North East Lincolnshire CCG

HUmber ccg’s EVIDENCE-BASED INTERVENTIONS Commissioning Statement DOCUMENT

Interventions subject to Prior Approval or an Individual Funding Request

To be read in conjunction with the NEL CCG IFR and Prior Approval Policy of which this document forms a part and is linked to that policy.

January 2019

East Riding of Yorkshire, hULL AND Northern lincolnshire CCGs

**Introduction**

This document outlines North East Lincolnshire CCG’s clinical commissioning statements on interventions that are not routinely commissioned or are restricted.

The objective of this policy is to support CCG decision-making on these interventions and procedures, aiming to provide a statement on interventions based on the available evidence to enable a reasoned and structured process for individual cases to be considered for funding by the CCG.

This policy, in line with National terminology, classifies interventions as follows:

Operational Definitions

- ***Category 1 Interventions*** – Interventions that are not routinely commissioned, due to there being little evidence to support the intervention. Cases are examined on an individual basis where clinical exceptionality is considered through the Individual Funding Request (IFR) process

- ***Category 2 Interventions*** – Interventions are restricted and should only be performed after specific criteria are met via the Prior Approval process (VBC Checker), which enables an immediate funding decision on the intervention requested at the point of care.

**No Category 1 or Category 2 intervention must be undertaken before securing CCG IFR approval or Prior Approval – activity will be monitored and audits will be regularly undertaken.**

Please note this document is not exhaustive of all interventions not routinely commissioned or restricted by the CCG. For any medical procedure or treatment that is not routinely commissioned where there is not a specific policy statement, a request via the IFR process must still be made.

North East Lincolnshire CCG holds an Individual Funding Request (IFR) procedure document for people living within that CCG area that can be accessed [**here**](https://portal.yhcs.org.uk/documents/5665646/5860321/Individual+Funding+Request+%28IFR%29+%26+Appeals+Policy/6947341d-a939-48e4-af81-fab16595ac77)therefore the policies listed in this document should be read alongside the relevant IFR procedure for each individual CCG.

**Humber CCG aligned Commissioning statements**

Hull, East Riding of Yorkshire, North Lincolnshire, and North East Lincolnshire Clinical Commissioning Groups (CCGs) have worked together to align a large number of CCG clinical commissioning statements across the Humber area. As part of this process, some of these statements have been amended and updated as per recommendations for interventions from the NHS England National Evidence-based Interventions Programme.

The Humber CCG Evidence Based Interventions Policy Document, accessed via the North east Lincolnshire CCG websiteshould be read alongside this suite of policies and in conjunction with North East Lincolnshire CCG’s IFR Procedure document above.

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# Colorectal Interventions

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| **Intervention** | Surgery for Anal Fissure - Adults |
| **For the treatment of** | Anal Fissures in Adults |
| **Commissioning Position** | This intervention is NOT routinely commissioned.  This intervention is a Category Two Evidence Based Intervention; therefore, any requests for funding should in the first instance be made via the Prior Approval System.  If unsuccessful via Prior Approval the referring clinician can choose to submit an Individual Funding Request if exceptionality is considered to be present.  Treatment for Anal Fissures should be considered for adults who meet at least one of the following criteria:   * Multiple, off the midline, large or irregular (atypical fissures) as these may be the manifestation of underlying disease * Chronic fissures that have not healed after 8 weeks of treatment with adequate dietary treatment measure, stool softeners or laxatives and treatment with topical GTN 0.4% ointment or if not tolerated diltiazem 2% ointment twice a day for 8 weeks. Stress to patients the importance of adherence. * Check if patient taking Nicorandil (a risk factor) |
| **Evidence/Summary of Rationale** | See Clinical Knowledge Summary for Anal Fissure July 2016 |
| **Effective From** | 1st April 2019 |
| **Policy Review Date** | 1st April 2021 |

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| **Intervention** | Surgery for Anal Fissure - Children |
| **For the treatment of** | Anal Fissures in Children (under 18) |
| **Commissioning Position** | This intervention is NOT routinely commissioned.  This intervention is a Category Two Evidence Based Intervention; therefore, any requests for funding should in the first instance be made via the Prior Approval System.  If unsuccessful via Prior Approval the referring clinician can choose to submit an Individual Funding Request if exceptionality is considered to be present.  Treatment for Anal Fissures should be considered for children who meet at least one of the following criteria:   * Presenting with an anal fissure for the first time, with a clear history of severe constipation as causation, where the anal fissure has not healed after two weeks despite GTN 0.05% to 0.1% ointment. This should be prescribed by a specialist as it is not licensed for use in people aged less than 18 years. * Presenting with an anal fissure without a clear history of severe constipation, refer at first presentation. * Recurrent anal fissures. |
| **Evidence/Summary of Rationale** | See Clinical Knowledge Summary for Anal Fissure July 2016 |
| **Effective From** | 1st April 2019 |
| **Policy Review Date** | 1st April 2021 |

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| **Intervention** | Haemorrhoid Surgery |
| **For the treatment of** | Surgical removal of haemorrhoids. |
| **Commissioning Position** | This intervention is NOT routinely commissioned.  This intervention is a Category Two Evidence Based Intervention; therefore, any requests for funding should in the first instance be made via the Prior Approval System. If unsuccessful via Prior Approval the referring clinician can choose to submit an Individual Funding Request if exceptionality is considered present.  Surgical treatment should only be considered for those that do not respond to non-operative measures of management (For example, as a 1st line management: eating more fibre and drinking more water. As a 2nd line management: outpatient treatment in the form of banding or injection) 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. |
| **Evidence/Summary of Rationale** | 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.  Evidence-Based Interventions: Guidance for CCG’s 2018. |
| **Effective From** | 1st April 2019 |
| **Policy Review Date** | 1st April 2021 |

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| **Intervention** | Sacral Nerve Stimulation (SNS) – Faecal Retention |
| **For the treatment of** | Adults with Faecal Retention |
| **Commissioning Position** | This intervention is NOT routinely commissioned.  This intervention is a Category Two Evidence Based Intervention; therefore, any requests for funding should in the first instance be made via the Prior Approval System.  If unsuccessful via Prior Approval the referring clinician can choose to submit an Individual Funding Request if exceptionality is considered to be present.  Sacral Nerve Stimulation for Adults with faecal retention/intractable constipation should be considered where patients meet ALL of the below criteria:   * Symptoms present for at least 12 months; * Refractory to all conventional behavioural treatments including biofeedback; * Refractory to all conventional treatments (laxatives, suppositories, enemas). |
| **Evidence/Summary of Rationale** | Percutaneous SNS helps to correct erroneous messages sent along these nerve pathways and involves the placing of electrodes in a sacral nerve and stimulation via an internal device. A temporary procedure is followed by permanent implantation if it produces symptom relief. The battery life for the permanent implant is approximately 7-9 years.  In line with NICE Interventional Procedure Guidance IPG 99, the procedure should only be performed in specialist units by clinicians with a particular interest in the assessment and treatment. |
| **Effective From** | 1st April 2019 |
| **Policy Review Date** | 1st April 2021 |

# Dermatology Interventions

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| **Intervention** | Tattoo Removal |
| **For the treatment of** | Permanent Tattoos |
| **Commissioning Position** | This intervention is NOT routinely commissioned.  This intervention is a Category One Evidence Based Intervention; therefore, any requests to fund must be made as an Individual Funding Request.  Tattoo removal will not be commissioned for cosmetic reasons, for example, if a tattoo is no longer liked or wanted.  Requests for tattoo removal will only be considered in certain circumstances, where the tattoo:   * Is the result of past trauma i.e. scarring from grit, coal or graphite (that in some cases may have remained despite immediate post injury cleansing treatment); * Was inflicted against the patient’s will; * Was applied during a period of documented significant mental illness; * Has resulted in a significant allergic reaction or impairment to daily living, * Where the individual was a child and not ‘Fraser competent’, and therefore not responsible for their action at the time of the tattooing. |
| **Evidence/Summary of Rationale** | Most dermatology surgeons caution that complete tattoo removal is not possible. Tattoos are meant to be permanent, so removing them is difficult. However a tattoo can be removed by laser, surgical excision, or dermabrasion.  Lasers have become the standard treatment for tattoo removal because they offer a bloodless, low risk, effective alternative with minimal side effects. Each procedure is done on an outpatient basis in a single or series of visits. Patients may or may not require topical or local anaesthesia. The type of laser used to remove a tattoo depends on the tattoo's pigment colour. Black, dark blue and red tattoos respond really well to laser removal.  More difficult tattoo colours to remove are white, yellow, purple and pink, but are easier to cover up. Green is probably the most difficult tattoo colour to remove. |
| **Effective From** | 1st April 2019 |
| **Policy Review Date** | 1st April 2021 |

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# Ear, Nose and Throat Interventions

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| **Intervention** | Adult Snoring Surgery in the absence of Obstructive Sleep Apnoea (OSA). Surgical procedures in adults to remove, refashion or stiffen the tissues of the soft palate (Uvulopalatopharyngoplasty, Laser assisted Uvulopalatoplasty & Radiofrequency ablation of the palate). |
| **For the treatment of** | The symptom of snoring.  Please note this statement 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. |
| **Commissioning Position** | This intervention is NOT routinely commissioned.  This intervention is a Category One Evidence Based Intervention; therefore, any requests to fund must be made as an Individual Funding Request. |
| **Evidence/Summary of Rationale** | 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)   Evidence-Based Interventions: Guidance for CCG’s 2018 |
| **Effective From** | 1st April 2019 |
| **Policy Review Date** | 1st April 2021 |

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| **Intervention** | Grommets for Glue Ear in Children |
| **For the treatment of** | Glue Ear (Otitis Media with Effusion) in Children |
| **Commissioning Position** | This intervention is NOT routinely commissioned.  This intervention is a Category Two Evidence Based Intervention; therefore, any requests for funding should in the first instance be made via the Prior Approval System. If unsuccessful via Prior Approval the referring clinician can choose to submit an Individual Funding Request if exceptionality is considered to be present.  The NHS will only commission this surgery for the treatment of glue ear in children when the criteria set out by the NICE guidelines are met, as performing the surgery outside of these criteria is unlikely to derive any clinical benefit:   * 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.   Evidence-Based Interventions: Guidance for CCG’s 2018 |
| **Evidence/Summary of Rationale** | 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. |
| **Effective From** | 1st April 2019 |
| **Policy Review Date** | 1st April 2021 |

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| **Intervention** | Rhinoplasty/Septorhinoplasty/Septoplasty |
| **For the treatment of** | Nasal Deformities |
| **Commissioning Position** | This intervention is NOT routinely commissioned.  This intervention is a Category Two Evidence Based Intervention; therefore, any requests for funding should in the first instance be made via the Prior Approval System. If unsuccessful via Prior Approval the referring clinician can choose to submit an Individual Funding Request if exceptionality is considered present.  Consideration will not be given to cosmetic Rhinoplasty.  Rhinoplasty may be considered medically necessary *only* in limited circumstances and where the case details clinical rationale in accordance with the evidence base as follows:   1. When it is being performed to correct a nasal deformity secondary to congenital cleft lip and/or palate; 2. Upon individual case review, to correct chronic non-septal nasal airway obstruction from vestibular stenosis (collapsed internal valves) due to trauma, disease, or congenital defect, when all of the following criteria are met:  * Airway obstruction will not respond to septoplasty and turbinectomy alone; *and* * Nasal airway obstruction is causing significant symptoms (e.g. chronic rhinosinusitis, difficulty breathing); *and* * Obstructive symptoms persist despite conservative management for three months or greater, which includes, where appropriate, nasal steroids or immunotherapy; *and* * Photos demonstrate an external nasal deformity, *and* * There is an average 50% or greater obstruction of nares (eg 50 % obstruction of both nares, or 75 % obstruction of one nare and 25 % obstruction of other nare, or 100 % obstruction of one nare), documented by endoscopy, CT scan or other appropriate imaging modality.   There are, however, contra indications that need to be addressed such as:   * Unstable mental status (e.g. unstable patient with schizophrenia) * Unrealistic patient expectations * Previous rhinoplasty within the last 9-12 months (applies only to major rhinoplasties) * Poor perioperative risk profile * History of too many previous rhinoplasties, resulting in an atrophic skin–soft tissue envelope and significant scarring * Nasal cocaine users |
| **Evidence/Summary of Rationale** | Guidance on commissioning is provided by the Modernisation Agency Document ‘Information for Commissioners of Plastic Surgery Services’, which was prepared by the British Association of Plastic and Reconstructive Surgery. |
| **Effective From** | 1st April 2019 |
| **Policy Review Date** | 1st April 2021 |

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| **Intervention** | Tonsillectomy for Recurrent Tonsillitis |
| **For the treatment of** | Recurrent Tonsillitis in adults and children. |
| **Commissioning Position** | This intervention is NOT routinely commissioned.  This intervention is a Category Two Evidence Based Intervention; therefore, any requests for funding should in the first instance be made via the Prior Approval System. If unsuccessful via Prior Approval the referring clinician can choose to submit an Individual Funding Request if exceptionality is considered to be present.  The NHS 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, Apthous stomatitis, Pharyngitis, Cervical adenitis) * Severe immune deficiency that would make episodes of recurrent tonsillitis dangerous |
| **Evidence/Summary of Rationale** | 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.  Evidence-Based Interventions: Guidance for CCG’s 2018 |
| **Effective From** | 1st April 2019 |
| **Policy Review Date** | 1st April 2021 |

# Endocrine Interventions

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| **Intervention** | Endoscopic Thoracic Sympathectomy - Hyperhidrosis |
| **For the treatment of** | Hyperhidrosis |
| **Commissioning Position** | This intervention is NOT routinely commissioned.  This intervention is a Category One Evidence Based Intervention; therefore, any requests to fund must be made as an Individual Funding Request.  In view of the risk of side effects, requests will only be considered via the IFR process for patients that meet all of the following criteria:   * Suffering from severe and debilitating primary hyperhidrosis * Refractory to other treatments. (These may include topical agents, oral medication, botulinum toxin injections and iontophoresis.)   In addition to the criteria above, evidence of clinical exceptionality must be provided. |
| **Evidence/Summary of Rationale** | Endoscopic Thoracic Sympathectomy does not work as well for those with excessive axillary (armpit) sweating.  NICE guidance indicates that the evidence base for the efficacy and safety of this procedure is “adequate” but there is a risk of serious complications (including death from major intrathoracic bleeding); it is not always effective; and it can cause hyperhidrosis (“compensatory”) elsewhere on the body (in around 80% of cases, of whom 33% reported symptoms that were “severe‟ or “incapacitating‟).  The primary indication is palmar hyperhidrosis because it is less effective for axillary symptoms. It should only be considered in patients suffering from severe and debilitating primary hyperhidrosis that has been refractory to other treatments.  Further research is required to establish good patient selection and to identify which patient characteristics might predict severe side-effects. |
| **Effective From** | 1st April 2019 |
| **Policy Review Date** | 1st April 2021 |

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| **Intervention** | Hair Removal for Hirsuitism |
| **For the treatment of** | Hirsuitism |
| **Commissioning Position** | This intervention is NOT routinely commissioned.  This intervention is a Category Two Evidence Based Intervention; therefore, any requests for funding should in the first instance be made via the Prior Approval System.  If unsuccessful via Prior Approval the referring clinician can choose to submit an Individual Funding Request if exceptionality is considered to be present.  Treatment for permanent or semi-permanent hair removal is not indicated for cosmetic purposes. Patients concerned with the appearance of their body and facial hair should be advised to self-manage their condition by conservative methods eg. Shaving, waxing, or depilatory creams.  Treatment for hair removal, by IPL, laser or electrolysis, should be considered for individuals where   * It is considered medically necessary   OR   * Have undergone reconstructive surgery leading to abnormally located hair-bearing skin   OR   * Have a proven underlying endocrine disturbance resulting in facial hirsutism (eg. polycystic ovary syndrome) that has not been able to be controlled by other methods that a reasonable person would tolerate   OR   * Are undergoing treatment for pilonidal sinuses to reduce recurrence   Where treatment is agreed, a maximum of 6 treatment sessions will be approved. If further sessions are required an additional request should be made to the IFR Panel.  For Gender Dysphoria patients, please refer to NHS England. |
| **Evidence/Summary of Rationale** | It is suggested that Hirsutism affects 5 - 15% of women. Possible underlying causes include PCOS (polycystic ovary syndrome), other rare hormone disorders (eg. congenital adrenal hyperplasia) and some forms of medication.  Intense pulsed light (IPL) is now the standard treatment with traditional laser and electrolysis as reserve options. Reported side effects of using the Lumina IPL system and Vasculight-SR multi-functional laser and IPL system to treat hair removal in hirsute patients include burning, leukotrichia, paradoxical hypertrichosis and folliculitis (Ref 1). In addition pain, skin redness, swelling, burned hairs and pigment changes were infrequently reported adverse effects (Ref 2).  Common side effects of laser depilation can include pigment changes, occasional blistering and rarely scarring. Other untoward effects can include: new growth of hair outside the treatment area, increase in co-existing vellus hair in the treatment area, induction or aggravation of acne, rosacea-like rash, premature greyness of hair, tunnelling of hair under the skin, prolonged diffuse redness and oedema of the face, focal hypopigmentation of the lip, angular cheilitis, allergic reaction, and inflammatory and pigment changes of pre-existing moles (Ref 3).  Case series evidence suggests that after laser depilation, hair growth is reduced for a period of weeks to months, but multiple treatments may be required to achieve complete hair loss. |
| **Effective From** | 1st April 2019 |
| **Policy Review Date** | 1st April 2021 |

# Fertility Interventions

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| **Intervention** | Reversal of Sterilisation |
| **For the treatment of** | Sterilised Male and Female Adults |
| **Commissioning Position** | This intervention is NOT routinely commissioned.  This intervention is a Category One Evidence Based Intervention; therefore, any requests to fund must be made as an Individual Funding Request.  Requests via the IFR process must demonstrate clinical exceptionality. |
| **Evidence/Summary of Rationale** | Sterilisation should be regarded as a permanent procedure and patients should be counselled pre-operatively to that effect.  Reversal involves complex surgery and is unlikely to produce a return to fertility. |
| **Effective From** | 1st April 2019 |
| **Policy Review Date** | 1st April 2021 |

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| **Intervention** | Vasectomy under General Anaesthetic |
| **For the treatment of** | Removal of Male Fertility |
| **Commissioning Position** | This intervention is NOT routinely commissioned.  This intervention is a Category Two Evidence Based Intervention; therefore, any requests for funding should in the first instance be made via the Prior Approval System.  If unsuccessful via Prior Approval the referring clinician can choose to submit an Individual Funding Request if exceptionality is considered to be present.  Surgical intervention should be considered for patients where there is:   * + Previous documented adverse reaction to local anaesthesia;   + Scarring or deformity (e.g. due to cryptorchidism or from previous scrotal surgery or trauma) that makes vasectomy under local anaesthetic difficult to achieve;   + The patient is on anticoagulation therapy (increased risk of postoperative haematoma formation)   Fear of the procedure, or patient choice, are notadequate reasons for requesting vasectomy under GA. |
| **Evidence/Summary of Rationale** | Most vasectomies are carried out under local anaesthetic. This means only the scrotum and testicles will be numbed and the patient will be awake for the procedure. The procedure should not be painful but may feel slightly uncomfortable. Most men will only need a local anaesthetic.  The RCOG Guidelines(4) recommend a general anaesthetic is used where:   * There is a history of allergy to local anaesthetic; * Surgery has been carried out before on the scrotum or genital area.   The RCOG Guidelines also recommend:   * A ‘no-scalpel’ approach, as there are lower levels of complications such as bleeding, pain and infection; * The use of fascial interposition or diathermy; * That clips are not used, due to high failure rates ; * That local anaesthesia is used wherever possible; * Effective contraception be used before the operation and until follow-up tests show that the vasectomy has been successful; * Practitioners must be trained to the level of the FSRHC requirement |
| **Effective From** | 1st April 2019 |
| **Policy Review Date** | 1st April 2021 |

# General Surgery

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| **Intervention** | Cholecystectomy |
| **For the treatment of** | Biliary Tract Problems |
| **Commissioning Position** | This intervention is routinely commissioned and does not require Prior Approval or application for funding via the Individual Funding Request (IFR) process providing the criteria below are met.  Referral for Cholecystectomy will only be funded if the patient fulfils ANY of the criteria below:   * Symptomatic gallstones with a thickened gallbladder wall * A dilated common bile duct on ultrasound * Asymptomatic gallstones with abnormal liver function test (LFT) results * Asymptomatic gall bladder polyp(s) reported on ultrasound * Symptomatic gall bladder ‘sludge’ reported on ultrasound   Elective cholecystectomy surgery will only be commissioned where the patient fulfils ANY of the criteria below:   * Symptomatic gallstones * Gall bladder polyp(s) larger than 8mm or growing rapidly * Common bile duct stones * Acute pancreatitis   Documentation that the threshold criteria are fulfilled is mandatory and the referral letter or form should, as a minimum, contain a clear indication of the grounds for referral against the threshold criteria:   * any relevant medical history and current medication; * any known factors affecting the patients fitness for day surgery; * a recent ultrasound report conducted within 2 months at the point of referral; * recent liver function test report conducted within 1 month at point of referral.   Cholecystectomy should be performed laparoscopically in patients with an uncomplicated abdomen and in the absence of contra-indications. (The standard laparoscopic approach uses several small incisions in the abdomen).  Cholecystectomy should be offered as a day case procedure in the absence of contra-indications. Routine laparoscopic cholecystectomy does not generally require a consultant outpatient follow up.  If the gall bladder is sent for histological examination, the results should be reviewed by the requesting consultant and communicated to the GP.  Secondary providers offering cholecystectomy must be able to offer intraoperative on-table cholangiography and have arrangements in place for urgent access to ERCP and interventional radiology for the management of postoperative complications.  Patients should be encouraged by their GP and surgeon to lose weight prior to any surgery and given appropriate support to address lifestyle factors that would improve their fitness for surgery and recovery afterwards.  GPs can refer patients for a surgical opinion whilst patients lose weight and surgeons (and anaesthetists) can consider the safety of surgery. There is a clinical balance between risk of surgical complications with obesity and with potential complications of gallstones whilst delaying surgery |
| **Evidence/Summary of Rationale** | Cholecystectomy is the surgical removal of the gall bladder. Prophylactic Cholecystectomy is not indicated in most patients with asymptomatic gallstones. Possible exceptions include patients who are at increased risk for gallbladder carcinoma or gallstone complications, in which prophylactic Cholecystectomy or incidental Cholecystectomy at the time of another abdominal operation can be considered. Although patients with diabetes mellitus may have an increased risk of complications, the magnitude of the risk does not warrant prophylactic Cholecystectomy. Primary and secondary care discussions with patients should include identifying options (surgery vs no surgery), including the risks and benefits of each. |
| **Effective From** | 1st April 2019 |
| **Policy Review Date** | 1st April 2021 |

# Gynaecological Interventions

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| **Intervention** | Dilation and Cutterage (D&C) for Heavy Menstrual Bleeding in Women. |
| **For the treatment of** | Heavy menstrual bleeding in women. |
| **Commissioning Position** | This intervention is NOT routinely commissioned.  This intervention is a Category One Evidence Based Intervention; therefore, any requests to fund must be made as an Individual Funding Request. |
| **Evidence/Summary of Rationale** | 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), as well as weight loss (if appropriate) can treat heavy periods.  Evidence-Based Interventions: Guidance for CCG’s 2018 |
| **Effective From** | 1st April 2019 |
| **Policy Review Date** | 1st April 2021 |

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| **Intervention** | Hysterectomy for Heavy Menstrual Bleeding |
| **For the treatment of** | Heavy menstrual bleeding. |
| **Commissioning Position** | This intervention is NOT routinely commissioned.  This intervention is a Category One Evidence Based Intervention; therefore, any requests to fund must be made as an Individual Funding Request.  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.  This intervention will only be commissioned where the IFR application demonstrates that the criteria outlined in the NICE guidance have been met.  Evidence-Based Interventions: Guidance for CCG’s 2018 |
| **Evidence/Summary of Rationale** | NICE recommends that hysterectomy should not be used as a first-line treatment solely for heavy menstrual bleeding (HMB).13 Heavy periods can be reduced by using medicines or intrauterine systems (IUS) or losing weight (if necessary). |
| **Effective From** | 1st April 2019 |
| **Policy Review Date** | 1st April 2021 |

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| **Intervention** | Labiaplasty / Vaginaplasty |
| **For the treatment of** | Malformed, enlarged labia / vulva causing functional discomfort which has not responded to conservative management. |
| **Commissioning Position** | The NHS will routinely commission reconstructive Labiaplasty / Vaginaplasty:   * following surgery for cancer * repair after trauma (including tears / scars from childbirth).   All other requests for Labiaplasty / Vaginaplasty are NOT routinely commissioned.  This intervention is a Category Two Evidence Based Intervention; therefore, any requests for funding should in the first instance be made via the Prior Approval System. If unsuccessful via Prior Approval the referring clinician can choose to submit an Individual Funding Request if exceptionality is considered to be present.  There are circumstances where Labiaplasty / Vaginaplasty may be considered where the following are met:   * Where the woman is 18 years of age or older * Where the woman has completed pubertal development (RCOG, 2013). * Where the labia / vulva causes functional discomfort * Where simple measures to relieve functional discomfort are not successful (Harsh soaps and shower gels in the genital area should be avoided. The use of emollients should be recommended, as well as comfortable underwear). * Where the clinician’s sensitive genital examination (visual inspection) has determined that benign labial disease, significant congenital malformation or structural anomalies are identified.   Labiaplasty / Vaginaplasty for cosmetic purposes is NOT commissioned.  The Royal College of Gynaecology recommends that Labiaplasty or Vaginaplasty should not be offered to children below 18 years of age owing to anatomical development during puberty. If a child is referred via IFR, please note this will be passed directly to CCG Safeguarding in the first instance and does not guarantee IFR consideration.  British Society for Paediatric & Adolescent Gynaecology (2013). *Position Statement: Labial reduction surgery (Labiaplasty) on adolescents.* |
| **Evidence/Summary of Rationale** | Labiaplasty / Vaginaplasty for cosmetic purposes has no clinical benefit.  RCOG states that the risk of revisional surgery in patients who receive surgery prior to completion of pubertal development is high.  There are risks of infection and bleeding post-surgery, loss of sensation and dissatisfaction with appearance. |
| **Effective From** | 1st April 2019 |
| **Policy Review Date** | 1st April 2021 |

# Minor Surgery Procedures

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| **Intervention** | Benign Skin Lesions – Surgical Removal |
| **For the treatment of** | Symptomatic benign skin lesions |
| **Commissioning Position** | This intervention is NOT routinely commissioned.  This intervention is a Category Two Evidence Based Intervention; therefore, any requests for funding should in the first instance be made via the Prior Approval System. If unsuccessful via Prior Approval the referring clinician can choose to submit an Individual Funding Request if exceptionality is considered present.  This policy refers to the following benign lesions when there is diagnostic certainty and they 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 regular 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 > 5cms, 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 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. * Requests for treatment where a patient meets the criteria do not require prior approval or an IFR. * This policy applies to all providers, including general practitioners (GPs), GPs with enhanced role (GPwer), independent providers, and community or intermediate services. |
| **Evidence/Summary of Rationale** | 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.  Evidence-Based Interventions: Guidance for CCG’s 2018. |
| **Effective From** | 1st April 2019 |
| **Policy Review Date** | 1st April 2021 |

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| **Intervention** | Chalazia Removal |
| **For the treatment of** | Chalazia (meibomian cysts). Benign lesions on the eyelids due to blockage and swelling of an oil gland. |
| **Commissioning Position** | This intervention is NOT routinely commissioned.  This intervention is a Category Two Evidence Based Intervention; therefore, any requests for funding should in the first instance be made via the Prior Approval System. If unsuccessful via Prior Approval the referring clinician can choose to submit an Individual Funding Request if exceptionality is considered present.  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, demonstrated by visual fields test * 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   Evidence-Based Interventions: Guidance for CCG’s 2018. |
| **Evidence/Summary of Rationale** | 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. |
| **Effective From** | 1st April 2019 |
| **Policy Review Date** | 1st April 2021 |

# Neurological and Pain Interventions

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| **Intervention** | Functional Electrical Stimulation (FES) |
| **For the treatment of** | Foot Drop |
| **Commissioning Position** | This intervention is NOT routinely commissioned.  This intervention is a Category Two Evidence Based Intervention; therefore, any requests for funding should in the first instance be made via the Prior Approval System.  If unsuccessful via Prior Approval the referring clinician can choose to submit an Individual Funding Request if exceptionality is considered to be present.  Skin surface Functional Electrical Stimulation should be considered in the following circumstances:   * The individual has an upper motor neuron lesion resulting from stroke, multiple sclerosis (MS), cerebral palsy (CP) or spinal cord injury (SCI) (but has an intact peroneal nerve); * There is evidence that the foot drop interferes significantly with the individual’s day to day living; * There is evidence that FES has been recommended for the individual after a thorough assessment of their suitability by the local NHS physiotherapy service or MDT specialising in rehabilitation. * The request to the IFR Panel must include evidence that first line treatments have been tried and failed. * First-line treatment is usually physiotherapy or the use of an ankle foot orthosis (AFO).  Agreed to delete these lines? Evidence will be required to demonstrate that first line treatments have been tried. * Other options may include medical therapy, electrical stimulation of the affected nerves and surgery. These options can be used alone or in combination with one another.   If Prior Approval is granted it is expected that the patient will demonstrate a positive trial of FES before proceeding to a permanent stimulator.  In this case it will not be necessary to seek further permission to proceed with the surface electrode device, the ‘Odstock drop foot stimulator’, but individual funding approval must be sought if an implanted electrode is being considered. |
| **Evidence/Summary of Rationale** | A body of evidence, based largely on uncontrolled observational studies in patients with stroke with drop foot and patients with multiple sclerosis with drop foot, using heterogeneous outcome measures, indicates that functional electrical stimulation (FES) (mainly using surface electrodes) is associated with improved walking speed and reduced walking effort.  There are preliminary findings of a therapeutic effect of FES use in patients in the chronic phase of stroke rehabilitation. Three large randomised controlled trials are underway in chronic stroke patients which may provide data on comparison with the ankle foot orthosis.  There are few safety concerns around the use of surface-applied FES and patient acceptability appears to be high, however the use of implanted electrodes may be associated with more serious adverse events. |
| **Effective From** | 1st April 2019 |
| **Policy Review Date** | 1st April 2021 |

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| **Intervention** | Spinal Injections of Local Anaesthetic and Steroid in people with Non-Specific Low Back Pain without Sciatica. |
| **For the treatment of** | Non-specific back pain without sciatica |
| **Commissioning Position** | This intervention is NOT routinely commissioned.  This intervention is a Category One Evidence Based Intervention; therefore, any requests to fund must be made as an Individual Funding Request. |
| **Evidence/Summary of Rationale** | 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 moderateto 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.  Evidence-Based Interventions: Guidance for CCG’s 2018. |
| **Effective From** | 1st April 2019 |
| **Policy Review Date** | 1st April 2021 |

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| **Intervention** | Wireless or Implantable Functional Electrical Stimulation (FES) |
| **For the treatment of** | Foot Drop |
| **Commissioning Position** | This intervention is NOT routinely commissioned.  This intervention is a Category One Evidence Based Intervention; therefore, any requests to fund must be made as an Individual Funding Request.  Patients must fulfil the required criteria for standard FES (please see separate Functional Electrical Stimulation policy).  Requests for wireless or implantable FES must demonstrate clinical exceptionality and include:   * Detailed clinical evidence which demonstrates the extent to which the patient’s condition affects the quality of life; * Lifestyle modifications including weight management (where appropriate) that have been made and relevant services such as Occupational therapy and Falls team have been involved; * There is evidence that FES has been recommended for the individual after a thorough assessment of their suitability by an NHS Commissioned Physiotherapy service or MDT specialising in rehabilitation. This recommendation must specify how any benefit will be measured for the individual. * Clinical evidence as to why standard FES is not appropriate |
| **Evidence/Summary of Rationale** | A body of evidence, based largely on uncontrolled observational studies in patients with stroke with drop foot and patients with multiple sclerosis with drop foot, using heterogeneous outcome measures, indicates that functional electrical stimulation (FES) (mainly using surface electrodes) is associated with improved walking speed and reduced walking effort2.  There are preliminary findings of a therapeutic effect of FES use in patients in the chronic phase of stroke rehabilitation. Three large randomised controlled trials are underway in chronic stroke patients which may provide data on comparison with the ankle foot orthosis2.  There are few safety concerns around the use of surface-applied FES and patient acceptability appears to be high, however the use of implanted electrodes may be associated with more serious adverse events2. |
| **Effective From** | 1st April 2019 |
| **Policy Review Date** | 1st April 2021 |

# Ophthalmology Interventions

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| **Intervention** | Cataracts Surgery |
| **For the treatment of** | Cataracts |
| **Commissioning Position** | This intervention is routinely commissioned and does not require Prior Approval or application for funding via the Individual Funding Request (IFR) process providing the criteria below are met.  Prior to referral for cataracts, the referral should be made using the agreed referral form and should only be made where the patient has been provided with approved information in a suitable format (e.g. Royal College of Ophthalmologists leaflet ‘Understanding Cataracts’) and is willing to undergo surgery.  Surgery for cataract extractions should only be funded for patients whose visual impairment is mainly attributable to cataracts, and after correction (e.g. with glasses or other adjustments):   * Have a best corrected visual acuity of 6/12 or worse with both eyes open   AND   * have significant effects on daily living e.g. with mobility (difficulty with steps, risk of falls, ability to drive), independent living, or reading   OR   * have diabetes and removal of the cataract is necessary to facilitate effective retinal screening   OR   * have glaucoma and / or narrow drainage angles and cataract surgery is required to control intra-ocular pressure |
| **Evidence/Summary of Rationale** | Cataracts affect over a third of people aged over 65. Smoking and diabetes (associated with BMI > 30) are further risk factors for cataract.  80-90% of patients report a benefit from surgery, which include improved clarity of vision and improved colour vision. This in turn has implications for a positive impact on other health and social care needs including a reduction in slips, trips and falls amongst the elderly.  There are risks associated with cataract surgery, some common and many very rare; however complications are usually treatable and reasonably good outcome s can be expected.  Royal College of Ophthalmologists published guidelines on the management of cataract recognise that “Visual acuity is the most common measurement of visual function as it can be quickly and easily measured” but goes on to point out that “the sole use of visual acuity can underestimate visual disability because it does not take account of symptoms such as glare or reduced contrast sensitivity.” This can, however, be hard to quantify objectively.  A best corrected visual acuity (BCVA) of better than 6/12 [Snellen], in the worse eye, normally allows a patient to function without significant visual difficulties. In population studies using BCVA as an indicator of morbidity, BCVA better than 6/12 is not considered a visually impairing cataract and acuity of 6/9 is considered a good outcome post-surgery. This applies to both first and second eye surgery.  Significant improvements in visual symptoms and visual function may occur following cataract surgery even where the preoperative visual acuity is better than 6/12. However, the risk of worse visual acuity after surgery also increases where the preoperative visual acuity is very good, so surgery should be considered at this level of visual acuity only where the patient is experiencing significant symptoms attributable to cataract.  There is no set level of vision for which an operation is essential. The rate at which cataracts progress is unpredictable. Reading glasses are usually needed after cataract surgery, and some people may require glasses for distance vision who did not previously require them.  Cataract surgery does not always result in an improvement in visual acuity or patient satisfaction with visual function. |
| **Effective From** | 1st April 2019 |
| **Policy Review Date** | 1st April 2021 |

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| **Intervention** | Second Eye Cataracts Surgery |
| **For the treatment of** | Cataracts |
| **Commissioning Position** | This intervention is routinely commissioned and does not require Prior Approval or application for funding via the Individual Funding Request (IFR) process providing the criteria below are met.  Second Eye Surgery should be funded, after post-operative review, if:   * There is resultant significant anisometropia (difference in refractive error between the two eyes of more than 1.00D) which would result in poor binocular vision or diplopia. |
| **Evidence/Summary of Rationale** | Cataracts affect over a third of people aged over 65. Smoking and diabetes (associated with BMI > 30) are further risk factors for cataract.  80-90% of patients report a benefit from surgery, which include improved clarity of vision and improved colour vision. This in turn has implications for a positive impact on other health and social care needs including a reduction in slips, trips and falls amongst the elderly.  There are risks associated with cataract surgery, some common and many very rare; however complications are usually treatable and reasonably good outcome s can be expected.  Royal College of Ophthalmologists published guidelines on the management of cataract recognise that “Visual acuity is the most common measurement of visual function as it can be quickly and easily measured” but goes on to point out that “the sole use of visual acuity can underestimate visual disability because it does not take account of symptoms such as glare or reduced contrast sensitivity.” This can, however, be hard to quantify objectively.  A best corrected visual acuity (BCVA) of better than 6/12 [Snellen], in the worse eye, normally allows a patient to function without significant visual difficulties. In population studies using BCVA as an indicator of morbidity, BCVA better than 6/12 is not considered a visually impairing cataract and acuity of 6/9 is considered a good outcome post-surgery. This applies to both first and second eye surgery.  Significant improvements in visual symptoms and visual function may occur following cataract surgery even where the preoperative visual acuity is better than 6/12. However, the risk of worse visual acuity after surgery also increases where the preoperative visual acuity is very good, so surgery should be considered at this level of visual acuity only where the patient is experiencing significant symptoms attributable to cataract.  There is no set level of vision for which an operation is essential. The rate at which cataracts progress is unpredictable. Reading glasses are usually needed after cataract surgery, and some people may require glasses for distance vision who did not previously require them.  Cataract surgery does not always result in an improvement in visual acuity or patient satisfaction with visual function. |
| **Effective From** | 1st April 2019 |
| **Policy Review Date** | 1st April 2021 |

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| **Intervention** | Corrective Surgery, Lens Implants and Laser Treatment for Refractive error (short or long sightedness, astigmatism) |
| **For the treatment of** | Refractive Error |
| **Commissioning Position** | This intervention is NOT routinely commissioned as short-sightedness (myopia), astigmatism, and long-sightedness (hyperopia) because these conditions are usually corrected by wearing spectacles or contact lenses.  This intervention is a Category One Evidence Based Intervention; therefore, any requests to fund must be made as an Individual Funding Request, making a clear clinical case of need must be evidenced, such as treatment for keratoconus that cannot be corrected by other means |
| **Evidence/Summary of Rationale** | Laser refractive surgery is generally effective for up to 10 dioptres of myopia, 6 dioptres of hyperopia and 4 dioptres of astigmatism, though the predictability of correction tends to diminish towards the extremes of these ranges. Current evidence suggests that laser surgery for the correction of refractive errors is safe and efficacious for use in appropriately selected patients, including when used to correct refractive error resulting from other forms of ophthalmic surgery (1, 2). The Royal College of Ophthalmologists issued a statement on Standards for Laser Refractive Surgery in 2012 (3).  However corrective surgery is considered a cosmetic treatment and compared to the use of spectacles or contact lenses, not an efficient use of NHS resources. Private laser surgery treatment is now offered by many treatment centres.  Complications of laser refractive surgery include infection, bleeding, over/under correction, corneal haze, glare, halo ortarburst, corneal damage, retinal detachment and dry eye. However risks which have the potential to cause permanent damage are very rare.  A 2005 review (4)of the efficacy of laser treatment found a broadly similar performance for PRK, LASEK and LASIK. People with a milder degree of myopia were more likely to achieve the intended refractive correction. Treatment of hyperopia was less successful than treatment of myopia.  **Intraocular lens implants**  Current evidence from NICE on the efficacy of corneal implants for the correction of refractive error shows limited and unpredictable benefit. In addition, there are concerns about the safety of the procedure for patients with refractive error. Therefore, corneal implants should only be used for the treatment of refractive error when there is other ocular pathology present e.g. keratoconus (5)  There is good evidence for the short term efficacy and safety of phakic IOL insertion, but the long term risks of cataract, corneal damage or retinal detachment remain uncertain and require ongoing audit (6). Other complications of IOL implantation are similar to those of cataract surgery and include infection, poor night vision, glare and eye damage. Eyes with higher refractive errors have a greater risk. |
| **Effective From** | 1st April 2019 |
| **Policy Review Date** | 1st April 2021 |

# Orthopaedic Interventions

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| **Intervention** | Arthroscopic Shoulder Decompression for Subacromial Shoulder Pain |
| **For the treatment of** | Subacromial shoulder pain. |
| **Commissioning Position** | This intervention is NOT routinely commissioned.  This intervention is a Category One Evidence Based Intervention; therefore, any requests to fund must be made as an Individual Funding Request. |
| **Evidence/Summary of Rationale** | Arthroscopic subacromial decompression for pure subacromial shoulder impingement should only 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. |
| **Effective From** | 1st April 2019 |
| **Policy Review Date** | 1st April 2021 |

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| **Intervention** | Bunion Surgery |
| **For the treatment of** | Bunions |
| **Commissioning Position** | This intervention is NOT routinely commissioned.  This intervention is a Category Two Evidence Based Intervention; therefore, any requests for funding should in the first instance be made via the Prior Approval System.  If unsuccessful via Prior Approval the referring clinician can choose to submit an Individual Funding Request if exceptionality is considered to be present.  Treatment for Bunions should only be considered for patients where:   * Conservative measures have failed (these include trying accommodative footwear, considering orthoses and using appropriate analgesia.)   AND   * The patient suffers from severe pain on walking (not relieved by chronic standard analgesia) that causes significant functional impairment   OR   * Severe deformity (with or without lesser toe deformity) that causes significant functional impairment OR prevents them from finding adequate footwear   OR   * Recurrent or chronic ulceration or infection |
| **Evidence/Summary of Rationale** | NICE CKS makes clear that referral for bunion surgery is indicated for pain and is not routinely performed for cosmetic purposes1.  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.  Referral for orthopaedic or podiatric surgery consultation may be of benefit if the deformity is painful and worsening; the second toe is involved; the person has difficulty obtaining suitable shoes; or there is significant disruption to lifestyle or activities.  If the person is referred for consideration of surgery, advise that surgery is usually done as a day case. Bunion surgery may help relieve pain and improve the alignment of the toe in most people (85%–90%); but there is no guarantee that the foot will be perfectly straight or pain-free after surgery.  Complications after bunion surgery may include infection, joint stiffness, transfer pain (pain under the ball of the foot), hallux varus (overcorrection), bunion recurrence, damage to the nerves, and continued long-term pain.  There is very little good evidence with which to assess the effectiveness of either conservative or operative treatments or the potential benefit of one over the other.  Untreated HV in patients with diabetes (and other causes of peripheral neuropathy) may lead to ulceration, deep infection and even amputation. |
| **Effective From** | 1st April 2019 |
| **Policy Review Date** | 1st April 2021 |

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| **Intervention** | Carpal Tunnel Syndrome Release Open or endoscopic surgical procedure to release median nerve from carpal tunnel. |
| **For the treatment of** | Moderate and Severe cases of Carpal Tunnel Syndrome. |
| **Commissioning Position** | This intervention is NOT routinely commissioned.  This intervention is a Category Two Evidence Based Intervention; therefore, any requests for funding should in the first instance be made via the Prior Approval System. If unsuccessful via Prior Approval the referring clinician can choose to submit an Individual Funding Request if exceptionality is considered present.   1. Mild cases with intermittent symptoms causing little or no interference with sleep or activities require no treatment. 2. Cases with intermittent symptoms which interfere with activities or sleep should first be treated with: 3. corticosteroid injection(s) (medication injected into the wrist: good evidence for short (8-12 weeks) term effectiveness)   Or   1. night splints (a support which prevents the wrist from moving during the night: not as effective as steroid injections) 2. Surgical treatment of carpal tunnel should be considered if one of the following criteria are met: 3. 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   1. There is either: 2. a permanent (ever-present) reduction in sensation in the median nerve distribution, or 3. muscle wasting or weakness of thenar abduction (moving the thumb away from the hand). |
| **Evidence/Summary of Rationale** | 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 (≈4%) and the lifetime risk of the carpal tunnel syndrome recurring and requiring revision surgery has been estimated at between 4 and 15%. |
| **Effective From** | 1st April 2019 |
| **Policy Review Date** | 1st April 2021 |

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| **Intervention** | Dupuytren’s Contracture Release - Adults |
| **For the treatment of** | Dupuytren’s contracture |
| **Commissioning Position** | This intervention is NOT routinely commissioned.  This intervention is a Category Two Evidence Based Intervention; therefore, any requests for funding should in the first instance be made via the Prior Approval System. If unsuccessful via Prior Approval the referring clinician can choose to submit an Individual Funding Request if exceptionality is considered present.  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 either: * finger contractures causing loss of finger extension of 30° or more at the metacarpophalangeal joint or 20° at the proximal interphalangeal joint. * severe thumb contractures which interfere with function * NICE concluded that collagenase should only be used for either: * Participants in the ongoing clinical trial (HTA-15/102/04), or * Adult patients with a palpable cord if: * 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   * needle fasciotomy is not considered appropriate, but limited fasciectomy is considered appropriate by the treating hand surgeon |
| **Evidence/Summary of Rationale** | 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. |
| **Effective From** | 1st April 2019 |
| **Policy Review Date** | 1st April 2021 |

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| **Intervention** | Ganglion – Surgical Excision |
| **For the treatment of** | Ganglions |
| **Commissioning Position** | This intervention is NOT routinely commissioned.  This intervention is a Category Two Evidence Based Intervention; therefore, any requests for funding should in the first instance be made via the Prior Approval System.  If unsuccessful via Prior Approval the referring clinician can choose to submit an Individual Funding Request if exceptionality is considered to be present.  Treatment is not indicated in cases that are asymptomatic and where it is not impairing function. However, if there is diagnostic uncertainty, this must be investigated.  Surgical intervention should be considered if:   * Aspiration fails to resolve pain or tingling/numbness, and there is restricted hand function. * The ganglion persists or recurs after puncture/aspiration * There is recurrent spontaneous discharge of fluid or significant nail deformity. |
| **Evidence/Summary of Rationale** | 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.  Evidence-Based Interventions (2008) |
| **Effective From** | 1st April 2019 |
| **Policy Review Date** | 1st April 2021 |

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| **Intervention** | Hip Arthroscopy |
| **For the treatment of** | Diagnostic and Therapeutic Arthroscopy – Hip |
| **Commissioning Position** | This intervention is NOT routinely commissioned.  This intervention is a Category One Evidence Based Intervention; therefore, any requests to fund must be made as an Individual Funding Request  The CCG does not currently commission hip arthroscopy on a routine basis other than where patients are shown to fulfil ALL the following criteria:   * Diagnosis of definite labral pathology and/or hip impingement syndrome as defined above through clinical and radiological investigation (e.g. X-rays, MRI, CT scans) * A recognised Orthopaedic Surgeon who specialises in young adult hip surgery has made the diagnosis, which should include discussion of each case with a specialist musculo-skeletal radiologist * Severe symptoms with compromised function measured by objective scoring tools and with a duration of at least six months where diagnosis has been made (see scoring tools below) * Failure to respond to conservative treatment including activity modification, specialist physiotherapy and maximal pharmacological interventions for a period of 6 months * Treatment with hip replacement, resurfacing or other more established procedure is not clinically viable * Patient is aged between 18 and 50 years (clinical experience has shown that these patients are likely to gain the greatest benefit).   Hip arthroscopy is not routinely funded for patients with the following conditions:   * Patients with advanced degenerative OA on a preoperative X-ray (Tonnis grade 2 or more) or severe cartilage injury (Outerbridge grade III or IV). * Patients with joint space on plain radiograph of the pelvis that is less than 2mm wide anywhere along the sourcil. * Patients who are candidates for total hip replacements. * Patients who have hip dysplasia or considerable protrusion * Patients with osteonecrosis with femoral head collapse * Patients with grade III or IV heterotopic bone formation * Patients with sepsis and accompanying osteomyelitis or abscess formation * Patients with joint ankylosis * Patients with generalised joint laxity syndromes associated with hypermobility of the joints such as Marfan and Ehlers-Danlos syndromes * Patients with osteogenesis imperfecta |
| **Evidence/Summary of Rationale** | The most recent systematic review of Femoro-acetabular Hip Arthroscopy was the Washington State HTA review undertaken in 2011. The main findings from the HTA are summarised below:  ‘The causes of hip pain, the natural history of FAI and its relationship to osteoarthritis are unclear, and the case definition and selection criterion of patients for hip surgery remain uncertain. Significant questions remain about the efficacy and effectiveness, safety and cost effectiveness of hip surgery for FAI’.  NICE IPG 408 replaces previous guidance on arthroscopic femoro–acetabular surgery for hip impingement syndrome. The guidance states that current evidence on the efficacy of arthroscopic femoro–acetabular surgery for FAI is adequate in terms of symptom relief in the short and medium term. With regard to safety, there are well recognised complications. It recommends that the procedure may be used with normal arrangements in place for clinical governance, consent and audit with local review of outcomes and should be performed by surgeons with specialist expertise in arthroscopic hip surgery. |
| **Effective From** | 1st April 2019 |
| **Policy Review Date** | 1st April 2021 |

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| **Intervention** | Ilizarov Technique/Taylor Spatial Frame (TSF) |
| **For the treatment of** | Non-union/mal-union of bones, shortened limb, long bone deformities |
| **Commissioning Position** | Ilizarov Frames is NOT routinely commissioned where limb lengthening alone is the desired outcome as this would be deemed cosmetic and not medically necessary.  This intervention is a Category One Evidence Based Intervention; therefore, any requests to fund must be made as an Individual Funding Request.  However, the use of the Ilizarov technique/TSFs will be routinely commissioned for routine elective use in orthopaedics in:   * individual carefully selected cases, * where there is agreement by the regional orthopaedic MDT that of all available treatments, Ilizarov/TSF is the best clinical option for the patient in terms of a favourable functional limb outcome (bone and functional outcomes are not always the same). * the patient understands the long duration of external fixation, the likelihood of marked discomfort and possible complications * the patient has been a non-smoker for at least 4 weeks * Ideally, the MDT should comprise at least two consultant orthopaedic surgeons, with input from specialist nursing, physiotherapy and musculoskeletal radiology.   Cases that will be routinely commissioned after approval by the MDT include the following:   * Complex mal-union or non-union of fractures (after at least 6 months duration or 9 months where the ‘Exogen’ ultrasound bone healing system has been tried and failed2 ). * Bone deformity (affecting the leg/knee/ankle), including limb length discrepancy, that has resulted in chronic pain and/or difficulty walking and/or an increased risk of developing osteoarthritis.   The use of the Ilizarov technique will be routinely commissioned subject to patients meeting the clinical criteria above, which will be ascertained by retrospective audit. |
| **Evidence/Summary of Rationale** | Studies of clinical and cost effectiveness quoted in the literature are diverse in their quality, findings, patient numbers and statistical power. However, the high complication rate reported in the earlier years of this technique (used in Western countries since the 1980s) has now reduced dramatically, in particular, the incidence of pin site infection, which can now be minimised with specialist care and preventative measures |
| **Effective From** | 1st April 2019 |
| **Policy Review Date** | 1st April 2021 |

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| **Intervention** | Knee Arthroscopy - Osteoarthritis |
| **For the treatment of** | Patients with osteoarthritis. |
| **Commissioning Position** | This intervention is NOT routinely commissioned.  This intervention is a Category One Evidence Based Intervention; therefore, any requests to fund must be made as an Individual Funding Request. |
| **Evidence/Summary of Rationale** | 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, 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.  Evidence-Based Interventions: Guidance for CCG’s 2018. |
| **Effective From** | 1st April 2019 |
| **Policy Review Date** | 1st April 2021 |

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| **Intervention** | Trigger Finger/Thumb Surgery |
| **For the treatment of** | Stenosing Tenosynovitis (Trigger/Thumb Finger) |
| **Commissioning Position** | This intervention is NOT routinely commissioned.  This intervention is a Category Two Evidence Based Intervention; therefore, any requests for funding should in the first instance be made via the Prior Approval System. If unsuccessful via Prior Approval the referring clinician can choose to submit an Individual Funding Request if exceptionality is considered present.  Mild cases that cause no loss of function require no treatment or avoidance of activities that precipitate triggering and may resolve spontaneously.  Cases interfering with activities or causing pain should be first treated with:   * One or two steroid injections * Splinting of the affected finger for 3-12 weeks   Surgery should be considered if any one of the below occurs:   * The triggering persists or recurs after one of the above conservative measures * The finger is permanently locked in the palm * The patient has previously had 2 other trigger digits unsuccessfully treated with appropriate non-operative methods * The patient is diabetic |
| **Evidence/Summary of Rationale** | Treatment with steroid injections usually resolve troublesome trigger fingers within 1 week, but sometimes the triggering keeps recurring. Surgery is normally successful, provides a permanent cure.  Recovery after surgery takes 2-4 weeks. Problems sometimes occur after surgery, but these are rare (35).  Evidence-Based Interventions: Guidance for CCG’s 2018. |
| **Effective From** | 1st April 2019 |
| **Policy Review Date** | 1st April 2021 |

# Plastic Surgery Interventions

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| **Intervention** | Abdominoplasty / Apronectomy |
| **For the treatment of** | Excess Skin |
| **Commissioning Position** | This intervention is NOT routinely commissioned.  This intervention is a Category One Evidence Based Intervention; therefore, any requests to fund must be made as an Individual Funding Request.  Abdominoplasty / Apronectomy and the removal of excessive skin for patients who have lost a significant amount of weight and have been left with an overhang of skin are NOT supported unless exceptional circumstances can be demonstrated to address a specific clinical need, where treatments have failed.  Abdominoplasty / Apronectomy have minimum criteria for the procedure as follows   * patients who have had a stable BMI of 25 Kg/m2 or below for at least 2 years and are suffering from severe functional problems   OR   * Those with significant scarring following trauma or previous abdominal surgery or where it is required as part of abdominal hernia correction or other abdominal wall surgery   Severe functional problems include experiencing severe difficulties with mobility |
| **Evidence/Summary of Rationale** | Any operation involving a general anaesthetic should be approached with caution, especially if for cosmetic reasons. Generally, the more extensive the procedure, the higher the risk. Cosmetic procedures are regarded as low priority. |
| **Effective From** | 1st April 2019 |
| **Policy Review Date** | 1st April 2021 |

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| **Intervention** | Blepharoplasty |
| **For the treatment of** | Excess skin on eyelid |
| **Commissioning Position** | This intervention is NOT routinely commissioned.  This intervention is a Category Two Evidence Based Intervention; therefore, any requests for funding should in the first instance be made via the Prior Approval System.  If unsuccessful via Prior Approval the referring clinician can choose to submit an Individual Funding Request if exceptionality is considered to be present.  Removal of excess skin from the upper or lower lid should be considered where:   * It is causing significant functional impairment in the patient’s ability to open and close the eyelid   OR   * It is causing significant visual impairment, evidenced by provision of visual fields test and clinical photographs   Requests for removal of excess skin from the lower lid may additionally be considered for the correction of entropion or ectropion |
| **Evidence/Summary of Rationale** | Many people acquire excess skin in the upper eyelids as part of the process of ageing and this may be considered normal. However if this starts to interfere with vision or function of the eyelid apparatus then this can warrant treatment. |
| **Effective From** | 1st April 2019 |
| **Policy Review Date** | 1st April 2021 |

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| **Intervention** | Breast Correctional Surgery - Asymmetry |
| **For the treatment of** | Adults with Breast Asymmetry |
| **Commissioning Position** | This intervention is NOT routinely commissioned.  This intervention is a Category One Evidence Based Intervention; therefore, any requests to fund must be made as an Individual Funding Request.  Requests will only be considered via the IFR process in women meet the following criteria:   * BMI is within the range 18-25 * 18 years of age or older * sternal notch to nipple difference of 4cm or more * infra-mammary fold to nipple for each breast 30% or more * 30% or more difference in volume * Significant difference in nipple areola diameter of 50% or more   \*As part of individual CCG pathways for Breast Surgery, Infra-Red Scanning may be used to obtain measurements to confirm compliance with the criteria above. |
| **Evidence/Summary of Rationale** | Information for commissioners of Plastic Surgery - referrals and guidelines in Plastic Surgery *Modernisation Agency (Action on Plastic Surgery)* |
| **Effective From** | 1st April 2019 |
| **Policy Review Date** | 1st April 2021 |

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| **Intervention** | Breast Enlargement Surgery |
| **For the treatment of** | Adults with Amastia or Congenital abnormalities related to Breast Development |
| **Commissioning Position** | This intervention is NOT routinely commissioned.  This intervention is a Category One Evidence Based Intervention; therefore, any requests to fund must be made as an Individual Funding Request.  Requests will only be considered via the IFR process in women meet the following criteria:   * 18 years of age of older * BMI is within the range 18-25   AND   * certain congenital abnormalities such as Poland’s syndrome, constricted tubular breast, pectus deformity, or chest wall asymmetry associated with scoliosis   OR   * a complete absence of breast tissue (amastia) in one or both breasts is causing severe functional or medical |
| **Evidence/Summary of Rationale** | Breast implants may be associated with significant morbidity and the need for secondary or revisional surgery (such as implant replacement) is common. In fact, it is estimated that one in three women will require further surgery within 10 years of their initial operation. It should be noted that not all patients demonstrate improvement in psychosocial outcome measures following breast augmentation.  Information for commissioners of Plastic Surgery - referrals and guidelines in Plastic Surgery *Modernisation Agency (Action on Plastic Surgery)* |
| **Effective From** | 1ST April 2019 |
| **Policy Review Date** | 1st April 2021 |

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| **Intervention** | Breast Reduction Surgery |
| **For the treatment of** | 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. |
| **Commissioning Position** | This intervention is NOT routinely commissioned.  This intervention is a Category Two Evidence Based Intervention; therefore, any requests for funding should in the first instance be made via the Prior Approval System. If unsuccessful via Prior Approval the referring clinician can choose to submit an Individual Funding Request if exceptionality is considered to be present.  Surgery will not be funded for cosmetic reasons. The NHS will only consider 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 500gms 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.   \*As part of individual CCG pathways for Breast Surgery, Infra-Red Scanning may be used to obtain measurements to confirm compliance with the criteria above.  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.  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. |
| **Evidence/Summary of Rationale** | 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.  Evidence-Based Interventions: Guidance for CCG’s 2018. |
| **Effective From** | 1ST April 2019 |
| **Policy Review Date** | 1st April 2021 |

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| **Intervention** | Breast Revisional Surgery (prosthesis removal) |
| **For the treatment of** | Clinical complications related to Breast Implants |
| **Commissioning Position** | This intervention is NOT routinely commissioned.  This intervention is a Category Two Evidence Based Intervention; therefore, any requests for funding should in the first instance be made via the Prior Approval System.  If unsuccessful via Prior Approval the referring clinician can choose to submit an Individual Funding Request if exceptionality is considered to be present.  The removal of breast implants for any of the following in patients who have undergone cosmetic augmentation mammoplasty that was performed either in the NHS or privately will be considered for the following indications:   * Breast disease * Implants complicated by severe recurrent infections * Implants with grade 4 capsule formation that is associated with severe pain * Implants with capsule formation that interferes with mammography * Intra or extra capsular rupture of silicone gel filled implants * Implant is a PiP implant   Patients will be offered the choice of removing both prostheses in the event that only one has been ruptured with the intention of ensuring symmetry.  This policy does not include replacement of removed implants. Please see relevant policy for this intervention that requires a separate via the Individual Funding Request (IFR) process. |
| **Evidence/Summary of Rationale** | Breast implants may be associated with significant morbidity and the need for secondary or revisional surgery is common. In fact, it is estimated that one in three women will require further surgery within 10 years of their initial operation. It should be noted that not all patients demonstrate improvement in psychosocial outcome measures following breast augmentation. |
| **Effective From** | 1ST April 2019 |
| **Policy Review Date** | 1st April 2021 |

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| **Intervention** | Replacement of Breast Implants |
| **For the treatment of** | Implant removal due to clinical need |
| **Commissioning Position** | This intervention is NOT routinely commissioned.  This intervention is a Category One Evidence Based Intervention; therefore, any requests to fund must be made as an Individual Funding Request.  Replacement of implants will only be considered under exceptional clinical circumstances. Requests for funding under this circumstance will need to be approved by the IFR Panel.  Individuals must meet the required criteria for removal of implants in order to be considered for implant replacement. (see separate policy for Breast Revisional Surgery – Prosthesis Removal)  The replacement of breast implants for patients whose original surgery was paid for on a privately funded basis is NOT commissioned. |
| **Evidence/Summary of Rationale** | Breast implants may be associated with significant morbidity and the need for secondary or revisional surgery (such as implant replacement) is common. In fact, it is estimated that one in three women will require further surgery within 10 years of their initial operation. It should be noted that not all patients demonstrate improvement in psychosocial outcome measures following breast augmentation. |
| **Effective From** | 1ST April 2019 |
| **Policy Review Date** | 1st April 2021 |

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| **Intervention** | Gynaecomastia Surgery |
| **For the treatment of** | Adult Males with excess Breast Tissue |
| **Commissioning Position** | This intervention is NOT routinely commissioned.  This intervention is a Category One Evidence Based Intervention; therefore, any requests to fund must be made as an Individual Funding Request.  If there are red flag symptoms for suspecting possible underlying breast malignancy, this must be excluded prior to applying through the IFR process.  Requests will only be considered via the IFR process in adult males that meet all of the following criteria:   * True Gynaecomastia has been diagnosed (i.e. true breast tissue is present not just adipose tissue - pseudogynaecomastia), and is causing gross breast enlargement, confirmed at grade 3 or 4; * Evidence that treating an underlying cause (e.g. endocrine or drug related), where known, has not resolved the problem; * BMI is 30 or below * The BMI has been stable for at least 2 years * There is clear evidence of clinical need (such as significant pain) that has remained unresolved despite usual medical treatment. * if aged< 20, a clinical view of whether full body maturity has been reached * Confirmation that there has never been use of steroids or cannabis. If there has, request may be considered if usage ceased at least 2 years previously and it has been out ruled as the cause of the Gynaecomastia. |
| **Evidence/Summary of Rationale** | Notwithstanding the serious nature of any operation involving a general anaesthetic, removal of excess skin and subcutaneous tissue from the abdomen, upper arms or thighs by plastic surgery is generally a safe procedure without serious complications, giving rise to good functional and aesthetic results |
| **Effective From** | 1ST April 2019 |
| **Policy Review Date** | 1st April 2021 |

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| **Intervention** | Liposuction – Lipoedema |
| **For the treatment of** | Lipoedema |
| **Commissioning Position** | This intervention is NOT routinely commissioned.  This intervention is a Category One Evidence Based Intervention; therefore, any requests to fund must be made as an Individual Funding Request.  Liposuction for the treatment of lipoedema is not routinely commissioned. All cases will be considered by the IFR panel on the basis of exceptional clinical circumstances.  Clinical evidence will be considered where there is clear demonstration of exceptional effect on functionality of the activities of daily living. |
| **Evidence/Summary of Rationale** | Studies have shown that abdominal liposuction does not significantly improve obesity-associated metabolic abnormalities, and so decreasing adipose tissue mass alone will not achieve the metabolic benefits of weight loss. |
| **Effective From** | 1ST April 2019 |
| **Policy Review Date** | 1st April 2021 |

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| **Intervention** | Pinnaplasty |
| **For the treatment of** | Prominent ears. |
| **Commissioning Position** | This intervention is NOT routinely commissioned.  This intervention is a Category One Evidence Based Intervention; therefore, any requests to fund must be made as an Individual Funding Request.  To be eligible for consideration of funding **ALL** the following criteria must apply:   * The patient must be 5 or more but under the age of 19 years at the time of referral. * Where the Child is deemed Fraser Competent the child, rather than the parent alone, expresses concern about the prominent ears. * There is independent evidence from a health professional or a teacher that the child’s health and wellbeing is being severely adversely affected and there is evidence of substantial psychological distress which has not been addressed by steps to support the child’s psychological wellbeing. * In the case of psychological distress e.g. bullying, requests should state the mental health impact on the patient and demonstrate what other steps have been taken to address the issue. I.e. dealing with the bullying, prior to consideration of exceptional circumstances. (eg. dealing with bullying). * Consideration may be given to cases where the patient is between the age of 5 and 19 years, and the patient has congenital ear deformity.   If the criteria above are met, approval will need to be sought from the panel for an initial assessment and report by a plastic surgeon prior to any surgery being considered. All patients seeking Pinnaplasty must be seen by a plastic surgeon and if there is any concern may be referred for an assessment by a psychologist.  For individuals aged 19 years and over, the IFR request must demonstrate a clear clinical need for the surgery, as Pinnaplasty will not be commissioned in adults for purely cosmetic reasons. |
| **Evidence/Summary of Rationale** | Ears are one of the first parts of the body to reach full size, which is why protruding ears can be more noticeable in children.  Children under the age of 5 rarely experience teasing and referrals may reflect concerns expressed by the parents rather than the child. Conservative management with psychosocial support from school or mental health services (if required) is recommended.  Requests on the grounds of clinical exceptionality would need to include evidence that such support has been obtained and fully utilised.  The national service framework for children defines childhood as ending at 19 years.  The premise for otoplasty being performed exclusively on children in the NHS is based on motivational factors; children being motivated by psychosocial factors where the majority of adults are motivated by the need to change their appearance. |
| **Effective From** | 1ST April 2019 |
| **Policy Review Date** | 1st April 2021 |

# Respiratory Interventions

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| **Intervention** | Sleep Study |
| **For the treatment of** | Referral to secondary care sleep medicine services for assessment (e.g. via home-based overnight sleep study) of |
| **Commissioning Position** | This intervention is NOT routinely commissioned.  This intervention is a Category Two Evidence Based Intervention; therefore, any requests for funding should in the first instance be made via the Prior Approval System. If unsuccessful via Prior Approval the referring clinician can choose to submit an Individual Funding Request if exceptionality is considered present.  Requests for approval for referral for Sleep studies should be based on any of the following criteria:   * Patient has symptoms of excessive daytime sleepiness (EDS) that score >10 on the Epworth Sleepiness Score (ESS) combined with objective clinical judgement that indicates need for referral * Patient displays symptoms of chronic snoring as well as witness apnoeic episodes or daytime sleepiness with a score of >10 on the Epworth Sleepiness Score (ESS) * Sleepiness in dangerous situations, even with a normal ESS score, in combination with symptoms associated with obstructive sleep apnoea/hypopnoea * Excessive daytime sleepiness, despite a normal time in bed at night, which may interfere with his/her driving ability/occupation   Conservative management addressing lifestyle factors such as weight reduction, smoking and alcohol intake should commence at the earliest opportunity.  It is a legal requirement on every driver not to drive when their ability to drive safely is impaired, including when they are tired.  Untreated OSAHS leads to an increased risk of motor accidents. It is the responsibility of drivers to cease driving until their symptoms resolve and inform the DVLA if appropriate (as advised by clinicians). The DVLA are usually willing to allow car drivers to continue driving once they are established on a successful therapy and reviewed by clinicians at intervals of not more than 3 years. |
| **Evidence/Summary of Rationale** | There is some evidence that clinical history and physical examination alone are not as reliable for diagnosing obstructive sleep apnoea as an overnight sleep study and treatment pathways suggest that PSG is the most accurate means of confirming a diagnosing of adult sleep apnoea. However, some guidelines have suggested that a home based sleep study may be useful, cost-effective and convenient for patients and can significantly speed up the investigation pathway, compared with an overnight inpatient stay. |
| **Effective From** | 1ST April 2019 |
| **Policy Review Date** | 1st April 2021 |

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| **Intervention** | Trial of Continuous Positive Airway Pressure (CPAP) for Obstructive Sleep Apnoea |
| **For the treatment of** | Sleep Apnoea |
| **Commissioning Position** | This intervention is NOT routinely commissioned.  This intervention is a Category Two Evidence Based Intervention; therefore, any requests for funding should in the first instance be made via the Prior Approval System. If unsuccessful via Prior Approval the referring clinician can choose to submit an Individual Funding Request if exceptionality is considered present.  Treatment trial to include the issue of a single CPAP device for a 6 month period, will only be commissioned for patients where the following criteria are met:   * Diagnosis of moderate/severe OSAHS, confirmed by sleep study where appropriate, indicating at least 15 episodes per hour of sleep * OSAHS is interfering significantly with activities of daily living * They have signed an agreement to appropriately insure and maintain the CPAP device and return it to the service if treatment stops or reimburse the full replacement cost of the device to the NHS.   Conservative management addressing lifestyle factors such as weight reduction, smoking and alcohol intake should continue.  It is a legal requirement on every driver not to drive when their ability to drive safely is impaired, including when they are tired.  Untreated OSAHS leads to an increased risk of motor accidents. It is the responsibility of drivers to cease driving until their symptoms resolve and inform the DVLA if appropriate (as advised by clinicians). The DVLA are usually willing to allow car drivers to continue driving once they are established on a successful therapy and reviewed by clinicians at intervals of not more than 3 years. |
| **Evidence/Summary of Rationale** | The evidence for treatment of symptomatic patients with mild OSA is not as strong. However, there may be people with mild severity grading, who have considerable OSA symptoms affecting their quality of life that may benefit from CPAP (e.g. lorry drivers). |
| **Effective From** | 1st April 2019 |
| **Policy Review Date** | 1st April 2021 |

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| **Intervention** | Continued Continuous Positive Airway Pressure (CPAP) for Obstructive Sleep Apnoea |
| **For the treatment of** | Sleep Apnoea |
| **Commissioning Position** | This intervention is NOT routinely commissioned.  This intervention is a Category Two Evidence Based Intervention; therefore, any requests for funding should in the first instance be made via the Prior Approval System. If unsuccessful via Prior Approval the referring clinician can choose to submit an Individual Funding Request if exceptionality is considered present.  Treatment continuation will only be commissioned for patients where the following criteria are met:   * During the trial period the patient utilised the device in excess of 70% of nights. * During the trial period the patient utilised the device on average in excess of 4 hours per night. * The trial outcome has clinically indicated that the patient is benefitting from the device. There is improvement in their AHI or Epworth Scores.   It is a legal requirement on every driver not to drive when their ability to drive safely is impaired, including when they are tired.  Untreated OSAHS leads to an increased risk of motor accidents. It is the responsibility of drivers to cease driving until their symptoms resolve and inform the DVLA if appropriate (as advised by clinicians). The DVLA are usually willing to allow car drivers to continue driving once they are established on a successful therapy and reviewed by clinicians at intervals of not more than 3 years. |
| **Evidence/Summary of Rationale** | The evidence for treatment of symptomatic patients with mild OSA is not as strong. However, there may be people with mild severity grading, who have considerable OSA symptoms affecting their quality of life that may benefit from CPAP (e.g. lorry drivers). |
| **Effective From** | 1st April 2019 |
| **Policy Review Date** | 1st April 2021 |

# Urological Interventions

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| **Intervention** | Circumcision – Male Adults |
| **For the treatment of** | Clinical Health indications requiring surgical removal of foreskin(over 18 years old) |
| **Commissioning Position** | Circumcision is NOT commissioned for cultural, religious or cosmetic reasons.  This intervention is a Category Two Evidence Based Intervention; therefore, any requests for funding should in the first instance be made via the Prior Approval System. If unsuccessful via Prior Approval the referring clinician can choose to submit an Individual Funding Request if exceptionality is considered present.  It must be noted that any potentially malignant lesions of the prepuce or those causing diagnostic uncertainty must be referred via the 2 week wait pathway and do not require funding approval.  Any of the following clinical indications must be present:   * Congenital abnormalities with functional impairment * Distal scarring of the preputial orifice * Painful erections secondary to a tight foreskin * Recurrent bouts of infection (balanitis/balanoposthitis) * Redundant prepuce, phimosis (inability to retract the foreskin due to a narrow prepucial ring) sufficient to cause ballooning of the foreskin on micturition; and paraphimosis (inability to pull forward a retracted foreskin). * Lichen sclerosus (balanitis xerotica obliterans) -chronic inflammation leading to a rigid fibrous foreskin. * Pain on intercourse * Traumatic injury |
| **Evidence/Summary of Rationale** | The BMA states that to circumcise for therapeutic reasons where medical research has shown other techniques (such as topical steroids or manual stretching under local anaesthetic) to be at least as effective and less invasive, would be unethical and inappropriate. Common risks of surgical circumcision include bleeding, local sepsis, oozing, discomfort >7 days, meatal scabbing or stenosis, removal of too much or too little skin, urethral injury, amputation of the glans and inclusion cyst. Furthermore, long-term psychological trauma and possible decreased sexual pleasure have also been reported. There are claims that there may be health benefits associated with this procedure, for example a lower rate of penile cancer and a reduced chance of sexual transmitted diseases (including HIV among heterosexual men). However, the overall clinical and cost-effectiveness evidence is inconclusive. Condoms are far more effective (98% effective if used correctly) than circumcision for preventing STIs. |
| **Effective From** | 1st April 2019 |
| **Policy Review Date** | 1st April 2021 |

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| **Intervention** | Circumcision – Male Children |
| **For the treatment of** | Clinical Health indications requiring surgical removal of foreskin (under 18 years old) |
| **Commissioning Position** | Circumcision is NOT commissioned for cultural, religious or cosmetic reasons.  This intervention is a Category Two Evidence Based Intervention; therefore, any requests for funding should in the first instance be made via the Prior Approval System. If unsuccessful via Prior Approval the referring clinician can choose to submit an Individual Funding Request if exceptionality is considered present.  It must be noted that any potentially malignant lesions of the prepuce or those causing diagnostic uncertainty must be referred via the 2week wait pathway and do not require funding approval.  Referral to secondary care for children should only be made if there are any of the following circumstances:   * Distal scarring of the preputial orifice * Balanitis Xerotica Obliterans * Painful erections secondary to a tight foreskin * Recurrent bouts of infection (balanitis/balanoposthitis) |
| **Evidence/Summary of Rationale** | The BMA states that to circumcise for therapeutic reasons where medical research has shown other techniques (such as topical steroids or manual stretching under local anaesthetic) to be at least as effective and less invasive, would be unethical and inappropriate. Common risks of surgical circumcision include bleeding, local sepsis, oozing, discomfort >7 days, meatal scabbing or stenosis, removal of too much or too little skin, urethral injury, amputation of the glans and inclusion cyst. Furthermore, long-term psychological trauma and possible decreased sexual pleasure have also been reported. There are claims that there may be health benefits associated with this procedure, for example a lower rate of penile cancer and a reduced chance of sexual transmitted diseases (including HIV among heterosexual men). However, the overall clinical and cost-effectiveness evidence is inconclusive. Condoms are far more effective (98% effective if used correctly) than circumcision for preventing STIs. |
| **Effective From** | 1st April 2019 |
| **Policy Review Date** | 1st April 2021 |

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| **Intervention** | Sacral Nerve Stimulation (SNS) - Women with Urinary Retention |
| **For the treatment of** | Female Adults with Urinary Retention |
| **Commissioning Position** | This intervention is NOT routinely commissioned.  This intervention is a Category Two Evidence Based Intervention; therefore, any requests for funding should in the first instance be made via the Prior Approval System.  If unsuccessful via Prior Approval the referring clinician can choose to submit an Individual Funding Request if exceptionality is considered to be present.  Sacral Nerve Stimulation for women with non-obstructive urinary retention should be considered where patients meet ALL of the below criteria:   * The woman has a confirmed diagnosis defined by urodynamic assessment and has been reviewed by a Urology MDT. * The woman is unable to perform clean, intermittent self-catheterisation * Symptoms are refractory to:   + behavioural and lifestyle modification (diet, weight management, modification of fluid intake)   + bladder retraining   + bladder catheterisation |
| **Evidence/Summary of Rationale** | Percutaneous SNS helps to correct erroneous messages sent along these nerve pathways and involves the placing of electrodes in a sacral nerve and stimulation via an internal device. A temporary procedure is followed by permanent implantation if it produces symptom relief. The battery life for the permanent implant is approximately 7-9 years. Recent systematic reviews and retrospective analyses have shown SNS to be an effective therapy for treatment of non-obstructive urinary retention with a statistically significant improvement in symptoms.  In line with NICE Interventional Procedure Guidance IPG 99, the procedure should only be performed in specialist units by clinicians with a particular interest in the assessment and treatment. |
| **Effective From** | 1st April 2019 |
| **Policy Review Date** | 1st April 2021 |

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| **Intervention** | Sacral Nerve Stimulation (SNS) – Men with Urinary Retention |
| **For the treatment of** | Male Adults with Urinary Retention |
| **Commissioning Position** | This intervention is NOT routinely commissioned.  This intervention is a Category Two Evidence Based Intervention; therefore, any requests for funding should in the first instance be made via the Prior Approval System.  If unsuccessful via Prior Approval the referring clinician can choose to submit an Individual Funding Request if exceptionality is considered to be present.  Sacral Nerve Stimulation for women with non-obstructive urinary retention should be considered where patients meet ALL of the below criteria:  Men with non-obstructive urinary retention are usually offered drug therapy, catheterisation or prostate surgery, as appropriate, as outlined in the NICE Clinical Pathway on Lower Urinary Tract symptoms in men.  Any requests for SNS to treat confirmed, non-obstructive urinary retention in men must be submitted by a Consultant Urologist to the relevant CCG IFR Panels for consideration   * The male has a confirmed diagnosis defined by urodynamic assessment and has been reviewed by a Urology MDT. * The man is unable to perform clean, intermittent self-catheterisation * Symptoms are refractory to:   + behavioural and lifestyle modification (diet, weight management, modification of fluid intake)   + bladder retraining   + bladder catheterisation |
| **Evidence/Summary of Rationale** | Percutaneous SNS helps to correct erroneous messages sent along these nerve pathways and involves the placing of electrodes in a sacral nerve and stimulation via an internal device. A temporary procedure is followed by permanent implantation if it produces symptom relief. The battery life for the permanent implant is approximately 7-9 years. Recent systematic reviews and retrospective analyses have shown SNS to be an effective therapy for treatment of non-obstructive urinary retention with a statistically significant improvement in symptoms.  In line with NICE Interventional Procedure Guidance IPG 99, the procedure should only be performed in specialist units by clinicians with a particular interest in the assessment and treatment. |
| **Effective From** | 1st April 2019 |
| **Policy Review Date** | 1st April 2021 |

# Vascular Interventions

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| **Intervention** | Surgical Intervention for Varicose Veins (C5-C6) |
| **For the treatment of** | Grade C5 and C6 Varicose Veins  NICE Guideline 168 define C5 and C6 grade Varicose Veins as follows:   * **C5** changes in skin and subcutaneous tissue: eczema, lipodermatosclerosis or atrophie blanche with healed ulcers * **C6** skin changes with active ulcers venous insufficiency ulceration |
| **Commissioning Position** | This intervention is routinely commissioned and does not require Prior Approval or application for funding via the Individual Funding Request (IFR) process providing the criteria below are met.  Referral to a secondary care vascular service can be made for patients with classification C5 to C6 with any of the following symptoms that indicate a higher likelihood of disease progression:   * Bleeding varicose veins (immediate referral required) * Symptomatic primary or recurrent varicose veins that are causing severe pain, aching, discomfort, swelling, heaviness or itching * Lower-limb skin changes, such as pigmentation or eczema, thought to be caused by chronic venous insufficiency * Superficial vein thrombosis (characterised by the appearance of hard, painful veins) and suspected venous incompetence * An active or healed venous leg ulcer |
| **Evidence/Summary of Rationale** | 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.  Open surgery is a traditional treatment that involves surgical removal by stripping and ligation, but has been mainly superseded by endothermal ablation and ultrasound guided foam sclerotherapy.  Complications of interventions include recurrence of varicose veins, infection, pain, bleeding, and more rarely blood clot in the leg. Complications of non-intervention including decreasing quality of life for patients, increased symptomology, disease progression potentially skin changes and eventual leg ulceration, deep vein thrombosis and pulmonary embolism. |
| **Effective From** | 1st April 2019 |
| **Policy Review Date** | 1st April 2021 |

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| **Intervention** | Surgical Intervention for Varicose Veins (C4) |
| **For the treatment of** | Grade C4 Varicose Veins  NICE Guideline 168 define C4 grade Varicose Veins as ‘changes in skin and subcutaneous tissue: eczema, lipodermatosclerosis or atrophie blanche’ |
| **Commissioning Position** | This intervention is NOT routinely commissioned.  This intervention is a Category Two Evidence Based Intervention; therefore, any requests for funding should in the first instance be made via the Prior Approval System.  If unsuccessful via Prior Approval the referring clinician can choose to submit an Individual Funding Request if exceptionality is considered to be present.  Treatment is not indicated in cases that are asymptomatic and where it is purely cosmetic. However, if there is diagnostic uncertainty, this must be investigated.  Surgical intervention should be considered for patients with grade C4 Varicose Veins where:   * All conservative measures have been exhausted (walking and exercise, Avoidance of activities that exacerbate symptoms, Elevation of the legs when sitting down to increase venous return and losing weight, if appropriate)   AND  If patients are experiencing one of the following:   * Symptomatic primary or recurrent varicose veins that are causing severe pain, aching, discomfort, swelling, heaviness or itching * Lower-limb skin changes, such as pigmentation or eczema, thought to be caused by chronic venous insufficiency * Superficial vein thrombosis (characterised by the appearance of hard, painful veins) and suspected venous incompetence * An active or healed venous leg ulcer |
| **Evidence/Summary of Rationale** | 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.  Open surgery is a traditional treatment that involves surgical removal by stripping and ligation, but has been mainly superseded by endothermal ablation and ultrasound guided foam sclerotherapy.  Complications of interventions include recurrence of varicose veins, infection, pain, bleeding, and more rarely blood clot in the leg. Complications of non-intervention including decreasing quality of life for patients, increased symptomology, disease progression potentially skin changes and eventual leg ulceration, deep vein thrombosis and pulmonary embolism.  Evidence-Based Interventions (2008) |
| **Effective From** | 1st April 2019 |
| **Policy Review Date** | 1st April 2021 |

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| **Intervention** | Surgical Intervention for Varicose Veins (C0-C3) |
| **For the treatment of** | Grade C0-C3 Varicose Veins  NICE Guideline 168 define C0 – C3 grade Varicose Veins as follows:   * C0 no visible or palpable signs of venous disease * C1 telangectasia or reticular veins * C2 varicose veins * C3 oedema |
| **Commissioning Position** | This intervention is NOT routinely commissioned.  This intervention is a Category One Evidence Based Intervention; therefore, any requests to fund must be made as an Individual Funding Request, where clinical exceptionality must be demonstrated. |
| **Evidence/Summary of Rationale** | Open surgery is a traditional treatment that involves surgical removal by stripping and ligation, but has been mainly superseded by endothermal ablation and ultrasound guided foam sclerotherapy.  Complications of interventions include recurrence of varicose veins, infection, pain, bleeding, and more rarely blood clot in the leg. Complications of non-intervention including decreasing quality of life for patients, increased symptomology, disease progression potentially skin changes and eventual leg ulceration, deep vein thrombosis and pulmonary embolism.  Evidence-Based Interventions (2008) |
| **Effective From** | 1st April 2019 |
| **Policy Review Date** | 1st April 2021 |