>Mild</td>
<td>Pain interferes minimally on an intermittent basis with usual daily activities. Not related to rest or sleep. Pain controlled by one or more of the following: NSAIDs with no or tolerable side effects, aspirin at regular doses, paracetamol.</td>
</tr>
<tr>
<td>Moderate</td>
<td>Pain occurs daily with movement and interferes with usual daily activities. Vigorous activities cannot be performed. Not related to rest or sleep. Pain controlled by one or more of the following: NSAIDs with no or tolerable side effects, aspirin at regular doses, paracetamol.</td>
</tr>
<tr>
<td>Severe</td>
<td>Pain is constant and interferes with most activities of daily living. Pain at rest or interferes with sleep. Pain not controlled, even by narcotic analgesics.</td>
</tr>
<tr>
<td><strong>Previous non-surgical treatments</strong></td>
<td></td>
</tr>
<tr>
<td>Correctly Done</td>
<td>NSAIDs, paracetamol, aspirin or narcotic analgesics at regular doses during 6 months with no pain relief; weight control treatment if overweight, physical therapies done.</td>
</tr>
<tr>
<td>Incorrectly Done</td>
<td>NSAIDs, paracetamol, aspirin or narcotic analgesics at inadequate doses or less than 6 months with no pain relief; or no weight control treatment if overweight or no physical therapies done.</td>
</tr>
<tr>
<td><strong>Functional Limitations</strong></td>
<td></td>
</tr>
<tr>
<td>Minor</td>
<td>Functional capacity adequate to conduct normal activities and self care. Walking capacity of more than one hour. No aids needed.</td>
</tr>
<tr>
<td>Moderate</td>
<td>Functional capacity adequate to perform only a few or none of the normal activities and self care. Walking capacity of about one half hour. Aids such as a cane are needed.</td>
</tr>
<tr>
<td>Severe</td>
<td>Largely or wholly incapacitated. Walking capacity of less than half hour or unable to walk or bedridden. Aids such as a cane, a walker or a wheelchair are required.</td>
</tr>
</tbody>
</table>
### OXFORD HIP SCORE(1) TO BE COMPLETED BY THE PATIENT

**DURING THE PAST 4 WEEKS:**

<table>
<thead>
<tr>
<th>Score</th>
<th>Question</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 (scoring 4-0)</td>
<td>How would you describe the pain you usually have from your hip?</td>
</tr>
<tr>
<td></td>
<td>None o Very mild o Mild o Moderate o Severe o</td>
</tr>
<tr>
<td>2 (scoring 4-0)</td>
<td>Have you had any trouble with washing and drying yourself (all over) because of your hip?</td>
</tr>
<tr>
<td></td>
<td>No trouble at all o Very little trouble o Moderate trouble o Extreme difficulty o Impossible to do o</td>
</tr>
<tr>
<td>3 (scoring 4-0)</td>
<td>Have you had any trouble getting in and out of a car or using public transport because of your hip?</td>
</tr>
<tr>
<td></td>
<td>No trouble at all o Very little trouble o Moderate trouble o Extreme difficulty o Impossible to do o</td>
</tr>
<tr>
<td>4 (scoring 4-0)</td>
<td>Have you been able to put on a pair of socks, stocking or tights?</td>
</tr>
<tr>
<td></td>
<td>Yes, easily o With little difficulty o With moderate difficulty o With extreme difficulty o Impossible to do o</td>
</tr>
<tr>
<td>5 (scoring 4-0)</td>
<td>Could you do the household shopping on your own?</td>
</tr>
<tr>
<td></td>
<td>Yes, easily o With little difficulty o With moderate difficulty o With extreme difficulty o All of the time o</td>
</tr>
<tr>
<td>6 (scoring 4-0)</td>
<td>For how long have you been able to walk before pain from your knee becomes severe? (with or without a stick)</td>
</tr>
<tr>
<td></td>
<td>No pain/more than 30 minutes o 16-30 minutes o 5 to 15 minutes o Around the house only o</td>
</tr>
<tr>
<td></td>
<td>Not at all-pain severe when walking o</td>
</tr>
<tr>
<td>7 (scoring 4-0)</td>
<td>Have you been able to climb a flight of stairs?</td>
</tr>
<tr>
<td></td>
<td>Yes, easily o With little difficulty o With moderate difficulty o With extreme difficulty o All of the time o</td>
</tr>
<tr>
<td>8 (scoring 4-0)</td>
<td>After a meal (sat at a table), how painful has it been for you to stand up from a chair because of your hip?</td>
</tr>
<tr>
<td></td>
<td>Not at all painful o Slightly painful o Moderately painful o Very painful o Unbearable o</td>
</tr>
<tr>
<td>9 (scoring 4-0)</td>
<td>Have you been limping when walking because of your hip?</td>
</tr>
<tr>
<td></td>
<td>Rarely/Never o Sometimes, or just at first o Often, not just at first o Most of the time o All of the time o</td>
</tr>
<tr>
<td>10 (scoring 4-0)</td>
<td>Have you had any sudden, severe pain - &quot;shooting&quot;, &quot;stabbing&quot; or &quot;spasms&quot; from the affected hip?</td>
</tr>
<tr>
<td></td>
<td>No days o Only 1 or 2 days o Some days o Most days o Every day o</td>
</tr>
<tr>
<td>11 (scoring 4-0)</td>
<td>How much has pain from your hip interfered with your usual work (including housework)?</td>
</tr>
<tr>
<td></td>
<td>Not at all o A little bit o Moderately o Greatly o Totally o</td>
</tr>
<tr>
<td>12 (scoring 4-0)</td>
<td>Have you been troubled by pain from your hip in bed at night?</td>
</tr>
<tr>
<td></td>
<td>No nights o Only 1 or 2 nights o Some nights o Most nights o Every night o</td>
</tr>
</tbody>
</table>

### OXFORD HIP SCORE USER GUIDE

**System of scoring**

Each of the 12 questions on the Oxford hip score is scored in the same way with the score decreasing as the reported symptoms increase (ie. become worse). All questions are laid out similarly with response categories denoting least (or no) symptoms being to the left of the page (scoring 4) and those representing greatest severity lying on the right hand side (scoring 0).

**The overall score** is reached by simply summing the scores received for individual questions. This results in a continuous score ranging from 0 (most severe symptoms) to 48 (least symptoms). Score each question from 0 to 4 with 4 being the best outcome. This method, when summed, produces overall scores running from 0 to 48 with 48 being the best outcome.

**New scoring system for the Oxford hip score**

When the Oxford knee score was originally devised, the scoring system was designed to be as simple as possible, in order to encourage its use. Thus, in the original publication each question was scored from 1 to 5, with 1 representing best outcome/least symptoms. Scores from each question were added so the overall score was from 12 to 60 with 12 being the best outcome.

Since then, many surgeons have found this scoring unintuitive and have adapted the scoring - leading to considerable confusion. The new scoring system is now recommended.
# Appendix I: Knee Symptomatology, Radiology and Localisation and Oxford Knee Score

<table>
<thead>
<tr>
<th>Variable</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Mobility and Stability</strong></td>
<td></td>
</tr>
<tr>
<td>Preserved mobility and stable joint</td>
<td>Preserved mobility is equivalent to minimum range of movement from 0° to 90°. Stable or not lax is equivalent to an absence of slackness of more than 5mm in the extended joint.</td>
</tr>
<tr>
<td>Limited mobility and/or stable joint</td>
<td>Limited mobility is equivalent to a range of movement less than 0° to 90°. Unstable or lax is equivalent to the presence of slackness of more than 5mm in the extended joint.</td>
</tr>
<tr>
<td><strong>Symptomatology</strong></td>
<td></td>
</tr>
<tr>
<td>Slight</td>
<td>Sporadic pain.</td>
</tr>
<tr>
<td></td>
<td>Pain when climbing/descending stairs.</td>
</tr>
<tr>
<td></td>
<td>Allows daily activities to be carried out (those requiring great physical activity may be limited).</td>
</tr>
<tr>
<td></td>
<td>Medication: aspirin, paracetamol or NSAID to control pain with no side effects</td>
</tr>
<tr>
<td>Moderate</td>
<td>Occasional pain.</td>
</tr>
<tr>
<td></td>
<td>Pain when walking on level surfaces (half an hour, or standing).</td>
</tr>
<tr>
<td></td>
<td>Some limitation of daily activities.</td>
</tr>
<tr>
<td></td>
<td>Medication: aspirin, paracetamol or NSAIDs to control the pain with few or no side effects.</td>
</tr>
<tr>
<td>Intense</td>
<td>Pain of almost continuous nature.</td>
</tr>
<tr>
<td></td>
<td>Pain when walking short distances on level surfaces or standing for less than half an hour.</td>
</tr>
<tr>
<td></td>
<td>Daily activities significantly limited.</td>
</tr>
<tr>
<td></td>
<td>Continuous use of NSAIDs for treatment to take effect.</td>
</tr>
<tr>
<td></td>
<td>Requires the sporadic use of support systems (walking stick, crutches).</td>
</tr>
<tr>
<td>Severe</td>
<td>Continuous pain.</td>
</tr>
<tr>
<td></td>
<td>Pain when resting.</td>
</tr>
<tr>
<td></td>
<td>Daily activities significantly limited constantly.</td>
</tr>
<tr>
<td></td>
<td>Continuous use of analgesics- narcotics/NSAIDs with adverse effects or no response.</td>
</tr>
<tr>
<td></td>
<td>Requires more constant use of support systems (walking stick, crutches).</td>
</tr>
<tr>
<td><strong>Radiology</strong></td>
<td></td>
</tr>
<tr>
<td>Slight</td>
<td>Ahlback grade 1.</td>
</tr>
<tr>
<td>Moderate</td>
<td>Ahlback grade II and III.</td>
</tr>
<tr>
<td>Severe</td>
<td>Ahlback grade IV and V.</td>
</tr>
<tr>
<td><strong>Localisation</strong></td>
<td></td>
</tr>
<tr>
<td>Uni-compartmental</td>
<td>Excluded patello-femoral isolated.</td>
</tr>
<tr>
<td>Bi-compartmental</td>
<td>Unicompartmental plus patello-femoral.</td>
</tr>
<tr>
<td>Tri-compartmental</td>
<td>Disease affecting all three compartments of the knee.</td>
</tr>
</tbody>
</table>
### Oxford Knee Score

**Oxford Knee Score**

**To be completed by the patient during the past 4 weeks:**

<table>
<thead>
<tr>
<th>1 (scoring 4-0)</th>
<th>How would you describe the pain you usually have from your knee?</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>None ○ Very mild ○ Mild ○ Moderate ○ Severe ○</td>
</tr>
<tr>
<td>2 (scoring 4-0)</td>
<td>Have you had any trouble with washing and drying yourself (all over) <strong>because of your knee?</strong></td>
</tr>
<tr>
<td></td>
<td>No trouble at all ○ Very little trouble ○ Moderate trouble ○ Extreme difficulty ○ Impossible to do ○</td>
</tr>
<tr>
<td>3 (scoring 4-0)</td>
<td>Have you had any trouble getting in and out of a car or using public transport <strong>because of your knee?</strong></td>
</tr>
<tr>
<td></td>
<td>No trouble at all ○ Very little trouble ○ Moderate trouble ○ Extreme difficulty ○ Impossible to do ○</td>
</tr>
<tr>
<td>4 (scoring 4-0)</td>
<td>For how long have you been able to walk before <strong>pain from your knee becomes severe?</strong> (with or without a stick)</td>
</tr>
<tr>
<td></td>
<td>No pain/more than 30 minutes ○ 16-30 minutes ○ 5 to 15 minutes ○ Around the house only ○ Not at all-pain severe when walking ○</td>
</tr>
<tr>
<td>5 (scoring 4-0)</td>
<td>After a meal (sat at a table), how painful has it been for you to stand up from a chair <strong>because of your knee?</strong></td>
</tr>
<tr>
<td></td>
<td>Not at all painful ○ Slightly painful ○ Moderately painful ○ Very painful ○ Unbearable ○</td>
</tr>
<tr>
<td>6 (scoring 4-0)</td>
<td>Have you been limping when walking <strong>because of your knee?</strong></td>
</tr>
<tr>
<td></td>
<td>Rarely/Never ○ Sometimes, or just at first ○ Often, not just at first ○ Most of the time ○ All of the time ○</td>
</tr>
<tr>
<td>7 (scoring 4-0)</td>
<td><strong>Could</strong> you kneel down and get up again afterwards?</td>
</tr>
<tr>
<td></td>
<td>Yes, easily ○ With little difficulty ○ With moderate difficulty ○ With extreme difficulty ○ No, impossible ○</td>
</tr>
<tr>
<td>8 (scoring 4-0)</td>
<td>Have you been troubled by <strong>pain from your knee in bed at night?</strong></td>
</tr>
<tr>
<td></td>
<td>No nights ○ Only 1 or 2 nights ○ Some nights ○ Most nights ○ Every night ○</td>
</tr>
<tr>
<td>9 (scoring 4-0)</td>
<td>How much has <strong>pain from your knee</strong> interfered with your usual work (including housework)?</td>
</tr>
<tr>
<td></td>
<td>Not at all ○ A little bit ○ Moderately ○ Greatly ○ Totally ○</td>
</tr>
<tr>
<td>10 (scoring 4-0)</td>
<td>Have you felt your knee might suddenly ‘give way’ or let you down?</td>
</tr>
<tr>
<td></td>
<td>Rarely/Never ○ Sometimes, or just at first ○ Often, not just at first ○ Most of the time ○ No, impossible ○</td>
</tr>
<tr>
<td>11 (scoring 4-0)</td>
<td><strong>Could</strong> you do the household shopping <strong>on your own?</strong></td>
</tr>
<tr>
<td></td>
<td>Yes, easily ○ With little difficulty ○ With moderate difficulty ○ With extreme difficulty ○ All of the time ○</td>
</tr>
<tr>
<td>12 (scoring 4-0)</td>
<td><strong>Could</strong> you walk down one flight of stairs?</td>
</tr>
<tr>
<td></td>
<td>Yes, easily ○ With little difficulty ○ With moderate difficulty ○ With extreme difficulty ○ All of the time ○</td>
</tr>
</tbody>
</table>

### Oxford Knee Score User Guide

**System of scoring**

Each of the 12 questions on the Oxford knee score is scored in the same way with the score decreasing as the reported symptoms increase (ie. become worse). All questions are laid out similarly with response categories denoting least (or no) symptoms being to the left of the page (scoring 4) and those representing greatest severity lying on the right hand side (scoring 0).

The overall score is reached by simply summing the scores received for individual questions. This results in a continuous score ranging from 0 (most severe symptoms) to 48 (least symptoms). Score each question from 0 to 4 with 4 being the best outcome. This method, when summed, produces overall scores running from 0 to 48 with 48 being the best outcome.

**New scoring system for the Oxford knee score**

When the Oxford knee score was originally devised, the scoring system was designed to be as simple as possible, in order to encourage its use. Thus, in the original publication (2) each question was scored from 1 to 5, with 1 representing best outcome/least symptoms. Scores from each question were added so the overall score was from 12 to 60 with 12 being the best outcome.

Since then, many surgeons have found this scoring unintuitive and have adapted the scoring - leading to considerable confusion. The new scoring system is now recommended.
Appendix J – Lymphoedema Staging and Referral Criteria

Best Practice for the management of Lymphoedema 2006 guidelines

Referral Criteria

<table>
<thead>
<tr>
<th>BOX 15 Indications for referral to a lymphoedema service</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Special groups:</strong></td>
</tr>
<tr>
<td>- swelling of unknown origin</td>
</tr>
<tr>
<td>- midline lymphoedema (head, neck, trunk, breast, genitalia)</td>
</tr>
<tr>
<td>- children with chronic oedema</td>
</tr>
<tr>
<td>- primary lymphoedema</td>
</tr>
<tr>
<td>- lymphoedema in family members</td>
</tr>
<tr>
<td><strong>Factors complicating management:</strong></td>
</tr>
<tr>
<td>- concomitant arterial disease</td>
</tr>
<tr>
<td>- concomitant diabetes mellitus</td>
</tr>
<tr>
<td>- concomitant venous insufficiency with ulceration</td>
</tr>
<tr>
<td>- long-term complications due to surgery or radiotherapy</td>
</tr>
<tr>
<td>- severe papillomatosis, hyperkeratosis or other chronic skin condition</td>
</tr>
<tr>
<td>- severe foot distortion/ bulbous toes</td>
</tr>
<tr>
<td>- sudden increase in pain or swelling of lymphoedematous site</td>
</tr>
<tr>
<td>- chylous reflux, eg chyluria, chyle-filled lymphangiectasia</td>
</tr>
<tr>
<td>- neuropathy</td>
</tr>
<tr>
<td>- functional, social or psychological factors</td>
</tr>
<tr>
<td>- obesity</td>
</tr>
<tr>
<td><strong>Management difficulties:</strong></td>
</tr>
<tr>
<td>- compression garment fitting problems</td>
</tr>
<tr>
<td>- failure to respond after three months' standard treatment</td>
</tr>
<tr>
<td>- wound that deteriorates or is unresponsive after three months' treatment</td>
</tr>
<tr>
<td>- recurrent cellulitis/erysipelas</td>
</tr>
</tbody>
</table>

Staging of Lymphoedema

<table>
<thead>
<tr>
<th>BOX 11 International Society of Lymphology (ISL) lymphoedema staging⁶</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>ISL stage 0</strong></td>
</tr>
<tr>
<td>A subclinical state where swelling is not evident despite impaired lymph transport. This stage may exist for months or years before oedema becomes evident</td>
</tr>
<tr>
<td><strong>ISL stage I</strong></td>
</tr>
<tr>
<td>This represents early onset of the condition where there is accumulation of tissue fluid that subsides with limb elevation. The oedema may be pitting at this stage</td>
</tr>
<tr>
<td><strong>ISL stage II</strong></td>
</tr>
<tr>
<td>Limb elevation alone rarely reduces swelling and pitting is manifest</td>
</tr>
<tr>
<td><strong>ISL late stage II</strong></td>
</tr>
<tr>
<td>There may or may not be pitting as tissue fibrosis is more evident</td>
</tr>
<tr>
<td><strong>ISL stage III</strong></td>
</tr>
<tr>
<td>The tissue is hard (fibrotic) and pitting is absent. Skin changes such as thickening, hyperpigmentation, increased skin folds, fat deposits and warty overgrowths develop</td>
</tr>
</tbody>
</table>
Appendix K – NHS England Policies

Previous SWL ECI procedures now commissioned and managed by NHS England, effective from April 1st 2013.

- Bariatric Surgery
- Bone Anchored Hearing Aids (BAHAs)
- Cochlear Implants
- Deep Brain Stimulation (DBS) for Parkinson’s Disease
- Dental Policies:
  - Apicectomy
  - Dental Implants
  - Orthodontic Treatment
  - Wisdom Teeth
- Gender Reassignment Surgery
- Hyperbaric Oxygen Therapy
- Revision of Hip Arthroplasty
- Revision of Knee Arthroplasty
- Sacral Nerve Stimulation (SNS) for Faecal Incontinence
- Spinal Cord Stimulation for Neuropathic Pain
Appendix L – Governance 2014/2015

All amendments/additions to the 2014/2015 SWL ECI Document have gone through a rigorous governance process as detailed below:

Local GP’s invited to suggest new procedures for inclusion into the SWL ECI Document
↓
Suggested procedures taken through a prioritisation process and scored (top 5/6 scoring procedures worked up for discussion by Group)
↓
Procedures currently included in SWL ECI Document reviewed (in line with 3-year rolling programme)
↓
New/updated criteria discussed and agreed by the SWL ECI Group.
↓
Consultation with clinicians from the local acute trust.
↓
SWL ECI Group reviews feedback and updates draft criteria.
↓
Cluster wide consultation with clinical teams.
↓
SWL ECI Group reviews feedback and updates draft criteria.
↓
Draft policy submitted to local CCG’s for approval.
↓
SWL ECI Group ratify updated Document.
↓
New/updated criteria included into local secondary care contracts
Amendments/additions to the 2014/2015 were approved by local CCGs as follows:

<table>
<thead>
<tr>
<th>CCG</th>
<th>Approving Body</th>
<th>Date Approved</th>
</tr>
</thead>
<tbody>
<tr>
<td>Croydon</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Kingston</td>
<td>Kingston CCG Governing Body</td>
<td>02 September 2014</td>
</tr>
<tr>
<td>Merton</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Richmond</td>
<td>Richmond CCG Governing Body</td>
<td>July 2014</td>
</tr>
<tr>
<td>Sutton</td>
<td>Sutton CCG Governing Body</td>
<td>03 September 2014</td>
</tr>
<tr>
<td>Wandsworth</td>
<td>Wandsworth CCG Governing Body</td>
<td>09 July 2014</td>
</tr>
</tbody>
</table>
South West London ECI 2014/15 Document Changes Summary

<table>
<thead>
<tr>
<th>Policy Changes</th>
<th>Description of Changes</th>
<th>Rationale for changes</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Document formatted</strong></td>
<td>Criteria were numbered and text formatted.</td>
<td>Numbering of criteria and formatting of the descriptions of each criterion enable the document to be read and understood more easily. The numbering of criteria also enables specific sections of the document to be referenced with ease.</td>
</tr>
<tr>
<td><strong>Version Control</strong></td>
<td>Version control sheet added to document.</td>
<td>Version control sheet depicts the changes made to this document from February 2014 to June 2014. This sheet is a step by step guide to the changes made in chronological order for easy referral.</td>
</tr>
<tr>
<td><strong>Ambiguous Policies</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Aesthetic Surgery General Principles</strong></td>
<td>Statement added: The table below describes the criteria/guidelines for aesthetic procedures and should be considered against requests for procedures as indicated in this policy document.</td>
<td>To indicate this criteria be used throughout this document for aesthetic procedures where there is no specifically written criteria. E.g. Tattoo removal.</td>
</tr>
<tr>
<td><strong>Surgical Correction of nipple inversion</strong></td>
<td>See General Principles added to criteria.</td>
<td>Statement of instruction to refer to General Principles criteria in order to clarify criteria and indicate that there are further criteria which need to be considered for this policy.</td>
</tr>
<tr>
<td><strong>Rhytidectomy (face lift)</strong></td>
<td>See General Principles added to criteria.</td>
<td>Statement of instruction to refer to General Principles criteria in order to clarify criteria and indicate that there are further criteria which need to be considered for this policy.</td>
</tr>
<tr>
<td><strong>Pinnaplasty/Otoplasty</strong></td>
<td>See General Principles above, added to criteria. Inserted: The patient should be between 5 and 18 years of age (surgery under 5 should only be considered for children who require a hearing aid and where this will be better supported following a correction of ear prominence)The angle between the side of the head and the external ear should be more than 35 degrees. (Normal angle is between 20 to 35 degrees).</td>
<td>General Principles added to indicate further criteria to be considered for this procedure. Criteria added for consideration when application is being considered in exceptional circumstances. Ages of child where this procedure is most beneficial, have been highlighted. Angle between side of head and external ear has been included in order to define congenital deformity and ensure</td>
</tr>
</tbody>
</table>

---

Note: The table above includes the changes made to the document, the descriptions of the changes, and the rationale for those changes. The changes include formatting updates, the addition of a version control sheet, and clarification of ambiguous policies.
<table>
<thead>
<tr>
<th>Procedure</th>
<th>Change Description</th>
<th>Justification</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hair Replacement Techniques</td>
<td>Statement inserted: If clinical exceptional circumstances exist, applications for funding can be made in the form of an individual application (such as an Individual Funding Request (IFR)).</td>
<td>As exceptional circumstances are assumed to exist in these cases, criteria now provides clear instruction to consider the IFR route as an alternative route for funding, as this procedure is not routinely funded on the NHS.</td>
</tr>
</tbody>
</table>
| Abdominoplasty/Apronectomy      | Correct formula for calculating percentage of excess weight added to criteria.  

\[
\text{Percentage of excess weight lost} = \left(\frac{\text{initial weight} - \text{current weight}}{\text{initial weight} - (25 \times \text{height}^2)}\right) 
\times 100 
\]  

(NB where weight is in kilos and height is in metres)  

Correct formula added in order to provide applicants with the knowledge of how best to calculate this point of the Abdominoplasty/Apronectomy criteria. Criterion is therefore more user friendly and encourages applicants to provide all the necessary information when applying for funding. |
| Liposuction                     | Reworded criterion: Liposuction will not be routinely funded simply to correct the distribution of fat. If clinical exceptional circumstances exist, applications for funding can be made in the form of an individual application as per local agreement (such as an Individual Funding Request (IFR)).  

Criteria reworded to ensure that there is no blanket statement here with regards to funding. Statement included instruction for applicants to apply for funding through the IFR route, in order to suggest that funding may be granted if exceptional circumstances exist. |
| Facial Skin Procedures          | Reworded criterion: Skin resurfacing procedures for cosmetic purposes or purely to improve appearance will not be routinely funded.  

Individual requests will be considered on an exceptional basis where there is evidence that the procedure will improve clinically significant signs and symptoms  

Wording of criteria adjusted to avoid a blanket statement, that cosmetic skin resurfacing procedures will not be funded. Exhaustive list of conditions removed in order to expand the criteria and refrain from implying that only treatment of certain conditions will be considered. Rewording ensures that evidence to prove exceptionality is provided, and that this treatment would be appropriate. |
<table>
<thead>
<tr>
<th>Treatment of vascular lesions</th>
<th>Reworded: Individual requests will be considered on an exceptional basis which may include evidence that facial lesions cause significant disfigurement or obstructive symptoms.</th>
<th>Criteria previously had been worded such as to begin defining exceptionality with the use of specific conditions. The policy was reworded in order to broaden the realm of potential circumstances which could exist for funding. Policy now also raises the necessity of evidence to prove that facial lesions may cause obstruction or disfigurement. Examples of conditions which are not normally treated are still mentioned as examples.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Injection of facial Botulinum Toxin for Cosmetic Indications</td>
<td>Reworded criteria: Botulinum toxin is not routinely funded for the treatment of facial ageing or excessive wrinkles. If clinical exceptional circumstances exist, applications for funding can be made in the form of an individual application (such as an Individual Funding Request (IFR)). Botulinum toxin is available for the treatment of pathological conditions by appropriate specialists in cases such as Frey’s syndrome—gustatory sweating after parotid surgery; Botox A injection is recommended as a first line treatment for Frey’s syndrome and can be used in conjunction with or instead of oral anticholinergic medication.</td>
<td>Criteria reworded for clarification and avoidance of a blanket statement that Botulinum toxin is not funded for treatment of facial ageing or excessive wrinkles. Instruction given for applicants to explore the IFR route for funding in the event of exceptional circumstances. Conditions where this treatment is available is clarified.</td>
</tr>
<tr>
<td>Hair Depilation (hair removal)</td>
<td>Criterion reworded: Treatment of severe hirsutism on the facial, neck and/or chest area will be considered if standard treatments have failed and exceptionality is demonstrated. Inserted: Funding will be agreed for a course of treatment after which a review of effectiveness will be required prior to any further funding being agreed.</td>
<td>Criterion reworded in order to clarify the routes to follow for funding. I.e. Standard treatments must have failed in order for funding to be considered by ECI, and then exceptionality must be demonstrated if following the IFR route. As no specific timeframe for treatment was previously referred to in the criteria, a statement was inserted to allow for a curb in the number of treatments funded, prior to review. This prevents an indefinite number of treatments immediately being funded.</td>
</tr>
<tr>
<td>Asymptomatic Gallstones</td>
<td>Reworded criterion: CCGs will not routinely fund cholecystectomy for asymptomatic gallstones. Applications for funding should be made in the form of an individual application (via an Individual Funding Request (IFR))</td>
<td>Criterion reworded for clarification. This now clearly instructs applicants that funding requests for this procedure should be made via the IFR route, as this procedure is not routinely funded.</td>
</tr>
</tbody>
</table>
### Revised Policies

<table>
<thead>
<tr>
<th>Section</th>
<th>Changes</th>
</tr>
</thead>
</table>
| Circumcision | Statement inserted: Circumcision will be considered on medical grounds where clinically indicated.  
Recurrent balanoposthitis resistant to antibiotic treatment. Balanoposthitis can be successfully treated using antibiotics. Most people do not have further infections. Circumcision is usually recommended only in adults in rare cases where someone has repeated infections.  
Changes to this criterion agreed by ECI policy group 28.05.2014. Clause inserted to prevent the inclusion of a blanket statement saying that circumcision for religious or cultural reasons will not be funded. Additional criteria added to include an additional clinical condition where the procedure may be indicated. Evidence is also inserted for rationale of criteria, as well as references. Criteria reformatted for clarification. |
| Open MRI    | Patients who suffer from claustrophobia where taking an oral prescription sedative to support conventional MRI has been tried and was not effective.  
OR  
Patients who cannot fit safely or comfortably in a conventional MRI, due to obesity or to some other confirmed clinical condition.  
1. GPs should prescribe an oral sedative before referring for an Open MRI  
2. Standard MRI has a 60 cm bore and can tolerate a maximum weight of 250 kg. Latest Standard MRI machines have an 80cm bore and are able to scan obese patients. Please check before referring for an Open MRI.  
Criteria clarified and expanded in order to highlight the necessity of an oral sedative actually being attempted prior to funding request. Criteria also expanded in order to capture a cohort of patients who cannot fit safely in the closed MRI machine due to clinical conditions other than obesity. Additional information provided for applicants to refer to, prior to Open MRI referral. Statement inserted clarifying that standing MRIs etc. are not routinely funded, and these requests require an IFR application.  
Evidence included supporting changes with the criteria and the viewpoint of the ECI policy group members with regards to certain types of MRI machines. Further sections included on Open/Semi Open MRI as well as Standing/weight bearing MRI for the information of the applicant to consider prior to referral. This further information also supports the decisions of the policy members with regards to changing this criterion.  
CCGs will not routinely fund:  
Standing, Weight-Bearing, Positional, or Upright MRI except on an exceptional basis via the IFR route.  
Further information inserted to criteria describing evidence of studies between open MRI and short bore MRI with regards to the reduction of claustrophobic events.  
Further information on open/semi open MRI included in criteria, as well as further information on standing MRI, for which is has been detailed there is limited scientific data. |
<table>
<thead>
<tr>
<th>Condition</th>
<th>Description</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Carpal Tunnel Syndrome</td>
<td>Clause inserted: This policy is not applicable to St George’s Hospital - Refer to the ‘St. George’s Hospital Carpal Tunnel Management Guidelines &amp; Referral Protocol’.</td>
<td>Clauses inserted to bring attention to the fact those criteria at St George's Hospital for this procedure differ from those within the ECI policy. Policy members have agreed to postpone the revision of this criterion until next year’s document is released. No further changes are therefore made.</td>
</tr>
<tr>
<td>Dupuytren’s Contracture</td>
<td>Clause inserted: This policy is not applicable to St George’s Hospital - Refer to the ‘St. George’s Hospital Dupuytren’s Contracture Guidelines &amp; Referral Checklist’.</td>
<td>Clauses inserted to bring attention to the fact those criteria at St George's Hospital for this procedure differ from those within the ECI policy. Policy members have agreed to postpone the revision of this criterion until next year’s document is released. No further changes are therefore made.</td>
</tr>
<tr>
<td>Manual Lymphatic Drainage</td>
<td>Statement inserted: CCGs will not routinely fund MLD as part of the Decongestive Lymphoedema Treatment (DLT) or on its own. It can only be considered through the prior approval route. Applications for funding can be made in the form of an individual application (such as an Individual Funding Request (IFR)) The panels may consider referral criteria, staging (at appendix J) and guidelines contained in the Best Practice for the management of Lymphoedema (Lymphoedema Framework 2006) to determine exceptionality. In all circumstances, MLD should not be funded on its own but in combination with DLT.</td>
<td>Statement inserted to clarify that this procedure is not normally funded. An IFR request is therefore necessary. Blanket statement avoided. An additional reference for best practice guide is inserted as guidance in appendix of document.</td>
</tr>
<tr>
<td>Varicose veins</td>
<td>Entire policy developed in line with NICE guidance. Reworded and new criterion added. Further background inserted, as well as management information, rationale and evidence supporting this information.</td>
<td>Entire policy reworded and developed for clarification, in line with NICE guidance. Statement inserted regarding varicose veins in pregnancy, which would exclude requests of this nature. Symptomatic patients are specifically said to be referred to a vascular service, this criteria therefore specifies the difference between clinical reasons and cosmetic. Policy is consequently clearer, though will effectively lower the</td>
</tr>
</tbody>
</table>
current thresholds for access to surgical treatment. It is anticipated that an increase in activity levels will ensue. A financial forecast has therefore been recommended by the ECI policy group. Evidence regarding the use of support stockings has been included, as well as interventional management in order to further support the criteria and rationale newly developed.

<table>
<thead>
<tr>
<th>IVF</th>
</tr>
</thead>
<tbody>
<tr>
<td>Reference to new NICE guidance added to indicate any individual CCG reviews have been made following consideration of this guidance.</td>
</tr>
</tbody>
</table>

## Further Document Changes

| Appendix A – Prior Approval                                      | Out of date Prior Approval Sheet removed from Appendix A of document. |
|----------------------------------------------------------------------|
| This sheet was in need of updating by each CCG. This is currently being developed by each CCG and will be replaced once completed for each procedure. |

| Croydon CCG Request Funding Pathway                              | CReSS arrangements added. |
|----------------------------------------------------------------------|
| Prior Approval chart for Croydon CCG has been amended to include the CReSS arrangements in order to provide a clear indication of how requests are processed. |

| Appendix B – ECI/IFR application form                            | ECI request form has been removed and replaced with the new and up to date IFR request form. |
|----------------------------------------------------------------------|
| Up to date IFR request form has been included. Significant changes made to the application form and to opportunity for applicants to provide essential information through a clear tick box format. Entire application form has been reformatted in order to be more user friendly. |

<table>
<thead>
<tr>
<th>IVF</th>
</tr>
</thead>
<tbody>
<tr>
<td>Old polices removed and replaced with updated CCG policies. New Policies for Kingston, Richmond and Wandsworth. Merton and Sutton updated noting review is under way. Croydon no changes with only date updated for 14/15.</td>
</tr>
<tr>
<td>Updated policies reviewed with reference to new NICE guidance. Unchanged policies currently under review and will be included within the document once formally approved by their CCG.</td>
</tr>
</tbody>
</table>

| Appendix J – Lymphoedema Staging and Referral Criteria.          | Best Practice for the Management of Lymphoedema Guidelines 2006 has been inserted, including referral criteria and staging of lymphoedema. |
|----------------------------------------------------------------------|
| Inserted for clarification of information. |

| Appendix K – NHS England Policies                               | List of procedures inserted that previously were commissioned by SWL ECI and now managed and commissioned by NHS England. |
|----------------------------------------------------------------------|
| Inserted for clarification of information. |
| Appendix L – Governance 2014-2015 | Dates changed to current dates for document. Chart depicting approval from each CCG for document sign off. | Up to date Governance page including up to date chart for the eventual approval from each CCG with regards to the criteria. |