NHS
South West London

# South West London

# Evidence Based Interventions Policy

# V4.1 – April 2023

| Version | Description of Change(s) | Reason for Change | Author | Date |
|---|---|---|---|---|
| 2.0 | Alignment of all SWL CCGs ECI policies following via Task and Finish groups in June – Sept 2017.<br>NB: IVF and fertility preservation criteria novated to individual CCGs policy statement document and now excluded from this policy.<br>Formatting and wording corrections to the version presented to SWL CiC. | Policy required improvement both in terms of content and format to ensure that there is a clear policy in place and the same thresholds apply to all SWL patients.<br>To ensure any mistakes are removed and format is consistent. | Zoli Zambo | 16/11/2017 |
| 3.0 | Updates to the policy to take in to account changes and updates required based on a number of areas either locally, regionally or nationally | Updates to the policy to take in to account the following:<br>a) local V2 feedback<br>b) NHS England EBI programme<br>c) London Choosing Wisely programme | Zoli Zambo | 26/02/2019 |
| 3.1 | DRAFT Minor updates agreed by clinical leads for post sign off feedback marked in red within the document. FINAL version only includes corrected version in red to ensure clarity. | Comments received in relation to the following policy changes:<br>1.1 Page 10/1.5 page 16/ 7.2 page 66/9.1 page 83/ 10.1 page 94/11.2 page 103/14.3 page 126 | Zoli Zambo | 30/08/2019 |
| 4.0 | Sections 1-15 - ICB logo and language updates only.<br>Sections 16-31 ACT/Fertility Preservation: Clarification of certain criteria within pre-existing policy, for the benefit of SWL patients seeking NHS fertility funding. No change to current policy criteria made, consultation therefore not required.<br>Section 33: Addition of Ovulation Induction section to formalise existing clinical practice across SWL. | SWL transition from a CCG to an ICB<br><br>Policy merge | Gill Schram | June 2022 |
| 4.1 | Updates to Fertility Preservation Section (18). | Aligned criteria for all patients requiring NHS funded fertility preservation where their treatment is likely to have a permanent harmful effect on subsequent sperm or egg production. | Gill Schram | April 2023 |
| **Approvals:** | Sections 16-31 ACT/Fertility Preservation:<br>Approved by the SWL Fertility Network Group (16 June 2022) and the SWL Gynae Clinical Network (17 June 2022).<br>Section 17 Ovulation Induction: Approved by the above and at the SWL Integrated Medicines Optimisation Committee (IMOC) 15 June 2022.<br><br>V4: SWL ICB policy approved by the SWL ICB Board 1 July 2022<br>V4.1: Approved by the SWL ICB Board 17 April 2023 | | | |

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# INTRODUCTION TO EVIDENCE BASED INTERVENTIONS (EBI) PREVIOUSLY EFFECTIVE COMMISSIONING INITIATIVE (ECI)

This policy deals with treatments and procedures for which restricted access criteria were agreed by the South West London Committees in Common on the 26th February 2019.

## Background

The South West London Effective Commissioning Initiative (ECI) was established in 2006 for the then Primary Care Trust (PCTs) in South West London, which then became the SWL Clinical Commissioning Groups (CCGs). With effect from 1st July 2022 the SWL CCG will transition to the SWL Integrated Care Board (ICB) resulting in the need for previous SWL ECI Policy to be updated, reflecting this organisational change.

The EBI policy is driven by the need to ensure that NHS funded treatments are evidenced-based, clinically effective and safe, and that access to treatments throughout SWL is equitable for patients with similar clinical need, thereby reducing variation in care.

Although not the main driving force, the policy also ensures that the NHS provides value for money and uses its resources effectively to achieve financial balance.

## Content of the policy

Prior to the set-up of the ICB the SWL CCG considered evidence of clinical practice, clinical effectiveness and cost-effectiveness, information on current activity, resources, costs and service provision across SWL when formulating these recommendations.

The SWL EBI policy lists 62 procedures, which are categorised into:

- Prior Approval Procedure
- Individual Funding Request

## Prior Approval Procedures (PAP)

Clinical criteria have been provided where the available evidence on clinical and cost effectiveness indicates the patients who will benefit the most from a procedure funded by the NHS.

Prior to the procedure being undertaken authorisation must be obtained by the treating clinician. This should be done by using the Prior Approval Tick box forms on the BlueTeq system (a secure online communication platform). This will demonstrate to the ICB that the patient meets the agreed criteria for treatment and assures the ICB that both the concerned individual and the local population can expect to get maximum health benefits from the procedure in question.

## Individual Funding Request (IFR)

The IFR process set out in the South-West London IFR Policy will be used to consider individual requests for funding approval where a service, intervention or treatment falls outside existing service agreements.

Some treatments are “not routinely funded” because either their clinical and cost effectiveness is marginal or where NHS provision may be inappropriate (e.g. the benefits are purely cosmetic and not clinical).

Prior to the procedure being undertaken authorisation must be obtained by the treating clinician (i.e., the practitioner who is responsible for administering the treatment requested). This should be done by using the IFR application form.

IFRs will be approved only when the SWL IFR panel agrees that the patient is clinically exceptional, or the patient has a very rare clinical condition. This is detailed in the South-West London IFR policy.

Exceptionality is defined as:

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

Any procedures not routinely funded can be requested via the IFR process. The policy cannot exhaustively list all procedures falling into this category but takes into account current clinical practice.

This IFR process will ensure that each request for individual funding is considered in a fair and transparent way, with decisions based on the best available evidence and in accordance with the South-West London IFR policy.

## Scope of the policy

The policy covers the procedures listed in this document when they are undertaken as routine planned treatments. When patients require the procedure due to an emergency this is excluded.

Procedures for the diagnosis and treatment of cancer are also excluded from the policy.

The SWL ICB may modify how authorisation is granted to treating clinicians based on continuous evaluation of the services.

Patients accessing services outside of SWL may be subject to the local clinical criteria set by the host ICB.

## Recent developments

The alignment and update of the SWL policy has been coordinated by the SWL ICB EBI/ (including IFR) team. The updates for V4 reflect an updated logo and changes to the previous CCG (commissioning) language.

## Review

This policy will be reviewed and updated annually considering new evidence and clinical guidance as well as further regional or national initiatives impacting on clinical thresholds and planning and funding arrangements.

# 1. Back pain interventions

### Overview for Back pain interventions

This policy relates to interventional treatments for back pain only, as described in detail below. For many patients, consideration of such treatments only arises after unsuccessful conservative management in primary care or specialist musculoskeletal services.

The following categories of patients are excluded from this policy:

- If there is any suspicion of malignancy, patients should be referred immediately to the appropriate service.

  See the London Cancer guidance at: https://www.healthylondon.org/our-work/cancer/.

- Paediatric patients (under 16 years of age)
- Patient has neurological deficit (spinal cord compression or cauda equina symptoms)
- Patient has fracture of the spine
- Patient has infection of the spine

Please note:

The SWL ICB does not routinely fund the following procedures for back pain:

- Acupuncture - Complementary medicine in which fine needles are inserted into the skin at specific points along lines of energy, unless this is delivered as part of a multi-disciplinary pain management programme
- Epidural Lysis - A minimally invasive form of surgery used to treat people with low back and leg pain caused by epidural adhesions laser ablation
- Therapeutic Spinal injections - Including facet joint injections, medical branch blocks, intradiscal therapy, prolotherapy, trigger point injections, sacroiliac joint injections
- Spinal Fusion
- Lumbar Disc Replacement - Replacing intervertebral units with artificial discs that can act as a functional prosthetic replacement
- Ozone Discectomy

### Primary care advice

Although primary care is not directly responsible for requesting prior approval, primary care needs to be aware of the detailed clinical criteria relating to this policy before referring the patient to the appropriate service.

Low back pain is a very common presentation, especially to General Practice. It is a soreness or stiffness in the back, between the bottom of the rib cage and the top of the legs. Most people's low back pain is described as 'non-specific'. Some people also get back symptoms radiating down one or both legs (radicular symptoms/sciatica). Radicular symptoms are caused, when the nerves from the back are irritated, causing pain, numbness or tingling down the leg.

This pain is usually self-limiting, and most patients will find their symptoms resolve without treatment or with conservative management. Conservative management may include reassurance, advice and

guidance with a holistic assessment where tools such as STarT Back (5) can be helpful and/or simple analgesia with safety netting. Patients with “red flag” pathologies should be treated on alternative pathways.

Currently much health service resource is utilised to provide very little positive benefit for patients. However, it can lead to considerable disability, in part through well-intentioned over-medicalisation of initial care management.

The funding criteria set out in this document should not delay referral for assessment of patients with uncontrollable pain despite conventional treatment, and patients with radiculopathy.

Primary care practitioners must also ensure that patients have engaged in shared decision making for potential further intervention and that they supply all the relevant information to secondary care, particularly concerning conservative treatments.

Primary care should ensure that, where appropriate, the patient has meaningfully engaged with conservative management. These include education and lifestyle modifications, exercise and physiotherapy. Primary care practitioners should encourage smoking cessation and weight reduction (where appropriate), offering referral to appropriate services, where required. These lifestyle changes have the potential to improve general health and wellbeing, as well as intervention success rates and enhance recovery times from surgery.

Imaging such as MRI and SPECT may be needed prior to the procedures listed in the policy and these are best requested by specialist clinical teams rather than by primary care, hence not needed prior to referral.

## 1.1 Diagnostic spinal injections

Including facet joint injections, medial branch blocks

**Compliance requirement**

Prior Approval must be obtained by the treating clinician. This must include details of how the patient meets the criteria as specified on the Prior Approval Tick Box Form.

**Clinical threshold**

The SWL ICB funds this procedure when all of the following criteria (1 - 3) are met.

1. Patient is 16 or over at the time of application

*NB. Children for complex pain management should receive their care at a specialist centre, the planning and funding for which is the responsibility of NHS England.*

**AND**

2. Patient has spinal pain (VAS>5)

*NB. Pre-procedure VAS score will need to be provided on the Tick box form; other pain scales such as Oswestry or Roland Morris are also accepted.*

**AND**

3. Patient requires therapeutic testing prior to undergoing radiofrequency denervation

Please note:

The SWL ICB does not routinely fund more than 2 injections per pain episode; approval of further treatment will be needed through the IFR process.

If the first spinal injections elicited at least 50% improvement this needs to be documented in the case notes and if needed it can be repeated once without another Prior Approval request.

The SWL ICB does not routinely fund spinal injections for therapeutic indications.

## 1.2 Discectomy (open)

**Compliance requirement**

Prior Approval must be obtained by the treating clinician. This must include details of how the patient meets the criteria as specified on the Prior Approval Tick Box Form.

**Malignancy**

If there is any suspicion of malignancy, patients should be referred immediately to the appropriate service.

See the London Cancer guidance at: https://www.healthylondon.org/our-work/cancer/.

**Clinical threshold**

NB: closed discectomy is not routinely funded.

The SWL ICB funds this procedure when criteria (1 - 4) met.

1. Patient is 16 or over at the time of application

*NB. Children for complex pain management should receive their care at a specialist centre, the planning and funding for which is the responsibility of NHS England.*

**AND**

2. Patient has spinal pain (VAS>5) associated with radicular pain/myotomal pain consistent with the level of spinal involvement

*NB. Pre-procedure VAS score will need to be provided on the tick box form; other pain scales such as Oswestry or Roland Morris are also accepted.*

**AND**

3. Patients have acute, severe and unremitting sciatica concordant with disc herniation demonstrated on MRI scan within 12 weeks (unless contraindicated)

*NB. Date of MRI will need to be provided on the tick box form.*

**AND**

4. Patient has shown no sign of improvement despite conventional therapy for 12-weeks

Please note:

This policy only covers low back pain other indications of discectomy such as spinal compression or lumbar disc prolapse are outside of this policy.

## 1.3 Epidural injections for Back Pain

Injections into the epidural space, includes interlaminar, transforaminal, caudal approaches.

**Compliance requirement**

Prior Approval must be obtained by the treating clinician. This must include details of how the patient meets the criteria as specified on the Prior Approval tick box Form.

**Malignancy**

If there is any suspicion of malignancy, patients should be referred immediately to the appropriate service.

See the London Cancer guidance at: https://www.healthylondon.org/our-work/cancer/.

**Clinical threshold**

The SWL ICB will fund this procedure when all of the following criteria are met in Group 1, 2 or 3.

Group 1: First Injections criteria (1 – 4) must be met.

1. Patient is 16 or over at the time of application

*NB. Children for complex pain management should receive their care at a specialist centre, the planning and funding for which is the responsibility of NHS England.*

**AND**

2. Patient has spinal pain (VAS>5) associated with radicular pain/myotomal pain consistent with the level of spinal involvement

*NB. Pre-procedure VAS score will need to be provided on the tick box form; other pain scales such as Oswestry or Roland Morris are also accepted.*

**AND**

3. Patient has moderate-severe symptoms that have persisted for 12 weeks or more (earlier if there are motor symptoms or no access to MRI)

**AND**

4. Patient has shown no sign of improvement despite the conventional therapy of advice, reassurance, analgesia and manual therapy

Group 2: Repeat Injections criteria (5 – 7) must be met

5. Patient is 16 or over at the time of application

*NB. Children for complex pain management should receive their care at a specialist centre, the planning and funding for which is the responsibility of NHS England.*

**AND**

6. Patient has spinal pain associated with radicular pain/myotomal pain consistent with the level of spinal involvement

*NB. Pre-procedure VAS score will need to be provided on the tick box form; other pain scales such as Oswestry or Roland Morris are also accepted.*

**AND**

7. **Patient has improved by at least 50% following the previous epidural injection that lasted for a minimum of 6 months.**

*NB. Post-procedure VAS score will need to be provided on the tick box form; other pain scales such as Oswestry or Roland Morris are also accepted.*

Group 3: Complex patient criteria (8 – 10) must be met.

- **NB: Applications for this group must include detailed clinical background**

8. Patient has spinal pain (VAS>5) associated with radicular pain/myotomal pain consistent with the level of spinal involvement

*NB. Patient's VAS scores pre-; and post procedure will need to be provided on the tick box form; other pain scales such as Oswestry or Roland Morris are also accepted.*

**AND**

9. Patient is unable to self-manage and other treatment options have been unsuccessful or are inappropriate

*NB. Detailed clinical history is required with the application to state what treatments have been tried and if certain treatment modalities are not appropriate the reasoning for this.*

**AND**

10. **Patient has improved by at least 50% following the previous epidural injection that lasted for a minimum of 6 months (only applicable for repeat requests).**

*NB. Post-procedure VAS score will need to be provided on the tick box form; other pain scales such as Oswestry or Roland Morris are also accepted.*

Please note:

The SWL ICB does not routinely fund more than 3 injections per pain episode; approval of further treatment with epidural injections will be needed through the IFR process.

Epidurals are not indicated for back pain without radiculopathy.

Rationale for the clinical threshold

This policy has been developed to ensure that resources are targeted at those with the greatest clinical need. In addition, this policy aims to reduce the variation in access to this procedure.

Low back pain is a common disorder, affecting around one-third of the UK adult population each year. Around 20% of people with low back pain will consult their GP about it. In patients experiencing lower back pain, symptoms usually improve within weeks, however, about 10% remain off work and about 20% have persistent symptoms at one year.

Epidural injections are provided in order to provide temporary pain relief. They can break the cycle of pain and inflammation and allow for conservative treatment, including physiotherapy and guided exercise as part of a comprehensive pain management plan. In this way, the injections can provide benefits that outlast the effects of the steroid itself. For patients with non-specific back pain, NICE does not recommend the use of therapeutic injections. Although there appears to be short-term pain relief, trials do not show evidence of longer-term benefit on pain and function in patients with non-specific Chronic Low Back Pain (CLBP), spinal stenosis or

radicular CLBP. However, epidural steroid injections may bring short-term relief and are recommended as an option in patients with persistent radiculopathy due to herniated lumbar disc.

**Primary care advice**

Although primary care is not directly responsible for requesting prior approval, primary care needs to be aware of the detailed clinical criteria relating to this commissioning policy before referring the patient to the appropriate service.

Primary care must also ensure that they supply the all the relevant information to secondary care, particularly concerning symptoms and their duration and the conservative treatments tried including dates where relevant.

Epidural injections are provided to provide temporary pain relief. They can break the cycle of pain and inflammation and allow for conservative treatment, including physiotherapy and guided exercise as part of a comprehensive pain management plan. In this way, the injections can provide benefits that outlast the effects of the steroid itself.

For patients with non-specific back pain, NICE does not recommend the use of therapeutic injections.

**Conservative treatments**

Primary care should be aware of the conservative treatment options for managing of chronic low back pain which may include self-management, physiotherapy treatments and guided exercise programmes where a patient is able to participate, and pharmacotherapy including analgesia, as well as and psychological therapies (which may be combined with physical programmes) according to NICE recommendations. Where appropriate these options should be tried over a period of 12 months prior to referral.

Primary care should consider the use of risk stratification using the STarT back risk assessment tool.

The Comprehensive Pain Management Programme could be part of an MSK care pathway within the community (NB the role of the community MSK service is to accept referrals from GPs for assessment and treatment and for triaging of patients suitable for treatment in secondary care).

## 1.4 Spinal Decompression

Removal of pressure from the nervous structures within the spinal column.

**Compliance requirement**

Prior Approval must be obtained by the treating clinician. This must include details of how the patient meets the criteria as specified on the Prior Approval tick box Form.

Malignancy

If there is any suspicion of malignancy, patients should be referred immediately to the appropriate service.

See the London Cancer guidance at: https://www.healthylondon.org/our-work/cancer/.

**Clinical threshold**

The SWL ICB funds this procedure when criteria (1 - 4) met.

1. Patient is 16 or over at the time of application

*NB. Children for complex pain management should receive their care at a specialist centre, the planning and funding for which is the responsibility of NHS England.*

**AND**

2. Patient has spinal pain (VAS>5) associated with radicular pain/myotomal pain consistent with the level of spinal involvement

*NB. Pre-procedure VAS score will need to be provided on the tick box form; other pain scales such as Oswestry or Roland Morris are also accepted.*

**AND**

3. MRI scan (unless contraindicated) shows one or more areas of spinal stenosis whereby the pathology is concordant with the clinical diagnosis)

*NB. Date of MRI will need to be provided on the tick box form.*

**AND**

4. Patient has shown no sign of improvement despite conventional therapy for 12-months including advice, reassurance, analgesia and manual therapy

## 1.5 Radiofrequency Denervation

Including non-anterior radicular cervical, thoracic and lumbar areas

**Compliance requirement**

Prior Approval must be obtained by the treating clinician. This must include details of how the patient meets the criteria as specified on the Prior Approval tick box Form.

**Malignancy**

If there is any suspicion of malignancy, patients should be referred immediately to the appropriate service.

See the London Cancer guidance at: https://www.healthylondon.org/our-work/cancer/.

**Clinical threshold**

The SWL ICB funds this procedure when all of the following criteria are met in Group 1, 2 or 3.

Group 1: First Injections criteria (1 – 4) must be met.

1. Patient is 16 or over at the time of application

*NB. Children for complex pain management should receive their care at a specialist centre, the planning and funding for which is the responsibility of NHS England.*

**AND**

2. Patient has spinal pain (VAS>5)

*NB. Pre-procedure VAS score will need to be provided on the tick box form; other pain scales such as Oswestry or Roland Morris are also accepted.*

**AND**

3. Patient has had a 50% improvement in pain from a diagnostic medial branch block

*NB. Post-procedure VAS score will need to be provided on the tick box form; other pain scales such as Oswestry or Roland Morris are also accepted.*

**AND**

4. Patient has shown no sign of improvement despite conventional therapy of advice, reassurance, analgesia and manual therapy

Group 2: Repeat Injections criteria (5 – 7) must be met.

**NB: Applications for this group must include detailed clinical background**

5. Patient has spinal pain (VAS>5)

*NB. Patient's VAS scores pre-; and post procedure will need to be provided on the tick box form; other pain scales such as Oswestry or Roland Morris are also accepted.*

**AND**

6. Patient is unable to self-manage and other treatment options have been unsuccessful or are inappropriate

*NB. Detailed clinical history is required with the application to state what treatments have been tried and if certain treatment modalities are not appropriate the reasoning for this.*

**AND**

7. Patient has improved by at least 50% following the previous radiofrequency denervation that lasted for a minimum of 9 months (only applicable for repeat requests).

*NB. Post-procedure VAS score will need to be provided on the tick box form; other pain scales such as Oswestry or Roland Morris are also accepted.*

Please note:

The SWL ICB does not routinely fund more than 3 injections per pain episode; approval of further treatment with epidural injections will be needed through the IFR process.

The SWL ICB does not routinely fund pulsed radiofrequency denervation approval for these must be obtained via the IFR process if it is known before the procedures is agreed with the patient.

# 2. Breast Procedures

## 2.1 Breast enlargement

Breast augmentation/mammoplasty.

**Compliance requirement**

Providers should be aware that this procedure is not routinely funded in South West London, application only via the IFR process by the treating clinician.

**Clinical threshold**

The SWL ICB does not routinely fund this procedure.

## 2.2 Breast enlargement Revision

Revision breast augmentation/mammoplasty.

**Compliance requirement**

Prior Approval must be obtained by the treating clinician. This must include details of how the patient meets the criteria as specified on the Prior Approval tick box Form.

**Clinical threshold**

The SWL ICB funds this procedure when all of the following criteria are met in Group 1 or 2.

Group 1: Criteria 1 and 2 must be met

Women, whose implants were inserted for cosmetic reasons funding is provided for removal but not for replacement of breast implants according to the following criteria.

1. Patient is 18 or over at the time of application

**AND**

2. Patient has

a) Remnant breast cancer or cancer in the contralateral breast

**OR**

b) Implants complicated by recurrent infections

**OR**

c) Implants with Baker Class IV contracture associated with severe pain

**OR**

d) Implants with severe contracture that interferes with mammography

**OR**

e) Intra- or extra-capsular rupture of silicone gel-filled implants.

Group 2: Criteria 3 and 4 must be met

Women, whose implants were inserted for medical reasons funding is provided for removal and replacement of breast implants according to the following criteria.

3. Patient is 18 or over at the time of application

**AND**

4.Patient has

a) Remnant breast cancer or cancer in the contralateral breast

**OR**

b) Implants complicated by recurrent infections

**OR**

c) Implants with Baker Class III or IV contracture

**OR**

d) Implants with severe contracture that interferes with mammography

**OR**

e) Intra- or extra-capsular rupture of silicone gel-filled implants

**OR**

f) Extra-capsular rupture of saline implant if the rupture compromises the cosmetic outcome of the implant.

Please note:

Removal of ruptured saline-filled breast implants is not carried out for patients who have previously undergone cosmetic breast augmentation surgery.

Rationale for the clinical threshold

This policy has been developed to ensure that resources are targeted at those with the greatest clinical need. In addition, this policy aims to reduce the variation in access to this procedure.

Demand for breast enlargement is rising in the UK. Most breast implants are undertaken in the private health sector. Breast implants may be associated with significant morbidity and the need for secondary or revision surgery (such as implant replacement) at some point in the future is common. Capsular contracture is an unavoidable complication of breast implant surgery.

After having a breast implant, the body will create a capsule of fibrous scar tissue around the implant as part of the healing process. This is a natural reaction that occurs when any foreign object is surgically implanted into the body. Over time the scar tissue will begin to shrink. The shrinkage is known as capsular contraction. The rate and extent at which the shrinkage occurs varies from person to person. In some people, the capsule can tighten and squeeze the implant, making the breast feel hard and patients may also experience pain and discomfort. Implants have a variable life span and the need for replacement or removal in the future is likely in young patients.

The Department of Health advises patients contemplating private surgery that breast implants are considered a long-term commitment, and do not come with a lifetime guarantee. Moreover, not all patients demonstrate improvement in psychosocial outcome measures following breast augmentation. It is important that patients understand that they may not automatically be entitled to replacement of the implants in the future if they do not meet the criteria for augmentation at that time.

Primary care advice

Although primary care is not directly responsible for requesting prior approval, primary care needs to be aware of the detailed clinical criteria relating to this commissioning policy before referring the patient to the appropriate service.

Primary care must also make sure that they supply any relevant information to secondary care.

Primary care should assess the grade of capsular contraction where appropriate, according to the Baker Classification as given in the clinical threshold.

Primary care should be aware of information for patients who have received PIP silicone gel implants which is available via NHS Choices: http://www.nhs.uk/Conditions/Breast-implants/Pages/PIP-introduction.aspx. National guidance may apply to such patients.

Patients contemplating breast enlargement for cosmetic reasons can access information on breast implants via NHS Choices: http://www.nhs.uk/Conditions/Breast-implants/Pages/PIP-introduction.aspx

* Baker classification

| | |
|---|---|
| Class I | Augmented breast feels soft as a normal breast. |
| Class II | Augmented breast is less soft and implant can be palpated, but is not visible. |
| Class III | Augmented breast is firm, palpable and the implant (or distortion) is visible. |
| Class IV | Augmented breast is hard, painful, cold, tender, and distorted |

## 2.3 Breast lift (Mastopexy)

**Compliance requirement**

Providers should be aware that this procedure is not routinely funded in South West London, application only via the IFR process by the treating clinician.

**Clinical threshold**

The SWL ICB does not routinely fund this procedure.

## 2.4 Breast reduction surgery – Male (Gynaecomastia)

**Compliance Requirement**

Prior Approval must be obtained by the treating clinician. This must include details of how the patient meets the criteria as specified on the Prior Approval tick box form.

**Malignancy**

If there is any suspicion of malignancy, patients should be referred immediately to the appropriate service.

See the London Cancer guidance at: https://www.healthylondon.org/our-work/cancer/.

**Clinical threshold**

The SWL ICB funds this procedure when all of the following criteria (1 - 6) are met.

1. Patient is 18 or over at the time of application

**AND**

2. Patient's BMI equal to or below 25 and has maintained this for at least 12 months *NB. Patient's height and weight with dates will need to be provided on the tick box form.*

**AND**

3. Patient's smoking status has been noted and if a smoker then been advised to give up smoking (including referral to appropriate smoking cessation services)

**AND**

4. Patient has Grade III gynaecomastia

**AND**

5. Pseudo-Gynaecomastia has been ruled out

**AND**

6. Patient has been assessed and treated for any one of the following:

**a) Endocrinological causes (e.g. related to the balance of male and female hormones in the body).**

**OR**

**b) Therapeutic drug-related causes**

**OR**

**c) Recreational drug-related causes (including alcohol, cannabis and body building drugs containing anabolic steroids)**

**OR**

**d) Patient has Gynaecomastia as a result of drug therapy following prostate cancer**

**Rationale for the clinical threshold**

This policy has been developed to ensure that resources are targeted at those with the greatest clinical need. In addition, this policy aims to reduce the variation in access to this procedure.

Gynecomastia (NB including pseudo-gynaecomastia) is a common medical problem presenting in nearly a third of the male population. Treatment for gynecomastia can be either pharmacological or surgical, depending on the cause. Most cases of gynaecomastia are idiopathic.

Commonly gynaecomastia is seen during puberty and may correct once the post-pubertal fat distribution is complete if the patient has a normal BMI. It may be unilateral or bilateral. It can also occur secondary to medication. Rarely it may be caused by an underlying endocrine abnormality or a drug related cause including the abuse of anabolic steroids. 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.

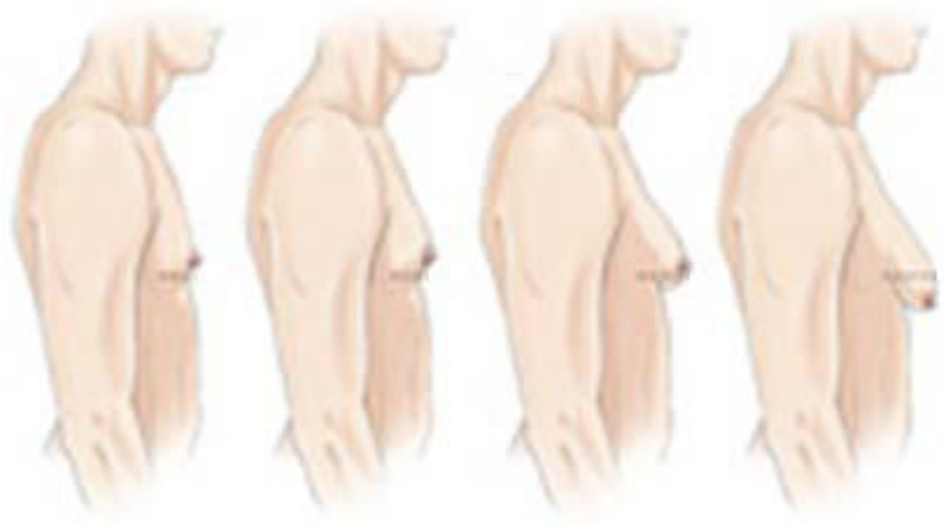
**Primary care advice**

Although primary care is not directly responsible for requesting prior approval, primary care needs to be aware of the detailed clinical criteria relating to this commissioning policy before referring the patient to the appropriate service.

Primary care must also make sure that they supply the relevant information to secondary care. In particular this includes smoking cessation services, duration or changes in patient BMI and the grade of gynecomastia.

Primary care should ensure that the patient has 'true' gynaecomastia (i.e., excess of breast tissue) as distinct from pseudo-gynaecomastia (i.e., excess of chest fat).

**Grading of gynaecomastia**



*I Minor but visible breast enlargement without skin redundancy*

*IIa 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*

Primary care needs to be aware that in some cases (following assessment) treatment may entail cessation of the drug-related cause, as a period of abstinence for one to three years will lead to the regression of Gynaecomastia in the vast majority of cases.

**Therapeutic drug-related causes**

Some drugs may give rise to Gynaecomastia. These include calcium channel blockers, cimetidine, phenothiazines, spironolactone, theophylline, diazepam, tricyclic anti-depressants, antibiotics and anti-retroviral therapy for HIV. Treatment in such cases should include consideration of substitution drug therapy.

## 2.5 Breast reduction surgery – Female (Reduction mammoplasty)

### Compliance requirement

Prior Approval must be obtained by the treating clinician. This must include details of how the patient meets the criteria as specified on the Prior Approval tick box form.

### Malignancy

If there is any suspicion of malignancy, patients should be referred immediately to the appropriate service.

See the London Cancer guidance at: https://www.healthylondon.org/our-work/cancer/.

### Clinical Threshold

The SWL ICB funds this procedure when all of the following criteria are met in Group 1 or 2.

Group 1: Criteria (1 – 5) must be met

1. Patient is 18 or over at the time of application and her breast development is considered to be complete

**AND**

2. Patient's BMI equal to or below 26, and has maintained this for at least 12 months

*NB. Patient's height and weight with dates will need to be provided on the tick box form*

**AND**

3. Patient's smoking status has been noted and if a smoker then been advised to give up smoking (including referral to appropriate smoking cessation services)

**AND**

4. Patient has been made aware of side-effects of breast reduction surgery including scarring, loss of sensitivity of nipples, and inability to breast feed post-surgery

**AND**

5. Patient has gross asymmetry of at least 3 cup sizes* difference between the breasts

*NB. Patient's cup sizes will need to be provided on the tick box form.*

Group 2: Criteria (6-11) must be met

6. Patient is 18 or over at the time of application and her breast development is considered complete

**AND**

7. Patient's BMI equal to or below 26, and has maintained this for at least 12 months

*NB. Patient's height and weight with dates will need to be provided on the tick box form*

**AND**

8. Patient's smoking status has been noted and if a smoker then been advised to give up smoking (including referral to appropriate smoking cessation services)

**AND**

9. Patient has a bra cup size of G or more

*NB. Patient's cup sizes will need to be provided on the tick box form.*

**AND**

10. Patient continues to have pain symptoms despite a 6-month trial of therapeutic measures including **ALL** of the following (unless clinically contra-indicated):

a) Use of an appropriate supportive bra with wide bra straps, where the advice of an expert bra-fitter has been sought.

b) Analgesic /non-steroidal anti-inflammatory drugs (NSAIDs) interventions.

c) A course of physiotherapy has been completed without improvement of symptoms.

**AND**

11. Patient must meet the following clinical criteria:

d) At least TWO of the following symptoms affecting their daily activities for at least 12 months:

i. Severe pain in the neck

ii. Severe pain in the shoulder or upper back

iii. Painful kyphosis documented by X-rays

iv. Pain/ ulceration from bra straps cutting into shoulders

**OR**

a) Chronic intertrigo, in the infra-mammary skin fold which has failed to respond to at least 6 months of documented conservative treatment, (including good skin hygiene, adequate nutrition, and antibiotics or antifungal therapy).

Please note:

Due to risks and long-term implications relating to breast implants, surgery to reduce the larger breast only will be approved (i.e. breast implants are not routinely funded).

Bra cup sizes: AA, A, B, C, D, DD, E, F, FF, G, GG, H, HH, J, JJ, K, L

**Rationale for the clinical threshold**

This policy has been developed to ensure that resources are targeted at those with the greatest clinical need. In addition, this policy aims to reduce the variation in access to this procedure.

All surgery involving incision into healthy tissue, in this case, a healthy breast, whatever its size and shape, is generally considered to be aesthetic, with a few exceptions which have been listed in this policy.

Gross asymmetry may be considered as a deformity, and breast reduction surgery may be carried out for clinical reasons if the size of breasts has led to the patient suffering from intractable back pain, despite trying a range of conservative measures. Reduction mammoplasty is performed to relieve back and shoulder pain on the theory that reducing breast weight will relieve this pain. Because of their inherently subjective nature, pain symptoms are especially prone to placebo effects. In the case of reduction mammoplasty for relief of back, neck and shoulder pain, Aetna considered this procedure medically necessary in women with excessively large breasts because it seems logical, even in the absence of firm clinical trial evidence, that this excessive weight would contribute to back and shoulder pain, and that removal of this excessive breast tissue would provide substantial pain relief, reductions in disability, and improvements in function.

**Primary care advice**

Although primary care is not directly responsible for requesting prior approval, primary care needs to be aware of the detailed clinical criteria relating to this commissioning policy before referring the patient to the appropriate secondary care service.

Primary care must also ensure that they supply the all the relevant information to secondary care, particularly concerning height with weight, therapeutic measures with dates and bra cup sizes.

Prior to referring the patient to secondary care, primary care should ensure that the patient meets the criterion for age, BMI and smoking cessation as specified in the clinical threshold. Primary care should also ensure that the severity of the patient's pain, together attempts to control this has been recorded in the patient's notes, as well as ensuring that all the criteria for conservative measures attempted over a period of 12 months are met (NB with the exception of referrals for gross asymmetry).

## 2.6 Surgical correction of nipple inversion

**Compliance requirement**

Providers should be aware that this procedure is not routinely funded in South West London, application only via the IFR process by the treating clinician.

**Malignancy**

If there is any suspicion of malignancy, patients should be referred immediately to the appropriate service.

See the London Cancer guidance at: https://www.healthylondon.org/our-work/cancer/.

**Clinical threshold**

The SWL ICB does not routinely fund this procedure.

# 3. Cosmetic Procedures

## 3.1 Botox injection for cosmetic reasons

**Compliance requirement**

Providers should be aware that this procedure is not routinely funded in South West London, application only via the IFR process by the treating clinician.

**Clinical threshold**

The SWL ICB does not routinely fund this procedure.

## 3.2 Body contouring surgery

(Abdominoplasty, apronectomy, panniculectomy, 'tummy tuck' procedures, excision of excess skin, buttock lift, thigh lift, arm lift, brachioplasty)

**Compliance requirement**

Prior Approval must be obtained by treating clinician. This must include details of how the patient meets the criteria as specified on the Prior Approval tick box form.

**Malignancy**

If there is any suspicion of malignancy, patients should be referred immediately to the appropriate service.

See the London Cancer guidance at: https://www.healthylondon.org/our-work/cancer/.

**Clinical threshold**

The SWL ICB funds this procedure when all of the following criteria are met in Group 1 or 2.

Group 1: Criteria (1-5) must be met

1. Patient is 18 or over at the time of application

**AND**

2. Patient has not already had the body contouring procedure(s) requested performed

**AND**

3. Patient's smoking status has been noted and if a smoker then been advised to give up smoking (including referral to appropriate smoking cessation services)

**AND**

**4. Patient maintains low and stable BMI:**

a) Post bariatric surgery – patient has lost at least 50% of their excess weight* and has maintained this for at least six months, and is at least 18 months post-op.

**OR**

b) Following significant weight loss (NB without bariatric surgery) – patient has BMI equal to or below 27 and has maintained this for at least 18 months

*NB. Patient's height and weight with dates will need to be provided on the tick box form.*

**AND**

5. Patient has

a) Severe difficulties with activities of daily living** (e.g. ambulatory restrictions) in relation to each of the affected body parts for which body contouring procedures are requested

**OR**

b) Evidence of recurrent intertrigo beneath the skin folds that fails to respond despite appropriate medical therapy (oral or topical prescription medication) for at least 6 months

Group 2: criteria (6-8) must be met (Abdominoplasty for problems with Stoma Bags)

6. Patient has a poorly fitting stoma bag where the problems are caused by an apron of loose abdominal skin

**AND**

7. Problems with the stoma bag are due to the apron of loose abdominal skin impacting on their ability to maintain hygiene standards

**AND**

8. Written clinical opinion from the specialist that abdominoplasty is necessary to enable them to maintain their use of stoma bags

*NB. Name of the specialist and the date of request for the procedure to maintain the use of the stoma bag will need to be provided on the tick box form.*

* Percentage of excess weight lost = $\frac{\text{initial weight – current weight}}{\text{initial weight – (25 x height}^2\text{)}} \times 100$

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

** For the purposes of this policy, 'activities of daily living' covers functions such as dressing, personal hygiene (washing and toileting), functional mobility (moving from one place to another to perform activities required in the home or at work), and meeting nutritional needs (shopping, preparing and eating food). Difficulties of activities of daily living, including where appropriate ambulatory restrictions, must be described and documented

Please note:

Body contouring comprises the removal of excess skin only. Liposuction does not form part of body contouring following significant weight loss.

Abdominoplasty or apronectomy (including panniculectomy) ('tummy tuck' procedures), together with other body contouring procedures (i.e. excision of excess skin, including buttock lift, thigh lift, arm lift (brachioplasty)) are considered cosmetic and will not be funded unless the above criteria are met.

It is important that patients who are considering bariatric surgery are given full information prior to undergoing surgery about the possible cosmetic consequences of significant weight loss following the bariatric procedure in terms of excess skin, and advised that they will not be eligible for abdominoplasty or any other body contouring procedure on the NHS unless these criteria are met in full for each procedure.

**Rationale for the clinical threshold**

This policy has been developed to ensure that resources are targeted at those with the greatest clinical need. In addition, this policy aims to reduce the variation in access to this procedure.

Removal of excess skin following bariatric surgery or massive weight loss is considered cosmetic and is not routinely funded in the absence of serious clinical symptoms, or serious loss of function affecting activities of daily living, and after conservative measures have been tried or failed (with the exception of patients having problems with poorly fitting stoma bags).

**Primary care advice**

Although primary care is not directly responsible for requesting prior approval, primary care needs to be aware of the detailed clinical criteria relating to this commissioning policy before referring the patient to the appropriate service.

Primary care must also make sure that they supply the relevant information to secondary care. In particular, primary care should ensure that the patient meets the clinical criteria for BMI or loss of excess weight, and the clinical criteria for maintaining a stable weight over the stipulated period of time (see clinical threshold). Primary care should also document the impact of the patient's excess skin on their activities of daily living.

Where recurrent intertrigo beneath the skin folds is a relevant clinical criterion (see 'clinical threshold' below), primary care should ensure that appropriate medical therapy (oral or topical prescription medication) has been tried for at least 6 months without success.

Primary care should ensure that patients are made aware of the possible cosmetic consequences of significant weight loss following a bariatric procedure in terms of excess skin and should advise them that they will not be eligible for NHS-funded abdominoplasty or any other body contouring procedure unless they have serious clinical symptoms and meet the criteria in the clinical threshold.

## 3.3 Face - Brow lift surgery (Rhytoidectomy)

**Compliance requirement**

Providers should be aware that this procedure is not routinely funded in South West London, application only via the IFR process by the treating clinician.

**Clinical threshold**

The SWL ICB does not routinely fund this procedure.

## 3.4 Fat removal (Liposuction)

**Compliance requirement**

Providers should be aware that this procedure is not routinely funded in South West London, application only via the IFR process by the treating clinician.

**Clinical threshold**

The SWL ICB does not routinely fund this procedure.

## 3.5 Hair removal (Hair depilation by Laser and Electrolysis)

**Compliance requirement**

Providers should be aware that this procedure is not routinely funded in South West London, application only via the IFR process by the treating clinician.

**Clinical threshold**

The SWL ICB does not routinely fund this procedure.

## 3.6 Hair replacement techniques

**Compliance requirement**

Providers should be aware that this procedure is not routinely funded in South West London, application only via the IFR process by the treating clinician.

**Clinical threshold**

The SWL ICB does not routinely fund this procedure.

## 3.7 Tattoo removal

**Compliance requirement**

Providers should be aware that this procedure is not routinely funded in South West London, application only via the IFR process by the treating clinician.

**Clinical threshold**

The SWL ICB does not routinely fund this procedure.

## 3.8 Treatment of hyperpigmentation

**Compliance requirement**

Providers should be aware that this procedure is not routinely funded in South West London, application only via the IFR process by the treating clinician.

**Clinical threshold**

The SWL ICB does not routinely fund this procedure.

# 4. Diagnostics

## 4.1 Open Magnetic Resonance Imaging (Open MRI)

**Compliance requirement**

Prior Approval must be obtained by the provider performing the intervention. Clinical teams must refer to the provider using the agreed referral form for Open MRI to ensure that the Prior Approval tick box form can be completed in full.

**Clinical threshold**

The SWL ICB funds this procedure (0.5 Tesla or more) when all of the following criteria (1 -2) are met.

1. There is a clear diagnostic need consistent with supported agreed local clinical pathways

**AND**

2. Patient

a) Cannot fit comfortably in a closed MRI machine due to obesity (measurements required with the application)

**OR**

b) Cannot lie properly in a closed MRI machine due to severe pain or other significant medical conditions (details of evidence must be provided with the application)

**OR**

c) Suffers from claustrophobia and has not been able tolerate a closed MRI (date of the attempted MRI must be provided with the application)

*NB. Details of the reason who the patient meets the criteria will need to be provided on the tick box form (e.g., date of attempted MRI).*

Please note:

The SWL ICB does not routinely fund this procedure:

- In standing, weight-bearing, positional, or upright MRI scanners
- For whole spine or body imaging (i.e., imaging for the specific anatomy requested will only be funded)

Low field MRI for interventional and intraoperative procedures fall outside the scope of this policy and do not require prior approval.

**Rationale for the clinical threshold**

This policy has been developed to ensure that resources are targeted at those with the greatest clinical need. In addition, this policy aims to reduce the variation in access to this procedure.

Open MRI should not be considered as an equally effective alternative for patients who express apprehension prior to closed MRI due to suspected claustrophobia. Such patients should be encouraged to attempt a closed MRI with the aid of an oral sedative. Only patient physically unable to undergo conventional MRI should be considered for open MRI. This is because 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 0.5T - 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, which may lead to a less distinct image due to movement of the patient.

**Primary care advice**

Primary care (and other clinical team) can request an Open MRI via the Open MRI referral form to In-Health. The following indications will meet the clinical threshold criteria for Open MRI, once there is a clinical indication for MRI in the first place. The following patient will be accepted:

- Cannot fit comfortably in a closed MRI machine due to obesity (measurements required with the application)
- Cannot lie properly in a closed MRI machine due to severe pain or other significant medical conditions (details of evidence must be provided with the application)
- Suffers from claustrophobia and has not been able tolerate a closed MRI (date of the attempted MRI must be provided with the application)

**Claustrophobia**

When requesting an MRI, the requesting clinician (primary or secondary care) should identify patients susceptible to claustrophobia or who may not be able to tolerate a closed MRI. By advising the radiology teams, they can support patients and possibly allow more time for the MRI.

**Closed vs. Open MRI**

Patients should be encouraged to have closed MRIs in all cases due to their effectiveness over Open MRIs. 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, which may lead to a less distinct image due to movement of the patient.

**MRI capacity**

| Location | Max weight | Bore size | Notes |
|---|---|---|---|
| Croydon Hospital 1 | 300kg | 180 cm | Open MRI |
| Croydon Hospital 2 | 200kg | 180cm | For patients on trolley |
| Epsom Hospital | 227kg | 70cm | Any patients |
| St Helier Hospital | 152kg | 50cm | Any patients |
| Queen Mary's Hospital – In Health | 140kg | 60 cm | Mobile unit |
| Kingston Hospital – In Health | 140kg | 60 cm | Mobile unit |
| St George's Hospital – In Health | 140kg | 60 cm | Mobile unit |
| St George's Hospital AMH | 200 kg | 65 cm | Neurology only<br>Secondary care only |
| Waterloo 1 – In Health | 160kg | 65 cm | Any patients |
| Waterloo 1 – In Health | 200kg | 72 cm | Mainly for private patients |

The girth of the patient and reason for the scan may impact on the need for open MRI and should take precedence over consideration of the patient's weight. For example, any scans to investigate back issues will require complete insertion of the patient into the conventional MRI machine, and a patient's girth may preclude this.

## 4.2 Wireless Capsule Endoscopy and Double Balloon Enteroscopy

**Compliance requirement**

Prior Approval must be obtained by the treating clinician. This must include details of how the patient meets the criteria as specified on the Prior Approval tick box form.

a) Clinical threshold for obscure gastrointestinal bleeding

The SWL ICB funds this procedure when at least one of the following criteria (1 -3) is met.

1. Patient had a gastroscopy and/or endoscopy and results are negative then patients are eligible for a **wireless capsule endoscopy**.

*NB. The date of the gastroscopy and/or endoscopy will need to be provided on the tick box form.*

**OR**

2. Patient had a wireless capsule endoscopy that identified the source of bleeding in small bowel then the patients are eligible for **double balloon enteroscopy for treatment**

*NB. The date of the wireless capsule endoscopy will need to be provided on the tick box form.*

**OR**

3. Patient had a wireless capsule endoscopy with normal results but there is persistent bleeding then the patient is eligible for a **repeat wireless capsule endoscopy or double balloon enteroscopy for treatment**

*NB. The date of the wireless capsule endoscopy will need to be provided on the tick box form.*

**Rationale for obscure gastrointestinal bleeding clinical threshold**

This policy has been developed to ensure that resources are targeted at those with the greatest clinical need. In addition, this policy aims to reduce the variation in access to this procedure.

The evidence available shows that Wireless Capsule Endoscopy (WCE) and Double Balloon Enteroscopy (DBE) are safe and effective diagnostic procedures for the detection of obscure gastrointestinal bleeding OGIB. Both have a higher diagnostic yield than conventional methods.

WCE and DBE have common indications but different features. WCE 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 WCE-guided DBE may be associated with better long-term outcomes because of the potential for fewer complications and decreased utilisation of endoscopic resources.

b) Clinical threshold for Crohn's disease

The SWL ICB funds this procedure when all of the following criteria are met in Group 1 or 2.

Group 1: Wireless capsule endoscopy - criteria 1 and 2 must be met.

1. Patient had an inconclusive ileocolonoscopy and/or small bowel radiology clinical suspicion of Crohn's disease remains

*NB. The date of the inconclusive ileocolonoscopy and/or small bowel radiology will need to be provided on the tick box form.*

**AND**

2. Pain is not a significant feature **or** where pain is a significant feature and there is no evidence of strictures on small bowel radiography.

Group 2: Double balloon enteroscopy - criteria 3 and 4 must be met.

3. Patient had an inconclusive ileocolonoscopy and/or small bowel radiology clinical suspicion of Crohn's disease remains

*NB. The date of the inconclusive ileocolonoscopy and/or small bowel radiology will need to be provided on the tick box form.*

**AND**

4.

a) Pain is a significant feature **and** there is evidence of strictures on small bowel radiography

**OR**

b) There is evidence of strictures on small bowel radiography

**OR**

c) Wireless capsule endoscopy results are inconclusive.

Rationale for Crohn's disease clinical threshold

This policy has been developed to ensure that resources are targeted at those with the greatest clinical need. In addition, this policy aims to reduce the variation in access to this procedure.

The evidence available shows that Wireless Capsule Endoscopy (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.

# 5. ENT

## 5.1 Interventions for Snoring (not OSA)

**Compliance requirement**

Providers should be aware that this procedure is not routinely funded in South West London, application only via the IFR process by the treating clinician.

**Clinical threshold**

The SWL ICB does not routinely fund this procedure.

## 5.2 Nasal Surgery (Rhinoplasty, Septoplasty, Septo-rhinoplasty, Nasal Polyps)

**Compliance requirement**

Prior Approval must be obtained by the treating clinician. This must include details of how the patient meets the criteria as specified on the Prior Approval tick box form.

**Malignancy**

If there is any suspicion of malignancy, patients should be referred immediately to the appropriate service.

See the London Cancer guidance at: https://www.healthylondon.org/our-work/cancer/.

**Clinical threshold**

The SWL ICB funds this procedure when all of the following criteria are met in Group 1, 2, 3, 4 or 5.

Group 1: Intra-nasal septoplasty: at least one of criteria are met.

1. Patient is/has

**a) Asymptomatic septal deformity that prevents access to other intranasal areas when such access is required to perform medical necessary surgical procedures (e.g., ethmoidectomy)**

**OR**

**b) Patient has recurrent rhino-sinusitis due to a deviated septum not relieved by appropriate medical and antibiotic therapy after at least 6 months of medical therapy**

**OR**

**c) Patient suffers from recurrent epistaxis (nosebleeds) related to a septal deformity**

**OR**

**d) Patient suffers from continuous nasal airway obstruction resulting in nasal breathing difficulty due to obvious and severe septal deviation with no other cause for the patient's apparent breathlessness (e.g., rhinitis, COPD)**

**OR**

e) **Patient requires this procedure with the association of cleft palate repair.**

Group 2: Extracorporeal (Open) Septoplasty: criteria 2 and 3 must be met.

2.Patient is/has

f) **Asymptomatic septal deformity that prevents access to other intranasal areas when such access is required to perform medical necessary surgical procedures (e.g., ethmoidectomy)**

**OR**

g) **Patient has recurrent rhino-sinusitis due to a deviated septum not relieved by appropriate medical and antibiotic therapy after at least 6 months of medical therapy**

**OR**

h) **Patient suffers from recurrent epistaxis (nosebleeds) related to a septal deformity**

**OR**

i) **Patient suffers from continuous nasal airway obstruction resulting in nasal breathing difficulty due to obvious and severe septal deviation with no other cause for the patient's apparent breathlessness (e.g., rhinitis, COPD)**

**OR**

j) **Patient requires this procedure with the association of cleft palate repair.**

**AND**

3. Patient has an extremely deviated nasal septum that cannot be corrected adequately with an intranasal septoplasty.

Group 3: Rhinoplasty: criteria 4 must be met.

4. Patient is/has

a) **Nasal deformity is secondary to congenital cleft lip and/or palate**

- **NB: this should be managed by a specialist cleft team**

**OR**

**b) Chronic non-septal nasal airway obstruction from vestibular stenosis (collapsed internal valves), which may be due to trauma, disease, or congenital defect, when**

- **ALL of the following criteria are met:**

**i. Prolonged, persistent obstructed nasal breathing**

**ii. Physical examination confirming moderate to severe vestibular obstruction**

**iii. Airway obstruction will not respond to septoplasty alone**

**iv. Nasal obstruction is causing significant symptoms (e.g., chronic rhinosinusitis, difficulty breathing)**

**v. Conservative management for 6 months or more failed to relieve symptoms**

**vi. Patient suffers from severe or extreme obstruction of one or both nares.**

- **NB: Recommend use of Nasal Obstruction Symptom Evaluation (NOSE) Scale instrument (score 55 or more) see Appendix**

**OR**

**c) Significant distortion of external anatomy subsequent to recent trauma**

- **NB: A humped or bent nose is not by itself sufficient evidence of injury.**

Group 4: Septorhinoplasty: criteria 5 and 6 must be met.

5. Patient requires the procedure as an integral part of a medically necessary septoplasty.

**AND**

6. Patient has gross nasal obstruction on the same side as the septal deviation, so that to correct the nasal obstruction the external skeleton will also need correction.

Group 5 Surgery for Nasal Polyps criteria 7 or 8 must be met.

7. Patient has a nasal polyp that

**d) Fails to improve after a trial of maximal medical treatment for a period of at least 6 months**

**AND**

**e) Causing severe or extreme functional impairment of breathing**

- **NB: Recommend use of Nasal Obstruction Symptom Evaluation (NOSE) Scale instrument (score 55 or more) see Appendix.**

**OR**

8. Patient has a large nasal polyp causing complete obstruction of the nasal cavity.

Please note the SWL ICB does not routinely fund the following procedures:

- **Inferior Turbinate reduction surgery such as Turbinoplasty, Radiofrequency Ablation and Turbinectomy**
- **Surgery to repair septal perforation**
- **Extracorporeal septoplasty for revision of deviated septum is considered experimental and investigational because its effectiveness for this indication has not been established.**

**Rationale for the clinical thresholds**

This policy has been developed to ensure that resources are targeted at those with the greatest clinical need.

Rhinoplasty is considered an aesthetic procedure and no evidence was found for its use in treating any underlying medical conditions.

Septoplasty is an effective intervention in patients who have known septal deviation causing nasal obstruction. Outcomes are best where non-invasive interventions have failed, and the nasal obstruction is having an impact on the individual's quality of life.

Where the obstruction is the result of trauma, septo-rhinoplasty may be indicated to get the best outcome for the patient.

There is evidence from randomised controlled trials that conventional medical management with saline irrigation, antibiotics, corticosteroids and short-term decongestants is effective for the treatment of chronic rhinosinusitis, and that corticosteroids are effective for the treatment of nasal polyps. Surgical management of chronic rhinosinusitis has not been shown to be more effective compared with medical management in randomised controlled trials of patients with or without nasal polyps.

**Primary care advice**

Although primary care is not directly responsible for requesting prior approval, primary care needs to be aware of the detailed clinical criteria relating to this commissioning policy before referring the patient to the appropriate secondary care service.

Primary care must also ensure that they supply the all the relevant information to secondary care, particularly concerning conservative treatments attempted.

**Documentation**

For consideration for rhinoplasty or septorhinoplasty is maintained and includes all of the following:

Documentation of duration and degree of symptoms related to nasal obstruction, such as chronic rhinosinusitis, mouth breathing, etc.

Documentation of results of conservative management of symptoms.

If there is an external nasal deformity, pre-operative photographs may be helpful if the patient agrees but are not an essential requirement.

It is essential that any relevant history of accidental or surgical trauma, congenital defect, or disease (e.g., Wegener's granulomatosis, choanal atresia, nasal malignancy, abscess, septal infection with saddle deformity, or congenital deformity) be provided.

There is severe or extreme obstruction of one or both nares. The use of Nasal Obstruction Symptom Evaluation (NOSE) Scale instrument (score 55 or more) is recommended (see Appendix).

**Conservative management**

Primary care should be aware that conventional medical management with saline irrigation, antibiotics, corticosteroids and short-term decongestants is effective for the treatment of chronic rhinosinusitis.

**Appendix: Nasal Obstruction Symptom Evaluation (NOSE) Scale instrument**

**Nasal Obstruction and Septoplasty Effectiveness Scale**

**Physician AAO-HNS#:**_____ **Patient ID:** _____ **Today's date:** __ __/__ __/__ __ __ __

➔ **To the Patient:** Please help us to better understand the impact of nasal obstruction on your quality of life by **completing following survey**. Thank You!

**Over the past *ONE* month, how much of a problem were the following conditions for you?**

**Please circle the most correct response**

| | *Not a Problem* | *Very Mild Problem* | *Moderate problem* | *Fairly Bad Problem* | *Severe problem* |
|---|---|---|---|---|---|
| 1. Nasal congestion or stuffiness | 0 | 1 | 2 | 3 | 4 |
| 2. Nasal blockage or obstruction | 0 | 1 | 2 | 3 | 4 |
| 3. Trouble breathing through my nose | 0 | 1 | 2 | 3 | 4 |
| 4. Trouble sleeping | 0 | 1 | 2 | 3 | 4 |
| 5. Unable to get enough air through my nose during exercise or exertion | 0 | 1 | 2 | 3 | 4 |

NOSE SCALE ADMINISTRATION

1. **Have patient complete the questionnaire as indicated by circling the response closest to describing their current symptoms.**

2. **Sum the answers the patient circles and multiply by 20 to base the scale out of a possible score of 100 for analysis.**

| **Category** | **Score range** |
|---|---|
| Mild | 5 - 25 |
| Moderate | 30 - 50 |
| Severe | 55 – 75 |
| Extreme | 80 - 100 |

jamanetwork.com/journals/jamafacialplasticsurgery/fullarticle/1709837

## 5.3 Surgery for glue ear - Adults (Grommets)

**Compliance requirement**

Prior Approval must be obtained by the treating clinician care. This must include details of how the patient meets the criteria as specified on the Prior Approval tick box form.

**Malignancy**

If there is any suspicion of malignancy, patients should be referred immediately to the appropriate service.

See the London Cancer guidance at: https://www.healthylondon.org/our-work/cancer/.

**Clinical threshold**

The SWL ICB funds this procedure when all of the following criteria are met in Group 1 or 2.

**NB: repeat grommets must meet the same criteria and require a new prior approval.**

Group 1: Criteria (1 – 5) must be met.

1. Patient has persistent bilateral Otitis Media with Effusion (OME) over a period of 6 months

*NB. The dates of the first and the second confirmatory audiological tests will need to be provided on the tick box form (minimum 6 months in between the two).*

**AND**

2. Patient's hearing level in the better ear of at least 25 dBHL (decibels hearing level) or worse, based on averages at 0.5, 1, 2 and 4 kHz

*NB. The results of the last audiological test will need to be provided on the tick box form.*

**AND**

3. Patient suffers from conductive hearing loss due to OME confirmed by audiology assessment.

**AND**

4. Investigation and treatment of underlying causes has been completed without improvement in hearing.

**AND**

5. Patient has been engaged in shared decision making to ensure he/she is well informed about the treatment options available and personal values, preferences and circumstances are taken into consideration

*NB: It is recommended that the SWL Patient Decision Aid is completed. This needs to be recorded in the patient's medical notes, including the written or other materials provided.*

Group 2: Criteria 6 and 7 must be met

6. Patient has a severe retraction of the tympanic membrane that is considered to be reversible to avoid erosion of the ossicular chain or the development of cholesteatoma.

**AND**

7. Patient has been engaged in shared decision making to ensure he/she is well informed about the treatment options available and personal values, preferences and circumstances are taken into consideration

*NB: It is recommended that the SWL Patient Decision Aid is completed. This needs to be recorded in the patient's medical notes, including the written or other materials provided.*

**Rationale for the clinical threshold**

This policy has been developed to ensure that resources are targeted at those with the greatest clinical need. In addition, this policy aims to reduce the variation in access to this procedure.

National guidance advises that management of adults with Otitis Media with Effusion (OME) should focus on determining the underlying cause.

The outcome of OME is less clear in adults than children. Insertion of grommets in adults is a much less common procedure than in children, primarily because adults benefit from certain changes in the anatomy of the middle ear that occur after childhood.

Grommet insertion in adults with OME is a procedure with limited or no evidence of effectiveness and/or only effective within a limited threshold range.

**Primary care advice**

Although primary care is not directly responsible for requesting prior approval, primary care needs to be aware of the detailed clinical criteria relating to this commissioning policy before referring the patient to the appropriate secondary care service.

Primary care must also ensure that they supply the all the relevant information to secondary care in particular dates and results of audiological tests.

The lack of published research trials means that there is a high level of uncertainty about the benefits, harms and costs of myringotomy with or without grommet insertion as a means of relieving symptoms of OME in adults.

Primary care should be aware that:

Management of adults with OME should focus on determining the underlying cause.

Grommet insertion is rarely indicated for adults with OME, and that the main role is to ensure that adequate investigations are done if OME fails to resolve spontaneously.

At least 6 months (24 weeks) should have elapsed between the first and the second confirmatory audiological tests before referring for consideration of surgery.

Primary care should refer adults to ENT for assessment of persistent OME in order to exclude underlying malignancy.

## 5.4 Surgery for glue ear - Children (Grommets)

**Compliance requirement**

Prior Approval must be obtained by the treating clinician. This must include details of how the patient meets the criteria as specified on the Prior Approval tick box form.

**Malignancy**

If there is any suspicion of malignancy, patients should be referred immediately to the appropriate service.

See the London Cancer guidance at: https://www.healthylondon.org/our-work/cancer/.

**Clinical threshold**

The SWL ICB funds this procedure when all of the following criteria are met in Group 1, 2 or 3.

**NB: repeat grommets must meet the same criteria and require a new prior approval.**

Group 1: Children under 12 criteria (1 – 4) must be met.

1. Patient has persistent bilateral Otitis Media with Effusion (OME) over a period of 3 months

*NB. The dates of the first and the second confirmatory audiological tests will need to be provided on the tick box form (minimum 3 months in between the two).*

**AND**

2. Patient's hearing level in the better ear of at least 25 dBHL (decibels hearing level) or worse based on average at 0.5, 1, 2 and 4 kHz

*NB. The results of the last audiological test will need to be provided on the tick box form.*

**AND**

3. Patient suffers from conductive hearing loss due to OME confirmed by audiology assessment at 3 months.

**AND**

4. Patient or their carer has been engaged in shared decision making to ensure he/she is well informed about the treatment options available and personal values, preferences and circumstances are taken into consideration

*NB: It is recommended that the SWL Patient Decision Aid is completed. This needs to be recorded in the patient's medical notes, including the written or other materials provided.*

Group 2 - Children 12 to under 18: criteria (5 – 8) must be met

5. Patient has persistent bilateral Otitis Media with Effusion (OME) over a period of 6 months

*NB. The dates of the first and the second confirmatory audiological tests will need to be provided on the tick box form (minimum 6 months in between the two).*

**AND**

6. Patient's hearing level in the better ear of at least 25 dBHL (decibels hearing level) or worse based on average at 0.5, 1, 2 and 4 kHz

*NB. The results of the last audiological test will need to be provided on the tick box form.*

**AND**

7. Patient suffers from conductive hearing loss due to OME confirmed by audiology assessment at 6 months.

**AND**

8. Patient or their carer has been engaged in shared decision making to ensure he/she is well informed about the treatment options available and personal values, preferences and circumstances are taken into consideration

*NB: It is recommended that the SWL Patient Decision Aid is completed. This needs to be recorded in the patient's medical notes, including the written or other materials provided.*

Group 3: Children under 18 with complex conditions: criteria 9 and 10 must be met

9. Patient is/has

**a) Preparing for insertion of cochlear implants**

**OR**

b) Severe learning difficulties and is suspected to have impaired hearing.

**AND**

10. Patient or their carer has been engaged in shared decision making to ensure he/she is well informed about the treatment options available and personal values, preferences and circumstances are taken into consideration

*NB: It is recommended that the SWL Patient Decision Aid is completed. This needs to be recorded in the patient's medical notes, including the written or other materials provided.*

**Rationale for the clinical threshold**

This policy has been developed to ensure that resources are targeted at those with the greatest clinical need. In addition, this policy aims to reduce the variation in access to this procedure.

The clinical threshold is based on NICE guidance surgical management of Otitis Media with Effusion (OME) in children (NICE CG60).

OME is a common condition of early childhood in which an accumulation of fluid within the middle ear space causes hearing impairment. The clinical criteria require the monitoring of persistent OME associated with significant hearing loss over a period of time (which is shorter for the younger age range), in view of the following:

The hearing loss is usually transient and self-limiting over several weeks, but may be more persistent and lead to educational, language and behavioural problems.

It is most common in young children, with a bimodal peak at 2 and 5 years of age; 80% of children will have had at least one episode of OME by the age of 10 years.

In most instances of uncomplicated OME, no intervention is required because the fluid clears spontaneously.

In cases of significant hearing loss sustained over a period of several months, surgical insertion of grommets may be beneficial in terms of the child's development in the domestic and educational environment.

However, these benefits should be balanced against the risks of serious complications of anaesthesia and surgery.

Children with certain specified complex conditions may also be funded for insertion of grommets.

**Primary care advice**

Although primary care is not directly responsible for requesting prior approval, primary care needs to be aware of the detailed clinical criteria relating to this commissioning policy before referring the patient to the appropriate secondary care service.

Primary care must also ensure that they supply the all the relevant information to secondary care in particular dates and results of audiological tests.

**Advice for parents during the period of assessment**

Primary care should be aware of the types of advice to give to parents and patients during the active observation period. This should include advice on the following strategies to minimise the effects of the hearing loss in the home and school environments:

When speaking to the child, face them, slow the rate of speech, raise the level, and speak clearly.

Turn off competing auditory stimuli, such as music or television.

Daily reading helps language development. Books with explanatory pictures are useful.

Discuss seating arrangements with the school, ideally placing the child near the teacher.

Parents of children should be advised that parental smoking increases the risk of OME. Parents with concern of speech, language and developmental delay of their child should be advised that the evidence shows that the child quickly recovers following resolution of the OME.

Referral of children for an ENT opinion from primary care is advised:

Urgent:

The child has hearing loss suggestive of sensori-neural deafness

The otoscopic features are atypical and accompanied by a foul-smelling discharge lasting for more than 6 weeks, suggestive of cholesteatoma.

Soon:

There is a reasonable suspicion of hearing loss plus a delay in speech or language development, poor educational progress, social or behavioural problems or another disability such as Down's syndrome or cleft palate.

Routine:

The child has persistent hearing loss detected on two occasions separated by 3 months or more; NICE guidelines suggest a threshold of 25 dBHL or worse in the better ear,

The child has suffered more than 6 episodes of acute otitis media effusion in 12 months.

Primary care should refer to audiology services (school, community or secondary care) prior to making routine referrals to ENT services and include the audiology report with the referral.

## 5.5 Surgery for Obstructive Sleep Apnoea in Adults

**Compliance requirement**

Prior Approval must be obtained by the treating clinician. This must include details of how the patient meets the criteria as specified on the Prior Approval tick box form.

**Clinical threshold**

The SWL ICB funds this procedure when all of the following criteria (1 -5) are met.

NB: OSA for children is covered in the Tonsillectomy clinical threshold

Snoring is covered in the Interventions for Snoring (not OSA) policy.

1. Patient has moderate to severe symptoms (Epworth score 15 or above) or sleepy in dangerous situations such as driving.

**AND**

2. Patient has significant sleep disordered breathing.

**AND**

3. Patient has already tried the entire range of conservative therapies available.

**AND**

4. Patient has already tried Continuous Positive Airways Pressure (CPAP) unsuccessfully for 6 months prior to being considered for surgery or had major side effects to CPAP such as significant nosebleeds.

**AND**

5. Patient has been engaged in shared decision making to ensure he/she is well informed about the treatment options available and personal values, preferences and circumstances are taken into consideration

*NB: It is recommended that the SWL Patient Decision Aid is completed. This needs to be recorded in the patient's medical notes, including the written or other materials provided.*

Please note:

The SWL ICB does not routinely fund this procedure to reduce the impact of normal snoring.

Surgical treatments specifically for OSA such as uvulopalatopharyngoplasty (UPPP), laser-assisted uvuloplatoplasty (LAUP), soft palate implants, and radiofrequency ablation are not routinely funded. These should be considered as a last resort as a one-off exceptional treatment where all other treatments have failed.

The choice of procedure should be decided based on a multi-disciplinary team planning approach between all specialists treating the patient.

**Rationale for the clinical threshold**

This policy has been developed to ensure that resources are targeted at those with the greatest clinical need. In addition, this policy aims to reduce the variation in access to this procedure.

Surgery to treat OSA is not routinely recommended because evidence shows that it is not as effective as CPAP at controlling the symptoms of the condition. It also carries the risk of more

serious complications. Surgery is usually only considered as a last resort when all other treatment options have failed, and only if the condition is severely affecting quality of life.

**Primary care advice**

Although primary care is not directly responsible for requesting prior approval, primary care needs to be aware of the detailed clinical criteria relating to this commissioning policy before referring the patient to the appropriate service.

Primary care should ensure that patients attempt the following range of lifestyle changes and conservative therapies **before referring them for consideration for surgery for OSA.** In addition, patients complaining of the impact of snoring (i.e., not OSA) should be counselled without referral to secondary care, and advice should be given on implementing the following lifestyle changes and conservative therapies where appropriate:

Lose weight if above recommended BMI

Advised to stop smoking if a smoker

Reduce or stop evening alcohol intake

Keeping the nose clear (including therapies such as nasal sprays or strips)

Partners using ear plugs whilst asleep to minimise sleep disruption

Self-training to alter their sleep position to avoid lying on back (e.g., sewing lump into back of pyjamas/nightdress as temporary training method).

Obtaining a mandibular advancement device to be worn at night. (NB patients may obtain this device from their orthodontist and should be advised that this device is not funded by the NHS.)

In addition, patients suffering from OSA should attempt Continuous Positive Airways Pressure (CPAP).

Please note OSA for children is covered in the tonsillectomy clinical threshold.

## 5.6 Surgical correction of prominent ears (Pinnaplasty)

**Compliance requirement**

Prior Approval must be obtained by treating clinician. This must include details of how the patient meets the criteria as specified on the Prior Approval tick box form.

**Clinical threshold**

The SWL ICB funds this procedure when all of the following criteria (1 - 4) are met.

1. Patient is aged between 5 and 18 years of age at the time of application

**AND**

2. Patient suffers from psychological distress due to prominent ears in whom corrective surgery should help to resolve these issues

*NB: Evidence of episodes of bullying and/or school refusal will need to be provided on the tick box form.*

**AND**

3. The prominence measures >30mm (using the measuring guide below)

*NB: Measurements of the prominence will need to be provided on the tick box form.*

**AND**

4. Patient has been engaged in shared decision making to ensure he/she is well informed about the treatment options available and personal values, preferences and circumstances are taken into consideration

It is recommended that the SWL Patient Decision Aid is completed.

NB: It is the child (and not the parent/carer) who desires surgical correction; referral should not be made for children who appear indifferent or opposed to the idea of surgery. This needs to be recorded in the patient's medical notes, including the written or other materials provided.

Please note:

The SWL ICB does not routinely fund this procedure for:

- **Adults with prominent ears**

- **Prophylactic reasons in either adults or children**

Surgery below the age of 5 should only be offered if correction of prominence will help in retaining hearing aids securely, in children for whom they are required.

**Rationale for the clinical threshold**

This policy has been developed to ensure that resources are targeted at those with the greatest clinical need. In addition, this policy aims to reduce the variation in access to this procedure.

Prominent ears are an inherited problem affecting 1-2% of the population (although its diagnosis is somewhat subjective, and this figure depends on what is considered to be a prominent ear). It may be unilateral or bilateral and arises as a result of a lack (or malformation) of cartilage during primitive ear development in intrauterine life. The ear subsequently has abnormal helical folds or grows laterally. Occasionally, folds seen at birth resolve spontaneously (source: www.patient.co.uk).

Prominence of the ears is often associated with bullying and consequent significant psychological distress. In individuals in whom distress is high, psychological therapy, whether or not subsequent surgery is offered, should be provided.

**Primary care advice**

Although primary care is not directly responsible for requesting prior approval, primary care needs to be aware of the detailed clinical criteria relating to this commissioning policy before referring the patient to the appropriate service.

Primary care must also ensure that they supply the all the relevant information to secondary care, particularly about psychological distress and measurements of prominence.

This procedure is for patients aged between 5 and 18 who suffer from psychological distress due to prominent ears. Evidence of this could be documented episodes of bullying and or school refusal.

Patients should desire surgical correction, not the parent of carer. Referral should not be made for children who appear indifferent or opposed to the idea of surgery.

Cartilage moulding devices are advised in infants up to 6 months of age (this is not funded on the NHS).

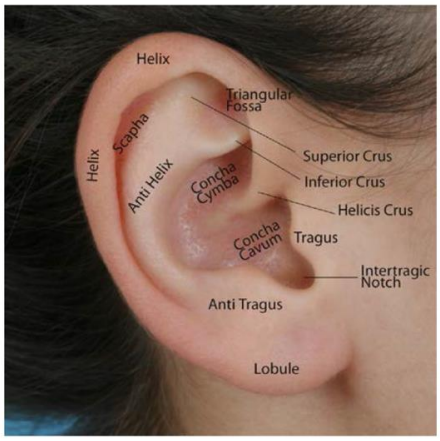
This procedure is not routinely funded for cosmetic reason or for any reason for adults.

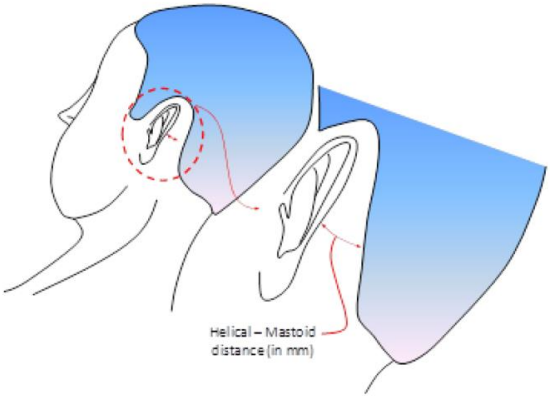
Measuring Guide:

One of the most consistent methods for measuring the degree of prominence is the helical-mastoid (H-M) distance. Typically, the HM distance is 18-20 mm. As the H-M distance increases, the ear is perceived to be increasingly prominent.

Measure from the posterior aspect of the Helix. Prominence = H-M distance > 20mm, but Surgical correction of prominent ears will only be considered in patients who have a >30mm prominence, unless there are other considerations e.g. in helping to retain hearing aids.

See diagram below for guidance on how to measure.




Psychological Distress:

Parents requesting surgery for their child in order to prevent psychological distress when their child starts school or at some time in the future should be advised that referral should wait until their child specifically requests treatment.

Prominence of the ears is often associated with bullying and consequent significant psychological distress. In individuals in whom distress is high, psychological therapy, whether or not subsequent surgery is offered, should be provided.

## 5.7 Surgical repair of external ear lobe (Lobules)

**Compliance requirement**

Providers should be aware that this procedure is not routinely funded in South West London, application only via the IFR process by the treating clinician.

**Clinical threshold**

The SWL ICB does not routinely fund this procedure.

Please note:

Repair of split ear lobes is generally considered to be an aesthetic procedure and is normally only available where the ear lobes have split as a result of direct trauma. Repair should be carried out in the period immediately following the trauma unless clinically contraindicated. When repaired in this time frame the repair will be considered to be an integral part of the standard care pathway for trauma aftercare.

Where repair was deferred as the result of a clinical decision at the time the original trauma was managed due to the clinical team assigning a lower priority to repairing the earlobe damage than dealing with other injuries or where other surgery needed to be completed before the repair to the earlobe was

carried out. The deferred repair will be commissioned via monitored approval however the decision to delay repair should be clearly recorded in the patient's clinical notes.

Where repair of an earlobe has been funded it is on the understanding that the ear will not be re-pierced.

Repair of a split/tear (or cleft) that is result of the wearing of heavy ornamentation is not commissioned.

Repair of a hole in the ear lobe resulting from gauge piercing is not commissioned.

## 5.8 Tonsillectomy

**Compliance requirement**

Prior Approval must be obtained by secondary care. This must include details of how the patient meets the criteria as specified on the Prior Approval tick box form.

**Clinical threshold**

The SWL ICB funds this procedure when all of the following criteria (1 -5) are met.

NB*:* OSA for adults is covered in the OSA in Adults clinical threshold

**Clinical threshold**

The SWL ICB funds this procedure when all of the following criteria are met in Group 1, 2 or 3.

Group 1: Quinsy: criteria 1 must be met.

1. Patient has had two or more episodes of Peri-tonsillar abscess (Quinsy) requiring hospital admission

*NB. The dates of admissions will need to be provided on the tick box form.*

Group 2: Tonsillar enlargement causing upper airways obstruction: criteria 2 and 3 must be met.

2.Patient suffers from recurrent sore throat due to acute tonsillitis

a) **7 or more episodes of tonsillitis in the last year**

**OR**

b) **5 episodes per year in the preceding two years**

**OR**

c) **3 episodes per year in the preceding three years**

*NB. Referral letters from GPs providing the dates or clearly stating the number of episodes the patient had in a given timeframe will be accepted on the tick box form.*

**AND**

3. Patient experiences significant impact on quality of life due to acute tonsillitis.

Group 3: Obstructive Sleep Apnoea children: criteria (4 – 6) must be met.

4. Patient experiences significant impact on quality of life.

**AND**

5. Patient's

**d) Medical notes show strong clinical history suggestive of sleep apnoea**

OR

**e) A habitual snorer with labored breathing and falls into complex high-risk category for sleep apnoea:**

**f) Down's syndrome**

**g) Cerebral palsy**

**h) Craniofacial disorders**

**i) Chronic lung disease**

**j) Sickle cell disease**

**k) Neuromuscular disorders**

**l) Genetic/metabolic/storage disease**

**m) Central hyperventilation syndromes.**

**AND**

6. Patient has been engaged in shared decision making to ensure he/she is well informed about the treatment options available and personal values, preferences and circumstances are taken into consideration

*NB: It is recommended that the SWL Patient Decision Aid is completed. This needs to be recorded in the patient's medical notes, including the written or other materials provided.*

Please note:

The SWL ICB does not routinely fund this procedure for:

- **Tonsillar Crypts**
- **Tonsilloliths**
- **Tonsillar Stones**

**Rationale for the clinical threshold**

This policy has been developed to ensure that resources are targeted at those with the greatest clinical need. In addition, this policy aims to reduce the variation in access to this procedure.

The natural history of tonsillitis is for the episodes to get less frequent with time.

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.

Watchful waiting is more appropriate than tonsillectomy in children with mild sore throats.

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

**Primary care advice**

Although primary care is not directly responsible for requesting prior approval, primary care needs to be aware of the detailed clinical criteria relating to this commissioning policy before referring the patient to the appropriate service.

Primary care must also make sure that they supply the relevant information to secondary care or referrals may be rejected if for example the dates of tonsillitis are not provided.

Primary care should inform patients about the risks and benefits of the possible procedure by leaflets and shared decision aids.

As there are multiple indications for tonsillectomy, careful assessment of the patients is essential. For assessment for referral, Primary care should follow the SIGN guidance for sore throat and management of tonsillectomy: http://www.sign.ac.uk/sign-117-management-of-sore-throat-and-indications-for-tonsillectomy.html

Sleep apnoea

Primary care should not refer children with simple snoring without symptoms or signs of apnoea as they are unlikely to benefit from adeno-tonsillectomy. Consider allergy testing and appropriate treatment first.

In older children >6 years with mild/moderate symptoms of obstructive sleep disordered breathing consider a trial of nasal saline irrigation and/or intranasal steroids for 6-8 weeks.

However, patients who are high risk for sleep apnoea may benefit from referral to specialist services if they suffer from laboured breathing. These risk factors are:

- Down’s syndrome
- Cerebral palsy
- Craniofacial disorders
- Chronic lung disease
- Sickle cell disease
- Neuromuscular disorders
- Genetic/metabolic/storage disease
- Central hyperventilation syndromes.

# 6 Eyes

## 6.1 Cataract surgery

**Compliance requirement**

Prior Approval must be obtained by secondary care. This must include details of how the patient meets the criteria as specified on the Prior Approval tick box form.

**Malignancy**

If there is any suspicion of malignancy, patients should be referred immediately to the appropriate service.

See the London Cancer guidance at: https://www.healthylondon.org/our-work/cancer/.

**Clinical threshold**

**NB: Patients under the age of 16 are not subject to the policy no prior approval needed**

The SWL ICB funds this procedure when all of the following criteria are met in Group 1, 2 or 3.

Group 1: Criteria (1-3) must be met.

1. The best corrected visual acuity is 6/9 or worse in either the first or second eye

*NB. The best corrected visual acuity for both eyes will need to be provided on the tick box form.*

**AND**

2. The patient suffers impairment of vision which has a substantial negative impact on **one or more** of the following:

**a) Quality of life (e.g., reading, watching TV, doing hobbies, etc.)**

**b) Social functioning (e.g., recognising people, coins, etc.)**

**c) Mobility (e.g., driving, recognising road signs, seeing steps or curbs, crossing roads)**

*NB. Examples of the most significant impairment will need to be provided on the tick box form.*

**AND**

3. Patient has been engaged in shared decision making to ensure he/she is well informed about the treatment options available and personal values, preferences and circumstances are taken into consideration

*NB: It is recommended that the SWL Patient Decision Aid is completed. This needs to be recorded in the patient's medical notes, including the written or other materials provided.*

Group 2: Criteria 4 and 5 must be met.

4. Surgery (at any visual acuity) is indicated for management of ocular co-morbidities for patients with at least one of the following:

**d) Glaucoma**

**e) Diabetic and other retinopathies including retinal vein occlusion, and age-related macular degeneration where the cataract is becoming dense enough to potentially hinder management**

**f) Occuloplastics disorders where fellow eye requires closure as part of eyelid reconstruction**

**g) Inadequate view of fundus during diabetic retinopathy screening**

**h) Corneal disease where early cataract removal would reduce the chance of losing corneal clarity (e.g., Fuch's corneal dystrophy or after keratoplasty)**

**i) Corneal or conjunctival disease where delays might increase the risk of complications (e.g., cicatrising conjunctivitis)**

**j) Severe anisometropia in patients who wear glasses**

**k) Posterior subcapsular cataracts.**

**AND**

5. Patient has been engaged in shared decision making to ensure he/she is well informed about the treatment options available and personal values, preferences and circumstances are taken into consideration

*NB: It is recommended that the SWL Patient Decision Aid is completed. This needs to be recorded in the patient's medical notes, including the written or other materials provided.*

Group 3: IFR criteria must be met

Patients whose best corrected visual acuity is better than 6/9, surgery MAY still be considered in exceptional cases.

Prior to undertaking the procedure Individual Funding Request (IFR) approval must be obtained by the treating clinician (i.e. secondary care) for NHS treatment to be provided. This must be obtained via the IFR application form from the IFR service.

**Rationale for the clinical threshold**

This policy has been developed to ensure that resources are targeted at those with the greatest clinical need. In addition, this policy aims to reduce the variation in access to this procedure.

Visually impairing cataract is common in persons aged 65 years and over.

The effectiveness of cataract surgery is established for first and second eyes.

**Primary care advice**

Although primary care is not directly responsible for requesting prior approval, primary care needs to be aware of the detailed clinical criteria relating to this commissioning policy before referring the patient to the appropriate service.

Primary care or community services (community optometrists) must also ensure that they supply all the relevant information to secondary care, particularly visual acuity and the impact of the visual impairment of the patient's life.

Primary care should avoid referring patients who do not meet the clinical criteria as providers can reject referrals not meeting the clinical criteria. Primary care should also utilise conferral systems, such as Kinesis where primary care can liaise with providers, to seek specialist advice if needed.

## 6.2 Chalazia removal

**Compliance requirement**

Prior Approval must be obtained by the treating clinician. This must include details of how the patient meets the criteria as specified on the Prior Approval tick box form.

Malignancy and biopsies

If there is any suspicion of malignancy, patients should be referred immediately to the appropriate service.

If there is any suspicion of malignancy, patients should be referred immediately to the appropriate service.

See the London Cancer guidance at: https://www.healthylondon.org/our-work/cancer/.

**Clinical threshold**

**NB: Patients under the age of 10 are not subject to the policy no prior approval needed**

The SWL ICB funds this procedure when all of the following criteria (1 - 2) are both met.

1. Patient has a lesion that is/has

a) **Been present for more than 6 months and has been managed conservatively with heat, lid cleaning and massage for 4 weeks**

**OR**

b) **Interferes significantly with vision (e.g. blurred vision, interference with peripheral vision, contact lens intolerance)**

**OR**

c) **Interferes with the protection of the eye by the eyelid through affecting lid closure or lid anatomy**

**OR**

d) **A source of infection that has required topical or oral antibiotic treatment twice or more within a six-month time frame**

**OR**

e) **A source of infection causing an abscess requiring drainage**

*NB. Details of the reason who the patient meets the criteria will need to be provided on the Tick box form (e.g., conservative management used and duration).*

**AND**

2**.** Injection with triamcinolone has been considered by the ophthalmologist

**Rationale for the clinical threshold**

This policy has been developed to ensure that resources are targeted at those with the greatest clinical need. In addition, this policy aims to reduce the variation in access to this procedure.

Eyelid problems are common and rarely serious and there are multiple conservative treatment options available in primary care. If these failed and the patient continues to have symptoms or there is a risk of complications blepharoplasty will be funded by the SWL ICB.

In order to promote the cost-effective use of healthcare resources conservative management options must be exhausted before blepharoplasty is considered and it will not be funded for purely cosmetic reasons.

**Primary care advice**

Although primary care is not directly responsible for requesting prior approval, primary care needs to be aware of the detailed clinical criteria relating to this commissioning policy before referring the patient to the appropriate secondary care service.

Primary care must also ensure that they supply the all the relevant information to secondary care.

> If there is any suspicion of malignancy, patients should be referred immediately to the appropriate service.
>
> See the London Cancer guidance at: https://www.healthylondon.org/our-work/cancer/.

This procedure involves incision and curettage (scraping away) of chalazia (meibomian cysts), which are benign lesions on the eyelids due to blockage and swelling of an oil gland that normally change size over a few weeks and many resolve within six months with regular application of heat packs and massage.

Conservative treatment is the first line of management in resolving chalazia. This includes the management of risk factors, i.e., blepharitis, seborrhoeic dermatitis and acne rosacea, to reduce the risk of future episodes.

Conservative management also entails advice regarding regular ‘lid hygiene’:

- Apply a warm compress (for example, using a clean flannel that has been rinsed with hot water) to the affected eye for 5–10 minutes. Repeat three to four times daily for up to 4 weeks. This will help to liquefy the lipid content of the cyst, thus encouraging drainage of the cyst contents.
- After this, gently massage the meibomian cyst (to aid expression of the cyst contents). This should be done in the direction of the eyelashes, using fingers or cotton buds.
- Avoid excessively hot compresses (to avoid scalding, particularly in children)
- Clean the affected eyelid twice daily (to clear debris and oily secretions from the eyelid and lashes). This can be performed by rubbing a moistened cotton bud (for example, using baby shampoo diluted 1:10 with warm water (one part shampoo to nine parts water)) along the lid margin.

## 6.3 Eyelid surgery (Blepharoplasty)

**Compliance requirement**

Prior Approval must be obtained by the treating clinician. This must include details of how the patient meets the criteria as specified on the Prior Approval Tick Box Form.

**Clinical threshold**

The SWL ICB funds this procedure when all of the following criteria are met in Group 1, 2, 3 or 4.

Any requests must relate to a Prior Approval for a single eye.

Group 1: Patients suffering from ptosis or dermatochalasis: criteria (1 – 3) must be met.

1**.** Patient has ptosis or dermatochalasis that impacts on their quality of life**.**

**Two or more** items from the list below are reported by the patient:

a) Eyelids block vision i.e., a noticeable deficit in vision
b) Must raise eyelid/eyebrow to see out
c) Problems with fine manual work
d) Superior visual field blocked
e) Problems with reading
f) Problems with watching television
g) Problems with hanging or reaching for objects above eye level
h) Problems with reading road signs at side of the road

**i) Problems with reading road signs or see stoplights above driver.**

**AND**

2**.** Patient has adequate visual acuity in affected eye (i.e., visual acuity of 3/60 or better)

*NB. The best corrected visual acuity for both eyes will need to be provided on the Tick box form.*

**AND**

3. Patient has

a) **Reduced Marginal Reflex Distance (bilateral MRD1 of 1.0 mm or smaller)**

**OR**

b) **Significant Visual Field loss, such as one of the following:**

i. The horizontal visual field should be at least 160 degrees (full distance left to right around horizontal meridian)
ii. The extension should be at least 70 degrees left and right
iii. The extension should be at least 30 degrees up and down

*NB: Binocular or Integrated Visual Field Testing is the preferred mode of testing.*

*These tests must be with central fixation. It is acceptable to have a total of up to 3 missed points wholly or partly within the $30^0$, which may or may not be contiguous.*

Group 2: Patients with ectropion at least one of criteria 4, 5 or 6 must be met.

4**.** Patient has ectropion and conservative managements failed

iv. Taping lids closed at night to reduce risk of exposure keratopathy

**AND**

v. Therapeutic contact lens

**AND**

vi. Ocular lubricants

*NB: It is recognised that for some patients some or all of the above treatments are impractical, if this is the case, please state this on the Tick box form.*

**OR**

5. Patient's cornea is exposed (e.g., in paralytic ectropion) and hence there is an increased risk of keratopathy.

**OR**

6. Patient suffers from persistent and troublesome overflowing of tears onto the face (epiphora) resulting in watery eyes where at least one of the following applies:

**a) Impaired vision on a daily basis, causing smearing on glasses**

**b) Watering occurs both in outdoor and indoor settings**

**c) Symptoms of persistent clear watering plus 3 episodes of infection or sticky discharge within 12 months.**

Group 3: Patients with entropion: criteria 7 and 8 must be met.

7**.** Patient has entropion and conservative managements failed

**a) Epilation of eye lashes**

**AND**

**b) Therapeutic contact lenses (protect cornea)**

**AND**

**c) Ocular lubricants**

*NB: It is recognised that for some patients some or all of the above treatments are impractical, if this is the case, please state this on the Tick box form.*

**AND**

8. Patient has eyelashes that cause persistent and on-going irritation to the eye risking trauma to the cornea.

Group 4: Patients needing blepharopasty as part of other surgery/treatment for other conditions: criterion 9 must be met.

9. Patient require blepharoplasty to:

**d) Harvest skin for periocular reconstructions**

- **(e.g.: congenital defects, after tumour excision, following trauma, repair malpositions, etc.)**

**OR**

**e) De-bulking the upper/lower lids in patients with thyroid problems as part of their rehabilitation once the disease is no longer active.**

Please note:

The SWL ICB does not routinely fund this procedure for purely cosmetic reasons.

**Rationale for the clinical threshold**

This policy has been developed to ensure that resources are targeted at those with the greatest clinical need. In addition, this policy aims to reduce the variation in access to this procedure.

Eyelid problems are common and rarely serious and there are multiple conservative treatment options available in primary care. If these failed and the patient continues to have symptoms or there is a risk of complications blepharoplasty will be funded by the SWL ICB.

In order to promote the cost-effective use of healthcare resources conservative management options must be exhausted before blepharoplasty is considered and it will not be funded for purely cosmetic reasons.

**Primary care advice**

Although primary care is not directly responsible for requesting prior approval, primary care needs to be aware of the detailed clinical criteria relating to this commissioning policy before referring the patient to the appropriate secondary care service.

Primary care must also ensure that they supply the all the relevant information to secondary care.

**Dermatochalasis**

Dermatochalasis is defined as an excess of skin in the upper or lower eyelid. Eyelid Surgery should only be performed if the dermatochalasis is severe enough to obstruct the peripheral or superior visual fields. The improvement of vision is an indication for Eyelid Surgery on the superior eyelid. In general, Eyelid Surgery of the inferior eyelid is considered cosmetic, as dermatochalasis in the lower eyelid does not interfere with vision.

**Ptosis**

Ptosis is the dropping of the eyelid. It can be unilateral, bilateral, complete, incomplete, acquired or congenital.

**Ectropion**

Ectropion is the outward drooping of the lower eye lid, away from the ocular surface. It is most commonly seen in older patients as a part of ageing – referred to as involutional or senile entropion. Clinical features include irritation (like that of the presence of a foreign body), watering of the eye, conjunctival hyperaemia and exposure keratopathy.

Mild cases often do not require any treatment. Management options that can be considered are listed below:

Taping lids closed at night to reduce risk of exposure keratopathy

Therapeutic contact lens

Ocular lubricants.

If the patient's cornea is exposed (e.g., in paralytic ectropion) then there is an increased risk of keratopathy so urgent referral is needed.

**Entropion**

Entropion is defined as inward rotation of the tarsus and lid margin, causing the eyelashes to come into contact with the ocular surface. This is most commonly seen in older patients as a part of ageing – referred to as involutional or senile entropion. Clinical features include irritation (like that of the presence of a foreign body), watering of the eye, blurred vision, corneal abrasions, conjunctival hyperaemia.

Management options that can be considered are listed:

Epilation of eye lashes

Therapeutic contact lenses (protect cornea)

Ocular lubricants.

Please note the SWL ICB will not routinely fund this procedure for purely cosmetic reasons.

# 7 General Surgery

## 7.1 Haemorrhoidectomy

**Compliance requirement**

Prior Approval must be obtained by the treating clinician. This must include details of how the patient meets the criteria as specified on the Prior Approval Tick Box Form.

**Malignancy**

If there is any suspicion of malignancy, patients should be referred immediately to the appropriate service.

See the London Cancer guidance at: https://www.healthylondon.org/our-work/cancer/.

**Clinical threshold**

The SWL ICB funds this procedure when all of the following criteria (1 - 4) are met.

1. Patient has

a) **Haemorrhoids that are prolapsed and non-reducible**

**OR**

b) **Haemorrhoids are associated with recurrent bleeding**

**AND**

2. Patient tried the entire range of conservative therapies available over a period of at least 6 months prior to referral:

**a) Increasing fluid and fibre intake (using bulking agents if necessary)**

**b) Use of appropriate laxatives**

**c) Avoidance of straining**

**d) Weight management: reduce weight if BMI > 25**

**e) Maintain alcohol intake within normal range**

**f) Regular physical exercise**

**g) Abstinence from smoking**

**AND**

3. Patient tried all appropriate non-surgical interventions have been attempted and failed, unless contra-indicated:

**a) Rubber band ligation**

**OR**

***b)*** **Injection sclerotherapy**

**AND**

4. Patient has been engaged in shared decision making to ensure he/she is well informed about the treatment options available and personal values, preferences and circumstances are taken into consideration.

*It is recommended that the SWL Patient Decision Aid is completed. This needs to be recorded in the patient's medical notes, including the written or other materials provided.*

Please note: The SWL ICB will not routinely fund this procedure for the removal of anal skin tags (see also Minor Skin Lesions policy).

Pregnancy predisposes women to symptomatic haemorrhoids that usually resolve after delivery. Surgical intervention is contraindicated because of the risk of inducing labour.

**Rationale for the clinical threshold**

This policy has been developed to ensure that resources are targeted at those with the greatest clinical need. In addition, this policy aims to reduce the variation in access to this procedure.

Haemorrhoids (piles) occur when vascular tissue in the anal canal becomes enlarged. These are termed 'internal haemorrhoids' as they originate inside the anal canal. They may prolapse out of the rectum and are often associated with bleeding, itching or discomfort. External haemorrhoids arise in the area around the anus and are usually left untreated. It has been estimated that up to 25% of the UK population is affected by haemorrhoids. In 2014–15, approximately 23,000 haemorrhoidal procedures were carried out in England, of which around 8,000 were excisional procedures.

In people with symptomatic internal haemorrhoids, randomised controlled trials have shown that conventional management with added dietary fibre improves rates of symptom relief and reduces rates of bleeding compared with usual diet. Bulk laxatives have been shown to be as effective as minor interventions (rubber band ligation/injection sclerotherapy) in randomised trials at six months and patients should, therefore, be encouraged to engage with lifestyle changes before more intensive intervention. Where conservative management fails, minor interventions, such as rubber band ligation or injection sclerotherapy may be effective. These have been shown to have reasonable effectiveness compared with surgical treatments. Although rates of recurrence are slightly higher, minor interventions are associated with less post-procedural pain, lower risk of complications and lower cost.

Therefore, surgical treatments such as haemorrhoidectomy, haemorrhoidopexy, and haemorrhoid artery ligation should only be considered as a last resort, when all other conservative and less invasive treatment options have failed.

**Primary care advice**

Although primary care is not directly responsible for requesting prior approval, primary care needs to be aware of the detailed clinical criteria relating to this commissioning policy before referring the patient to the appropriate secondary care service.

Primary care must also ensure that they supply the all the relevant information to secondary care, particularly concerning conservative treatments.

**Conservative management**

Primary care should manage patients with haemorrhoids by giving advice on lifestyle including increasing fluids and fibre intake and the avoidance of straining. Bulking agents or medications may be recommended.

Lifestyle changes should be over a period of at least 6 months prior to referral including all of the following:

- **Increasing fluids and fibre intake (using bulking agents if necessary)**
- **Use of appropriate laxatives**
- **Avoidance of straining**
- **Weight management: be within the range of normal BMI, or reduce weight if BMI> 25**
- **Maintain alcohol intake within normal range**
- **Regular physical exercise**
- **Abstinence from smoking**

**Haemorrhoids in pregnancy**

Pregnancy predisposes women to symptomatic haemorrhoids that usually resolve after delivery. Surgical intervention is contraindicated because of the risk of inducing labour.

**Referral to secondary care**

This should only be made for patients who have tried lifestyle alterations for longer than 6 months and experience daily discomfort (itching or pain) or frequent (weekly) blood loss.

Only patients with grade 3 or 4 should be referred to secondary care. Grade 1 and 2 patients may need referral for non-surgical treatments.

Grading of haemorrhoids

| | |
|---|---|
| Grade 1 | Normal appearance. Bleeding but not prolapsing |
| Grade 2 | Bleeding and prolapsing, but will reduce spontaneously |
| Grade 3 | Bleeding and prolapsing, but requires manual reduction |
| Grade 4 | Bleeding and permanently prolapsed |

## 7.2 Hernia repair surgery (Herniorrhaphy)

**Compliance requirement**

Prior Approval must be obtained by the treating clinician. This must include details of how the patient meets the criteria as specified on the Prior Approval Tick Box Form.

**Clinical threshold**

The SWL ICB funds this procedure when all of the following criteria are met in Group 1, 2, 3 or 4.

The clinical criteria below include primary, recurrent and bilateral hernias.

NB: children under the age of 16 are excluded from the policy, no prior approval required for these patients.

Group 1: Criteria 1 and 2 must be met.

1. Patient has a hernia causing symptoms of incarceration, strangulation or obstruction

**AND**

2. Patient has been engaged in shared decision making to ensure he/she is well informed about the treatment options available and personal values, preferences and circumstances are taken into consideration.

*NB: It is recommended that the SWL Patient Decision Aid is completed. This needs to be recorded in the patient's medical notes, including the written or other materials provided.*

Group 2: Criteria 3 must be met.

3. Patient has a femoral hernia.

Group 3: Criteria 4 and 5 must be met.

4. Patient with inguinal hernia has

a) **Difficulty in reducing the hernia**

**OR**

b) **Inguino-scrotal hernia**

**OR**

c) **Pain with strenuous activity, prostatism, or discomfort significantly interfering with activities of daily living**

**AND**

5. Patient has been engaged in shared decision making to ensure he/she is well informed about the treatment options available and personal values, preferences and circumstances are taken into consideration.

*NB: It is recommended that the SWL Patient Decision Aid is completed. This needs to be recorded in the patient's medical notes, including the written or other materials provided.*

Group 4: Criteria 6 and 7 must be met.

6. Patient with abdominal (including incisional, umbilical, epigastric and spigelian) hernia has pain/discomfort significantly impairing activities of daily living*

*NB: Patients with BMI≥30kg/m$^2$, should attempt weight reduction to resolve the pain/discomfort.*

**AND**

8. Patient has been engaged in shared decision making to ensure he/she is well informed about the treatment options available and personal values, preferences and circumstances are taken into consideration.

*NB: It is recommended that the SWL Patient Decision Aid is completed. This needs to be recorded in the patient's medical notes, including the written or other materials provided.*

* For the purposes of this policy, 'activities of daily living' covers functions such as dressing, personal hygiene (washing and toileting), functional mobility (moving from one place to another to perform activities required in the home or at work) and meeting nutritional needs (shopping, preparing and eating food).

Please note:

The SWL ICB does not routinely fund this procedure for:

- **Small, asymptomatic inguinal hernias**
- **Minimally symptomatic inguinal hernias**
- **Large, wide necked hernias unless there is demonstrable clinical evidence that it is causing significant symptoms**
- **Groin pain, including 'athletic pubalgia', sometimes known as 'sports hernia'**
- **Impalpable hernias/abdominal wall weakness including divarication of rectill**

**Rationale for the clinical threshold**

This policy has been developed to ensure that resources are targeted at those with the greatest clinical need. In addition, this policy aims to reduce the variation in access to this procedure.

The incidence of patients presenting in primary care rises from 11 per 10,000 person years in those aged 16-24 years to 200 per 10,000 person years in those aged 75 years or above. Most cases are groin hernias (inguinal or femoral hernia). Inguinal hernias account for 96% of all groin hernias which predominantly present in men (95%). Femoral hernias account for 4% of groin hernias and they are more common in women than men (3:1 incidence).

Patients with symptoms of incarceration, strangulation or obstruction

These patients need to be referred urgently.

Femoral hernia

Has a high risk of morbidity and mortality and surgery is recommended, even in the absence of symptoms.

Inguinal hernia

Surgical hernia repair is associated with low rates of mortality (0.05%), but a proportion of patients are likely to experience chronic pain and discomfort, with a significant impact on Health-Related Quality of Life (HRQL). Randomised controlled trials of asymptomatic and minimally symptomatic patients show no difference in pain scores or general health status at 1-2 years for watchful waiting compared to surgery. In these trials, a low number of emergency hernia repairs (1.5%) occurred in the watchful waiting group over long-term follow-up (~7 years) and guidelines recommend watchful waiting for male adults with asymptomatic or mildly symptomatic hernia. Given the risks of surgical morbidity, evidence of equivalent health status following surgery and watchful waiting and low risk of emergency herniations, observation and review for asymptomatic patients is justified. However, it is recommended that, where symptoms are affecting activities of daily life, patients should be treated surgically.

Abdominal hernia

Incidence is associated with obesity. It increases with increasing BMI and is higher even in the overweight (BMI 25-30 kg/m2) and non-morbidly obese (BMI 30-40 kg/m2) (odds ratio 1.63 and 2.62 respectively) compared to lean. When surgery is conducted on incisional or umbilical hernias, rates of recurrence are around 5-25%12-16 and increased BMI is associated with even higher rates of recurrence and with post-surgical morbidity.

Considering the costs and risks of recurrence, surgery for these hernias should be avoided where possible by attempted weight loss.

Divarication of recti

Does not carry the risks that are associated with actual hernias and repairs are primarily cosmetic. There are high rates of recurrence following surgery (40%) and other commonly reported complications include haematomas, minor skin necrosis, wound infections, dehiscence, post-operative pain and nerve damage. Surgery should, therefore, be avoided unless extreme symptoms present.

Groin pain with clinical suspicion of hernia (obscure pain or swelling)

A quarter to a third of patients presenting with groin pain were found to have an occult hernia. Diagnostic procedures may identify the majority of occult hernias, but the specificity of some tests may be low (ultrasound -77%, CT - 65%) and incorrectly identify patients as having a hernia. Where symptoms do not indicate incarceration, strangulation or obstruction of a potential hernia, the costs of diagnostic procedures and any surgical interventions, and the risks associated with misdiagnosis and surgical morbidity, do not justify investigation with imaging tests and patients should be offered watchful waiting.

Day surgery

European guidelines for the management of inguinal hernia recommend that: 'An operation in day surgery should be considered for every patient. This may be possible for many cases of non-emergency hernia surgery.

Recurrent and bilateral hernias

NICE guidance recommends that "Laparoscopic surgery for inguinal hernia repair should only be performed by appropriately trained surgeons who regularly carry out the procedure."

**Primary care advice**

Although primary care is not directly responsible for requesting prior approval, primary care needs to be aware of the detailed clinical criteria relating to this commissioning policy before referring the patient to the appropriate secondary care service.

Please note that this policy does not apply to children under the age of 16, they do not require prior approvals.

Patients with symptoms of incarceration, strangulation or obstruction

Refer urgently.

Femoral hernia

High risk of morbidity and mortality hence surgery is recommended, even if asymptomatic.

Inguinal hernia

Randomised controlled trials of asymptomatic and minimally symptomatic patients show no difference in pain scores or general health status at 1-2 years for watchful waiting compared to surgery.

Given the risks of surgical morbidity, evidence of equivalent health status following surgery and watchful waiting and low risk of emergency herniations, observation and review for asymptomatic patients is justified. However, it is recommended that, where symptoms are affecting activities of daily life, patients should be treated surgically.

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Where symptoms do not indicate incarceration, strangulation or obstruction of a potential hernia, the costs of diagnostic procedures and any surgical interventions, and the risks associated with misdiagnosis and surgical morbidity, do not justify investigation with imaging tests and patients should be offered watchful waiting.

## 7.3 Obesity surgery (Bariatric surgery)

**Compliance requirement**

Prior Approval must be obtained by the treating clinician. This must include details of how the patient meets the criteria as specified on the Prior Approval Tick Box Form.

**Clinical threshold**

The SWL ICB funds this procedure when all of the following criteria (1 - 6) are met.

1. Patient is 18 or over at the time of application.

**AND**

2. Patient's BMI is

    a) **Over 40kg/m2**

**OR**

    b) **Over 35kg/m2 in the presence of other significant diseases/co-morbidities**

*NB. Patient's height and weight will need to be provided on the Tick box form.*

**AND**

3. Patient has been morbidly or severely obese for at least five years.

**AND**

4. Patient has followed dietary and exercise advice for at least 12 months.

*NB: Patients with BMI greater than 50 attending a specialist bariatric service, this period of 12 months may include the stabilisation and assessment period prior to bariatric surgery. The minimum period is six months.*

**AND**

5. Patient has undergone a formalised MDT-led process for the screening of co-morbidities and the detection of other significant diseases.

**AND**

6. Patient has been engaged in shared decision making to ensure he/she is well informed about the treatment options available and personal values, preferences and circumstances are taken into consideration.

*NB: It is recommended that the SWL Patient Decision Aid is completed. This needs to be recorded in the patient's medical notes, including the written or other materials provided.*

Please note:

The SWL ICB does not routinely fund the removal of excess skin resulting from weight loss following bariatric surgery. Please ensure that the patient is aware of this before proceeding with bariatric surgery.

Criteria for revision of bariatric surgery to be agreed and added later as an integral part of the bariatric surgery pathway for SWL.

**Rationale for the clinical threshold**

This policy has been developed to ensure that resources are targeted at those with the greatest clinical need. In addition, this policy aims to reduce the variation in access to this procedure.

Bariatric surgery for the morbidly obese is an increasingly available intervention. However, surgical intervention is not the whole solution and appropriate clinical selection of fully informed patients is important. It is also important to ensure that surgery is not offered prematurely in a patient's weight loss pathway. Bariatric surgery is only one component of the multimodal lifetime treatment pathway: multidisciplinary medical assessment, pre-operative management of comorbidities, conservative treatments and life-long follow–up care. Patients need to be informed of the benefits and risks as well as the life-long implications of bariatric surgery.

With informed choice patients are better able to cope with the eating restrictions of a post surgically altered gastrointestinal anatomy and mandatory follow up for nutritional supplementation and monitoring to prevent nutritional deficiencies; the management of comorbidities; and adjustment of medications and dosage post operatively. Preparation will improve patient awareness of their role in following a healthy lifestyle to consolidate surgically achieved weight loss and resolution of co-morbidities.

**Primary care advice**

Although primary care is not directly responsible for requesting prior approval, primary care needs to be aware of the detailed clinical criteria relating to this commissioning policy before referring the patient to the appropriate secondary care service.

Primary care must also ensure that they supply the all the relevant information to secondary care, particularly concerning conservative treatments.

Weight management has multiple tiers, and the following pyramid provides an overview.

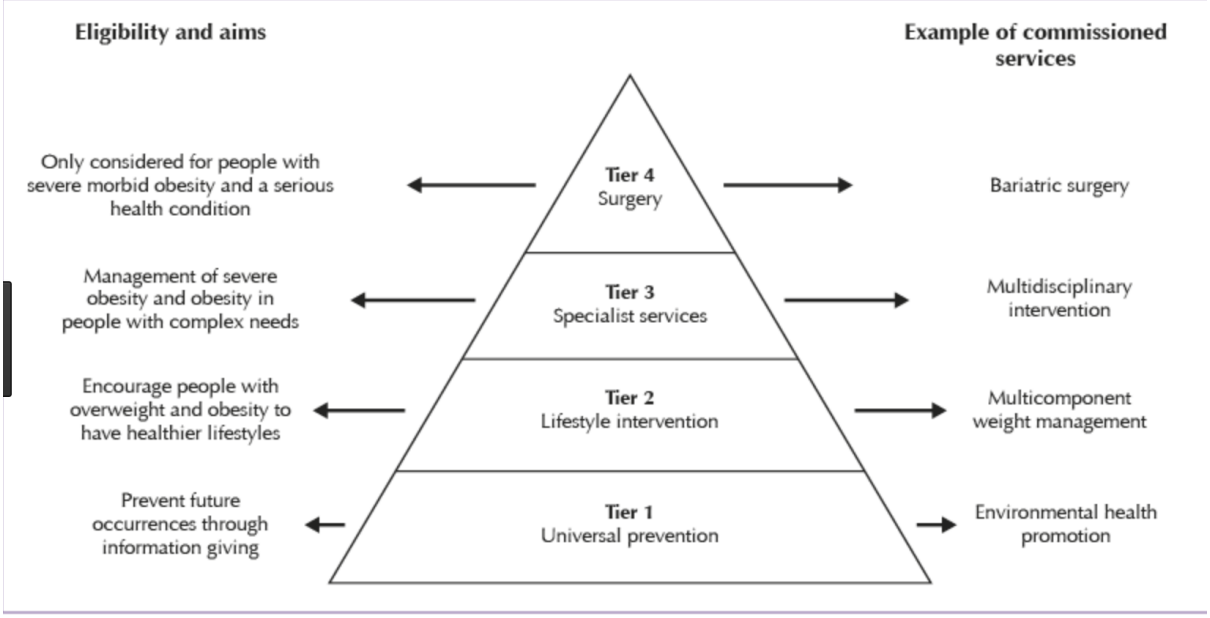



*Figure 1. The UK Obesity Care Pathway (Department of Health, 2013).*

Bariatric surgery for the morbidly obese is an increasingly available intervention. However, surgical intervention is not the whole solution and appropriate clinical selection of fully informed patients is important. It is also important to ensure that surgery is not offered prematurely in a patient's weight loss pathway. Bariatric surgery is only one component of the multimodal lifetime treatment pathway: multidisciplinary medical assessment, pre-operative management of co-morbidities, conservative treatment and life-long follow–up care. Patients need to be informed of the benefits and risks as well as the life-long implications of bariatric surgery.

With informed choice patients are better able to cope with the eating restrictions of a post surgically altered gastrointestinal anatomy and mandatory follow up for nutritional supplementation and monitoring to prevent nutritional deficiencies; the management of co-morbidities; and adjustment of medications and dosage post operatively. Preparation will improve patient awareness of their role in following a healthy lifestyle to consolidate surgically achieved weight loss and resolution of co-morbidities.

The removal of excess skin resulting from weight loss following bariatric surgery is not routinely funded. Please ensure that the patient is aware of this before proceeding with bariatric surgery.

### 7.4 Surgery for Asymptomatic gallstones

**Compliance requirement**

Providers should be aware that this procedure is not routinely funded in South West London, application only via the IFR process by the treating clinician.

**Clinical threshold**

The SWL ICB does not routinely fund this procedure.

**Rationale for the clinical threshold**

The natural history of asymptomatic gallstones is that serious symptoms and complications only develop in 1-2% of patients annually.

The cumulative risk of requiring treatment in the first 5 years after the detection of asymptomatic gallstones is 7.6%.

The World Gastroenterology Organisation (WGO) Practice Guidelines do not recommend cholecystectomy in patients with asymptomatic gallstones.

**Primary care advice**

The SWL ICB will not support the funding of cholecystectomy in asymptomatic patients.

If there is any suspicion of malignancy, patients should be referred immediately to an appropriate service as described in the NICE Clinical Guidance 27: *Referral Guidelines for Suspected Cancer*.

Primary care GPs can refer to secondary care for an expert opinion in cases where diagnostic uncertainty exists.

Patients experiencing one episode of pain only and who can be safely managed in primary care/a community setting do not require referral for surgery. In keeping with the Royal College of Surgeons guidelines on gallstones, these patients can be managed with oral analgesia and advised to follow a low fat diet. If they develop further episodes or they have symptoms in addition to the pain, or their pain cannot be safely managed in primary care or a community setting then they can follow the referral pathway for patients with symptomatic gallstones.

# 8 Gynaecology

## 8.1 Cosmetic genital surgery

(Labiaplasty, Clitoral reduction, Vaginoplasty, Hymenoplasty, Re-virginisation, G-spot amplification, Pubic liposuction or lift, Labia majora surgery, Vaginal tightening)

**Compliance requirement**

Providers should be aware that this procedure is not routinely funded in South West London, application only via the IFR process by the treating clinician.

**Clinical threshold**

The SWL ICB does not routinely fund this procedure.

Please note:

Female Circumcision, often known as Female Genital Mutilation (FGM), is prohibited by law (Serious Crime Act 2015) and will therefore not be funded by the ICB. Incidences where parents seek advice on FGM must be reported to the local Safeguarding Children Team.

## 8.2 Dilatation and Curettage (D&C)

**Compliance requirement**

Prior Approval must be obtained by the treating clinician. This must include details of how the patient meets the criteria as specified on the Prior Approval Tick Box Form.

**Malignancy**

If there is any suspicion of malignancy, patients should be referred immediately to the appropriate service.

See the London Cancer guidance at: https://www.healthylondon.org/our-work/cancer/.

The SWL ICB will fund this procedure when at least one of the criteria 1 or 2 are met.

1. Patient had a hysteroscopy with targeted biopsy that failed or was not possible due to cervical stenosis

*NB. Date of hysteroscopy will need to be provided on the Tick box form.*

**OR**

2. Patient has had a hysteroscopy and endometrial biopsy with an inconclusive histological result

*NB. Date of the inconclusive endometrial biopsy will need to be provided on the Tick box form.*

Please note:

The SWL ICB does not routinely fund this procedure for:

- **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.**

**Rationale for the clinical threshold**

This policy has been developed to ensure that resources are targeted at those with the greatest clinical need. In addition, this policy aims to reduce the variation in access to this procedure.

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.

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. Evidence suggests that vacuum aspiration/suction curettage was safe, quick and easy to perform, and less painful than D&C and is therefore recommended as the first treatment option, with D&C only recommended where this is contraindicated.

**Primary care advice**

Although primary care is not directly responsible for requesting prior approval, primary care needs to be aware of the detailed clinical criteria relating to this commissioning policy before referring the patient to the appropriate secondary care service.

D&C is no longer recommended as a diagnostic tool in HMB. To detect histological abnormalities in HMB endometrial sampling or hysteroscopy with directed biopsy have superseded D&C for obtaining endometrial tissue.

## 8.3 Hysterectomy for Heavy Menstrual Bleeding (Menorrhagia)

**Compliance requirement**

Prior Approval must be obtained by the treating clinician. This must include details of how the patient meets the criteria as specified on the Prior Approval Tick Box Form.

**Malignancy**

If there is any suspicion of malignancy, patients should be referred immediately to the appropriate service.

See the London Cancer guidance at: https://www.healthylondon.org/our-work/cancer/.

**Clinical threshold**

The SWL ICB funds this procedure when all of the following criteria (1 - 4) are met.

1. Patient had an unsuccessful trial with a levonorgestrel intrauterine system (e.g. Mirena®) for at least 6 months that

   **a) Failed to relieve symptoms**

**OR**

   **b) Was medically inappropriate or contraindicated**

**OR**

c) **Declined by the patient**

**AND**

2. Patient had **at least two** of the following treatments that have failed after trial for at least 3 months for each treatment

a) **Non-steroidal anti-inflammatory agents**

b) **Tranexamic acid**

c) **Other hormone methods (injected progesterones, combined oral contraceptives, Gn-RH analogue)**

*NB: It is recognised that for some patients some or all of the above treatments are inappropriate or contraindicated in line with NICE CG44, if this is the case please state this on the Tick box form.*

**AND**

3. Patient had surgical treatments such as endometrial ablation, or myomectomy that

d) **Failed to relieve symptoms**

**OR**

e) **Was medically inappropriate or contraindicated**

**OR**

a) **Declined by the patient**

**AND**

4. Patient has been engaged in shared decision making to ensure he/she is well informed about the treatment options available and personal values, preferences and circumstances are taken into consideration.

*NB: It is recommended that the SWL Patient Decision Aid is completed. This needs to be recorded in the patient's medical notes, including the written or other materials provided.*

Please note the SWL ICB does not routinely fund the following procedures:

- **Uterine artery ligation**
- **Magnetic Resonance guided Focused Ultrasound (MRgFUS)**
- **Myolysis**

**Rationale for the clinical threshold**

This policy has been developed to ensure that resources are targeted at those with the greatest clinical need. In addition, this policy aims to reduce the variation in access to this procedure.

NICE released clinical guidelines on heavy menstrual bleeding in January 2007 (CG44), and these form the basis of these proposals.

Hysterectomy should not be used as a first-line treatment solely for Heavy Menstrual Bleeding (HMB).

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 contraindicated.

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.

**Primary care advice**

Although primary care is not directly responsible for requesting prior approval, primary care needs to be aware of the detailed clinical criteria relating to this commissioning policy before referring the patient to the appropriate secondary care service.

In women whose physical examination is normal, HMB should be managed in primary care with medical treatment (unless contraindicated), until all reasonable options have been exhausted, and are demonstrated to have failed.

Primary care must also ensure that they supply the all the relevant information to secondary care, particularly concerning conservative treatments, including dates of these.

**Conservative treatments**

Primary care must attempt conservative treatments in line with NICE recommendations (CG44) for the management of HMB.

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. This (e.g., Mirena®) should be tried for at least 6 months.

A number of effective conservative treatments are available as second line treatments after failure of Mirena® or where it is contraindicated. A minimum of 3 months trial of this is recommended:

- **Non-steroidal anti-inflammatory agents**
- **Tranexamic acid**
- **Other hormone methods (injected progesterones, combined oral contraceptives, Gn-RH analogue)**

## 8.4 Surgery for Bartholin cyst

**Compliance requirement**

Prior Approval must be obtained by the treating clinician. This must include details of how the patient meets the criteria as specified on the Prior Approval Tick Box Form.

**Malignancy**

If there is any suspicion of malignancy, patients should be referred immediately to the appropriate service.

See the London Cancer guidance at: https://www.healthylondon.org/our-work/cancer/.

**Clinical threshold**

The SWL ICB funds this procedure when all of the following criteria (1 - 3) are met.

1. Patient has a cyst causing significant functional impairment of activities of daily living* or cause Dyspareunia (painful sexual intercourse).

**AND**

2. Conservative management has been tried and failed to resolve the condition for at least 6 months.

**AND**

3. Patient had

**a) At least one clinically significant, episode of infection in the last 6 months**

**OR**

**b) An infected lesion incised and drained in secondary care as an urgent/emergency case in the last 6 months**

*NB. Date of infection or emergency treatment will need to be provided on the Tick box form.*

* For the purposes of this policy, 'activities of daily living' covers functions such as dressing, personal hygiene (washing and toileting), functional mobility (moving from one place to another to perform activities required in the home or at work) and meeting nutritional needs (shopping, preparing and eating food).

NB: Being unable or unwilling to sunbathe, swim or take part in other recreational activities due to the cosmetic impact of a Bartholin's cyst does not indicate that the patient is suffering from significant functional impairment.

Please note the SWL ICB does not routinely fund the insertion of a balloon catheter for the treatment of Bartholin's Cyst.

**Rationale for the clinical threshold**

This policy has been developed to ensure that resources are targeted at those with the greatest clinical need. In addition, this policy aims to reduce the variation in access to this procedure.

The Bartholin's glands are at the entrance of the vagina. A cyst or abscess can form in the Bartholin's duct (which drains the glands) if it becomes blocked or infected. Cysts are usually treated either by 'incision and drainage' or 'marsupialisation', which involves cutting into the cyst and placing stitches to make a permanent opening so that the gland can drain freely. Insertion of a balloon catheter is a non-surgical alternative to incision and drainage or marsupialisation. However, NICE IPG 323: 'Inserting an inflatable balloon to treat a Bartholin's cyst or abscess' does not provide any information regarding cost effectiveness.

A systematic review of 4 studies (5 controlled trials, 2 cohort studies, and 17 case series) identified there are multiple treatments for Bartholin duct cysts and abscesses. A review of the literature failed to identify a best treatment approach.

**Primary care advice**

Although primary care is not directly responsible for requesting prior approval, primary care needs to be aware of the detailed clinical criteria relating to this commissioning policy before referring the patient to the appropriate secondary care service.

Primary care must also ensure that they supply the all the relevant information to secondary care, particularly concerning conservative treatments.

Management of Bartholin's cyst in primary care

- Exclude gonococcal infection
- Small and asymptomatic cyst - watchful waiting
- Symptomatic or enlarging cyst – at least six months of conservative management
- Warm compresses/baths
- Analgesics and/or antibiotics where appropriate

Referral to specialist

Urgent referral is needed for patients with acutely infected Bartholin's cyst.

Refer to secondary care when the cyst is enlarging or symptomatic despite at least six months of conservative management.

## 8.5 Surgery for Female Genital Prolapse

**Compliance requirement**

Prior Approval must be obtained by the treating clinician care. This must include details of how the patient meets the criteria as specified on the Prior Approval Tick Box Form.

**Clinical threshold**

The SWL ICB funds this procedure when all of the following criteria 1 and 2 are met.

1. Patient completed all the conservative treatments prior to referral.

**AND**

2. Patient

   a) **Requires an assessment and fitting of pessary that cannot be undertaken in primary care**

OR

   b) **Declines to have a pessary inserted and requests surgery for the prolapse**

OR

   c) **Prolapse combined with urinary or faecal incontinence**

   d) **Red flag symptoms hence urgent referral is needed**

OR

   e) **Has moderate to severe (grade 3-4) symptoms of prolapse**

OR

**f) Had failure of pessary.**

Please note the SWL ICB does not routinely fund this procedure for asymptomatic prolapse.

**Rationale for the clinical threshold**

This policy has been developed to ensure that resources are targeted at those with the greatest clinical need. In addition, this policy aims to reduce the variation in access to this procedure.

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.

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.

Primary care advice

Although primary care is not directly responsible for requesting prior approval, primary care needs to be aware of the detailed clinical criteria relating to this commissioning policy before referring the patient to the appropriate secondary care service.

Primary care must also ensure that they supply the all the relevant information to secondary care, particularly concerning conservative treatments (see checklist and GP referral letter below).

Pelvic organ prolapse – quantification system

| | |
|---|---|
| 0 | No prolapse |
| I | > 1 cm above the hymen |
| II | ≤ 1 cm proximal or distal to the plane of the hymen |
| III | > 1 cm below the plane of the hymen, but protrudes no farther than 2 cm less than the total vaginal length |
| IV | Eversion of the lower genital tract is complete |

**Checklist for Conservative Management**

Has the patient kept a bladder diary and has the patient undergone bladder drill exercises?

Has the patient had access to gynae physiotherapy for a course of pelvic floor exercises?

If underlying atrophy is present, has the patient had a course of vagifem 10mg/gynest cream daily for 2 weeks, then twice weekly for 3 months?

If Cystocele / Uterine Prolapse present – has a ring pessary been fitted*?

Referral letter content

Reason for referral

Examination findings: Grade 1 to Grade 4 uterine prolapse with/without cystocele or rectocele or enterocele

Treatment to date

- **Gynae physiotherapy completed**
- **Atrophy treated**
- **Bladder drill/urinary symptoms addressed**

Bladder diary completed and attached

Past medical/surgical history

Drug history

BMI (should be below 35)

Smoking cessation

Excessive BMI predisposes patients to genital prolapse hence as part of any conservative management weight management should be signposted.

'Red Flags' for early referral

Exclude cancerous cause for 'lump'

New presentation of procidentia (Grade 4 Prolapse) with poor urinary output – consider acute gynaecology admission

Genital prolapse with urinary or faecal incontinence.

## 8.6 Surgery for Uterine Fibroids (minimally invasive)

**Compliance requirement**

Prior Approval must be obtained by the treating clinician. This must include details of how the patient meets the criteria as specified on the Prior Approval Tick Box Form.

**Clinical threshold**

The SWL ICB funds this procedure when all of the following criteria (1 - 4) are met.

1. Patient has a fibroid that is greater than 3cm in diameter.

**AND**

2. Patient has a fibroid which is causing symptoms that have a severe impact on her quality of life including **at least one** of the following:

**a) Heavy or painful menstrual bleeding**

**OR**

**b) Problems with fertility**

**OR**

**c) Pressure symptoms**

**AND**

3. Patient wants to avoid surgery and/or retain her uterus.

**AND**

3. Patient has been engaged in shared decision making to ensure he/she is well informed about the treatment options available and personal values, preferences and circumstances are taken into consideration

*NB: It is recommended that the SWL Patient Decision Aid is completed. This needs to be recorded in the patient's medical notes, including the written or other materials provided.*

Please note the SWL ICB does not routinely fund the following procedures for the removal of uterine fibroids:

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

**Rationale for the clinical threshold**

This policy has been developed to ensure that resources are targeted at those with the greatest clinical need. In addition, this policy aims to reduce the variation in access to this procedure.

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 a grape to large masses that can be palpated through the uterine wall.

Current evidence on Uterine Artery Embolisation (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 that 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.

NICE clinical guideline on heavy menstrual bleeding (CG44) 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.

**Primary care advice**

Although primary care is not directly responsible for requesting prior approval, primary care needs to be aware of the detailed clinical criteria relating to this commissioning policy before referring the patient to the appropriate secondary care service.

Primary care must also ensure that they supply the all the relevant information to secondary care.

If the patient has heavy menstrual bleeding which is due to fibroids less than 3 cm in diameter, primary care should try conservative medical management as specified in NICE (CG 44).

# 9 Miscellaneous Procedures

## 9.1 Botulinum Toxin A for Axillary Hyperhidrosis

**Compliance requirement**

Prior Approval must be obtained by the treating clinician. This must include details of how the patient meets the criteria as specified on the Prior Approval Tick box Form.

**Clinical threshold**

The SWL ICB funds this procedure when all of the following criteria (1 - 5) are met.

1. Patient has **primary axillary hyperhidrosis** which occurs without stimulus of heat or exercise, and which has no other underlying clinical cause such as secondary hyperhidrosis due to hyperthyroidism, menopause, medication, or amphetamines, etc.

**AND**

2a) The excessive axillary sweating has a significant impact on the patient's personal/professional life i.e. Hyperhidrosis Disease Severity Score* (HDSS) 3 or 4

**OR**

2b) The patient has complications due to axillary hyperhidrosis such as skin maceration with secondary skin infections

*NB: Details of the complications or the HDSS score will need to be provided on the Tick box form*

**AND**

3a) Patient has failed to respond to a six- month trial of topical aluminium chloride or extra strength antiperspirants (i.e., no change in HDSS score)

**OR**

3b) Patient is unable to tolerate topical aluminium chloride (e.g. causes a severe rash)

**AND**

4. The patient is unresponsive or unable to tolerate at least one of the following pharmacotherapies prescribed for excessive sweating if sweating is episodic: anti-cholinergics or beta-blockers

**AND**

5. Patient does not have any contraindications to the use of Botox injections

- Pregnancy or breast feeding
- Previous allergy to botulinum toxin
- Muscle disorders or use of muscle relaxant therapy
- Coagulation disorders, on concurrent aspirin or anticoagulant therapy
- Previous surgery to the axilla

*Hyperhidrosis Disease Severity Scale (HDSS)

| *HDSS Score* | *Subjective Score* |
|---|---|
| *1 Mild* | *Sweating is never noticeable and never interferes with daily activities* |
| *2 Moderate* | *Sweating is tolerable but sometimes interferes with daily activities* |
| *3 Severe* | *Sweating is barely tolerable and frequently interferes with daily activities* |
| *4 Severe* | *Sweating is intolerable and always interferes with daily activities* |

Please note: BTX-A is unlicensed for the treatment of palmar, plantar or craniofacial hyperhidrosis, and is not routinely funded application only via the IFR process by the treating clinician.

**Rationale for the clinical threshold**

This policy has been developed to ensure that resources are targeted at those with the greatest clinical need. In addition, this policy aims to reduce the variation in access to this procedure.

Four large, randomised control trials involving approximately 1000 patients have assessed the efficacy and safety of Botox A in axillary hyperhidrosis. All reported statistically significant reduction in symptoms with Botox compared to placebo, with 75-95% of patients achieving treatment response. Ten to twelve percent experienced side effects including non-axillary sweating or injection site pain or reactions compared with 3-8% of the placebo groups.

Successful treatment for hyperhidrosis can be defined as a reduction in HDSS from 3 or 4 to HDSS 1 or 2.

Treatment failure can be defined as no change in HDSS score after 1 month of therapy or lack of tolerability for the treatment.

**Primary care advice**

Although primary care is not directly responsible for requesting prior approval, primary care needs to be aware of the detailed clinical criteria relating to this commissioning policy before referring the patient to the appropriate secondary care service.

Primary hyperhidrosis only affects certain parts of the body, most commonly the armpits, then the feet and hands or, more rarely, the face or scalp; some patients exhibit primary hyperhidrosis at more than one location. Symptoms typically start during childhood or adolescence and peak in the third decade. Hyperhidrosis can lead to emotional and physical impairment, affecting professional and social activities and reducing health-related quality of life.

Primary care should consider the following conservative treatments, and recommend lifestyle measures:

People with primary focal hyperhidrosis:

- Modify behaviour to avoid identified triggers (such as crowded rooms, caffeine, or spicy foods), where possible.
- Consider treating any underlying anxiety, which may be an exacerbating factor (NB cognitive behavioural therapy may be preferable to antidepressants or propranolol, which can cause or worsen hyperhidrosis).

BTX-A is unlicensed for the treatment of palmar, plantar or craniofacial hyperhidrosis, and is therefore not routinely funded.

People with primary axillary hyperhidrosis:

- Use a commercial antiperspirant (as opposed to a deodorant) frequently.
- Avoid tight clothing and manmade fabrics.
- Wear white (as opposed to blue) shirts or black clothing to minimize the signs of sweating.

- Consider using dress shields (also known as armpit or sweat shields) to absorb excess sweat and protect delicate or expensive clothing. These can be obtained via the internet or the Hyperhidrosis Support Group.
- Recommend 20% aluminium chloride hexahydrate (NB Driclor® and Anhydrol Forte® roll-ons are licensed and can bought over the counter).

Primary care must also ensure that they supply the all the relevant information to secondary care concerning conservative treatments attempted, and how the patient meets the relevant clinical criteria.

Successful treatment for hyperhidrosis can be defined as a reduction in HDSS from 3 or 4 to HDSS 1 or 2 (see table below).

Treatment failure can be defined as no change in HDSS score after 1 month of therapy or lack of tolerability for the treatment.

## 9.2 Circumcision – Male

**Compliance requirement**

Prior Approval must be obtained by the treating clinician. This must include details of how the patient meets the criteria as specified on the Prior Approval Tick box Form.

**Malignancy**

If there is any suspicion of malignancy, patients should be referred immediately to the appropriate service.

See the London Cancer guidance at: https://www.healthylondon.org/our-work/cancer/.

**Clinical threshold**

The SWL ICB funds this procedure when at least one of the following criteria (1 - 10) are met.

1. Recurrent Paraphimosis

a) **Patient is 16 or over at the time of application**

**AND**

b) **Patient is suffering from Recurrent Paraphimosis with at least three clinically significant episodes in the past 12 months**

*NB. Referral letters from GPs providing the dates or clearly stating the number of episodes the patient had in a given timeframe will be accepted on the Tick box form*

**OR**

2. Pathological Phimosis in adults

**a) Patient is 16 or over at the time of application**

AND

**b) Patient suffering from pathological white scarring of the foreskin secondary to lichen sclerosus (Balanitis Xerotica Obliterans [BXO])**

AND

c) **Patient is suffering from pain or difficulty in passing urine**

AND

d) **Conservative management has failed or is inappropriate**

NB: Details of the reason who the patient meets the criteria will need to be provided on the Tick box form (e.g. conservative treatments tried and timeframes or dates)

**OR**

3. Pathological Phimosis in children

a) **Patient is 16 or under at the time of application**

**AND**

b) **Patient suffering from Pathological Phimosis due to**

- **Severe balanitis OR**
- **Balanitis Xerotica Obliterans (BXO) including one or more of the following (white scarring, fissures, weeping)**

*NB: Details of the reason who the patient meets the criteria will need to be provided on the Tick box form (e.g. conservative treatments tried and timeframes or dates)*

Please note: Pathological phimosis is often the unintended result of incorrect advice by family or nurses or medical staff to attempt foreskin retraction in children under 7 years of age. Only boys over 7 years of age should be asked or encouraged to retract and stretch their own foreskins gradually over several months.

- **OR**

4. Balanitis or Balanoposthitis

a) **Patient is 16 or over at the time of application**

**AND**

b) **Patient is suffering from Recurrent Balanitis or Balanoposthitis with at least three clinically significant episodes in the past 12 months**

**AND**

c) **Conservative management has failed or is inappropriate**

*NB: Details of the reason who the patient meets the criteria will need to be provided on the Tick box form (e.g., conservative treatments tried and timeframes or dates)*

Please note that non-retractile ballooning of the foreskin and/or spraying of urine does not constitute Balanitis or Balanoposthitis

- **OR**

5. Congenital abnormalities of the urinary tract

a) **Patient is 16 or over at the time of application**

**AND**

b) **Patient has Congenital abnormalities of the urinary tract**

**AND**

c) **Circumcision is proposed as part of the management of this underlying condition**

*NB: Details of the reason who the patient meets the criteria will need to be provided on the Tick box form (e.g. name of the condition such as hypospadius, epispadius)*

- **OR**

6. Physiological Phimosis in adults

**a) Patient is 16 or over at the time of application**

**AND**

**b) Patient is suffering from recurrent urinary tract infection**

**AND**

**c) Conservative management has failed or is inappropriate (minimum 4 weeks)**

*NB: Details of the reason who the patient meets the criteria will need to be provided on the Tick box form (e.g., conservative treatments tried and timeframes or dates)*

- **OR**

7. Physiological Phimosis in children under 3 years old

a) **Patient is 3 or under at the time of application**

**AND**

b) **Patient has an abnormal urinary tract and is suffering from urinary tract infections despite prophylactic antibiotics**

**AND**

c) **Circumcision is proposed as part of the management of this underlying condition**

- **OR**

8. Physiological Phimosis in children over 10 years old

a) **Patient is 10 or over at the time of application**

**AND**

b) **Patient is suffering from recurrent urinary tract infections**

**AND**

c) **Conservative management have been all failed or inappropriate including**

- **Daily foreskin retraction for at least a year AND**

- **Topical steroids (0.05%-0.1% betamethasone or equivalent) for 6 weeks**

*NB: Details of the reason who the patient meets the criteria will need to be provided on the Tick box form (e.g., conservative treatments tried and time frames or dates)*

**OR**

9. Severe Pain on Arousal

a) **Patient is 16 or over at the time of application**

**AND**

b) **Patient suffering from recurrent Severe Pain on Arousal**

**AND**

c) **Conservative management have been all failed or inappropriate**

*NB: Details of the reason who the patient meets the criteria will need to be provided on the Tick box form (e.g. conservative treatments tried and time frames or dates)*

**OR**

10. Severe Traumatic Injury

a) **Patient had a Severe Traumatic Injury (e.g. zipper or strangulation injury)**

Please note:

Female Circumcision, often known as Female Genital Mutilation (FGM), is prohibited by law (Serious Crime Act 2015) and will therefore not be funded by the ICB. Incidences where parents seek advice on FGM must be reported to the local Safeguarding Children Team.

The SWL ICB will not routinely fund this procedure for:

- **Purely personal, social, cultural or religious reasons**

- **The prevention of sexually transmitted diseases**

The SWL ICB will not routinely fund the following procedures:

- **Division of preputial adhesions for pre-pubertal boys**

- **Dorsal slits or preputioplasty for pre-pubertal boys, unless it is on an emergency basis if para-phimosis cannot be corrected otherwise.**

The SWL ICB will fund Frenuloplasty for boys 12 years of age and over who are having painful erections resulting from a tight penile frenulum.

**Rationale for the clinical threshold**

This policy has been developed to ensure that resources are targeted at those with the greatest clinical need. In addition, this policy aims to reduce the variation in access to this procedure.

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 3-11 years of age 90% of boys will have a partially or fully retractable foreskin. By the age of 14+, only 1% of boys will have an unretractable 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.

The World Health Organisation does not recommend circumcision in developed nations* and the BMA position** is that the evidence for the health benefits of non-therapeutic circumcision is insufficient for the health benefits alone to be a justification for carrying out the procedure. WHO guidance*** is that routine infant male circumcision should only be undertaken “if the infant is healthy, full-term, weighs more than 2500g, has a normal physical examination, and has a penis and scrotum of completely normal appearance.”…..“Contraindications for early infant male circumcision include any known haematological disorders and jaundice.”

* WHO (2010) Manual for early infant male circumcision under local anaesthesia

** BMA (2006) The law and ethics of male circumcision – guidance for doctors

*** Patient.co.uk (2013) Circumcision, http://patient.info/health/circumcision-leaflet

**Primary care advice**

Although primary care is not directly responsible for requesting prior approval, primary care needs to be aware of the detailed clinical criteria relating to this commissioning policy before referring the patient to the appropriate service. Without this commissioner face significant costs in out-patient appointments for patients that may not qualify for surgery and inappropriately raises the patient’s expectation of treatment. Providers are encouraged to reject referrals not meeting the clinical criteria.

It is important to note that pathological phimosis is often the unintended result of incorrect advice by family or nurses or medical staff to attempt foreskin retraction in children under 7 years of age. Only boys over 7 years of age should be asked or encouraged to retract and stretch their own foreskins gradually over several months.

Primary care must also make sure that they supply the relevant information to secondary care.

Primary care should also utilise conferral systems, such as Kinesis where primary care can liaise with providers, to seek specialist advice if needed.

Please note: Female circumcision, often known as Female Genital Mutilation (FGM), is prohibited by law (Serious Crime Act 2015) and will therefore not be funded by the ICB. Incidences where parents seek advice on FGM must be reported to the local Safeguarding Children Team.

## 9.3 Complementary therapies

**Compliance requirement**

Providers should be aware that this procedure is not routinely funded in South West London, application only via the IFR process by the treating clinician.

**Clinical threshold**

The SWL ICB does not routinely fund complementary therapies, unless these are commissioned as part of an integrated service or care pathway (e.g. pain management or physiotherapy).

Complementary/alternative therapies which will not be routinely funded include the following (NB this list is not exhaustive):

Active release technique; Acupressure; Acupuncture (outside of a treatment pathway, see below); Aimspro (hyperimmune goat serum); Alexander Technique; AMMA Therapy; Anthroposophical medicine; Antineoplastons; Antineoplaston therapy and sodium phenylbutyrate; Apitherapy; Applied kinesiology; Aromatherapy; Art therapy; Autogenic Therapy; Auto urine therapy; Ayurveda;

Bach and other flower remedies; Bioenergetic therapy; Biofield Cancell (Entelev) cancer therapy; Bioidentical hormones;

Carbon dioxide therapy; Cellular therapy; Chelation therapy for atherosclerosis; Chinese herbal medicine; Traditional Chinese Medicine; Chiropractic; Crystal therapy; Chung Moo Doe therapy; Coley's toxins; Colonic irrigation; Conceptual mind-body techniques; Craniosacral therapy; Cupping;

Dance/Movement therapy; Digital myography; Dowsing;

Ear Candling; Eastern medicine; Egoscue method; Electroacupuncture according to Voll (EAV); Equine therapy; Essential and Metabolic Fatty Acids Analysis (EMA); Essiac; Environmental Medicine;

Feldenkrais method of exercise therapy; Flower essence; Fresh cell therapy; Functional intracellular analysis;

Gemstone therapy; Gerson therapy; Glyconutrients; Graston Technique; Greek cancer cure; Guided imagery;

Hair analysis; Hako-Med machine (electromedicicine horizontal therapy); Healing Nutritional medicine; Hellerwork; Herbal Medicines, Homeopathy; Hoxsey therapy; Humor therapy; Hydrazine sulphate; Hypnosis and Hypnotherapy; Hyperoxygen/Hyperbaric Oxygen therapy;

Immuno-augmentative therapy; Infratronic Qi-Gong machine; Insulin potentiation therapy; Inversion therapy; Iridology; Iscador (Mistletoe therapy);

Kelley/Gonzales therapy; Kinesiology

Laetrile (amydgalin or vitamin B17); Live blood cell analysis;

Macrobiotic diet; Magnet therapy; Massage, Meditation/transcendental meditation; Megavitamin therapy; Meridian therapy; Mesotherapy; Mistletoe therapy (Iscador); Moxibustion (except for foetal breech presentation);MTH-68/H vaccine; Music therapy; Myotherapy Neural therapy;

Naturopathy; Neutralising Antigens/clinical ecology/environmental medicine;

Osteopathy; Ozone therapy;

Pfrimmer deep muscle therapy; Pilates; Polarity therapy; (Poon's) Chinese blood cleansing; Primal therapy; Psychodrama; Purging;

Qigong for longevity exercises;

Radionics; Reams' testing; Reflexology (zone therapy); Reflex Therapy; Reiki; Remedial massage; Revici's guided chemotherapy; Rolfing (structural integration); Rubenfeld synergy method (RSM); 714-X (for cancer);

Sarapin injections; Shark cartilage products; Shiatsu;

Therapeutic Eurythmy-movement therapy; Therapeutic touch; Thought field therapy (TFT) (Callahan Techniques Training); Trager approach;

Visceral manipulation therapy;

Whitcomb technique; Wurn technique/clear passage therapy;

Yoga.

## 9.4 Scrotal surgery (hydroceles,epididymal cysts,varicocele,testicular implants)

**Compliance requirement**

Prior Approval must be obtained by the treating clinician. This must include details of how the patient meets the criteria as specified on the Prior Approval Tick box Form.

**Malignancy**

If there is any suspicion of malignancy, patients should be referred immediately to the appropriate service.

See the London Cancer guidance at: https://www.healthylondon.org/our-work/cancer/.

**Clinical threshold**

The SWL ICB funds this procedure when all of the following criteria are met in Group 1, 2, 3 or 4

Group 1: Removal of benign epididymal cysts criteria (1-3) must be met

1. Patient has a cyst is large enough to cause change in shape and size of scrotum

**AND**

2. The cyst is putting pressure on other structures in the testes

**AND**

3. The cyst is causing prolonged or significant pain

*NB: Details of the reason who the patient meets the criteria will need to be provided on the Tick box form (e.g. pain caused by the cyst needs to be stated)*

Group 2: Surgical treatment for hydroceles criteria 4 or 5 must be met

4. Patient is aged over 18 months and has a communicating hydrocele

**OR**

5. Patient has a non-communicating hydrocele, the patient is experiencing

a) Discomfort and/or disfigurement resulting in inability to participate in normal social and educational activity (adolescent)

**OR**

b) **Discomfort and/or disfigurement resulting in functional impairment preventing individual fulfilling work/study/carer or domestic duties (adult)**

*NB: Details of the reason who the patient meets the criteria will need to be provided on the Tick box form (e.g. impact on quality of life)*

Group 3: Surgical removal of varicocele criteria 6 must be met

6. Patient has a varicocele that

a) Cause a haemorrhage which cannot be controlled by conservative measures

**OR**

b) **Cause persistent pain despite adequate conservative management**

**OR**

c) **Is associated with persistent ipsilateral testicular growth retardation in patient who is under 16 years old and have Grade 2 or 3 varicoceles***

*NB: Details of the reason who the patient meets the criteria will need to be provided on the Tick box form (e.g. conservative measures used)*

***Classification of varicoceles**

| Grade | Description |
|---|---|
| **0** | No evidence of a varicocele with inspection or palpation, but positive scrotal thermography or Doppler reflux detection. |
| **1** | Not visible, palpable only with a Valsalva manoeuvre |
| **2** | Not visible, palpable without a Valsalva manoeuvre |
| **3** | Visible through the scrotum without a Valsalva manoeuvre |

Please note:

Men should not be offered surgery for varicoceles as a form of fertility treatment because it does not improve pregnancy rates.

Group 4: Surgical insertion of testicular prosthesis criteria 7 must be met

7. Patient

a) Has a congenital absence of testes

**OR**

b) **Requires reconstructive surgery following destruction of the testes due to disease or trauma**

*NB: Details of the reason who the patient meets the criteria will need to be provided on he Tick box form (e.g. reason for reconstructive surgery)*

Please note: The SWL ICB does not routinely fund this procedure in the following circumstances:

- For purely cosmetic reasons
- Undescended testes

Testicular prostheses provided for patients undergoing genital reconstruction as part of the gender dysphoria pathway is the planning and funding responsibility of NHS England and is not subject to this policy.

**Rationale for the clinical threshold**

This policy has been developed to ensure that resources are targeted at those with the greatest clinical need. In addition, this policy aims to reduce the variation in access to this procedure.

**Primary care advice**

Although primary care is not directly responsible for requesting prior approval, primary care needs to be aware of the detailed clinical criteria relating to this commissioning policy before referring the patient to the appropriate secondary care service.

Primary care must also ensure that they supply the all the relevant information to secondary care, particularly concerning symptoms and their duration and the conservative treatments tried including dates where relevant.

**Conditions covered**

**An epididymal cyst** is a fluid filled sac which grows at the top end of the testicle. It is benign – not caused by cancer. Some men only get one; others get several on both testicles. Rarely, they can be associated with illness that causes cysts in other parts of the body. Small cysts do not need treatment. Larger ones can be removed by a surgeon, especially if painful. Men are more likely to get an epididymal cyst around the age of 40.

**Hydroceles** (fluid collection around the testicles) may be present at birth and are common, affecting around one male baby in every 10. They do not usually require treatment as they often disappear on their own during the first 2 years of life (NICE). Less commonly, hydroceles can develop in adult men and may follow infection, injury or radiotherapy.

**A varicocele** is a scrotal swelling consisting of a collection of dilated veins of the pampiniform plexus in the spermatic cord. A varicocele is usually asymptomatic, but 2–10% of affected men may have vague dragging or heavy sensations and aching pain in the scrotum or groin. In most men a varicocele does not require any treatment. (8). Men should not be offered surgery for varicoceles as a form of fertility treatment because it does not improve pregnancy rates.

**A testicular prosthesis** is a replica testicle made out of silicone, which replaces testicle(s) if one or both have been removed. Orchidectomy is most commonly performed due to testicular cancer; however some men have one or both testicles removed for other reasons such as undescended tests, trauma, severe torsion (twisted testicle) or as a treatment option for advanced prostate cancer

Patients should be directed to appropriate supporting information e.g.: NHS Choices, www.patient.co.uk

# 10 Skin

## 10.1 Photodynamic therapy for skin lesions

**Compliance requirement**

Prior Approval must be obtained by the treating clinician. This must include details of how the patient meets the criteria as specified on the Prior Approval Tick box Form.

Malignancy

If there is any suspicion of malignancy, patients should be referred immediately to the appropriate service.

If there is any suspicion of malignancy, patients should be referred immediately to the appropriate service.

See the London Cancer guidance at: https://www.healthylondon.org/our-work/cancer/.

**Clinical threshold**

The SWL ICB funds this procedure when all of the following criteria are met.

1.Patient has

a) Actinic keratoses with documentation that other treatments have been trialed, contraindicated or are not practical (e.g. poorly healing sites, multiple lesions or large lesions) with ONE of the following:

- Non-hyperkeratotic lesions OR
- Hyperkeratotic lesions that have been debrided with a dermatological curette or liquid nitrogen to remove scales and crusts, resulting in a non-hyperkeratotic lesion

**OR**

**b) Low-risk basal cell carcinoma (e.g., superficial and nodular) with documentation that other treatments have been trialed, contraindicated or are not practical (e.g. poorly healing sites, multiple lesions or large lesions)**

**OR**

c) Bowen's disease (squamous cell carcinoma in situ) with documentation that other treatments have been trialed, contraindicated or are not practical (e.g. poorly healing sites, multiple lesions or large lesions)

**OR**

d) Residual lesions where the previously treated lesion have shown a good response to the PDT treatment (only one further treatment will be funded)

- Actinic keratoses OR
- Low risk BCC OR
- Bowen's disease

*NB: appropriate treatments trialed, contraindicated or why they are not practical treatments should be recorded in patients records for audit purposes.*

## 10.2 Interventions for minor skin lesions

**Compliance requirement**

Prior Approval must be obtained by the treating clinician. This must include details of how the patient meets the criteria as specified on the Prior Approval Tick box Form.

**Malignancy and biopsies**

If there is any suspicion of malignancy, patients should be referred immediately to the appropriate service. Biopsies are not covered by this policy and may be undertaken as required at the discretion of the managing clinician.

If there is any suspicion of malignancy, patients should be referred immediately to the appropriate service.

See the London Cancer guidance at: https://www.healthylondon.org/our-work/cancer/.

**Clinical threshold**

The SWL ICB funds this procedure when all of the following criteria are met in Group 1 or 2.

**NB: Scar Revision Surgery and Photodynamic Therapy are covered separately.**

Group 1: Criteria (1-2) must be met

1. Patient has a lesion that

a) Is unavoidably and significantly traumatized* on a regular basis

**OR**

**b) Has been significantly infected, requiring more than 2 courses of antibiotics (oral or IV)**

**OR**

c) Obstructs an orifice, or impairs vision

**OR**

**d) Significantly restricts activities of daily living****

**OR**

e) Causes regular pain (moderate to severe, VAS>5), which substantially interferes with the patient's ability to perform activities of daily living

**OR**

f) Is a large, proven lipomata (>5cms)

*NB: Details of the reason who the patient meets the criteria will need to be provided on the Tick box form (e.g. size and location of lipomata)*

**AND**

2. Patient or their carer has been engaged in shared decision making to ensure he/she is well informed about the treatment options available and personal values, preferences and circumstances are taken into consideration.

Including discussions about recurrence and complication rates.

Group 2: Criteria (3 - 4) must be met

3. Patient has (an)

a) Ano-genital warts that have failed treatment within primary care setting or Genito-Urinary Medicine (GUM) clinic

**OR**

b) Multiple recalcitrant (plantar or mosaic) warts AND is immunocompromised

*NB: Details of the reason who the patient meets the criteria will need to be provided on the Tick box form (e.g .treatments that failed to treat the ano-genital wart)*

**AND**

4. Patient or their carer has been engaged in shared decision making to ensure he/she is well informed about the treatment options available and personal values, preferences and circumstances are taken into consideration.

Including discussions about recurrence and complication rates.

* For the purposes of this policy, 'Traumatised': e.g. catching on clothes daily, or regularly disturbed by combing of hair, or located under the waistband or bra strap causing clothes to be unwearable

** For the purposes of this policy, 'activities of daily living' covers functions such as dressing, personal hygiene (washing and toileting), functional mobility (moving from one place to another to perform activities required in the home or at work) and meeting nutritional needs (shopping, preparing and eating food).

Please note: The SWL ICB does not routinely fund this procedure for the treatment of the following skin conditions considered cosmetic. These conditions include, but are not limited to:

- **Congenital Naevi**
- **Vascular birth marks in children**
- **Naevus of Ota / Naevus of Ito**
- **Café au lait patches**
- **Milia**
- **Comedones**

**Rationale for the clinical threshold**

This policy has been developed to ensure that resources are targeted at those with the greatest clinical need. In addition, this policy aims to reduce the variation in access to this procedure.

There is limited evidence that interventions 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.

**Primary care advice**

Although primary care is not directly responsible for requesting prior approval, primary care needs to be aware of the detailed clinical criteria relating to this commissioning policy before referring the patient to the appropriate secondary care service.

Primary care must also ensure that they supply the all the relevant information to secondary care, particularly concerning symptoms and their severity including dates where relevant.

**Malignancy and biopsy**

If there is any suspicion of malignancy*, patients should be referred immediately to an appropriate service as described in the London Cancer guidance https://www.healthylondon.org/our-work/cancer/.

Biopsies are not covered by this policy and may be undertaken as required at the discretion of the managing clinician.

Soft tissue subcutaneous lesions, particularly over 5cms, that are not clearly longstanding and asymptomatic may of course be a soft tissue sarcoma. NICE guidance suggests that a rapid access ultrasound scan is usually the most appropriate diagnostic test to check the nature of any suspicious lesions which then, if abnormal, should be referred on to the appropriate Specialist London Sarcoma Service as a Two Week Wait.

**Types of minor skin lesions**

There are a number of very common skin lesions that are benign in nature and represent little or no risk to patients. Whilst procedures and interventions for these lesions are effective, the reason for requesting intervention is often cosmetic.

This policy applies at any and all levels of clinical care regarding benign skin lesions, and it is the responsibility of all clinicians to apply the commissioning criteria when a patient reaches their particular care setting.

Where removal is supported, this should generally be undertaken in Primary Care through the Minor Surgery Direct Enhanced Service. Treatment in secondary care will only be approved where the removal is beyond GP surgical care.

Scars (keloids) are covered in the Scar Revision Surgery clinical threshold and the Photodynamic therapy is covered separately.

**Clinical threshold for interventions**

Only the following indications will be routinely funded

Patient has a lesion that:

- **Is unavoidably and significantly traumatized* on a regular basis**
- **Has been significantly infected, requiring more than 2 courses of antibiotics**
- **Obstructs an orifice, or impairs vision**
- **Significantly restricts activities of daily living****

- **Causes regular pain (moderate to severe, VAS>5), which substantially interferes with the patient's ability to perform activities of daily living**

- **Is a large, proven lipomata (>5cms)**

- **Is an ano-genital warts that have failed treatment within primary care setting or Genito-Urinary Medicine (GUM) clinic**

- **Multiple recalcitrant wart AND the patient is immunocompromised**

* For the purposes of this policy, 'Traumatised': e.g., catching on clothes daily, or regularly disturbed by combing of hair, or located under the waistband or bra strap causing clothes to be unwearable

** For the purposes of this policy, 'activities of daily living' covers functions such as dressing, personal hygiene (washing and toileting), functional mobility (moving from one place to another to perform activities required in the home or at work) and meeting nutritional needs (shopping, preparing and eating food).

Please note: Asymptomatic conditions which could be submitted for consideration via IFR may include severe disfiguring non-malignant lesions of the face, or severe port wine stains (haemangiomas) that extend onto the face and/or neck. In such circumstances requests should be supported by photographic evidence, or confirmation of the extent to which the face is covered, taking into account the patient's normal hairstyle.

## 10.3 Scar revision surgery (Keloidectomy)

**Compliance requirement**

Prior Approval must be obtained by the treating clinician. This must include details of how the patient meets the criteria as specified on the Prior Approval Tick box Form.

**Malignancy and biopsies**

If there is any suspicion of malignancy, patients should be referred immediately to the appropriate service.

See the London Cancer guidance at: https://www.healthylondon.org/our-work/cancer/.

**Clinical threshold**

The SWL ICB funds this procedure when ALL of the following criteria (1 - 3) are met.

1. Patient has scarring as a consequence of burns or trauma, or previous surgery (either directly funded by the NHS, or surgery taking place overseas which would have merited funding by the NHS)

*NB. The cause of the scarring with dates will need to be provided on the Tick box form.*

**AND**

2. Patient has scarring causing

**a) Adverse physical consequences leading to significant functional impairment which impacts upon activities of daily living* (e.g. pain due to contraction, tethering or recurrent breakdown, or obstruction of orifice or vision),**

**OR**

**b) Recurrent bleeding over a period of at least 3 months**

**AND**

3. Conservative therapies aimed at arresting the development of adverse, keloid or hypertrophic scarring have been tried (where clinically appropriate) over a period of at least 18 months, but have not been effective (e.g. steroid injections, pressure garments, medication or massage).

* For the purposes of this policy, 'activities of daily living' covers functions such as dressing, personal hygiene (washing and toileting), functional mobility (moving from one place to another to perform activities required in the home or at work) and meeting nutritional needs (shopping, preparing and eating food).

Please note:

The SWL ICB does not require additional approval for adjuvant radiotherapy following an approved scar revision surgery.

The SWL ICB does not routinely fund this procedure (including skin resurfacing and dermabrasion) in secondary care for any of the categories listed below:

**c) Hypertrophic or keloid scars that are not causing adverse consequences or functional impairments (e.g. keloid scarring after ear piercing and other body piercings)**

**d) Scarring / ulceration from chronic tattoo breakdowns**

**e) Post-acne scarring**

**f) Scars resulting from self-harm**

**g) Scar treatment for skin rejuvenation or other cosmetic purposes**

**Rationale for the clinical threshold**

This policy has been developed to ensure that resources are targeted at those with the greatest clinical need. In addition, this policy aims to reduce the variation in access to this procedure.

Scar revision is usually carried out for aesthetic reasons and is therefore considered a procedure of low clinical value. This type of surgery is only commissioned where function, e.g. movement of a joint, is restricted by the scar.

**Primary care advice**

Although primary care is not directly responsible for requesting prior approval, primary care needs to be aware of the detailed clinical criteria relating to this commissioning policy before referring the patient to the appropriate secondary care service.

Primary care must also ensure that they supply the all the relevant information to secondary care, particularly concerning symptoms and their duration and the conservative treatments tried including dates where relevant.

**Malignancy and biopsy**

If there is any suspicion of malignancy, patients should be referred immediately to an appropriate service as described in the London cancer guidance https://www.healthylondon.org/our-work/cancer/.

# 11 Trauma and Orthopaedics – Hand

## 11.1 Surgery for Carpal Tunnel

**Compliance requirement**

Prior Approval must be obtained by the treating clinician. This must include details of how the patient meets the criteria as specified on the Prior Approval Tick Box Form.

**Malignancy**

If there is any suspicion of malignancy, patients should be referred immediately to the appropriate service.

See the London Cancer guidance at: https://www.healthylondon.org/our-work/cancer/.

**Clinical threshold**

The SWL ICB funds this procedure when all of the following criteria 1 and 2 are met.

1. Patient has

**a) Mild or moderate symptoms after 6 months of conservative management which includes:**

**i. Steroid injections over 6 months (maximum 2 injections)**

- **AND**

**ii. Nocturnal splinting used for at least 8 weeks**

**OR**

**iii. Severe signs/symptoms significantly interfering with activities of daily living* (e.g.: severe sensory blunting, muscle wasting, weakness on thenar abduction)**

**OR**

**b) Neurological deficit or median nerve denervation**

**AND**

2. Patient has been engaged in shared decision making to ensure he/she is well informed about the treatment options available and personal values, preferences and circumstances are taken into consideration

*NB: It is recommended that the SWL Patient Decision Aid is completed. This needs to be recorded in the patient's medical notes, including the written or other materials provided.*

* For the purposes of this policy, 'activities of daily living' covers functions such as dressing, personal hygiene (washing and toileting), functional mobility (moving from one place to another to perform activities required in the home or at work) and meeting nutritional needs (shopping, preparing and eating food).

**Rationale for the policy**

This policy has been developed to ensure that resources are targeted at those with the greatest clinical need. In addition, this policy aims to reduce the variation in access to this procedure.

There are a relatively large numbers of patients with mild to moderate CTS, however the majority of these cases will resolve with the aid of conservative treatment within six months. Annual incidence of 139 cases per 100,000 females and 67 per 100,000 males. CTS is more common in middle age (older than 40 years) and in women (during pregnancy and menopause).

Untreated Carpal Tunnel Syndrome has been shown to resolve or significantly improve in up to 49% of cases. Non-surgical treatment, including oral steroids, splinting, ultrasound, yoga and carpal bone mobilisation show short-term benefit compared with placebo or other non-surgical interventions.

Conservative treatment is preferred in mild to moderate cases and surgical treatment is mainly applied in severe cases including nerve denervation. Surgical treatment is indicated in cases where initial conservative management has failed. Corticosteroid injection has been shown to be effective at one month, but the effect decreases by 30% at one year.

**Primary care advice**

Although primary care is not directly responsible for requesting prior approval, primary care needs to be aware of the detailed clinical criteria relating to this commissioning policy before referring the patient to the appropriate service.

Primary care must also make sure that they supply all the relevant information regarding the grading of the severity of carpal tunnel syndrome, as well as the conservative treatment attempted (i.e. steroid injections and/or wrist splinting).

**Grading of Carpal Tunnel Syndrome**

Mild: Intermittent paraesthesia with or without pain that may be nocturnal or occurs with a certain hand position.

Moderate: Paraesthesia that interferes with activities of daily living or causes constant night waking; and/or reversible numbness and/or pain (perhaps by clenching and unclenching of fist or hand shaking).

Severe: Constant numbness or disabling pain with wasting of thenar muscles, and/or weakness of thumb muscles (Abductor Pollicis Brevis and Opponens Pollicis).

Patients with severe symptoms should be referred urgently without attempting conservative therapies.

## 11.2 Surgery for Dupuytren's Contracture (Fasiotomy/fasiectomy)

**Compliance requirement**

Prior Approval must be obtained by the treating clinician. This must include details of how the patient meets the criteria as specified on the Prior Approval Tick Box Form.

**Malignancy**

If there is any suspicion of malignancy, patients should be referred immediately to the appropriate service.

See the London Cancer guidance at: https://www.healthylondon.org/our-work/cancer/.

**Clinical threshold**

The SWL ICB funds this procedure when all of the following criteria are met in Group 1, 2 or 3.

Group 1: Criteria 1 and 2 must be met.

1. Patient is unable to put hand flat on the table.

**AND**

2. Patient has

a) **Proximal interphalangeal joint contracture of at least 30°**

OR

b) **Metacarpophalangeal joint contracture of at least 30°**

NB. The name and the angle of the joint contracture will need to be provided on the Tick box form.

Group 2: Criterion 3 must be met

3. Patient has at least 10° loss of extension in 2 or more joints

*NB. The names and the angle of the joint contractures will need to be provided on the Tick box form.*

Group 3: Criteria (4 – 6) must be met

*4. Patient has*

a) **Proximal interphalangeal joint contracture of at least 30°**

*OR*

b) **Metacarpophalangeal joint contracture of at least 30°**

*NB. The name and the angle of the joint contracture will need to be provided on the Tick box form.*

**AND**

5. Patient has severe symptoms significantly interfering with activities of daily living*.

* For the purposes of this policy, 'activities of daily living' covers functions such as dressing, personal hygiene (washing and toileting), functional mobility (moving from one place to another to perform activities required in the home or at work) and meeting nutritional needs (shopping, preparing and eating food).

Please note: the SWL ICB does not routinely fund radiation therapy for Dupuytren's Contracture.

**Rationale for the clinical threshold**

This policy has been developed to ensure that resources are targeted at those with the greatest clinical need. In addition, this policy aims to reduce the variation in access to this procedure.

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 comprise of reassurance and observation.

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.

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.

Surgery should not be considered a cure and patients should be advised of the risks of recurrence when deciding whether to consider surgical intervention.

**Primary care advice**

Although primary care is not directly responsible for requesting prior approval, primary care needs to be aware of the detailed clinical criteria relating to this commissioning policy before referring the patient to the appropriate secondary care service.

Primary care must also ensure that they supply the all the relevant information to secondary care, particularly concerning conservative treatments.

Treatment for Dupuytren's contracture is usually only required if the condition affects the function of the hand. Many cases are mild and painless and do not require treatment. In such cases management should comprise of reassurance and observation.

Primary care needs to be aware that simple nodules in the palm are not an indication for referral.

Please note: the SWL ICB does not routinely fund radiation therapy for Dupuytren's Contracture.

## 11.3 Surgery for Trigger finger

**Compliance requirement**

Prior Approval must be obtained by the treating clinician. This must include details of how the patient meets the criteria as specified on the Prior Approval Tick Box Form.

**Malignancy**

If there is any suspicion of malignancy, patients should be referred immediately to the appropriate service.

See the London Cancer guidance at: https://www.healthylondon.org/our-work/cancer/.

**Clinical threshold**

NB: children under the age of 16 are not excluded from the policy, an IFR application is required for patients under the age of 16.

The SWL ICB funds this procedure when at least one of the criteria 1 or 2 are met.

1. Patient suffers from triggering despite **ALL** conservative management have been attempted

   **a) Rest from aggravating activates**

   **b) Non-steroidal anti-inflammatory drugs for pain control**

   **c) Splinting**

   **d) Corticoid steroid injections (max of 2 with 10 weeks between the injections)**

**OR**

2. Patient has a fixed flexion deformity that cannot be corrected.

**Rationale for the clinical threshold**

This policy has been developed to ensure that resources are targeted at those with the greatest clinical need. In addition, this policy aims to reduce the variation in access to this procedure.

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.

**Primary care advice**

Although primary care is not directly responsible for requesting prior approval, primary care needs to be aware of the detailed clinical criteria relating to this commissioning policy before referring the patient to the appropriate secondary care service.

Primary care must also ensure that they supply the all the relevant information to secondary care, concerning conservative treatments and steroid injections in particular.

**Conservative treatments**

Primary care should ensure that all conservative measures have been attempted prior to referral to specialists:

- **Activity modification (i.e. rest from aggravating activities)**
- **Non-steroidal anti-inflammatory drugs for pain control**
- **Joint immobilisation (splinting).**
- **Corticosteroid injections (unless contra-indicated): up to two injections ten weeks apart**

Please note:

- **Patients with diabetes are less likely to respond to corticosteroid injections.**
- **Patients who smoke should be encouraged to stop smoking prior to surgery.**
- **Overweight or obese patients should be encouraged to lose weight prior to surgery**

# 12 Trauma and Orthopaedics – Hip

## 12.1 Surgery for Hip Impingement

**Compliance requirement**

Prior Approval must be obtained by the treating clinician. This must include details of how the patient meets the criteria as specified on the Prior Approval Tick Box Form.

**Malignancy**

If there is any suspicion of malignancy, patients should be referred immediately to the appropriate service.

See the London Cancer guidance at: https://www.healthylondon.org/our-work/cancer/.

**Clinical threshold**

The SWL ICB funds this procedure when all of the following criteria (1 - 6) are met.

1. Patients is skeletally mature at the time of application

*NB: Aged 19 or over and have completed puberty.*

**AND**

2. Patient has a positive impingement sign with sudden pain on $90^0$ hip flexion with adduction and internal rotation or extension and external rotation.

**AND**

3. Patient has severe symptoms significantly interfering with activities of daily living*.

**AND**

4. Patient engaged with conservative therapy for at least 6 months and these **ALL** failed, including:

a) **Activity modification (e.g., restriction of athletic pursuits and avoidance of symptomatic motion)**

b) **Pharmacological intervention (e.g., non-steroidal anti-inflammatory drugs [NSAIDS], injections of local anesthetics into the joint)**

c) **Physiotherapy**

**AND**

5. Patient's diagnosis has been confirmed by appropriate radiological investigation

a) **Cam impingement (alpha angle greater than 50 degrees)**

**OR**

b) **Pincer impingement (center edge angle greater than or equal to 40 degrees)**

**OR**

**d) Pistol grip deformity (non-spherical femoral head shape)**

*NB: Date and modality of the radiology to be provided on the Tick box form.*

- **AND**

6. Patient has been engaged in shared decision making to ensure he/she is well informed about the treatment options available and personal values, preferences and circumstances are taken into consideration

*NB: It is recommended that the SWL Patient Decision Aid is completed. This needs to be recorded in the patient's medical notes, including the written or other materials provided.*

* For the purposes of this policy, 'activities of daily living' covers functions such as dressing, personal hygiene (washing and toileting), functional mobility (moving from one place to another to perform activities required in the home or at work) and meeting nutritional needs (shopping, preparing and eating food).

Please note: the SWL ICB does not routinely fund the following indications:

- **Patients who are a candidate for hip replacement**
- **Patient with severe hip dysplasia or with a Crowe grading classification of 4**
- **Patients with osteogenesis imperfecta**
- **Patients with a joint space that is less than 2.0mm wide anywhere along the sourcil (shadow of dense osseous tissue) on plain radiograph of the pelvis**
- **Patients who have severe hip dysplasia**
- **Presence of generalised joint laxity especially in diseases connected with hypermobility of the joints, such as Marfan syndrome and Ehlers-Danlos syndrome**
- **Absence of advanced osteoarthritis change on pre-operative X-ray (Tonnis grade 2 or more) or severe cartilage injury (Outerbridge grade III or IV)**

The SWL ICB does not routinely fund the following procedures:

- **Capsular plication**
- **Autologous osteochondral mosaicplasty in combination with femoral neck osteochondroplasty**
- **Labral reconstruction**
- **If provided as an adjunct to hip impingement surgery:**

- **Debridement of trochanteric bursitis**
- **Hip microfracture**
- **Gluteus medius repair**
- **Lesser trochanteric resection.**

The SWL ICB will seek annual confirmation with supporting evidence on the following:

- Any surgeon undertaking this procedure must have completed specialist training and has experience of providing arthroscopic hip surgery and for each case had discussion with a specialist musculoskeletal radiologist.
- Data will be entered for each patient undergoing this procedure to the British Hip Society register (British Hip Society, 2016) to support assessment of long term outcomes as well as undertake local review of cases to monitor safety and short term outcomes.

**Rationale for the clinical threshold**

This policy has been developed to ensure that resources are targeted at those with the greatest clinical need. In addition, this policy aims to reduce the variation in access to this procedure.

Hip impingement syndrome is caused by unwanted contact between abnormally shaped parts of the head of the thigh bone and the hip socket. This results in limited hip movement and pain.

Femoroacetabular impingement is characterised by abnormal contact between the femoral head/neck and acetabulum (ball & socket). There are two described types:

"Cam" impingement is defined as an abnormality of the anterolateral femoral head/neck junction

"Pincer" impingement is described as over coverage of the acetabulum over the femoral head causing abnormal compressive forces between the rim of the acetabulum and the femoral head/neck during hip movement.

In the majority of cases (86%), cam and pincer forms exist together i.e. "mixed impingement". The aim of femoro-acetabular surgery is to reduce pain and improve range of movement. It is believed that it may also help prevent hip arthritis in later life, although longer term studies are needed to prove this.

There is limited evidence of clinical and cost effectiveness available for surgical interventions for FAI syndrome. With regard to safety, there are well recognised complications. Open femoro–acetabular surgery for hip impingement syndrome involves major surgery with the potential for serious complications and should only be undertaken by surgeons who are well- trained and highly experienced in this type of procedure. Arthroscopic femoro–acetabular surgery for hip impingement syndrome should only be carried out by surgeons with specialist expertise in arthroscopic hip surgery.

**Primary care advice**

Although primary care is not directly responsible for requesting prior approval, primary care needs to be aware of the detailed clinical criteria relating to this commissioning policy before referring the patient to the appropriate MSK services.

Primary care must also ensure that they supply the all the relevant information to MSK or T&O services, particularly concerning conservative treatments. Conservative treatments should be documented in the patient's primary care record, or via Musculoskeletal Services' letters, or other clinic letters and provided with any referrals to secondary care.

Prior to referral for consideration of surgery, primary care should ensure that the patient has fully engaged with conservative therapy for at least 6 months including all of the following:

- Activity modification (e.g., restriction of athletic pursuits and avoidance of symptomatic motion)
- Pharmacological intervention (e.g., nonsteroidal anti-inflammatory drugs [NSAIDS]), injections of local anaesthetics into the joint)
- Physiotherapy

## 12.2 Hip replacement surgery

**Compliance requirement**

Prior Approval must be obtained by the treating clinician. This must include details of how the patient meets the criteria as specified on the Prior Approval Tick Box Form.

**Malignancy**

If there is any suspicion of malignancy, patients should be referred immediately to the appropriate service.

See the London Cancer guidance at: https://www.healthylondon.org/our-work/cancer/.

**Clinical threshold**

The SWL ICB funds this procedure when ALL of the following criteria (1 - 4) are met.

1. Patient have osteoarthritis with joint symptoms (pain, stiffness, reduced function, joint instability) that have a substantial impact on quality of life

*NB. Details of the reason who the patient meets the criteria will need to be provided on the Tick box form (e.g., symptoms affecting the quality of life).*

**AND**

2. All conservative management options have been tried and failed

Including pain relief, exercise, physiotherapy and weight loss where appropriate

**AND**

3. Patient's symptoms are consistent with degenerative disease, and prior to arthroplasty there is radiological confirmation of this

*NB. Details of the radiology is needed on the Tick box form (date and modality)*

**AND**

4. Patient has been engaged in shared decision making to ensure he/she is well informed about the treatment options available and personal values, preferences and circumstances are taken into consideration

*NB: It is recommended that the SWL Patient Decision Aid is completed. This needs to be recorded in the patient's medical notes, including the written or other materials provided.*

Please note:

The SWL ICB does not routinely fund specialist custom hip prosthesis.

The following are not covered in the policy: acute trauma, suspected infections, inflammatory arthropathies and patients under the age of 16.

**Rationale for the clinical threshold**

This policy has been developed to ensure that resources are targeted at those with the greatest clinical need. In addition, this policy aims to reduce the variation in access to this procedure.

Patients with lower than severe pain or lower than severe functional impairment should be treated conservatively as evidence assessed by NICE found that hip replacement was not the most effective treatment for this group of patients. Shared decision-making taking account of severity of pain and functional impairment is of key importance in deciding the most appropriate time for surgery.

**Primary care advice**

Although primary care is not directly responsible for requesting prior approval, primary care needs to be aware of the detailed clinical criteria relating to this commissioning policy before referring the patient to the appropriate service.

Primary care must also ensure that they supply the all the relevant information to MSK or T&O services, particularly concerning conservative treatments. Conservative treatments should be documented in the patient's primary care record, or via Musculoskeletal Services' letters, or other clinic letters and provided with any referrals to secondary care.

Osteoarthritis (OA) is the most common form of arthritis in the United Kingdom and the hip is a commonly affected site. Important consequences are pain, limitation of daily activities and reduction in quality of life.

It is important to recognise that OA may not be progressive, and most patients may be successfully managed with non-surgical measures in primary or intermediate care.

Patients should be encouraged to engage in conservative treatments, which include education and lifestyle modifications, exercise and weight loss (where appropriate). Primary care practitioners should encourage smoking cessation and weight reduction, offering referral to appropriate services, where required. An earlier referral to secondary care for those with suspected end stage hip OA may be appropriate as conservative measures are unlikely to improve the patient's pain or quality of life.

Primary care practitioners should ensure that the patient has meaningfully engaged with conservative management, where appropriate, prior to referral for hip replacement surgery. These lifestyle changes have the potential to improve general health and wellbeing, as well as intervention success rates and enhance recovery times from surgery.

Clinical judgement should be used to assess severity of symptoms and consideration of referral for surgical opinion, as there are currently no scoring systems validated for clinical use. In conjunction with this, patients should be given the opportunity to engage with shared decision making prior to referral for surgery. This may occur in primary care or interface services, such as MCATS, where applicable. In line with best practice, this should involve the use of a decision-making aid, such as "Arthritis: should I have hip replacement surgery?" (https://www.healthwise.net/cochranedecisionaid/Content/StdDocument.aspx?DOCHWID=uh1515-av2356).

**Conservative treatments**

Primary care should ensure that ALL the following conservative measures are attempted over a period of 6 months prior to referral for hip replacement surgery:

- Weight reduction where appropriate, particularly when the patient has a BMI greater than 35.
- Education and self-management such as elimination of damaging influence on hips, activity modification (avoid impact and excessive exercise), good shock-absorbing shoes.

Non-pharmacological management such as biomechanical interventions, physiotherapy and exercising to improve local muscle strength and general aerobic fitness (note: physiotherapy is ineffective in bone-on-bone osteoarthritis).

Management with medication including where appropriate oral/topical nonsteroidal anti-inflammatory drugs [NSAIDS] and paracetamol-based analgesics (COX-2 Inhibitor of NSAIDS). Opioid analgesics can be used effectively if paracetamol or NSAIDS are ineffective or poorly tolerated.

**Oxford score**

The Oxford Hip Score may be used in primary care to guide clinicians whether to make a referral to specialist or not. Patients with a score of 20 or more could be considered for referral. However, it is not a validated tool and should not be used to make the final decision on hip replacement.

See: http://www.orthopaedicscore.com/scorepages/oxford_hip_score.html. Similarly, the tables given in the Appendix below may help patients and clinicians to classify pain and functional impairment in order to judge whether it is the appropriate time to refer a patient to secondary care**.**

**Classification systems for hip**

Pain Levels - at least one of following is met in any category.

*Slight*

- *Sporadic pain.*
- *Pain when climbing/descending stairs.*
- *Allows daily activities to be carried out (those requiring great physical activity may be limited).*
- *Medication, aspirin, paracetamol or NSAIDs to control pain with no/few side effects.*

*Moderate*

- *Occasional pain.*
- *Pain when walking on level surfaces (half an hour, or standing).*
- *Some limitation of daily activities.*
- *Medication, aspirin, paracetamol or NSAIDs to control with no/few side effects.*

*Intense*

- *Pain of almost continuous nature.*
- *Pain when walking short distances on level surfaces or standing for less than half an hour.*
- *Daily activities significantly limited.*
- *Continuous use of NSAIDs for treatment to take effect.*
- *Requires the sporadic use of support systems walking stick, crutches).*

*Severe*

- *Continuous pain.*
- *Pain when resting.*
- *Daily activities significantly limited constantly.*
- *Continuous use of analgesics - narcotics/NSAIDs with adverse effects or no response.*
- *Requires more constant use of support systems (walking stick, crutches).*

*Source:* https://www.aetnabetterhealth.com

# 13 Trauma and Orthopaedics - Knee

## 13.1 Autologous Chondrocyte Implantation (ACI)

**Compliance requirement**

Providers should be aware that this procedure is not routinely funded in South West London, application only via the IFR process by the treating clinician.

**Clinical threshold**

The SWL ICB does not routinely fund this procedure.

## 13.2 Knee arthroscopy (including knee washout)

**Compliance requirement**

Prior Approval must be obtained by the treating clinician. This must include details of how the patient meets the criteria as specified on the Prior Approval Tick Box Form.

**Clinical threshold**

The SWL ICB funds this procedure when criteria (1 or 2) and criteria 3 are met.

1. Patient have osteoarthritis of the knee and needs arthroscopic lavage and debridement where there is a clear history of a truly locked knee

(i.e. inability of knee extension on clinical examination, as opposed to morning joint stiffness (aka gelling), 'giving way', or X-ray evidence of loose bodies).

*NB. Details of the reason how the patient meets the criteria will need to be provided on the Tick box form (e.g. symptoms or date of X-ray).*

**OR**

2. Patient **does not** have osteoarthritis of the knee where the patient has:

**a) Acute trauma/injury**

OR

**b) Ligament rupture**

- **OR**

**c) Meniscal surgical target**

- **OR**

**d) Suspected infection**

**OR**

**e) Suspected avascular necrosis**

**OR**

**f) Inflammatory arthropathies**

OR

**g) Requires an arthroscopic procedure as part of another surgical procedure e.g. high tibial osteotomy or unicompartmental arthroplasty**

OR

**h) Requires chondroplasty**

OR

**i) Requires synovial biopsy and synovectomy**

OR

**j) Requires excision synovial plica**

AND

3. Patient has been engaged in shared decision making to ensure he/she is well informed about the treatment options available and personal values, preferences and circumstances are taken into consideration

*NB: It is recommended that the SWL Patient Decision Aid is completed. This needs to be recorded in the patient's medical notes, including the written or other materials provided.*

Please note:

The following are not covered in the policy: patients under the age of 16.

The SWL ICB does not routinely fund the following procedures:

- **Routine lavage (knee washout) alone (in the absence of associated knee arthroscopy surgery)**
- **Procedures restricted by NICE, e.g., knee meniscus replacement with biodegradable scaffold mosaicplasty, autologous chondrocyte implantation and trochleoplasty for patellar instability**
- **Debridement, except in cases where there is mechanical locking**
- **Use as a diagnostic tool, except in cases where there is on-going diagnostic uncertainty following both clinical examination and non-invasive imaging procedures (e.g., MRI) conducted by specialists.**

**Rationale for the clinical threshold**

This policy has been developed to ensure that resources are targeted at those with the greatest clinical need. In addition, this policy aims to reduce the variation in access to this procedure.

**Primary care advice**

Although primary care is not directly responsible for requesting prior approval, primary care needs to be aware of the detailed clinical criteria relating to this commissioning policy before referring the patient to the appropriate service.

Primary care must also ensure that they supply the all the relevant information to MSK or T&O services, particularly concerning conservative treatments. Conservative treatments should be documented in the patient's primary care record, or via Musculoskeletal Services' letters, or other clinic letters and provided with any referrals to secondary care.

The following section is designed to aid decision making in primary care and does not form part of the commissioning criteria. The advice is based on the LCW consideration of the evidence.

High quality evidence does not support the use of knee arthroscopic surgery in most patients with degenerative disease (with or without OA) in the absence of a clear surgical target.

Asymptomatic meniscal tears are very common in middle and older aged patients and are often an incidental finding on MRI. There is mixed opinion regarding the clinical identification of those tears for which arthroscopic treatment is clinically effective.

The use of imaging in primary care to confirm a diagnosis is not usually required (where knee x-rays are requested for degenerative disease, these should be standing films).

For patients who are symptomatic with degenerative disease including OA (and / or a meniscal lesion), first-line treatment should be with a comprehensive programme of non-surgical measures, including education, exercise, physiotherapy, simple analgesia and steroid injection (where locally available and acceptable to the patient).

Corticosteroid injections can be offered in primary care or community care (where locally available and acceptable to the patient); they can provide effective pain relief and may allow patients to better engage with physiotherapy.

Referrals to secondary care should be triaged via the MSK Single Point of Access services (where such pathways are in place).

Patients who smoke should be offered support with smoking cessation at least 12 weeks prior to surgery.

Patients with raised BMI should be supported to lose weight and, where appropriate, offered access to local weight loss services (where available).

Patients should be offered the opportunity to engage with shared decision making either in primary or secondary care:

There are decision tools available online for the treatment of knee OA: https://www.england.nhs.uk/rightcare/shared-decision-making.

MRIs

Referral for MRI scans should only be made by secondary care consultants or specialists working in ICB funding approved MSK services.

Primary care should also utilise conferral systems, such as Kinesis where primary care can liaise with providers, to seek specialist advice if needed.

## 13.3 Knee replacement surgery

**Compliance requirement**

Prior Approval must be obtained by the treating clinician. This must include details of how the patient meets the criteria as specified on the Prior Approval Tick Box Form.

**Clinical threshold**

The SWL ICB funds this procedure when ALL of the following criteria (1 - 4) are met.

1. Patient have osteoarthritis with joint symptoms (pain, stiffness, reduced function, joint instability) that have a substantial impact on quality of life

*NB. Details of the reason who the patient meets the criteria will need to be provided on the Tick box form (e.g., symptoms affecting the quality of life).*

**AND**

2. All conservative management options have been tried and failed

Including pain relief, exercise, physiotherapy and weight loss where appropriate

**AND**

3. Patient's symptoms are consistent with degenerative disease, and prior to arthroplasty there is radiological confirmation of this

*NB. Details of the radiology is needed on the Tick box form (date and modality)*

**AND**

4. Patient has been engaged in shared decision making to ensure he/she is well informed about the treatment options available and personal values, preferences and circumstances are taken into consideration

*NB: It is recommended that the SWL Patient Decision Aid is completed. This needs to be recorded in the patient's medical notes, including the written or other materials provided.*

Please note:

The SWL ICB does not routinely funded Patellar Resurfacing as a stand-alone procedure. The following are not covered in the policy: acute trauma, suspected infections, inflammatory arthropathies and patients under the age of 16.

**Rationale for the clinical threshold**

This policy has been developed to ensure that resources are targeted at those with the greatest clinical need. In addition, this policy aims to reduce the variation in access to this procedure.

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. Total knee replacement (TKR) is most commonly performed for knee joint failure caused by osteoarthritis (OA); other indications include rheumatoid arthritis (RA), juvenile rheumatoid arthritis, osteonecrosis and other types of inflammatory arthritis. The

aims of TKR are relief of pain and improvement in function. TKR can be very successful for carefully selected patients with over 90% of TKRs still in place and functioning well at 10 to 15 years after surgery. However, optimum selection of patients is uncertain, a wide range of conservative measures may be effective in alleviating symptoms in the majority of patients affected by osteoarthritis. Hence, shared decision-making taking account of the patient's severity of pain and functional impairment is of key importance in deciding the most appropriate treatment option including surgery.

**Primary care advice**

Although primary care is not directly responsible for requesting prior approval, primary care needs to be aware of the detailed clinical criteria relating to this commissioning policy before referring the patient to the appropriate service.

Primary care must also ensure that they supply the all the relevant information to MSK or T&O services, particularly concerning conservative treatments. Conservative treatments should be documented in the patient's primary care record, or via Musculoskeletal Services' letters, or other clinic letters and provided with any referrals to secondary care.

Knee replacement surgery is typically an elective procedure performed under anaesthetic and is the commonest type of surgery performed for osteoarthritis (OA). Depending on the extent of osteoarthritis in the joint, a knee replacement can be either partial (one compartment is replaced) or total (the whole joint is replaced). It is important to note that OA may not be progressive, and many patients can be successfully managed with non-surgical measures in primary care.

Primary Care clinicians should consider the following actions:

- Patients should be encouraged to be involved in self-management of core (non- surgical) treatments, which includes education and lifestyle modifications, exercise and weight loss (where appropriate).
- Patients who smoke should be advised to attempt to stop smoking at least 12 weeks before surgery and should be offered support with smoking cessation services.
- Patients with raised BMI should be supported to lose weight and, where appropriate, offered access to local weight loss services (where these services are available).
- Clinical judgement should be used with regards to the assessment of symptom severity and considering referral for surgical opinion, as there are currently no classification scores validated for clinical use.
- Prior to referral, primary care practitioners should ensure that patients have meaningfully engaged with non-surgical management.

Consider earlier referral to secondary care for patients with suspected end-stage OA.

To support with informed decision making, patients should be given the opportunity in primary care to complete the Decision Aid tools on knee osteoarthritis and knee replacement surgery. Examples of Decision Aid tools include:

"What are my options for managing hip or knee arthritis?" (Cochrane musculoskeletal)

"Arthritis: should I have knee replacement surgery?" (Healthwise) These tools can be accessed online at: https://www.england.nhs.uk/rightcare/shared-decision-making/

Where patients have difficulties accessing decision aid tools online, primary care practitioners should offer support with access wherever possible.

**Oxford score**

The Oxford Hip Score may be used in primary care to guide clinicians whether to make a referral to specialist or not. Patients with a score of 20 or more could be considered for referral. However, it is not a validated tool and should not be used to make the final decision on hip replacement.

See: http://www.orthopaedicscore.com/scorepages/oxford_hip_score.html. Similarly, the tables given in the Appendix below may help patients and clinicians to classify pain and functional impairment in order to judge whether it is the appropriate time to refer a patient to secondary care**.**

**Classification systems for knee**

Pain Levels - at least one of following is met in any category.

*Slight*

- *Sporadic pain.*
- *Pain when climbing/descending stairs.*
- *Allows daily activities to be carried out (those requiring great physical activity may be limited).*
- *Medication, aspirin, paracetamol or NSAIDs to control pain with no/few side effects.*

*Moderate*

- *Occasional pain.*
- *Pain when walking on level surfaces (half an hour, or standing).*
- *Some limitation of daily activities.*
- *Medication, aspirin, paracetamol or NSAIDs to control with no/few side effects.*

*Intense*

- *Pain of almost continuous nature.*
- *Pain when walking short distances on level surfaces or standing for less than half an hour.*
- *Daily activities significantly limited.*
- *Continuous use of NSAIDs for treatment to take effect.*
- *Requires the sporadic use of support systems walking stick, crutches).*

*Severe*

- *Continuous pain.*
- *Pain when resting.*
- *Daily activities significantly limited constantly.*
- *Continuous use of analgesics - narcotics/NSAIDs with adverse effects or no response.*
- *Requires more constant use of support systems (walking stick, crutches).*

*Source:* https://www.aetnabetterhealth.com

# 14 Trauma and Orthopaedics – Other

## 14.1 Arthroscopic Shoulder Decompression for subacromial shoulder pain

**Compliance requirement**

Prior Approval must be obtained by the treating clinician. This must include details of how the patient meets the criteria as specified on the Prior Approval Tick Box Form.

**Malignancy**

If there is any suspicion of malignancy, patients should be referred immediately to the appropriate service.

See the London Cancer guidance at: https://www.healthylondon.org/our-work/cancer/.

**Clinical threshold**

NB: not applicable for rotator cuff procedure and patients under the age of 16

The SWL ICB funds this procedure when ALL of the following criteria (1 - 6) are met.

1. Patient has had symptoms for at least 3 months from the start of treatment:

**AND**

2. Symptoms are intrusive and debilitating (for example waking several times a night, pain when putting on a coat)

*NB. Details of the reason who the patient meets the criteria will need to be provided on the Tick box form (e.g., symptoms affecting the quality of life)*

**AND**

3. Patient has been compliant with conservative management for at least 6 weeks (education, rest, NSAIDs, simple analgesia, appropriate physiotherapy)

**AND**

4. A bursal injection has been considered (if available and acceptable to the patient)

**AND**

5. Following bursal injection (where given) above symptoms have returned

**AND**

6. Patient has been engaged in shared decision making to ensure he/she is well informed about the treatment options available and personal values, preferences and circumstances are taken into consideration

*NB: It is recommended that the SWL Patient Decision Aid is completed. This needs to be recorded in the patient's medical notes, including the written or other materials provided.*

**Rationale for the clinical threshold**

This policy has been developed to ensure that resources are targeted at those with the greatest clinical need. In addition, this policy aims to reduce the variation in access to this procedure.

There is limited evidence to support the effectiveness of subacromial decompression surgery. There is a shortage of high-quality randomised trials and much of the evidence available gives conflicting results regarding the effectiveness of the procedure.

**Primary care advice**

Although primary care is not directly responsible for requesting prior approval, primary care needs to be aware of the detailed clinical criteria relating to this commissioning policy before referring the patient to the appropriate service.

Subacromial pain and impingement syndrome are most typically seen in relatively active patients between 35-60 years of age, it is uncommon in patients under 30 years or over 80 years and consideration should be given to alternative causes of symptoms.

Assessment and diagnosis of subacromial shoulder pain should be clinically guided and imaging is not usually an essential component of assessment in primary care. However, where patients present with traumatic or sudden change to subacromial pain, referral and imaging are advisable.

First-line management of most patients should be with conservative measures, including rest, education, simple analgesia, physiotherapy and a bursal injection (where locally available and acceptable to the patient). The majority of patients will not require a surgical procedure and can be successfully managed with conservative treatment in primary care.

Many patients with subacromial shoulder pain will have pathology amenable to improvements with appropriate structured physiotherapy which should start to show benefits over a course of six weeks e.g. through postural correction and strengthening of the rotator cuff and scapula muscles. If patients have improved following six weeks of appropriate physiotherapy, it is reasonable to consider a second six-week (or longer) course of physiotherapy.

A bursal injection of steroid or local anaesthetic may provide pain relief for up to three months and allow patients to better engage with physiotherapy and rehabilitation (a maximum of two bursal injections can be offered).

When making a referral for patients with subacromial pain, it is expected that this should be via the MSK Single Point of Access (SPA) services (where such pathways are in place).

Evidence regarding the effectiveness of surgical management of subacromial pain is conflicting, however the procedure can be effective in certain circumstances and patient selection is key. Prior to referral to secondary care, the primary care practitioner should ensure that patient wishes to discuss surgical treatment options

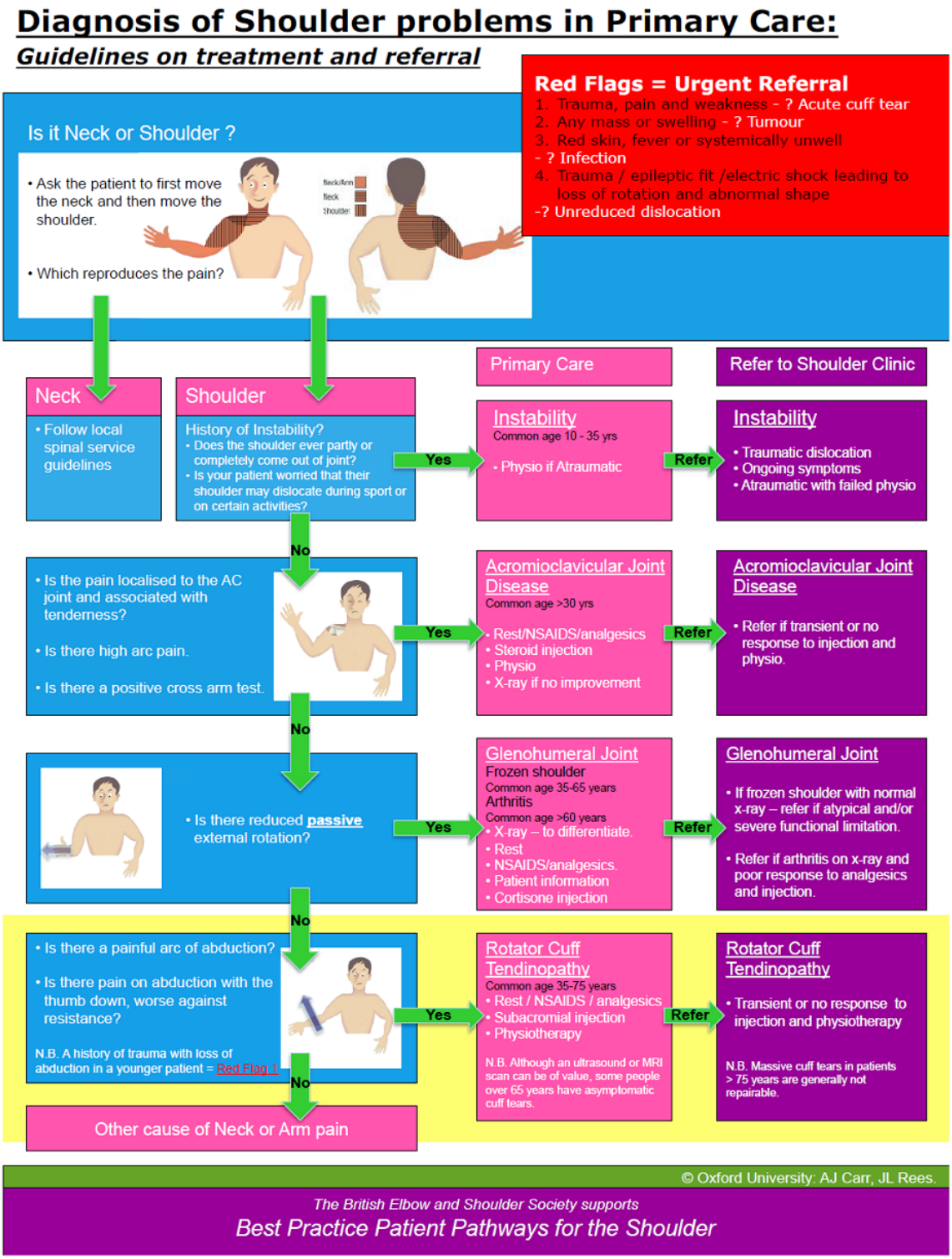
Patients undergoing surgery for subacromial pain and shoulder impingement can expect a period of recovery and rehabilitation of up to six months. As neither conservative nor operative pathways seem to offer a faster restoration of function, patient involvement in decision making is crucial; and high-quality decision support tools would be valuable.

The risk profile of subacromial decompression is low and similar to other shoulder arthroscopy procedures; the commonest adverse events are:

- Pain and stiffness: around 5 to 20 people in 100 will have some degree of ongoing pain and / or stiffness (including frozen shoulder),
- Infection: most commonly a superficial infection and occurs in <1 in 100 people; deep infection is rare (c. 0.02%)

Primary care practitioners should encourage smoking cessation and weight reduction (where appropriate), offering referral to appropriate services where required. These lifestyle changes have the potential to improve general health and wellbeing, as well as intervention success rates and enhance recovery times from surgery.

Consider earlier referral to secondary care services in certain situations (for example patients who are wheelchair bound and / or patients with lower limb amputations).




Taken from: Subacromial shoulder pain BESS/BOA Patient Care Pathways as a guide. Please consider all differential diagnoses and if in doubt please refer to your local MSK SPA for expert triage and review.

## 14.2 Excision of Bunion (Hallux Valgus)

**Compliance requirement**

Prior Approval must be obtained by the treating clinician. This must include details of how the patient meets the criteria as specified on the Prior Approval Tick Box Form.

**Malignancy**

If there is any suspicion of malignancy, patients should be referred immediately to the appropriate service.

See the London Cancer guidance at: https://www.healthylondon.org/our-work/cancer/.

**Clinical threshold**

The SWL ICB funds this procedure when ALL of the following criteria (1 - 3) are met.

1. The patient suffers from:

   **a) Severe deformity (with or without second toe deformity*) that causes significant functional impairment that impacts on activities of daily living****

**OR**

   **b) Severe pain to the hallux valgus, and/or to the second toe, that causes significant functional impairment**.**

**AND**

2. Conservative management has been tried and failed to resolve the condition for at least 6 months.

**AND**

3. Patient has been engaged in shared decision making to ensure he/she is well informed about the treatment options available and personal values, preferences and circumstances are taken into consideration

*NB: It is recommended that the SWL Patient Decision Aid is completed. This needs to be recorded in the patient's medical notes, including the written or other materials provided.*

*Second toe deformity includes: Claw toe, hammer toe and mallet toe

** For the purposes of this policy, 'activities of daily living' covers functions such as dressing, personal hygiene (washing and toileting), functional mobility (moving from one place to another to perform activities required in the home or at work) and meeting nutritional needs (shopping, preparing and eating food).

Rationale for the clinical threshold

This policy has been developed to ensure that resources are targeted at those with the greatest clinical need. In addition, this policy aims to reduce the variation in access to this procedure.

NICE have published two interventional procedure guidance (IPG 140) concerning hallux valgus. This supports the metatarsophalangeal joint replacement of the hallux, whereas IPG 332 stresses caution for the implementation of surgical correction of hallux valgus using minimal access techniques.

There are two commissioning guides, both published in November 2013, which are considered in the development of this commissioning policy.

NHS England's Interim Clinical Policy: Bunion Surgery which was published in November 2013.

This policy sets down clear criteria for the removal of symptomatic or painful bunions, this includes:

- Conservative methods have failed
- Severe deformity causing significant impairment

- Severe pain causing significant functional impairment

It stresses that referral for surgery should not be offered for cosmetic reasons.

The British Orthopaedic Foot and Ankle Society, British Orthopaedic Association, Royal College of Surgeons of England, (2013), Commissioning guide: Painful deformed great toe in adults. The most relevant and up-to-date studies are referenced, and the guidance presents a high value care pathway for painful deformed great toe with criteria for Primary Care, Intermediate Care and Secondary Care. The guide states that referral to Secondary Care should not occur for prophylactic or cosmetic reasons.

**Primary care advice**

Although primary care is not directly responsible for requesting prior approval, primary care needs to be aware of the detailed clinical criteria relating to this commissioning policy before referring the patient to the appropriate service.

Primary care must also make sure that they supply the relevant information to secondary care.

**Conservative measures**

Ensure that the following conservative measures have been implemented by the clinician and/or patient over a period of 6 months:

- Avoiding high heels shoes, and tight pointed footwear
- Wearing roomier footwear with soft leather uppers
- Having podiatry care to remove corns and calluses
- The use of bunion pads to reduce irritation and protect prominent areas
- The use of oral analgesia to help reduce pain and inflammation
- Treatments for recurrent ulceration (where necessary).

**Prior to referral**

Ensure that the patient is made aware of and understands the following:

- There is no guarantee that the foot will be perfectly straight or pain-free after surgery
- Post-surgery, the patient may still not be able to wear normal shoes (or high heels)
- They will be out of sedentary work for 2-6 weeks, and physical work for 2-3 months
- They will be unable to drive for 6-8 weeks
- Full recovery can take an average of 4-6 months.

**Patients with diabetes**

Patients with poorly controlled diabetes should be referred for further management at the Diabetic Service and only referred for bunion surgery when their diabetes is under control.

Complication rates for patients with poorly controlled diabetes are very high for this procedure.

## 14.3 Excision of Ganglia

**Compliance requirement**

Prior Approval must be obtained by the treating clinician. This must include details of how the patient meets the criteria as specified on the Prior Approval Tick Box Form.

**Malignancy**

If there is any suspicion of malignancy, patients should be referred immediately to the appropriate service.

See the London Cancer guidance at: https://www.healthylondon.org/our-work/cancer/.

**Clinical threshold**

The SWL ICB funds this procedure when the following criteria 1 is met.

1. Patient has a ganglion causing

    a) **Severe pain due to size and location**

OR

    b) **Significantly interfering with activities of daily living***

OR

    c) **Recurrent spontaneous discharge of fluid or significant nail deformity.**

* For the purposes of this policy, 'activities of daily living' covers functions such as dressing, personal hygiene (washing and toileting), functional mobility (moving from one place to another to perform activities required in the home or at work) and meeting nutritional needs (shopping, preparing and eating food).

**Rationale for the clinical threshold**

This policy has been developed to ensure that resources are targeted at those with the greatest clinical need. In addition, this policy aims to reduce the variation in access to this procedure.

Management of ganglia is considered to be a procedure of low clinical value. Ganglia are benign lesions that often spontaneously resolve and which only rarely cause functional problems. The evidence suggests that aspiration is useful for reassurance and where there is diagnostic uncertainty. Injection into the ganglion does not have any advantage over aspiration alone.

Surgery is the treatment of choice for those that are symptomatic.

**Primary care advice**

Although primary care is not directly responsible for requesting prior approval, primary care needs to be aware of the detailed clinical criteria relating to this commissioning policy before referring the patient to the appropriate secondary care service.

Primary care must also ensure that they supply the all the relevant information to secondary care, particularly concerning symptoms and their duration and the conservative treatments tried including dates where relevant.

Primary care should consider utilising conferral systems such as Kinesis, where primary care can liaise with providers to seek specialist advice if needed.

If there is a suspicion of malignancy patients should be referred via the established cancer referral pathways and are excluded from this policy.

If there are concerns about the diagnosis an ultrasound scan may be required.

Clinicians should consider aspiration as an alternative to excision due to its lower complication rates. If aspiration has not been attempted and there are local minor surgery services referral to these services should be considered.

**Grading and treatment options for ganglion cysts**

Mild**:** An asymptomatic lump.

Treatment is reassurance and observation.

Moderate: Symptomatic lump with a long duration of symptoms **OR** Occult ganglion.

Treatment is reassurance and observation, with aspiration in primary care for reassurance.

Severe: Severe pain due to size or location **OR** Restriction of activities of daily living*.

Treatment is referral for surgical removal or surgical opinion.

* ‘activities of daily living’ covers functions such as dressing, personal hygiene (washing and toileting), functional mobility (moving from one place to another to perform activities required in the home or at work) and meeting nutritional needs (shopping, preparing and eating food).

# 15 Vascular

## 15.1 Manual Lymphatic Drain (MLD)

**Compliance requirement**

Providers should be aware that this procedure is not routinely funded in South West London, application only via the IFR process by the treating clinician.

**Clinical threshold**

The SWL ICB does not routinely fund this procedure.

## 15.2 Surgery for Varicose Veins

**Compliance requirement**

Prior Approval must be obtained by the treating clinician. This must include details of how the patient meets the criteria as specified on the Prior Approval Tick Box Form.

**Malignancy**

If there is any suspicion of malignancy, patients should be referred immediately to the appropriate service.

See the London Cancer guidance at: https://www.healthylondon.org/our-work/cancer/.

**Clinical threshold**

The SWL ICB funds this procedure when all of the following criteria are met in Group 1 or 2.

Group 1: Criteria (1-4) must be met

1. Patient has a lesion that is Classified on the CEAP* score as
    a) C2 - visible or palpable varicose veins

OR

**b) C3 - swelling (oedema) due to varicose veins**

*NB: CEAP score will need to be provided on the Tick box form*

AND

2. Patient has
    a) One documented episode of superficial thrombophlebitis above the knee

OR

**b) Two documented episodes of superficial thrombophlebitis below the knee**

OR

c) Oedema above the ankle in the affected leg AND Patient experiences severe daily symptoms (such as pain, heaviness, soreness or burning) that affect activities of daily living

AND

3. Patient had a duplex ultrasound that shows truncal reflux

*NB. Date of duplex ultrasound that shows truncal reflux will need to be provided on the Tick box form.*

AND

4. Patient or their carer has been engaged in shared decision making to ensure he/she is well informed about the treatment options available and personal values, preferences and circumstances are taken into consideration.

Including discussions about recurrence and complication rates.

Group 2: Criteria (5-7) must be met

5. Patient has a lesion that is Classified on the CEAP* score as

a) C4 - Skin damage due to varicose veins e.g. varicose eczema, lipodermatosclerosis

OR

**b) C5 - Healed venous leg ulcer (a break in the skin below the knee taking more than 2 weeks to heal)**

OR

**c) C6 - Active venous leg ulcer (a break in the skin below the knee not healed within 2 weeks)**

*NB: CEAP score will need to be provided on the Tick box form*

AND

6. Patient had a duplex ultrasound that shows truncal reflux

*NB. Date of duplex ultrasound that shows truncal reflux will need to be provided on the Tick box form.*

AND

7. Patient or their carer has been engaged in shared decision making to ensure he/she is well informed about the treatment options available and personal values, preferences and circumstances are taken into consideration.

Including discussions about recurrence and complication rates.

* Clinical severity, Etiology, Anatomical location, Pathophysiology (CEAP)

| *CEAP* | *Subjective Score* |
|---|---|
| *C0* | No visible or palpable varicose veins |
| *C1* | Telangiectasia / reticular veins |
| *C2* | Visible/palpable varicose veins (symptomatic or asymptomatic) |
| *C3* | Swelling (oedema) due to varicose veins (venous oedema) |
| *C4* | Skin damage due to varicose veins (e.g. varicose eczema, atrophie blanche) |
| *C5* | Healed venous leg ulcer |
| *C6* | Active venous leg ulcer |

Please note:

The following are not covered in the policy: pregnant women, patients with haemorrhage of varicose veins and patients under the age of 18.

The SWL ICB does not routinely fund the following:

- **Patients with no symptoms or skin changes associated with venous disease**
- **Patients whose concerns are cosmetic including telangectasia and reticular veins**
- **Patients with mild symptoms including itch, ache, mild swelling, minor changes of skin eczema and haemosiderosis**

Pregnant women presenting with varicose veins should be given information on the effect of pregnancy on varicose veins. Interventional treatment for varicose veins during pregnancy should not be carried out other than in exceptional circumstances. Compression hosiery should be considered for symptom relief of leg swelling associated with varicose veins during pregnancy.

**Rationale for the clinical threshold**

This policy has been developed to ensure that resources are targeted at those with the greatest clinical need. In addition, this policy aims to reduce the variation in access to this procedure in line with NICE guidelines CG168

The prevalence of significant venous incompetence is around 40% in men and 32% in women with up to 80% people having minor venous abnormalities. Risk factors for developing varicose veins include two or more pregnancies, obesity (women only) and work that involves prolonged standing.

Venous symptoms include pain limiting normal activity, eczema with progressive skin changes, phlebitis, bleeding and, if untreated, venous ulceration. 1% of the adult population have active leg ulceration, most of which is due to underlying venous disease.

Symptomatic varicose veins are defined as those that are significantly affecting the individual's activities of daily living* including their ability to work or provide care.

**Primary care advice**

Although primary care is not directly responsible for requesting prior approval, primary care needs to be aware of the detailed clinical criteria relating to this commissioning policy before referring the patient to the appropriate secondary care service.

Primary care must also ensure that they supply the all the relevant information to secondary care, particularly concerning conservative treatments including dates and modalities of treatments.

Most varicose veins require no treatment. The key role of primary care is to provide reassurance, explanation and education, including advice on exercise, leg elevation and weight reduction if necessary. Primary care is also involved in overseeing skin care and making recommendations about the use and application of support hosiery and compression bandaging.

For patients with asymptomatic varicose veins - offer patients information and explanation:

- **This should include information on the likelihood of developing symptoms as well as complications such as skin changes, leg ulcers, bleeding, thrombophlebitis and deep vein thrombosis**

- **Lifestyle advice should be offered that encourages people to maintain a healthy weight, undertake moderate physical exercise and avoid prolonged standing, and stop smoking (where appropriate)**

**Conservative treatment**

Patients should have received 6 months of conservative treatment (listed below) before referral and will not normally be accepted for interventional treatment without evidence that conservative treatment has failed:

- Patients should lose weight loss if their BMI is raised
- Taking up light to moderate exercise
- Avoidance of prolonged immobility
- Patients should also be advised to stop smoking – in particular, patients with thrombophlebitis

**Grading of varicose veins**

There are seven grades of increasing clinical severity listed below. For the initial assessment of a patient, the clinical severity assessment can be simple observation and does not need special tests:

Clinical severity, Etiology, Anatomical location, Pathophysiology (CEAP)

| *CEAP* | *Subjective Score* |
|---|---|
| *C0* | No visible or palpable varicose veins |
| *C1* | Telangiectasia / reticular veins |
| *C2* | Visible/palpable varicose veins (symptomatic or asymptomatic) |
| *C3* | Swelling (oedema) due to varicose veins (venous oedema) |
| *C4* | Skin damage due to varicose veins (e.g. varicose eczema, atrophie blanche) |
| *C5* | Healed venous leg ulcer |
| *C6* | Active venous leg ulcer |

**Pregnancy**

Particular attention should be paid to the conservative management of varicose veins in primary care during pregnancy. So in addition to the conservative management listed above these should be considered:

- Give pregnant women presenting with varicose veins advice on varicose veins
- Do not carry out interventional treatment for varicose veins during pregnancy
- Consider compression hosiery for symptom relief.

**Referral to vascular services**

Patients should be referred to vascular services when patients have at least one of these:

- At least two episodes of superficial thrombophlebitis

- A major episode of bleeding from the varicosity
- An active ulcer
- Skin changes including: eczema, lipodermatosclerosis or a healed venous ulcer.

Please note: The SWL ICB does not routinely fund the following:

- Patients with no symptoms or skin changes associated with venous disease
- Patients whose concerns are cosmetic including telangectasia and reticular veins
- Patients with mild symptoms including itch, ache, mild swelling, minor changes of skin eczema and haemosiderosis

# 16 ASSISTED CONCEPTION TREATMENTS (ACT)

## 16.1 Introduction and purpose

This Policy sets out the criteria for access to specialist fertility services for the South-West London population. It is published as a refresh to the "SWL CCG ACT and Fertility Preservation Policy V1" (March 2020) to reflect both the transition of the SWL CCG to an Integrated Care Board (ICB) and the continuing ambition to ensure equity of assisted conception and fertility preservation service provision across South-West London.

## 16.2 Objective

The objectives of this policy are:

- To reduce unwarranted variation in access to treatments/procedures,
- To ensure that the treatments/procedures contained within it have acceptable evidence of clinical benefit and cost-effectiveness, and
- To promote the cost-effective use of healthcare resources

## 16.3 Definition of Assisted Conception Treatments

Assisted Conception Treatments ("ACT") can be broadly defined as *"any medical, surgical or obstetric services provided for the purpose of assisting a person to carry a child."* This is based on the definition of "Treatment Services" in Section 2 of the Human Fertilisation and Embryology Act (1990). This includes any medicines, surgery or procedures that are required to diagnose and treat sub-fertility so that a person can have a child.

Please see Section 19 for the list of interventions that are covered by this policy.

## 16.4 Scope of policy

This policy addresses ACT for diagnosed sub-fertility for which the responsibility for strategy and planning rests with the SWL ICB, rather than with NHS England. It details the funding position for patients and their partners, if they have one, regardless of their sexual orientation and their partnership status.

The policy applies to all adult patients, defined as aged 18 years of age or over.

## 16.5 Principles of an Integrated Care System

In line with the plan for the SWL CCG to transition its role into one that is part of an Integrated Care Board (ICB) in 2022, this policy has been developed to ensure that it works to the core principles of an integrated care system, with it playing a critical role in aligning action between partners to achieve their shared purpose: to improve outcomes and tackle inequalities, to enhance productivity and make best use of resources and to strengthen local communities.

The core principles are:

- System leadership, partnerships and change capability: When it comes to contracting and procurement activities, this will be done with strong collaboration of all partners across the system in a proactive and transparent manner.

- System architecture and strong financial management and planning: Ensuring there is value for money and appropriate incentives to support strategy and planning and health objectives across the system.

- Integrated care models: Integration of services and teams will be considered for service models and transformation projects.

- Track record of delivery: Robust contract management and engagement to ensure services are being delivered as needed and are demonstrating positive impact on population health outcomes.

- Coherent and defined population: Developing services that respect patient flows across SWL as a system whilst promoting patient choice and standard availability.

### 16.6 Adherence to NICE guidance and constraints on NHS resources

Whilst this policy gives due consideration to the recommendations of NICE clinical guidance, specifically CG156 (published February 2013, last updated September 2017) it does not follow all CG156 recommendations as CG156 is a regulation 5 NICE clinical guidance, which allows the ICB to apply discretion in the implementation of its recommendations. This is required as the ICB also has other statutory parliamentary obligations which must be met, but which are not always compatible with fully implementing all clinical guidance issued by NICE.

NICE CG156 recommends three cycles of IVF, however, the SWL ICB will fund one cycle. The reason for this decision is that the ICB has determined that within the currently available resources, it wishes to enable more individuals to have access to IVF treatments rather than place restricted entry to a smaller number of individual people who are offered three cycles of NHS-funded IVF.

In 2017-18, almost two thirds of CCGs in England and Wales provided only one cycle of IVF, four per cent of CCGs provided no IVF funding at all and only 13 per cent funded the three cycles recommended by NICE CG1561.

The summary of the access criteria for ACT is available in Section 21.

# 17 Epidemiology of sub-fertility

### 17.1 Prevalence

Around 1 in 7 couples may have difficulty conceiving. 84% of women in the general population will conceive within one year if the woman is aged under 40 years AND they do not use contraception and have regular sexual intercourse (every 2 – 3 days). This increases to 92% after 2 years and 93% after 3 years.

The epidemiology of male and female sub-fertility is covered in detail in NICE CG156 which outlines that the main causes of sub-fertility in the UK are

- Factors in the male causing infertility 30%
- Unexplained infertility 25%
- Ovulatory disorders 25%
- Tubal damage 20%

- Uterine or peritoneal disorders 10%

In about 40% of cases, disorders are found in both the man and the woman.

### 17.2 Unexplained sub-fertility

Most causes of sub-fertility can be treated by medical or surgical interventions, after which patients can become fertile and achieve conception normally.

When the results of a standard sub-fertility evaluation are normal, practitioners assign a diagnosis of unexplained sub-fertility.

# 18 Investigations of sub-fertility and onward referral

### 18.1 Access to investigations of sub-fertility

Anyone can be referred for investigation of their sub-fertility if they meet the guidelines set by NICE, regardless of their eligibility status for ACT,

This is with the exception of overseas visitors: Where two people are seeking assisted conception services with NHS funding, and one of the two people is covered by health surcharge arrangements and the other is ordinarily resident in the UK and therefore not subject to charge, the services required by the health surcharge payer will be chargeable. Any services required by the ordinarily resident person will continue to be freely available, subject to the established local or national contracting and funding arrangements. Please note that this applies to both investigations and treatment.

*Source: Dept of Health & Social Care Guidance on implementing the overseas visitor charging regulations. Updated 1st November 2021*

### 18.2 Initial consultation with patients in primary care

Patients and their partners if they have one, should be consulted with as a couple and the initial consultation with them should cover the following areas:

- Prevalence of sub-fertility and delays in conception
- Discussion of the patient's and their partner's sexual history
- Advice on lifestyle:
- Smoking
- Alcohol and recreational drug use
- Caffeine intake
- Weight management and healthy eating
- NHS-funded assisted conception treatments: access criteria for IUI, IVF and ICSI
- Success rates of IVF (as outlined in the table below)

| Age of women | Live birth rate |
|---|---|
| Under 35 | 29% |
| 35 - 37 | 23% |
| 38 – 39 | 15% |
| 40- 42 | 9% |
| 43 – 44 | 3% |
| Over 44 | 2% |

The above figures show national 2014-2016 data, for women using their own eggs and their partner's sperm, using the per embryo transferred measure.

## 18.3 Expectant management for heterosexual couples

Couples in a heterosexual relationship where the woman has not conceived after 12 months of regular unprotected vaginal intercourse should be investigated for the causes of sub-fertility. If the prospective mother is aged 36 years or over (i.e., after their 36th birthday) at the first time of presenting to Primary Care with sub-fertility concerns, they should be investigated after 6 months of regular unprotected vaginal intercourse.

During the investigation stage into sub-fertility heterosexual couples must continue to have regular unprotected vaginal intercourse, as after a total of 24 months the cumulative pregnancy success rates rises to 92% for patients under 40.

This expectant management involves supportively offering an individual or couple information and advice about the regularity and timing of intercourse as well as any lifestyle changes which may improve their chances of conceiving.

All couples must demonstrate 24 months of regular unprotected vaginal intercourse before they can access ACT, unless the cause of sub-fertility has already been identified either before or during this 24-month period.

Heterosexual couples who are unable to have unprotected vaginal intercourse must demonstrate their sub-fertility by receiving Unstimulated Intrauterine Insemination (IUI) in the same way as women in same sex relationships and single women, in line with NICE CG156.

Please see Section 22 of this policy for details of eligibility and exclusion criteria.

## 18.4 Women in a same sex relationship and single women

Women in a same sex relationship and single women who have had six cycles of unstimulated Intrauterine Insemination (IUI) over a period of at least six months would be considered the equivalent of having 12 months of unprotected vaginal intercourse.

Women in a same sex relationship and single women who have not conceived after six cycles of IUI should be investigated for the causes of sub-fertility. If the prospective mother is aged 36 years or over (i.e., after their 36th birthday) at the first time of presenting to Primary Care with sub-fertility concerns, they should be investigated after 3 cycles of IUI over a period of at least three months.

Women in a same sex relationship and single women must demonstrate that they have had a total of 12 cycles of IUI over a period of at least 12 months before they can access ACT, unless a cause of sub-fertility has already been identified either before or during this 12-month period.

Patients should provide documented evidence that IUI has taken place in a HFEA licensed clinical setting. Cycle summaries obtained from the Unit where patients have had previous treatments must be shared with fertility specialists.

## 18.5 Men in a same sex relationship and single men

Men in a same sex relationship and single men are eligible for semen analysis, although it must be stated to them that surrogacy is not funded by the NHS for anyone.

## 18.6 Transgender people

Transgender people are eligible for a direct tertiary care referral on the recommendation of the NHS transgender provider they attend.

## 18.7 Primary care investigations of sub-fertility

The following investigations and interventions should be carried out in primary care.

### 18.7.1 Female Partner

- Optimisation of BMI (target range between 19 and 30)
- Provision of lifestyle advice and referral as appropriate on:
    - Smoking
    - Alcohol and recreational drug use
    - Caffeine intake
- FSH taken between day two and five of the cycle
- The mid-luteal phase (7 days before period) progesterone level
- Thyroid function tests (only where there are symptoms of thyroid disease)
- Prolactin only if there are symptoms of ovulatory disorder, galactorrhoea or a pituitary tumour, and
- Rubella and Chlamydia testing via Polymerase chain reaction (PCR) swab.

### 18.7.2 Male partner

- Semen analysis test, repeat if results of first test are abnormal
- Optimisation of BMI (target range between 19 and 30)
- Provision of lifestyle advice and referral as appropriate on:
    - Smoking
    - Alcohol and recreational drug use, and
    - Caffeine intake

## 18.8 Onward referral to secondary care

Patients and their partners if they have one, should only be referred to secondary care once the above investigations have been undertaken.

All patients are eligible for an onward referral for investigation of sub-fertility if clinically indicated even if they do not meet the access criteria for ACT set out in this policy. As outlined within Section 18.1 above, this is with the exception of overseas visitors, this exception applying to both investigations and treatment.

If the prospective mother is aged 36 years or over (i.e., after their 36th birthday) at the first time of presenting to primary care with sub-fertility concerns, they should be referred after six months of regular unprotected vaginal intercourse or three cycles of unstimulated IUI over a period of at least three months.

If the sub-fertility has already been investigated and a cause for the sub-fertility has been diagnosed, or if resulting from previous investigations relating to a separate issue the individual is known to be sub-fertile, they should be referred for appropriate treatment for the sub-fertility without further delay.

Primary care providers must ensure that:

- All results for the patient and their partners if they have one are sent to secondary care, and
- They attend as a couple if they are in a relationship.

## 18.9 Secondary care investigations of sub-fertility

Patients and their partners if they have one, should attend consultations as a couple.

All patients should be investigated in line with NICE CG156 and Primary Care must provide results of all investigations undertaken to avoid unnecessary testing.

Please note that, in line with NICE CG156 the SWL ICB does not fund the following tests:

- Routine post coital testing of cervical mucus,
- Thyroid function tests (unless symptoms of thyroid disease),
- Prolactin (unless ovulatory disorder, galactorrhoea or pituitary tumour),
- Screening for anti-sperm antibodies,
- Use of basal body temperature charts to confirm ovulation,
- Endometrial biopsy to investigate the luteal phase, and
- Hysteroscopy as a treatment procedure.

## 18.10 Referral to Assisted Conception Units (ACU)

Referral to Assisted Conception Units (ACU) should be considered for women and their partners if they have one, if they meet the access criteria for receiving NHS-funded ACT as detailed in Section 21 of this policy. If they do not meet the access criteria, they should be advised that they can access ACT privately.

Referrals must be made by the prospective mother's GP or the investigating gynaecology team, confirming that the patient meets the access criteria and providing the entire relevant medical history, including all previous investigation results.

Referral must be made to HFEA licenced and SWL accredited ACU providers.

### 18.11 Specialist referral

Specialist referral should be considered for people with chronic viral infections such as hepatitis B, hepatitis C, or HIV, to the centres that have the appropriate expertise and facilities to provide safe, risk-reduction investigation and treatment.

All individuals undergoing IVF treatment should be offered testing for HIV, hepatitis B and hepatitis C and referred to the specialist centre if found to be positive.

### 18.12 Additional tests and investigations

Primary Care providers are only expected to undertake the investigations and interventions outlined in Section 18.7 above.

Additional tests (e.g., anti-Mullerian hormone test, hepatitis B serology, HIV) and drug prescriptions are covered within the secondary or tertiary care provider tariffs and should not be undertaken by Primary Care. This includes requests from private providers, regardless of whether the treatment is NHS- or self-funded.

The management of the patient and their partner if they have one becomes the responsibility of Primary Care once the pregnancy enters the antenatal care stage.

Additional medication requested from Primary Care must be in line with the recommendations of the Royal College of Obstetricians & Gynaecologists and the HFEA traffic light system.

## 19 Treatments of sub-fertility

Once a diagnosis of sub-fertility has been established, treatment falls into three main categories:

- Medical treatments i.e., the use of drugs for ovulation induction, OR
- Surgical treatments i.e., repair of the fallopian tubes, OR
- Assisted Conception Treatments – any treatment that deals with the means of conception which is other than vaginal intercourse.

This policy covers only the ACT, where natural conception is not possible, within which the SWL ICB will fund the following treatments based on the patient meeting the access criteria outlined with Sections 20 to 22 of this policy.

- Sperm washing
- Unstimulated Intrauterine Insemination (IUI)
- In Vitro Fertilisation (IVF) and Intracytoplasmic Sperm Injection (ICSI) including the cryopreservation of frozen embryos to complete a full cycle.

Explained sub-fertility which has a treatable cause, should be treated prior to the patient being referred for assisted conception.

# 20 Sperm washing to prevent HIV transmission

Sperm washing is a process in which individual sperm are removed from the semen then used in assisted conception treatments. 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. Hence, sperm washing decreases the transmission rate of HIV to an unborn child.

The SWL ICB will fund sperm washing for the prevention of HIV transmission when:

- The male patient is HIV positive and compliant with Highly Active Antiretroviral therapy (HAART),

  AND
- Plasma viral load is 50 copies/ml or greater,

  AND
- Female partner is HIV negative.

Please note:

- The SWL ICB does not routinely fund sperm washing for any other indication, such as hepatitis B or hepatitis C, as current evidence does not support this.
- NHS England is responsible for the funding of all antiretroviral medicines for all indications.

# 21 Access criteria for Assisted Conception Treatments

The following table provides a summary of the funding criteria formthe provision of assisted conception treatments across South West London. Additional clarification may be found in the sections directly referenced.

| Title | Funding Criteria | Explanation |
|---|---|---|
| **Status** | The prospective mother must be a registered patient of a GP practice in SWL at the time of commencing on the ACT pathway.<br><br>Patients already on the ACT pathway, who move to SWL and register with a GP practice in SWL will be treated in line with this policy. | Charges relating to ACT are linked to the prospective mother (as the receiver of the treatment).<br><br>All SWL residents have access to one cycle of NHS-funded IVF/ICSI. |
| **Sub-fertility or infertility** | Patient either has an identified cause of sub-fertility/infertility or has had 24 months of unexplained infertility.<br><br>For single women or same-sex female couples this means 12 cycles of unstimulated IUI over at least 12 months. | 84% of women under the age of 40 conceive within 12 months if they do not use contraception and have regular sexual intercourse. This increases to 92% after 24 months.<br><br>Please see section 18 for further details. |
| **Sterilisation** | Neither the patient nor their partner, if they have one, should have undergone previous sterilisation. | Sterilisation is offered by the NHS as an irreversible method of contraception. This funding criteria also applies to those who have undergone reversal of sterilisation regardless of whether any part of this was NHS- or otherwise funded. |
| **FSH level** | Highest ever level of FSH taken between day 2 and 5 of the cycle must be less than or equal to 8.9iu/L. However, if the levels are >8.9 and <11.8 and the AMH $\geq$5.4 then funding approval could be sought using only AMH. | NICE recommendation. |

| | | |
|---|---|---|
| **AMH level** | AMH level has always been equal or greater than 5.4pmol/l within the last 6 months. | NICE recommendation. |
| **Childlessness** | The couple has no living child from their current relationship and at least one of the prospective parents does not have any living children from a previous relationship.<br><br>A child adopted by a patient or adopted in a previous relationship is considered to have the same status as a biological child. | If both partners have living children, they do not qualify for further NHS-funded ACT. This is to enable those without children to be prioritised. |
| **Welfare of the child** | Each patient and their partner, if they have one must conform to the HFEA 'Code of Practice' to be able to access to NHS-funded ACT. | This includes consideration of the 'welfare of the child which may be born' which may take into account the importance of a stable and supportive environment for children as well as the pre-existing health status of the parents. |
| **Age of woman** | Please note that this policy only applies to adults only.<br><br>Prospective mothers must be no more than 42 years of age (i.e., before their 43rd birthday) at start of the full IVF/ICSI treatment cycle. | Age is a robust indicator of success of ACT and the younger the woman is, the higher the success rate is.<br><br>The start of the treatment cycle is defined in Section 23.4. |
| **Body mass index (BMI)** | Prospective mothers must have a BMI of between 19 and 30 for a period of at least six months prior to commencement of treatment. | NICE recommendation. |
| **Smoking status** | Each patient and their partner, if they have one, must have been non-smokers for at least six months prior to commencement of treatment. | Smoking and other nicotine products can adversely affect the success rates of ACT.<br><br>Patients are advised to avoid vaping as currently there is limited and uncertain evidence around its safety.<br><br>Consider carbon monoxide (CO) testing if there is suspicion that patients continue to smoke. |

| | | |
|---|---|---|
| **Alcohol and recreational drug use** | Each patient and their partner, if they have one, must give assurances that their alcohol intake is within current Department of Health guidelines, and they are not currently using recreational drugs. | HEFA guidance.<br><br>Any evidence to the contrary will result in the cessation of treatment. |
| **Number of IUI cycles of treatment** | The SWL ICB will fund up to 12 NHS-funded unstimulated IUI cycles for eligible patients.<br><br>Please note that IUI for single women and same-sex couples is not routinely funded unless the criteria in Section 22 are met. | See Section 22 for details of eligibility and exclusion criteria. |
| **Number of IVF/ICSI cycles of treatment** | The SWL ICB will fund one NHS-funded full IVF/ICSI cycle for eligible patients.<br><br>Please note that patients who have previously had NHS-funded IVF/ICSI or patients who have had more than two full cycles of IVF/ICSI (if aged under 40) and more than one cycle (if over 40), whether privately or NHS-funded will not receive any further NHS-funded IVF/ICSI.<br><br>For women aged 40 to 42 who have been trying for 2 years or longer, or they have had 12 cycles of IUI, SWL will fund 1 full cycle of IVF if the following apply:<br><br>• they have never had IVF before<br>• they have discussed the risks of IVF and becoming pregnant at this age with their doctor. | See Section 23 for details.<br><br>Age limits as per NICE Guidance and Quality Statement |

# 22 Intrauterine Insemination (IUI)

Intrauterine insemination (IUI) is a technique to place sperm into a woman's womb through the cervix. This may be carried out using the partner's sperm, or using sperm donated by another man (either anonymously or not). The SWL ICB will fund up to 12 cycles of unstimulated IUI, however this does not include any costs or expenses associated with donor sperm.

## 22.1 Indications for IUI

Patients will qualify for NHS-funded IUI if they meet the following criteria:

- Had all appropriate tests and investigations in primary and secondary care in line with NICE guidelines, AND
- Meet all the access criteria given in Section 21, AND
- Heterosexual couples who are unable to, or who find it very difficult to have vaginal intercourse because of:
    - A clinically diagnosed physical disability OR
    - Psychosexual problems formally diagnosed*.

## 22.2 Please note that:

- SWL does not routinely fund the following:
    - IUI for same sex female couples and single women.
    - Stimulated IUI.
- Patients must be advised that it is their responsibility to source and pay all costs associated with the donor sperm, including transportation cost to the ACU.

**Patients/couples with psychosexual problems must access psychosexual counselling services to address the underlying causes.*

# 23 In Vitro Fertilisation (IVF/ICSI)

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 to fertilise it, with the resulting embryo subsequently transferred to the womb.

## 23.1 Number of cycles to be funded

The SWL ICB will fund one full cycle of IVF/ICSI for eligible patients with proven sub-fertility. NICE states that the overall chance of a live birth following IVF treatment will fall as the number of unsuccessful cycles increases.

Patients who have previously had NHS-funded IVF/ICSI or patients who have had more than two full cycles of IVF/ICSI (if aged under 40) and more than one cycle (if over 40), whether privately or NHS-funded will not receive any further NHS-funded IVF/ICSI.

## 23.2 Indications for IVF

Patients will qualify for NHS-funded IVF if they meet the following criteria:

- Had all appropriate tests and investigations in line with NICE guidelines, AND
- Meet all the access criteria given in section 21.

## 23.3 Indications for ICSI

The decision on whether to use IVF alone or IVF with ICSI should be undertaken by the specialist in line with the HFEA Code of Practice 9th edition. The recognised indications for treatment by ICSI include:

- Severe deficits in semen quality,
- Obstructive azoospermia,
- Non-obstructive azoospermia,
- Previous IVF treatment cycle that has resulted in failed or very poor fertilisation.

## 23.4 Definition of a full IVF/ICSI treatment cycle

The full IVF/ICSI cycle as defined by the SWL ICB will consist of one fresh embryo transfer followed by one Frozen Embryo Transfer (FET), if good quality embryos were frozen as part of the cycle. A successful fresh embryo transfer (in terms of a live birth) would make the couple ineligible for a FET.

A full cycle of IVF/ICSI as defined by the SWL ICB includes the following:

- Ovarian stimulation including all the drugs used in preparation for IVF/ICSI (including down regulation if required)
- Egg recovery
- Fertilisation and fresh embryo transfer

- Frozen Embryo Transfer (FET) if the fresh embryo transfer failed
- Freezing of good quality spare embryos
- The ICB will fund storage of frozen embryos for 12 months following egg collection
- Following this period, continued storage will need to be funded by the couple

An NHS-funded cycle of IVF/ICSI treatment is considered to have commenced once ovarian stimulation drugs have been initiated. A cancelled cycle is one where an egg collection procedure is not undertaken. In this event, patients may be eligible for a further IVF/ICSI cycle if their ovarian reserves meet the eligibility criteria at this stage.

Beyond this stage, a cycle will be counted as complete, whether a fresh embryo transfer is or is not attempted.

If a fresh embryo transfer isn't available or is deemed clinically unsuitable, for example where patients have had eggs or sperm frozen due to medical reasons (please see the Fertility Preservation Section) the patient will be eligible for two Frozen Embryo Transfers (FET). If the thawing of the frozen eggs or sperm fails, this does not count as a completed FET. In this event, patients may be eligible for a further FET cycle if there are further frozen eggs or sperm.

Where eligible couples have frozen embryos from previous treatment, they must first utilise these embryos rather than undergo ovarian stimulation, egg retrieval and fertilisation again.

Any pre-existing conditions should be managed prior to starting Assisted Conception Treatments. If the patient should require fertility preservation in these circumstances, all patients should meet the Fertility Preservation criteria as outlined within the policy.

All drug and investigation costs will be met by the ACU as part of the contracted service and must not be prescribed by a GP.

Switching providers should not take place before the full IVF cycle is complete (including fresh and, where indicated, frozen embryo transfer).

## 23.5 Multiple births strategy

The SWL ICB requires accredited SWL ACU providers to adhere to the 'One Child at a Time' HFEA guidance to minimising multiple births and the recommendations of NICE *Quality statement 8: Number of embryos transferred*.

https://www.nice.org.uk/guidance/qs73/chapter/Quality-statement-8-Number-of-embryos-transferred.

The rationale for avoiding multiple pregnancies is based on the costs of mitigating the additional health risks to mother and child, which have been identified widely1.

The SWL ICB will fund embryo transfers and freezing, to support this single embryo transfer strategy.



1 A report by the National Guideline Alliance about twin pregnancy costing. September 2018. Available at: http://www.multiplebirths.org.uk/twin_pregnancy_costing_final.pdf

### 23.6 Timeframes for IVF/ICSI

It is the responsibility of SWL accredited ACU to ensure that criteria set within this policy is adhered to, including commencement of ACT specified for the ages of prospective mothers. The start of IVF/ICSI treatment is defined as the start of the stimulating phase of the IVF cycle.

Patients and their partners if they have one must take up the offer of IVF/ICSI within six months of being offered IVF/ICSI by the accredited SWL ACU.

Once the NHS-funded full IVF/ICSI treatment has commenced, patients can delay treatment between the fresh cycle and frozen cycle for up to 12 months, and the cryopreservation of the embryos following the fresh cycle is funded for up to 12 months.

## 24 Sperm donation for IUI/IVF/ICSI

Sperm donation is a process by which a man donates his sperm to enable a woman who is not his sexual partner to conceive as part of an assisted conception treatment.

The SWL ICB will not fund the actual donor sperm but will fund the associated IUI/IVF/ICSI treatment in line with the criteria in this policy, providing the sperm meets the criteria defined by the accredited SWL ACU.

Patients must be advised that it is their responsibility to source and pay all costs associated with the donor, including transportation cost to the SWL accredited ACU.

## 25 Egg donation for IUI/IVF/ICSI

Egg donation is the process by which a woman donates eggs to enable another woman to conceive as part of an assisted conception treatment.

The SWL ICB will not fund the actual egg donor/donation but will fund the associated IUI/IVF/ICSI treatment in line with the criteria in this policy, providing the eggs meet the criteria defined by the accredited SWL ACU.

Patients must be advised that it is their responsibility to source and pay all costs associated with the donor, including transportation cost to the SWL accredited ACU.

# 26 Treatments and interventions not routinely funded by the SWL ICB

The SWL ICB will not routinely fund the following, which includes but is not limited to:

- Surrogacy in any form (e.g., part surrogacy),
- Natural IVF, where no drugs are used,
- In vitro maturation (IVM): Involves the removal of immature eggs that have yet to complete their growth, and then maturing these eggs in the laboratory,
- Procurement, transport or storage of donor sperm or eggs,
- Endometrial scratch: A procedure in which a superficial scratch is made in the uterus lining (endometrium) at a certain point during the menstrual cycle to better prepare the womb for the implantation of an embryo.
- Aneuploidy screening: The testing of embryos for evidence of sex-linked diseases and structural chromosomal defects before their implantation in the uterus during assisted reproduction.
  (NB Pre-implantation genetic diagnosis (PGD) is funded by NHS England),
- Varicocele surgery for male infertility,
- Experimental investigations including, but not limited to:
    - Assessment of sperm movements (e.g.: videomicrography, cinematography, time-exposure photography, computer assisted sperm analysis),
    - Analysis of ATP concentration (Adenosine triphosphate) in ejaculate,
    - Tubaloscopy,
    - Anti-zona pellucida antibodies,
    - Sperm hyaluronan binding assay (HBA),
    - Tests of sperm DNA integrity, including, but not limited to, sperm chromatin assays and sperm DNA fragmentation assays,
    - Hemizona assay,
    - Hypo-osmotic swelling test.
- Modifications of the IVF procedure including, but not limited to:
    - GIFT (gamete intrafallopian transfer),
    - ZIFT (zygote intrafallopian transfer),
    - PROST (pronuclear stage transfer),
    - TEST (tubal embryo stage transfer).
- TET (tubal embryo transfer),
- Other additional ‘add-on’ IVF treatments and procedures not listed here will not be funded unless they have received ‘green light’ approval from the HFEA.

Note that providers are not allowed to offer or charge for ‘add-on’ IVF treatments to those receiving NHS-funded ACT.

# 27 NHS England funded treatments

NHS England has the funding responsibility for the following interventions. For up-to-date details of the specific criteria please visit the NHS England website.

## 27.1 Pre-implantation genetic diagnosis (PGD)

Pre-implantation genetic diagnosis (PGD) is a technique that involves testing cell(s) from embryos created outside the body by IVF for a genetic disorder. Tests are carried out for the specific disorder that the embryos are known to be at significant risk of inheriting. Unaffected embryos are selected for transfer to the uterus in the hope that a normal birth will ensue. Whilst the PGD technology requires IVF and ICSI services, it is not part of tertiary assisted conception services, and as such does not form part of this policy. PGD is contracted and funded by NHS England[3].

## 27.2 Surgical sperm retrieval

Spermatozoa can be retrieved from both the epididymis and the testes using a variety of techniques with the intention of achieving pregnancies for couples where the male partner has 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 epididymis) and have low fertilising ability with standard IVF. It is therefore necessary to use ICSI. Surgical sperm retrieval is funded by NHS England[3].

Surgical sperm retrieval is always accompanied by cryopreservation, which is funded within SWL ICB as per this policy. Cryopreserved sperm will need to meet all the eligibility criteria before subsequent IVF/ICSI can take place.

# 28 FERTILITY PRESERVATION

## 28.1 Introduction and purpose

This Policy sets out the criteria for equitable access to fertility preservation services for the population of the South-West London ICB. It is published as a refresh to the "SWL CCG ACT and Fertility Preservation Policy V1" (March 2020) to reflect the transition of the SWL CCG to an Integrated Care Board (ICB) and as part of continuing ambition to ensure equity of assisted conception and fertility preservation service provision across South-West London.

## 28.2 Objective

The objectives of this policy are as follows:

- Reduce unwarranted variation in access to fertility preservations treatments and procedures,
- Ensure that the treatments/procedures contained within it have acceptable evidence of clinical benefit and cost-effectiveness, and
- Promote the cost-effective use of healthcare resources across the SWL region.

## 28.3 Definition of fertility preservation

Fertility preservation may entail the harvesting and freezing of eggs or sperm that may then be thawed for use in future assisted conception treatment (ACT). Alternatively, it may entail the creation of embryos for freezing that may be implanted in the womb later.

Cryopreservation or cryo-storage may be used as a synonym for fertility preservation.

If any fertility treatment results in a living child, the couple will no longer be considered childless and will not be eligible for further NHS funded fertility treatments, including the implantation of any stored embryos. Any costs relating to the continued storage of the embryos beyond the first calendar year of the retrieval date is the responsibility of the couple.

The SWL ICB will fund one cycle of fertility preservation, including sperm, egg and embryo cryo-storage in the following circumstances:

- Patients in receipt of a clinically appropriate diagnosis, usually in line with NHS Guidance, who are preparing to undergo medical, non-medical and surgical treatment that is likely to have a permanent harmful effect on subsequent sperm or egg production. Such treatment may include but is not limited to:
    - Surgery, radiotherapy or chemotherapy for malignant disease,
    - Treatment for gender dysphoria.

- Patients whose ongoing medical condition or treatment causes harmful effects on sperm or egg production or has possible teratogenic effects and when stopping treatment for a prolonged period, to enable conception is not possible.

**Please note** The SWL ICB does not routinely fund the following:

- Pre-pubertal individuals, as treatment is regarded as experimental,
- Fertility preservation (including egg (oocyte) or embryo cryo-storage) in women of over 42 years of age,
- Patients who choose to undergo medical or surgical treatment whose primary purpose is infertility, such as sterilisation,
- Patients who have previously undergone sterilisation, even if it has been reversed,
- Cryopreservation of ovarian or testicular tissue, as this is regarded as experimental,
- 'Elective freezing': where a man or woman requests this for non-medical reasons,
- Patients who are already infertile for any reasons,
- An extension of the 12-month cryopreservation period outlined in section 23.6 above.

# 29 Access to assisted conception following fertility preservation

Eligibility for fertility preservation is assessed separately from eligibility for ACT, and commencement of NHS-funded fertility preservation does not automatically entitle patients to access NHS-funded ACT. Therefore, there is the potential for patients to meet the eligibility criteria for fertility preservation and not to meet the eligibility criteria for ACT at a later date.

If a patient who has undergone fertility preservation wishes to access ACT, they will be assessed against the ACT criteria as detailed within the ACT Policy, however the FSH and AMH ovarian reserve criteria will not apply in the assessment.

Patients who had eggs or sperm frozen due to medical reasons, funded by the NHS, will be eligible for two Frozen Embryo Transfer (FET) cycles, as in these circumstances a fresh cycle is not available for them.

# 30 Duration of fertility preservation

The duration of NHS-funded fertility preservation is based on the circumstances and needs of the patients, with the scenarios detailed below.

## 30.1 Patients under 23 years of age

The SWL ICB will fund fertility preservation for patients under 23 years of age until they reach their 23rd birthday. At the point when the patient reaches their 23rd birthday funding will be available for up to an additional five years from this date, similarly to those aged 23 years or over detailed in Section 30.2.

The combined funded storage period up to age 28 years (23 + 5) gives those youngest patients entering the cryopreservation pathway the opportunity to reach an age of maturity approaching the UK averages at which men and women have children. In 2012, the most recent data at the time of writing, for first births the standardised average age of mothers was 28.1 years.

Example: a young person entering the cryopreservation pathway at 15 years of age would be eligible for seven years funded storage up to age 23, then an additional five years funded storage up to age 28. Giving them a total potential funded storage period of 12 years.

### 30.2 Patients aged 23 years or over

The SWL ICB funds fertility preservation for patients aged 23 years or over for up to five years, and will only be terminated sooner in the following circumstances:

- Following a live birth, OR
- The period of cryo-storage reaches five years, OR
- The woman's 43rd birthday for eggs or embryos.

If either partner dies after the freezing of gametes, the requirements of the Human Fertilisation and Embryology Act 1990 consent process must be followed.

### 30.3 Funding of additional years

Patients may choose to self-fund cryo-storage for a further period in accordance with HFEA guidelines. Retrieval and storage of sperm, eggs or embryos should also be in accordance with HFEA guidelines.

In the case where patients continue to undergo active medical treatments that result in them being unable to start their families at the time their NHS-funded fertility preservation expires, the patient's treating clinician can apply on behalf of the patient for an extension to the period of storage.

## 31 Funding considerations specific to fertility preservation

Fertility preservation may have a considerable duration for some patients, during which they may move home. This section addresses the funding implications of this:

### 31.1 Patients moving into the SWL ICB

Patients moving into SWL ICB who have used NHS-funded fertility preservation services elsewhere will continue to be funded as per their previous CCG/ICB's funding arrangements. This is the same as any other treatment commenced whilst registered to another CCG/ICB's GP practice.

Once the original policy agreement has elapsed (or is about to), then an application for continuing storage in accordance with the local policy would need to be made. At this time the applicant will need to demonstrate compliance with the SWL ICB policy for further storage to be supported.

Fertility preservation services will continue to be funded at the same provider. When the sperm or egg requires transfer for an NHS-funded IUI/IVF/ICSI treatment the patient is responsible for all costs including transportation cost to the ACU.

### 31.2 Patients leaving the SWL ICB

Patients leaving the SWL ICB, who have used NHS-funded fertility preservation services, will no longer be the responsibility of the SWL ICB for ongoing funding of storage. In England the new CCG/ICB will need to honour and apply the SWL ICB's original policy until it expires i.e., the end of the currently agreed period of storage. After this time the new CCG/ICB's policy will apply.

## 32 Appendix 1: ACT/Fertility Preservation Funding Arrangements and Scenarios

This section the following situation and scenarios, to provide clarification about funding responsibilities, with special consideration to Assisted Conception Treatments (ACT) and Fertility Preservation.

### 32.1 Establishing the responsible ICB

ACT treatments are funded by the ICB with whom the prospective mother is registered, except for those treatments where the specified contracting arrangements sit with NHS England.

### 32.2 Immigration health surcharge; removal of ACT

Amendments to the NHS (Charges to Overseas Visitors) Regulations 2015 were introduced into Parliament on 19 July 2017. As a result, from 21 August 2017, ACT services are no longer included in the scope of services. Those who are required to pay the NHS surcharge are therefore no longer eligible for NHS-funded ACT, as follows:

Where two people are seeking assisted conception services with NHS funding, and one of the two people is covered by health surcharge arrangements and the other is ordinarily resident in the UK and therefore not subject to charge, the services required by the health surcharge payer will be chargeable. Any services required by the ordinarily resident person will continue to be freely available, subject to the established local or national funding arrangements. Please note that this applies to both diagnosis and treatment. *Source: Dept of Health & Social Care Guidance on implementing the overseas visitor charging regulations. Updated 1st November 2021.*

### 32.3 Funding for military serving personnel

ACT for current serving personnel and their partners is the responsibility of NHS England and as such is contained within the specific NHS England policy[5]. Veterans who are in receipt of compensation for loss of fertility (received as a result of service/partner of same) and who require access to ACT are also the funding responsibility of NHS England2. Veterans without



2 Armed Forces and their Families Commissioning Intentions – 2017/18 to 2018/19. Available at: https://www.england.nhs.uk/commissioning/wp-content/uploads/sites/12/2016/10/armed-forces-comms-intent-1617-1819.pdf

relevant injury impacting on fertility are the funding responsibility of ICB and the content of this policy applies.

### 32.4 Private and self-funded patients

Patients who are undergoing ACT outside of an NHS pathway will not be funded or reimbursed for drugs or additional tests incurred resulting from self-funded/private treatment. Nor will Primary Care carry out investigations or prescribe drugs for self-funded ACT.

All couples/patients including those who have previously self-funded must meet the eligibility criteria in section 21, to receive NHS-funded ACT cycles. The number of previous self-funded fresh cycles of IVF/ICSI must not exceed two to be eligible for NHS-funded ACT cycle.

At the point that the patient or couple seeks to transfer back to NHS care they will be assessed against the eligibility criteria and their private medical records must be made available to accredited SWL ACU.

# 33 OVULATION INDUCTION FOR ANOVULATORY DISORDERS

## 33.1 Introduction & Purpose

This policy sets out the criteria for access to ovulation induction services for the population of the South-West London ICB.

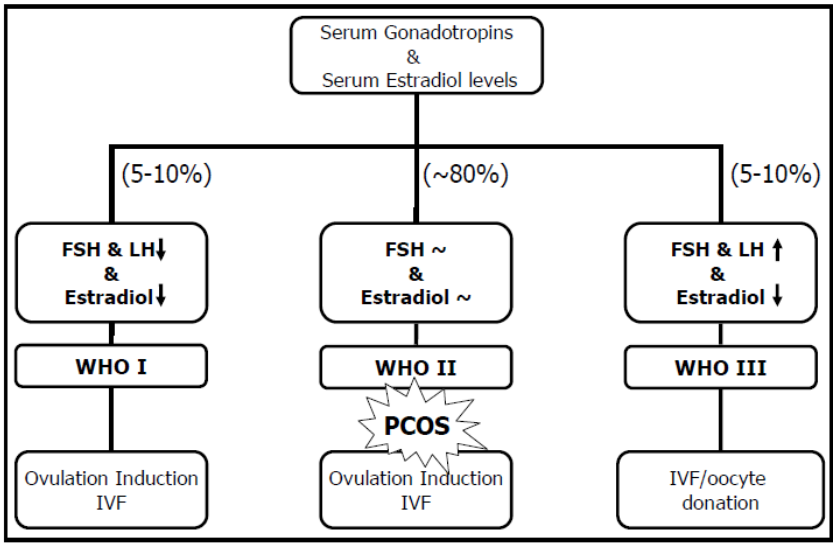
## 33.2 Objective

The objectives of this policy are:

- To reduce unwarranted variation in access to treatments/procedures,
- To ensure that the treatments/procedures contained within it have acceptable evidence of clinical benefit and cost-effectiveness, and
- To ensure equitable access and reduce variation in the provision of ovulation induction therapies across SWL

## 33.3 Definition and classification of Anovulatory Disorders

Anovulatory disorders are classified into the following 3 groups:




### 33.3.1 WHO Class 1: Hypogonadotrophic hypogonadism (HH):

Anovulation results from gonadotrophic insufficiency (hypogonadotrophic hypogonadism). The hormonal features of WHO class 1 anovulation include low serum estradiol levels (i.e., <30 pg/ml with the assays most-commonly used) associated with low or normal serum LH and FSH levels (i.e., <2 and <4 IU/L with the most commonly used assays, respectively).

Congenital and acquired causes can be distinguished as follows, but is not limited to:

- Congenital HH (CHH): Kallmann syndrome, normosmic CHH
- Acquired HH: HPRL (hyperprolactinaemia), functional hypothalamic amenorrhea (FHA)
- Other causes: Sheehan syndrome, haemochromatosis, history of cerebral radiotherapy, sarcoidosis, lymphocytic hypophysitis, head trauma, subarachnoid heamorrhage, cushing syndrome, acromegaly, Iatrogenic HH (opiates, corticosteroids).

### 33.3.2 WHO Class 2:

**Polycystic ovary syndrome (PCOS)**

And

**Normogonadotrophic anovulation**

Mechanisms for normogonadotrophic anovulation:

- Endocrine/hypothalamo-pituitary-ovarian axis: inability to generate LH surge in response to an oestrogen challenge, either from lack of maturation at puberty (failure of positive feedback) or interference by 'ectopic' steroids, e.g., adrenal androgens, progestogens (e.g., Congenital Adrenal Hyperplasia),
- Dysfunction of follicle maturation: premature acquisition of LH receptors by a small antral follicle; relative lack of FSH at the critical point when follicles are selected for final ovulatory maturation,
- Failure of follicle rupture: inappropriate LH surge; drugs (non-steroidal anti-inflammatory drugs, clomiphene citrate, progesterone antagonists)

### 33.3.3 WHO Class 3:

**Hypergonadotrophic hypogonadism (or Primary ovarian insufficiency (POI)**

Also called

**Premature ovarian failure**

POI is diagnosed in adolescents with primary amenorrhea or in adolescents or young women presenting with secondary amenorrhea lasting more than 6 months and occurring before the age of 40. In all cases, plasma gonadotrophins are in the postmenopausal range, and oestradiol levels are low. Classically, FSH serum levels, measured twice, at least 1 month apart, are higher than 40 IU/L. European Society of Human Reproduction and Embriology (ESHRE) guidelines recommend an elevated FSH level >25 IU/L on two occasions >4 weeks apart. In most cases, the antral follicle count (AFC) evaluated by pelvic ultrasound examination is diminished, and AMH serum level is very low.

## 33.4 Treatment Options

### 33.4.1 WHO Class 1: Hypogonadotrophic hypogonadism (HH):

Offer gonadotrophin injections after diagnosis of HH when the patient:

- Has random low follicle stimulating hormone (FSH)/ luteinising hormone (LH)/oestradiol
- Has normal prolactin and thyroid stimulating hormone (TSH)
- Has normal semen analysis and tubal patency
- Is no more than 42 years of age (i.e., before their 43rd birthday) at the start of ovulation induction treatment
- Has a BMI of a minimum of 18.5kg/$m^2$ and a maximum of 30kg/$m^2$

For WHO Class 1 anovulatory disorders the SWL ICB will fund 3 cycles of gonadotrophin injections, plus a further 3 cycles if treatment produces ovulation (up to a total of 6 cycles). Women with WHO Class 1 anovulatory disorders who do not respond to the treatment will be able to access further fertility assessment and treatment under the SWL ACT/Fertility Preservation policy, subject to meeting the SWL ACT/Fertility Preservation criteria.

**Patients with ovulatory disorders due to hyperprolactinaemia:**

Women with ovulatory disorders due to hyperprolactinaemia should be offered ovulation induction treatment with dopamine agonists such as bromocriptine. Consideration should be given to safety for use in pregnancy and minimising cost when prescribing.
These should be administered and managed in line with NICE CG156.

**Patients with Hypothalamic Amenorrhoea (HA):**

HA is caused by, but this is not limited to, anorexia nervosa, over exercise and stress.

Only offer gonadotrophin injections in women with Hypothalamic Amenorrhoea (HA) after attempts to normalise energy balance to both optimise health before pregnancy and to reduce the risk of foetal loss, small-for-gestational-age babies, preterm labour and delivery by caesarean section.

### 33.4.2 WHO Class 2:

**Polycystic ovary syndrome (PCOS)**

And

**Normogonadotrophic anovulation**

First line treatment:

- Provide weight-loss advice to patients with a BMI of over 30kg/m2 as this may:
    - Restore ovulation
    - Improve the patient's response to ovulation induction
    - Positively impact on pregnancy outcomes

- In patients with a BMI of <35kg/m2 offer one of the following treatments (after taking into account the potential adverse effects, the ease and mode of use, the patient's BMI and the required monitoring):
    - Clomiphene citrate, or
    - Metformin, or
    - A combination of the above

Medications for ovulation induction should be prescribed in secondary care. Drug prescriptions are covered within the secondary or tertiary care provider tariffs and should not be undertaken by Primary Care. This includes requests from private providers, regardless of whether the treatment is NHS- or self-funded.

Monitoring for women who are taking clomiphene citrate:

- Offer ultrasound monitoring during at least the first cycle of treatment to ensure that the patient is taking a dose that minimises the risk of multiple pregnancy, and
- Do not continue treatment for longer than 6 months.

Second-line treatment:

Consider the following for patients who are known to be resistant to clomiphene citrate (i.e., no ovulation after 3 cycles of induction with 150mg/day OR no pregnancy after 6 ovulatory cycles):

- Trial of an alternative oral medication if not already offered, or
- Combined treatment with clomiphene citrate and metformin if not already offered as the first-line treatment, or
- Laparoscopic ovarian drilling

The ICB will not routinely fund gonadotrophin injections for patients with WHO Class II anovulatory disorders. However, women with WHO Class 2 anovulatory disorders who don't respond to the above first- and second-line treatments will be able to access further fertility assessment and treatment under the SWL ACT/Fertility Preservation policy, subject to meeting the SWL ACT/Fertility Preservation criteria.

Do not offer women with polycystic ovary syndrome who are being treated with gonadotrophins concomitant treatment with gonadotrophin-releasing hormone agonist, as research suggest that it is not shown to improve pregnancy rates and is also associated with an increased risk of ovarian hyperstimulation.

Do not offer adjuvant growth hormone treatment with gonadotrophin-releasing hormone agonist and/or human menopausal gonadotrophin during ovulation induction in women with polycystic ovary syndrome who do not respond to clomiphene citrate because it is not shown to improve pregnancy rates.

### 33.4.3 WHO Class 3:

**Hypergonadotrophic hypogonadism (or Primary ovarian insufficiency (POI)**

Also called

**Premature ovarian failure**

Primary ovarian insufficiency is defined as:

- Amenorrhea of at least 12 months duration with a hormonal profile in the menopausal range, and
- Where the patient is under the age of 40.

Women with primary ovarian insufficiency (the cause of which may be spontaneous, or as a result of other morbidity, or congenital abnormality or iatrogenic) should be referred direct for assisted conception assessment under the SWL ACT/Fertility Preservation policy.

### 33.5 Ovulation Induction: Funding Exclusions:

The NHS will not fund any assessment or treatment that is considered experimental. A treatment may be considered experimental where any of the following applies:

- The treatment is still undergoing clinical trials and/or is a drug that is yet to undergo a phase III clinical trial for the indication in question

- The treatment does not have marketing approval from the relevant government body for the indication in question
- The treatment does not conform to a usual clinical practice in the relevant field
- The treatment is being used in a way other than that previously studied or that for which it has been granted approval by the relevant government body, or
- The treatment is rarely used, novel, or unknown and there is a lack of authoritative evidence of safety and efficacy
- If it is part of a pilot study

### 33.6 Ovulation Induction: References:

- SWL ICB Assisted Conception/Fertility Preservation Policy:

Infertility and assisted conception - South West London CCG (swlondonccg.nhs.uk)

- SWL ICB Evidence Based Interventions Policy:

Microsoft Word - SWL ECI Policy v3.1 - FINAL - Mar 2020 - 2 (swlondonccg.nhs.uk)

- WHO classification of anovulatory disorders:

Health and fertility in World Health Organization group 2 anovulatory women | Human Reproduction Update | Oxford Academic

# APPENDIX A: EQUALITY IMPACT ASSESSMENT

NHS South West London

**Equality Impact Assessment:**
**SWL Evidence Based Commissioning (EBI) Policy:**
**Incorporating ACT/Fertility Preservation**
**and Ovulation Induction**

**Stage 1: Initial Screening**

**The aim of the screening is to identify any negative impact that will need mitigation put in place to reduce the impact**

| | | | |
|---|---|---|---|
| **5** | **What evidence is available to suggest that the proposed service / policy / function could have an impact on people from the protected characteristics?**<br>**Document reasons, e.g. research, results of consultation, monitoring data and assess relevance as: *Not relevant or Relevant Low / Medium / High*** | | |
| **Protected Characteristic** | **Relevance** | **Evidence** | |
| | **Introduction:**<br><br>SWL ICB Evidenced Based Interventions (EBI) Policy has been developed to provide guidance on the way in which the ICB will consider funding for treatment for individual patients for whom it is responsible but which treatment is not included in existing ICB contracts. Its development was driven by the need to ensure that NHS funded treatments are evidenced-based, clinically effective and safe, and that access to treatments throughout SWL is equitable for patients with similar clinical need, thereby reducing variation in care.<br><br>Its purpose is to act as a mechanism for addressing some of the inequality that may be introduced by blanket funding decision-making. Applications for funding are assessed using a fair and transparent process so, by design the policy focuses on ensuring equality and equity across the protected characteristics.<br><br>Using information on current activity all procedures and interventions contained within this policy have undergone consideration and analysis of the following prior to their inclusion: national policy, clinical practice, clinical effectiveness and cost-effectiveness, resources, costs and service provision across SWL. The procedures within the policy are categorised into Prior Approval Procedure (PAP) and Individual Funding Request (IFR). | | |

| | | | |
|---|---|---|---|
| | For Prior Approvals, clinical criteria have been provided where the available evidence on clinical and cost effectiveness indicates the patients who will benefit the most from a procedure funded by the NHS. Prior to the procedure being undertaken authorisation must be obtained by the treating clinician, using a form containing the pre-defined threshold criteria and submitted on Blueteq (a secure online communication platform), demonstrate to the ICB that the patient meets the agreed criteria for treatment and assures the ICB that both the concerned individual and the local population can expect to get maximum health benefits from the procedure in question.<br><br>Current SWL IFR Policy (V2 July 2022) has been developed as a standalone policy to sit alongside SWL EBI Policy and contains an approved EIA assessment as an appendix to the policy. | | |
| a | Race | Medium | • SWL EBI Policy is written to ensure equity of access for all, regardless of race.<br>• Assisted Conception Treatment (ACT)/Fertility Preservation and Ovulation Induction policy provides that services are equally available to all people who meet the clinical criteria. However, there is anecdotal evidence that women in ethnic minority groups access services less frequently and later than white women.<br>• ACT/Fertility Preservation: There is no bar on access to treatment if one partner already has a living child, this will continue to improve access for people of all races. |
| b | Religion / Spirituality | Not relevant | • SWL EBI Policy has been developed to ensure equity of access across for all religions, beliefs and areas of spirituality.<br>• ACT/Fertility Preservation and Ovulation Induction policy provide services regardless of religion or belief. |
| c | Sex | Low | • The processes underpinning EBI Policy do not consider a person's identified sex when determining the outcome of funding requests and it is not visible within the funding application.<br>• ACT/Fertility Preservation policy provides for fertility treatment for both men and women, equally. |
| d | Disability | Medium | • EBI Policy is written to ensure equity of access to people of all abilities.<br>• ACT/Fertility Preservation policy provides specific advice regarding access to assisted conception for patients with physical and psychosexual disabilities. In particular, the recommendations in relation to the latter will continue to improve access to assisted conception by setting out a clear treatment pathway.<br>• Ovulation Induction: Not relevant |
| e | Sexual Orientation | Medium | • The processes underpinning EBI Policy do not consider a person's sexual orientation when determining the outcome of funding requests and it is not visible within the funding application.<br>• ACT/Fertility Preservation policy is written to ensure equity of access for all, regardless of sexual orientation. |

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| | | | • Heterosexual couples must have 2 years' unprotected sex before they are deemed infertile (national evidence supports that 1 in 7 couples may have difficulty conceiving, however the cumulative pregnancy success rate at 2 years is 92%).<br>• Updated policy provides greater clarity that single women and same-sex couples will need to demonstrate that they are infertile prior to accessing IVF by undergoing 12 cycles of unstimulated IUI in a clinical setting, over a period of at least 12 months. This equates to 2 years unprotected sex and these 12 cycles are not NHS funded.<br>• Single men and men in same sex relationships will be offered fertility investigations.<br>• Ovulation induction: Not relevant |
| f | Age | High | • Age in considered within EBI Policy when it is appropriate for ensuring that procedures are undertaken appropriately and safely.<br>• ACT/Fertility Preservation policy, in line with NICE Guidance sets an upper age limit of 42 years for prospective mothers.<br>• Again, in line with NICE it requires AMH and FSH thresholds, which has the effect of screening out women whose ovarian reserves are such that they are less likely to become pregnant by assisted conception. This is likely to affect women at the upper end of the age range and it is estimated that this could affect up to 20% of NHS funded patients.<br>• Since fertility declines with age specific concessions in relation to length of time trying to get pregnant are given to women aged over 36, who are referred and treated sooner to increase their chance of success.<br>• Women aged 40 to 42 who have been trying for 2 years or longer, or have had 12 cycles of IUI, are able to access 1 cycle of IVF in total.<br>• There is growing evidence that a man's age has an impact on the chances of a successful pregnancy, with an evidence base suggesting an upper age limit of 55, however this policy does not recommend change at this time as this is not in the NICE guidance and would require wider consultation. Very few patients would fall into this category.<br>• Ovulation Induction Policy, in line with NICE Guidance sets an upper age limit of 42 years for the commencement of ovulation induction injections for women with WHO Class 1 anovulatory disorders. |
| g | Pregnancy/ maternity | Not relevant | The EBI policy does not contain any guidelines relevant to pregnancy and maternity. |

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| h | Gender Reassignment | Low | • The EBI policy does not contain any guidelines relevant to gender reassignment, all procedures for which are covered by NHS England.<br>• Updated ACT/Fertility Preservation policy clarifies that funding will be made available for patients on the transgender pathway to access assisted conception and fertility preservation, and that this is included within the policy on the same terms as other people requiring fertility preservation such as those who require it prior to acute medical interventions that may affect fertility, such as cancer.<br>• Ovulation Induction: N/A |
| i | Marriage and Civil Partnership | Low | • The processes underpinning EBI Policy do not consider a person's marital or civil partnership status when determining the outcome of funding requests and it is not visible within the funding application.<br>• ACT/Fertility Preservation policy is written to ensure equity of access for all, regardless of relationship status<br>• It does not require that a monogamous and enduring relationship exists between the prospective mother and partner to enable access to assisted conception and fertility preservation. However, where a relationship does exist the policy recommends that couples jointly attend appointments, regardless of marital status.<br>• Ovulation Induction: Not relevant |
| j | Carers | Not relevant | Not relevant |
| k | Other - Overseas Status | Medium | • ACT/Fertility Preservation: In line with updated DH Guidance on implementing the overseas visitor charging regulations November 2021, the policy includes clarification on the charging regulations where one of two people who are seeking assisted conception services with NHS funding is covered by health surcharge arrangements and the other is ordinarily resident in the UK (and therefore not subject to charge), the services required by the health surcharge payer will be chargeable. |

If you assess all the above factors as not relevant, please proceed to section 12.

If you assess any of the above factors as relevant, continue to Stage 2, Full Equality Impact Assessment.



**Stage 2: Full Equality Impact Assessment**

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| **6** | **What engagement and / or consultation has been undertaken? For example, with service users or staff.** |

- EBI Policy – consultation not required as the then CCGs (now the SWL ICB) were required to implement national EBI policy
- ACT/Fertility Preservation – consultation not required as amendments within the updated policy have been made to provide clarity on current policy, nothing has been added or removed that would require additional consultation.

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| **7** | **Are there service user, public or staff concerns that the proposed service / policy / function may be discriminatory, or have an adverse impact on people from the protected characteristics?** |

- EBI Policy – None, as the July 2022 policy has been updated to reflect the changes driven by the transition from the CCG to the ICB, no other policy change has been made.
- Support in the development of the SWL ACT/Fertility Preservation and Ovulation Induction policies has been provided by the 4 acute provider Trusts and the SWL Fertility Network. Both policies have been agreed at the 16 June 2022 SWL Fertility Network and 17 June 2022 SWL Gynae Clinical Network meetings, in addition to which the Ovulation Induction policy was agreed at the 15 June 2022 SWL Integrated Medicines Optimisation Committee (IMOC).
- SWL women in ethnic minority groups access to IVF, fertility preservation and ovulation induction services. As highlighted in the above race section, whilst existing SWL policy ensures that fertility services are available equally to all people who meet the clinical criteria, what is known anecdotally is that women in ethnic minority groups access these services less frequently and later than white women. As part of the launch of this policy plans are in place to increase awareness within the community of available SWL fertility services and to gather insight from ethnic minority groups to further understand any barriers they might face accessing fertility services.

If there are **no concerns**, proceed to section 12.
If **there are concerns,** amend service / policy / function to mitigate adverse impact, consider actions to eliminate adverse impact, or justify adverse impact.

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| **8** | **Can the adverse impact be justified?** |

Not applicable. The purpose of the updated policy is to address any adverse impact

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| **9** | **What changes were made to the service / policy / function as result of information gathering?** |

Changes have been made to:

- Reflect the ICB landscape within which the policy will be applied (via the adoption of the core principles of an ICB model)

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| • Reflect a case review of prior approval funding applications for ACT/Fertility Assessment received in 2021/22, identifying all opportunities for where clarification of current policy would be beneficial for the applicant, and for the patient and their partner if they have one<br>• Introduction of common Ovulation Induction policy across SWL is intended to ensure consistency of clinical approach to the treatment of each of the 3 types of anovulatory disorder. An example of where this is required is that currently patients with polycystic ovary syndrome (PCOS) as a WHO Class 2 anovulatory disorder can be prescribed gonadotrophin therapy inappropriately. | |
| **10** | **What arrangements will you put in place to monitor impact of the proposed service/policy/function on individuals from the protected characteristics?** |
| • An audit of the demographic information relating to the protected characteristics contained within the EBI funding applications<br>• On-going case learning, including a review of cases approved verses those not approved<br>• Ongoing interface meetings with clinicians and the clinical networks | |
| **11** | **List below actions you will take to address any unjustified impact and promote equality of outcome for individuals from protected characteristics. Consider actions for any procedures, services, training and projects related to the service / policy / function which have the potential to promote equality.** |

| Action | Lead | Timescales |
|---|---|---|
| 1) Action planning from point 10 above | • Gill Schram<br>• EBI Policy Development Group | FY 2022/23 and ongoing |
| 2) A review of queries/ complaints and whether/how they should drive policy refresh | • As above | FY 2022/23 and ongoing |
| 3) A review of how the applications and interactions with clinicians then feed into iterative process of EBI development | • As above | FY 2022/23 and ongoing |

| 12 | Review date | |
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Author: Gill Schram

Job title: Interim Head of Cancer & EBI Programmes

Signed: Signed electronically

Date: 13 June 2022

Approved by: Melissa Berry

Title: Program Director Equality, Diversity and Inclusion

Signed: 

Date: 17 June 2022