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# HUMBER CCG'S EVIDENCE-BASED INTERVENTIONS POLICY DOCUMENT

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Interventions subject to Prior Approval or an Individual Funding Request

JANUARY 2020 (VERSION 2)

EAST RIDING OF YORKSHIRE, HULL AND NORTHERN LINCOLNSHIRE CCGS

## Introduction

Hull, East Riding of Yorkshire, North Lincolnshire, and North East Lincolnshire Clinical Commissioning Groups (CCGs) have worked together to align their CCG clinical commissioning policy 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 aim for establishing harmonised clinical commissioning policies is to reduce the variation in the content and implementation of adopted policies, in terms of the ability of people to access certain treatments in the different CCG areas where treatments are not routinely commissioned or restricted.

This document outlines the four Humber CCG's aligned policy 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 CCGs.

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 accessed via <https://ifryh.necsu.nhs.uk/>
- **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 accessed via <https://vbcchecker.necsu.nhs.uk/Account/Login?ReturnUrl=%2F>

**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.

Each CCG across Humber still operates a number of commissioning policy statements individual to their locality and have their own Individual Funding Request (IFR) procedures for people living within that CCG area – all of which can be found on each individual CCG website.

The policies listed this document should therefore be read alongside the relevant IFR procedure for each individual CCG.

## Contents

Introduction .....	1
Colorectal Interventions .....	6
Surgery for Anal Fissure - Adults.....	6
Surgery for Anal Fissure - Children .....	6
Botulinum toxin type A for Anal Fissure .....	7
Haemorrhoid Surgery.....	7
12 week trial of Percutaneous Tibial Nerve Stimulation (PTNS) – Faecal Incontinence.....	8
Continued Percutaneous Tibial Nerve Stimulation (PTNS) – Faecal Incontinence .....	9
Sacral Nerve Stimulation (SNS) – Faecal Retention .....	9
Dermatology Interventions.....	10
Hair Loss Treatments .....	10
Tattoo Removal.....	11
Ear, Nose and Throat Interventions.....	12
Adult Snoring Surgery in the absence of Obstructive Sleep Apnoea (OSA).....	12
Botulinum toxin type A for Spasmodic Dysphonia .....	13
Grommets for Glue Ear in Children.....	13
Irrigation of the external Auditory Canal.....	14
Rhinoplasty/Septorhinoplasty/Septoplasty.....	15
Tonsillectomy for Recurrent Tonsillitis .....	16
Endocrine Interventions.....	17
Botulinum toxin type A for Hyperhidrosis .....	17
Continuous Glucose Monitoring System (CGMS) .....	18
Endoscopic Thoracic Sympathectomy - Hyperhidrosis.....	19
Flash Glucose Monitoring (FGM) Systems such as Freestyle Libre® .....	20
Hair Removal for Hirsutism.....	22
Fertility Interventions .....	23
Reversal of Sterilisation .....	23
Vasectomy under General Anaesthetic .....	23
General Surgery .....	24
Cholecystectomy.....	24
Gynaecological Interventions .....	26
Dilation and Cutterage (D&C) for Heavy Menstrual Bleeding in Women. ....	26
Elective Caesarean Section (non-clinical reasons).....	26
Hysterectomy for Heavy Menstrual Bleeding.....	27
Labiaplasty / Vaginaplasty .....	28
Mental Health Interventions.....	29

Referral to Specialist Chronic Fatigue Services .....	29
Minor Surgery Procedures .....	30
Benign Skin Lesions – Surgical Removal.....	30
Chalazia Removal .....	32
Eyelid Surgery - Ectropion.....	32
Eyelid Surgery - Entropion .....	33
Eyelid Surgery - Epiphora .....	33
Neurological and Pain Interventions.....	33
Botulinum toxin type A for Chronic Migraine.....	33
Extra Corporeal Shockwave Therapy (ESWT) - Ankle .....	34
Extra Corporeal Shockwave Therapy (ESWT) - Elbow.....	35
Extra Corporeal Shockwave Therapy (ESWT) - Heel .....	36
Extra Corporeal Shockwave Therapy (ESWT) - Hip.....	37
Extra Corporeal Shockwave Therapy (ESWT) - Shoulder .....	37
Functional Electrical Stimulation (FES) .....	38
Sativex - Delta-9-Tetrahydrocannabinol and Cannabidiol Oromucosal Spray.....	39
Spinal Injections of Local Anaesthetic and Steroid in people with Non-Specific Low Back Pain without Sciatica.....	40
Wireless or Implantable Functional Electrical Stimulation (FES) .....	40
Ophthalmology Interventions.....	41
Cataracts Surgery .....	41
Second Eye Cataracts Surgery.....	43
Corrective Surgery, Lens Implants and Laser Treatment for Refractive error.....	44
Intravitreal Therapies for Eye Disease .....	45
Photodynamic Therapy (PDT) – for CSR.....	49
Orthopaedic Interventions.....	50
Arthroscopic Lavage and Debridement .....	50
Arthroscopic Shoulder Decompression for Subacromial Shoulder Pain.....	51
Bunion Surgery.....	51
Carpal Tunnel Syndrome Release .....	52
Dupuytren’s Contracture Release - Adults .....	53
Facet Joint Injections .....	54
Ganglion – Surgical Excision.....	55
Hip Arthroscopy .....	56
Hyaluronic Acid Injections for Musculoskeletal Joint Pain (Synvisc) .....	57
Ilizarov Technique/Taylor Spatial Frame (TSF) .....	58
Knee Arthroscopy - Osteoarthritis .....	58
Trigger Finger/Thumb Surgery (Adults) .....	59

Other .....	60
Any medical procedure or treatment NOT routinely commissioned where there is not a specific policy statement .....	60
Open and Wide-Bore Magnetic Resonance Imaging (MRI) Scanning.....	60
Plastic Surgery Interventions .....	62
Abdominoplasty / Apronectomy .....	62
Blepharoplasty .....	63
Breast Correctional Surgery - Asymmetry .....	63
Breast Enlargement Surgery .....	64
Breast Reduction Surgery .....	64
Breast Revisional Surgery (prosthesis removal) .....	66
Replacement of Breast Implants.....	66
Cleft Earlobe Surgery .....	67
Face, Neck and Brow Lifts .....	68
Gynaecomastia Surgery .....	68
Liposuction – Lipoedema .....	69
Pinnaplasty.....	69
Scar Revision and Skin Resurfacing.....	70
Surgical Fillers .....	72
Respiratory Interventions .....	72
Sleep Study.....	72
Trial of Continuous Positive Airway Pressure (CPAP) for Obstructive Sleep Apnoea.....	73
Continued Continuous Positive Airway Pressure (CPAP) for Obstructive Sleep Apnoea .....	74
Urological Interventions .....	75
Botox for Overactive Bladder.....	75
Circumcision – Male Adults.....	76
Circumcision – Male Children .....	77
Epididymal Cyst Surgery.....	78
Hydrocele Correction.....	78
Penile Implants .....	79
12 week trial of Percutaneous Tibial Nerve Stimulation (PTNS) – Urinary Incontinence.....	80
Continued Percutaneous Tibial Nerve Stimulation (PTNS) – Urinary Incontinence .....	81
Sacral Nerve Stimulation (SNS) – Men with Urinary Retention.....	82
Sacral Nerve Stimulation (SNS) - Women with Urinary Retention .....	83
Varicoceles (Adolescents) .....	84
Varicoceles (Adults) .....	85
Vascular Interventions .....	86
Resperate© (Intercure Ltd) .....	86

Surgical Intervention for Varicose Veins (C5-C6).....	86
Surgical Intervention for Varicose Veins (C4) .....	87
Surgical Intervention for Varicose Veins (C0-C3).....	88
Appendix 1 – Chronic Fatigue Service IFR Referral Form.....	90
Appendix 2 – References .....	92
Appendix 3 – OPCS Codes .....	120

## Colorectal Interventions

<b>Intervention</b>	<b>Surgery for Anal Fissure - Adults</b>
<b>For the treatment of</b>	Anal Fissures in Adults
<b>Commissioning Position</b>	<p>This intervention is NOT routinely commissioned.</p> <p>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.</p> <p>Treatment for Anal Fissures should be considered for adults who meet at least one of the following criteria:</p> <ul style="list-style-type: none"> <li>• Multiple, off the midline, large or irregular (atypical fissures) as these may be the manifestation of underlying disease</li> <li>• 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.</li> <li>• Check if patient taking Nicorandil (a risk factor)</li> </ul>
<b>Evidence/Summary of Rationale</b>	See Clinical Knowledge Summary for Anal Fissure July 2016
<b>Effective From</b>	1 <sup>st</sup> April 2019
<b>Policy Review Date</b>	1 <sup>st</sup> April 2021

<b>Intervention</b>	<b>Surgery for Anal Fissure - Children</b>
<b>For the treatment of</b>	Anal Fissures in Children (under 18)
<b>Commissioning Position</b>	<p>This intervention is NOT routinely commissioned.</p> <p>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.</p> <p>Treatment for Anal Fissures should be considered for children who meet at least one of the following criteria:</p> <ul style="list-style-type: none"> <li>• 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.</li> <li>• Presenting with an anal fissure without a clear history of severe constipation, refer at first presentation.</li> <li>• Recurrent anal fissures.</li> </ul>
<b>Evidence/Summary of Rationale</b>	See Clinical Knowledge Summary for Anal Fissure July 2016
<b>Effective From</b>	1 <sup>st</sup> April 2019
<b>Policy Review Date</b>	1 <sup>st</sup> April 2021

<b>Intervention</b>	<b>Botulinum toxin type A for Anal Fissure</b>
<b>For the treatment of</b>	Anal Fissure (Adults only)
<b>Commissioning Position</b>	<p>This intervention is NOT routinely commissioned.</p> <p>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.</p> <p>Treatment should only be considered commissioned for treating chronic or recurrent anal fissures in adults only when all the criteria outlined below are met:</p> <ul style="list-style-type: none"> <li>• The condition has failed to heal spontaneously</li> <li>• Chronic symptoms (pain and / or rectal bleeding) have persisted for more than 6 weeks</li> <li>• All other appropriate non-surgical, pharmacological (e.g. topical diltiazem, glyceryl trinitrate [GTN]) and dietary treatments have been tried and failed.</li> </ul> <p>One treatment with Botulinum toxin A will be commissioned - if the anal fissure fails to heal during the three-month period after injection, and chronic symptoms persist, surgical intervention may be indicated.</p>
<b>Evidence/Summary of Rationale</b>	<p>NICE evidence review: (ref 4) Evidence from 2 systematic reviews and 4 further randomised controlled trials (RCTs) suggests that botulinum toxin type A injection is less effective than surgery, no better or worse than topical glyceryl trinitrate (GTN; mostly 0.2% ointment) or isosorbide dinitrate, and no better than placebo or lidocaine at healing anal fissure. The Medicines and Healthcare products Regulatory Agency (MHRA) has warned healthcare professionals about the rare but serious risk of toxin spread when using all types of botulinum toxin.</p>
<b>Effective From</b>	1 <sup>st</sup> November 2019
<b>Policy Review Date</b>	1 <sup>st</sup> November 2021

<b>Intervention</b>	<b>Haemorrhoid Surgery</b>
<b>For the treatment of</b>	Surgical removal of haemorrhoids.
<b>Commissioning Position</b>	<p>This intervention is NOT routinely commissioned.</p> <p>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.</p> <p>Surgical treatment should only be considered for those that do not respond to non-operative measures of management (For example, as a 1<sup>st</sup> line management: eating more fibre and drinking more water. As a 2<sup>nd</sup> line management: outpatient treatment in the form of banding or injection) or if the haemorrhoids are more severe, specifically:</p> <ul style="list-style-type: none"> <li>• Recurrent grade 3 or grade 4 combined internal/external haemorrhoids with persistent pain or bleeding; or</li> <li>• Irreducible and large external haemorrhoids</li> </ul>



	In cases where there is significant rectal bleeding the patient should be examined internally by a specialist.
<b>Evidence/Summary of Rationale</b>	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.
<b>Effective From</b>	1 <sup>st</sup> April 2019
<b>Policy Review Date</b>	1 <sup>st</sup> April 2021

<b>Intervention</b>	<b>12 week trial of Percutaneous Tibial Nerve Stimulation (PTNS) – Faecal Incontinence</b>
<b>For the treatment of</b>	Adults with refractory Faecal Incontinence
<b>Commissioning Position</b>	<p>This intervention is NOT routinely commissioned.</p> <p>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.</p> <p>Treatment is not indicated in cases that are asymptomatic.</p> <p>Requests for a 12 week trial of PTNS for faecal incontinence will be considered for patients who fulfil all of the following criteria:</p> <ul style="list-style-type: none"> <li>• Voiding diary data is kept to record frequency and severity of episodes</li> <li>• Symptoms refractory to ≥12 months of first line treatment to include: <ul style="list-style-type: none"> <li>- dietary management</li> <li>- antidiarrhoeal medication</li> <li>- pelvic floor muscle and anal sphincter training (where appropriate)</li> </ul> </li> </ul>
<b>Evidence/Summary of Rationale</b>	<p>Incontinence definition as per: NICE IPG 395: faecal incontinence, the loss of ability to control a person's anal sphincter and bowel movement, resulting in leakage of faeces.</p> <p>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.</p> <p>PTNS achieves a modulatory effect similar to that of SNS through a less invasive route, but its exact mechanism of action is unclear. A fine needle is inserted just above the ankle next to the Posterior Tibial Nerve and a surface electrode is placed near the arch of the foot. Stimulation of the nerve produces a motor and sensory response. Initial treatment usually consists of 12 outpatient sessions lasting 30 minutes, usually weekly. NICE IPG 395 states that PTNS for faecal incontinence has no major safety concerns but the evidence only points to short term efficacy in a</p>

	limited number of patients. The large placebo-controlled study (RELAX 2012) found urgency and incontinence improve more than frequency with a magnitude of improvement considerably larger than that after anticholinergic medication.
<b>Effective From</b>	1 <sup>st</sup> November 2019
<b>Policy Review Date</b>	1 <sup>st</sup> November 2021

<b>Intervention</b>	<b>Continued Percutaneous Tibial Nerve Stimulation (PTNS) – Faecal Incontinence</b>
<b>For the treatment of</b>	Adults with refractory Faecal Incontinence
<b>Commissioning Position</b>	<p>This intervention is NOT routinely commissioned.</p> <p>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.</p> <p>Requests for an additional 12 weeks of PTNS for faecal incontinence will be considered for patients who fulfil all of the following criteria:</p> <ul style="list-style-type: none"> <li>• They have already undertaken an approved 12 week trial of PTNS</li> <li>• The trial has resulted in a 50% or more improvement in symptoms (measured as a weekly reduction in incontinence episodes).</li> </ul>
<b>Evidence/Summary of Rationale</b>	<p>Incontinence definition as per: NICE IPG 395: faecal incontinence, the loss of ability to control a person’s anal sphincter and bowel movement, resulting in leakage of faeces.</p> <p>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.</p> <p>PTNS achieves a modulatory effect similar to that of SNS through a less invasive route, but its exact mechanism of action is unclear. A fine needle is inserted just above the ankle next to the Posterior Tibial Nerve and a surface electrode is placed near the arch of the foot. Stimulation of the nerve produces a motor and sensory response. Initial treatment usually consists of 12 outpatient sessions lasting 30 minutes, usually weekly. NICE IPG 395 states that PTNS for faecal incontinence has no major safety concerns but the evidence only points to short term efficacy in a limited number of patients. The large placebo-controlled study (RELAX 2012) found urgency and incontinence improve more than frequency with a magnitude of improvement considerably larger than that after anticholinergic medication.</p>
<b>Effective From</b>	1 <sup>st</sup> November 2019
<b>Policy Review Date</b>	1 <sup>st</sup> November 2021

<b>Intervention</b>	<b>Sacral Nerve Stimulation (SNS) – Faecal Retention</b>
<b>For the treatment of</b>	Adults with Faecal Retention
<b>Commissioning Position</b>	This intervention is NOT routinely commissioned.

	<p>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.</p> <p>Sacral Nerve Stimulation for Adults with faecal retention/intractable constipation should be considered where patients meet ALL of the below criteria:</p> <ul style="list-style-type: none"> <li>• Symptoms present for at least 12 months;</li> <li>• Refractory to all conventional behavioural treatments including biofeedback;</li> <li>• Refractory to all conventional treatments (laxatives, suppositories, enemas).</li> </ul>
<b>Evidence/Summary of Rationale</b>	<p>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.</p> <p>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.</p>
<b>Effective From</b>	1 <sup>st</sup> April 2019
<b>Policy Review Date</b>	1 <sup>st</sup> April 2021

## Dermatology Interventions

<b>Intervention</b>	<b>Hair Loss Treatments</b>
<b>For the treatment of</b>	Balding, Hair Thinning, Alopecia , Trichilomania
<b>Commissioning Position</b>	<p>This intervention is NOT routinely commissioned.</p> <p>This intervention is a Category One Evidence Based Intervention; therefore, any requests to fund must be made as an Individual Funding Request.</p> <p>Requests for the following must be submitted via the IFR process, evidencing clinical exceptionality:</p> <ul style="list-style-type: none"> <li>• Surgical treatments for hair loss e.g. hair transplantation;</li> <li>• The 'Intralace' hair system</li> <li>• Dermatography (tattooing)</li> <li>• Drugs for the treatment of baldness e.g. Finasteride</li> </ul> <p>It should be noted that the provision of wigs or hair loss treatment for Gender Dysphoria patients is <b>NOT</b> part of the NHS commissioned pathway for transgender patients and is not routinely commissioned.</p> <p>Additionally, it should be noted that this policy does NOT affect the existing local NHS pathways that exist for the provision of wigs to chemotherapy or alopecia patients. Reconstructive treatment for the correction of disfiguring permanent hair loss from face/scalp that is the result of previous surgery or trauma, including burns, is routinely commissioned</p>

<b>Evidence/Summary of Rationale</b>	<p>Alopecia areata usually presents as patches of hair loss on the scalp but any hair-bearing skin can be involved. Hair follicles are preserved in alopecia areata and the potential for recovery of hair growth is maintained, even in longstanding disease. However the condition may progress to total hair loss of scalp hair (alopecia totalis) or loss of the entire scalp and body hair (alopecia universalis), from which full recovery is unusual. Disease severity at presentation is the strongest predictor of long-term outcome. Although the disease may have a serious psychological effect, it has no direct impact on general health that justifies the use of hazardous treatments, particularly of unproven efficacy. In addition, many patients, although by no means all, experience spontaneous regrowth of hair. Leaving alopecia areata untreated is a legitimate option for many patients. Spontaneous remission occurs in up to 80% of patients with limited patchy hair loss or short duration (&lt;1 year).</p> <p>Alopecia areata is difficult to treat and few treatments have been clinical trials. As cited in the British Association of Dermatologists Guidelines for the management of alopecia areata there has been a Cochrane review of 17 Random Controlled trials in Alopecia areata concluded that only one trial gave evidence of short term benefit and none showed long term benefit. The tendency to spontaneous remission and the lack of adverse effects on general health are important considerations in management, and not treating is the best option in many cases. However, the prognosis in longstanding extensive alopecia is poor and a wig may be a better option in such patients than indulging in treatments that are unlikely to be effective in this group.</p> <p>There is little clear evidence for the use of the 'Intralace' hair system for abnormal hair loss. Current providers are unable to demonstrate clear evidence for any real effectiveness, except for 'before and after' photos. Ongoing maintenance of the system is costly and time consuming.</p> <p>There are no mentions of the 'Intralace' system in any studies on alopecia. Due to the lack of clinical and cost effectiveness evidence use of the 'Intralace' Hair System for abnormal hair loss will not be routinely commissioned.</p>
<b>Effective From</b>	1 <sup>st</sup> November 2019
<b>Policy Review Date</b>	1 <sup>st</sup> November 2021

<b>Intervention</b>	<b>Tattoo Removal</b>
<b>For the treatment of</b>	Permanent Tattoos
<b>Commissioning Position</b>	<p>This intervention is NOT routinely commissioned.</p> <p>This intervention is a Category One Evidence Based Intervention; therefore, any requests to fund must be made as an Individual Funding Request.</p> <p>Tattoo removal will not be commissioned for cosmetic reasons, for example, if a tattoo is no longer liked or wanted.</p> <p>Requests for tattoo removal will only be considered in certain circumstances, where the tattoo:</p> <ul style="list-style-type: none"> <li>• 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);</li> </ul>

	<ul style="list-style-type: none"> <li>• Was inflicted against the patient's will;</li> <li>• Was applied during a period of documented significant mental illness;</li> <li>• Has resulted in a significant allergic reaction or impairment to daily living,</li> <li>• Where the individual was a child and not 'Fraser competent', and therefore not responsible for their action at the time of the tattooing.</li> </ul>
<b>Evidence/Summary of Rationale</b>	<p>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.</p> <p>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.</p> <p>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.</p>
<b>Effective From</b>	1 <sup>st</sup> April 2019
<b>Policy Review Date</b>	1 <sup>st</sup> April 2021

## Ear, Nose and Throat Interventions

<b>Intervention</b>	<p><b>Adult Snoring Surgery in the absence of Obstructive Sleep Apnoea (OSA).</b></p> <p>Surgical procedures in adults to remove, refashion or stiffen the tissues of the soft palate (Uvulopalatopharyngoplasty, Laser assisted Uvulopalatoplasty &amp; Radiofrequency ablation of the palate).</p>
<b>For the treatment of</b>	<p>The symptom of snoring.</p> <p>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.</p>
<b>Commissioning Position</b>	<p>This intervention is NOT routinely commissioned.</p> <p>This intervention is a Category One Evidence Based Intervention; therefore, any requests to fund must be made as an Individual Funding Request.</p>
<b>Evidence/Summary of Rationale</b>	<p>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.</p> <p><b><u>Alternative Treatments</u></b></p> <p>There are a number of alternatives to surgery that can improve the symptom of</p>

	<p>snoring. These include:</p> <ul style="list-style-type: none"> <li>• Weight loss</li> <li>• Stopping smoking</li> <li>• Reducing alcohol intake</li> <li>• Medical treatment of nasal congestion (rhinitis)</li> <li>• Mouth splints (to move jaw forward when sleeping)</li> </ul> <p>Evidence-Based Interventions: Guidance for CCG's 2018</p>
<b>Effective From</b>	1 <sup>st</sup> April 2019
<b>Policy Review Date</b>	1 <sup>st</sup> April 2021

<b>Intervention</b>	<b>Botulinum toxin type A for Spasmodic Dysphonia</b>
<b>For the treatment of</b>	Spasmodic Dysphonia
<b>Commissioning Position</b>	<p>This intervention is NOT routinely commissioned.</p> <p>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.</p> <p>Botox injections into the vocal cords should be considered for patients in whom:</p> <ul style="list-style-type: none"> <li>• Spasmodic dysphonia has been diagnosed by a Consultant Otolaryngologist (and a more generalised dystonia has been ruled out by a Consultant Neurologist)</li> <li>• Speech and language therapy has not adequately improved the voice quality</li> <li>• The resulting communication difficulties are interfering significantly with daily living</li> </ul>
<b>Evidence/Summary of Rationale</b>	<p>The Clinical Practice Guideline states” “Botulinum toxin is beneficial despite the potential need for repeated treatments considering the lack of other effective interventions for spasmodic dysphonia.” Botulinum toxin injections into the muscles that are spasming have thus become the mainstay of therapy starting in the late 1980s. Voice therapy for treating spasmodic dysphonia is useful as an adjunct to botulinum toxin, but voice therapy alone for treating spasmodic dysphonia does not work for everyone and study results have not been consistent.</p>
<b>Effective From</b>	1 <sup>st</sup> November 2019
<b>Policy Review Date</b>	1 <sup>st</sup> November 2021

<b>Intervention</b>	<b>Grommets for Glue Ear in Children</b>
<b>For the treatment of</b>	Glue Ear (Otitis Media with Effusion) in Children
<b>Commissioning Position</b>	<p>This intervention is NOT routinely commissioned.</p> <p>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.</p> <p>The NHS will only commission this surgery for the treatment of glue ear in children</p>

	<p>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:</p> <ul style="list-style-type: none"> <li>• All children must have had specialist audiology and ENT assessment.</li> <li>• Persistent bilateral otitis media with effusion over a period of 3 months.</li> <li>• Hearing level in the better ear of 25-30dbHL or worse averaged at 0.5, 1, 2, &amp; 4kHz</li> <li>• 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.</li> <li>• 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.</li> <li>• 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.</li> <li>• 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.</li> </ul> <p>Evidence-Based Interventions: Guidance for CCG's 2018</p>
<b>Evidence/Summary of Rationale</b>	<p>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.</p>
<b>Effective From</b>	1 <sup>st</sup> April 2019
<b>Policy Review Date</b>	1 <sup>st</sup> April 2021

<b>Intervention</b>	<b>Irrigation of the external Auditory Canal</b>
<b>For the treatment of</b>	Ear Wax
<b>Commissioning Position</b>	<p>This intervention is NOT routinely commissioned.</p> <p>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.</p> <p>Prior to referral to acute care for an ear problem, evidence must be collated to show the treatments received in primary care. A referral for ear wax removal to acute care is only commissioned for patients meeting at least one of the criteria set out below:</p> <ul style="list-style-type: none"> <li>• The patient has previously undergone ear surgery (other than grommets insertion that have been extruded for at least 18 months);</li> <li>• Has a recent history of Otolgia and /or Otitis media middle ear infection (in the</li> </ul>

	<p>past 6 weeks);</p> <ul style="list-style-type: none"> <li>• Recurrent Acute Otitis Externa which is not responding to primary care treatment;</li> <li>• Has a current perforation or history of ear discharge in the past 12 months;</li> <li>• Has had previous complications following ear irrigation including perforation of the ear drum, severe pain, deafness, or vertigo;</li> <li>• Two attempts at irrigation of the ear canal following intensive use of ear wax softeners in primary care are unsuccessful;</li> <li>• Cleft palate, whether repaired or not.</li> <li>• Painful or acute otitis externa with an oedematous ear canal and painful pinna.</li> <li>• Presence of a foreign body in the ear</li> <li>• Hearing in only one ear if it is the ear to be treated, as there is a remote chance that irrigation could cause permanent deafness.</li> <li>• Confusion or agitation, as they may be unable to sit still.</li> <li>• Inability to cooperate, for example young children and some people with learning difficulties.</li> </ul> <p>Patients who are not eligible for treatment under this policy may be considered on an individual basis where their GP or consultant believes exceptional circumstances warrant deviation from the rule of this policy.</p> <p>Individual cases will be reviewed at the Commissioner’s Individual Funding Request Panel upon receipt of a completed request form from the patient’s GP, Consultant or Clinician. Requests cannot be considered from patients personally.</p>
<b>Evidence/Summary of Rationale</b>	The vast majority of patients presenting with problems to primary care will be managed in primary care with advice or irrigation.
<b>Effective From</b>	1 <sup>st</sup> November 2019
<b>Policy Review Date</b>	1 <sup>st</sup> November 2021

<b>Intervention</b>	<b>Rhinoplasty/Septorhinoplasty/Septoplasty</b>
<b>For the treatment of</b>	Nasal Deformities
<b>Commissioning Position</b>	<p>This intervention is NOT routinely commissioned.</p> <p>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.</p> <p>Consideration will not be given to cosmetic Rhinoplasty.</p> <p>Rhinoplasty may be considered medically <u>necessary only in</u> limited circumstances and where the case details clinical rationale in accordance with the evidence base as follows:</p> <ol style="list-style-type: none"> <li>1. When it is being performed to correct a nasal deformity secondary to congenital cleft lip and/or palate;</li> <li>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: <ul style="list-style-type: none"> <li>• Airway obstruction will not respond to septoplasty and turbinectomy alone;</li> </ul> </li> </ol>



	<p><i>and</i></p> <ul style="list-style-type: none"> <li>• Nasal airway obstruction is causing significant symptoms (e.g. chronic rhinosinusitis, difficulty breathing); <i>and</i></li> <li>• Obstructive symptoms persist despite conservative management for three months or greater, which includes, where appropriate, nasal steroids or immunotherapy; <i>and</i></li> <li>• Photos demonstrate an external nasal deformity, <i>and</i></li> <li>• 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.</li> </ul> <p>There are, however, contra indications that need to be addressed such as:</p> <ul style="list-style-type: none"> <li>• Unstable mental status (e.g. unstable patient with schizophrenia)</li> <li>• Unrealistic patient expectations</li> <li>• Previous rhinoplasty within the last 9-12 months (applies only to major rhinoplasties)</li> <li>• Poor perioperative risk profile</li> <li>• History of too many previous rhinoplasties, resulting in an atrophic skin–soft tissue envelope and significant scarring</li> <li>• Nasal cocaine users</li> </ul>
<b>Evidence/Summary of Rationale</b>	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.
<b>Effective From</b>	1 <sup>st</sup> April 2019
<b>Policy Review Date</b>	1 <sup>st</sup> April 2021

<b>Intervention</b>	<b>Tonsillectomy for Recurrent Tonsillitis</b>
<b>For the treatment of</b>	Recurrent Tonsillitis in adults and children.
<b>Commissioning Position</b>	<p>This intervention is NOT routinely commissioned.</p> <p>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.</p> <p>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:</p> <ul style="list-style-type: none"> <li>• Sore throats are due to acute tonsillitis AND</li> <li>• The episodes are disabling and prevent normal functioning AND</li> <li>• Seven or more, documented, clinically significant, adequately treated sore throats in the preceding year OR</li> <li>• Five or more such episodes in each of the preceding two years OR</li> <li>• Three or more such episodes in each of the preceding three years.</li> </ul> <p>There are a number of medical conditions where episodes of tonsillitis can be</p>

	<p>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:</p> <ul style="list-style-type: none"> <li>• Acute and chronic renal disease resulting from acute bacterial tonsillitis.</li> <li>• As part of the treatment of severe guttate psoriasis.</li> <li>• Metabolic disorders where periods of reduced oral intake could be dangerous to health.</li> <li>• PFAPA (Periodic fever, Aphthous stomatitis, Pharyngitis, Cervical adenitis)</li> <li>• Severe immune deficiency that would make episodes of recurrent tonsillitis dangerous</li> </ul>
<b>Evidence/Summary of Rationale</b>	<p>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.</p> <p>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.</p> <p>Evidence-Based Interventions: Guidance for CCG's 2018</p>
<b>Effective From</b>	1 <sup>st</sup> April 2019
<b>Policy Review Date</b>	1 <sup>st</sup> April 2021

## Endocrine Interventions

<b>Intervention</b>	<b>Botulinum toxin type A for Hyperhidrosis</b>
<b>For the treatment of</b>	Hyperhidrosis (excessive sweating)
<b>Commissioning Position</b>	<p>This intervention is NOT routinely commissioned.</p> <p>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.</p> <p>Treatment with Botulinum toxin type A should only be considered when medically necessary for intractable, disabling focal primary hyperhidrosis, in cases where ALL of the following criteria are fulfilled:</p> <ul style="list-style-type: none"> <li>• All lifestyle measures have been tried but have failed to resolve symptoms: avoiding identified triggers such as crowded rooms, caffeine, or spicy foods; frequent use of commercial antiperspirant (as opposed to a deodorant); avoiding tight clothing and manmade fabrics; wearing white or black clothing to</li> </ul>

	<p>minimize the signs of sweating and using dress shields to absorb excess sweat.</p> <ul style="list-style-type: none"> <li>• Topical aluminium chloride or other extra-strength antiperspirants are ineffective or result in a severe rash;</li> <li>• The patient is unresponsive or unable to tolerate pharmacotherapy prescribed for excessive sweating (e.g. anticholinergics, beta-blockers, or benzodiazepines) if sweating is episodic;</li> <li>• In appropriate patients a trial of iontophoresis* treatment has been unsuccessful.</li> <li>• Significant disruption of professional and / or social life has occurred because of excessive sweating. (NB. In line with NICE recommendations, botulinum toxin is not commissioned for the treatment of hyperhidrosis (excessive sweating) in people with social anxiety disorder). Providing these criteria are met, the IFR Panel will approve a maximum of 2 treatments per year per patient to be commissioned, when used by an appropriately trained specialist (not for GP prescribing).</li> </ul> <p>If Botox treatment is approved, but more than two treatments per year are required, the specialist should re-submit an Individual Funding Request to the CCG for consideration.</p> <p>Treatment should be discontinued if not tolerated or there is no objective evidence of response.</p> <p>* Water iontophoresis is a non-invasive treatment where the hands / axillae are immersed in warm water, or a wet contact pad applied, through which a weak electric current is passed. A hospital trial of the treatment is offered on the NHS in York, usually consisting of 2– 4 sessions (of 20-30 mins) per week. Improvement usually occurs after 4–10 weeks, and where the hospital trial is positive, the patient has the option to purchase their own equipment and continue the treatment at home.</p>
<b>Evidence/Summary of Rationale</b>	Some autonomic disorders (resulting in hypersecretion of glands) such as hyperhidrosis respond well to Botox, which is licensed for the treatment of axillary hyperhidrosis; botulinum toxin can also be helpful for palmar, plantar, and craniofacial hyperhidrosis but the procedure may be more difficult and painful at these sites, since Botulinum toxin is delivered by multiple intradermal injections to the affected areas. Adverse effects include compensatory sweating (5–10%) and injection site pain or reactions (9–12%).
<b>Effective From</b>	1 <sup>st</sup> November 2019
<b>Policy Review Date</b>	1 <sup>st</sup> November 2021

<b>Intervention</b>	<b>Continuous Glucose Monitoring System (CGMS)</b>
<b>For the treatment of</b>	Type 1 Diabetes in Adults and Children
<b>Commissioning Position</b>	<p>This intervention is NOT routinely commissioned.</p> <p>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.</p>

	<p>CGMS will only be commissioned as an option for the management of Type 1 Diabetes Mellitus in adults and children in accordance with NICE Guidance (Ref 1 and 2) if any of the following criteria are fulfilled:</p> <p><b>Adults</b> with type 1 diabetes who are willing to commit to using it at least 70% of the time and to calibrate it as needed, and who have any of the following despite optimised use of insulin therapy and conventional blood glucose monitoring:</p> <p>More than 1 episode a year of severe hypoglycaemia (requiring the assistance of others) with no obviously preventable precipitating cause.</p> <ul style="list-style-type: none"> <li>• Complete loss of awareness of hypoglycaemia.</li> <li>• Frequent (more than 2 episodes a week) asymptomatic hypoglycaemia that is causing problems with daily activities.</li> <li>• Extreme fear of hypoglycaemia.</li> <li>• Hyperglycaemia (HbA1c level of 75mmol/mol [9%] or higher) that persists despite testing at least 10 times a day.</li> <li>• Continue real-time continuous glucose monitoring only if HbA1c can be sustained at or below 53 mmol/mol (7%) and/or there has been a fall in HbA1c of 27 mmol/mol (2.5%) or more.</li> </ul> <p><b>Children and Young People</b> Ongoing real-time continuous glucose monitoring, with alarms if needed, will be offered to children and young people with Type1diabetes who have:</p> <ul style="list-style-type: none"> <li>• frequent severe hypoglycaemia or</li> <li>• impaired awareness of hypoglycaemia associated with adverse consequences (for example, seizures or anxiety) or</li> <li>• Inability to recognise, or communicate about, symptoms of hypoglycaemia (for example, because of cognitive or neurological disabilities).</li> </ul> <p>NICE state it may also be considered for:</p> <ul style="list-style-type: none"> <li>• neonates, infants and pre-school children</li> <li>• children and young people who undertake high levels of physical activity (for example, sport at a regional, national or international level)</li> <li>• children and young people who have comorbidities (for example anorexia nervosa) or who are receiving treatments (for example corticosteroids) that can make blood glucose control difficult.</li> </ul> <p>Consider intermittent (real-time or retrospective) continuous glucose monitoring to help improve blood glucose control in children and young people who continue to have hyperglycaemia despite insulin.</p>
<b>Evidence/Summary of Rationale</b>	In line with NICE Guidelines.
<b>Effective From</b>	1 <sup>st</sup> November 2019
<b>Policy Review Date</b>	1 <sup>st</sup> November 2021

<b>Intervention</b>	<b>Endoscopic Thoracic Sympathectomy - Hyperhidrosis</b>
<b>For the treatment of</b>	Hyperhidrosis
<b>Commissioning Position</b>	This intervention is NOT routinely commissioned.

	<p>This intervention is a Category One Evidence Based Intervention; therefore, any requests to fund must be made as an Individual Funding Request.</p> <p>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:</p> <ul style="list-style-type: none"> <li>• Suffering from severe and debilitating primary hyperhidrosis</li> <li>• Refractory to other treatments. (These may include topical agents, oral medication, botulinum toxin injections and iontophoresis.)</li> </ul> <p>In addition to the criteria above, evidence of clinical exceptionality must be provided.</p>
<b>Evidence/Summary of Rationale</b>	<p>Endoscopic Thoracic Sympathectomy does not work as well for those with excessive axillary (armpit) sweating.</p> <p>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”).</p> <p>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.</p> <p>Further research is required to establish good patient selection and to identify which patient characteristics might predict severe side-effects.</p>
<b>Effective From</b>	1 <sup>st</sup> April 2019
<b>Policy Review Date</b>	1 <sup>st</sup> April 2021

<b>Intervention</b>	<b>Flash Glucose Monitoring (FGM) Systems such as Freestyle Libre®</b>
<b>For the treatment of</b>	Type 1 Diabetes in Adults and Children (aged 4+)
<b>Commissioning Position</b>	<p>This intervention is NOT routinely commissioned.</p> <p>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.</p> <p>It is recommended that Freestyle Libre® should only be used for:</p> <ul style="list-style-type: none"> <li>• People with Type 1 diabetes OR with any form of diabetes on haemodialysis and on insulin treatment who, in either of the above, are clinically indicated as requiring intensive monitoring &gt;8 times daily, as demonstrated on a meter download/review over the past 3 months OR with diabetes associated with cystic fibrosis on insulin treatment</li> <li>• Pregnant women with Type 1 Diabetes - 12 months in total inclusive of post-delivery period.</li> <li>• People with Type 1 diabetes unable to routinely self-monitor blood glucose due to disability who require carers to support glucose monitoring and insulin management.</li> <li>• People with Type 1 diabetes for whom the specialist diabetes MDT determines have occupational (e.g. working in insufficiently hygienic conditions to safely</li> </ul>

facilitate finger-prick testing) or psychosocial circumstances that warrant a 6-month trial of Libre with appropriate adjunct support.

- Previous self-funders of Flash Glucose Monitors with Type 1 diabetes where those with clinical responsibility for their diabetes care are satisfied that their clinical history suggests that they would have satisfied one or more of these criteria prior to them commencing use of Flash Glucose Monitoring had these criteria been in place prior to April 2019 AND has shown improvement in HbA1c since self-funding.
- For those with Type 1 diabetes and recurrent severe hypoglycaemia or impaired awareness of hypoglycaemia, NICE suggests that Continuous Glucose Monitoring with an alarm is the standard. Other evidence-based alternatives with NICE guidance or NICE TA support are pump therapy, psychological support, structured education, islet transplantation and whole pancreas transplantation. However, if the person with diabetes and their clinician consider that a Flash Glucose Monitoring system would be more appropriate for the individual's specific situation, then this can be considered.

In addition, all patients (or carers) must undertake the following:

- Education on Flash Glucose Monitoring has been provided (online or in person)
- Agree to scan glucose levels no less than 8 times per day and use the sensor >70% of the time.
- Agree to regular reviews with the local clinical team.
- Previous attendance, or due consideration given to future attendance, at a Type 1 diabetes structured education programme (DAFNE or equivalent if available locally)

The specialist service is responsible for assessing patients who meet the criteria and if appropriate initiating Flash Glucose Monitoring. The specialist service is responsible for providing sufficient sensors for the first 28 days. The patient's GP should then be provided with the relevant information to allow them to prescribe subsequent sensors. The specialist service will also need to ensure arrangements are in place for the safe disposal of the sensors.

The continued prescribing for long-term use of Flash Glucose Monitoring (post initial 6 months) would be contingent upon evidence of agreeing with the above conditions and that on-going use of the Flash Glucose Monitoring is demonstrably improving an individual's diabetes self-management- for example improvement of HbA1c or Time In Range; improvement in symptoms such as DKA or hypoglycaemia; or improvement in psycho-social wellbeing.

Please note, for North Lincolnshire where there is an Integrated Diabetes model, GPs will be required to prescribe the sensors for those that meet any of the criteria in the APC guidance, but that are not under the specialist team, and do not clinically require referral into the specialist team. This includes:

- Prescribing of the sensors for people that are T1 diabetic and who have previously self-funded; only where you are satisfied that their clinical history suggests that they would have satisfied one or more of the NHSE criteria prior to them commencing the use of Freestyle Libre had those criteria been in place prior to April 2019 **and** if the patient has shown improvement in HbA1c since

	<p>self-funding.</p> <ul style="list-style-type: none"> <li>On-going prescribing of sensors for those people that have previously been under the care of the specialist service and started on Freestyle Libre, and who have now been discharged from the service to primary care under the integrated diabetes service.</li> </ul>
<b>Evidence/Summary of Rationale</b>	<p>Freestyle Libre® is an innovative new device that has the potential to improve quality of life for patients and support self-management. However, at the present point in time there are significant limitations in available clinical trial data and economic analysis that make it difficult to make an appropriate judgment as to its place in therapy.</p>
<b>Effective From</b>	1 <sup>st</sup> November 2019
<b>Policy Review Date</b>	1 <sup>st</sup> November 2021

<b>Intervention</b>	<b>Hair Removal for Hirsutism</b>
<b>For the treatment of</b>	Hirsutism
<b>Commissioning Position</b>	<p>This intervention is NOT routinely commissioned.</p> <p>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.</p> <p>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.</p> <p>Treatment for hair removal, by IPL, laser or electrolysis, should be considered for individuals where</p> <ul style="list-style-type: none"> <li>It is considered medically necessary</li> </ul> <p>OR</p> <ul style="list-style-type: none"> <li>Have undergone reconstructive surgery leading to abnormally located hair-bearing skin</li> </ul> <p>OR</p> <ul style="list-style-type: none"> <li>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</li> </ul> <p>OR</p> <ul style="list-style-type: none"> <li>Are undergoing treatment for pilonidal sinuses to reduce recurrence</li> </ul> <p>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.</p> <p>For Gender Dysphoria patients, please refer to NHS England.</p>
<b>Evidence/Summary of Rationale</b>	<p>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.</p>

	<p>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).</p> <p>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).</p> <p>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.</p>
<b>Effective From</b>	1 <sup>st</sup> April 2019
<b>Policy Review Date</b>	1 <sup>st</sup> April 2021

## Fertility Interventions

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

<b>Intervention</b>	<b>Vasectomy under General Anaesthetic</b>
<b>For the treatment of</b>	Removal of Male Fertility
<b>Commissioning Position</b>	<p>This intervention is NOT routinely commissioned.</p> <p>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.</p>



	<p>Surgical intervention should be considered for patients where there is:</p> <ul style="list-style-type: none"> <li>• Previous documented adverse reaction to local anaesthesia;</li> <li>• Scarring or deformity (e.g. due to cryptorchidism or from previous scrotal surgery or trauma) that makes vasectomy under local anaesthetic difficult to achieve;</li> <li>• The patient is on anticoagulation therapy (increased risk of postoperative haematoma formation)</li> </ul> <p>Fear of the procedure, or patient choice, are not adequate reasons for requesting vasectomy under GA.</p>
<b>Evidence/Summary of Rationale</b>	<p>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.</p> <p>The RCOG Guidelines (4) recommend a general anaesthetic is used where:</p> <ul style="list-style-type: none"> <li>• There is a history of allergy to local anaesthetic;</li> <li>• Surgery has been carried out before on the scrotum or genital area.</li> </ul> <p>The RCOG Guidelines also recommend:</p> <ul style="list-style-type: none"> <li>• A 'no-scalpel' approach, as there are lower levels of complications such as bleeding, pain and infection;</li> <li>• The use of fascial interposition or diathermy;</li> <li>• That clips are not used, due to high failure rates ;</li> <li>• That local anaesthesia is used wherever possible;</li> <li>• Effective contraception be used before the operation and until follow-up tests show that the vasectomy has been successful;</li> <li>• Practitioners must be trained to the level of the FSRHC requirement</li> </ul>
<b>Effective From</b>	1 <sup>st</sup> April 2019
<b>Policy Review Date</b>	1 <sup>st</sup> April 2021

## General Surgery

<b>Intervention</b>	<b>Cholecystectomy</b>
<b>For the treatment of</b>	Biliary Tract Problems
<b>Commissioning Position</b>	<p>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.</p> <p>Referral for Cholecystectomy will only be funded if the patient fulfils ANY of the criteria below:</p>

	<ul style="list-style-type: none"> <li>• Symptomatic gallstones with a thickened gallbladder wall</li> <li>• A dilated common bile duct on ultrasound</li> <li>• Asymptomatic gallstones with abnormal liver function test (LFT) results</li> <li>• Asymptomatic gall bladder polyp(s) reported on ultrasound</li> <li>• Symptomatic gall bladder 'sludge' reported on ultrasound</li> </ul> <p>Elective cholecystectomy surgery will only be commissioned where the patient fulfils ANY of the criteria below:</p> <ul style="list-style-type: none"> <li>• Symptomatic gallstones</li> <li>• Gall bladder polyp(s) larger than 8mm or growing rapidly</li> <li>• Common bile duct stones</li> <li>• Acute pancreatitis</li> </ul> <p>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:</p> <ul style="list-style-type: none"> <li>• any relevant medical history and current medication;</li> <li>• any known factors affecting the patients fitness for day surgery;</li> <li>• a recent ultrasound report conducted within 2 months at the point of referral;</li> <li>• recent liver function test report conducted within 1 month at point of referral.</li> </ul> <p>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).</p> <p>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.</p> <p>If the gall bladder is sent for histological examination, the results should be reviewed by the requesting consultant and communicated to the GP.</p> <p>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.</p> <p>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.</p> <p>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</p>
<b>Evidence/Summary of Rationale</b>	<p>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</p>

	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.
<b>Effective From</b>	1 <sup>st</sup> April 2019
<b>Policy Review Date</b>	1 <sup>st</sup> April 2021

## Gynaecological Interventions

<b>Intervention</b>	<b>Dilation and Cutterage (D&amp;C) for Heavy Menstrual Bleeding in Women.</b>
<b>For the treatment of</b>	Heavy menstrual bleeding in women.
<b>Commissioning Position</b>	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.
<b>Evidence/Summary of Rationale</b>	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
<b>Effective From</b>	1 <sup>st</sup> April 2019
<b>Policy Review Date</b>	1 <sup>st</sup> April 2021

<b>Intervention</b>	<b>Elective Caesarean Section (non-clinical reasons)</b>
<b>For the treatment of</b>	Childbirth
<b>Commissioning Position</b>	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.  Any request for an elective caesarean section outside of the criteria below must be considered via the Individual Funding request process with clear supporting evidence. Maternal request is not on its own an indication for caesarean section.  Elective caesarean sections in line with the requirements stipulated by NICE CG 132 will be commissioned for women who fulfil at least ONE of the following criteria: <ul style="list-style-type: none"> <li>• Singleton breach at term, for whom external cephalic version is contraindicated or unsuccessful</li> <li>• Twin pregnancy where the first twin is not cephalic</li> <li>• Minor or major placenta praevia</li> <li>• Primary genital Herpes Simplex Virus infection in the third trimester • Previous significant uterine perforation/surgery breaching the cavity • Previous third or fourth degree tear</li> <li>• Previous shoulder dystocia</li> </ul>

	<ul style="list-style-type: none"> <li>• Previous surgical procedure for which a vaginal delivery may lead to complications (e.g. pelvic, hip, vaginal or bowel surgery)</li> <li>• Tocophobia (fear of pregnancy and childbirth) after referral and assessment by the Specialist Perinatal Mental Health Team.</li> <li>• Patients with Human Immunodeficiency Virus (HIV) who are: <ul style="list-style-type: none"> <li>- Not receiving retroviral therapy</li> <li>- On retroviral therapy with a viral load of 50 – 400 copies per ml</li> <li>- Have a viral load greater than 400 copies per ml</li> <li>- Also have Hepatitis C</li> </ul> </li> </ul>
<b>Evidence/Summary of Rationale</b>	<p>In November 2011 NICE carried out a partial update of NICE clinical guideline 13 (2004): Caesarean section". In the original remit, the Department of Health asked NICE to produce evidence based guidelines on, "When a caesarean section is appropriate and the circumstances under which routine procedures in normal labour may be unnecessary".</p> <p>The NICE guidance was developed and updated following changes to current practice and changes to the evidence base. The following areas of the guideline have been updated: morbidly adherent placenta, women who are HIV positive, time from decision to delivery, planned vaginal birth versus planned caesarean section following previous caesarean birth, and antibiotic prophylaxis.</p> <p>As a result of the changes to the guidelines NICE recommend the following are identified as priorities for implementation:</p> <ul style="list-style-type: none"> <li>• Pregnant women with a singleton breech presentation at term, for whom external cephalic version is contraindicated or has been unsuccessful, should be offered CS because it reduces perinatal mortality and neonatal morbidity.</li> <li>• In twin pregnancies where the first twin is not cephalic the effect of CS in improving outcome is uncertain, but current practice is to offer a planned CS</li> <li>• Pregnant women who are co-infected with hepatitis C virus and HIV should be offered planned CS because it reduces mother-to-child transmission of both hepatitis C virus and HIV</li> <li>• Women with primary genital herpes simplex virus (HSV) infection occurring in the third trimester of pregnancy should be offered planned CS because it decreases the risk of neonatal HSV infection</li> <li>• When a woman requests a CS because she has anxiety about childbirth, offer referral to a healthcare professional with expertise in providing perinatal mental health support to help her address her anxiety in a supportive manner.</li> </ul> <p>The purpose of this guideline is to enable healthcare professionals to give appropriate research-based advice to women and their families</p>
<b>Effective From</b>	1 <sup>st</sup> November 2019
<b>Policy Review Date</b>	1 <sup>st</sup> November 2021

<b>Intervention</b>	<b>Hysterectomy for Heavy Menstrual Bleeding</b>
<b>For the treatment of</b>	Heavy menstrual bleeding.
<b>Commissioning Position</b>	This intervention is NOT routinely commissioned.  This intervention is a Category One Evidence Based Intervention; therefore, any

	<p>requests to fund must be made as an Individual Funding Request.</p> <p>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.</p> <p>This intervention will only be commissioned where the IFR application demonstrates that the criteria outlined in the NICE guidance have been met.</p> <p>Evidence-Based Interventions: Guidance for CCG's 2018</p>
<b>Evidence/Summary of Rationale</b>	NICE recommends that hysterectomy should not be used as a first-line treatment solely for heavy menstrual bleeding (HMB). <sup>13</sup> Heavy periods can be reduced by using medicines or intrauterine systems (IUS) or losing weight (if necessary).
<b>Effective From</b>	1 <sup>st</sup> April 2019
<b>Policy Review Date</b>	1 <sup>st</sup> April 2021

<b>Intervention</b>	<b>Labiaplasty / Vaginaplasty</b>
<b>For the treatment of</b>	Malformed, enlarged labia / vulva causing functional discomfort which has not responded to conservative management.
<b>Commissioning Position</b>	<p>The NHS will routinely commission reconstructive Labiaplasty / Vaginaplasty:</p> <ul style="list-style-type: none"> <li>• following surgery for cancer</li> <li>• repair after trauma (including tears / scars from childbirth).</li> </ul> <p>All other requests for Labiaplasty / Vaginaplasty are NOT routinely commissioned.</p> <p>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.</p> <p>There are circumstances where Labiaplasty / Vaginaplasty may be considered where the following are met:</p> <ul style="list-style-type: none"> <li>• Where the woman is 18 years of age or older</li> <li>• Where the woman has completed pubertal development (RCOG, 2013).</li> <li>• Where the labia / vulva causes functional discomfort</li> <li>• 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).</li> <li>• Where the clinician's sensitive genital examination (visual inspection) has determined that benign labial disease, significant congenital malformation or structural anomalies are identified.</li> </ul> <p>Labiaplasty / Vaginaplasty for cosmetic purposes is NOT commissioned.</p> <p>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.</p>

	British Society for Paediatric & Adolescent Gynaecology (2013). <i>Position Statement: Labial reduction surgery (Labiaplasty) on adolescents.</i>
<b>Evidence/Summary of Rationale</b>	<p>Labiaplasty / Vaginaplasty for cosmetic purposes has no clinical benefit.</p> <p>RCOG states that the risk of revisional surgery in patients who receive surgery prior to completion of pubertal development is high.</p> <p>There are risks of infection and bleeding post-surgery, loss of sensation and dissatisfaction with appearance.</p>
<b>Effective From</b>	1 <sup>st</sup> April 2019
<b>Policy Review Date</b>	1 <sup>st</sup> April 2021

## Mental Health Interventions

<b>Intervention</b>	<b>Referral to Specialist Chronic Fatigue Services</b>
<b>For the treatment of</b>	Chronic Fatigue Syndrome
<b>Commissioning Position</b>	<p>This intervention is NOT routinely commissioned.</p> <p>This intervention is a Category One Evidence Based Intervention; therefore, any requests to fund must be made as an Individual Funding Request and using the proforma found in <b>Appendix 1</b>.</p> <p>Clinicians must ensure that any red flag symptoms are investigated prior to referral via the IFR process.</p> <p>Funding requests for this treatment may be considered by exception, for all patients whose symptoms align with characteristic features of Chronic Fatigue Syndrome, as defined per NICE guidance:</p> <p>Fatigue with all of the following features:</p> <ul style="list-style-type: none"> <li>• New or had a specific onset (that is, it is not lifelong)</li> <li>• Persistent and/or recurrent</li> <li>• Unexplained by other conditions</li> <li>• Has resulted in a substantial reduction in activity level</li> <li>• Characterised by post-exertional malaise and/or fatigue (typically delayed, for example by at least 24 hours, with slow recovery over several days)</li> </ul> <p>AND one or more of the following symptoms:</p> <ul style="list-style-type: none"> <li>• Difficulty with sleeping, such as insomnia, hypersomnia, unrefreshing sleep, a disturbed sleep–wake cycle</li> <li>• Muscle and/or joint pain that is multi-site and without evidence of inflammation</li> <li>• Headaches</li> <li>• Painful lymph nodes without pathological enlargement</li> <li>• Sore throat</li> <li>• Cognitive dysfunction, such as difficulty thinking, inability to concentrate, impairment of short-term memory, and difficulties with word-finding, planning/organising thoughts and information processing</li> </ul>

	<ul style="list-style-type: none"> <li>• Physical or mental exertion makes symptoms worse</li> <li>• General malaise or 'flu-like' symptoms</li> <li>• Dizziness and/or nausea</li> <li>• Palpitations in the absence of identified cardiac pathology.</li> </ul> <p>Symptoms must have persisted for:</p> <ul style="list-style-type: none"> <li>- 4 months in adults</li> <li>- 3 months in a child or young person, confirmed by paediatrician.</li> </ul> <p>Clinicians must:</p> <ul style="list-style-type: none"> <li>• Confirm all relevant and appropriate history, examinations and investigations been carried out as per NICE CG53 section 1.2.2.</li> <li>• Evidence appropriate symptoms managed methods have been exhausted</li> <li>• Demonstrate significant impact on daily life and activities</li> </ul> <p>Where a referral is approved, funding will be provided for an assessment only. If the diagnosis for Chronic Fatigue Syndrome is confirmed and specialist intervention recommended, a further request for funding treatment must be submitted.</p>
<b>Evidence/Summary of Rationale</b>	<p>This policy covers diagnosing and managing Chronic Fatigue Syndrome (CFS) which is also known as Myalgic Encephalomyelitis (ME) (or Encephalopathy). It aims to improve the quality of life for people with CFS/ME by setting out the care and treatment options that are available within North Lincolnshire CCG. The CCG provides an assessment only and further services may be identified. The policy has been developed using Chronic Fatigue Syndrome/Myalgic Encephalomyelitis (or Encephalopathy): diagnosis and management (2007) NICE guideline CG53</p>
<b>Effective From</b>	1 <sup>st</sup> November 2019
<b>Policy Review Date</b>	1 <sup>st</sup> November 2021

## Minor Surgery Procedures

<b>Intervention</b>	<b>Benign Skin Lesions – Surgical Removal</b>
<b>For the treatment of</b>	Symptomatic benign skin lesions
<b>Commissioning Position</b>	<p>This intervention is NOT routinely commissioned.</p> <p>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.</p> <p>This policy refers to the following benign lesions when there is diagnostic certainty and they meet the criteria listed below:</p> <ul style="list-style-type: none"> <li>• benign moles (excluding large congenital naevi)</li> <li>• solar comedones</li> </ul>

	<ul style="list-style-type: none"> <li>• corn/callous</li> <li>• dermatofibroma</li> <li>• lipomas</li> <li>• milia</li> <li>• molluscum contagiosum (non-genital)</li> <li>• epidermoid &amp; pilar cysts (sometimes incorrectly called sebaceous cysts)</li> <li>• seborrhoeic keratoses (basal cell papillomata)</li> <li>• skin tags (fibroepithelial polyps) including anal tags</li> <li>• spider naevi (telangiectasia)</li> <li>• non-genital viral warts in immunocompetent patients</li> <li>• xanthelasmata</li> <li>• neurofibromata</li> </ul> <p>The benign skin lesions, which are listed above, must meet at least ONE of the following criteria to be removed:</p> <ul style="list-style-type: none"> <li>• 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</li> <li>• There is repeated infection requiring 2 or more antibiotics per year</li> <li>• The lesion bleeds in the course of normal everyday activity</li> <li>• The lesion causes regular pain</li> <li>• The lesion is obstructing an orifice or impairing field vision</li> <li>• The lesion significantly impacts on function e.g. restricts joint movement</li> <li>• The lesion causes pressure symptoms e.g. on nerve or tissue</li> <li>• If left untreated, more invasive intervention would be required for removal</li> <li>• Facial viral warts</li> <li>• Facial spider naevi in children causing significant psychological impact</li> <li>• Lipomas on the body &gt; 5cms, or in a sub-facial position, with rapid growth and/or pain. These should be referred to Sarcoma clinic.</li> </ul> <p>The following are outside the scope of this policy recommendation:</p> <ul style="list-style-type: none"> <li>• Lesions that are suspicious of malignancy should be treated or referred according to NICE skin cancer guidelines.</li> <li>• 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.</li> <li>• Removal of lesions other than those listed above.</li> </ul> <p>Referral to dermatology or plastic surgery:</p> <ul style="list-style-type: none"> <li>• 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.</li> <li>• Requests for treatment where a patient meets the criteria do not require prior approval or an IFR.</li> <li>• This policy applies to all providers, including general practitioners (GPs), GPs with enhanced role (GPwer), independent providers, and community or intermediate services.</li> </ul>
<b>Evidence/Summary of</b>	There is little evidence to suggest that removing benign skin lesions to improve



<b>Rationale</b>	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.
<b>Effective From</b>	1 <sup>st</sup> April 2019
<b>Policy Review Date</b>	1 <sup>st</sup> April 2021

<b>Intervention</b>	<b>Chalazia Removal</b>
<b>For the treatment of</b>	Chalazia (meibomian cysts). Benign lesions on the eyelids due to blockage and swelling of an oil gland.
<b>Commissioning Position</b>	<p>This intervention is NOT routinely commissioned.</p> <p>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.</p> <p>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:</p> <ul style="list-style-type: none"> <li>• Has been present for more than 6 months and has been managed conservatively with warm compresses, lid cleaning and massage for 4 weeks</li> <li>• Interferes significantly with vision, demonstrated by visual fields test</li> <li>• Interferes with the protection of the eye by the eyelid due to altered lid closure or lid anatomy</li> <li>• Is a source of infection that has required medical attention twice or more within a six month time frame</li> <li>• Is a source of infection causing an abscess which requires drainage</li> <li>• 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</li> </ul> <p>Evidence-Based Interventions: Guidance for CCG's 2018.</p>
<b>Evidence/Summary of Rationale</b>	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.
<b>Effective From</b>	1 <sup>st</sup> April 2019
<b>Policy Review Date</b>	1 <sup>st</sup> April 2021

<b>Intervention</b>	<b>Eyelid Surgery - Ectropion</b>
<b>For the treatment of</b>	Ectropion
<b>Commissioning Position</b>	<p>This intervention is NOT routinely commissioned.</p> <p>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.</p>

	Treatment should only be considered if: <ul style="list-style-type: none"> <li>Patients are experiencing recurrent infection</li> </ul>
<b>Effective From</b>	1 <sup>st</sup> November 2019
<b>Policy Review Date</b>	1 <sup>st</sup> November 2021

<b>Intervention</b>	<b>Eyelid Surgery - Entropion</b>
<b>For the treatment of</b>	Entropion
<b>Commissioning Position</b>	<p>This intervention is NOT routinely commissioned.</p> <p>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.</p> <p>Treatment should only be considered if:</p> <ul style="list-style-type: none"> <li>The condition is symptomatic</li> </ul> <p>and</p> <ul style="list-style-type: none"> <li>Risks causing trauma to the cornea</li> </ul>
<b>Effective From</b>	1 <sup>st</sup> November 2019
<b>Policy Review Date</b>	1 <sup>st</sup> November 2021

<b>Intervention</b>	<b>Eyelid Surgery - Epiphora</b>
<b>For the treatment of</b>	Epiphora
<b>Commissioning Position</b>	<p>This intervention is NOT routinely commissioned.</p> <p>This intervention is a Category One Evidence Based Intervention; therefore, any requests to fund must be made as an Individual Funding Request.</p> <p>However, referral to secondary care may be made for diagnostic purposes or tear duct syringing.</p>
<b>Effective From</b>	1 <sup>st</sup> November 2019
<b>Policy Review Date</b>	1 <sup>st</sup> November 2021

## Neurological and Pain Interventions

<b>Intervention</b>	<b>Botulinum toxin type A for Chronic Migraine</b>
<b>For the treatment of</b>	Prophylaxis of headaches in adults with Chronic Migraine
<b>Commissioning Position</b>	<p>This intervention is NOT routinely commissioned.</p> <p>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.</p> <p>The CCG will only commission the use of Botox as an option for the prophylactic</p>

	<p>treatment of chronic migraine in adults in accordance with NICE Guidance TAG 260 in cases where ALL of the following criteria are fulfilled:</p> <ul style="list-style-type: none"> <li>• The patient is under the care of the specialist neurology service and has been assessed as meeting the definition for chronic migraine</li> <li>• The patient has chronic migraine that significantly interferes with their daily routine despite appropriate use of symptomatic medication</li> <li>• Symptoms have not responded to at least three prior pharmacological prophylaxis therapies</li> <li>• The condition has been appropriately managed for medication overuse.</li> </ul> <p>NB. Treatment with botulinum toxin type A should be stopped in people whose condition:</p> <ul style="list-style-type: none"> <li>• is not adequately responding to treatment (defined as less than a 30% reduction in headache days per month after two treatment cycles)</li> </ul> <p>OR</p> <ul style="list-style-type: none"> <li>• has changed to episodic migraine (defined as fewer than 15 headache days per month) for three consecutive months (which is not covered in Allergan's licence for Botox).</li> </ul>
<b>Evidence/Summary of Rationale</b>	<p>The treatment has been appraised by NICE, which considered evidence from two phase III randomised controlled trials, PREEMPT 1 and PREEMPT 2 as well as the pooled analysis of results from these trials. Prior to publication of the NICE Guidance the North East Treatment Advisory Group and the Scottish Medicines Consortium had appraised the same trial evidence and concluded that the treatment should not be recommended for the prevention of migraine because of uncertainty around its cost-effectiveness. NICE also concluded that although the treatment effects were generally in favour of Botox, the actual magnitude of treatment benefit was modest, but was nevertheless clinically meaningful in people whose chronic migraine had not responded to 3 prior treatments. As in the previous appraisals NICE also noted the large placebo effect, concerns over blinding being maintained in the PREEMPT trials, the lack of long term clinical trial data and numerous concerns over the manufacturer's economic modelling. However after a revised model was submitted using the NICE preferred assumptions, it was concluded that £18,900 was the most plausible ICER (incremental cost effectiveness ratio) per QALY (quality adjusted life year) and that this was considered an appropriate use of NHS resources, with certain specified criteria</p>
<b>Effective From</b>	1 <sup>st</sup> November 2019
<b>Policy Review Date</b>	1 <sup>st</sup> November 2021

<b>Intervention</b>	<b>Extra Corporeal Shockwave Therapy (ESWT) - Ankle</b>
<b>For the treatment of</b>	Achilles Tendinopathy (ankle)
<b>Commissioning Position</b>	<p>This intervention is NOT routinely commissioned.</p> <p>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.</p>

	<p>Treatment is not indicated in cases that are asymptomatic.</p> <p>Surgical intervention should be considered for patients who have</p> <ul style="list-style-type: none"> <li>• have an established diagnosis</li> <li>• causes significant pain and/or interference with activities of daily living</li> </ul> <p>AND</p> <p>is refractory to :</p> <ul style="list-style-type: none"> <li>• rest (reducing activity that worsens symptoms)</li> <li>• physiotherapy</li> <li>• application of ice</li> <li>• NSAIDs</li> <li>• orthotic devices</li> <li>• corticosteroid injection</li> </ul> <p>Where the treatment is approved for an individual, no more than three outpatient sessions will be commissioned.</p>
<b>Evidence/Summary of Rationale</b>	<p>NICE have reviewed this therapeutic intervention in several types of localised tendonitis (Refs 1-5). The evidence for efficacy of ESWT in tendonitis of the elbow, ankle and heel is equivocal since the results of clinical studies were conflicting and there was evidence of a substantial placebo response.</p> <p>Because the benefits and risks are uncertain and there is a lack long term data, NICE recommends that patients must first have tried other evidence based treatments.</p>
<b>Effective From</b>	1 <sup>st</sup> November 2019
<b>Policy Review Date</b>	1 <sup>st</sup> November 2021

<b>Intervention</b>	<b>Extra Corporeal Shockwave Therapy (ESWT) - Elbow</b>
<b>For the treatment of</b>	Lateral Epicondylitis (tennis elbow)
<b>Commissioning Position</b>	<p>This intervention is NOT routinely commissioned.</p> <p>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.</p> <p>Treatment is not indicated in cases that are asymptomatic.</p> <p>Surgical intervention should be considered for patients who have</p> <ul style="list-style-type: none"> <li>• have an established diagnosis</li> <li>• causes significant pain and/or interference with activities of daily living</li> </ul> <p>AND</p> <p>is refractory to :</p> <ul style="list-style-type: none"> <li>• rest (reducing activity that worsens symptoms)</li> <li>• physiotherapy</li> <li>• application of ice</li> <li>• analgesic medication</li> </ul>

	<ul style="list-style-type: none"> <li>• NSAIDs</li> <li>• orthotic devices</li> <li>• eccentric training/stretching</li> <li>• corticosteroid injection</li> </ul> <p>Where the treatment is approved for an individual, no more than three outpatient sessions will be commissioned.</p>
<b>Evidence/Summary of Rationale</b>	<p>NICE have reviewed this therapeutic intervention in several types of localised tendonitis (Refs 1-5). The evidence for efficacy of ESWT in tendonitis of the elbow, ankle and heel is equivocal since the results of clinical studies were conflicting and there was evidence of a substantial placebo response.</p> <p>Because the benefits and risks are uncertain and there is a lack long term data, NICE recommends that patients must first have tried other evidence based treatments.</p>
<b>Effective From</b>	1 <sup>st</sup> November 2019
<b>Policy Review Date</b>	1 <sup>st</sup> November 2021

<b>Intervention</b>	<b>Extra Corporeal Shockwave Therapy (ESWT) - Heel</b>
<b>For the treatment of</b>	Plantar Fasciitis (heel)
<b>Commissioning Position</b>	<p>This intervention is NOT routinely commissioned.</p> <p>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.</p> <p>Treatment is not indicated in cases that are asymptomatic.</p> <p>Surgical intervention should be considered for patients who have</p> <ul style="list-style-type: none"> <li>• have an established diagnosis</li> <li>• causes significant pain and/or interference with activities of daily living</li> </ul> <p>AND</p> <p>is refractory to :</p> <ul style="list-style-type: none"> <li>• rest (reducing activity that worsens symptoms)</li> <li>• physiotherapy</li> <li>• application of ice</li> <li>• analgesic medication</li> <li>• NSAIDs</li> <li>• orthotic devices</li> <li>• corticosteroid injection</li> <li>• eccentric training/stretching</li> </ul> <p>Where the treatment is approved for an individual, no more than three outpatient sessions will be commissioned.</p>
<b>Evidence/Summary of Rationale</b>	<p>NICE have reviewed this therapeutic intervention in several types of localised tendonitis (Refs 1-5). The evidence for efficacy of ESWT in tendonitis of the elbow,</p>

	<p>ankle and heel is equivocal since the results of clinical studies were conflicting and there was evidence of a substantial placebo response.</p> <p>Because the benefits and risks are uncertain and there is a lack long term data, NICE recommends that patients must first have tried other evidence based treatments.</p>
<b>Effective From</b>	1 <sup>st</sup> November 2019
<b>Policy Review Date</b>	1 <sup>st</sup> November 2021

<b>Intervention</b>	<b>Extra Corporeal Shockwave Therapy (ESWT) - Hip</b>
<b>For the treatment of</b>	Trochanteric Bursitis (Hip)
<b>Commissioning Position</b>	<p>This intervention is NOT routinely commissioned.</p> <p>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.</p> <p>Treatment is not indicated in cases that are asymptomatic.</p> <p>Surgical intervention should be considered for patients who have</p> <ul style="list-style-type: none"> <li>• have an established diagnosis</li> <li>• BMI of 30 or below</li> <li>• causes significant pain and/or interference with activities of daily living</li> </ul> <p>AND</p> <p>is refractory to :</p> <ul style="list-style-type: none"> <li>• rest (reducing activity that worsens symptoms)</li> <li>• physiotherapy</li> <li>• 1 month of drug treatment with Paracetamol or non-steroidal anti-inflammatory drugs (NSAIDs)</li> <li>• 3 corticosteroid injections</li> </ul> <p>Where the treatment is approved for an individual, no more than three outpatient sessions will be commissioned.</p>
<b>Evidence/Summary of Rationale</b>	<p>NICE have reviewed this therapeutic intervention in several types of localised tendonitis (Refs 1-5). The evidence for efficacy of ESWT in Trochanteric Bursitis was found to be one of the more robust.</p> <p>Because the benefits and risks are uncertain and there is a lack long term data, NICE recommends that patients must first have tried other evidence based treatments.</p>
<b>Effective From</b>	1 <sup>st</sup> November 2019
<b>Policy Review Date</b>	1 <sup>st</sup> November 2021

<b>Intervention</b>	<b>Extra Corporeal Shockwave Therapy (ESWT) - Shoulder</b>
<b>For the treatment of</b>	Calcific Tendonitis (shoulder)
<b>Commissioning Position</b>	This intervention is NOT routinely commissioned.

	<p>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.</p> <p>Treatment is not indicated in cases that are asymptomatic.</p> <p>Surgical intervention should be considered for patients who have</p> <ul style="list-style-type: none"> <li>• have an established diagnosis</li> <li>• causes significant pain and/or interference with activities of daily living</li> </ul> <p>AND</p> <p>is refractory to :</p> <ul style="list-style-type: none"> <li>• rest (reducing activity that worsens symptoms)</li> <li>• physiotherapy</li> <li>• anti-inflammatory drugs</li> <li>• corticosteroids</li> <li>• aspiration or lavage</li> </ul> <p>Where the treatment is approved for an individual, no more than three outpatient sessions will be commissioned.</p>
<b>Evidence/Summary of Rationale</b>	<p>NICE have reviewed this therapeutic intervention in several types of localised tendonitis (Refs 1-5). The evidence for efficacy of ESWT in Calcific Tendonitis of the Shoulder was found to be one of the more robust.</p> <p>Because the benefits and risks are uncertain and there is a lack long term data, NICE recommends that patients must first have tried other evidence based treatments.</p>
<b>Effective From</b>	1 <sup>st</sup> November 2019
<b>Policy Review Date</b>	1 <sup>st</sup> November 2021

<b>Intervention</b>	<b>Functional Electrical Stimulation (FES)</b>
<b>For the treatment of</b>	Foot Drop
<b>Commissioning Position</b>	<p>This intervention is NOT routinely commissioned.</p> <p>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.</p> <p>Skin surface Functional Electrical Stimulation should be considered in the following circumstances:</p> <ul style="list-style-type: none"> <li>• 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);</li> <li>• There is evidence that the foot drop interferes significantly with the individual's day to day living;</li> <li>• There is evidence that FES has been recommended for the individual after a thorough assessment of their suitability by the local NHS physiotherapy</li> </ul>

	<p>service or MDT specialising in rehabilitation.</p> <ul style="list-style-type: none"> <li>• The request to the IFR Panel must include evidence that first line treatments have been tried and failed.</li> <li>• 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.</li> <li>• 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.</li> </ul> <p>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.</p>
<b>Evidence/Summary of Rationale</b>	<p>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.</p> <p>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.</p> <p>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.</p>
<b>Effective From</b>	1 <sup>st</sup> April 2019
<b>Policy Review Date</b>	1 <sup>st</sup> April 2021

<b>Intervention</b>	<b>Sativex - Delta-9-Tetrahydrocannabinol and Cannabidiol Oromucosal Spray</b>
<b>For the treatment of</b>	Symptoms associated with multiple sclerosis, including spasticity and pain
<b>Commissioning Position</b>	<p>This intervention is NOT routinely commissioned.</p> <p>This intervention is a Category One Evidence Based Intervention; therefore, any requests to fund must be made as an Individual Funding Request.</p> <p>Sativex is not routinely funded for patients with multiple sclerosis. The medicine should not be withdrawn from patients already established on treatment but other treatment options should be considered at routine review</p>
<b>Evidence/Summary of Rationale</b>	<p>Following appraisal of the available evidence and anticipated costs, the Yorkshire and the Humber Expert Panel for disease modifying therapies in multiple sclerosis recommend that Sativex should not be routinely funded. The Panel advised that, on the available evidence, Sativex lacked compelling evidence of benefit for the target population and was unlikely to be cost-effective. NICE CG 186 Multiple sclerosis: management of multiple sclerosis in primary and secondary care (June 2015) stated</p>



	do not offer Sativex to treat spasticity as it is not a cost effective treatment.
<b>Effective From</b>	1 <sup>st</sup> November 2019
<b>Policy Review Date</b>	1 <sup>st</sup> November 2021

<b>Intervention</b>	<b>Spinal Injections of Local Anaesthetic and Steroid in people with Non-Specific Low Back Pain without Sciatica.</b>
<b>For the treatment of</b>	Non-specific back pain without sciatica
<b>Commissioning Position</b>	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.
<b>Evidence/Summary of Rationale</b>	<p>Spinal injections of local anaesthetic and steroid should not be offered for patients with non-specific low back pain.</p> <p>For people with non-specific low back pain the following injections should not be offered:</p> <ul style="list-style-type: none"> <li>• Facet joint injections</li> <li>• Therapeutic medial branch blocks</li> <li>• Intradiscal therapy</li> <li>• Prolotherapy</li> <li>• Trigger point injections with any agent, including botulinum toxin</li> <li>• Epidural steroid injections for chronic low back pain or for neurogenic claudication in patients with central spinal canal stenosis</li> <li>• Any other spinal injections not specifically covered above</li> </ul> <p>Radiofrequency denervation can be offered according to NICE guideline (NG59) if all non-surgical and alternative treatments have been tried and there is moderate to severe chronic pain that has improved in response to diagnostic medial branch block.</p> <p>Epidurals (local anaesthetic and steroid) should be considered in patients who have acute and severe lumbar radiculopathy at time of referral.</p> <p>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.</p> <p>Evidence-Based Interventions: Guidance for CCG's 2018.</p>
<b>Effective From</b>	1 <sup>st</sup> April 2019
<b>Policy Review Date</b>	1 <sup>st</sup> April 2021

<b>Intervention</b>	<b>Wireless or Implantable Functional Electrical Stimulation (FES)</b>
<b>For the treatment of</b>	Foot Drop
<b>Commissioning Position</b>	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

	<p>Functional Electrical Stimulation policy).</p> <p>Requests for wireless or implantable FES must demonstrate clinical exceptionalism and include:</p> <ul style="list-style-type: none"> <li>• Detailed clinical evidence which demonstrates the extent to which the patient's condition affects the quality of life;</li> <li>• Lifestyle modifications including weight management (where appropriate) that have been made and relevant services such as Occupational therapy and Falls team have been involved;</li> <li>• 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.</li> <li>• Clinical evidence as to why standard FES is not appropriate</li> </ul>
<b>Evidence/Summary of Rationale</b>	<p>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.</p> <p>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.</p> <p>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.</p>
<b>Effective From</b>	1 <sup>st</sup> April 2019
<b>Policy Review Date</b>	1 <sup>st</sup> April 2021

## Ophthalmology Interventions

<b>Intervention</b>	<b>Cataracts Surgery</b>
<b>For the treatment of</b>	Cataracts
<b>Commissioning Position</b>	<p>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.</p> <p>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.</p> <p>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</p>

	<p>or other adjustments):</p> <ul style="list-style-type: none"> <li>• Have a best corrected visual acuity of 6/12 or worse with both eyes open</li> </ul> <p>AND</p> <ul style="list-style-type: none"> <li>• have significant effects on daily living e.g. with mobility (difficulty with steps, risk of falls, ability to drive), independent living, or reading</li> </ul> <p>OR</p> <ul style="list-style-type: none"> <li>• have diabetes and removal of the cataract is necessary to facilitate effective retinal screening</li> </ul> <p>OR</p> <ul style="list-style-type: none"> <li>• have glaucoma and / or narrow drainage angles and cataract surgery is required to control intra-ocular pressure</li> </ul>
<p><b>Evidence/Summary of Rationale</b></p>	<p>Cataracts affect over a third of people aged over 65. Smoking and diabetes (associated with BMI &gt; 30) are further risk factors for cataract.</p> <p>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.</p> <p>There are risks associated with cataract surgery, some common and many very rare; however complications are usually treatable and reasonably good outcomes can be expected.</p> <p>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.</p> <p>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.</p> <p>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.</p> <p>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.</p> <p>Cataract surgery does not always result in an improvement in visual acuity or patient satisfaction with visual function.</p>
<p><b>Effective From</b></p>	<p>1<sup>st</sup> April 2019</p>
<p><b>Policy Review Date</b></p>	<p>1<sup>st</sup> April 2021</p>

<b>Intervention</b>	<b>Second Eye Cataracts Surgery</b>
<b>For the treatment of</b>	Cataracts
<b>Commissioning Position</b>	<p>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.</p> <p>Second Eye Surgery should be funded, after post-operative review, if:</p> <ul style="list-style-type: none"> <li>• 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.</li> </ul>
<b>Evidence/Summary of Rationale</b>	<p>Cataracts affect over a third of people aged over 65. Smoking and diabetes (associated with BMI &gt; 30) are further risk factors for cataract.</p> <p>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.</p> <p>There are risks associated with cataract surgery, some common and many very rare; however complications are usually treatable and reasonably good outcomes can be expected.</p> <p>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.</p> <p>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.</p> <p>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.</p> <p>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.</p> <p>Cataract surgery does not always result in an improvement in visual acuity or patient satisfaction with visual function.</p>
<b>Effective From</b>	1 <sup>st</sup> April 2019
<b>Policy Review Date</b>	1 <sup>st</sup> April 2021

<b>Intervention</b>	<b>Corrective Surgery, Lens Implants and Laser Treatment for Refractive error</b> (short or long sightedness, astigmatism)
<b>For the treatment of</b>	Refractive Error
<b>Commissioning Position</b>	<p>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.</p> <p>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</p>
<b>Evidence/Summary of Rationale</b>	<p>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).</p> <p>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.</p> <p>Complications of laser refractive surgery include infection, bleeding, over/under correction, corneal haze, glare, halo or burst, corneal damage, retinal detachment and dry eye. However risks which have the potential to cause permanent damage are very rare.</p> <p>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.</p> <p><b>Intraocular lens implants</b></p> <p>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)</p> <p>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.</p>
<b>Effective From</b>	1 <sup>st</sup> April 2019
<b>Policy Review Date</b>	1 <sup>st</sup> April 2021

<b>Intervention</b>	<b>Intravitreal Therapies for Eye Disease</b>
<b>For the treatment of</b>	Eye Disease
<b>Commissioning Position</b>	<p>This intervention is routinely commissioned and does not require Prior Approval or application for funding via the Individual Funding Request (IFR) process, unless outside of the criteria listed below:</p> <p>CCG commissioning of the use of intravitreal therapies in eye disease as set out below:</p> <p><b>A) Wet Age Related Macular Degeneration (ARMD)</b></p> <p>Ranibizumab therapy is routinely commissioned in line with NICE TAG 155, where all of the following circumstances apply in the eye to be treated:</p> <ul style="list-style-type: none"> <li>• The best possible visual acuity (VA) after correction with glasses or contact lenses is between 6/12 and 6/96.</li> <li>• There is no permanent damage to the fovea</li> <li>• The area affected by ARMD is no larger than 12 times the size of the area inside the eye where the optic nerve connects to the retina.</li> <li>• There are signs that the condition has been getting worse. (i.e. blood vessel growth, as indicated by fluorescein angiography, or recent VA changes)</li> </ul> <p><b>and</b></p> <ul style="list-style-type: none"> <li>• The manufacturer provides ranibizumab with the discount agreed in the patient access scheme (as revised in 2012).</li> </ul> <p>NB. Treatment should be stopped if:</p> <ul style="list-style-type: none"> <li>• Vision in the treated eye falls below 15 letters on 2 consecutive visits</li> <li>• Vision falls by 30 letters or more compared to the best recorded vision</li> <li>• There is evidence of deterioration of the lesion morphology despite treatment.</li> </ul> <p>Requests for treatment in patients with wet ARMD where the above NICE criteria are not met must be submitted for consideration to the CCG IFR (Individual Funding Request) Panel outlining the rationale for expected clinical benefit. Such cases might include those where visual loss is due to fluid rather than scarring or where vision in the other eye is already poor.</p> <p>Aflibercept (Eylea) is an alternative, licensed (Nov 2012) intravitreal injection for wet ARMD, recommended in the NICE TAG 294 which uses the same eligibility criteria as NICE TAG 155. Both aflibercept and ranibizumab have the same mode of action and are equivalent in terms of efficacy and safety.</p> <p>The CCG commissions the use of aflibercept in patients with wet age-related macular degeneration if:</p> <ul style="list-style-type: none"> <li>• it is used in accordance with the recommendations for ranibizumab in NICE TAG 155; <b>and</b></li> <li>• the manufacturer provides aflibercept solution for injection with the discount agreed in the patient access scheme.</li> </ul> <p>NB. It has been locally agreed that Consultant Ophthalmologists may, in selected ARMD patients, 'switch' between the use of Eylea and Lucentis in 'heavy users' of either drug or where there is a sub-optimal response or an allergic reaction.</p>

This is also in line with advice from NICE and the Royal College of Ophthalmologists.

Requests for treatment in patients with wet ARMD where the above criteria are not met must be submitted for consideration to the CCG IFR (Individual Funding Request) Panel.

#### **B) Diabetic macular oedema (DMO) / retinopathy**

Ranibizumab therapy is routinely commissioned in line with NICE TAG 274 in patients where:

- the retina has a central retinal thickness of 400 micrometres or more at the start of treatment; **and**
- the manufacturer provides ranibizumab with the discount agreed in the patient access scheme (as revised in 2012).

In addition, in line with NICE TAG 301 the CCG routinely commissions Fluocinolone acetonide (Iluvien) intravitreal implants for people with chronic DMO who have an intra-ocular lens implant in the eye to be treated if their diabetic macular oedema has failed to respond to other treatments.

Requests for treatment in patients with DMO where the NICE criteria are not met must be submitted for consideration to the CCG IFR Panel.

#### **C) Macular oedema due to retinal vein occlusion (RVO)**

Ranibizumab therapy is routinely commissioned as an option for treating visual impairment caused by macular oedema in line with the criteria in NICE TAG 283:

- following central retinal vein occlusion (CRVO); **or**
- following branch retinal vein occlusion (BRVO) in patients where treatment with laser photocoagulation has failed or is deemed unsuitable due to the extent of macular haemorrhage; **and**
- only if the manufacturer provides ranibizumab with the discount agreed in the patient access scheme (as revised in 2012).

The CCG also routinely commissions the use of Ozurdex in line with NICE TAG 229 for patients where laser therapy has failed or is contraindicated due to extensive haemorrhage.

The CCG also routinely commissions the use of Eylea (Aflibercept) in line with NICE TAG 305 as an option for patients with central retinal vein occlusion (CRVO) only if the manufacturer provides aflibercept solution for injection with the discount agreed in the patient access scheme.

Requests for treatment in patients with RVO where the NICE criteria are not met must be submitted for consideration to the CCG IFR Panel.

#### **D) Myopic Choroidal Neovascularisation (Myopic CNV)**

The CCG routinely commissions Ranibizumab therapy as an option for treating visual

	<p>impairment caused by myopic CNV in line with the criteria in NICE TAG 298 only if the manufacturer provides ranibizumab with the discount agreed in the patient access scheme (as revised in 2012).</p> <p><b>E) Inflammatory CNV</b></p> <p>Ranibizumab is currently unlicensed for this indication. Requests for ranibizumab treatment in patients with inflammatory CNV must be submitted for consideration to the CCG IFR Panel. Treatment will only be considered in patients where all the following criteria are met:</p> <ul style="list-style-type: none"> <li>• Sub/juxta foveal CNV associated with underlying inflammatory disease; <b>and</b></li> <li>• Intra-retinal OR sub-retinal fluid on OCT scans OR leakage on FFA</li> </ul> <p>Where treatment is approved, both myopic and inflammatory CNV should be treated with a single injection of ranibizumab on an 'as needed' basis from the outset.</p> <p>Re-treatments will only be commissioned (after application to the CCG IFR Panel) in cases where:</p> <ul style="list-style-type: none"> <li>• Intra/sub-retinal fluid is seen on OCT scans (persistent or recurrent); <b>or</b></li> <li>• Lesion leakage is documented on FFA.</li> </ul> <p><b>F) Visual Loss due to Vitreo-Macular Traction</b></p> <p>The CCG routinely commissions Ocriplasmin (Jetrea, single injection) therapy as an option for treating visual impairment in adults caused by vitreomacular traction in line with the criteria in NICE TAG 29, where the following criteria are met:</p> <ul style="list-style-type: none"> <li>• no epiretinal membrane (a thin layer of scar tissue over their retina, the light-sensitive area at the back of the eye); <b>and</b></li> <li>• a macular hole (up to 400 micrometers) in the centre of their retina or • severe sight problems.</li> </ul> <p><b>G) Other eye disease</b></p> <p>Requests for treating other rarer eye diseases with intravitreal therapies outside licensed indications must be submitted to the CCG IFR Panel for consideration together with accompanying evidence of previous treatments and the expected clinical benefit from the requested treatment.</p>
<p><b>Evidence/Summary of Rationale</b></p>	<p><b>Wet Age Related Macular Degeneration</b></p> <p>NICE TAG 155 considered data from 4 RCTS: MARINA, ANCHOR, PIER and FOCUS trials. The 3 published trials reported mean increases in visual acuity in the 0.5 mg ranibizumab group compared with baseline. In addition, for wet ARMD aflibercept showed equivalence to ranibizumab (given monthly) when studied within the VIEW 1+2 RCTS. It can be given as an automatic 2 monthly dose in the first year (7 injections in total) - compared to a mean of 6 injections with ranibizumab as required - but the fixed aflibercept dosing reduces the need to assess the eye regularly and allows partial booking of the first year of treatment. In the second year of the VIEW studies; aflibercept and ranibizumab were again compared head to head using an as required 'prn' regime and again both drugs showed equivalence. The mechanism of</p>



injection and the safety profile appear identical between the two drugs and the price of both drugs has reduced under the recent patient access scheme.

**Diabetic macular oedema (DMO) / retinopathy**

NIICE TAG 274 concluded treatment of DMO with ranibizumab was cost effective as long as patients could access a discounted drug cost via the patient access scheme and there was a more tightly defined eligibility criteria, i.e. patients with greater than 400 micrometres of diabetic macular oedema. Evidence came from the RESTORE trial which showed gains in best corrected VA with ranibizumab were greatest in the subgroup of people with central foveal thickness greater than 300 micrometres, with no evidence for a benefit in adding laser to ranibizumab.

The Fluocinolone acetonide intravitreal implant (Iluvien) despite it being substantially more expensive it has the advantage that 70% of patients will only need 1 injection over 3 years

**Macular oedema due to central retinal vein occlusion (CRVO)**

CRVO has been untreatable until recently and patients with this condition have a very poor natural history. Of those presenting with vision poorer than 6/60, only 20% get any spontaneous visual improvement. Prior to the advent of intra-vitreous therapies the central visual loss in these patients would have been untreatable. The CRUISE trial, a phase III prospective, randomized, double masked, multicentre clinical trial involving 392 patients with CRVO, indicated that a 6 month improvement in VA is maintained after ranibizumab therapy - the mean letter gain is 14.9 letters with monthly 0.5mg ranibizumab injections versus 0.8 letters with sham treatment.

**Macular oedema due to branch retinal vein occlusion (BRVO)**

Some patients with BRVO get better spontaneously in the first year, so the RCOphth recommends initially observing for 3 months prior to considering macular argon laser therapy if the patient's vision is between 6/12 and 6/60 and the condition has been present for 3 to 12 months. However argon laser can generate ocular co-morbidity including central scotoma, visual loss and late onset choroidal neovascularisation. In patients for whom treatment with laser photocoagulation either has not been beneficial or is deemed unsuitable due to the extent of macular haemorrhage or ischaemia, ranibizumab is commissioned as a treatment option.

Ozurdex (dexamethasone implant) is also now recommended by NICE as an option for treating retinal vein occlusions. Evidence came from the 2 GENEVA trials multi-centre, randomised, parallel group, sham-controlled studies with identical designs, involving 1,267 patients with macular oedema secondary to BRVO or CRVO. Both studies consisted of an initial 6-month masked phase, followed by a further 6-month, open-label period. In the initial 6-month phase patients were randomised to receive a single administration of either DEX 700µg intravitreal implant or sham (needleless applicator). In the open-label phase, patients received

**Myopic CNV**

Patients with CNV caused by pathological myopia previously offered photodynamic therapy (PDT) did well at avoiding 8 letters of visual loss at 1 yr. with PDT. However long term benefit is often lost due to retinal pigment epithelial atrophy. Recent evidence suggests ranibizumab therapy in these patients can deliver an average mean 12.78 letter gain in an eye with no prior treatment at 12 months and that eyes previously treated with PDT may not achieve such a good prognosis. Most patients with myopic CNV are young and given the guarded prognosis with PDT are keen to

	<p>regain vision and would opt for Lucentis therapy, which is now recommended as a treatment option by NICE. PDT should however remain available according to patient preference e.g. for those who are needle phobic. (The numbers of patients with myopic CNV estimated to be treated with ranibizumab at Hull Eye Hospital is about 9 per year).</p> <p><b>Inflammatory CNV</b></p> <p>Patients with inflammatory CNV have conventionally been treated with PDT or systemic or depot steroids. Response to these agents is variable and steroid treatments in particular are well recognised as inducing glaucoma and cataract formation. A recent case series proved Anti-VEGF therapy increased visual acuity to better than 20/30 in 5/6 eyes at 6 months.</p> <p><b>Visual Loss from Vitreo-Macular Traction</b></p> <p>Vitreo-retinal traction is a degenerative condition in which the vitreous gel in the centre of the eye is pathologically adherent to the retinal surface causing structural damage that can impair the vision. Previously the only option was surgery to remove the vitreous gel but the use of one Ocriplasmin injection in the affected eye gives an alternative less invasive treatment option for some patients. Repeat injections are not recommended.</p>
<b>Effective From</b>	1 <sup>st</sup> November 2019
<b>Policy Review Date</b>	1 <sup>st</sup> November 2021

<b>Intervention</b>	<b>Photodynamic Therapy (PDT) – for CSR</b>
<b>For the treatment of</b>	Chronic Central Serous Retinopathy (CSR)
<b>Commissioning Position</b>	<p>This intervention is NOT routinely commissioned.</p> <p>This intervention is a Category One Evidence Based Intervention; therefore, any requests to fund must be made as an Individual Funding Request</p> <p>In addition to details regarding exceptionality ,the minimum criteria for requests to be considered by IFR could be:</p> <ul style="list-style-type: none"> <li>• Meet the definition of Chronic, having not resolved within 6 months</li> <li>• Worsening visual acuity (evidenced with serial visual acuity readings)</li> </ul> <p>It must be noted that this policy does not apply to ‘Acute CSR’ or ‘Acute Persistent CSR’ which tend to resolve spontaneously or where visual acuity is stable.</p>
<b>Evidence/Summary of Rationale</b>	<p>The majority of cases of CSR resolve spontaneously, often within three months of diagnosis, but there is a small cohort of patients for whom symptoms will persist, producing chronic CSR</p> <p>The disease is often unilateral and is self-limiting in about 60% of cases, but sometimes the retinal detachment persists, leading to damage to the RPE and the photoreceptors and resulting in vision loss. Because CSR is so often self-limiting, treatment is reserved for chronic cases: i.e., cases in which the condition persists for 6 months or more or in which long-standing fluid accumulation and retinal separation over a long period are associated with RPE changes.</p> <p>Good visual and anatomic results in chronic CSR have been demonstrated with half-</p>

	<p>dose verteporfin photodynamic therapy (PDT).</p> <p>There is currently no indication for use of standard-fluence PDT in CSR. The consensus of most experts is that reduced-fluence PDT is as effective as standard-fluence PDT, but safer. Moderate to significant choriocapillaris nonperfusion was seen in 44% of eyes treated with standard fluence compared with 0% of eyes treated with reduced fluence. Reduced fluence had the same efficacy as standard fluence, but there was less associated damage to the surrounding healthy choriocapillaris.</p> <p>* Half-dose verteporfin PDT has been studied for chronic CSR. It proved to be much safer than full dose fluence therapy and as effective.</p> <p>* No safety issues have been identified from this off-license use of verteporfin to date.</p>
<b>Effective From</b>	1 <sup>st</sup> November 2019
<b>Policy Review Date</b>	1 <sup>st</sup> November 2021

## Orthopaedic Interventions

<b>Intervention</b>	<b>Arthroscopic Lavage and Debridement</b>
<b>For the treatment of</b>	Osteoarthritis
<b>Commissioning Position</b>	<p>This intervention is NOT routinely commissioned.</p> <p>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.</p> <p>Arthroscopic Lavage and Debridement should not be offered as part of treatment for osteoarthritis, unless:</p> <ul style="list-style-type: none"> <li>• the person has knee osteoarthritis</li> <li>• with a clear history of mechanical locking</li> </ul> <p>Please note, gelling, 'giving way' and X-ray evidence of 'loose' bodies are not sufficient indications for arthroscopic lavage and debridement.</p>
<b>Evidence/Summary of Rationale</b>	<p>Specialist Advisers stated that there is uncertainty about the efficacy of this procedure. They listed the key efficacy outcomes as relief of pain and reduction of mechanical symptoms.</p> <p>A systematic review on arthroscopic washout (lavage) for osteoarthritis of the knee was published in 2003.<sup>10</sup> The review identified five RCTs (one of which was considered to be good quality) and two non-randomised studies. The review concluded from the RCTs that there was no evidence that arthroscopic washout or debridement improves patient-reported pain, function or disability compared with non-arthroscopic treatments</p> <p>A second systematic review was published in 2005.<sup>11</sup> The review identified four RCTs, three of which were included in the previous review; one was a more recent publication. The review concluded that there was insufficient evidence to compare</p>

	the clinical effects of arthroscopic lavage and other treatments for osteoarthritis of the knee. Although none of the trials found a significant effect, small sample sizes and methodological weaknesses made it difficult to conclude that effects were truly absent.
<b>Effective From</b>	1 <sup>st</sup> November 2019
<b>Policy Review Date</b>	1 <sup>st</sup> November 2021

<b>Intervention</b>	<b>Arthroscopic Shoulder Decompression for Subacromial Shoulder Pain</b>
<b>For the treatment of</b>	Subacromial shoulder pain.
<b>Commissioning Position</b>	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.
<b>Evidence/Summary of Rationale</b>	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.
<b>Effective From</b>	1 <sup>st</sup> April 2019
<b>Policy Review Date</b>	1 <sup>st</sup> April 2021

<b>Intervention</b>	<b>Bunion Surgery</b>
<b>For the treatment of</b>	Bunions
<b>Commissioning Position</b>	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: <ul style="list-style-type: none"> <li>• Conservative measures have failed (these include trying accommodative footwear, considering orthoses and using appropriate analgesia.)</li> </ul> AND <ul style="list-style-type: none"> <li>• The patient suffers from severe pain on walking (not relieved by chronic standard analgesia) that causes significant functional impairment</li> </ul> OR <ul style="list-style-type: none"> <li>• Severe deformity (with or without lesser toe deformity) that causes significant functional impairment OR prevents them from finding adequate footwear</li> </ul>

	<p>OR</p> <ul style="list-style-type: none"> <li>Recurrent or chronic ulceration or infection</li> </ul>
<b>Evidence/Summary of Rationale</b>	<p>NICE CKS makes clear that referral for bunion surgery is indicated for pain and is not routinely performed for cosmetic purposes</p> <p>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.</p> <p>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.</p> <p>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.</p> <p>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.</p> <p>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.</p> <p>Untreated HV in patients with diabetes (and other causes of peripheral neuropathy) may lead to ulceration, deep infection and even amputation.</p>
<b>Effective From</b>	1 <sup>st</sup> April 2019
<b>Policy Review Date</b>	1 <sup>st</sup> April 2021

<b>Intervention</b>	<p><b>Carpal Tunnel Syndrome Release</b> Open or endoscopic surgical procedure to release median nerve from carpal tunnel.</p>
<b>For the treatment of</b>	Moderate and Severe cases of Carpal Tunnel Syndrome.
<b>Commissioning Position</b>	<p>This intervention is NOT routinely commissioned.</p> <p>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.</p> <ol style="list-style-type: none"> <li>Mild cases with intermittent symptoms causing little or no interference with sleep or activities require no treatment.</li> <li>Cases with intermittent symptoms which interfere with activities or sleep should first be treated with: <ol style="list-style-type: none"> <li>corticosteroid injection(s) (medication injected into the wrist: good evidence for short (8-12 weeks) term effectiveness)</li> </ol> </li> </ol> <p>Or</p> <ol style="list-style-type: none"> <li>night splints (a support which prevents the wrist from moving during the night: not as effective as steroid injections)</li> </ol>

	<p>3. Surgical treatment of carpal tunnel should be considered if one of the following criteria are met:</p> <p>a) The symptoms significantly interfere with daily activities and sleep symptoms and have not settled to a manageable level with either one local corticosteroid injection and/or nocturnal splinting for a minimum of 8 weeks;</p> <p>Or</p> <p>b) There is either:</p> <p>i. a permanent (ever-present) reduction in sensation in the median nerve distribution, or</p> <p>ii. muscle wasting or weakness of thenar abduction (moving the thumb away from the hand).</p>
<b>Evidence/Summary of Rationale</b>	<p>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.</p> <p>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.</p> <p>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%.</p>
<b>Effective From</b>	1 <sup>st</sup> April 2019
<b>Policy Review Date</b>	1 <sup>st</sup> April 2021

<b>Intervention</b>	<b>Dupuytren's Contracture Release - Adults</b>
<b>For the treatment of</b>	Dupuytren's contracture
<b>Commissioning Position</b>	<p>This intervention is NOT routinely commissioned.</p> <p>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.</p> <p>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.</p>

	<ul style="list-style-type: none"> <li>• An intervention (collagenase injections, needle fasciotomy, fasciectomy and dermofasciectomy) should be considered for either: <ul style="list-style-type: none"> <li>- finger contractures causing loss of finger extension of 30° or more at the metacarpophalangeal joint or 20° at the proximal interphalangeal joint.</li> <li>- severe thumb contractures which interfere with function</li> </ul> </li> <li>• NICE concluded that collagenase should only be used for either: <ul style="list-style-type: none"> <li>- Participants in the ongoing clinical trial (HTA-15/102/04), or</li> <li>- Adult patients with a palpable cord if: <ul style="list-style-type: none"> <li>▪ 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;</li> </ul> </li> </ul> </li> </ul> <p style="text-align: center;">And</p> <ul style="list-style-type: none"> <li>▪ needle fasciotomy is not considered appropriate, but limited fasciectomy is considered appropriate by the treating hand surgeon</li> </ul>
<b>Evidence/Summary of Rationale</b>	<p>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.</p> <p>Common complications after collagenase injection are normally transient and include skin breaks and localised pain. Tendon injury is possible but very rare.</p> <p>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.</p>
<b>Effective From</b>	1 <sup>st</sup> April 2019
<b>Policy Review Date</b>	1 <sup>st</sup> April 2021

<b>Intervention</b>	<b>Facet Joint Injections</b>
<b>For the treatment of</b>	Back Pain
<b>Commissioning Position</b>	<p>This intervention is NOT routinely commissioned.</p> <p>This intervention is a Category One Evidence Based Intervention; therefore, any requests to fund must be made as an Individual Funding Request.</p> <p>Facet Joint Injections will be considered to achieve Medical Branch Blocks as a diagnostic trial to establish the origin of a patient's pain in patients without a clear diagnosis. It is expected patients will be concurrently within tier 2 pain management programme (including physiotherapy, psychosocial support, medication and patient education).</p> <p>Repeat diagnostic or therapeutic facet joint injections are not routinely funded and will also require prior approval.</p> <p><b>Please note:</b></p> <p>The CCG does not routinely commission facet joint blocks for patients with diagnosed chronic persistent non-specific back pain</p>

	Facet Joint Injections will not be commissioned for acute or chronic spinal due to poor evidence, other than in exceptional clinical circumstances as per NICE CG88.
<b>Evidence/Summary of Rationale</b>	<p>The published evidence is adequate to support the therapeutic use of facet joint injections and medial branch blocks for chronic low back or neck pain. There is evidence from three published systematic reviews and one RCT that facet joint injections / medial branch blocks do not produce long-term benefits in chronic back or neck pain in terms of employment status or pain.</p> <p>There are no published cost-effectiveness studies of facet joint injections. The NICE clinical guideline on low back pain (CG88) recommends that injection therapy should not be offered for back pain lasting greater than 6 weeks and less than 1 year.</p>
<b>Effective From</b>	1 <sup>st</sup> November 2019
<b>Policy Review Date</b>	1 <sup>st</sup> November 2021

<b>Intervention</b>	<b>Ganglion – Surgical Excision</b>
<b>For the treatment of</b>	Ganglions
<b>Commissioning Position</b>	<p>This intervention is NOT routinely commissioned.</p> <p>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.</p> <p>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.</p> <p>Surgical intervention should be considered if:</p> <ul style="list-style-type: none"> <li>• Aspiration fails to resolve pain or tingling/numbness, and there is restricted hand function.</li> <li>• The ganglion persists or recurs after puncture/aspiration</li> <li>• There is recurrent spontaneous discharge of fluid or significant nail deformity.</li> </ul>
<b>Evidence/Summary of Rationale</b>	<p>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.</p> <p>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.</p> <p>Complication and recurrence are rare after aspiration and surgery for seed ganglia.</p> <p>Evidence-Based Interventions (2008)</p>
<b>Effective From</b>	1 <sup>st</sup> April 2019
<b>Policy Review Date</b>	1 <sup>st</sup> April 2021



<b>Intervention</b>	<b>Hip Arthroscopy</b>
<b>For the treatment of</b>	Diagnostic and Therapeutic Arthroscopy – Hip
<b>Commissioning Position</b>	<p>This intervention is NOT routinely commissioned.</p> <p>This intervention is a Category One Evidence Based Intervention; therefore, any requests to fund must be made as an Individual Funding Request</p> <p>The CCG does not currently commission hip arthroscopy on a routine basis other than where patients are shown to fulfil ALL the following criteria:</p> <ul style="list-style-type: none"> <li>• 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)</li> <li>• 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</li> <li>• 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)</li> <li>• Failure to respond to conservative treatment including activity modification, specialist physiotherapy and maximal pharmacological interventions for a period of 6 months</li> <li>• Treatment with hip replacement, resurfacing or other more established procedure is not clinically viable</li> <li>• Patient is aged between 18 and 50 years (clinical experience has shown that these patients are likely to gain the greatest benefit).</li> </ul> <p>Hip arthroscopy is not routinely funded for patients with the following conditions:</p> <ul style="list-style-type: none"> <li>• Patients with advanced degenerative OA on a preoperative X-ray (Tonnis grade 2 or more) or severe cartilage injury (Outerbridge grade III or IV).</li> <li>• Patients with joint space on plain radiograph of the pelvis that is less than 2mm wide anywhere along the sourcil.</li> <li>• Patients who are candidates for total hip replacements.</li> <li>• Patients who have hip dysplasia or considerable protrusion</li> <li>• Patients with osteonecrosis with femoral head collapse</li> <li>• Patients with grade III or IV heterotopic bone formation</li> <li>• Patients with sepsis and accompanying osteomyelitis or abscess formation</li> <li>• Patients with joint ankylosis</li> <li>• Patients with generalised joint laxity syndromes associated with hypermobility of the joints such as Marfan and Ehlers-Danlos syndromes</li> <li>• Patients with osteogenesis imperfecta</li> </ul>
<b>Evidence/Summary of Rationale</b>	<p>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:</p> <p>‘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’.</p>

	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.
<b>Effective From</b>	1 <sup>st</sup> April 2019
<b>Policy Review Date</b>	1 <sup>st</sup> April 2021

<b>Intervention</b>	<b>Hyaluronic Acid Injections for Musculoskeletal Joint Pain (Synvisc)</b>
<b>For the treatment of</b>	Musculoskeletal Joint Pain
<b>Commissioning Position</b>	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.
<b>Evidence/Summary of Rationale</b>	<p>The NICE Clinical Guideline 177: Osteoarthritis considered the clinical and cost effectiveness of hyaluronic injections in the management of Osteoarthritis in the knee, ankle, big toe and hip, although the vast majority of data relates to the knee. NICE considered trials including licenced and unlicensed preparations, and trials that compared hyaluronic acid injections with placebo, usual treatment, steroid injections, and another hyaluronan. Outcomes considered included joint pain, quality of life (QOL), and adverse events. No relevant economic evaluations were identified and therefore not included in the NICE guideline.</p> <p><b>Knee OA</b></p> <p>A clinically important reduction in pain compared to placebo was demonstrated for two licenced products, however, all these effects were surrounded by uncertainty and the quality of the trials ranged from low to very low. There was no evidence of improved QOL available and two licenced products demonstrated higher rates of adverse effects versus placebo.</p> <p><b>Hip OA</b></p> <p>No clinically important difference was demonstrated over placebo on any pain scale. No QOL data was available and higher rates of adverse effects were demonstrated versus placebo</p> <p><b>Ankle OA</b></p> <p>There was very limited data available and the quality of the data that was available ranged from low to very low.</p> <p><b>Base of Thumb OA</b></p> <p>The data available suggests no clinically important difference in adverse events versus placebo.</p>
<b>Effective From</b>	1 <sup>st</sup> November 2019
<b>Policy Review Date</b>	1 <sup>st</sup> November 2021

<b>Intervention</b>	<b>Ilizarov Technique/Taylor Spatial Frame (TSF)</b>
<b>For the treatment of</b>	Non-union/mal-union of bones, shortened limb, long bone deformities
<b>Commissioning Position</b>	<p>Ilizarov Frames is NOT routinely commissioned where limb lengthening alone is the desired outcome as this would be deemed cosmetic and not medically necessary.</p> <p>This intervention is a Category One Evidence Based Intervention; therefore, any requests to fund must be made as an Individual Funding Request.</p> <p>However, the use of the Ilizarov technique/TSFs will be routinely commissioned for routine elective use in orthopaedics in:</p> <ul style="list-style-type: none"> <li>• individual carefully selected cases,</li> <li>• 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).</li> <li>• the patient understands the long duration of external fixation, the likelihood of marked discomfort and possible complications</li> <li>• the patient has been a non-smoker for at least 4 weeks</li> <li>• Ideally, the MDT should comprise at least two consultant orthopaedic surgeons, with input from specialist nursing, physiotherapy and musculoskeletal radiology.</li> </ul> <p>Cases that will be routinely commissioned after approval by the MDT include the following:</p> <ul style="list-style-type: none"> <li>• 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 ).</li> <li>• 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.</li> </ul> <p>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.</p>
<b>Evidence/Summary of Rationale</b>	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
<b>Effective From</b>	1 <sup>st</sup> April 2019
<b>Policy Review Date</b>	1 <sup>st</sup> April 2021

<b>Intervention</b>	<b>Knee Arthroscopy - Osteoarthritis</b>
<b>For the treatment of</b>	Patients with osteoarthritis.
<b>Commissioning Position</b>	<p>This intervention is NOT routinely commissioned.</p> <p>This intervention is a Category One Evidence Based Intervention; therefore, any</p>

	requests to fund must be made as an Individual Funding Request.
<b>Evidence/Summary of Rationale</b>	<p>Arthroscopic knee washout (lavage and debridement) should not be used as a treatment for osteoarthritis because it is clinically ineffective.</p> <p>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.</p> <p>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.</p> <p>Evidence-Based Interventions: Guidance for CCG's 2018.</p>
<b>Effective From</b>	1 <sup>st</sup> April 2019
<b>Policy Review Date</b>	1 <sup>st</sup> April 2021

<b>Intervention</b>	<b>Trigger Finger/Thumb Surgery (Adults)</b>
<b>For the treatment of</b>	Stenosing Tenosynovitis (Trigger/Thumb Finger) in Adults
<b>Commissioning Position</b>	<p>This intervention is NOT routinely commissioned.</p> <p>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.</p> <p>Mild cases that cause no loss of function require no treatment or avoidance of activities that precipitate triggering and may resolve spontaneously.</p> <p>Cases interfering with activities or causing pain should be first treated with:</p> <ul style="list-style-type: none"> <li>• One or two steroid injections</li> <li>• Splinting of the affected finger for 3-12 weeks</li> </ul> <p>Surgery should be considered if any one of the below occurs:</p> <ul style="list-style-type: none"> <li>• The triggering persists or recurs after one of the above conservative measures</li> <li>• The finger is permanently locked in the palm</li> <li>• The patient has previously had 2 other trigger digits unsuccessfully treated with appropriate non-operative methods</li> <li>• The patient is diabetic</li> </ul>
<b>Evidence/Summary of Rationale</b>	<p>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.</p> <p>Recovery after surgery takes 2-4 weeks. Problems sometimes occur after surgery, but these are rare (35).</p> <p>Evidence-Based Interventions: Guidance for CCG's 2018.</p>
<b>Effective From</b>	1 <sup>st</sup> April 2019

<b>Policy Review Date</b>	1 <sup>st</sup> April 2021
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## Other

<b>Intervention</b>	<b>Any medical procedure or treatment NOT routinely commissioned where there is not a specific policy statement</b>
<b>For the treatment of</b>	Clinical Health indications requiring medical intervention
<b>Commissioning Position</b>	<p>This policy is in place to enable clinicians to make a Category One Individual Funding Request where the referring clinician identifies a clinical need to recommend an intervention for their patient.</p> <p>The referring clinician must provide a reasoned application for the request, outlining why the intervention is indicated, how the intervention meets the evidence-base (Including or not limited to; NICE and Royal College Guidance) and the intended/predicted benefits/outcome for the patient if they receive the treatment.</p>
<b>Effective From</b>	1 <sup>st</sup> November 2019
<b>Policy Review Date</b>	1 <sup>st</sup> November 2021

<b>Intervention</b>	<b>Open and Wide-Bore Magnetic Resonance Imaging (MRI) Scanning</b>
<b>Commissioning Position</b>	<p>This intervention is NOT routinely commissioned.</p> <p>This intervention is a Category One Evidence Based Intervention; therefore, any requests to fund must be made as an Individual Funding Request.</p> <p>Standing, upright, weight-bearing or positional MRI are not routinely commissioned.</p> <p>Urgent open MRI requests in cases with red flag symptoms or signs should be made urgently by the referring clinician directly to the commissioned provider and are excluded from this policy.</p> <p>Referral for open or wide-bore MRI scanning as an alternative to conventional MRI in secondary care is commissioned only for the specific anatomy requested where:</p> <ul style="list-style-type: none"> <li>• There is a clear diagnostic need consistent with supported clinical pathways</li> <li>• The purpose of the scan is a last resort to exclude larger lesions if this is clinically relevant in the brain and spine. Peripheral body parts will not normally be considered for upright MRI unless at the specific request of an acute consultant who believes this is essential to clinical management due to failed trial of single body part MRI.</li> </ul> <p><b>AND the patient falls within one of the categories below:</b></p> <p><b>1. Claustrophobia</b></p> <p>Patients who are unable to tolerate conventional MRI due to claustrophobia despite:</p> <ul style="list-style-type: none"> <li>• Conservative management of anxiety (including noise-cancelling headphones, visual aids and scanning feet first)</li> <li>• Where oral prescription sedative has not been effective or is clinically</li> </ul>

	<p>contraindicated.</p> <ul style="list-style-type: none"> <li>• IV sedation can be tried if suitably qualified staff is available to administer it.</li> </ul> <p>Scanning using general anaesthesia should only be undertaken where:</p> <ul style="list-style-type: none"> <li>• The patient has an underlying condition e.g. a movement disorder - that prevents them from remaining still in the scanner (whatever the type being used)</li> </ul> <p><b>OR</b></p> <ul style="list-style-type: none"> <li>• It is considered essential for the clinical management of the patient and no alternative is available.</li> </ul> <p><b>AND</b></p> <ul style="list-style-type: none"> <li>• All other options to attain a scan have been tried and failed</li> </ul> <p><b>2. Obesity</b></p> <p>Patients who cannot fit into a standard scanner due to obesity should be referred to an NHS provider with a wide bore scanner in the first instance.</p> <p>If the patient is unsuitable for a wide bore scanner, for example if also claustrophobic or unable to lie flat due to extreme pain, they should be referred for an open scan at an NHS provider.</p> <p><b>3. Non-standard MRI Clinically Indicated</b></p> <ul style="list-style-type: none"> <li>• If an upright scan is required for clinical reasons then patients may be referred to an NHS provider) with an open upright scanner.</li> </ul> <p>If a patient is unable to lie flat for the duration of the scan for medical reasons, including extreme pain or with debilitating symptoms which are thought to be due to weight bearing pathology, where previous conventional MRI has shown no pathology, they may be referred for an open upright scan at an NHS provider.</p>
<p><b>Evidence/Summary of Rationale</b></p>	<p>A Closed MRI scan often involves a cylinder-shaped scanner that is uncomfortable for larger patients and leaves some patients claustrophobic.</p> <p>For many patients Open MRI minimizes anxiety and claustrophobia because its 'C' shaped design offers a spacious environment in which patients lie between two plates. They are also used for intraoperative imaging or image guided interventions where easy access to the patient is required.</p> <p>The main drawbacks of Open MRI are that the sequences needed (length of time to get an image) are longer, the signal-to-noise ratio is lower, and the spatial resolution is poorer. Consequently, for the analysis of small structures such as joints (wrists, fingers and toes), Closed MRI is always recommended because the quality and detail of the image will be superior. Also, the field strength of open magnets is significantly reduced and may be inadequate for some scanning purposes.</p> <p>Furthermore, the increasing number of overweight and obese patients produces more problems for high-field MRI units. A third advantage of low field MRI is that the images obtained are affected to a much lesser degree by metallic structures that may be present in the body such as pins in the spine, implants or even shrapnel.</p> <p>Open MRI has become the standard of care when conventional design is</p>

	<p>contraindicated. Specifically, this includes patients who would require sedation for a conventional MRI such as severely claustrophobic or paediatric patients.</p> <p>Evidence for the benefit of open MRI in patients with claustrophobia is mixed and there are no comparative diagnostic studies of open/upright MRI compared with standard MRI showing an advantage for diagnosing weight-bearing pathology. Therefore, since the cost of open/upright MRI is considerably higher than for standard MRI, these will only be funded where a patient is unable to undergo a standard MRI or where there is a case for exceptionality.</p> <p><u>Standing, Weight-Bearing, Positional, or Upright MRI</u></p> <ul style="list-style-type: none"> <li>• There is limited scientific data available on the accuracy and diagnostic utility of standing, upright, weight-bearing or positional MRI</li> <li>• There is no evidence from well-designed clinical trials demonstrating the accuracy or effectiveness of weight-bearing MRI for specific conditions or patient populations</li> <li>• There is a lack of evidence addressing diagnostic accuracy or diagnostic utility, standing or weight-bearing.</li> </ul> <p><u>Wide Bore MRIs</u></p> <p>These can manage patients up to 550lbs in weight (patients with a lower weight but an increased girth may not be suitable – please be aware of the girth limitation prior to referral).</p> <p>With high-field, wide-bore MRIs, the extra-wide bore architecture makes it comfortable for patients of all sizes (up to 550lbs/ 39st 4lbs / approx. 249.47kg). The diameter of the bore is 27.5 inches / approx. 69.85cm versus 23.5 inches / approx. 59.69cm; allowing typical patients 1 foot of headroom and more elbowroom.</p>
<b>Effective From</b>	1 <sup>st</sup> November 2019
<b>Policy Review Date</b>	1 <sup>st</sup> November 2021

## Plastic Surgery Interventions

<b>Intervention</b>	<b>Abdominoplasty / Apronectomy</b>
<b>For the treatment of</b>	Excess Skin
<b>Commissioning Position</b>	<p>This intervention is NOT routinely commissioned.</p> <p>This intervention is a Category One Evidence Based Intervention; therefore, any requests to fund must be made as an Individual Funding Request.</p> <p>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.</p> <p>Abdominoplasty / Apronectomy have minimum criteria for the procedure as follows</p> <ul style="list-style-type: none"> <li>• patients who have had a stable BMI of 25 Kg/m<sup>2</sup> or below for at least 2 years</li> </ul>

	<p>and are suffering from severe functional problems</p> <p>OR</p> <ul style="list-style-type: none"> <li>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</li> </ul> <p>Severe functional problems include experiencing severe difficulties with mobility</p>
<b>Evidence/Summary of Rationale</b>	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.
<b>Effective From</b>	1 <sup>st</sup> April 2019
<b>Policy Review Date</b>	1 <sup>st</sup> April 2021

<b>Intervention</b>	<b>Blepharoplasty</b>
<b>For the treatment of</b>	Excess skin on eyelid
<b>Commissioning Position</b>	<p>This intervention is NOT routinely commissioned.</p> <p>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.</p> <p>Removal of excess skin from the upper or lower lid should be considered where:</p> <ul style="list-style-type: none"> <li>It is causing significant functional impairment in the patient's ability to open and close the eyelid</li> </ul> <p>OR</p> <ul style="list-style-type: none"> <li>It is causing significant visual impairment, evidenced by provision of visual fields test and clinical photographs</li> </ul> <p>Requests for removal of excess skin from the lower lid may additionally be considered for the correction of entropion or ectropion</p>
<b>Evidence/Summary of Rationale</b>	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.
<b>Effective From</b>	1 <sup>st</sup> April 2019
<b>Policy Review Date</b>	1 <sup>st</sup> April 2021

<b>Intervention</b>	<b>Breast Correctional Surgery - Asymmetry</b>
<b>For the treatment of</b>	Adults with Breast Asymmetry
<b>Commissioning Position</b>	<p>This intervention is NOT routinely commissioned.</p> <p>This intervention is a Category One Evidence Based Intervention; therefore, any requests to fund must be made as an Individual Funding Request.</p> <p>Requests will only be considered via the IFR process in women meet the following criteria:</p>



	<ul style="list-style-type: none"> <li>• BMI is within the range 18-25</li> <li>• 18 years of age or older</li> <li>• sternal notch to nipple difference of 4cm or more</li> <li>• infra-mammary fold to nipple for each breast 30% or more</li> <li>• 30% or more difference in volume</li> <li>• Significant difference in nipple areola diameter of 50% or more</li> </ul> <p>*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.</p>
<b>Evidence/Summary of Rationale</b>	Information for commissioners of Plastic Surgery - referrals and guidelines in Plastic Surgery <i>Modernisation Agency (Action on Plastic Surgery)</i>
<b>Effective From</b>	1 <sup>st</sup> April 2019
<b>Policy Review Date</b>	1 <sup>st</sup> April 2021

<b>Intervention</b>	<b>Breast Enlargement Surgery</b>
<b>For the treatment of</b>	Adults with Amastia or Congenital abnormalities related to Breast Development
<b>Commissioning Position</b>	<p>This intervention is NOT routinely commissioned.</p> <p>This intervention is a Category One Evidence Based Intervention; therefore, any requests to fund must be made as an Individual Funding Request.</p> <p>Requests will only be considered via the IFR process in women meet the following criteria:</p> <ul style="list-style-type: none"> <li>• 18 years of age of older</li> <li>• BMI is within the range 18-25</li> </ul> <p>AND</p> <ul style="list-style-type: none"> <li>• certain congenital abnormalities such as Poland's syndrome, constricted tubular breast, pectus deformity, or chest wall asymmetry associated with scoliosis</li> </ul> <p>OR</p> <ul style="list-style-type: none"> <li>• a complete absence of breast tissue (Amastia) in one or both breasts is causing severe functional or medical problems.</li> </ul>
<b>Evidence/Summary of Rationale</b>	<p>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.</p> <p>Information for commissioners of Plastic Surgery - referrals and guidelines in Plastic Surgery <i>Modernisation Agency (Action on Plastic Surgery)</i></p>
<b>Effective From</b>	1 <sup>st</sup> April 2019
<b>Policy Review Date</b>	1 <sup>st</sup> April 2021

<b>Intervention</b>	<b>Breast Reduction Surgery</b>
<b>For the treatment of</b>	Women with breast hyperplasia (enlargement), where breasts are large enough to

	<p>cause problems like shoulder girdle dysfunction, intertrigo and adverse effects to quality of life.</p>
<p><b>Commissioning Position</b></p>	<p>This intervention is NOT routinely commissioned.</p> <p>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.</p> <p>Surgery will not be funded for cosmetic reasons. The NHS will only consider breast reduction for women if all the following criteria are met:</p> <ul style="list-style-type: none"> <li>• The woman has received a full package of supportive care from their GP such as advice on weight loss and managing pain.</li> <li>• In cases of thoracic/ shoulder girdle discomfort, a physiotherapy assessment has been provided</li> <li>• 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).</li> <li>• Breast reduction planned to be 500gms or more per breast or at least 4 cup sizes.</li> <li>• Body mass index (BMI) is &lt;27 and stable for at least twelve months.</li> <li>• Woman must be provided with written information to allow her to balance the risks and benefits of breast surgery.</li> <li>• Women should be informed that smoking increases complications following breast reduction surgery and should be advised to stop smoking.</li> <li>• Women should be informed that breast surgery for hypermastia can cause permanent loss of lactation.</li> </ul> <p>*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.</p> <p>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.</p> <p>Resection weights, for bilateral or unilateral (both breasts or one breast) breast reduction should be recorded for audit purposes.</p> <p>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.</p>
<p><b>Evidence/Summary of Rationale</b></p>	<p>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.</p>

	Evidence-Based Interventions: Guidance for CCG's 2018.
<b>Effective From</b>	1 <sup>ST</sup> April 2019
<b>Policy Review Date</b>	1 <sup>ST</sup> April 2021

<b>Intervention</b>	<b>Breast Revisional Surgery (prosthesis removal)</b>
<b>For the treatment of</b>	Clinical complications related to Breast Implants
<b>Commissioning Position</b>	<p>This intervention is NOT routinely commissioned.</p> <p>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.</p> <p>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:</p> <ul style="list-style-type: none"> <li>• Breast disease</li> <li>• Implants complicated by severe recurrent infections</li> <li>• Implants with grade 4 capsule formation that is associated with severe pain</li> <li>• Implants with capsule formation that interferes with mammography</li> <li>• Intra or extra capsular rupture of silicone gel filled implants</li> <li>• Implant is a PiP implant</li> </ul> <p>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.</p> <p>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.</p>
<b>Evidence/Summary of Rationale</b>	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.
<b>Effective From</b>	1 <sup>ST</sup> April 2019
<b>Policy Review Date</b>	1 <sup>ST</sup> April 2021

<b>Intervention</b>	<b>Replacement of Breast Implants</b>
<b>For the treatment of</b>	Implant removal due to clinical need
<b>Commissioning Position</b>	<p>This intervention is NOT routinely commissioned.</p> <p>This intervention is a Category One Evidence Based Intervention; therefore, any requests to fund must be made as an Individual Funding Request.</p> <p>Replacement of implants will only be considered under exceptional clinical circumstances. Requests for funding under this circumstance will need to be</p>

	<p>approved by the IFR Panel.</p> <p>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)</p> <p>The replacement of breast implants for patients whose original surgery was paid for on a privately funded basis is NOT commissioned.</p>
<b>Evidence/Summary of Rationale</b>	<p>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.</p>
<b>Effective From</b>	1 <sup>ST</sup> April 2019
<b>Policy Review Date</b>	1 <sup>ST</sup> April 2021

<b>Intervention</b>	<b>Cleft Earlobe Surgery</b>
<b>For the treatment of</b>	Acquired earlobe clefts
<b>Commissioning Position</b>	<p>This intervention is NOT routinely commissioned.</p> <p>This intervention is a Category One Evidence Based Intervention; therefore, any requests to fund must be made as an Individual Funding Request.</p> <p>Requests from secondary care consultants to commission surgical repair of rare cases of congenital cleft earlobes will be considered if clinical evidence of exceptionality is provided.</p> <p>The surgical repair of acquired ear lobe clefts is not routinely funded because this is considered a cosmetic procedure. This indication includes:</p> <ul style="list-style-type: none"> <li>• partially split lobes (i.e. where the split does not reach the edge of the lobe);</li> <li>• elongated holes in lobes;</li> <li>• a split that recurs after a previously repaired earlobe has been pierced.</li> </ul> <p>Please note the immediate surgical repair of completely split ear lobes that have occurred as a result of direct trauma or violence is routinely commissioned.</p>
<b>Evidence/Summary of Rationale</b>	<p>Torn earlobes may be classified as either a complete or partial cleft. Acquired clefts or splitting of the earlobe commonly occurs after prolonged traction from wearing excessively heavy earrings, with insufficient tissue to support them, so that the earring slowly “cheese-wires” through the lobe. The repair of this type of split earlobe is not always successful and is a site where poor scar formation is a recognised risk. In rare cases, splits can also occur from pressure necrosis from clip-on earrings. These clefts are most commonly incomplete; however, complete clefts are also common. Bleeding is minimal, and the defect edges heal with little scar formation except when keloids occur. However, most people seek quick repair so they can once again wear earrings. The low grade evidence base reported on techniques used to treat patients with torn ear lobes. There was a lack of evidence both on the outcomes of the repair of torn earlobes as well as the associated complications, for example the risk of scarring. Although high success rates are reported, the study numbers are small, leading to a higher risk of confounding and</p>

	bias
<b>Effective From</b>	1 <sup>st</sup> November 2019
<b>Policy Review Date</b>	1 <sup>st</sup> November 2021

<b>Intervention</b>	<b>Face, Neck and Brow Lifts</b>
<b>For the treatment of</b>	Cosmetic Indications
<b>Commissioning Position</b>	<p>This intervention is NOT routinely commissioned.</p> <p>This intervention is a Category One Evidence Based Intervention; therefore, any requests to fund must be made as an Individual Funding Request.</p> <p>A face, neck or brow lift will only be considered on clinical grounds when any of the following circumstances apply:</p> <ul style="list-style-type: none"> <li>• corrective surgery for structural or soft tissue anatomical anomaly resulting from a congenital or acquired pathological condition;</li> <li>• following extensive facial scarring;</li> <li>• correction of facial nerve palsy or facial paralysis (congenital or acquired);</li> <li>• the correction of the consequences of trauma; the treatment of specific conditions affecting facial skin (e.g. cutis laxa, pseudoxanthoma elasticum, neurofibromatosis);</li> <li>• to correct deformity following NHS surgery.</li> </ul> <p>Face/neck/brow lifts for cosmetic reasons or to treat the natural process of ageing will not be commissioned.</p>
<b>Evidence/Summary of Rationale</b>	<p>These surgical procedures are performed to lift the loose skin of the face and forehead to achieve a firmer and smoother appearance. Guidance (Ref:1) on commissioning states the rationale is that “there are many changes to the face and brow as a result of ageing that may be considered normal, however, there are a number of specific conditions for which these procedures may form part of the treatment to restore appearance and function.”</p>
<b>Effective From</b>	1 <sup>st</sup> November 2019
<b>Policy Review Date</b>	1 <sup>st</sup> November 2021

<b>Intervention</b>	<b>Gynaecomastia Surgery</b>
<b>For the treatment of</b>	Adult Males with excess Breast Tissue
<b>Commissioning Position</b>	<p>This intervention is NOT routinely commissioned.</p> <p>This intervention is a Category One Evidence Based Intervention; therefore, any requests to fund must be made as an Individual Funding Request.</p> <p>If there are red flag symptoms for suspecting possible underlying breast malignancy, this must be excluded prior to applying through the IFR process.</p> <p>Requests will only be considered via the IFR process in adult males that meet all of the following criteria:</p> <ul style="list-style-type: none"> <li>• True Gynaecomastia has been diagnosed (i.e. true breast tissue is present not just adipose tissue - pseudogynaecomastia), and is causing gross breast</li> </ul>

	<p>enlargement, confirmed at grade 3 or 4;</p> <ul style="list-style-type: none"> <li>• Evidence that treating an underlying cause (e.g. endocrine or drug related), where known, has not resolved the problem;</li> <li>• BMI is 30 or below</li> <li>• The BMI has been stable for at least 2 years</li> <li>• There is clear evidence of clinical need (such as significant pain) that has remained unresolved despite usual medical treatment.</li> <li>• if aged &lt; 20, a clinical view of whether full body maturity has been reached</li> <li>• 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.</li> </ul>
<b>Evidence/Summary of Rationale</b>	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
<b>Effective From</b>	1 <sup>ST</sup> April 2019
<b>Policy Review Date</b>	1 <sup>st</sup> April 2021

<b>Intervention</b>	<b>Liposuction – Lipoedema</b>
<b>For the treatment of</b>	Lipoedema
<b>Commissioning Position</b>	<p>This intervention is NOT routinely commissioned.</p> <p>This intervention is a Category One Evidence Based Intervention; therefore, any requests to fund must be made as an Individual Funding Request.</p> <p>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.</p> <p>Clinical evidence will be considered where there is clear demonstration of exceptional effect on functionality of the activities of daily living.</p>
<b>Evidence/Summary of Rationale</b>	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.
<b>Effective From</b>	1 <sup>ST</sup> April 2019
<b>Policy Review Date</b>	1 <sup>st</sup> April 2021

<b>Intervention</b>	<b>Pinnaplasty</b>
<b>For the treatment of</b>	Prominent ears.
<b>Commissioning Position</b>	<p>This intervention is NOT routinely commissioned.</p> <p>This intervention is a Category One Evidence Based Intervention; therefore, any requests to fund must be made as an Individual Funding Request.</p> <p>To be eligible for consideration of funding <b>ALL</b> the following criteria must apply:</p> <ul style="list-style-type: none"> <li>• The patient must be 5 or more but under the age of 19 years at the time of</li> </ul>

	<p>referral.</p> <ul style="list-style-type: none"> <li>• Where the Child is deemed Fraser Competent the child, rather than the parent alone, expresses concern about the prominent ears.</li> <li>• 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.</li> <li>• 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. (e.g. dealing with bullying).</li> <li>• 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.</li> </ul> <p>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.</p> <p>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.</p>
<b>Evidence/Summary of Rationale</b>	<p>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.</p> <p>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.</p> <p>Requests on the grounds of clinical exceptionality would need to include evidence that such support has been obtained and fully utilised.</p> <p>The national service framework for children defines childhood as ending at 19 years.</p> <p>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.</p>
<b>Effective From</b>	1 <sup>ST</sup> April 2019
<b>Policy Review Date</b>	1 <sup>ST</sup> April 2021

<b>Intervention</b>	<b>Scar Revision and Skin Resurfacing</b>
<b>For the treatment of</b>	Scars
<b>Commissioning Position</b>	<p>This intervention is NOT routinely commissioned.</p> <p>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.</p>

	<p>The CCG will routinely commission scar revision surgery only in patients where ALL of the following criteria apply:</p> <ul style="list-style-type: none"> <li>• The scarring is a consequence of previous NHS surgery, burns or trauma;</li> </ul> <p><b>and</b></p> <ul style="list-style-type: none"> <li>• The scarring is causing adverse physical consequences (due to contraction, tethering or recurrent breakdown); significant functional impairment (for example obstruction of orifice or vision); bleeding or suspicion of malignancy;</li> </ul> <p><b>and</b></p> <ul style="list-style-type: none"> <li>• Where clinically appropriate, proactive conservative therapies (steroid injections, vitamin E creams, silicone therapy, pressure garments, medication or massage) aimed at arresting the development of adverse, keloid or hypertrophic scarring have been tried but have not been effective;</li> </ul> <p><b>and</b></p> <ul style="list-style-type: none"> <li>• At least 18 months of the natural healing process has passed.</li> </ul> <p>Where revision surgery is required in patients whose circumstances do not quite meet the above criteria, the secondary care Consultant must seek approval from the CCG via the IFR process.</p> <p>The CCG will not routinely commission scar therapy or surgery, including skin resurfacing, in secondary care for any of the categories listed below:</p> <ul style="list-style-type: none"> <li>• Hypertrophic or keloid scars that are not causing adverse consequences or functional impairments (e.g. keloid scarring after ear piercing)</li> <li>• Scarring / ulceration from chronic tattoo breakdowns</li> <li>• Post-acne scarring</li> <li>• Scars resulting from self-harm</li> <li>• Scar treatment for skin rejuvenation or other cosmetic purposes</li> </ul> <p>In these cases, individual requests for scar treatment / revision must come from primary care, and if approved via the IFR process this would allow referral to secondary care to assess and/or treat as clinically appropriate, including surgery.</p> <p>All IFR requests for scar revision must include details of the cause, appearance, size and location of the scarring (clinical photographs may help); the outcome of any previous conservative therapies and the extent and nature of the adverse effects that the scarring is causing to the individual.</p>
<b>Evidence/Summary of Rationale</b>	In line with the Modernisation Agency guidelines for Plastic Surgery, surgery undertaken exclusively to improve appearance is excluded from NHS provision in the absence of previous trauma, disease or congenital deformity.
<b>Effective From</b>	1 <sup>st</sup> November 2019
<b>Policy Review Date</b>	1 <sup>st</sup> November 2021



<b>Intervention</b>	<b>Surgical Fillers</b>
<b>For the treatment of</b>	Various Indications
<b>Commissioning Position</b>	<p>This intervention is NOT routinely commissioned.</p> <p>This intervention is a Category One Evidence Based Intervention; therefore, any requests to fund must be made as an Individual Funding Request.</p> <p>Surgical fillers for any indication that may be deemed as a cosmetic procedure is not routinely commissioned. This commissioning position applies to the use of both natural (e.g. fat, dermis) and synthetic fillers (temporary or permanent) including hyaluronic acid fillers and collagen.</p> <p>In addition, the treatment of complications arising from the cosmetic use of surgical fillers in private practice is not routinely commissioned.</p> <p>The use of surgical fillers will be routinely commissioned in cases of clinical need, such as:</p> <ul style="list-style-type: none"> <li>• in post-trauma cases;</li> <li>• as part of planned reconstructive surgery ;</li> <li>• to treat rare cases of acquired or congenital facial asymmetry or hemi-facial atrophy.</li> </ul>
<b>Evidence/Summary of Rationale</b>	<p>Cosmetic or Aesthetic Plastic Surgery is defined as elective surgery designed to alter and enhance a patient's physical appearance, with the objective of bringing about an improvement in appearance rather than to treat disease. Surgical Fillers are widely used in cosmetic surgery, for the treatment of wrinkles and skin aging, to improve the appearance of scars and for augmenting the volume of soft tissue such as in the lips.</p>
<b>Effective From</b>	1 <sup>st</sup> November 2019
<b>Policy Review Date</b>	1 <sup>st</sup> November 2021

## Respiratory Interventions

<b>Intervention</b>	<b>Sleep Study</b>
<b>For the treatment of</b>	Referral to secondary care sleep medicine services for assessment (e.g. via home-based overnight sleep study) of
<b>Commissioning Position</b>	<p>This intervention is NOT routinely commissioned.</p> <p>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.</p> <p>Requests for approval for referral for Sleep studies should be based on any of the following criteria:</p> <ul style="list-style-type: none"> <li>• Patient has symptoms of excessive daytime sleepiness (EDS) that score &gt;10 on the Epworth Sleepiness Score (ESS) combined with objective clinical judgement that indicates need for referral</li> <li>• Patient displays symptoms of chronic snoring as well as witness apnoeic</li> </ul>

	<p>episodes or daytime sleepiness with a score of &gt;10 on the Epworth Sleepiness Score (ESS)</p> <ul style="list-style-type: none"> <li>• Sleepiness in dangerous situations, even with a normal ESS score, in combination with symptoms associated with obstructive sleep apnoea/hypopnoea</li> <li>• Excessive daytime sleepiness, despite a normal time in bed at night, which may interfere with his/her driving ability/occupation</li> </ul> <p>Conservative management addressing lifestyle factors such as weight reduction, smoking and alcohol intake should commence at the earliest opportunity.</p> <p>It is a legal requirement on every driver not to drive when their ability to drive safely is impaired, including when they are tired.</p> <p>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.</p>
<b>Evidence/Summary of Rationale</b>	<p>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.</p>
<b>Effective From</b>	1 <sup>st</sup> April 2019
<b>Policy Review Date</b>	1 <sup>st</sup> April 2021

<b>Intervention</b>	<b>Trial of Continuous Positive Airway Pressure (CPAP) for Obstructive Sleep Apnoea</b>
<b>For the treatment of</b>	Sleep Apnoea
<b>Commissioning Position</b>	<p>This intervention is NOT routinely commissioned.</p> <p>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.</p> <p>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:</p> <ul style="list-style-type: none"> <li>• Diagnosis of moderate/severe OSAHS, confirmed by sleep study where appropriate, indicating at least 15 episodes per hour of sleep</li> <li>• OSAHS is interfering significantly with activities of daily living</li> <li>• 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.</li> </ul> <p>Conservative management addressing lifestyle factors such as weight reduction,</p>

	<p>smoking and alcohol intake should continue.</p> <p>It is a legal requirement on every driver not to drive when their ability to drive safely is impaired, including when they are tired.</p> <p>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.</p>
<b>Evidence/Summary of Rationale</b>	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).
<b>Effective From</b>	1 <sup>st</sup> April 2019
<b>Policy Review Date</b>	1 <sup>st</sup> April 2021

<b>Intervention</b>	<b>Continued Continuous Positive Airway Pressure (CPAP) for Obstructive Sleep Apnoea</b>
<b>For the treatment of</b>	Sleep Apnoea
<b>Commissioning Position</b>	<p>This intervention is NOT routinely commissioned.</p> <p>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.</p> <p>Treatment continuation will only be commissioned for patients where the following criteria are met:</p> <ul style="list-style-type: none"> <li>• During the trial period the patient utilised the device in excess of 70% of nights.</li> <li>• During the trial period the patient utilised the device on average in excess of 4 hours per night.</li> <li>• The trial outcome has clinically indicated that the patient is benefitting from the device. There is improvement in their AHI or Epworth Scores.</li> </ul> <p>It is a legal requirement on every driver not to drive when their ability to drive safely is impaired, including when they are tired.</p> <p>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.</p>
<b>Evidence/Summary of Rationale</b>	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).
<b>Effective From</b>	1 <sup>st</sup> April 2019
<b>Policy Review Date</b>	1 <sup>st</sup> April 2021

## Urological Interventions

<b>Intervention</b>	<b>Botox for Overactive Bladder</b>
<b>For the treatment of</b>	Overactive bladder (OAB) (neurogenic or idiopathic detrusor over-activity [DO])
<b>Commissioning Position</b>	<p>This intervention is NOT routinely commissioned.</p> <p>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.</p> <p>We will commission BTX-A treatment for overactive bladder in patients where <b>ALL</b> the following criteria are met:</p> <p><b>Women</b> (idiopathic detrusor over-activity – see NICE CG171)</p> <ul style="list-style-type: none"> <li>• Symptoms are refractory to lifestyle modification (caffeine reduction, modification of fluid intake, weight loss if BMI &gt;30);</li> <li>• Symptoms are refractory to behavioural interventions: a minimum of 6 weeks of bladder retraining OR 3 months of pelvic floor muscle training (in mixed urinary incontinence only, where there is some stress incontinence as well as OAB);</li> <li>• Symptoms are refractory to 4 weeks of anticholinergic medication to a maximal tolerated dose (a number of drugs may be tried in accordance with NICE CG171)[OR Mirabegron, in people for whom anticholinergic drugs are contraindicated or clinically ineffective, or have unacceptable side effects (NICE TA290)];</li> <li>• The woman has been referred to secondary care, reviewed by a urinary incontinence MDT and a diagnosis of detrusor over-activity has been confirmed by urodynamic assessment;</li> <li>• The woman is willing and able to perform clean intermittent catheterisation;</li> <li>• The treatment with BTX-A is initiated by a Consultant Urologist or Gynaecologist within the provider Trust.</li> </ul> <p><b>Men</b> (idiopathic detrusor over-activity – see NICE CG97 )</p> <ul style="list-style-type: none"> <li>• Symptoms are refractory to conservative management: lifestyle advice, advice on fluid intake, supervised bladder training and use of containment products (pads, sheaths etc.)</li> <li>• Symptoms are refractory to 4-6 weeks of anticholinergic medication [OR Mirabegron, in people for whom anticholinergic drugs are contraindicated or clinically ineffective, or have unacceptable side effects (NICE TA290)]</li> <li>• The man has been referred to secondary care for specialist assessment and a diagnosis of detrusor over-activity has been confirmed</li> <li>• The man is willing and able to self-catheterise</li> <li>• The treatment with BTX-A is initiated by a Consultant Urologist within the provider Trust.</li> </ul>

	<p><b>Neurogenic detrusor over-activity</b> (see NICE CG148) in people with spinal cord disease (for example, spinal cord injury or multiple sclerosis):</p> <ul style="list-style-type: none"> <li>• Who have symptoms of an overactive bladder OR where urodynamic investigations have shown impaired bladder storage;</li> <li>• In whom a behavioural management programme (for example, timed voiding, bladder retraining or habit retraining) has been ineffective or is not appropriate</li> <li>• In whom antimuscarinic drugs have proved to be ineffective or poorly tolerated.</li> <li>• Who are able and willing to manage a catheterisation regimen should urinary retention develop after the treatment with BTX- A.</li> </ul> <p>With all patients the risks and benefits of BTX-A injections must be fully discussed and informed consent gained.</p> <p>If BTX-A treatment is effective, we will commission follow-up at 6 months or sooner if symptoms return for repeat treatment without an MDT referral.</p> <p>Requests to treat patients who do not meet the above criteria should be submitted to for consideration via the IFR process.</p>
<b>Evidence/Summary of Rationale</b>	There is evidence to suggest that this treatment in the aforementioned cases is clinically effective.
<b>Effective From</b>	1 <sup>st</sup> November 2019
<b>Policy Review Date</b>	1 <sup>st</sup> November 2021

<b>Intervention</b>	<b>Circumcision – Male Adults</b>
<b>For the treatment of</b>	Clinical Health indications requiring surgical removal of foreskin(over 18 years old)
<b>Commissioning Position</b>	<p>Circumcision is NOT commissioned for cultural, religious or cosmetic reasons.</p> <p>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.</p> <p>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.</p> <p>Any of the following clinical indications must be present:</p> <ul style="list-style-type: none"> <li>• Congenital abnormalities with functional impairment</li> <li>• Distal scarring of the preputial orifice</li> <li>• Painful erections secondary to a tight foreskin</li> <li>• Recurrent bouts of infection (balanitis/balanoposthitis)</li> <li>• Redundant prepuce, phimosis (inability to retract the foreskin due to a narrow prepuce ring) sufficient to cause ballooning of the foreskin on micturition; and paraphimosis (inability to pull forward a retracted foreskin).</li> <li>• Lichen sclerosus (balanitis xerotica obliterans) -chronic inflammation leading to a rigid fibrous foreskin.</li> <li>• Pain on intercourse</li> </ul>

	<ul style="list-style-type: none"> <li>• Traumatic injury</li> </ul>
<b>Evidence/Summary of Rationale</b>	<p>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 &gt;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.</p>
<b>Effective From</b>	1 <sup>st</sup> April 2019
<b>Policy Review Date</b>	1 <sup>st</sup> April 2021

<b>Intervention</b>	<b>Circumcision – Male Children</b>
<b>For the treatment of</b>	Clinical Health indications requiring surgical removal of foreskin (under 18 years old)
<b>Commissioning Position</b>	<p>Circumcision is NOT commissioned for cultural, religious or cosmetic reasons.</p> <p>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.</p> <p>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.</p> <p>Referral to secondary care for children should only be made if there are any of the following circumstances:</p> <ul style="list-style-type: none"> <li>• Distal scarring of the preputial orifice</li> <li>• Balanitis Xerotica Obliterans</li> <li>• Painful erections secondary to a tight foreskin</li> <li>• Recurrent bouts of infection (balanitis/balanoposthitis)</li> </ul>
<b>Evidence/Summary of Rationale</b>	<p>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 &gt;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.</p>

<b>Effective From</b>	1 <sup>st</sup> April 2019
<b>Policy Review Date</b>	1 <sup>st</sup> April 2021

<b>Intervention</b>	<b>Epididymal Cyst Surgery</b>
<b>For the treatment of</b>	Asymptomatic Epididymal Cyst
<b>Commissioning Position</b>	<p>This intervention is NOT routinely commissioned for asymptomatic Epididymal Cysts.</p> <p>This intervention is a Category One Evidence Based Intervention; therefore, any requests to fund must be made as an Individual Funding Request.</p> <p>Prior approval is not required for symptomatic Epididymal cysts where there is:</p> <ul style="list-style-type: none"> <li>• Persistent pain and discomfort,</li> <li>• Sudden increase in size</li> <li>• Significant mechanical problems.</li> </ul>
<b>Evidence/Summary of Rationale</b>	<p>Epididymal cysts usually develop in adults around the age of 40. Epididymal cysts are rare in children and, when they occur, are usually present around puberty. Cysts are found in as many as 30% of asymptomatic patients having scrotal ultrasound for other reasons but most of these are spermatocytes. The prevalence in the general population is difficult to estimate.</p>
<b>Effective From</b>	1 <sup>st</sup> November 2019
<b>Policy Review Date</b>	1 <sup>st</sup> November 2021

<b>Intervention</b>	<b>Hydrocele Correction</b>
<b>For the treatment of</b>	Hydrocele
<b>Commissioning Position</b>	<p>This intervention is NOT routinely commissioned</p> <p>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.</p> <p>Treatment should only be considered if:</p> <ul style="list-style-type: none"> <li>• Aspiration has failed or considered inappropriate</li> <li>• The hydrocele is large (&gt;3cm in size)</li> <li>• The hydrocele is recurrent</li> <li>• There is atypical presentation (malignancy excluded)</li> </ul>
<b>Evidence/Summary of Rationale</b>	<p>Hydroceles (fluid collection around the testicles) may be present at birth and are common, affecting around one male baby in every 10. They do not usually require treatment as they often disappear on their own during the first 2 years of life. The CCG will fund treatment for hydroceles in children if they do not disappear by the age of 2. Less commonly, hydroceles can develop in adult men and may follow infection, injury or radiotherapy. Often hydroceles are asymptomatic. Therefore, in adults treatment is not funded unless the hydrocele is causing significant symptoms.</p>
<b>Effective From</b>	1 <sup>st</sup> November 2019
<b>Policy Review Date</b>	1 <sup>st</sup> November 2021

<b>Intervention</b>	<b>Penile Implants</b>
<b>For the treatment of</b>	Erectile Dysfunction
<b>Commissioning Position</b>	<p>This intervention is NOT routinely commissioned.</p> <p>This intervention is a Category One Evidence Based Intervention; therefore, any requests to fund must be made as an Individual Funding Request.</p> <p>Funding will only be considered where exceptional clinical circumstances are demonstrated. Requests must be submitted by a Consultant Urologist and must provide details of all clinical problems associated with the ED, treatments tried and outcomes to date.</p> <p>To be eligible for consideration for a penile the patient must comply with 3 or more of the following criteria:</p> <ul style="list-style-type: none"> <li>• The ED is a consequence of a severe structural condition such as Peyronie’s disease, post-riapism or complex penile malformation</li> </ul> <p>OR</p> <ul style="list-style-type: none"> <li>• is associated with one of the following medical conditions : <ul style="list-style-type: none"> <li>- Diabetes</li> <li>- Multiple Sclerosis</li> <li>- Parkinson's Disease</li> <li>- Poliomyelitis</li> <li>- Prostate Cancer</li> <li>- Prostatectomy</li> <li>- Radical Pelvic Surgery</li> <li>- Severe Pelvic Injury</li> <li>- Renal Failure treated by dialysis or transplant</li> <li>- Single Gene Neurological Disease</li> <li>- Spinal Cord Injury</li> <li>- Spina Bifida</li> </ul> </li> <li>• Where applicable, risk factor modification and lifestyle changes such as losing weight, stopping smoking, reducing alcohol consumption, and increasing exercise have all been tried and have failed to improve the condition. (Advice and support is available from the Sexual Dysfunction Association <a href="http://www.sda.uk.net">www.sda.uk.net</a>).</li> <li>• Appropriate psychological, urological or endocrine assessments have been carried out and have excluded a treatable underlying psychogenic or hormonal cause or physical abnormality.</li> <li>• First line treatment with at least two phosphodiesterase-5 (PDE-5) inhibitors (Sildenafil, Tadalafil, Vardenafil), regardless of suspected cause, or testosterone replacement therapy or combination therapy with testosterone is contraindicated or has been ineffective.</li> <li>• Second line treatment with intracavernous injection therapy and intraurethral alprostadil is contraindicated or has been ineffective.</li> </ul>
<b>Evidence/Summary of Rationale</b>	There is considerable evidence that adequate levels of testosterone are required for



	<p>ED therapies, especially phosphodiesterase type 5 (PDE5) inhibitors, to achieve maximal response and in many cases normalisation of testosterone levels can restore erectile function. PDE5 inhibitors are effective in approximately 75% of patients, but for non-responders alternative therapies are available including vacuum erection devices, intracavernous or intraurethral injections, or as a possible third line therapy, a penile implant.</p> <p>NICE CG 175 includes the following advice on managing sexual dysfunction following radical treatment for prostate cancer:</p> <ul style="list-style-type: none"> <li>- 1.3.31 Ensure that men have early and ongoing access to specialist erectile dysfunction services</li> <li>- 1.3.32 Offer men with prostate cancer who experience loss of erectile function phosphodiesterase type 5 (PDE5) inhibitors to improve their chance of spontaneous erections</li> <li>- 1.3.33 If PDE5 inhibitors fail to restore erectile function or are contraindicated, offer men vacuum devices, intraurethral inserts penile injections, penile prostheses as an alternative or approved topical treatments.</li> </ul> <p>A Cochrane Review from 20074 mainly covered the effectiveness of PDE5 and did not mention penile implants.</p>
<b>Effective From</b>	1 <sup>st</sup> November 2019
<b>Policy Review Date</b>	1 <sup>st</sup> November 2021

<b>Intervention</b>	<b>12 week trial of Percutaneous Tibial Nerve Stimulation (PTNS) – Urinary Incontinence</b>
<b>For the treatment of</b>	Adults with refractory Urinary Incontinence
<b>Commissioning Position</b>	<p>This intervention is NOT routinely commissioned.</p> <p>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.</p> <p>Treatment is not indicated in cases that are asymptomatic.</p> <p>Requests for a 12 week trial of PTNS for urinary incontinence due to overactive bladder (OAB) syndrome in men and women will be considered for patients who fulfil all the following criteria:</p> <ul style="list-style-type: none"> <li>• The patient has a confirmed diagnosis defined by urodynamic assessment and has been reviewed by a Urology MDT.</li> <li>• The patient is unable to perform clean, intermittent self-catheterisation</li> <li>• Evidence of the condition having a severe and debilitating impact on activities of daily living</li> <li>• Voiding diary data is kept to record frequency and severity of episodes</li> <li>• Symptoms refractory to ≥12 months of first line treatments including: <ul style="list-style-type: none"> <li>- behavioural and lifestyle modification (diet, weight management, modification of fluid intake)</li> <li>- bladder retraining and catheterisation</li> </ul> </li> </ul>

	<ul style="list-style-type: none"> <li>- pelvic floor muscle training</li> <li>- anticholinergic drugs</li> <li>- Botox injections have been unsuccessful or deemed inappropriate</li> </ul>
<b>Evidence/Summary of Rationale</b>	<p>Incontinence definition as per NICE IPG 362: urinary urgency, with or without urge incontinence, usually with frequency and nocturia.</p> <p>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.</p> <p>PTNS achieves a modulatory effect similar to that of SNS through a less invasive route, but its exact mechanism of action is unclear. A fine needle is inserted just above the ankle next to the Posterior Tibial Nerve and a surface electrode is placed near the arch of the foot. Stimulation of the nerve produces a motor and sensory response. Initial treatment usually consists of 12 outpatient sessions lasting 30 minutes, usually weekly. NICE IPG 362 concludes “current evidence on PTNS for OAB syndrome shows it is efficacious in reducing symptoms in the short and medium term, with no major safety concerns.” NICE CG171 (2013) says there is good evidence to suggest that conservative treatment should include Botulinum Toxin A for refractory detrusor over activity in women. The large placebo-controlled study (RELAX 2012) found urgency and incontinence improve more than frequency with a magnitude of improvement considerably larger than that after anticholinergic medication.</p>
<b>Effective From</b>	1 <sup>st</sup> November 2019
<b>Policy Review Date</b>	1 <sup>st</sup> November 2021

<b>Intervention</b>	<b>Continued Percutaneous Tibial Nerve Stimulation (PTNS) – Urinary Incontinence</b>
<b>For the treatment of</b>	Adults with refractory Urinary Incontinence
<b>Commissioning Position</b>	<p>This intervention is NOT routinely commissioned.</p> <p>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.</p> <p>Continued PTNS for urinary incontinence due to overactive bladder (OAB) syndrome in men and women will be considered for patients who fulfil all the following criteria:</p> <ul style="list-style-type: none"> <li>• They have already undertaken an approved 12 week trial of PTNS</li> <li>• The trial has resulted in a 50% or more improvement in symptoms (measured as a weekly reduction in incontinence episodes).</li> </ul>
<b>Evidence/Summary of Rationale</b>	<p>Incontinence definition as per NICE IPG 362: urinary urgency, with or without urge incontinence, usually with frequency and nocturia.</p> <p>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</p>

	<p>it produces symptom relief. The battery life for the permanent implant is approximately 7-9 years.</p> <p>PTNS achieves a modulatory effect similar to that of SNS through a less invasive route, but its exact mechanism of action is unclear. A fine needle is inserted just above the ankle next to the Posterior Tibial Nerve and a surface electrode is placed near the arch of the foot. Stimulation of the nerve produces a motor and sensory response. Initial treatment usually consists of 12 outpatient sessions lasting 30 minutes, usually weekly. NICE IPG 362 concludes “current evidence on PTNS for OAB syndrome shows it is efficacious in reducing symptoms in the short and medium term, with no major safety concerns.” NICE CG171 (2013) says there is good evidence to suggest that conservative treatment should include Botulinum Toxin A for refractory detrusor over activity in women. The large placebo-controlled study (RELAX 2012) found urgency and incontinence improve more than frequency with a magnitude of improvement considerably larger than that after anticholinergic medication.</p>
<b>Effective From</b>	1 <sup>st</sup> November 2019
<b>Policy Review Date</b>	1 <sup>st</sup> November 2021

<b>Intervention</b>	<b>Sacral Nerve Stimulation (SNS) – Men with Urinary Retention</b>
<b>For the treatment of</b>	Male Adults with Urinary Retention
<b>Commissioning Position</b>	<p>This intervention is NOT routinely commissioned.</p> <p>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.</p> <p>Sacral Nerve Stimulation for women with non-obstructive urinary retention should be considered where patients meet ALL of the below criteria:</p> <p>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.</p> <p>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</p> <ul style="list-style-type: none"> <li>• The male has a confirmed diagnosis defined by urodynamic assessment and has been reviewed by a Urology MDT.</li> <li>• The man is unable to perform clean, intermittent self-catheterisation</li> <li>• Symptoms are refractory to: <ul style="list-style-type: none"> <li>– behavioural and lifestyle modification (diet, weight management, modification of fluid intake)</li> <li>– bladder retraining</li> <li>– bladder catheterisation</li> </ul> </li> </ul>
<b>Evidence/Summary of Rationale</b>	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

	<p>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.</p> <p>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.</p>
<b>Effective From</b>	1 <sup>st</sup> April 2019
<b>Policy Review Date</b>	1 <sup>st</sup> April 2021

<b>Intervention</b>	<b>Sacral Nerve Stimulation (SNS) - Women with Urinary Retention</b>
<b>For the treatment of</b>	Female Adults with Urinary Retention
<b>Commissioning Position</b>	<p>This intervention is NOT routinely commissioned.</p> <p>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.</p> <p>Sacral Nerve Stimulation for women with non-obstructive urinary retention should be considered where patients meet ALL of the below criteria:</p> <ul style="list-style-type: none"> <li>• The woman has a confirmed diagnosis defined by urodynamic assessment and has been reviewed by a Urology MDT.</li> <li>• The woman is unable to perform clean, intermittent self-catheterisation</li> <li>• Symptoms are refractory to: <ul style="list-style-type: none"> <li>- behavioural and lifestyle modification (diet, weight management, modification of fluid intake)</li> <li>- bladder retraining</li> <li>- bladder catheterisation</li> </ul> </li> </ul>
<b>Evidence/Summary of Rationale</b>	<p>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.</p> <p>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.</p>
<b>Effective From</b>	1 <sup>st</sup> April 2019
<b>Policy Review Date</b>	1 <sup>st</sup> April 2021

<b>Intervention</b>	<b>Varicoceles (Adolescents)</b>
<b>For the treatment of</b>	Adolescent males (aged 10-17) with Grade II or Grade III Scrotal Swelling
<b>Commissioning Position</b>	<p>This intervention is NOT routinely commissioned.</p> <p>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.</p> <p>For diagnostic uncertainty, patients should be referred via the 2 week wait pathway.</p> <p>Urgent referral to a urologist will be funded if:</p> <ul style="list-style-type: none"> <li>• A varicocele appears suddenly and is painful.</li> <li>• The varicocele does not drain when lying down</li> <li>• There is a solitary right-sided varicocele</li> </ul> <p>Referral to a urologist will be considered, provided the patient:</p> <ul style="list-style-type: none"> <li>• is aged 10 - 17</li> <li>• Has Grade II or III and asymmetrical testes</li> <li>• If experiencing pain or discomfort</li> <li>• If there are concerns about reduced ipsilateral testicular volume.</li> <li>• If the patients or parents/guardians are concerned by the appearance, or symptoms, and cannot be fully reassured in primary care.</li> </ul> <p>Treatment will not be considered for adolescent males with:</p> <ul style="list-style-type: none"> <li>• Subclinical or grade I varicocele. NICE advises treatment is not necessary and clinicians should provide advice and reassurance.</li> <li>• Grade II or III varicocele and symmetrical testes. NICE advises observation with annual examinations.</li> </ul>
<b>Evidence/Summary of Rationale</b>	<ul style="list-style-type: none"> <li>- Sub-clinical — detected only by Doppler ultrasound.</li> <li>- Grade I (small) — palpable only with Valsalva manoeuvre.</li> <li>- Grade II (moderate) — palpable without Valsalva manoeuvre.</li> <li>- Grade III (large) — visible through the scrotal skin</li> </ul> <p>Around 25% of boys who present with a grade II or III varicocele and testes of equal size will ultimately develop testicular growth arrest.</p> <p>Patients can expect a 50–80% chance of ipsilateral catch-up growth of the affected testis following surgery this may take up to 6 months.</p> <p>The RCS recommends that varicocele should not be treated unless there are significant functional problems (or signs of ipsilateral testicular growth arrest in adolescents</p>
<b>Effective From</b>	1 <sup>st</sup> November 2019
<b>Policy Review Date</b>	1 <sup>st</sup> November 2021

<b>Intervention</b>	<b>Varicoceles (Adults)</b>
<b>For the treatment of</b>	Adult males (18+) with Scrotal Swelling
<b>Commissioning Position</b>	<p>This intervention is NOT routinely commissioned.</p> <p>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.</p> <p>For diagnostic uncertainty, patients should be referred via the 2 week wait pathway.</p> <p>Urgent referral to a urologist will be funded if:</p> <ul style="list-style-type: none"> <li>• A varicocele appears suddenly and is painful.</li> <li>• The varicocele does not drain when lying down</li> <li>• There is a solitary right-sided varicocele</li> </ul> <p>Referral to a urologist will be considered, provided the patient:</p> <ul style="list-style-type: none"> <li>• is aged 18 or older</li> <li>• Has Grade II or III symptomatic varicocele, or with abnormal semen parameters</li> <li>• If experiencing pain or discomfort</li> </ul> <p>Treatment will not be considered for adult males with:</p> <ul style="list-style-type: none"> <li>• Sub-clinical or grade I varicocele – NICE advised that treatment is not necessary and semen analysis should be offered if fertility is a concern.</li> <li>• Grade II or III asymptomatic varicocele and normal semen parameters. NICE advises observation with semen analysis every 1–2 years.</li> </ul>
<b>Evidence/Summary of Rationale</b>	<ul style="list-style-type: none"> <li>- Sub-clinical — detected only by Doppler ultrasound.</li> <li>- Grade I (small) — palpable only with Valsalva manoeuvre.</li> <li>- Grade II (moderate) — palpable without Valsalva manoeuvre.</li> <li>- Grade III (large) — visible through the scrotal skin</li> </ul> <p>Patients can expect a 50–80% chance of ipsilateral catch-up growth of the affected testis following surgery this may take up to 6 months.</p> <p>The National Institute for Health and Care Excellence (NICE) recommends that men should not be offered surgery for varicoceles as a form of fertility treatment, because it does not improve pregnancy rates</p>
<b>Effective From</b>	1 <sup>st</sup> November 2019
<b>Policy Review Date</b>	1 <sup>st</sup> November 2021

## Vascular Interventions

<b>Intervention</b>	<b>Resperate© (Intercure Ltd)</b>
<b>For the treatment of</b>	Hypertension
<b>Commissioning Position</b>	<p>This intervention is NOT routinely commissioned.</p> <p>This intervention is a Category One Evidence Based Intervention; therefore, any requests to fund must be made as an Individual Funding Request.</p> <p>The use of the Resperate® device for the treatment of hypertension is not routinely commissioned owing to inadequate evidence of long term benefit over other relaxation techniques. As such, clinicians should not routinely prescribe or recommend this product to patients either as monotherapy or an adjunct to pharmacological management because there is limited clinical evidence of effectiveness.</p>
<b>Evidence/Summary of Rationale</b>	<p>A systematic review and meta-analysis (Ref 1) yielded a total of eight randomised controlled trials (RCTs) of &gt;4 weeks' duration (maximum 9 weeks) comparing Resperate® to a placebo device in adults, with a &gt;80% follow-up within both arms (total n=494). Seven trials attempted to control for the Resperate device using music or a standard BP monitoring unit, and one trial used standard care alone as the control. The following main results are reported:</p> <ul style="list-style-type: none"> <li>• Use of the Resperate® device reduced systolic BP by 3.67mmHg (95% CI -5.99 to -1.39; P=0.002) and diastolic BP by 2.51mmHg (-4.15 to -0.87; P=0.003).</li> <li>• A sensitivity analysis that excluded the 3 trials performed by the manufacturer (n=100) revealed no statistically significant effect of using the device on BP.</li> <li>• No overall effect was seen on heart rate or quality of life using the device.</li> <li>• The methodological quality of the studies was variable with a high risk of bias. The review concludes that despite the overall BP lowering effect seen, the results should be interpreted with caution due to small study sizes, variability in study quality, the cost of the device, and potential conflicts of interest from the trial sponsors and the manufacturers.</li> </ul> <p>To summarise, the data on the efficacy of Resperate® is contradictory and it is not mentioned in NICE guidance or any other national hypertension guidelines.</p> <p>The British Hypertension Society has issued a statement (Ref 2) on this device, as it has received a number of enquiries on its use since it became listed on the NHS Drug Tariff (cost of £132). The opinion of the BHS is that such small effects on BP over very short durations of time do not provide sufficient evidence for this equipment to be recommended.</p>
<b>Effective From</b>	1 <sup>st</sup> November 2019
<b>Policy Review Date</b>	1 <sup>st</sup> November 2021

<b>Intervention</b>	<b>Surgical Intervention for Varicose Veins (C5-C6)</b>
<b>For the treatment of</b>	<p>Grade C5 and C6 Varicose Veins</p> <p>NICE Guideline 168 define C5 and C6 grade Varicose Veins as follows:</p> <ul style="list-style-type: none"> <li>- <b>C5</b> changes in skin and subcutaneous tissue: eczema, lipodermatosclerosis or</li> </ul>

	<p>atrophie blanche with healed ulcers</p> <ul style="list-style-type: none"> <li>- <b>C6</b> skin changes with active ulcers venous insufficiency ulceration</li> </ul>
<b>Commissioning Position</b>	<p>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.</p> <p>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:</p> <ul style="list-style-type: none"> <li>• Bleeding varicose veins (immediate referral required)</li> <li>• Symptomatic primary or recurrent varicose veins that are causing severe pain, aching, discomfort, swelling, heaviness or itching</li> <li>• Lower-limb skin changes, such as pigmentation or eczema, thought to be caused by chronic venous insufficiency</li> <li>• Superficial vein thrombosis (characterised by the appearance of hard, painful veins) and suspected venous incompetence</li> <li>• An active or healed venous leg ulcer</li> </ul>
<b>Evidence/Summary of Rationale</b>	<p>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.</p> <p>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.</p> <p>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.</p>
<b>Effective From</b>	1 <sup>st</sup> April 2019
<b>Policy Review Date</b>	1 <sup>st</sup> April 2021

<b>Intervention</b>	<b>Surgical Intervention for Varicose Veins (C4)</b>
<b>For the treatment of</b>	<p>Grade C4 Varicose Veins</p> <p>NICE Guideline 168 define C4 grade Varicose Veins as ‘changes in skin and subcutaneous tissue: eczema, lipodermatosclerosis or atrophie blanche’</p>
<b>Commissioning Position</b>	<p>This intervention is NOT routinely commissioned.</p> <p>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</p>



	<p>submit an Individual Funding Request if exceptionality is considered to be present.</p> <p>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.</p> <p>Surgical intervention should be considered for patients with grade C4 Varicose Veins where:</p> <ul style="list-style-type: none"> <li>• 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)</li> </ul> <p>AND</p> <p>If patients are experiencing one of the following:</p> <ul style="list-style-type: none"> <li>• Symptomatic primary or recurrent varicose veins that are causing severe pain, aching, discomfort, swelling, heaviness or itching</li> <li>• Lower-limb skin changes, such as pigmentation or eczema, thought to be caused by chronic venous insufficiency</li> <li>• Superficial vein thrombosis (characterised by the appearance of hard, painful veins) and suspected venous incompetence</li> <li>• An active or healed venous leg ulcer</li> </ul>
<b>Evidence/Summary of Rationale</b>	<p>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.</p> <p>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.</p> <p>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.</p> <p>Evidence-Based Interventions (2008)</p>
<b>Effective From</b>	1 <sup>st</sup> April 2019
<b>Policy Review Date</b>	1 <sup>st</sup> April 2021

<b>Intervention</b>	<b>Surgical Intervention for Varicose Veins (C0-C3)</b>
<b>For the treatment of</b>	<p>Grade C0-C3 Varicose Veins</p> <p>NICE Guideline 168 define C0 – C3 grade Varicose Veins as follows:</p> <ul style="list-style-type: none"> <li>- C0 no visible or palpable signs of venous disease</li> <li>- C1 telangectasia or reticular veins</li> <li>- C2 varicose veins</li> </ul>

	- C3 oedema
<b>Commissioning Position</b>	<p>This intervention is NOT routinely commissioned.</p> <p>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.</p>
<b>Evidence/Summary of Rationale</b>	<p>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.</p> <p>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.</p> <p>Evidence-Based Interventions (2008)</p>
<b>Effective From</b>	1 <sup>st</sup> April 2019
<b>Policy Review Date</b>	1 <sup>st</sup> April 2021

# Appendix 1 – Chronic Fatigue Service IFR Referral Form

## CCG CHRONIC FATIGUE – SERVICE REFERRAL REQUEST FORM

Please complete and submit as supporting evidence via the IFR Request System

<https://www.nice.org.uk/guidance/cg53/chapter/1-Guidance>

### REQUEST & PATIENT DETAILS

PATIENT NAME  
DATE OF BIRTH  
NHS NUMBER  
REFERRING CLINICIAN  
GP PRACTICE  
DATE OF REQUEST

INTERVENTION  
REQUESTED  
PROVIDER OF  
INTERVENTION

### CURRENT PRESENTATION

<i>MILD CFS</i>	YES/NO	<i>6 months since presentation?</i>	YES/NO
<i>MODERATE CFS</i>	YES/NO	<i>3-4 months since presentation?</i>	YES/NO
<i>SEVERE CFS</i>	YES/NO	<i>Date of presentation</i>	__/__/__

IS THIS A RELAPSE?	YES/NO	IF YES, DATE OF RELAPSE	__/__/__
PREVIOUS SPECIALIST SERVICE TREATMENT?	YES/NO	DISCHARGE DATE	__/__/__

If a relapse, in the answers below please provide full history to include before and after relapse. Evidence must be provided that investigations and symptom management have been tried or excluded in relation to relapse.

### HISTORY OF CONDITION/SYMPTOMS EXPERIENCED

### IMPACT ON EDUCATION/EMPLOYMENT

Have all relevant and appropriate history, examinations and investigations been carried out as per recommendations in NICE CG53 section 1.2.2?

YES/NO

### HAVE THE SYMPTOMS PERSISTED FOR:

*ADULT: 4 months*  
YES/NO  
*If YES, when was CFS diagnosed?*

\_\_/\_\_/\_\_

*CHILD: 3 months*  
YES/NO  
*If YES, when was CFS diagnosed?*

\_\_/\_\_/\_\_

*Has this been confirmed by a Paediatrician?*

YES/NO

**SYMPTOM MANAGEMENT - please state if attempted, rationale if not, dates and outcomes for each intervention listed below**

***Pharmacological Treatment***

***Sleep Management***

***Rest Periods***

***Relaxation***

***Pacing***

***Diet***

***Equipment to maintain independence***

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Please provide any supporting clinical information/documentation relevant to your request.

## Appendix 2 – References

(in order of appearance)

### COLORECTAL INTERVENTIONS

#### Surgery for Anal Fissure (Adults and Children)

Clinical Guidelines 27: Referral guidelines for suspected cancer

Clinical Knowledge Summaries Anal Fissures

#### Botulinum Toxin type A for Anal Fissure

Nelson RL. Non surgical therapy for anal fissure. Cochrane Database of Systematic Reviews 2006, Issue 4. Art.No.: CD003431. <http://onlinelibrary.wiley.com/doi/10.1002/14651858.CD003431.pub3/pdf/abstract>

Cross et al. The Management of Anal Fissure: ACPGBI Position Statement (2008) The Association of Coloproctology of Great Britain and Ireland. *Colorectal Disease*, 10 (Suppl. 3), 1–7.

<http://www.acpgbi.org.uk/wp-content/uploads/Position-Statements-Managementof-Anal-Fissure-Management-of-Acute-Severe-Colitis.pdf>

UKMI Q+A 290.2. January 2013: How effective are calcium channel blockers for anal fissures.

NICE evidence review: ESUOM14: Chronic anal fissure: botulinum toxin type A injection.

<http://publications.nice.org.uk/esuom14-chronic-anal-fissure-botulinum-toxin-type-a-injection-esuom14>

Bhardwaj R, Parker MC. Modern perspectives in the treatment of chronic anal fissures. *Ann Surg* 2007; 90: 472–8. <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2048592/pdf/rcse8905-472.pdf>

NICE Clinical Knowledge Summary: Anal Fissure July 2016 <http://www.cks.nice.org.uk/anal-fissure>

#### Haemorrhoid Surgery

Watson AJM, Bruhn H, MacLeod K, et al. A pragmatic, multicentre, randomised controlled trial comparing stapled Haemorrhoidopexy to traditional excisional surgery for haemorrhoidal disease (eTHoS): study protocol for a randomised controlled trial. *Trials*. 2014;15:439. doi:10.1186/1745-6215-15-439.

Watson AJM, Hudson J, Wood J, et al. Comparison of stapled Haemorrhoidopexy with traditional excisional surgery for haemorrhoidal disease (eTHoS): a pragmatic, multicentre, randomised controlled trial. *Lancet* (London, England). 2016;388(10058):2375-2385. doi:10.1016/S0140-6736(16)31803-7.

Brown SR. Haemorrhoids: an update on management. *Therapeutic Advances in Chronic Disease*. 2017;8(10):141-147. doi:10.1177/2040622317713957.

NHS website: <https://www.nhs.uk/conditions/piles-haemorrhoids/>

Royal College of Surgeons: [https://www.rcseng.ac.uk/-/media/files/rcs/standards-andresearch/commissioning/rcsacpgbirectalbleeding2017documentfinal\\_jan18.pdf](https://www.rcseng.ac.uk/-/media/files/rcs/standards-andresearch/commissioning/rcsacpgbirectalbleeding2017documentfinal_jan18.pdf)

Health Technol Assess. 2016 Nov;20(88):1-150. The HubBLE Trial: haemorrhoidal artery ligation (HAL) versus rubber band ligation (RBL) for symptomatic second- and third-degree haemorrhoids: a multicentre randomised controlled trial and health-economic evaluation. Brown S et al.

## **Percutaneous Tibial Nerve Stimulation (PTNS) for Faecal Incontinence**

NICE IPG 395 (May 2011) Percutaneous Tibial Nerve stimulation (PTNS) for faecal incontinence

<https://www.nice.org.uk/guidance/ipg395>

<https://pathways.nice.org.uk/pathways/faecal-incontinence>

## **Sacral Nerve Stimulation (SNS) Adults with Faecal Retention**

Kamm et al. Sacral nerve stimulation for intractable constipation. Gut 2010;v59:p333-340.

<http://gut.bmj.com/content/59/3/333.full.pdf>

## **DERMATOLOGY INTERVENTIONS**

### **Hair Loss Treatments**

1.A.G. Messenger et al, British Association of Dermatologists' guidelines for the management of alopecia areata 2012. British Journal of Dermatology 2012 166, pp916–926.

<http://www.ncbi.nlm.nih.gov/pubmed/22524397>

NHS Wig Policy <http://www.nhs.uk/nhsengland/Healthcosts/pages/Wigsandfabricsupports.aspx>

NHS UK – Hair loss treatments <http://www.nhs.uk/Conditions/Hair-loss/Pages/Treatment.aspx>

NHS Choices – Hair Loss <http://www.nhs.uk/conditions/hair-loss/Pages/Introduction.aspx>

### **Tattoo Removal**

NHS Modernisation Agency. 'Action on plastic surgery. Referrals and guidelines in plastic surgery. Information for Commissioners of Plastic Surgery Services'. British Association of Plastic and Reconstructive Surgery. (March 2012)

## **EAR, NOSE AND THROAT INTERVENTIONS**

### **Adult Snoring Surgery in the absence of Obstructive Sleep Apnoea (OSA)**

Franklin KA, Anttila H, Axelsson S, Gislason T, Maasilta P, Myhre KI, Rehnqvist N. Effects and side-effects of surgery for snoring and obstructive sleep apnoea systematic review. Sleep. 2009 Jan. 32(1):27-36

Main C, Liu Z, Welch K, Weiner G, Jones SQ, Stein K. Surgical procedures and non-surgical devices for the management of non-apnoeic snoring: a systematic review of clinical effects and associated treatment costs. Health Technol Assess 2009;13(3). <https://www.ncbi.nlm.nih.gov/pubmed/19091167>

Jones TM, Earis JE, Calverley PM, De S, Swift AC. Snoring surgery: A retrospective review. Laryngoscope. 2005 Nov 115(11): 2015-20. <https://www.ncbi.nlm.nih.gov/pubmed/16319615>

### **Botulinum toxin type A for Spasmodic Dysphonia**

American Academy of Otolaryngology-Head and Neck Surgery, Clinical practice guideline: Hoarseness (Dysphonia). Otolaryngology-Head and Neck Surgery, Vol 141, No 3S2, September 2009.

<http://www.entnet.org/Practice/upload/Final-HoarsenessGuideline.pdf>

Blitzer A, Brin MF, Stewart CF. Botulinum toxin management of spasmodic dysphonia (laryngeal dystonia): a 12-year experience in more than 900 patients. Laryngoscope 1998; 108:1435–41.

<http://www.ncbi.nlm.nih.gov/pubmed/9778279>

Boutsen F, Cannito MP, Taylor M, et al. Botox treatment in adductor spasmodic dysphonia: a meta-analysis. J Speech Lang Hear Res 2002; 45:469–81. <http://jslhr.asha.org/cgi/reprint/45/3/469>

Cannito MP, Woodson GE, Murry T, et al. Perceptual analyses of spasmodic dysphonia before and after treatment. Arch Otolaryngol Head Neck Surg 2004; 130:1393–9.

<http://www.ncbi.nlm.nih.gov/pubmed/15611398>

Courey MS, Garrett CG, Billante CR, et al. Outcomes assessment following treatment of spasmodic dysphonia with botulinum toxin. Ann Otol Rhinol Laryngol 2000; 109:819–22.

<http://www.ncbi.nlm.nih.gov/pubmed/11007083>

Stong BC, DelGaudio JM, Hapner ER, et al. Safety of simultaneous bilateral botulinum toxin injections for abductor spasmodic dysphonia. Arch Otolaryngol Head Neck Surg 2005; 131: 793–5.

<http://www.ncbi.nlm.nih.gov/pubmed/16172357>

Sulica L. Contemporary management of spasmodic dysphonia. Curr Opin Otolaryngol Head Neck Surg 2004; 12:543–8. <http://www.ncbi.nlm.nih.gov/pubmed/15548915>

Truong DD, Rontal M, Rolnick M, et al. Double-blind controlled study of botulinum toxin in adductor spasmodic dysphonia. Laryngoscope 1991; 101:630–4. <http://onlinelibrary.wiley.com/doi/10.1288/00005537-199106000-00010/abstract>

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### **Grommets for Glue Ear in Children**

NICE guidance: <https://www.nice.org.uk/Guidance/CG60>

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### **Irrigation of the external Auditory Canal**

NICE Clinical Knowledge Summary - <http://cks.nice.org.uk/earwax>

## **Rhinoplasty/Septorhinoplasty/Septoplasty**

A Policy To Make Best Use of Resources in Plastic Surgery and Related Specialities November 2006 Northern, Eastern, Southern and Western Health and Social Services Board.

NHS Modernisation Agency: Action on Plastic, Information for Commissioners of Plastic Surgery Services: Referrals and Guidelines in Plastic Surgery 2004.

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## **Tonsillectomy**

Rubie I, Haighton C, O'Hara J, Rousseau N, Steen N, Stocken DD, Sullivan F, Vale L, Wilkes S, Wilson J. The National randomised controlled Trial of Tonsillectomy IN Adults (NATTINA): a clinical and cost-effectiveness study: study protocol for a randomised control trial. Trials. 2015 Jun 6;16:263.

<https://www.ncbi.nlm.nih.gov/pubmed/26047934>

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## **ENDOCRINE INTERVENTIONS**

### **Botulinum toxin type A for Hyperhidrosis**

Assessment: Botulinum neurotoxin in the treatment of autonomic disorders and pain (an evidence-based review): Report of the Therapeutics and Technology Assessment Subcommittee of the American Academy of Neurology Naumann et al. Neurology. 2008 May 6; 70(19):1707-14.

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NICE Clinical knowledge summary – Hyperhidrosis <http://cks.nice.org.uk/hyperhidrosis>

Guidelines for the primary care treatment and referral of focal hyperhidrosis [Lowe et al, 2003]

[http://www.eguidelines.co.uk/eguidelinesmain/gip/media/pdfs/Full\\_hh\\_guideline.pdf](http://www.eguidelines.co.uk/eguidelinesmain/gip/media/pdfs/Full_hh_guideline.pdf)

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DTB. Treatments for excessive armpit sweating. Drug & Therapeutics Bulletin 2005;43 (10):77-80.

<http://dtb.bmj.com/content/43/10/77.abstract>

NICE Clinical Guideline (May 2013) Social anxiety disorder: recognition, assessment and treatment (CG159)

<https://www.nice.org.uk/guidance/cg159>

### **Continuous Glucose Monitoring System (CGMS)**

NICE NG17 Type 1 Diabetes in Adults: diagnosis and management (August 2015) (updated July 2016)

<https://www.nice.org.uk/guidance/ng17/chapter/1-Recommendations>



NICE NG18 Diabetes (type1 and type 2) in Children and Young People: diagnosis and management (August 2015), (updated December 2015)

NICE QS125 (July2016) <https://www.nice.org.uk/guidance/qs125/chapter/Quality-statement->

[4-Continuous-glucose-monitoring-in-type-1-diabetes](#)

NHS England Letter re end of Specialised Commissioning of Insulin pumps and CGMS for some Paediatric patients.

### **Endoscopic Thoracic Sympathectomy**

NICE Clinical Knowledge Summary – Hyperhidrosis

NICE IPG 487 (May 2014) Endoscopic Thoracic Sympathectomy for primary hyperhidrosis of the upper limb: guidance

### **Flash Glucose Monitoring (FGM) Systems such as Freestyle Libre<sup>®</sup>**

Flash Glucose Monitoring: National arrangements for funding of relevant diabetes patients (March 2019), NHS England - <https://www.england.nhs.uk/wp-content/uploads/2019/03/flash-glucose-monitoring-national-arrangements-funding-v1.1.pdf>

### **Hair Removal for Hirsutism**

Radmanesh M, Azar-Beig M, Abtahian A, Naderi AH. Burning, paradoxical hypertrichosis, leukotrichia and folliculitis are four major complications of intense pulsed light hair removal therapy Journal of Dermatological Treatment, 2008, vol./is. 19/6 (360-3) <http://informahealthcare.com/doi/abs/10.1080/09546630802132627>

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Azziz R. The evaluation and management of hirsutism. Obstet Gynecol 2003; 101: 995–1007. <http://www.ncbi.nlm.nih.gov/pubmed/12738163>

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NHS Modernisation Agency. 'Action on plastic surgery. Referrals and guidelines in plastic surgery. Information for Commissioners of Plastic Surgery Services'. <http://www.bapras.org.uk/downloaddoc.asp?id=425>

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Koulouri O, Conway G. S. Management of hirsutism. BMJ 2009;338:b847 <http://www.bmj.com/content/338/bmj.b847>

NHS Choices – Treatment for Pilonidal Sinus <http://www.nhs.uk/Conditions/Pilonidal-sinus/Pages/Treatment.aspx>

## FERTILITY INTERVENTIONS

### Reversal of Sterilisation

Faculty of Sexual & Reproductive Healthcare Clinical Guidance Male and Female Sterilisation Clinical Effectiveness Unit, September 2014

### Vasectomy under GA

RCOG Faculty of Sexual & Reproductive Health Care. UK Medical Eligibility Criteria for Contraceptive Use. 2009. (Section on Male Surgical Sterilization pp101-104)

NICE Clinical Knowledge Summaries. Contraception -management. Male sterilization (last revised June 2012)

Cook LA, et al. Scalpel versus no-scalpel incision for vasectomy. Cochrane Database Syst Rev. 2007 Apr 18;(2):CD004112 (assessed as up to date Oct 2011)

Royal College of Obstetricians & Gynaecologists (RCOG). Male and female sterilisation. Evidence-based Clinical Guideline No 4. London: RCOG Press; 2004.

Faculty of Sexual & Reproductive Healthcare (FSRHC) of the Royal College of Obstetricians and Gynaecologists. Syllabus and Logbook for the Certificate in Local Anaesthetic Vasectomy. London: RCOG. Press; 2010.

FPA Factsheet on male and female sterilisation. (Nov 2012)

## GENERAL SURGERY

### Cholecystectomy

Royal College of Surgeons Commissioning Guide: Gallstone disease October 2013  
<http://www.rcseng.ac.uk/healthcare-bodies/docs/published-guides/gallstones>

Ahmed, R., Freeman, J.V., Ross, B., Kohler, B., Nicholl J.P., Johnson, A.G. Long term response to gallstone treatment – problems and surprises. The European Journal of Surgery 2000 V. 166 (6) pp: 447-54.  
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[http://www.bsg.org.uk/pdf\\_word\\_docs/cbds\\_08.pdf](http://www.bsg.org.uk/pdf_word_docs/cbds_08.pdf)

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NICE IPG 346 - Single incision laparoscopic cholecystectomy. NICE Interventional Procedure Guideline (May 2010)<http://guidance.nice.org.uk/IPG346>

## GYNAECOLOGY INTERVENTIONS

### Dilation and Curettage (D&C) for Heavy Menstrual Bleeding

NICE guidance: <https://www.nice.org.uk/guidance/ng88>

NHS advice: <https://www.nhs.uk/conditions/hysteroscopy/#alternatives-tohysteroscopy> MacKenzie IZ, Bibby JG. Critical assessment of dilatation and curettage in 1029 women. *Lancet* 1978;2(8089):566–8.

Ben-Baruch G, Seidman DS, Schiff E, et al. Outpatient endometrial sampling with the Pipelle curette. *Gynecologic and Obstetric Investigation* 1994;37(4):260–2.

Gimpelson RJ, Rappold HO. A comparative study between panoramic hysteroscopy with directed biopsies and dilatation and curettage. A review of 276 cases. *American Journal of Obstetrics and Gynecology* 1988;158(3 Pt 1):489–92.

Haynes PJ, Hodgson H, Anderson AB, et al. Measurement of menstrual blood loss in patients complaining of menorrhagia. *British Journal of Obstetrics and Gynaecology* 1977;84(10):763–8.

### Elective Caesarean Section (non-clinical reasons)

NICE Clinical Guidance CG13 April 2004

Caesarean Section - RCOG Clinical Guideline April 2004

Caesarean Section – NICE Clinical Guidance CG132 November 2011 <https://www.nice.org.uk/guidance/cg132>

### Hysterectomy for Heavy Menstrual Bleeding

NICE guidance: <https://www.nice.org.uk/guidance/ng88>.

NHS website: <https://www.nhs.uk/conditions/heavy-periods/#Causes>

Hurskainen R, Teperi J, Rissanen P, et al. Clinical outcomes and costs with the levonorgestrel-releasing intrauterine system or hysterectomy for treatment of menorrhagia: randomized trial 5-year follow-up. *JAMA: the journal of the American Medical Association* 2004;291(12):1456–63.

Learman LA, Summitt Jr RL, Varner RE, et al. Hysterectomy versus expanded medical treatment for abnormal uterine bleeding: Clinical outcomes in the medicine or surgery trial. *Obstetrics and Gynecology* 2004;103(5 I):824–33.

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Pinto I, Chimento P, Romo A, et al. Uterine fibroids: uterine artery embolization versus abdominal hysterectomy for treatment – a prospective, randomized, and controlled clinical trial. *Radiology* 2003;226(2):425–31.

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<http://onlinelibrary.wiley.com/doi/10.1111/j.1471-0528.2009.02426.x/pdf>

Goodman MP, Placik OJ, Benson RH et al, (2010) A large multicentre outcome study of female genital plastic surgery. *Journal of Sexual Medicine* 2010;7:1565- 77. <http://www.ncbi.nlm.nih.gov/pubmed/19912495>

## **MENTAL HEALTH INTERVENTIONS**

### **Referral to Specialist Chronic Fatigue Services**

<https://www.nice.org.uk/guidance/cg53>

## **MINOR SURGERY PROCEDURES**

### **Benign Skin Lesions – Surgical Removal**

Higgins JC, Maher MH, Douglas MS. Diagnosing Common Benign Skin Tumors. *Am Fam Physician*. 2015 Oct 1;92(7):601-7. PubMed PMID: 26447443.

Tan E, Levell NJ, Garioch JJ. The effect of a dermatology restricted-referral list upon the volume of referrals. *Clin Exp Dermatol*. 2007 Jan;32(1):114-5. PubMed PMID: 17305918.

### **Chalazia Removal**

NICE clinical knowledge summaries, <https://cks.nice.org.uk/meibomian-cystchalazion>

Moorfield’s Eye Hospital Patient Information, <https://www.moorfields.nhs.uk/sites/default/files/chalazion-adult.pdf>

Wu AY, Gervasio KA, Gergoudis KN, Wei C, Oestreicher JH, Harvey JT. Conservative therapy for chalazia: is it really effective? *Acta Ophthalmol.* 2018 Jan 16. doi: 10.1111/aos.13675. [Epub ahead of print] PubMed PMID: 29338124.

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McStay. Stye and Chalazion. *BMJ Best Practice* <https://bestpractice.bmj.com/topics/en-gb/214> (accessed 18/10/18)

### **Eyelid Surgery – Ectropian, Entropion and Epithoria**

Entropion and Ectropion Christopher DeBacker <http://emedicine.medscape.com/article/1844045-overview>

## **NEUROLOGICAL AND PAIN INTERVENTIONS**

### **Botulinum toxin type A for Chronic Migraine**

NICE TAG 260 (June 2012) Migraine (chronic) - botulinum toxin type A <http://guidance.nice.org.uk/ta260>

PREEMPT 1 Aurora S K, Dodick D W, Turkel C C ,et al. Onabotulinumtoxin A for treatment of chronic migraine: results from the double-blind, randomized, placebo controlled phase of the PREEMPT 1 trial. *Cephalalgia* 2010;30:793-803. <http://cep.sagepub.com/content/30/7/793.abstract>

PREEMPT 2 Diener H C, Dodick D W, Aurora S K ,et al. Onabotulinumtoxin A for treatment of chronic migraine: results from the double-blind, randomized, placebo controlled phase of the PREEMPT 2 trial. *Cephalalgia* 2010;30:804-14. <http://cep.sagepub.com/content/30/7/804.abstract>

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Botulinum toxin (Botox®) for chronic migraine. NE Treatment Advisory Group. NHS Regional Drug & Therapeutics Centre. September 2011

<http://www.netag.nhs.uk/files/appraisalreports/Botox%20for%20chronic%20migraine%20-%20NETAG%20appraisal%20report%20-Sept%202011- %20WEB%20VERSION.pdf>

Scottish Medicines Consortium advice on Botox for the Prophylaxis of headaches in adults with chronic migraine (April 2011)

[http://www.scottishmedicines.org.uk/SMCAdvice/Advice/692\\_11\\_botulinum\\_toxin\\_type\\_a\\_BOTOX/689\\_11\\_botulinum\\_toxin\\_type\\_a\\_Botox](http://www.scottishmedicines.org.uk/SMCAdvice/Advice/692_11_botulinum_toxin_type_a_BOTOX/689_11_botulinum_toxin_type_a_Botox)

### **Extra Corporeal Shockwave Therapy (ESWT)**

NICE (2011) IPG 376 Extracorporeal shockwave therapy for refractory greater trochanteric pain syndrome.

<http://www.nice.org.uk/ipg376>

NICE (2003) IPG 21 Extra-Corporeal Shockwave Lithotripsy for Calcific Tendonitis (Tendinopathy) of the Shoulder. [www.nice.org.uk/ipg21](http://www.nice.org.uk/ipg21)

NICE (2009) IPG 313 Extra-corporeal shockwave lithotripsy for refractory tennis elbow.

<http://www.nice.org.uk/ipg313>

NICE (2009) IPG 312 Extra-Corporeal Shockwave for refractory Achilles tendinopathy.

<http://www.nice.org.uk/ipg312>

NICE (2009) IPG 311 Extracorporeal shockwave therapy for refractory plantar fasciitis

<http://www.nice.org.uk/ipg311>

### **FES (including wireless and implantable)**

NICE IPG 278 Functional Stimulation for drop foot of central neurological origin. (January 2009)

National Guidelines for Stroke. Royal College of Physicians (2009)

The use of FES in adults with dropped foot. Evidence note. Quality Improvement NHS Scotland October 2008

NETAG Appraisal (Jan 2012) Orthotic functional electrical stimulation for drop foot of neurological origin.

NICE Stroke Pathway (movement difficulties)

### **Sativex (Delta-9 Tetrahydrocannabinol and Cannabidiol Oromucosal Spray)**

NICE CG 186 Multiple sclerosis: management of multiple sclerosis in primary and secondary care (October 2014) <https://www.nice.org.uk/guidance/cg186>

### **Spinal Injections of Local Anaesthetic and Steroid in people with Non-Specific Low Back Pain without Sciatica**

NICE guidance: <https://www.nice.org.uk/guidance/ng59>,

United Kingdom Spine Societies Board: <https://www.ukssb.com/improvingspinal-care-project>

Benjamin RM, Manchikanti L, Parr AT, Diwan S, Singh V, Falco FJ, et al. The effectiveness of lumbar interlaminar epidural injections in managing chronic low back and lower extremity pain. Pain Physician. 2012 Jul;15(4):E363-404.

Choi HJ, Hahn S, Kim CH, Jang BH, Park S, Lee SM, et al. Epidural steroid injection therapy for low back pain: a meta-analysis. Int J Technol Assess Health Care. 2013 Jul;29(3):244-53.

Cohen SP, Bicket MC, Jamison D, Wilkinson I, Rathmell JP. Epidural steroids: a comprehensive, evidence-based review. Reg Anesth Pain Med. 2013 May-Jun;38(3):175-200.

Royal College of Anaesthetists: <https://www.rcoa.ac.uk/documentstore/core-standards-pain-management-services-the-uk>

## OPHTHALMOLOGY INTERVENTIONS

### **Cataract Surgery (including Second Eye Cataracts)**

Driving eyesight rules Jan 2015

Royal College of Ophthalmologists Feb 2015 Commissioning Guide: Cataract Surgery Clinical Knowledge Summaries: Cataracts. Due during 2017

Routine pre-operative medical testing for cataract surgery Cochrane database 2012 Day A, Donachie PHJ, Sparrow JM, Johnston RL. The Royal College of Ophthalmologists' National Ophthalmology Database Study of Cataract Surgery: Report 1, Visual Outcomes and Complications. Eye. Feb 2015

Healthcare Improvement Scotland Technologies scoping report 9: What is the impact of using thresholds for first-eye cataract surgery on the delivery of the cataract service?

English National Health Service's Savings Plan May Have Helped Reduce The Use Of Three 'Low-Value' Procedures Sophie Coronini-Cronberg et al Health Affairs March 2015

Cataract surgical rates: is there overprovision in certain areas? Sparrow Br J Ophthalmol 2007 91: 852-853

Evidence review: cataract surgery Hampson and Briggs; Cheshire West and Chester public health collaborative service May 2014

Sophie Coronini-Cronberg, member of Royal College of Ophthalmologists working group commissioned by NICE to develop commissioning guidelines (see ref 2) and Honorary Research Fellow, Department of Primary Care and Public Health, Imperial College London (personal communication)

Cambridge and Peterborough CCG Cataracts policy March 2014.

### **Corrective Surgery, Lens Implants and Laser Treatment for Refractive error (short or long sightedness, astigmatism)**

NICE IPG 164 (2006) Photorefractive (laser) surgery for the correction of refractive errors (replaces previous guidance on laser in situ keratomileusis (LASIK) NICE IPG 102).

NICE IPG385 Laser correction of refractive error following non-refractive ophthalmic surgery (March 2011)

The Royal College of Ophthalmologists (2017) Statement on Standards for Laser Refractive Surgery.

Murray A, Jones L, Milne A et al. 'A systematic review of the safety and efficacy of elective photorefractive surgery for the correction of refractive error'. University of Aberdeen; 2005.

NICE IPG 225 (2007) Corneal implants for correction of refractive error.

NICE IPG 289 (2009) Intraocular lens insertion for correction of refractive error, with preservation of the natural lens

## **Intravitreal Therapies for Eye Disease**

NICE Technology Appraisal Guidance 155 (issued August 2008, updated May 2012) Macular degeneration (age-related) - ranibizumab and pegaptanib. <http://www.nice.org.uk/ta155>

Royal College of Ophthalmologists ( 2009) Guidelines for the Management of wet ARMD  
[http://www.rcophth.ac.uk/core/core\\_picker/download.asp?id=1185&filetitle=Age%2DRelated+Macular+Degeneration+2009+Guidelines+for+Management%2Dupdate](http://www.rcophth.ac.uk/core/core_picker/download.asp?id=1185&filetitle=Age%2DRelated+Macular+Degeneration+2009+Guidelines+for+Management%2Dupdate)

Scottish Medicines Consortium (March 2013) Advice on aflibercept 40mg/mL solution for intravitreal injection (Eylea®) in adults for the treatment of neovascular (wet) age-related macular degeneration.  
[http://www.scottishmedicines.org.uk/files/advice/aflibercept\\_Eylea\\_FINAL\\_March\\_2013\\_Amended\\_030413\\_for\\_website.pdf](http://www.scottishmedicines.org.uk/files/advice/aflibercept_Eylea_FINAL_March_2013_Amended_030413_for_website.pdf)

Statement from The Royal College of Ophthalmologists in response to the SMC Decision to accept Eylea® for wet AMD (April 2013). <http://www.rcophth.ac.uk/news.asp?section=24&itemid=1350&search>

NICE Technology Appraisal Guidance 294 (July 2013) Aflibercept solution for injection for treating wet age-related macular degeneration. <http://www.nice.org.uk/nicemedia/live/14227/64572/64572.pdf>

Jeffrey S. Heie et al for the VIEW 1 and VIEW 2 Study Groups (2012) Intravitreal Aflibercept (VEGF Trap-Eye) in Wet Age-related Macular Degeneration. Ophthalmology. 2012 Dec;119(12):2537-48  
[http://www.aaojournal.org/article/S0161-6420\(12\)00865-2/abstract](http://www.aaojournal.org/article/S0161-6420(12)00865-2/abstract)

NICE Technology Appraisal Guidance 274 (Feb 2013) Ranibizumab for the treatment of diabetic macular oedema <http://www.nice.org.uk/ta274>

NICE Technology Appraisal Guidance 283 (May 2013). Ranibizumab for treating visual impairment caused by macular oedema secondary to retinal vein occlusion  
<http://www.nice.org.uk/nicemedia/live/14169/63851/63851.pdf>

NICE Technology Appraisal Guidance 229. (July 2011) Dexamethasone intravitreal implant for the treatment of macular oedema secondary to retinal vein occlusion  
<http://www.nice.org.uk/nicemedia/live/13541/55611/55611.pdf>

NICE Technology Appraisal Guidance 298 (Nov 2013) Ranibizumab for treating choroidal neovascularisation associated with pathological myopia. <http://www.nice.org.uk/nicemedia/live/14305/65827/65827.pdf>

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<http://www.nature.com/eye/journal/v23/n6/full/eye200988a.html>

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Rosenfeld PJ, et al. Ranibizumab for neovascular age-related macular degeneration. N Engl J Med 2006;355:1419–31. (MARINA) <http://www.eyedocs.co.uk/ophthalmology-journal-articles-classic/441-marina-trial>

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<http://archophth.jamanetwork.com/article.aspx?articleid=418708>

Mitchell P, et al. Ophthalmology. 2011 Apr; 118(4):615-25. The RESTORE study: ranibizumab monotherapy or combined with laser versus laser monotherapy for diabetic macular edema.

<http://www.ncbi.nlm.nih.gov/pubmed/21459215>

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## PLASTIC SURGERY INTERVENTIONS

### **Abdominoplasty/Apronectomy**

Information for Commissioners of Plastic Surgery Services - Referrals and Guidelines in Plastic Surgery (NHS Modernisation Agency) London

### **Blepharoplasty**

Information for Commissioners of Plastic Surgery Services - Referrals and Guidelines in Plastic Surgery (NHS Modernisation Agency)

### **Breast Surgery (Asymmetry, Reduction, Enlargement, Revisional and Implant Replacement)**

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### **Face, Neck and Brow Lifts**

Information for Commissioners of Plastic Surgery Services - Referrals and Guidelines in Plastic Surgery (NHS Modernisation Agency) London <http://www.bapras.org.uk/docs/default-source/commissioning-and-policy/information-forcommissioners-of-plastic-surgery-services.pdf>

### **Gynaecomastia**

Information for Commissioners of Plastic Surgery Services - Referrals and Guidelines in Plastic Surgery (NHS Modernisation Agency) London <http://www.bapras.org.uk/docs/default-source/commissioning-and-policy/information-forcommissioners-of-plastic-surgery-services.pdf?sfvrsn=2>

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Information for Commissioners of Plastic Surgery Services - Referrals and Guidelines in Plastic Surgery (NHS Modernisation Agency) London

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### **Pinnaplasty**

Information for Commissioners of Plastic Surgery Services - Referrals and Guidelines in Plastic Surgery (NHS Modernisation Agency) London <http://www.bapras.org.uk/docs/default-source/commissioning-and-policy/information-forcommissioners-of-plastic-surgery-services.pdf>

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Modernisation Agency Document 'Information for Commissioners of Plastic Surgery Services' prepared by the British Association of Plastic and Reconstructive Surgery

### **Scar Revision and Skin Resurfacing**

Information for Commissioners of Plastic Surgery Services - Referrals and Guidelines in Plastic Surgery (NHS Modernisation Agency) London <http://www.bapras.org.uk/docs/default-source/commissioning-and-policy/informationfor-commissioners-of-plastic-surgery-services.pdf>

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[http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2922716/pdf/jcad\\_3\\_5\\_20.pdf](http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2922716/pdf/jcad_3_5_20.pdf)

### **Surgical Fillers**

Modernisation Agency - Information for Commissioners of Plastic Surgery Services (March 2012)

<http://www.bapras.org.uk/downloaddoc.asp?id=425>

## **RESPIRATORY INTERVENTIONS**

### **Sleep Study, Trial and Continuous Positive Airway Pressure (CPAP) for Obstructive Sleep Apnoea**

Specialised Services National Definitions Set (SSNDS) No.29 Specialised Respiratory Services (adult) third edition 2009 [http://www.specialisedservices.nhs.uk/library/26/Specialised Respiratory Services\\_adult.pdf](http://www.specialisedservices.nhs.uk/library/26/Specialised_Respiratory_Services_adult.pdf)

Murray W. Johns - A New Method For Measuring Daytime Sleepiness: The Epworth Sleepiness Scale - Sleep 1991; 14:540-5

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## **UROLOGICAL INTERVENTIONS**

### **Botox for Overactive Bladder**

Apostolidis et al (2009) Recommendations on the Use of Botulinum Toxin in the Treatment of Lower Urinary Tract Disorders and Pelvic Floor Dysfunctions: A European Consensus Report. European Urology Volume 55, issue 1, pages 1- 260, January 2009 [http://www.europeanurology.com/article/S0302-2838\(08\)01109-3/abstract](http://www.europeanurology.com/article/S0302-2838(08)01109-3/abstract)

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NICE Clinical Guideline 148 (2012) Urinary incontinence in neurological disease.

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<http://publications.nice.org.uk/idiopathic-overactive-bladdersyndrome-botulinum-toxin-a-esnm2#close>

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<http://www.nice.org.uk/nicemedia/live/14195/64256/64256.pdf>

Sahai et al. GKT Botulinum Study Group. Efficacy of Botulinum Toxin-A for Treating Idiopathic Detrusor Overactivity: Results From a Single Centre, Randomized, Double-Blind, Placebo Controlled Trial. *The Journal of Urology* June 2007 (Vol. 177, Issue 6, Pages 2231-2236) [http://www.jurology.com/article/S0022-5347\(07\)00268-6/abstract](http://www.jurology.com/article/S0022-5347(07)00268-6/abstract)

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### **Circumcision (Male Adults and Male Children)**

Female Genital Mutilation Act 2003 <http://www.legislation.gov.uk/ukpga/2003/31>

Female Genital Mutilation: multi-agency practice guidelines. Department of Health, February 2011 <https://www.gov.uk/government/publications/female-genital-mutilation-multi-agency-practiceguidelines>

Royal College of Surgeons Commissioning guide: Foreskin conditions October 2013

<http://www.rcseng.ac.uk/healthcare-bodies/docs/published-guides/foreskin-conditions>

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<http://www.cirp.org/library/statements/RCS2001/>

NHS Choices – Information on Circumcision and medical reasons why it may be necessary.

<http://www.nhs.uk/Conditions/Circumcision/Pages/Introduction.aspx>

British Medical Association (2006), London. The law and ethics of male circumcision: guidance for doctors. *J Med Ethics* 2004; 30: 259–263. <http://jme.bmj.com/content/30/3/259.full.pdf+html>

British Association of Paediatric Urologists (2013). Statement on Foreskin Conditions.

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### **Sacral Nerve Stimulation (SNS) Female Adults with Urinary Retention**

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### **Epididymal Cyst Surgery**

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Braslis KG, Moss DI; Long-term experience with sclerotherapy for treatment of epididymal cyst and hydrocele. Aust N Z J Surg. 1996 Apr;66(4):222-4. [abstract]

Homayoon K, Suhre CD, Steinhardt GF; Epididymal cysts in children: natural history. J Urol. 2004 Mar;171(3):1274-6. [abstract]

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### **Hydrocele Correction**

<https://cks.nice.org.uk/scrotal-swellings#!scenario:8>

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NHS Evidence - Clinical Knowledge Summaries ; Erectile Dysfunction <http://cks.nice.org.uk/erectile-dysfunction>

Guidelines on the management of erectile dysfunction, British Society for Sexual Medicine (BSSM) 2009. [http://www.bssm.org.uk/downloads/BSSM\\_ED\\_Management\\_Guidelines\\_2009.pdf](http://www.bssm.org.uk/downloads/BSSM_ED_Management_Guidelines_2009.pdf)

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### **Percutaneous Tibial Nerve Stimulation (PTNS) for Urinary Incontinence**

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<http://www.biomedcentral.com/content/pdf/1471-2490-13-61.pdf>

### **Sacral Nerve Stimulation (SNS) Male Adults with Urinary Retention**

<http://pathways.nice.org.uk/pathways/lower-urinary-tract-symptoms-in-men>

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### **Varicoceles**

<https://cks.nice.org.uk/varicocele>

## **VASCULAR INTERVENTIONS**

### **Resperate © (Intercure Ltd.)**

Mahtani KR, Nunan D, Heneghan CJ. Device-guided breathing exercises in the control of human blood pressure: systematic review and meta-analysis. Journal of Hypertension 2012; 30(5):852-860  
<http://www.ncbi.nlm.nih.gov/pubmed/22495126>

Meta-analysis of the RESPeRATE device for lowering BP and related statement from the British Hypertension Society. (April 2012) <http://www.bhsoc.org/pdfs/Statement%20on%20RESPeRATE%20April%2012.pdf>

### **Varicose Veins (C0-C6)**

NICE Guidance: <https://www.guidelinesinpractice.co.uk/nice-referral-advice11-varicose-veins/300594.article>

NICE Guidance: <https://www.nice.org.uk/guidance/cg168>

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Editor's Choice - Management of Chronic Venous Disease: Clinical Practice Guidelines of the European Society for Vascular Surgery (ESVS). Wittens C, Davies AH, Bækgaard N, Broholm R, Cavezzi A, Chastanet S, de Wolf M, Eggen C, Giannoukas A, Gohel M, Kakkos S, Lawson J, Noppeney T, Onida S, Pittaluga P, Thomis S, Toonder I, Vuylsteke M, Esvs Guidelines Committee, Kolh P, de Borst GJ, Chakfé N, Debus S, Hinchliffe R, Koncar I, Lindholt J, de Ceniga MV, Vermassen F, Verzini F, Document Reviewers, De Maeseneer MG, Blomgren L, Hartung O, Kalodiki E, Korten E, Lugli M, Naylor R, Nicolini P, Rosales A Eur J Vasc Endovasc Surg. 2015 Jun;49(6):678-737. doi: 10.1016/j.ejvs.2015.02.007. Epub 2015 Apr 25.

The care of patients with varicose veins and associated chronic venous diseases: clinical practice guidelines of the Society for Vascular Surgery and the American Venous Forum. Gloviczki P1, Comerota AJ, Dalsing MC, Eklof BG, Gillespie DL, Gloviczki ML, Lohr JM, McLafferty RB, Meissner MH, Murad MH, Padberg FT, Pappas PJ, Passman MA, Raffetto JD, Vasquez MA, Wakefield TW; Society for Vascular Surgery; American Venous Forum. *J Vasc Surg*. 2011 May;53(5 Suppl):2S-48S. doi: 10.1016/j.jvs.2011.01.079..

A Randomized Trial of Early Endovenous Ablation in Venous Ulceration. Gohel MS1, Heatley F1, Liu X1, Bradbury A1, Bulbulia R1, Cullum N1, Epstein DM1, Nyamekye I1, Poskitt KR1, Renton S1, Warwick J1, Davies AH1; EVRA Trial Investigators. *N Engl J Med*. 2018 May 31;378(22):2105-2114. doi: 10.1056/NEJMoa1801214. Epub 2018 Apr 24



## Appendix 3 – OPCS Codes

<b>COLORECTAL INTERVENTIONS</b>	
Surgery for Anal Fissure (Adults and Children)	H56.4, H562
Botulinum Toxin type A for Anal Fissure	S53.2 with X85.1 and Z49.2, H568
Haemorrhoid Surgery	H51, H511, H512, H513, H518, H519
Percutaneous Tibial Nerve Stimulation (PTNS) for Faecal Incontinence	A704 (both permanent and 12 week trial)
Sacral Nerve Stimulation (SNS) Adults with Faecal Retention	A701, A704

<b>DERMATOLOGY INTERVENTIONS</b>	
Hair Loss Treatments	S21.1, S21.2, S21.8, S21.9, S33.1, S33.2, S33.3, S33.8, S33.9
Tattoo Removal	S06.1, S06.2, S09.1, S09.2, S10.8, S10.9, S601, S602, S05*, S06*

<b>EAR, NOSE AND THROAT INTERVENTIONS</b>	
Adult Snoring Surgery in the absence of Obstructive Sleep Apnoea (OSA)	F325, F326, F328
Botulinum toxin type A for Spasmodic Dysphonia	E381
Grommets for Glue Ear in Children	D151, D158, D159
Irrigation of the external Auditory Canal	Primary procedure code D071
Rhinoplasty/Septorhinoplasty/Septoplasty	E02.3, E02.4, E02.5, E02.6, E028, E073, E022, E027, E029, E036, E037, E071, E072, E078, E079
Tonsillectomy	F34.1, F34.2, F34.3, F34.4, F34.5, F34.6, F34.7, F34.8, F34.9,

<b>ENDOCRINE INTERVENTIONS</b>	
Botulinum toxin type A for Hyperhidrosis	E381
Continuous Glucose Monitoring System (CGMS)	n/a
Endoscopic Thoracic Sympathectomy	A752
Flash Glucose Monitoring (FGM) Systems such as Freestyle Libre <sup>®</sup>	n/a
Hair Removal for Hirsutism	S60.6, S60.7, S608

<b>FERTILITY INTERVENTIONS</b>	
Reversal of Sterilisation	Q29.1, Q29.2, Q29.8, Q29.9 Q30.3, Q37.1, Q37.8, Q37.9. N18.1, N18.2, N18.8, N18.9
Vasectomy under GA	N17.1, N17.2, N17.8, N17.9, N17*

<b>GENERAL SURGERY</b>	
Cholecystectomy	J181, J182, J183, J184, J185, J188, J189

<b>GYNAECOLOGY INTERVENTIONS</b>	
Dilation and Curettage (D&C) for Heavy Menstrual Bleeding	Q10.3
Elective Caesarean Section (non-clinical reasons)	R17*
Hysterectomy for Heavy Menstrual Bleeding	Q071, Q072, Q073, Q074, Q075, Q076, Q078, Q079, Q081, Q082, Q083, Q088, Q089
Labiaplasty/Vaginoplasty	P05.5, P05.6, P05.7, P213, P214, P215, P218, P219

<b>Mental Health</b>	
Referral to Specialist Chronic Fatigue Services	n/a

<b>MINOR SURGERY PROCEDURES</b>	
Benign Skin Lesions – Surgical Removal	S05.1, S05.2, S05.3, S05.4, S05.5, S05.8, S05.9, S06.1, S06.2, S06.3, S06.4, S06.5, S06.8, S06.9, S08.1, S08.2, S08.3, S08.8, S08.9, S09.1, S09.2, S09.3, S09.8, S09.9, S10.1, S10.2, S10.3, S10.8, S10.9, S11.1, S11.2, S11.3, S11.4, S11.8, S11.9, D02.1, F02.1, B353, C101, D022, D028, D029, E091, E096, F022, F028, F029, S066, S067, S105, S115, E092
Chalazia Removal	C12*
Eyelid Surgery – Ectropian, Entropian and Epithoria	C12*, C15*, C16*, C17*, C253, C254, C251, C252

<b>NEUROLOGICAL AND PAIN INTERVENTIONS</b>	
Botulinum toxin type A for Chronic Migraine	X85.1, S532
Extra Corporeal Shockwave Therapy (ESWT)	T748 (ankle), T748 (elbow), T578 (heel), T628 (hip), T745 (shoulder)
FES (including wireless and implantable)	A70.1, A70.7, A704
Sativex (Delta-9 Tetrahydrocannabinol and Cannabidiol Ocomucosal Spray)	n/a
Spinal Injections of Local Anaesthetic and Steroid in people with Non-Specific Low Back Pain without Sciatica	A521, A522, A735, V544, X306, X308, X309, X375, X382, W903, W904, X305, V623, V633, A528, A529, A577, A735

<b>OPHTHALMOLOGY INTERVENTIONS</b>	
Cataract Surgery (including Second Eye Cataracts)	C75*, C71*, C72*, C73*, C74*
Corrective Surgery, Lens Implants and Laser Treatment for Refractive error (short or long sightedness, astigmatism)	C44*, C45*, C46*
Intravitreal Therapies for Eye Disease	C794
Photodynamic Therapy (PDT) – for CSR	C88.2

<b>ORTHOPAEDIC INTERVENTIONS</b>	
Arthroscopic Lavage and Debridement	W85.2
Arthroscopic Shoulder Decompression for Subacromial Shoulder Pain	029.1
Bunion Surgery	W15*, W59*, W79*, W03*, W083, W131, W132, W133, W144, W44*, W571, W572, W578
Carpal Tunnel Syndrome Release	A65.1, A65.9
Dupuytren's Contracture Release - Adults	(Surgery) T521, T522, T525, T526, T541, (CCH Injections) T578
Facet Joint Injections	V544
Ganglion Excision	T592, T602, T594, T604
Hip Arthroscopy	W83*, W84*, Y767 with Z843
Hyaluronic Acid Injections for Musculoskeletal Joint Pain (Synvisc)	W903
Illizarov Technique/Taylor Spatial Frame (TSF)	W304
Knee Arthroscopy	W852
Trigger Finger/Thumb Surgery	T711, T723, T744

<b>OTHER</b>	
Open and Wide-Bore Magnetic Resonance Imaging (MRI) Scanning	n/a

<b>PLASTIC SURGERY INTERVENTIONS</b>	
Abdominoplasty/Apronectomy	S02.1, S02.2, S02.8, S02.9
Blepharoplasty	C13.1, C13.2, C13.3, C13.4, C13.8, C13.9
Breast Surgery (Asymmetry, Reduction, Enlargement, Revisional and Implant Replacement)	B30.1, B30.2, B30.3, B30.4, B30.8, B30.9, B31.1, B31.2, B31.3, B37.5, B318, B319, B351, B352, B353, B354, B355, B356, B358, B359, B275
Cleft Earlobe Surgery	D062
Face, Neck and Brow Lifts	S01.1, S01.2, S01.3, S01.4, S01.5, S01.6
Gynaecomastia	B31.1, B275
Liposuction	S62.1 S62.2
Pinnaplasty	D03.3
Scar Revision and Skin Resurfacing	S10.3, S11.3, S60.1, S60.2, S09.1, S09.2, S60.4
Surgical Fillers	S534

<b>RESPIRATORY INTERVENTIONS</b>	
Sleep Study, Trial and Continuous Positive Airway Pressure (CPAP) for Obstructive Sleep Apnoea	U331, E913

<b>UROLOGICAL INTERVENTIONS</b>	
Botox for Overactive Bladder	M43.4
Circumcision (Male Adults and Children)	N30.3
Epididymal Cyst Surgery	N15.3
Hydrocele Correction	T193
Penile Implants	N29.1
Percutaneous Tibial Nerve Stimulation (PTNS) for Urinary Incontinence	A704
Sacral Nerve Stimulation (SNS) Female Adults with Urinary Retention	A701, A704, A707
Sacral Nerve Stimulation (SNS) Male Adults with Urinary Retention	A701, A704, A707
Varicoceles	N192

<b>VASCULAR INTERVENTIONS</b>	
Resperate © (Intercure Ltd.)	n/a
Varicose Veins (C0-C6)	L83.2 - L88.9, L841, L842, L843, L844, L845, L846, L848, L849, L851, L852, L853, L858, L859, L861, L862, L868, L869, L871, L872, L873, L874, L875, L876, L877, L878, L879, L881, L882, L883, L889, L841, L842, L843, L844, L845, L846, L848, L849, L851, L852, L853, L858, L859, L861, L862, L868, L869, L871, L872, L873, L874, L875, L876, L877, L878, L879, L881, L882, L883, L889, L841, L842, L843, L844, L845, L846, L848, L849, L851, L852, L853, L858, L859, L861, L862, L868, L869, L871, L872, L873, L874, L875, L876, L877, L878, L879, L881, L882, L883, L889,