
HUMBER CCG'S EVIDENCE-BASED INTERVENTIONS POLICY DOCUMENT

Interventions subject to Prior Approval or an Individual Funding Request

JANUARY 2020 (VERSION 2)

EAST RIDING OF YORKSHIRE, HULL AND NORTHERN LINCOLNSHIRE CCGS

Colorectal Interventions

Intervention	Surgery for Anal Fissure - Adults
For the treatment of	Anal Fissures in Adults
Commissioning Position	<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"> • Multiple, off the midline, large or irregular (atypical fissures) as these may be the manifestation of underlying disease • Chronic fissures that have not healed after 8 weeks of treatment with adequate dietary treatment measure, stool softeners or laxatives and treatment with topical GTN 0.4% ointment or if not tolerated diltiazem 2% ointment twice a day for 8 weeks. Stress to patients the importance of adherence. • Check if patient taking Nicorandil (a risk factor)
Evidence/Summary of Rationale	See Clinical Knowledge Summary for Anal Fissure July 2016
Effective From	1 st April 2019
Policy Review Date	1 st April 2021

Intervention	Surgery for Anal Fissure - Children
For the treatment of	Anal Fissures in Children (under 18)
Commissioning Position	<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"> • Presenting with an anal fissure for the first time, with a clear history of severe constipation as causation, where the anal fissure has not healed after two weeks despite GTN 0.05% to 0.1% ointment. This should be prescribed by a specialist as it is not licensed for use in people aged less than 18 years. • Presenting with an anal fissure without a clear history of severe constipation, refer at first presentation. • Recurrent anal fissures.
Evidence/Summary of Rationale	See Clinical Knowledge Summary for Anal Fissure July 2016
Effective From	1 st April 2019
Policy Review Date	1 st April 2021

Intervention	12 week trial of Percutaneous Tibial Nerve Stimulation (PTNS) – Faecal Incontinence
For the treatment of	Adults with refractory Faecal Incontinence
Commissioning Position	<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"> • Voiding diary data is kept to record frequency and severity of episodes • Symptoms refractory to ≥12 months of first line treatment to include: <ul style="list-style-type: none"> - dietary management - antidiarrhoeal medication - pelvic floor muscle and anal sphincter training (where appropriate)
Evidence/Summary of Rationale	<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.
Effective From	1 st November 2019
Policy Review Date	1 st November 2021

Intervention	Continued Percutaneous Tibial Nerve Stimulation (PTNS) – Faecal Incontinence
For the treatment of	Adults with refractory Faecal Incontinence
Commissioning Position	<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"> • They have already undertaken an approved 12 week trial of PTNS • The trial has resulted in a 50% or more improvement in symptoms (measured as a weekly reduction in incontinence episodes).
Evidence/Summary of Rationale	<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>
Effective From	1 st November 2019
Policy Review Date	1 st November 2021

Ear, Nose and Throat Interventions

Intervention	Grommets for Glue Ear in Children
For the treatment of	Glue Ear (Otitis Media with Effusion) in Children
Commissioning Position	<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"> • All children must have had specialist audiology and ENT assessment. • Persistent bilateral otitis media with effusion over a period of 3 months. • Hearing level in the better ear of 25-30dbHL or worse averaged at 0.5, 1, 2, & 4kHz • Exceptionally, healthcare professionals should consider surgical intervention in children with persistent bilateral OME with a hearing loss less than 25-30dbHL where the impact of the hearing loss on a child's developmental, social or educational status is judged to be significant. • Healthcare professionals should also consider surgical intervention in children who cannot undergo standard assessment of hearing thresholds where there is clinical and tympanographic evidence of persistent glue ear and where the impact of the hearing loss on a child's developmental, social or educational status is judged to be significant. • The guidance is different for children with Down's Syndrome and Cleft Palate, these children may be offered grommets after a specialist MDT assessment in line with NICE guidance. • It is also good practice to ensure glue ear has not resolved once a date of surgery has been agreed, with tympanometry as a minimum. <p>Evidence-Based Interventions: Guidance for CCG's 2018</p>
Evidence/Summary of Rationale	<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>
Effective From	1 st April 2019
Policy Review Date	1 st April 2021

Intervention	Irrigation of the external Auditory Canal
For the treatment of	Ear Wax
Commissioning Position	<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"> • The patient has previously undergone ear surgery (other than grommets insertion that have been extruded for at least 18 months); • Has a recent history of Otagia and /or Otitis media middle ear infection (in the

	<p>past 6 weeks);</p> <ul style="list-style-type: none"> • Recurrent Acute Otitis Externa which is not responding to primary care treatment; • Has a current perforation or history of ear discharge in the past 12 months; • Has had previous complications following ear irrigation including perforation of the ear drum, severe pain, deafness, or vertigo; • Two attempts at irrigation of the ear canal following intensive use of ear wax softeners in primary care are unsuccessful; • Cleft palate, whether repaired or not. • Painful or acute otitis externa with an oedematous ear canal and painful pinna. • Presence of a foreign body in the ear • 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. • Confusion or agitation, as they may be unable to sit still. • Inability to cooperate, for example young children and some people with learning difficulties. <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>
Evidence/Summary of Rationale	The vast majority of patients presenting with problems to primary care will be managed in primary care with advice or irrigation.
Effective From	1 st November 2019
Policy Review Date	1 st November 2021

Intervention	Rhinoplasty/Septorhinoplasty/Septoplasty
For the treatment of	Nasal Deformities
Commissioning Position	<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 <i>only in</i></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"> 1. When it is being performed to correct a nasal deformity secondary to congenital cleft lip and/or palate; 2. Upon individual case review, to correct chronic non-septal nasal airway obstruction from vestibular stenosis (collapsed internal valves) due to trauma, disease, or congenital defect, when all of the following criteria are met: <ul style="list-style-type: none"> • Airway obstruction will not respond to septoplasty and turbinectomy alone;

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

Gynaecological Interventions

Intervention	Labiaplasty / Vaginaplasty
For the treatment of	Malformed, enlarged labia / vulva causing functional discomfort which has not responded to conservative management.
Commissioning Position	<p>The NHS will routinely commission reconstructive Labiaplasty / Vaginaplasty:</p> <ul style="list-style-type: none"> • following surgery for cancer • repair after trauma (including tears / scars from childbirth). <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"> • Where the woman is 18 years of age or older • Where the woman has completed pubertal development (RCOG, 2013). • Where the labia / vulva causes functional discomfort • Where simple measures to relieve functional discomfort are not successful (Harsh soaps and shower gels in the genital area should be avoided. The use of emollients should be recommended, as well as comfortable underwear). • Where the clinician's sensitive genital examination (visual inspection) has determined that benign labial disease, significant congenital malformation or structural anomalies are identified. <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>
Evidence/Summary of Rationale	<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>
Effective From	1 st April 2019
Policy Review Date	1 st April 2021

Minor Surgery Procedures

Intervention	Benign Skin Lesions – Surgical Removal
For the treatment of	Symptomatic benign skin lesions
Commissioning Position	<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">• benign moles (excluding large congenital naevi)• solar comedones

	<ul style="list-style-type: none"> • corn/callous • dermatofibroma • lipomas • milia • molluscum contagiosum (non-genital) • epidermoid & pilar cysts (sometimes incorrectly called sebaceous cysts) • seborrheic keratoses (basal cell papillomata) • skin tags (fibroepithelial polyps) including anal tags • spider naevi (telangiectasia) • non-genital viral warts in immunocompetent patients • xanthelasmata • neurofibromata <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"> • The lesion is unavoidably and significantly traumatised on a regular basis with evidence of this causing regular bleeding or resulting in infections such that the patient requires 2 or more courses of antibiotics (oral or intravenous) per year • There is repeated infection requiring 2 or more antibiotics per year • The lesion bleeds in the course of normal everyday activity • The lesion causes regular pain • The lesion is obstructing an orifice or impairing field vision • The lesion significantly impacts on function e.g. restricts joint movement • The lesion causes pressure symptoms e.g. on nerve or tissue • If left untreated, more invasive intervention would be required for removal • Facial viral warts • Facial spider naevi in children causing significant psychological impact • Lipomas on the body > 5cms, or in a sub-facial position, with rapid growth and/or pain. These should be referred to Sarcoma clinic. <p>The following are outside the scope of this policy recommendation:</p> <ul style="list-style-type: none"> • Lesions that are suspicious of malignancy should be treated or referred according to NICE skin cancer guidelines. • Any lesion where there is diagnostic uncertainty, pre-malignant lesions (actinic keratoses, Bowen disease) or lesions with pre-malignant potential should be referred or, where appropriate, treated in primary care. • Removal of lesions other than those listed above. <p>Referral to dermatology or plastic surgery:</p> <ul style="list-style-type: none"> • The decision as to whether a patient meets the criteria is primarily with the referring clinician. If such lesions are referred, then the referrer should state that this policy has been considered and why the patient meets the criteria. • Requests for treatment where a patient meets the criteria do not require prior approval or an IFR. • This policy applies to all providers, including general practitioners (GPs), GPs with enhanced role (GPwer), independent providers, and community or intermediate services.
Evidence/Summary of	There is little evidence to suggest that removing benign skin lesions to improve

Rationale	appearance is beneficial. Risks of this procedure include bleeding, pain, infection and scarring. Though in certain specific cases as outlined by the criteria above, there are benefits for removing skin lesions, for example, avoidance of pain and allowing normal functioning. Evidence-Based Interventions: Guidance for CCG's 2018.
Effective From	1 st April 2019
Policy Review Date	1 st April 2021

Intervention	Chalazia Removal
For the treatment of	Chalazia (meibomian cysts). Benign lesions on the eyelids due to blockage and swelling of an oil gland.
Commissioning Position	<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"> • Has been present for more than 6 months and has been managed conservatively with warm compresses, lid cleaning and massage for 4 weeks • Interferes significantly with vision, demonstrated by visual fields test • Interferes with the protection of the eye by the eyelid due to altered lid closure or lid anatomy • Is a source of infection that has required medical attention twice or more within a six month time frame • Is a source of infection causing an abscess which requires drainage • If malignancy (cancer) is suspected e.g. Madarosis/recurrence/other suspicious features in which case the lesion should be removed and sent for histology as for all suspicious lesions <p>Evidence-Based Interventions: Guidance for CCG's 2018.</p>
Evidence/Summary of Rationale	The evidence shows that alternative treatment options (warm compresses, drops or ointment, steroid injection) or a "watch and wait" approach will lead to resolution of many chalazia without the risks of surgery.
Effective From	1 st April 2019
Policy Review Date	1 st April 2021

Intervention	Functional Electrical Stimulation (FES)
For the treatment of	Foot Drop
Commissioning Position	<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"> • The individual has an upper motor neuron lesion resulting from stroke, multiple sclerosis (MS), cerebral palsy (CP) or spinal cord injury (SCI) (but has an intact peroneal nerve); • There is evidence that the foot drop interferes significantly with the individual's day to day living; • There is evidence that FES has been recommended for the individual after a thorough assessment of their suitability by the local NHS physiotherapy service or MDT specialising in rehabilitation. <ul style="list-style-type: none"> • The request to the IFR Panel must include evidence that first line treatments have been tried and failed. • First-line treatment is usually physiotherapy or the use of an ankle foot orthosis (AFO). Agreed to delete these lines? Evidence will be required to demonstrate that first line treatments have been tried. • Other options may include medical therapy, electrical stimulation of the affected nerves and surgery. These options can be used alone or in combination with one another. <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>
Evidence/Summary of Rationale	<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>
Effective From	1 st April 2019
Policy Review Date	1 st April 2021

Ophthalmology Interventions

Intervention	Intravitreal Therapies for Eye Disease
For the treatment of	Eye Disease
Commissioning Position	<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>A) Wet Age Related Macular Degeneration (ARMD)</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"> • The best possible visual acuity (VA) after correction with glasses or contact lenses is between 6/12 and 6/96. • There is no permanent damage to the fovea • 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. • There are signs that the condition has been getting worse. (i.e. blood vessel growth, as indicated by fluorescein angiography, or recent VA changes) <p>and</p> <ul style="list-style-type: none"> • The manufacturer provides ranibizumab with the discount agreed in the patient access scheme (as revised in 2012). <p>NB. Treatment should be stopped if:</p> <ul style="list-style-type: none"> • Vision in the treated eye falls below 15 letters on 2 consecutive visits • Vision falls by 30 letters or more compared to the best recorded vision • There is evidence of deterioration of the lesion morphology despite treatment. <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"> • it is used in accordance with the recommendations for ranibizumab in NICE TAG 155; and • the manufacturer provides aflibercept solution for injection with the discount agreed in the patient access scheme. <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

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).

E) Inflammatory CNV

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:

- Sub/juxta foveal CNV associated with underlying inflammatory disease; **and**
- Intra-retinal OR sub-retinal fluid on OCT scans OR leakage on FFA

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.

Re-treatments will only be commissioned (after application to the CCG IFR Panel) in cases where:

- Intra/sub-retinal fluid is seen on OCT scans (persistent or recurrent); **or**
- Lesion leakage is documented on FFA.

F) Visual Loss due to Vitreo-Macular Traction

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:

- no epiretinal membrane (a thin layer of scar tissue over their retina, the light-sensitive area at the back of the eye); **and**
- a macular hole (up to 400 micrometers) in the centre of their retina or • severe sight problems.

G) Other eye disease

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.

Evidence/Summary of Rationale

Wet Age Related Macular Degeneration

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

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>Inflammatory CNV</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>Visual Loss from Vitreo-Macular Traction</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>
Effective From	1 st November 2019
Policy Review Date	1 st November 2021

Orthopaedic Interventions

Intervention	Arthroscopic Lavage and Debridement
For the treatment of	Osteoarthritis
Commissioning Position	<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"> • the person has knee osteoarthritis • with a clear history of mechanical locking <p>Please note, gelling, 'giving way' and X-ray evidence of 'loose' bodies are not sufficient indications for arthroscopic lavage and debridement.</p>
Evidence/Summary of Rationale	<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 2003.¹⁰ 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 2005.¹¹ 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.
Effective From	1 st November 2019
Policy Review Date	1 st November 2021

Intervention	Dupuytren's Contracture Release - Adults
For the treatment of	Dupuytren's contracture
Commissioning Position	<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"> • An intervention (collagenase injections, needle fasciotomy, fasciectomy and dermofasciectomy) should be considered for either: <ul style="list-style-type: none"> - finger contractures causing loss of finger extension of 30° or more at the metacarpophalangeal joint or 20° at the proximal interphalangeal joint. - severe thumb contractures which interfere with function • NICE concluded that collagenase should only be used for either: <ul style="list-style-type: none"> - Participants in the ongoing clinical trial (HTA-15/102/04), or - Adult patients with a palpable cord if: <ul style="list-style-type: none"> ▪ 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; <p>And</p> <ul style="list-style-type: none"> ▪ needle fasciotomy is not considered appropriate, but limited fasciectomy is considered appropriate by the treating hand surgeon
Evidence/Summary of Rationale	<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>
Effective From	1 st April 2019
Policy Review Date	1 st April 2021

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

Plastic Surgery Interventions

Intervention	Breast Enlargement Surgery
For the treatment of	Adults with Amastia or Congenital abnormalities related to Breast Development
Commissioning Position	<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"> • 18 years of age or older • BMI is within the range 18-25 <p>AND</p> <ul style="list-style-type: none"> • certain congenital abnormalities such as Poland's syndrome, constricted tubular breast, pectus deformity, or chest wall asymmetry associated with scoliosis <p>OR</p> <ul style="list-style-type: none"> • a complete absence of breast tissue (Amastia) in one or both breasts is causing severe functional or medical problems.
Evidence/Summary of Rationale	<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>
Effective From	1 st April 2019
Policy Review Date	1 st April 2021

Intervention	Breast Reduction Surgery
For the treatment of	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>Commissioning Position</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"> • The woman has received a full package of supportive care from their GP such as advice on weight loss and managing pain. • In cases of thoracic/ shoulder girdle discomfort, a physiotherapy assessment has been provided • Breast size results in functional symptoms that require other treatments/interventions (e.g. intractable candidal intertrigo; thoracic backache/kyphosis where a professionally fitted bra has not helped with backache, soft tissue indentations at site of bra straps). • Breast reduction planned to be 500gms or more per breast or at least 4 cup sizes. • Body mass index (BMI) is <27 and stable for at least twelve months. • Woman must be provided with written information to allow her to balance the risks and benefits of breast surgery. • Women should be informed that smoking increases complications following breast reduction surgery and should be advised to stop smoking. • Women should be informed that breast surgery for hypermastia can cause permanent loss of lactation. <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>Evidence/Summary of Rationale</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.
Effective From	1 st April 2019
Policy Review Date	1 st April 2021

Intervention	Scar Revision and Skin Resurfacing
For the treatment of	Scars
Commissioning Position	<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"> • The scarring is a consequence of previous NHS surgery, burns or trauma; <p>and</p> <ul style="list-style-type: none"> • 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; <p>and</p> <ul style="list-style-type: none"> • 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; <p>and</p> <ul style="list-style-type: none"> • At least 18 months of the natural healing process has passed. <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"> • Hypertrophic or keloid scars that are not causing adverse consequences or functional impairments (e.g. keloid scarring after ear piercing) • Scarring / ulceration from chronic tattoo breakdowns • Post-acne scarring • Scars resulting from self-harm • Scar treatment for skin rejuvenation or other cosmetic purposes <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>
Evidence/Summary of Rationale	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.
Effective From	1 st November 2019
Policy Review Date	1 st November 2021

Respiratory Interventions

Intervention	Sleep Study
For the treatment of	Referral to secondary care sleep medicine services for assessment (e.g. via home-based overnight sleep study) of
Commissioning Position	<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"> • Patient has symptoms of excessive daytime sleepiness (EDS) that score >10 on the Epworth Sleepiness Score (ESS) combined with objective clinical judgement that indicates need for referral • Patient displays symptoms of chronic snoring as well as witness apnoeic episodes or daytime sleepiness with a score of >10 on the Epworth Sleepiness Score (ESS)
	<ul style="list-style-type: none"> • Sleepiness in dangerous situations, even with a normal ESS score, in combination with symptoms associated with obstructive sleep apnoea/hypopnoea • Excessive daytime sleepiness, despite a normal time in bed at night, which may interfere with his/her driving ability/occupation <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>
Evidence/Summary of Rationale	There is some evidence that clinical history and physical examination alone are not as reliable for diagnosing obstructive sleep apnoea as an overnight sleep study and treatment pathways suggest that PSG is the most accurate means of confirming a diagnosing of adult sleep apnoea. However, some guidelines have suggested that a home based sleep study may be useful, cost-effective and convenient for patients and can significantly speed up the investigation pathway, compared with an overnight inpatient stay.
Effective From	1 ST April 2019
Policy Review Date	1 ST April 2021

Intervention	Trial of Continuous Positive Airway Pressure (CPAP) for Obstructive Sleep Apnoea
For the treatment of	Sleep Apnoea
Commissioning Position	<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"> • Diagnosis of moderate/severe OSAHS, confirmed by sleep study where appropriate, indicating at least 15 episodes per hour of sleep • OSAHS is interfering significantly with activities of daily living • They have signed an agreement to appropriately insure and maintain the CPAP device and return it to the service if treatment stops or reimburse the full replacement cost of the device to the NHS. <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>
Evidence/Summary of Rationale	The evidence for treatment of symptomatic patients with mild OSA is not as strong. However, there may be people with mild severity grading, who have considerable OSA symptoms affecting their quality of life that may benefit from CPAP (e.g. lorry drivers).
Effective From	1 st April 2019
Policy Review Date	1 st April 2021

Intervention	Continued Continuous Positive Airway Pressure (CPAP) for Obstructive Sleep Apnoea
For the treatment of	Sleep Apnoea
Commissioning Position	<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"> • During the trial period the patient utilised the device in excess of 70% of nights. • During the trial period the patient utilised the device on average in excess of 4 hours per night. • The trial outcome has clinically indicated that the patient is benefitting from the device. There is improvement in their AHI or Epworth Scores. <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>
Evidence/Summary of Rationale	The evidence for treatment of symptomatic patients with mild OSA is not as strong. However, there may be people with mild severity grading, who have considerable OSA symptoms affecting their quality of life that may benefit from CPAP (e.g. lorry drivers).
Effective From	1 st April 2019
Policy Review Date	1 st April 2021

Urological Interventions

Intervention	12 week trial of Percutaneous Tibial Nerve Stimulation (PTNS) – Urinary Incontinence
For the treatment of	Adults with refractory Urinary Incontinence
Commissioning Position	<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"> • The patient has a confirmed diagnosis defined by urodynamic assessment and has been reviewed by a Urology MDT. • The patient is unable to perform clean, intermittent self-catheterisation • Evidence of the condition having a severe and debilitating impact on activities of daily living • Voiding diary data is kept to record frequency and severity of episodes • Symptoms refractory to ≥12 months of first line treatments including: <ul style="list-style-type: none"> - behavioural and lifestyle modification (diet, weight management, modification of fluid intake) - bladder retraining and catheterisation

	<ul style="list-style-type: none"> - pelvic floor muscle training - anticholinergic drugs - Botox injections have been unsuccessful or deemed inappropriate
Evidence/Summary of Rationale	<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>
Effective From	1 st November 2019
Policy Review Date	1 st November 2021

Intervention	Continued Percutaneous Tibial Nerve Stimulation (PTNS) – Urinary Incontinence
For the treatment of	Adults with refractory Urinary Incontinence
Commissioning Position	<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"> • They have already undertaken an approved 12 week trial of PTNS • The trial has resulted in a 50% or more improvement in symptoms (measured as a weekly reduction in incontinence episodes).
Evidence/Summary of Rationale	<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>
Effective From	1 st November 2019
Policy Review Date	1 st November 2021

Intervention	Varicoceles (Adolescents)
For the treatment of	Adolescent males (aged 10-17) with Grade II or Grade III Scrotal Swelling
Commissioning Position	<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"> • A varicocele appears suddenly and is painful. • The varicocele does not drain when lying down • There is a solitary right-sided varicocele <p>Referral to a urologist will be considered, provided the patient:</p> <ul style="list-style-type: none"> • is aged 10 - 17 • Has Grade II or III and asymmetrical testes • If experiencing pain or discomfort • If there are concerns about reduced ipsilateral testicular volume. • If the patients or parents/guardians are concerned by the appearance, or symptoms, and cannot be fully reassured in primary care. <p>Treatment will not be considered for adolescent males with:</p> <ul style="list-style-type: none"> • Subclinical or grade I varicocele. NICE advises treatment is not necessary and clinicians should provide advice and reassurance. • Grade II or III varicocele and symmetrical testes. NICE advises observation with annual examinations.
Evidence/Summary of Rationale	<ul style="list-style-type: none"> - Sub-clinical — detected only by Doppler ultrasound. - Grade I (small) — palpable only with Valsalva manoeuvre. - Grade II (moderate) — palpable without Valsalva manoeuvre. - Grade III (large) — visible through the scrotal skin <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>
Effective From	1 st November 2019
Policy Review Date	1 st November 2021

Intervention	Varicoceles (Adults)
For the treatment of	Adult males (18+) with Scrotal Swelling
Commissioning Position	<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"> • A varicocele appears suddenly and is painful. • The varicocele does not drain when lying down • There is a solitary right-sided varicocele <p>Referral to a urologist will be considered, provided the patient:</p> <ul style="list-style-type: none"> • is aged 18 or older • Has Grade II or III symptomatic varicocele, or with abnormal semen parameters • If experiencing pain or discomfort <p>Treatment will not be considered for adult males with:</p> <ul style="list-style-type: none"> • Sub-clinical or grade I varicocele – NICE advised that treatment is not necessary and semen analysis should be offered if fertility is a concern. • Grade II or III asymptomatic varicocele and normal semen parameters. NICE advises observation with semen analysis every 1–2 years.
Evidence/Summary of Rationale	<ul style="list-style-type: none"> - Sub-clinical — detected only by Doppler ultrasound. - Grade I (small) — palpable only with Valsalva manoeuvre. - Grade II (moderate) — palpable without Valsalva manoeuvre. - Grade III (large) — visible through the scrotal skin <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>
Effective From	1 st November 2019
Policy Review Date	1 st November 2021

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

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>

Grommets for Glue Ear in Children

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

Browning, G; Rovers, M; Williamson, I; Lous, J; Burton, MJ. Grommets (ventilation tubes) for hearing loss associated with otitis media with effusion in children. Cochrane Database of Systematic Reviews 2010, Issue 10. Art. No.: CD001801. DOI: 10.1002/14651858.CD001801.pub3

Irrigation of the external Auditory Canal

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

GENERAL SURGERY

Cholecystectomy

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MINOR SURGERY PROCEDURES

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<http://guidance.nice.org.uk/ta301>

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ORTHOPAEDIC INTERVENTIONS

Arthroscopic Lavage and Debridement

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Dupuytren's Contracture Release - Adults

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Knee Arthroscopy

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NICE guidance: <https://www.nice.org.uk/donotdo/referral-forarthroscopic-lavage-and-debridement-should-not-be-offered-as-partof-treatment-for-osteoarthritis-unless-the-person-has-kneeosteoarthritis-with-a-clear-history-of-mechanical-locking-not>

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RESPIRATORY INTERVENTIONS

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

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UROLOGICAL INTERVENTIONS

Percutaneous Tibial Nerve Stimulation (PTNS) for Urinary Incontinence

NICE IPG 362 (Oct 2010) Percutaneous Posterior Tibial Nerve Stimulation (PTNS) for overactive bladder syndrome. www.nice.org.uk/ipg362

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Varicoceles

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

Appendix 3 – OPCS Codes

COLORECTAL INTERVENTIONS	
Percutaneous Tibial Nerve Stimulation (PTNS) for Faecal Incontinence	A704 (both permanent and 12 week trial)

EAR, NOSE AND THROAT INTERVENTIONS	
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

GENERAL SURGERY	
Cholecystectomy	J181, J182, J183, J184, J185, J188, J189

GYNAECOLOGY INTERVENTIONS	
Labioplasty/Vaginoplasty	P05.5, P05.6, P05.7, P213, P214, P215, P218, P219

MINOR SURGERY PROCEDURES

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*

OPHTHALMOLOGY INTERVENTIONS

Intravitreal Therapies for Eye Disease	C794

ORTHOPAEDIC INTERVENTIONS

Arthroscopic Lavage and Debridement	W85.2
Dupuytren’s Contracture Release - Adults	(Surgery) T521, T522, T525, T526, T541, (CCH Injections) T578
Knee Arthroscopy	W852

PLASTIC SURGERY INTERVENTIONS

Gynaecomastia	B31.1, B275
Scar Revision and Skin Resurfacing	S10.3, S11.3, S60.1, S60.2, S09.1, S09.2, S60.4

RESPIRATORY INTERVENTIONS

Sleep Study, Trial and Continuous Positive Airway Pressure (CPAP) for Obstructive Sleep Apnoea	U331, E913
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UROLOGICAL INTERVENTIONS

Percutaneous Tibial Nerve Stimulation (PTNS) for Urinary Incontinence	A704
Varicoceles	N192