

# **South East London**

## **Treatment Access Policy**

**2019/2020**  
**FINAL (Edited)**

**Fertility section amended 3<sup>rd</sup> December 2019**

This policy has been developed by the South East London Treatment Access Group in consultation with Health Care Advisory Group, a collaboration of the six Clinical Commissioning Groups in South East London – Bexley, Bromley, Greenwich, Lambeth, Lewisham, and Southwark, and Public Health representatives from each borough.

# South East London

## Treatment Access Policy (TAP)

This policy deals with treatments and procedures for which restricted access criteria have been agreed.

### Background

The six Clinical Commissioning Groups (CCGs) in the South East London (SEL) Sector have a joint policy and process for dealing with Individual Funding Requests (IFRs). There are a number of reasons for a sector-wide process for dealing with IFRs.

### Limited Resources

There will always be competing calls for limited resources and therefore a need for a clearly defined and co-ordinated approach to ensure that the resources are used in an equitable and effective way and that clear, consistent and fair procedures are in place. These are based on the principles of cost effectiveness found in the IFR policy.

### Incorporating NHSE Evidence Based Interventions Access Criteria

Local variations in treatment funding decisions are clearly undesirable, and from April 2019 this policy document has incorporated NHS England (NHSE) Evidence Based Interventions policy access criteria for 17 interventions. Where local guidance previously existed for some of these interventions these have been replaced by NHSE criteria.

### Efficiency

Joint working will avoid duplication of work and efforts across the area. It will also maximize the use of expertise and skills, building upon previous experience. This joint process will also enhance joint working and communication between the CCGs.

### Review

This policy is reviewed and updated annually.

### Procedures and treatments not mentioned in the SEL TAP

Clinical Commissioning Groups (CCGs) do not have policies in place for every procedure that a patient might request. If a particular procedure/approach is not listed within local policies then it is not commissioned and not available.

#### Equality Statement:

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

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## 1. Category 1 – Procedures requiring an Individual Funding Request

Procedures in Category 1 (formally known as Section 1) require prior approval through the 'Individual Funding Request Process'

Interventions that should not be routinely commissioned, with patients only able to access such treatments where they successfully make an individual funding request (referred to as Category 1 interventions).

All patients requiring a consultant opinion for diagnostic or symptomatic advice should continue to be referred by General Practitioners.

Please note that wherever the policy states that non surgical, alternative or conservative measures should have been tried, these must be documented and included in the referral. The same applies when a certain number of clinical episodes are required in order to meet the criteria for referral.

### 1.1 Adult snoring surgery (in the absence of obstructive sleep apnoea)<sup>1</sup>

#### Description of intervention

Snoring is a noise that occurs during sleep that can be caused by vibration of tissues of the throat and palate. It is very common and as many as one in four adults snore, as long as it is not complicated by periods of apnoea (temporarily stopping breathing) it is not usually harmful to health, but can be disruptive, especially to a person's partner.

This guidance relates to surgical procedures in adults to remove, refashion or stiffen the tissues of the soft palate (Uvulopalatopharyngoplasty, Laser assisted Uvulopalatoplasty & Radiofrequency ablation of the palate) in an attempt to improve the symptom of snoring.

Please note this guidance only relates to patients with snoring in the absence of Obstructive Sleep Apnoea (OSA) and should not be applied to the surgical treatment of patients who snore and have proven OSA who may benefit from surgical intervention as part of the treatment of the OSA.

It is important to note that snoring can be associated with multiple other causes such as being overweight, smoking, alcohol or blockage elsewhere in the upper airways (e.g. nose or tonsils) and often these other causes can contribute to the noise alongside vibration of the tissues of the throat and palate.

#### Recommendation

It is on the basis of limited clinical evidence of effectiveness, and the significant risks that patients could be exposed to, this procedure should no longer be routinely commissioned in the management of simple snoring.

#### Alternative Treatments

There are a number of alternatives to surgery that can improve the symptom of snoring. These include:

- Weight loss
- Stopping smoking
- Reducing alcohol intake
- Medical treatment of nasal congestion (rhinitis)
- Mouth splints (to move jaw forward when sleeping)

#### Rationale for recommendation

In two systematic reviews of 72 primary research studies there is no evidence that surgery to the palate to improve snoring provides any additional benefit compared to other treatments. While some

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<sup>1</sup> Evidence-Based Interventions: Guidance for CCGs. NHS England, November 2018.

studies demonstrate improvements in subjective loudness of snoring at 6-8 weeks after surgery; this is not longstanding (> 2years) and there is no long-term evidence of health benefit. This intervention has limited to no clinical effectiveness and surgery carries a 0-16% risk of severe complications (including bleeding, airway compromise and death). There is also evidence from systematic reviews that up to 58-59% of patients suffer persistent side effects (swallowing problems, voice change, globus, taste disturbance & nasal regurgitation). It is on this basis the interventions should no longer be routinely commissioned.

## **1.2 Dilatation and curettage (D&C) for heavy menstrual bleeding in women<sup>1</sup>**

### **Description of the intervention**

Dilation and curettage (D&C) is a minor surgical procedure where the opening of the womb (cervix) is widened (dilatation) and the lining of the womb is scraped out (curettage).

NICE guidelines recommend that D&C is not offered as a diagnostic or treatment option for heavy menstrual bleeding, as there is very little evidence to suggest that it works to investigate or treat heavy periods

Ultrasound scans and camera tests, with sampling of the lining of the womb (hysteroscopy and biopsy), can be used to investigate heavy periods. Medication and intrauterine systems (IUS), as well as weight loss (if appropriate) can treat heavy periods.

### **Recommendation**

D&C should not be used for diagnosis or treatment for heavy menstrual bleeding in women because it is clinically ineffective. Ultrasound scans and camera tests with sampling of the lining of the womb (hysteroscopy and biopsy) can be used to investigate heavy periods. Medication and intrauterine systems (IUS) can be used to treat heavy periods.

### **Rationale for recommendation**

NICE guidelines recommend that D&C is not offered as a treatment option for heavy menstrual bleeding. There is very little evidence to suggest that D&C works to treat heavy periods and the one study identified by NICE showed the effects were only temporary. D&C should not be used to investigate heavy menstrual bleeding as hysteroscopy and biopsy work better. Complications following D&C are rare but include uterine perforation, infection, adhesions (scar tissue) inside the uterus and damage to the cervix.

## **1.3 Knee arthroscopy for patients with osteoarthritis<sup>1</sup>**

### **Description of the intervention**

Arthroscopic washout of the knee is an operation where an arthroscope (camera) is inserted in to the knee along with fluid. Occasionally loose debris drains out with the fluid, or debridement, (surgical removal of damaged cartilage) is performed, but the procedure does not improve symptoms or function of the knee joint.

NICE recommends that arthroscopic knee washout should not be used as a treatment for patients with osteoarthritis, unless the knee locks (in which case it may be considered). More effective treatments include physiotherapy, exercise programmes like ESCAPE pain, losing weight (if necessary) and pain management. If symptoms do not resolve, knee replacement or osteotomy are effective procedures that should be considered.

### **Recommendation**

Arthroscopic knee washout (lavage and debridement) should not be used as a treatment for osteoarthritis because it is clinically ineffective. Referral for arthroscopic lavage and debridement should not be offered as part of treatment for osteoarthritis, unless the person has knee osteoarthritis with a clear history of mechanical locking. More effective treatment includes exercise programmes (e.g. ESCAPE pain), losing weight (if necessary) and managing pain. Osteoarthritis is relatively common in older age groups. Where symptoms do not resolve after non operative treatment, referral for consideration of knee replacement, or joint preserving surgery such as osteotomy is appropriate.

## **Rationale for recommendation**

NICE has reviewed the evidence for how well knee washout works for people with osteoarthritis. Seven clinical trials and three case studies have shown that knee wash out for people with osteoarthritis did not reduce pain nor improve how well their knees worked. There was a small increased risk of bleeding inside the knee joint (haemarthrosis) (2%) or blood clot in the leg (deep vein thrombosis) (0.5%).

## **1.4 Injections for nonspecific low back pain without sciatica<sup>1</sup>**

### **Description of the intervention**

Spinal injections of local anaesthetic and steroid in people with non-specific low back pain without sciatica.

### **Recommendation**

Spinal injections of local anaesthetic and steroid should not be offered for patients with non-specific low back pain.

For people with non-specific low back pain the following injections should not be offered:

- Facet joint injections
- Therapeutic medial branch blocks
- Intradiscal therapy
- Prolotherapy
- Trigger point injections with any agent, including botulinum toxin
- Epidural steroid injections for chronic low back pain or for neurogenic claudication in patients with central spinal canal stenosis
- Any other spinal injections not specifically covered above

Radiofrequency denervation can be offered according to NICE guideline (NG59) if all non-surgical and alternative treatments have been tried and there is moderate to severe chronic pain that has improved in response to diagnostic medical branch block.

Epidurals (local anaesthetic and steroid) should be considered in patients who have acute and severe lumbar radiculopathy at time of referral.

Alternative and less invasive options have been shown to work e.g. exercise programmes, behavioural therapy, and attending a specialised pain clinic. Alternative options are suggested in line with the National Back Pain Pathway.

### **Rationale for recommendation**

NICE guidelines recommend that spinal injections should not be offered for nonspecific low back pain.

Radiofrequency denervation (to destroy the nerves that supply the painful facet joint in the spine) can be considered in some cases as per NICE guidance.

Exclusion criteria for the NICE (NG59) include:

Conditions of a non-mechanical nature, including;

- Inflammatory causes of back pain (for example, ankylosing spondylitis or diseases of the viscera)
- Serious spinal pathology (for example, neoplasms, infections or osteoporotic collapse)

Neurological disorders (including cauda equina syndrome or mononeuritis)

Adolescent scoliosis

Not covered were conditions with a select and uniform pathology of a mechanical nature (e.g. spondylolisthesis, scoliosis, vertebral fracture or congenital disease)

Other agreed exclusions by the Guidance Development Group are: Pregnancy-related back pain, Sacroiliac joint dysfunction, Adjacent-segment disease, Failed back surgery syndrome, Spondylolisthesis and Osteoarthritis.

NICE recommends the following approach for non-surgical invasive treatments for low back pain and sciatica in over 16s

### **Spinal injections**

Do not offer spinal injections for managing nonspecific low back pain.

### **Radiofrequency denervation**

Consider referral for assessment for radiofrequency denervation for people with non-specific low back pain when: non-surgical treatment has not worked for them and the main source of pain is thought to come from structures supplied by the medial branch nerve and they have moderate or severe levels of localised back pain (rated as 5 or more on a visual analogue scale, or equivalent) at the time of referral. Only perform radiofrequency denervation in people with non-specific low back pain after a positive response to a diagnostic medial branch block.

Do not offer imaging for people with non-specific low back pain with specific facet joint pain as a prerequisite for radiofrequency denervation.

## **1.5 Breast reduction<sup>1</sup>**

### **Description of intervention**

Breast reduction surgery is a procedure used to treat women with breast hyperplasia (enlargement), where breasts are large enough to cause problems like shoulder girdle dysfunction, intertrigo and adverse effects to quality of life.

The evidence highlights that breast reduction is only successful in specific circumstances and the procedure can lead to complications -for example not being able to breast feed permanently. However in some cases breast reduction surgery is necessary where large breasts impact on day to day life, for example ability to drive a car. Therefore, breast reduction should only be undertaken under specific criteria.

Wearing a professionally fitted bra, losing weight (if necessary), managing pain and physiotherapy often work well to help with symptoms like back pain from large breasts.

### **Recommendation**

The NHS will only provide breast reduction for women if all the following criteria are met:

- The woman has received a full package of supportive care from their GP such as advice on weight loss and managing pain.
- In cases of thoracic/ shoulder girdle discomfort, a physiotherapy assessment has been provided
- Breast size results in functional symptoms that require other treatments/interventions (e.g. intractable candidal intertrigo; thoracic backache/kyphosis where a professionally fitted bra has not helped with backache, soft tissue indentations at site of bra straps).
- Breast reduction planned to be 500g or more per breast or at least 4 cup sizes.
- Body mass index (BMI) is <27 and stable for at least twelve months.
- Woman must be provided with written information to allow her to balance the risks and benefits of breast surgery.
- Women should be informed that smoking increases complications following breast reduction surgery and should be advised to stop smoking.
- Women should be informed that breast surgery for hypermastia can cause permanent loss of lactation.

Unilateral breast reduction is considered for asymmetric breasts as opposed to breast augmentation if there is an impact on health as per the criteria above. Surgery will not be funded for cosmetic reasons.

Surgery can be approved for a difference of 150 -200gms size as measured by a specialist. The BMI needs to be <27 and stable for at least twelve months.

Resection weights, for bilateral or unilateral (both breasts or one breast) breast reduction should be recorded for audit purposes.

This recommendation does not apply to therapeutic mammoplasty for breast cancer treatment or contralateral (other side) surgery following breast cancer surgery, and local policies should be adhered to. The Association of Breast Surgery support contralateral surgery to improve cosmesis as part of the reconstruction process following breast cancer treatment.

### **Rationale for recommendation**

One systematic review and three non-randomized studies regarding breast reduction surgery for hypermastia were identified and showed that surgery is beneficial in patients with specific symptoms. Physical and psychological improvements, such as reduced pain, increased quality of life and less anxiety and depression were found for women with hypermastia following breast reduction surgery.

Breast reduction surgery for hypermastia can cause permanent loss of lactation function of breasts, as well as decreased areolar sensation, bleeding, bruising, and scarring and often alternative approaches (e.g. weight loss or a professionally fitted bra) work just as well as surgery to reduce symptoms. For women who are severely affected by complications of hypermastia and for whom alternative approaches have not helped, surgery can be offered. The aim of surgery is not cosmetic; it is to reduce symptoms (e.g. back ache).

### **Gynaecomastia<sup>2</sup>**

This procedure is not available on cosmetic grounds. Exceptional cases brought to the individual funding request panel for consideration would need to meet the following criteria:

- True gynaecomastia (i.e. breast tissue is present as opposed to adipose tissue) has been diagnosed. Gynaecomastia is classified as Grade III (marked breast enlargement with major skin redundancy).
- The BMI is less than or equal to 25 kg/m<sup>2</sup>
- Screening for endocrinological or drug related causes has taken place.
- Underlying malignancy should be excluded, clinically or otherwise.

### **Breast reconstruction revision surgery following cancer**

For patients who have undergone a breast reconstruction for a mastectomy, either as an immediate reconstruction, as a delayed reconstruction and for those who have undergone a salvage reconstruction following a failed previous reconstruction. This policy applies for both implant based and autologous reconstructions. In addition this will apply to patients referred to the plastic surgery department at Guy's and St Thomas' Hospital who have undergone a reconstruction procedure by the plastic surgery team due to a poor outcome following a wide local excision procedure for breast cancer at another hospital.

After the initial reconstruction procedure has been performed two revision procedures will be offered to patients. These will include surgery for both the reconstructed breast and any symmetrisation procedure for the contralateral breast. If a nipple reconstruction procedure has not been performed in one of the two revision procedures then a nipple reconstruction under a local anaesthetic may also be performed at a third stage.

## **1.6 Breast augmentation**

This procedure is not available on cosmetic grounds. An exception may be made for congenital absence of breast tissue or there is gross asymmetry (difference in size minimum 2 cup sizes).

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<sup>2</sup> Gynaecomastia evidence review. SEL Exceptional Treatments Group, 2009.



## **1.7 Revision mammoplasty**

This procedure is not available on cosmetic grounds unless the original procedure was performed in a hospital within South East London on the NHS due to health reasons, and the patient now has a gross deformity.

## **1.8 Breast implants**

Breast implants and instant replacements are not available on the NHS. Ruptured breast implants, however, will be removed on the NHS if they are considered to be of danger to the patient. Replacement implants must not be inserted as part of the same procedure even if the patient wishes to self-fund this part of the treatment.

## **1.9 Correction of congenital nipple inversion**

This procedure is not available on cosmetic grounds. Nipple inversion is a common condition which responds well to conservative treatment, e.g. use of Nipplette device.

## **1.10 Mastopexy (relocating the nipple and improving the shape of the breast)**

This procedure is not available on cosmetic grounds. Breast ptosis is inevitable in most women due to a combination of maturity, gravity and pregnancy/lactation. An exception may be made in gross cases.

## **1.11 Body contouring**

### **(Abdominoplasty or tummy tuck, thigh lift and buttock lift, excision of redundant skin or fat liposuction)**

These procedures are not available on cosmetic grounds. An exception may be made for post-traumatic surgery for contouring at diabetes injection sites or for lymphoedema.

## **1.12 Genital surgery**

This procedure is not available on cosmetic grounds

## **1.13 Scar revision**

This procedure is not available on cosmetic grounds. An exception may be made for scars which significantly interfere with function (e.g. following burns) or where scarring is exceptionally severe.

## **1.14 Face or brow lift**

This procedure is not available on cosmetic grounds. An exception may be made for the treatment of facial palsy.

## **1.15 Repair of lobe of external ear**

This procedure is not available on cosmetic grounds

## **1.16 Tattoo removal**

This procedure is not available on cosmetic grounds

## **1.17 Blepharoplasty (eyelid reduction)**

This procedure is not available on cosmetic grounds. An exception may be made if the upper eyelid skin interferes with the visual field or if there is evidence that eyelids impinge on visual fields reducing field to 120° laterally and 40° vertically.

## **1.18 Dermabrasion (chemical peel)**

This procedure is not available for skin rejuvenation.

## **1.19 Male pattern baldness (hair grafting and flaps with or without tissue expansion)**

This procedure is not available on cosmetic grounds. Baldness is a natural condition.

## 1.20 Female baldness and alopecia – hair replacement

This procedure is not available on cosmetic grounds.

## 1.21 Pinnaplasty (correction of prominent or bat ears)

This procedure is not available on cosmetic grounds to adults. An exception may be made for children under the age of 18 at the time of referral for significant prominent or bat ears, where the prominence measures >30mm (using the measuring guide below):

- **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. To be confirmed by a clinician.

- Measure from the posterior aspect of the Helix.
- Prominence = H-M distance > 20mm

Pinnaplasty will only be considered in patients who have a >30mm prominence, unless there are other considerations e.g. in helping to retain hearing aids.

## 1.22 Non medical circumcision

Circumcision is an effective operative procedure with a range of medical indications. Some circumcisions are also requested for social, cultural or religious reasons; these procedures will not be funded on the NHS.

### Medical Indications

Circumcisions should continue to be performed for medical indications only, for example:

- Phimosis seriously interfering with urine flow and/or associated with recurrent infections
- Some cases of paraphimosis
- Suspected cancer or balanitis xerotica obliterans
- Congenital urological abnormalities when skin is required for grafting
- Interference with normal sexual activity in adult males

## 1.23 Reversal of vasectomy or female sterilisation

The decision to be sterilized is taken by mature adults on the understanding that it is an irreversible contraceptive choice. Therefore, any reversal or subsequent fertility treatment should be the responsibility of the individual and will not be funded by the CCG. Any requests with possible exceptions may be referred to the IFR Panel for consideration. There should be no live children from either of the partners.

### Female

- The woman should not be older than 35 years
- The procedure should be conducted in a Regional Centre by a surgeon performing sufficient procedures to report a success rate of over 50%

### Male

- The reversal of vasectomy should not be performed more than 10 years after the original sterilization procedure.
- The female partner should not be more than 36 years old

## 1.24 Caesarean section for non-clinical reasons

Caesarean section is only available for clinical reasons. Elective Caesarean section for non-clinical reasons, including maternal request, will not be funded on the NHS unless prior approval has been obtained. Such approval will only be granted if such an elective caesarean section justified is using published NICE guidelines. Applicants will have to document how the case fulfils those guidelines.

### **1.25 Hair removal<sup>3</sup>**

This procedure will not be funded on the NHS as there is no evidence of permanent effect with any type of hair removal treatment.

### **1.26 Alternative therapies**

#### **Osteopathy**

Osteopathy remains a low priority treatment due to the limited evidence of clinical effectiveness. Referral for osteopathy is not available on the NHS.

#### **Acupuncture**

Acupuncture remains a low priority treatment due to the limited evidence of clinical effectiveness. Referrals for acupuncture should be made in exceptional circumstances only. Funding for cases of nausea and vomiting and back pain shall be considered by the local Individual Funding Request (IFR) Panels.

#### **Homeopathy**

Homeopathy is not funded due to the lack of evidence that homeopathy has any identifiable biological effectiveness. Patients who are currently being treated should, in most cases, be encouraged to seek alternative treatments

#### **All other complementary therapies**

CCGs do not fund these services.

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<sup>3</sup> Hair removal evidence review. SEL Public Health Commissioning Support Group, 2015.

## **Category 2 – Interventions only routinely commissioned or performed when specific criteria is met**

The following procedures do not require prior agreement through an Individual Funding Request (IFR) process providing the specific access criteria are met.

Clinicians will need to demonstrate that the patient meets the criteria set out in this policy. If the patient does not meet the relevant access criteria, but the clinician feels the patient has exceptional clinical circumstances, the request for funding should be taken through the IFR process.

Please note that wherever the policy states that non-surgical, alternative or conservative measures should have been tried, these must be documented and included in the referral. The same applies when a certain number of clinical episodes are required in order to meet the criteria for referral.

Monitoring compliance will be through regular audit and engagements with clinicians.

### **2.1 Removal of benign skin lesions<sup>1</sup>**

#### **Description of the intervention**

Removal of benign skin lesions cannot be offered for cosmetic reasons. It should only be offered in situations where the lesion is causing symptoms according to the criteria outlined below. Risks from the procedure can include bleeding, pain, infection, and scarring.

Removal of benign skin lesions means treating asymptomatic lumps, bumps or tags on the skin that are not suspicious of cancer. Treatment carries a small risk of infection, bleeding or scarring and is not usually offered by the NHS if it is just to improve appearance. In certain cases, treatment (surgical excision or cryotherapy) may be offered if certain criteria are met. A patient with a skin or subcutaneous lesion that has features suspicious of malignancy must be treated or referred according to NICE skin cancer guidelines. This policy does not refer to pre-malignant lesions and other lesions with potential to cause harm.

#### **Recommendation**

This policy refers to the following benign lesions when there is diagnostic certainty and they do not meet the criteria listed below:

- benign moles (excluding large congenital naevi)
- solar comedones
- corn/callous
- dermatofibroma
- lipomas
- milia
- molluscum contagiosum (non-genital)
- epidermoid & pilar cysts (sometimes incorrectly called sebaceous cysts)
- seborrhoeic keratoses (basal cell papillomata)
- skin tags (fibroepithelial polyps) including anal tags
- spider naevi (telangiectasia)
- non-genital viral warts in immunocompetent patients
- xanthelasmata
- neurofibromata

The benign skin lesions, which are listed above, must meet at least ONE of the following criteria to be removed:

- The lesion is unavoidably and significantly traumatised on a regular basis with evidence of this causing regular bleeding or resulting in infections such that the patient requires 2 or more courses of antibiotics (oral or intravenous) per year
- There is repeated infection requiring 2 or more antibiotics per year
- The lesion bleeds in the course of normal everyday activity
- The lesion causes severe pain

- The lesion is obstructing an orifice or impairing field vision
- The lesion significantly impacts on function e.g. restricts joint movement
- The lesion causes pressure symptoms e.g. on nerve or tissue
- If left untreated, more invasive intervention would be required for removal
- Facial viral warts
- Facial spider naevi in children causing significant psychological impact
- Lipomas on the body > 5cm, or in a sub-facial position, with rapid growth and/or pain. These should be referred to Sarcoma clinic.

The following are **outside** the scope of this policy recommendation:

- Lesions that are suspicious of malignancy should be treated or referred according to NICE skin cancer guidelines.
- Any lesion where there is diagnostic uncertainty, pre-malignant lesions (actinic keratoses, Bowen disease) or lesions with pre-malignant potential should be referred or, where appropriate, treated in primary care.
- Removal of lesions other than those listed above.

Referral to appropriate speciality service (e.g. dermatology or plastic surgery):

- The decision as to whether a patient meets the criteria is primarily with the referring clinician. If such lesions are referred, then the referrer should state that this policy has been considered and why the patient meets the criteria
- This policy applies to all providers, including general practitioners (GPs), GPs with enhanced role (GPwER), independent providers, and community or intermediate services.

### **Rationale for recommendation**

There is little evidence to suggest that removing benign skin lesions to improve appearance is beneficial. Risks of this procedure include bleeding, pain, infection and scarring. Though in certain specific cases as outlined by the criteria above, there are benefits for removing skin lesions, for example, avoidance of pain and allowing normal functioning.

### **2.2 Removal of birthmarks**

This procedure is not available on cosmetic grounds to adults. An exception may be made for children up to the age of 18 for permanent large or prominent lesions on face or neck.

### **2.3 Tunable dye laser**

This treatment is offered for the removal of vascular birthmarks (port wine stains) often present on the neck and face and is the only successful treatment for this type of birthmark. The criteria for patients requiring this type of treatment will be:

- On the face or neck above the collar line in children up to the age of 18 years OR
- Chest area on women

Patients above the age of 18 years will be considered on an individual basis taking into account psychological and psychiatric effects of the birthmarks on the patient.

Referrals should be made on a tertiary basis

### **2.4 Grommets for glue ear in children<sup>1</sup>**

#### **Description of the intervention**

This is a surgical procedure to insert tiny tubes (grommets) into the eardrum as a treatment for fluid build up (glue ear) when it is affecting hearing in children.

Glue ear is a very common childhood problem (4 out of 5 children will have had an episode by age 10), and in most cases it clears up without treatment within a few weeks. Common symptoms can include

earache and a reduction in hearing. Often, when the hearing loss is affecting both ears it can cause language, educational and behavioural problems.

Evidence suggests that grommets only offer a short-term hearing improvement in children with glue ear who have no other serious medical problems or disabilities. They should be offered in cases that have a history of persistent (at least 3 months) bilateral, hearing loss as defined by the NICE guidance. Hearing aids can also be offered as an alternative to surgery.

### **Recommendation**

The NHS should only commission this surgery for the treatment of glue ear in children when the criteria set out by the NICE guidelines are met:

- All children must have had specialist audiology and ENT assessment.
- Persistent bilateral otitis media with effusion over a period of 3 months.
- Hearing level in the better ear of 25-30dbHL or worse averaged at 0.5, 1, 2, & 4kHz
- Exceptionally, healthcare professionals should consider surgical intervention in children with persistent bilateral OME with a hearing loss less than 25-30dbHL where the impact of the hearing loss on a child's developmental, social or educational status is judged to be significant.
- Healthcare professionals should also consider surgical intervention in children who cannot undergo standard assessment of hearing thresholds where there is clinical and tympanographic evidence of persistent glue ear and where the impact of the hearing loss on a child's developmental, social or educational status is judged to be significant.
- The guidance is different for children with Down's Syndrome and Cleft Palate; these children may be offered grommets after a specialist MDT assessment in line with NICE guidance.
- It is also good practice to ensure glue ear has not resolved once a date of surgery has been agreed, with tympanometry as a minimum.

For further information, please see: <https://www.nice.org.uk/Guidance/CG60>.

The risks to surgery are generally low, but the most common is persistent ear discharge (10-20%) and this can require treatment with antibiotic eardrops and water precautions. In rare cases (1-2%) a persistent hole in the eardrum may remain, and if this causes problems with recurrent infection, surgical repair may be required (however this is not normally done until around 8-10 years of age).

### **Rationale for recommendation**

In most cases glue ear will improve by itself without surgery. During a period of monitoring of the condition a balloon device (e.g. Otovent) can be used by the child if tolerated, this is designed to improve the function of the ventilation tube that connects the ear to the nose. In children with persistent glue ear, a hearing aid is another suitable alternative to surgery. Evidence suggests that grommets only offer a short-term hearing improvement in children with no other serious medical problems or disabilities.

The NHS should only commission this surgery when the NICE criteria are met, as performing the surgery outside of these criteria is unlikely to derive any clinical benefit.

## **2.5 Adenoidectomy for otitis media in children<sup>1</sup>**

Adenoidectomy combined with grommets may be considered in children who fulfil the criteria for grommets

## **2.6 Tonsillectomy for recurrent tonsillitis<sup>1</sup>**

### **Description of the intervention**

This guidance relates to surgical procedures to remove the tonsils as a treatment for recurrent sore throats in adults and children.

Recurrent sore throats are a very common condition that present a considerable health burden. In most cases they can be treated with conservative measures. In some cases, where there are recurrent, documented episodes of acute tonsillitis that are disabling to normal function, then tonsillectomy is beneficial, but it should only be offered when the frequency of episodes set out by the Scottish Intercollegiate Guidelines Network criteria are met.

### **Recommendation**

The NHS should only commission this surgery for treatment of recurrent severe episodes of sore throat when the following criteria are met, as set out by the SIGN guidance and supported by ENT UK commissioning guidance:

- Sore throats are due to acute tonsillitis AND
- The episodes are disabling and prevent normal functioning AND
- Seven or more, documented, clinically significant, adequately treated sore throats in the preceding year OR
- Five or more such episodes in each of the preceding two years OR
- Three or more such episodes in each of the preceding three years.

There are a number of medical conditions where episodes of tonsillitis can be damaging to health or tonsillectomy is required as part of the on-going management. In these instances tonsillectomy may be considered beneficial at a lower threshold than this guidance after specialist assessment:

- Acute and chronic renal disease resulting from acute bacterial tonsillitis.
- As part of the treatment of severe guttate psoriasis.
- Metabolic disorders where periods of reduced oral intake could be dangerous to health.
- PFAPA (Periodic fever, Aphthous stomatitis, Pharyngitis, Cervical adenitis)
- Severe immune deficiency that would make episodes of recurrent tonsillitis dangerous

Further information on the Scottish Intercollegiate Guidelines Network guidance can be found here: <http://www.sign.ac.uk/assets/sign117.pdf>.

Please note this guidance only relates to patients with recurrent tonsillitis. This guidance should not be applied to other conditions where tonsillectomy should continue to be funded, these include:

- Obstructive Sleep Apnoea / Sleep disordered breathing in Children
- Suspected Cancer (e.g. asymmetry of tonsils)
- Recurrent Quinsy (abscess next to tonsil)
- Emergency Presentations (e.g. treatment of parapharyngeal abscess)

It is important to note that national randomised control trial is underway comparing surgery versus conservative management for recurrent tonsillitis in adults in underway which may warrant review of this guidance in the near future.

### **Rationale for recommendation**

Recurrent sore throats are a very common condition that presents a considerable health burden. In most cases they can be treated with conservative measures. In some cases, where there are recurrent, documented episodes of acute tonsillitis that are disabling to normal function, then tonsillectomy is beneficial, but it should only be offered when the frequency of episodes set out by the Scottish Intercollegiate Guidelines Network criteria are met.

The surgery carries a small risk of bleeding requiring readmission to hospital (3.5%). A previous national audit quoted a 0.9% risk of requiring emergency surgery to treat bleeding after surgery but in a more recent study of 267, 159 tonsillectomies, 1.88% of patients required a return to theatre. Pain after surgery can be severe (especially in adults) for up to two weeks after surgery; this requires regular painkillers and can cause temporary difficulty swallowing. In addition to bleeding; pain or infection after surgery can require readmission to hospital for treatment. The Getting it Right First Time

ENT report is due late 2018 and will present updated figures on readmission rates in relation to tonsillectomy.

There is no alternative treatment for recurrent sore throats that is known to be beneficial, however sometimes symptoms improve with a period of observation.

## **2.7 Haemorrhoid surgery<sup>1</sup>**

### **Description of the intervention**

This procedure involves surgery for haemorrhoids (piles).

Numerous interventions exist for the management of haemorrhoids (piles). The evidence recommends that surgical treatment should only be considered for haemorrhoids that keep coming back after treatment or for haemorrhoids that are significantly affecting daily life. Changes to the diet like eating more fibre and drinking more water can often help with haemorrhoids. Treatments that can be done in clinic like rubber band ligation, may be effective especially for less severe haemorrhoids.

### **Recommendation**

Often haemorrhoids (especially early stage haemorrhoids) can be treated by simple measures such as eating more fibre or drinking more water. If these treatments are unsuccessful many patients will respond to outpatient treatment in the form of banding or perhaps injection. Surgical treatment should only be considered for those that do not respond to these non-operative measures or if the haemorrhoids are more severe, specifically:

- Recurrent grade 3 or grade 4 combined internal/external haemorrhoids with persistent pain or bleeding; or
- Irreducible and large external haemorrhoids in cases where there is significant rectal bleeding the patient should be examined internally by a specialist.

### **Rationale for recommendation**

Surgery should be performed, according to patient choice and only in cases of persistent grade 1 (rare) or 2 haemorrhoids that have not improved with dietary changes, banding or perhaps in certain cases injection, and recurrent grade 3 and 4 haemorrhoids and those with a symptomatic external component.

Haemorrhoid surgery can lead to complications. Pain and bleeding are common and pain may persist for several weeks. Urinary retention can occasionally occur and may require catheter insertion. Infection, iatrogenic fissuring (tear or cut in the anus), stenosis and incontinence (lack of control over bowel motions) occur more infrequently.

## **2.8 Hysterectomy for heavy menstrual bleeding<sup>1</sup>**

### **Description of the intervention**

Hysterectomy is the surgical removal of the uterus.

NICE recommends that hysterectomy should not be used as a first-line treatment solely for heavy menstrual bleeding (HMB). Heavy periods can be reduced by using medicines or intrauterine systems (IUS) or losing weight (if necessary).

### **Recommendation**

Based on NICE guidelines [Heavy menstrual bleeding: assessment and management [NG88] Published date: March 2018], hysterectomy should not be used as a first-line treatment solely for heavy menstrual bleeding.

It is important that healthcare professionals understand what matters most to each woman and support her personal priorities and choices.

Hysterectomy should be considered only when: other treatment options have failed, are contradicted; there is a wish for amenorrhoea (no periods); the woman (who has been fully informed) requests it; the woman no longer wishes to retain her uterus and fertility.



### **NICE guideline NG88 1.5 Management of HMB**

When agreeing treatment options for HMB with women, take into account: the woman's preferences, any comorbidities, the presence or absence of fibroids (including size, number and location), polyps, endometrial pathology or adenomyosis, other symptoms such as pressure and pain.

#### ***Treatments for women with no identified pathology, fibroids less than 3 cm in diameter, or suspected or diagnosed adenomyosis***

Consider an LNG-IUS (levonorgestrel-releasing intrauterine system) as the first treatment for HMB in women with: no identified pathology or fibroids less than 3 cm in diameter, which are not causing distortion of the uterine cavity or suspected or diagnosed adenomyosis.

If a woman with HMB declines an LNG-IUS or it is not suitable, consider the following pharmacological treatments: non-hormonal: tranexamic acid, NSAIDs (non-steroidal anti-inflammatory drugs), hormonal: combined hormonal contraception, cyclical oral progestogens.

Be aware that progestogen-only contraception may suppress menstruation, which could be beneficial to women with HMB.

If treatment is unsuccessful, the woman declines pharmacological treatment, or symptoms are severe, consider referral to specialist care for: investigations to diagnose the cause of HMB, if needed, taking into account any investigations the woman has already had and alternative treatment choices, including: pharmacological options not already tried, surgical options: second-generation endometrial ablation, hysterectomy.

For women with submucosal fibroids, consider hysteroscopic removal.

#### ***Treatments for women with fibroids of 3 cm or more in diameter***

Consider referring women to specialist care to undertake additional investigations and discuss treatment options for fibroids of 3 cm or more in diameter.

If pharmacological treatment is needed while investigations and definitive treatment are being organised, offer tranexamic acid and/or NSAIDs.

Advise women to continue using NSAIDs and/or tranexamic acid for as long as they are found to be beneficial.

For women with fibroids of 3 cm or more in diameter, take into account the size, location and number of fibroids, and the severity of the symptoms and consider the following treatments: pharmacological: non-hormonal: tranexamic acid, NSAIDs, hormonal: LNG-IUS, combined hormonal contraception, cyclical oral progestogens, uterine artery embolization, surgical: myomectomy, hysterectomy.

Be aware that the effectiveness of pharmacological treatments for HMB may be limited in women with fibroids that are substantially greater than 3 cm in diameter.

Prior to scheduling of uterine artery embolisation or myomectomy, the woman's uterus and fibroid(s) should be assessed by ultrasound. If further information about fibroid position, size, number and vascularity is needed, MRI should be considered. [2007]

Consider second-generation endometrial ablation as a treatment option for women with HMB and fibroids of 3 cm or more in diameter who meet the criteria specified in the manufacturers' instructions.

If treatment is unsuccessful: consider further investigations to reassess the cause of HMB, taking into account the results of previous investigations and offer alternative treatment with a choice of the options described for treating women with fibroids.

Pretreatment with a gonadotrophin-releasing hormone analogue before hysterectomy and myomectomy should be considered if uterine fibroids are causing an enlarged or distorted uterus.

### **Rationale for recommendation**

NICE's Guideline Development Group considered the evidence (including 2 reviews, four randomised control trials and one cohort study comparing hysterectomy with other treatments) as well as the views of patients and the public and concluded that hysterectomy should not routinely be offered as first line treatment for heavy menstrual bleeding. The Group placed a high value on the need for education and information provision for women with heavy menstrual bleeding.

Complications following hysterectomy are usually rare but infection occurs commonly. Less common complications include: intra-operative haemorrhage; damage to other abdominal organs, such as the urinary tract or bowel; urinary dysfunction –frequent passing of urine and incontinence. Rare complications include thrombosis (DVT and clot on the lung) and very rare complications include death. Complications are more likely when hysterectomy is performed in the presence of fibroids (non-cancerous growths in the uterus). There is a risk of possible loss of ovarian function and its consequences, even if their ovaries are retained during hysterectomy. If oophorectomy (removal of the ovaries) is performed at the time of hysterectomy, menopausal-like symptoms occur.

## **2.9 Chalazia removal<sup>1</sup>**

### **Description of the intervention**

This procedure involves incision and curettage (scraping away) of the contents of the chalazion. Chalazia (meibomian cysts) are benign lesions on the eyelids due to blockage and swelling of an oil gland that normally change size over a few weeks. Many but not all resolve within six months with regular application of warm compresses and massage.

The evidence shows that alternative treatment options (warm compresses, drops or ointment, steroid injection) or a “watch and wait” approach will lead to resolution of many chalazia without the risks of surgery

### **Recommendation**

Incision and curettage (or triamcinolone injection for suitable candidates) of chalazia should only be undertaken if at least **one** of the following criteria have been met:

- Has been present for more than 6 months and has been managed conservatively with warm compresses, lid cleaning and massage for 4 weeks
- Interferes significantly with vision
- Interferes with the protection of the eye by the eyelid due to altered lid closure or lid anatomy
- Is a source of infection that has required medical attention twice or more within a six month time frame
- Is a source of infection causing an abscess which requires drainage
- If malignancy (cancer) is suspected e.g. Madarosis/recurrence/other suspicious features in which case the lesion should be removed and sent for histology as for all suspicious lesions

### **Rationale for recommendation**

NICE recommend that warm compresses and lid massage alone are sufficient first line treatment for chalazia. If infection is suspected a drop or ointment containing an antibiotic (e.g. Chloramphenicol) should be added in addition to warm compresses. Only if there is spreading lid and facial cellulitis should a short course of oral antibiotics (e.g. co-amoxiclav) be used.

Where there is significant inflammation of the chalazion a drop or ointment containing an antibiotic and steroid can be used along with other measures such as warm compresses. However, all use of topical steroids around the eye does carry the risk of raised intraocular pressure or cataract although this is very low with courses of less than 2 weeks.

Many chalazia, especially those that present acutely, resolve within six months and will not cause any harm however there are a small number which are persistent, very large, or can cause other problems such as distortion of vision.

In these cases surgery can remove the contents from a chalazion. However all surgery carries risks. Most people will experience some discomfort, swelling and often bruising of the eyelids and the cyst can take a few weeks to disappear even after successful surgery. Surgery also carries a small risk of infection, bleeding and scarring, and there is a remote but serious risk to the eye and vision from any procedure on the eyelids. Lastly in a proportion of successful procedures the chalazion can come back. The alternative option of an injection of a steroid (triamcinolone) also carries a small risk of serious complications such as raised eye pressure, eye perforation or bleeding.

Some trials comparing the two treatments suggest that using a single triamcinolone acetonide injection followed by lid massage is almost as effective as incision and curettage in the treatment of chalazia and with similar patient satisfaction but less pain and patient inconvenience. However this is controversial and other studies show that steroid injection is less effective than surgery. Therefore both options can be considered for suitable patients.

## **2.10 Arthroscopic shoulder decompression for subacromial shoulder pain**

### **Description of the intervention**

Arthroscopic sub-acromial decompression is a surgical procedure that involves decompressing the sub-acromial space by removing bone spurs and soft tissue arthroscopically.

Recent research has indicated that in patients with pure subacromial impingement (with no other associated diagnoses such as rotator cuff tears, calcific tendinopathy and acromio-clavicular joint pain), non-operative management with a combination of exercise and physiotherapy is effective in the majority of cases.

Patients suffering with persistent symptoms, despite appropriate non-operative management, should be given the option to choose decompression surgery.

Treating clinicians and surgeons should refer to the 2015 BESS/BOA/NICE commissioning guidelines (guideline update due in 2018/19) for details of appropriate treatment of these patients.

[https://www.boa.ac.uk/wpcontent/uploads/2014/08/Subacromial-Shoulder-Commissioning-Guide\\_final.pdf](https://www.boa.ac.uk/wpcontent/uploads/2014/08/Subacromial-Shoulder-Commissioning-Guide_final.pdf)

In order to facilitate non-operative treatment in primary and intermediate care, BESS and Getting It Right First Time programme have produced patient exercise rehab videos and booklets for GPs and patients to use. <http://www.bess.org.uk/index.php/public-area/shpi-videos>

### **Recommendation**

Arthroscopic subacromial decompression for pure subacromial shoulder impingement should only be offered in appropriate cases. To be clear, 'pure subacromial shoulder impingement' means subacromial pain not caused by associated diagnoses such as rotator cuff tears, acromio-clavicular joint pain, or calcific tendinopathy. Non-operative treatment such as physiotherapy and exercise programmes are effective and safe in many cases.

For patients who have persistent or progressive symptoms, in spite of adequate non-operative treatment, surgery should be considered. The latest evidence for the potential benefits and risks of subacromial shoulder decompression surgery should be discussed with the patient and a shared decision reached between surgeon and patient as to whether to proceed with surgical intervention.

### **Rationale for recommendation**

Recruiting patients with pure subacromial impingement and no other associated diagnosis, a recent randomised, pragmatic, parallel group, placebo-controlled trial investigated whether subacromial decompression compared with placebo (arthroscopy only) surgery improved pain and function. While statistically better scores were reached by patients who had both types of surgery compared to no surgery, the differences were not clinically significant, which questions the value of this type of surgery.

On the other hand, a more recent prospective randomised trial comparing the long term outcome (10 year follow up) of surgical or non-surgical treatment of sub acromial impingement showed surgery to be superior to non-surgical treatment.

Other studies of limited quality identify certain patients with impingement syndrome that improve with surgical subacromial decompression if non-operative management fails.

There is also some evidence to show the benefit of surgery when used selectively and applying national clinical guidelines.

A review of the literature identified one further systematic review that looked at the effectiveness of surgery. The review was limited by the quality of evidence but their findings showed no difference between patients treated with surgery and those treated with non-surgical options.

Healthcare professionals treating patients with subacromial pain should be familiar with the NICE approved commissioning and treatment guidelines for the management of subacromial pain.

Risks associated with arthroscopic sub-acromial decompression are low but include infection, frozen shoulder, ongoing pain, potential damage to blood vessels or nerves and those associated with having a general anaesthetic.

## **2.11 Shoulder arthroscopy for other conditions<sup>4</sup>**

### **Description of the intervention**

Shoulder arthroscopy is a procedure performed by orthopaedic surgeons. A small camera is inserted into the shoulder joint to examine the cartilage bones, ligaments and tendons. It is also used to aid diagnosis and treat shoulder conditions.

### **Recommendations**

Shoulder arthroscopy will be funded for treatment purposes if one of the below criteria is met.

- Full thickness rotator cuff tear diagnosed through analysis of clinical picture and imaging.
- Partial thickness rotator cuff tear diagnosed through analysis of clinical picture and imaging which has failed to respond to 3 months conservative management.
- Adhesive capsulitis diagnose according to the clinical picture which has failed to respond to 6 months of conservative management.
- Shoulder joint instability diagnosed according to clinical picture which has failed to respond to 6 months of conservative management.
- Major superior labrum anterior posterior tear diagnosed through analysis of clinical picture and imaging.
- Minor superior labrum anterior posterior tear diagnosed through analysis of clinical picture and imaging which has failed to respond to 3 months of conservative management.
- Impingement syndrome diagnosed according to clinical picture which has failed to respond to 6 months of conservative management.

The arthroscopy will not be funded for solely diagnostic purposes. For traumatic injury or dislocation, there should be referral to secondary care for orthopaedic opinion.

### **Rationale for recommendation**

In cases of full thickness rotator cuff tears and major superior labrum anterior posterior tears, evidence supports the use of arthroscopy for treatment purposes. For partial rotator cuff tears, minor superior labrum anterior posterior tears, impingement syndrome, adhesive capsulitis and joint instability, evidence is suggestive that physiotherapy, use of NSAIDs and even steroid injections can all be used effectively.

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<sup>4</sup> Shoulder arthroscopy evidence review. SEL Health Care Advisory Group, 2019.

## 2.12 Carpal tunnel syndrome release<sup>1</sup>

### Description of the intervention

Open or endoscopic surgical procedure to release median nerve from carpal tunnel.

Carpal tunnel syndrome is common, and mild acute symptoms usually get better with time. Splinting at night, pain relief and corticosteroid injection should be considered. Surgery should be considered for persistent severe symptoms. Surgical treatment of carpal tunnel should only be offered under the criteria included below.

### Recommendation

- Mild cases with intermittent symptoms causing little or no interference with sleep or activities require no treatment.
- Cases with intermittent symptoms which interfere with activities or sleep should first be treated with:
  - a. corticosteroid injection(s) (medication injected into the wrist: good evidence for short (8-12 weeks) term effectiveness)
  - or**
  - b. night splints (a support which prevents the wrist from moving during the night: not as effective as steroid injections)
- Surgical treatment of carpal tunnel should be considered if one of the following criteria are met:
  - a. The symptoms significantly interfere with daily activities and sleep symptoms and have not settled to a manageable level with either one local corticosteroid injection and/or nocturnal splinting for a minimum of 8 weeks;
  - or**
  - b. There is either:
    - i. a permanent (ever-present) reduction in sensation in the median nerve distribution;
    - or**
    - ii. muscle wasting or weakness of thenar abduction (moving the thumb away from the hand).

Nerve Conduction Studies if available are suggested for consideration before surgery to predict positive surgical outcome or where the diagnosis is uncertain.

### Rationale for recommendation

Carpal tunnel syndrome is very common, and mild cases may never require any treatment. Cases which interfere with activities or sleep may resolve or settle to a manageable level with non-operative treatments such as a steroid injection (good evidence of short-term benefit (8-12 weeks) but many progress to surgery within 1 year). Wrist splints worn at night (weak evidence of benefit) may also be used but are less effective than steroid injections and reported as less cost-effective than surgery.

In refractory (keeps coming back) or severe case surgery (good evidence of excellent clinical effectiveness and long term benefit) should be considered. The surgery has a high success rate (75 to 90%) in patients with intermittent symptoms who have had a good short-term benefit from a previous steroid injection. Surgery will also prevent patients with constant wooliness of their fingers from becoming worse and can restore normal sensation to patients with total loss of sensation over a period of months.

The hand is weak and sore for 3-6 weeks after carpal tunnel surgery but recovery of normal hand function is expected, significant complications are rare ( $\approx 4\%$ ) and the lifetime risk of the carpal tunnel syndrome recurring and requiring revision surgery has been estimated at between 4 and 15%.

## 2.13 Dupuytren's contracture release in adults<sup>1</sup>

### Description of the intervention

NICE recommends no treatment is necessary for people with Dupuytren's disease who do not have contracture. Referral to hand surgery should be made for people with Dupuytren's contractures according to the criteria listed below.

Dupuytren's contracture is caused by fibrous bands in the palm of the hand which draw the finger(s) (and sometimes the thumb) into the palm and prevent them from straightening fully. If not treated the finger(s) may bend so far into the palm that they cannot be straightened. All treatments aim to straighten the finger(s) to restore and retain hand function for the rest of the patient's life. However none cure the condition which can recur after any intervention so that further interventions are required.

Splinting and radiotherapy have not been shown to be effective treatments of established Dupuytren's contractures.

Several treatments are available: collagenase injections, needle fasciotomy, fasciectomy and dermofasciectomy. None is entirely satisfactory with some having slower recovery periods, higher complication rates or higher reoperation rates (for recurrence) than others. The need for, and choice of, intervention should be made on an individual basis and should be a shared decision between the patient and a practitioner with expertise in the various treatments of Dupuytren's contractures.

No-one knows which interventions are best for restoring and maintaining hand function throughout the rest of the patient's life, and which are the cheapest and most cost-effective in the long term. Ongoing and planned National Institute for Health Research studies aim to address these questions.

### Recommendation

- Treatment is not indicated in cases where there is no contracture, and in patients with a mild (less than 20°) contractures, or one which is not progressing and does not impair function.
- An intervention (collagenase injections, needle fasciotomy, fasciectomy and dermofasciectomy) should be considered for:
  - a. finger contractures causing loss of finger extension of 30° or more at the metacarpophalangeal joint or 20° at the proximal interphalangeal joint.
  - or
  - b. severe thumb contractures which interfere with function
- NICE concluded that collagenase should only be used for:
  - a. Participants in the ongoing clinical trial (HTA-15/102/04)
  - or
  - a) Adult patients with a palpable cord if:
    - i. there is evidence of moderate disease (functional problems and metacarpophalangeal joint contracture of 30° to 60° and proximal interphalangeal joint contracture of less than 30° or first web contracture) plus up to two affected joints; and
    - ii. needle fasciotomy is not considered appropriate, but limited fasciectomy is considered appropriate by the treating hand surgeon

### Rationale for recommendation

Contractures left untreated usually progress and often fail to straighten fully with any treatment if allowed to progress too far. Complications causing loss, rather than improvement, in hand function occur more commonly after larger interventions, but larger interventions carry a lower risk of need for further surgery.

Common complications after collagenase injection are normally transient and include skin breaks and localised pain. Tendon injury is possible but very rare. Significant complications with lasting impact after needle fasciotomy are very unusual (about 1%) and include nerve injury. Such complications after fasciectomy are more common (about 4%) and include infection, numbness and stiffness.

## 2.14 Ganglion excision<sup>1</sup>

### Description of the intervention

Ganglia are cystic swellings containing jelly-like fluid which form around the wrists or in the hand. In most cases wrist ganglia cause only mild symptoms which do not restrict function, and many resolve without treatment within a year. Wrist ganglion rarely press on a nerve or other structure, causing pain and reduced hand function.

Ganglia in the palm of the hand (seed ganglia) can cause pain when carrying objects.

Ganglia which form just below the nail (mucous cysts) can deform the nail bed and discharge fluid, but occasionally become infected and can result in septic arthritis of the distal finger joint.

Most people live comfortably with ganglia and they often resolve spontaneously over time. Ganglion excision can be unnecessary, can cause complications, and recurrence is common following surgery. The complications may be similar to or worse than the original problem. Ganglion excision should only be offered under the criteria outlined below.

### Recommendation

#### Wrist ganglia

- no treatment unless causing pain or tingling/numbness or concern (worried it is a cancer).
- aspiration if causing pain, tingling/numbness or concern.
- surgical excision only considered if aspiration fails to resolve the pain or tingling/numbness and there is restricted hand function.

#### Seed ganglia that are painful

- puncture/aspirate the ganglion using a hypodermic needle.
- surgical excision only considered if ganglion persists or recurs after puncture/aspiration.

#### Mucous cysts

- no surgery considered unless recurrent spontaneous discharge of fluid or significant nail deformity.

### Rationale for recommendation

Most wrist ganglia get better on their own. Surgery causes restricted wrist and hand function for 4-6 weeks, may leave an unsightly scar and be complicated by recurrent ganglion formation. Aspiration of wrist ganglia may relieve pain and restore hand function, and “cure” a minority (30%). Most ganglia reform after aspiration but they may then be painless. Aspiration also reassures the patient that the swelling is not a cancer but a benign cyst full of jelly. Complication and recurrence are rare after aspiration and surgery for seed ganglia

## 2.15 Trigger finger release in adults<sup>1</sup>

### Description of the intervention

Trigger digit occurs when the tendons which bend the thumb/finger into the palm intermittently jam in the tight tunnel (flexor sheath) through which they run. It may occur in one or several fingers and causes the finger to “lock” in the palm of the hand. Mild triggering is a nuisance and causes infrequent locking episodes. Other cases cause pain and loss and unreliability of hand function. Mild cases require no treatment and may resolve spontaneously.

Trigger finger often resolves over time and is often a nuisance rather than a serious problem. If treatment is necessary steroid injection can be considered. Surgery should only be offered in specific cases according to NICE accredited guidelines by the British Society for Surgery to the Hand, where alternative measures have not been successful and persistent or recurrent triggering, or a locked finger occurs.

## **Recommendation**

Mild cases which cause no loss of function require no treatment or avoidance of activities which precipitate triggering and may resolve spontaneously.

Cases interfering with activities or causing pain should first be treated with:

- a. one or two steroid injections which are typically successful (strong evidence), but the problem may recur, especially in diabetics;  
or
- b. splinting of the affected finger for 3-12 weeks (weak evidence).

Surgery should be considered if:

- a. the triggering persists or recurs after one of the above measures (particularly steroid injections);  
or
- b. the finger is permanently locked in the palm;  
or
- c. the patient has previously had 2 other trigger digits unsuccessfully treated with appropriate nonoperative methods;  
or
- d. diabetics.

Surgery is usually effective and requires a small skin incision in the palm, but can be done with a needle through a puncture wound (percutaneous release).

## **Rationale for recommendation**

Treatment with steroid injections usually resolve troublesome trigger fingers within 1 week (strong evidence) but sometimes the triggering keeps recurring. Surgery is normally successful (strong evidence), provides better outcomes than a single steroid injection at 1 year and usually provides a permanent cure. Recovery after surgery takes 2-4 weeks. Problems sometimes occur after surgery, but these are rare (<3%).

## **2.16 Varicose vein interventions<sup>1</sup>**

### **Description of the intervention**

There are various interventional procedures for treating varicose veins. These include endothermal ablation, ultrasound guided foam sclerotherapy and traditional surgery (this is a surgical procedure that involves ligation and stripping of varicose veins) all of which have been shown to be clinically and cost effective compared to no treatment or treatment with compression hosiery. Varicose veins are common and can markedly affect patients quality of life, can be associated with complications such as eczema, skin changes, thrombophlebitis, bleeding, leg ulceration, deep vein thrombosis and pulmonary embolism that can be life threatening.

NICE has published detailed guidance on what treatment should be considered for varicose veins and when interventions for varicose veins (endothermal ablation, sclerotherapy or surgery) should be offered. Surgery is a traditional treatment that involves removal of the vein, patients can get recurrence of symptoms which may need further treatment. Treatments like endothermal ablation or ultrasound-guided foam sclerotherapy are less invasive than surgery and have replaced surgery in the management of most patients. However surgery is the most appropriate in some cases. Patients with symptomatic varicose veins should be offered treatment of their varicose veins. Compression hosiery is not recommended if an interventional treatment is possible.



## Recommendation

- Intervention in terms of, endovenous thermal (laser ablation, and radiofrequency ablation), ultrasound guided foam sclerotherapy, open surgery (ligation and stripping) are all cost effective treatments for managing symptomatic varicose veins compared to no treatment or the use of compression hosiery. For truncal ablation there is a treatment hierarchy based on the cost effectiveness and suitability, which is endothermal ablation then ultrasound guided foam, then conventional surgery.
- Refer people to a vascular service if they have any of the following;
  - Lower-limb skin changes, such as pigmentation or eczema, thought to be caused by chronic venous insufficiency.
  - Superficial vein thrombophlebitis (characterised by the appearance of hard, painful veins) and suspected venous incompetence.
  - A venous leg ulcer (a break in the skin below the knee that has not healed within 2 weeks).
  - A healed venous leg ulcer.

For patients whose veins are purely cosmetic and are not associated with any symptoms do not refer for NHS treatment

Refer people with bleeding varicose veins to a vascular service immediately.

Do not offer compression hosiery to treat varicose veins unless interventional treatment is unsuitable.

## Rationale for recommendation

International guidelines, NICE guidance and NICE Quality standards provide clear evidence of the clinical and cost-effectiveness that patients with symptomatic varicose veins should be referred to a vascular service for assessment including duplex ultrasound.

Open surgery is a traditional treatment that involves surgical removal by 'stripping' out the vein or ligation (tying off the vein), this is still a valuable technique, it is still a clinically and cost-effective treatment technique for some patients but has been mainly superseded by endothermal ablation and ultrasound guided foam sclerotherapy.

Recurrence of symptoms can occur due to the development of further venous disease, that will benefit from further intervention (see above). NICE guidance states that a review of the data from the trials of interventional procedures indicates that the rate of clinical recurrence of varicose veins at 3 years after treatment is likely to be between 10–30%.

For people with confirmed varicose veins and truncal reflux NICE recommends:

- Offer endothermal ablation of the truncal vein.
- If endothermal ablation is unsuitable, offer ultrasound-guided foam sclerotherapy.
- If ultrasound-guided foam sclerotherapy is unsuitable, offer surgery.
- Consider treatment of tributaries at the same time
- Do not offer compression hosiery to treat varicose veins unless interventional treatment is unsuitable.

Complications of intervention include recurrence of varicose veins, infection, pain, bleeding, and more rarely blood clot in the leg. Complications of non-intervention include decreasing quality of life for patients, increased symptomatology, disease progression potentially to skin changes and eventual leg ulceration, deep vein thrombosis and pulmonary embolism.

## 2.17 Hip arthroplasty<sup>5</sup>

### Description of the intervention

Hip arthroplasty, otherwise known as hip replacement, describes the surgical replacement of the hip joint.

### Recommendation

Funding for total hip replacement surgery is available for patients who meet ALL of the following criteria:

The patient has osteoarthritis with joint symptoms (pain, stiffness and reduced function) that have a substantial impact on quality of life as agreed with the patient and / or the patient's representative, referring clinicians and surgeons

AND

The symptoms are refractory to non-surgical treatment (including analgesia, exercise, physiotherapy and weight loss, where appropriate)

AND

The patient's symptoms are consistent with degenerative disease, and prior to arthroplasty there is radiological confirmation of this

AND

The patient has been engaged in shared decision making regarding treatment options.

Exclusions:

- Children
- Patients with confirmed or suspected malignancy, acute trauma, suspected infection and inflammatory arthropathy
- Patients with underlying disease (such as haemophilia or sickle cell) related hip disease
- Young adults with abnormal hip anatomy

## 2.18 Knee arthroplasty<sup>4</sup>

### Description of the intervention

Total knee arthroplasty: Surgical procedure performed under anaesthetic, which involves replacing the knee with an artificial joint. Also known as total knee replacement (TKR).

Partial knee arthroplasty: Surgical procedure performed under anaesthetic, which involves replacing only one compartment of the knee with a prosthesis. Also known as a unicompartmental knee replacement.

### Recommendation

Funding for total or partial knee replacement surgery is available for patients who meet ALL of the following criteria:

Osteoarthritis with joint symptoms (pain, stiffness, reduced function, joint instability) that have a substantial impact on quality of life as agreed with the patient and/or the patient's representative, referring clinicians and surgeons

AND

The symptoms are refractory to non-surgical treatment (including pain relief, exercise, physiotherapy and weight loss where appropriate)

AND

The patient's symptoms are consistent with degenerative disease, and prior to arthroplasty there is radiological confirmation of this

AND

The patient has been engaged in shared decision making regarding treatment options.

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<sup>5</sup> London Choosing Wisely, NHS England, 2018.

#### Exclusions:

- Patients with joint failure from causes other than degenerative disease / osteoarthritis
- Patients with confirmed or suspected malignancy
- Patients with acute trauma or suspected infection
- Patients with inflammatory arthropathies
- Paediatric patients

## 2.19 Bunion surgery<sup>6</sup>

### Description of intervention

A bunion (hallux valgus) is a common condition in which the big, or great, toe (hallux) deviates towards the other toes, and in severe cases can overlie it. As a result of this movement, a bony protrusion (bunion) occurs on the inside of the foot. There can be damage to the skin over the bunion, where it becomes inflamed.

There are a number of surgical options for Hallux valgus, including soft tissue procedures, osteotomy, arthrodesis, arthroplasty, and joint replacement surgery. The Royal College of Surgeons (RCS) guidance states that there is no conclusive evidence of the superiority of one operation over another, and that the procedure selected will depend on patient signs and symptoms and patient choice, having considered with the surgeon the risks and benefits of each.

### Recommendations

Patients may be referred for surgery for bunions when the following criteria are met:

- Failure of appropriate conservative measures (e.g. oral analgesia, orthotics, bunion pads, ice packs or footwear advice from podiatry) after three months.
- Persistent pain and disability, or significant disruption to lifestyle or activities, not responding to up to 12 weeks of non-surgical treatments; this time to include any treatment received in primary care.
- Patient must be prepared to undergo surgery understanding that they will be out of sedentary work for 2- 6 weeks and physical work for 2-3 months and they will be unable to drive for 6-8 weeks (2 weeks if left foot and driving automatic car).
- Patient must also understand that recurrence of deformity after hallux valgus surgery occurs in 8-15% of patients, and the risk of complications or side-effects of surgery.
- Patients should be informed that the decision to have surgery can be a dynamic process and that a decision to not undergo surgery does not exclude them from having surgery at a later date.
- Patients with significant co-morbidities [systemic or local] should have treatment which optimises these before referral.
- For clarification, co-morbidities must be managed through a shared decision making process with the patient, enabling patients to make joint decisions on referral and treatment.
- Surgery must not be undertaken for prophylactic or cosmetic reasons

If the patient has diabetes, they should be referred to the diabetic foot surgery service.

### Rationale for recommendation

Hallux valgus is a common foot deformity, which can lead to functional disability, pain in the foot, impaired gait pattern, poor balance and falls in older people. For patients with diabetes, untreated bunions can lead to ulceration and deep infection. Hallux valgus is common with a prevalence of 28.4% in adults older than 40 years.

Conservative treatments are recommended initially, as most bunion pain can be alleviated by modifying activities and/or shoes.

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<sup>6</sup> Surgery for bunions evidence review. SEL Health Care Advisory Group, 2019.

The Royal College of Surgeons (RCS) advises that the majority of patients with great toe deformity (such as those with bunions, but including other conditions) and mild pain are expected to be managed in primary care, with referral to a specialist provider such as musculoskeletal (MSK) physiotherapy, podiatry (non-surgical and surgical) and orthotics \* for patients meeting certain criteria.

\*Devices such as shoe inserts or foot pads placed to correct foot problems without surgery

Referral for bunion surgery is indicated for pain and is not routinely performed for cosmetic purposes.

Surgery entails a long recovery time, and small risks of complications. If pain is bearable, the RCS recommends that there is no harm in delaying surgery and that surgery is successful even for more severe bunions and at older age.

Conservative treatment may be more appropriate than surgery for some older people, or people with severe neuropathy or other comorbidities affecting their ability to undergo surgery.

## **2.20 Surgery for female genital prolapse<sup>7</sup>**

### **Description of intervention**

Pelvic organ prolapse (POP) can be defined as the downward descent of the female pelvic organs (vagina, uterus, bladder and/or rectum) into or beyond the vagina. It is difficult to determine exact prevalence, however it is estimated that between 30-76% of women will have some degree of POP.

Current management options for women with symptomatic POP include conservative (lifestyle modification and pelvic floor exercises), mechanical (vaginal pessary insertion) and surgical intervention.

Surgical management is generally reserved for patients where conservative interventions have failed or in patients who are highly symptomatic. Modes of surgery can be categorised into restorative (using patient endogenous tissue to enhance support), compensatory (use of mesh) and obliterative (colpocleisis). The goals of surgery are to restore functional anatomy and improve symptoms. The type of surgical intervention varies depending on the prolapse category, patient preference and pre-morbidity.

### **Clinical criteria**

- Conservative and mechanical interventions should remain first-line treatment for the majority of cases. This includes pelvic floor muscle exercises and vaginal pessaries.
- Surgery should be offered to women in whom conservative management fails or if declined.
- Referral for further investigation or specialist opinion is appropriate in certain cases including pain and patients presenting with obstructive symptoms/incontinence.
- Adequate pre-operative counselling is crucial prior to any surgical intervention.
- Use of mesh should be avoided unless clearly clinically indicated and only if agreed by regional multi-disciplinary team (MDT). Risk of complication must be discussed with the patient

### **Rationale for recommendations**

Current NICE guidelines [2017] state that mesh can be used provided that arrangements are in place for clinical audit, clinical governance and research, although use of mesh in transvaginal repair of anterior or posterior prolapse, in addition to laparoscopic mesh pectopexy for apical prolapse of the uterus or vagina should be used in the context of research only. New guidelines are in development with a draft proposal suggesting mesh can be considered on a case-by-case basis, if an abdominal approach is contraindicated or if apical support is adequate and the risks are explained and accepted by the patient and agreed by a regional MDT.

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<sup>7</sup> Female genital prolapse evidence review. SEL Health Care Advisory Group, 2019.

The evidence for efficacy of surgical intervention in POP is varied, as are rates of recurrence, pending on procedure and patient pre-morbid status. There is currently limited evidence as to the best surgical technique, and thus it is clinician dependent and is individualised to patient needs.

There was limited data directly comparing success rates of conservative and surgical intervention. Further analysis is needed to determine the differences in efficacy between these two treatment groups.

## 2.21 Micro-suction for ear wax removal<sup>8</sup>

### General principles

- All non-complex patients with 'normal' ears and wax should be managed in primary care. Only patients who meet the criteria in this policy should be referred to secondary care.
- Patients who are suspected of suffering from cancer should be referred under the 2 week wait cancer forms via e-RS.

**Please note:** Where it is not clearly demonstrated that the patient meets the criteria for referral to and treatment in secondary care, **the referral will be returned to primary care**. This will also apply to poor quality referrals that are either incomplete and do not demonstrate the level of clinical information as indicated in the referral form. The referral form is available on DXS in the Ear Nose and Throat (ENT) section.

### Referral to secondary care can be made if:

- The patient has any of the contraindications to ear irrigation:
  - A foreign body, including vegetable matter in the ear canal is suspected which could swell during irrigation with water.
  - The patient is unable to maintain head position suitable for irrigation with water and valid consent has not been obtained.
  - The patient has experienced complications following this procedure in the past.
  - There is a history of a middle ear infection in the last two months.
  - The patient has undergone ANY form of ear surgery (apart from grommets that have extruded at least 2 years previously and the patient has been discharged from the ENT Department). This does not include cosmetic surgery to the pinna.
  - The patient has a perforation of the ear drum or there is a history of a mucous discharge in the last 2 years.
  - The patient has a cleft palate (repaired or not).
  - There is evidence of acute otitis externa with pain and tenderness of the pinna and a swollen ear canal. If there is debris present refer to emergency ENT clinic.
- If there has been a minimum of two failed attempts of irrigation with water.

## 2.22 Bariatric surgery<sup>9</sup>

This includes but is not limited to gastric banding and gastric by-pass surgery.

NICE issued clinical guidance on obesity, which is comprehensive guidance on identification, prevention and management of obesity. The guidance also includes criteria for bariatric surgery which the CCGs have to take into account when planning services.

### Criteria for bariatric surgery

Priority for bariatric surgery will be offered to patients who fulfil all of the following criteria:

- BMI 40-44 plus two major co-morbidities

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<sup>8</sup> Ear-wax removal evidence review. SEL Health Care Advisory Group, 2018.

<sup>9</sup> Bariatric Surgery evidence review. SEL Health Care Advisory Group, 2018.

- BMI 45 or more plus one major co-morbidity
- All appropriate non-surgical methods have been tried but the person has not achieved or maintained adequate, clinically beneficial weight loss
- The person has been receiving or will receive intensive management in a Tier 3 service
- The person is generally fit for anaesthesia and surgery
- The person commits to the need for long-term follow-up

Patients with BMI more than 50 can be referred directly to bariatric surgery.

### **Co-morbidities**

The major co-morbidities, which evidence suggests can be improved by losing weight, are the following:

- Type 2 Diabetes
- Hypertension
  - Requiring three antihypertensive drugs to control hypertension
  - Taking three antihypertensive drugs but hypertension not controlled
  - Taking fewer than three antihypertensive drugs, hypertension not controlled and unable to increase antihypertensive medication further due to clear contraindication or proven poor tolerance of additional medications
- Asthma
  - Attended ED within the last year with acute asthma exacerbation
  - Any previous admission to hospital ward with acute asthma exacerbation
  - Any near fatal asthma exacerbation Currently requiring significant corticosteroid treatment – ongoing inhaled corticosteroid treatment or more than two courses of oral corticosteroid treatment in the last year
  - Currently requiring three or more classes of asthma medication
  - “Brittle” asthma
  - Is asthma impeding the patient’s ability to exercise and hence lose weight?
- Sleep Apnea requiring Continuous positive airway pressure ( CPAP)
- Diagnosis of coronary heart disease

### **Surgery is not generally recommended for children or young people.**

Funding for surgery for young people should only be considered in exceptional circumstances.

Any cosmetic surgery is not part of the bariatric surgery and patients should be advised accordingly.

### **Revision for weight re-gain**

Any surgical revisions for weight re-gain will be considered using the same criteria as for original bariatric surgery.

## **2.23 Hyperhidrosis treatment in adults<sup>10</sup>**

Sweating is the human body’s usual response to environmental heat or exercise, so as to regulate body temperature. Hyperhidrosis is excessive sweating much beyond normal amounts and can be very disruptive to activities of daily living. It usually affects specific parts such as palms, axillae or feet (planter). Specific tiers of treatments with a research evidence-base for effectiveness have been developed and should be followed-see below. For example, the first line of treatment is usually topical aluminium chloride. Botox® should only be a second line intervention. Surgery should only be considered as a last resort. It is recommended that the Hyperhidrosis disease severity scale is used to assess every patient with symptoms of excessive sweating.

<sup>10</sup> Review of non-surgical treatment of primary hyperhidrosis. London and South East Regional Medicines Information, 2012.

### Hyperhidrosis Disease Severity Scale (HDSS)

**How would you rate the severity of your hyperhidrosis?**

1. My sweating is never noticeable and never interferes with my daily activities
2. My sweating is tolerable but sometimes interferes with my daily activities
3. My sweating is barely tolerable and frequently interferes with my daily activities
4. My sweating is intolerable and always interferes with my daily activities

*A score of 1 or 2 indicates mild or moderate hyperhidrosis. A score of 3 or 4 indicates severe hyperhidrosis. A 1-point and 2-point improvement in HDSS score is associated with a 50% and 80% reduction in sweat production respectively.*

### Flow Chart: Management Pathway for Hyperhidrosis

Symptom Assessment	
General measures & disease severity assessment	
Axilla – 1 <sup>st</sup> line treatment	Palmar/plantar – 1 <sup>st</sup> line treatment
Aluminium chloride (topical)	Aluminium chloride (topical)
Axilla – 2 <sup>nd</sup> line treatment	Palmar/plantar – 2 <sup>nd</sup> line treatment
Botox injections	Botox injections
Axilla – 3 <sup>rd</sup> line treatment	Palmar/plantar – 3 <sup>rd</sup> line treatment
Anticholinergic agents (oral)	Iontophoresis
Axilla – 4 <sup>th</sup> line treatment	Palmar/plantar – 4 <sup>th</sup> line treatment
Surgery	Anticholinergic agents (oral)
	Palmar – 5 <sup>th</sup> line treatment
	Surgery

With regard to Botulinum toxin therapy within the above pathway, funding will only be considered for **severe** (defined as *Hyperhidrosis Disease Severity Scale (HDSS)* score 3 or 4), when the patient has had a documented, 6 month trial of conservative management, including all the following:

- The use of topical aluminium chloride or extra-strength antiperspirants, which has been ineffective **or** resulted in a severe rash which does not resolve with topical steroids/recommended treatment;
- General measures have been addressed, including wearing light coloured, non-tight fitting clothing; identifying and avoiding triggers e.g. spicy food, consider treating any underlying anxiety.

Funding for further treatments, at intervals of no less than 16 weeks, will only be approved provided at least a 2 point reduction on HDSS score can be shown during the 4 months following initial treatment.

Please note: Botulinum toxin preparations are not interchangeable. Botox® is the only preparation licensed for severe, axillary hyperhidrosis in adults.

At time of writing, none of the available botulinum toxin preparations are licensed for the treatment of hyperhidrosis in children. If the patient is a child (aged < 18 years) but the clinician feels he/she has exceptional clinical circumstances, the request for funding should be taken through the Individual Funding Request process.

Pregnant women and nursing mothers should avoid treatment.

## 2.24 Septo-rhinoplasty (reshaping of the nose)<sup>11</sup>

This procedure is not available on cosmetic grounds. Septo-rhinoplasty will be considered in cases involving severe nasal deformity with chronic and complete obstruction of at least one nostril due to congenital or traumatic causes and severe functional limitation must be demonstrated.

<sup>11</sup> Septo-rhinoplasty evidence review. SEL Individual Funding Request Strategy Group, 2011.

## 2.25 Surgery for asymptomatic gallstones<sup>12</sup>

Approximately 10-20% of people in western countries have gallstones, and some 50-70% are asymptomatic at the time of diagnosis. Asymptomatic disease has a benign natural course and progression to symptomatic disease is relatively low, ranging from 10-25%. The majority of patients rarely develop gallstone-related complications without first having at least one episode of pain.

There is no evidence, and in particular no evidence from randomized controlled trials that surgery for asymptomatic gallstones is beneficial and it will not therefore be routinely funded

## 2.26 Fertility treatments<sup>13</sup> (Amended 4<sup>th</sup> December 2019)

Infertility is a condition that requires investigation, management and treatment in accordance with national guidance. As part of the provision of prevention, treatment and care Commissioners are committed to ensuring that access to NHS fertility services is provided fairly and consistently.

### Initial assessment

It will be the responsibility of the General Practitioners to initially assess that the person meets the local CCG's criteria for treatment for NHS funded cycles. Further support and advice is available from the CCG Medicines Optimisation Teams, Public Health Department and Commissioning team in implementing this guidance.

### Referral to hospital

Assisted conception services are provided by agreed providers. The units must comply with the Human Fertilisation and Embryology Authority (HFEA) regulations and follow appropriate protocols. Couples must take up the offer of Intracytoplasmic sperm injection (ICSI)/In vitro Fertilisation (IVF) within 3 months or risk being removed from the NHS waiting list.

### Prescribing of medication

- The clinical prescribing of all drugs will be the responsibility of the providing Trust or the GP. (for local agreement)
- If a patient has started a privately funded cycle, the CCG will not fund the provision of prescribed drugs, which forms part of that treatment.

### Timescale for treatment

Couples and individuals must be made aware at the time of being placed on the waiting list of the likely waiting time and the treatment for which the CCG will pay.

### Eligibility criteria

All couples and individuals must be registered with a General Practitioner within the boundaries of the CCG and be eligible for NHS treatment. Patients whose sperm or eggs have been stored prior to

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<sup>12</sup>Gurusamy KS, Samraj K. *Cholecystectomy for patients with silent gallstones*. Cochrane Database of Systematic Reviews 2007, Issue 1.

Gurusamy KS, Davidson BR. *Surgical treatment of gallstones (review)*. *Gastroenterol Clin North Am*. 2010 Jun;39(2):229-44, viii.

Sakorafas GH, Milingos D, Peros G. *Asymptomatic cholelithiasis: is cholecystectomy really needed? A critical reappraisal 15 years after the introduction of laparoscopic cholecystectomy*. *Dig Dis Sci*. 2007 May;52(5):1313-25. Epub 2007 Mar 28.

<sup>13</sup>National Institute for Health and Clinical Excellence. NICE Clinical Guidelines 156: Fertility: Assessment and treatment for people with fertility problems, February 2013



chemotherapy or radiotherapy will be entitled to NHS funded infertility treatment provided they meet the eligibility criteria.

The criteria for GP referrals for investigation and management of infertility should be in accordance with the following:

- The person who is to receive treatment must be aged between 23 and 39 years old (up to 39 years and 364 days) at the time of treatment.\*
- Couples who have been diagnosed as having male factor or female factor problems

**or**

have had unexplained infertility for at least 3 years, taking into consideration both age and waiting list times.

- Persons aged under 23 years old will be considered for treatment where medical investigations have confirmed that conception is impossible without fertility treatment, e.g. following unsuccessful fallopian tube surgery.
- Neither partner, nor individual in the case of a single woman, should have had more than 2 previous Intrauterine insemination (IUI)/IVF/ICSI attempts (either NHS or privately funded).
- Neither partner nor individual should have had any previous NHS funded attempts at IVF or ICSI and not more than three NHS funded attempts at IUI.
- Women will be only considered for treatment if their BMI is between 19 and 30 (kg/m<sup>2</sup>).
- Women with the BMI>30 should be referred to the appropriate obesity management pathway.
- Couples and individuals should be non-smoking at the time of treatment. Smokers should be referred to smoking cessation.
- IVF cannot be used as a substitute for reversal of sterilization.
- There are no problems with signing a form concerning the welfare of the child.
- There must be no other medical problems making the chance of success less than 20%.
- This service will be only be available at agreed providers and will include all clinically prescribed drugs.
- Fertility treatment will only be offered to couples and single women where the following two criteria are met:
  - where there are no living children in the current relationship
  - where neither partner nor the single woman already has children from previous relationships or conceived through NHS funded IVF.
- No individual (male or female) can access more than the number of NHS funded fertility treatments under any circumstances, even if they are in a new relationship.

Where the eligibility criteria are not met but clinicians feel there are exceptional reasons, a case should be referred to the Individual Funding Requests Panel for consideration.

Eligible Couples will be offered:

- 3 cycles of IUI  
and / or
- 1 full cycle of IVF +/- ICSI

*\*NICE Guidance (CG 156, Feb 2013) has been noted but, due to resources prioritisation, assisted conception will continue to be funded according to the current criteria.*

## **Surrogate pregnancy**

The implications of a number of important legal points related to surrogate pregnancy mean that fertility treatment involving a surrogate mother will not be funded.

### **Same sex couples**

In accordance with legal opinion related to surrogacy, assisted conception for couples where both partners are male will not be provided by the SEL CCGs.

Where both partners are female, funding can be provided as long as the relevant criteria above are met. Infertility needs to be demonstrated in the partner who is seeking to become pregnant; that partner has to have undergone at least three attempts of IUI, but should not have had more than two previous attempts at IVF or ICSI (either NHS or privately funded).

If three cycles of privately funded IUI have been unsuccessful, the couple will be eligible for one NHS funded cycle of IVF or ICSI.

A final criterion for these couples is that they meet the Human Fertilisation Embryology Authority (HFEA) requirements for parenthood and that both partners consent to be parents of the child. The HFEA guidance and a suitable statement for both partners to sign are available on request

### **Single women**

As for same sex female couples, eligible single women should have confirmed infertility, evidenced by unsuccessful cycles of artificial insemination (AI) within the 12 past months. This would be an indication for further assessment to take place, following which, IVF may be offered if the woman is eligible. The woman should have undergone at least three attempts of IUI, but should not have had more than two previous attempts at IVF or ICSI (either NHS or privately funded).

### **Definition of one full cycle (NICE, CG156, 2013):**

The CCGs will fund up to 2 frozen embryos per patient for 2 years. This will include the cost of freezing and storage. For unsuccessful patients, i.e. those not resulting in a live birth, the CCG will also fund the transfer of these frozen embryos (maximum 2 frozen embryo transfers per patient). The age of mother at the time that the embryos are frozen is required to be within the age limits set out in the policy. This does not apply to the age at transfer.

The CCGs will fund the freezing and storage of up to two embryos per patient for two years. Where treatment does not result in a live birth, the CCG will also fund the transfer of a maximum of two frozen embryos. The age of the woman at the time that the embryos are frozen should be within the age limits set out in the policy. This does not apply to the age at transfer.

A full cycle of IVF treatment, with or without intracytoplasmic sperm injection (ICSI), should comprise 1 episode of ovarian stimulation and the transfer of any resultant fresh and frozen embryo(s).

### **Egg donation/donor insemination**

The CCG does not routinely fund these procedures

### **Sperm washing (for HIV and other viral infections)**

As this is not a treatment for infertility sperm washing is not covered by this policy. NICE guidelines should be followed.

## **2.26 Fertility preservation techniques**

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

- Where a person under the age of 40 requires medical or surgical treatment that is likely to have

a permanent harmful effect on subsequent sperm or egg production. Such treatment includes radiotherapy or chemotherapy for malignant disease

OR

- Where a person under the age of 40 requires on going medical treatment that, whilst on treatment, causes harmful effects on sperm or egg production, impotence or has possible teratogenic effects, and in whom stopping treatment for a prolonged period of time to enable conception is not an option.

One collection cycle will be provided.

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

**Note:**

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

**Storage:**

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

**Post-storage treatment**

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

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

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

**Embryo cryostorage after NHS funded assisted conception**

Suitable embryos that are not transferred in IVF/ICSI cycle - Storage will be funded for a minimum period of one year