

## 2. Specialist Cosmetic Surgery

Treatment	Coomatic an existint assument proceeds use
reatment	Cosmetic specialist surgery procedures
Background	Cosmetic surgery is any surgery carried out to enhance outward appearance. It is carried out on people with abnormal appearance from a range of clinical or congenital conditions or syndromes or as a result of surgery or injury. It can also be carried out to enhance appearance changes due to ageing or obesity.
	In any health care system there are limits set on what is available and on what people can expect.
	Clinical Commissioning Groups are required to achieve financial balance. They have a complex task in balancing this with individuals' rights to health care. It is the purpose of the criteria set out in this document to make the limits on cosmetic specialist cosmetic surgery procedures fair, clear and explicit.
	Referrals within the NHS for the revision of treatments originally performed outside the NHS will not normally be permitted.
	Referrals should where possible be made to the practitioner who carried out the original procedure.
	This policy will be reviewed by the review date or in the light of any new guidance or clinical evidence, whichever is the earliest.
	These guidelines cover a group of surgical procedures with cosmetic indications.
	It is important to note that a substantial proportion of specialist cosmetic surgery is carried out by a number of specialities other than Plastic Surgery e.g. ENT Surgery, Ophthalmology, Maxillofacial Surgery, General Surgery and Dermatology. This policy only concerns procedures carried out in hospitals.
	Severity, effectiveness of intervention requested, cost and cost effectiveness should all be taken into consideration in the decision making process.
	Commissioning approval is required for NHS funding prior to referral to the specialist clinician.
	The decision of whether or not to go through with a particular procedure rests with the clinician and the patient in relation to the appropriateness of the procedure, its likelihood of success, and the risks of failure.
General Guidelines	Patients requiring reconstruction surgery to restore normal or near



normal appearance or function following cancer treatment or post trauma do not fall within this statement.

For cosmetic procedures an NHS referral is inappropriate if the patient falls within the normal morphological range.

Patients should not be referred to the specialist service until approval

has been obtained from the CCG and a copy of the approval should be appended to the referral.

Inevitably some patients may not fit the guidelines. Nevertheless if the referring clinician feels that a case merits funding on an exceptional basis they should discuss the case with the IFR team or submit an IFR to be considered by the panel. A significant degree of exceptionality must be demonstrated before funding can be considered outside of these policies.

Patients who have been operated on privately will not normally be eligible for NHS treatment for complications or secondary procedures. However there may be unusual or severe complications or circumstances that require transfer of a patient to the NHS for appropriate management.

Whilst some degree of distress is usual among people who consider aspects of their physical appearance as undesirable, the degree of this will not routinely be taken into account in any funding decision. Further, it is expected clinicians consider the possibility of psychological problems including Body Dysmorphic Syndrome (NICE Clinical Guideline 31), assess for these and ensure appropriate management before considering any referral for plastic surgery..

Photographic evidence may be requested to facilitate thorough consideration of a case.

The following treatments are included in this policy:

- Cleft earlobe surgery
- Face, neck, brow lift
- Hair loss treatment
- Hair removal (for hirsutism)
- Liposuction
- Resurfacing: dermabrasion, chemical peels and laser treatment
- Surgical Fillers



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	Please see the relevant specific statements for the following
	treatments:
	Abdominoplasty
	Breast Implants (removal)
	Breast Implants (replacement)
	Cosmetic Breast Surgery (including Gynaecomastia)
	Pinnaplasty
	Removal of benign skin lesions
	Rhinoplasty / septoplasy for nasal deformities
	<u>Vaginaplasty / labiaplasty</u>
Cleft Earlobe Surgery	Background: the external ear lobe can split partially or completely as result of trauma or wearing ear rings. Correction of split earlobes is not always successful and the earlobe is a site where poor scar formation is a recognised risk.
	Policy: Surgical repair of acquired ear lobe clefts is NOT routinely commissioned as this is considered a cosmetic procedure. This indication includes:
	<ul> <li>partially split lobes (i.e. where the split does not reach the edge of the lobe);</li> </ul>
	elongated holes in lobes ;
	<ul> <li>a split that recurs after a previously repaired earlobe has been pierced.</li> </ul>
Face and/or Brow	Background: These surgical procedures are performed to lift the
Lift	loose skin of the face and forehead to get a firm and smoother
	appearance of the face. These procedures will not be
S01.1/.2/.3/.4/.5/ .6/.8/.9	commissioned to treat the natural processes of ageing.
.0/.0/.0	Policy: Face lift or brow lift is NOT routinely commissioned.



Hair Loss Treatment S21.1/.2/.8/.9;S33.1/	Background: Hair loss, also known as alopecia or baldness, refers to a loss of hair from the head or body. Baldness can refer to general hair loss or male pattern hair loss.
.2/.3/.8/.9	Policy: Hair loss treatment will not be routinely commissioned by the NHS for cosmetic reasons, regardless of gender. This includes:
	Surgical treatments for hair loss e.g. hair transplantation  The 'Intralace' hair system  Dermatography (tattooing)  Drugs for the treatment of baldness e.g. <i>Finasteride</i>
	Hair loss treatment may be considered on an exceptional basis, for example when reconstruction of the eyebrow is needed following cancer or trauma.
	To manage hair loss for solely cosmetic reasons:
	It should be noted that the provision of wigs or hair loss treatment for Gender Dysphoria patients is NOT part of the NHS commissioned pathway for transgender patients and is not routinely commissioned 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.
	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 exist that warrant deviation from the rule of this policy. Individual cases will be reviewed as per the CCG policy.
Hair Removal for Hirsutism S60.6/.7	Background: IPL/Laser/Electrolosis treatment is increasingly being used as a cosmetic intervention to remove body hair. Patients with excessive body hair are described as having hirsutism. Hair depilation (for the management of hypertrichosis) involves
	permanent removal/reduction of hair from face, neck, legs, armpits and other areas of body usually for cosmetic reasons
	Policy: Hair removal for Hirsutism is NOT routinely commissioned. This includes surgical, medical and pharmaceutical treatments
Liposuction	Background: Liposuction (also known as liposculpture), is a surgical procedure performed to improve body shape by removing unwanted
S62.1/.2	fat from areas of the body such as abdomen, hips, thighs, calves, ankles, upper arms, chin, neck and back. Liposuction is sometimes done as an adjunct to other surgical procedures.
	Policy: Liposuction simply to correct the distribution of fat is NOT routinely commissioned.



Resurfacing: Dermabrasion, Chemical Peels and Laser Treatment S10.1/.3/.4/.8/.9;	Background: Dermabrasion involves removing the top layer of the skin with an aim to make it look smoother and healthier. Scarring and permanent discolouration of skin are the rare complications  Policy: Resurfacing procedures are NOT routinely commissioned.
S11.1/.3/.4/.8/.9; S09.1/.2	
Surgical Fillers	Background: 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.  Policy: Surgical fillers for any indication that may be deemed as a cosmetic procedure are 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.  Please note, the treatment of complications arising from the cosmetic use of surgical fillers in private practice is not routinely
Date effective from	commissioned September 2016
Date published	July 2019
Review date	September 2020
Author	Dr Alison Forrester, Healthcare public health advisor, VOYCCG
Approved by	Clinical Research & Effectiveness Committee 25.08.16
Responsible officer	Shaun O'Connell, GP Lead valeofyork.contactus@nhs.net

## NHS Scarborough and Ryedale and Vale of York Clinical Commissioning Groups

## **Breast Implants – Removal Commissioning Policy**

Intervention	Breast Implants - Removal
Definition	The presence of breast implants may cause patients a range of
	symptoms over time. These include a change in appearance of implants
	or increased associated pain. Common problems include age related
	sagging; calcification of breast tissue; capsular correction; leak from
	implant; implant wrinkling or rippling; infection; inflammation or irritation.
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	Concerns about cosmetic appearance should not be referred to
	secondary care. These procedures will not be funded.
Red Flag	In all cases, exclude Red Flag Symptoms and if present, refer
symptoms	2WW or to symptomatic breast clinic
Exclusions to	This policy does not apply to breast reconstruction as part of the
policy	treatment for breast cancer
Commissioning	NHS Scarborough & Ryedale and Vale of York CCG's do not routinely
position	commission the removal of breast implants.
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	Where there is a clinical indication for removal of breast implants this
	will <b>only</b> be commissioned in the following circumstances:
	will offly be confinissioned in the following circumstances.
	Breast cancer
	Breast Implant associated – Anaplastic Large Cell Lymphoma  (BIA ALCL) is averaged at
	(BIA-ALCL) is suspected
	Implants complicated by recurrent infections
	Implants with capsule formation that is associated with severe
	pain
	Implant is proven to be ruptured (intra or extra capsular)
	Baker Grade IV capsular contracture
	<ul> <li>Implants with a capsule formation that interferes with breast</li> </ul>
	imaging
	Implant is a PiP implant
	This commissioning decision applies regardless of funding source of
	the original surgery (i.e. whether funded by the NHS or on a private
	basis**). Patients will be offered the choice of removing both
	prostheses in the event that only one has been ruptured with the
	intention of ensuring symmetry.
	This policy does not include replacement of removed implants – please
	see separate policy.
	** in the first instance the patient should be directed back to the original
	private provider for the procedure. If the private provider is unable to
	support the patient, the NHS will undertake removal only. The CCG
	reserves the right to seek reimbursement from the provider.
OPCS codes	B30.
OPCS codes	
Effective from	15 <sup>th</sup> July 2019
Review Date	2021

### NHS Scarborough and Ryedale and Vale of York Clinical Commissioning Groups

### **Breast Implants – Removal Commissioning Policy**

### References:

1. Poly implant Prothese (PiP) breast implants; Final report of the Expert Group June 2012 Sir Bruce Keogh NHS Medical Director <a href="http://www.nhs.uk/conditions/breast-implants/Documents/PIP%20expert%20group%20final%20report.pdf">http://www.nhs.uk/conditions/breast-implants/Documents/PIP%20expert%20group%20final%20report.pdf</a>

Version	Created /actioned by	Nature of Amendment	Approved by	Date
1.0	Lead Clinician and Senior Service Imp Manager	Re-drafting of STP and SR/VoY policies	n/a	March 19
2.0	Senior Service Improvement Manager	Share of new draft for consultation		March 19
3.0	Senior Service Improvement Manager	Update of threshold following consultation		April 19
FINAL	Senior Service Improvement Manager	Approval of threshold	SRCCG Business Committee VoY Clinical Executive	June 19 June 19

## **Cosmetic Breast Procedures Commissioning Policy**

Intervention	Cosmetic Breast Procedures
Definition	Cosmetic surgery is any surgery carried out to enhance outward
	appearance. It may be carried out on people who perceive their
	appearance is abnormal from a range of clinical or congenital conditions
	or syndromes or as a result of surgery or injury. It can also be carried out
	to enhance appearance changes due to ageing or obesity.
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	This guideline covers a group of surgical procedures with cosmetic
	indications.
Red Flag	In all cases exclude Red Flag Symptoms and if present, refer 2WW
symptoms	or to symptomatic breast clinic.
Exclusions to	This policy does not apply to patients as part of the treatment for breast
policy	cancer.
Background	Breast asymmetry
<b>3</b>	Breast asymmetry is a degree of difference in the size of an individual's
	breasts and is entirely normal. The difference can be corrected
	surgically and may involve breast reduction surgery or breast
	augmentation surgery
	augmentation ourgory
	Breast augmentation
	Breast augmentation/enlargement involves inserting artificial implants
	behind the normal breast tissue to improve its size and shape.
	befilled the normal breast tissue to improve its size and shape.
	Breast mastopexy
	Breasts begin to sag and droop with age as a natural process.
	Pregnancy, lactation and substantial weight loss may escalate this
	process. This is sometimes complicated by the presence of a
	prosthesis which becomes separated from the main breast tissue
	leading to 'double bubble' appearance.
	Breast nipple correction
	The term inverted nipple refers to a nipple that is tucked into the breast
	instead of sticking out or being flat. It can be unilateral or bilateral. It
	may cause functional and psychological disturbance. Nipple inversion
	may occur as a result of an underlying breast malignancy and it is
	essential that this be excluded.
	Breast reduction
	Excessively large breasts can cause physical and psychological
	problems. Breast reduction procedures involve removing excess
	breast tissue to reduce size and improve shape.
	Gynaecomastia
	Gynaecomastia is a benign enlargement of the male breast. Most
	cases are idiopathic. For other cases, endocrinological disorders and
	certain drugs such as oestrogens, gonadotrophins, digoxin,
	spironolactone, cimetidine; proton pump inhibitors or drugs for
	treatment of prostate cancer could be the primary cause. Obesity can
	also give the appearance of breast development as part of the wide
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### NHS Scarborough and Ryedale and Vale of York Clinical Commissioning Groups

## **Cosmetic Breast Procedures Commissioning Policy**

	distribution of excess adipose tissue. Early onset gynaecomastia is often tender but this usually resolves in 3 to 4 months.  Full assessment of men with gynaecomastia should be undertaken, including screening for endocrinological and drug related causes and necessary treatment is given prior to request for NHS funding. It is important to exclude inappropriate use of anabolic steroids or cannabis.
Commissioning position	NHS Scarborough and Ryedale and Vale of York CCGs do not routinely commission the above procedures for cosmetic reasons.  Patients should not be referred unless clinical exceptionality is demonstrated and approved prior to initial referral by the Individual Funding Request panel.
OPCS codes	Z15 Breast Z151 Upper inner quadrant of breast Z152 Upper outer quadrant of breast Z153 Lower inner quadrant of breast Z154 Lower outer quadrant of breast Z155 Axillary tail of breast Z156 Nipple Z158 Specified breast NEC Z159 Breast NEC  Breast Asymmetry/Breast augmentation — B30.1/.8/.9; B31.2; B37.5 Breast —Inverted nipple correction — B35.4/.6 Breast — Mastopexy — B31.3 Breast — Prosthesis Removal and/or replacement — B30 Breast — reduction — B31.1 Gynaecomastia — B31.1
Date effective from	15 <sup>th</sup> July 2019
Review Date	2021

### References:

• NHSE Evidence Based Interventions Policy – published November 2018 – <a href="https://www.england.nhs.uk/wp-content/uploads/2018/11/ebi\_statutory-guidance-v2.pdf">https://www.england.nhs.uk/wp-content/uploads/2018/11/ebi\_statutory-guidance-v2.pdf</a>

Version	Created /actioned by	Nature of Amendment	Approved by	Date
1.0	Lead Clinician and Senior Service Imp	Re-drafting of STP and SR/VoY policies	n/a	March 19
	Manager			
2.0	Senior Service Improvement Manager	Share of new draft for consultation		March 19
2.0	Senior Service Improvement Manager	Update of statement following consultation		April 19

## NHS Scarborough and Ryedale and Vale of York Clinical Commissioning Groups

## **Cosmetic Breast Procedures Commissioning Policy**

FINAL	Senior Service	Approval of threshold	SRCCG Business Committee	June 19
	Improvement Manager		VoY Clinical Executive	June 19

## NHS Scarborough & Ryedale and Vale of York Clinical Commissioning Groups

## **Removal of Tattoos Commissioning Policy**

Intervention	Removal of Tattoos
For the	Tattoo removal
treatment of	Tattoo removai
Background	This commissioning policy is needed because tattoo removal is not routinely commissioned by NHS Scarborough & Ryedale or Vale of York CCGs and therefore exceptional circumstances have to be demonstrated in all cases and considered by the Individual Funding Request (IFR) Panel.
Commissioning position	NHS Scarborough & Ryedale and Vale of York CCGs do not commission tattoo removal for cosmetic reasons, for example, if a tattoo is no longer liked or wanted.
	Approval via IFR is required for <b>ALL cases</b> .
	The IFR panel will only consider requests for tattoo removal in certain circumstances, including those which reflect the criteria of the Modernisation Agency guidance <sup>1</sup> .
	Cases that may be considered in any of the circumstances below where the tattoo:
	<ul> <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> <li>Was inflicted against the patient's will;</li> <li>Was incurred during a period of documented serious and enduring mental illness and on the balance of probabilities lacked capacity at that time</li> </ul>
	<ul> <li>Has resulted in a significant allergic reaction or impairment to daily living,</li> <li>Where the individual was a child and not 'Gillick competent', and therefore not responsible for their action at the time of the tattooing.</li> </ul>
	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 exist that warrant deviation from the rule of this policy.
Summary of evidence / rationale	A tattoo is a mark made by inserting pigment into the skin. People choose to be tattooed for various cosmetic, social or religious reasons. It carries certain health risks such as infection and allergic reaction.
	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.

### **NHS Scarborough & Ryedale and Vale of York Clinical Commissioning Groups**

### **Removal of Tattoos Commissioning Policy**

	Lasers have become the standard treatment for tattoo removal because they offer a bloodless, low risk, effective alternative with minimal side effects. Each procedure is done on an outpatient basis in a single or series of visits. Patients may or may not require topical or local anaesthesia. The type of laser used to remove a tattoo depends on the tattoo's pigment colour. Black, dark blue and red tattoos respond really well to laser removal.  More difficult tattoo colours to remove are white, yellow, purple and pink, but are easier to cover up. Green is probably the most difficult tattoo colour to remove.
Date effective from	26th March 2018
Date published	March 2018
Review date	March 2020

<sup>\*</sup> When deciding whether a child is mature enough to make decisions, it is often described as whether a child is 'Gillick competent' (if under 16):

### References

1. 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)

Version	Created /actioned by	Nature of Amendment	Approved by	Date
1.0	Lead Clinician and Senior	Re-drafting of STP and SR/VoY policies.	n/a	01.02.18
	Service Imp Mngr			
		No changes to previous commissioning		
2.0	Senior Service	Share of new draft internally	Lead Clinicians – VoY and SR	01.02.18
	Improvement Manager		CCGs	
FINAL		Approval of threshold	SRCCG Business Committee	07.03.18
			VoY Clinical Executive	21.03.18

<sup>&</sup>quot;Whether or not a child is capable of giving the necessary consent will depend on the child's maturity and understanding and the nature of the consent required. The child must be capable of making a reasonable assessment of the advantages and disadvantages of the treatment proposed, so the consent, if given, can be properly and fairly described as true consent."



## Minor Skin Surgery for Skin Lesions Commissioning Policy

Interventions	Minor Surgery for Skin Lesions		
Policy Criteria	<ul> <li>Skin Lesions must meet at least ONE of the following criteria to be removed<sup>3</sup>:</li> <li>The lesion is unavoidably and significantly traumatised on a regular basis (e.g. causing regular bleeding or recurrent infections). There is repeat infection requiring 2 or more antibiotics per year</li> <li>The lesion bleeds in the course of normal everyday activity</li> <li>The lesion is obstructing an orifice or impairing visual access. The lesion significantly impacts on function eg: restricts joint movement</li> <li>If left untreated, more invasive intervention would be required for removal</li> <li>Facial viral warts that have not resolved with an appropriate trial of topical treatment.</li> <li>Facial spider naevi in children causing significant psychological impact</li> </ul>		
Background	1		

## Commissioning Treatment of any condition for purely cosmetic reasons Position is not commissioned. NHS Scarborough and Ryedale CCG and NHS Vale of York CCG only commission referrals to secondary care dermatology / plastic surgery in the following circumstances: Where there is diagnostic uncertainty or a possibility of malignancy OR • A lesion has been excised in primary care and a reexcision has been subsequently recommended on clinical grounds by the histopathologist OR After individual approval by the Individual Funding Request Panel (IFR) The following conditions should always be referred direct to secondary care (dermatology, head and neck surgery or plastic surgery as appropriate) and IFR approval is not required for: Malignant Melanoma (2 week pathway) • Squamous Cell Carcinoma (SCC) including extensive premalignant changes to the lip (2 week pathway) Basal Cell Carcinoma (refer as urgent and not via 2 week pathway. Where possible those <1cm and below the clavicle should be excised in Primary Care). Removal by accredited GP Minor Surgeon (either in-house or through Practice-to-Practice referral via LES scheme Remove with 4mm margins, send for histology Lentigo Maligna Naevus Sebaceous Indications Criteria for secondary care referral Benign Skin Lesions The removal of benign skin lesions is not routinely commissioned for cosmetic reasons. Where there is diagnostic uncertainty GPs should send three photos, (field, close-up and dermatoscopic) to the Dermatologists for advice on whether the patient needs to be seen in secondary care or whether primary care excision biopsy is appropriate ("permission to biopsy") Under the Minor Surgery Directed Enhanced Service, GP practices may undertake:

- Incision and drainage of an abscess requiring local anaesthetic
- Excision of sebaceous cysts where there is a history of more than one infection
- Incision and Curettage of Meibomian Cysts (as per the Commissioning Statement <u>Click Here</u>)

### **Referral to Secondary Care services**

Indications for referral to an appropriate alternative provider include:

- lesions suspicious of being a basal cell carcinoma (BCC) that are > 1cm in size or above the clavicle or squamous cell carcinoma (SCC) and melanomas.
- lesions of uncertain significance where a specialist opinion is that primary care treatment is appropriate or a histological diagnosis is required that should be seen and managed by an accredited clinician who has links with the local skin cancer MDT. This would include secondary care dermatologists and also (where commissioned) GPwSIs.
- sebaceous cysts where there is a history of one or more episodes of infection and so which would be appropriate for removal under this enhanced service, but where the
  - patient has a history of keloid scarring or hypertrophic scarring and the lesion is in an area where the patient would not want to risk the development of such scarring

### OR

 where the lesion lies in a position which is not appropriate for removal in primary care e.g. face or centre of spine

All other requests must have prior approval through Individual Funding request Panel.

## Molluscum contagiosum

Patients need to be managed in primary care. Referral to the dermatology department should only be made if patients have either of the following:

molluscum contagiosum in immunosuppressed patients

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	Diagnostic uncertainty of a solitary lesion.
	All other requests for referral for secondary care should have prior approval from individual funding request panel. Funding for treatment will not normally be commissioned.
	Where molluscum contagiosum is causing significant problems in the management of atopic eczema, or other widespread conditions, specialised opinion should be sought in Advice & Guidance attaching clinical photographs.
Viral warts	Children found to have ano-genital warts should be referred to the York 'Child Sexual Assault Assessment Centre' for confirmation of diagnosis.
	Treatment for Viral Warts is restricted to the minimum eligibility criteria below. This is because most plantar warts can be managed with over the counter topical treatments or by treatments prescribed in Primary Care. Treatment for Viral Warts that do not meet the criteria below are deemed to be cosmetic and will not be funded. Referral to secondary care dermatology should only be made:
	<ul> <li>for ano-genital warts in adults that have failed treatment in the Primary Care setting or Genito-Urinary (GUM) Clinic</li> <li>for viral warts in immunosuppressed patients</li> <li>if there is doubt about the diagnosis and concern about possible malignancy</li> <li>Facial viral warts that have not resolved with an appropriate trial of topical treatment.</li> </ul>
	Where there are exceptional circumstances, referral should be made to the Individual Funding Request Panel. Viral warts on face where there are physical or mental sequelae should be referred to IFR for funding.
Skin tags (including anal skin tags)	Treatment is not routinely commissioned. Where there is diagnostic uncertainty requesting a specialist opinion by sending photos via Advice and Guidance is recommended Where exceptional clinical indications exist (e.g. intractable pruritus ani) then referral to the Individual Funding Request Panel is advised.
Cyst of moll	Not routinely commissioned. Where there is diagnostic uncertainty requesting a specialist opinion by sending photos via Advice and Guidance is recommended.
Cyst of Zeis	Not routinely commissioned. Where there is diagnostic uncertainty requesting a specialist opinion by sending photos via Advice and Guidance is recommended.
Pingueculum	Not routinely commissioned. Where there is diagnostic

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	uncertainty requesting a specialist opinion by sending photos via Advice and Guidance is recommended.	
Eyelid papillomas and skin tags	Not routinely commissioned. Where there is diagnostic uncertainty requesting an ophthalmologist opinion by sending photos via Advice and Guidance is recommended. See oculoplastic eye problems commissioning statement.	
Actinic solar keratosis (AK)	Referral to secondary care for Actinic Keratosis is not expected unless primary care treatments have failed, (guidance on primary care treatment is on the Referral Support Site website under Dermatology).	
	Refer to secondary care for:	
	<ul> <li>severe AK when there may be a possibility of invasive malignancy: these are thicker and harder and may have an infiltrated base refer to secondary care where there is diagnostic uncertainty.</li> </ul>	
	failure of 2 different treatments	
	Immuno-compromised patients	
Pigmented Naevi	Refer if there is clinical suspicion of malignancy or diagnostic	
(moles)	uncertainty.	
Lipoma	Surgery is NOT routinely funded for cosmetic reasons and concerns about cosmetic appearance should NOT be referred to secondary care unless there are clinically exceptional circumstances with IFR Panel approval or criteria below are met.	
	Surgery is NOT routinely funded for excision of lipomas of any size that are confirmed as <u>benign</u> (clinically OR radiologically OR histologically following biopsy).	
	Surgery is ONLY funded	
	<ul> <li>for lipomas that impair function such that the impaired function resulting from the lipoma could be harmful, e.g. restricts neck movements, unable to wear a safety helmet, restricting movement of a joint, obstructing an orifice. These examples are not meant to be exhaustive. Referring clinicians and/or surgeons will need to justify the prioritisation of NHS resources for such surgery.</li> </ul>	
	OR	
	where, if left untreated, more invasive intervention would be required for removal. Such cases may require secondary care surgeons opinion.	
	Surgery for excision out with these criteria needs IFR Panel	

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	approval
See detailed clinical guidance, <u>published on the RSS u</u> <u>General Surgery here</u> . Diagnosis is usually clinical – Us not routinely required to confirm the diagnosis.	
	Where there is diagnostic uncertainty patients should be referred for imaging at York Teaching Hospitals Foundation Trust, not Yorkshire Health Solutions or other providers as per the pathway in the clinical guidance.
Summary of	Minor surgery should only be carried out when clinically
evidence / rationale	necessary and after weighing up the risks and benefits.
	The use of NHS resources to manage benign cosmetic lesions is not a current priority and expectations of such should be discouraged.
	The risks of carrying out minor surgery on skin lesions include damage to nerves, haemorrhage, failure to achieve wound closure, wound infection, wound dehiscence, over granulation, incomplete excision rate, unsatisfactory scar formation and distortion to local anatomy <sup>1</sup>
	A comparison of minor surgery in primary and secondary care carried out in the South of England suggested that the quality of minor surgery carried out in general practice is not quite as high as that carried out in hospital, but patients prefer the convenience of treatment in General Practice. However, there

	may be clear deficiencies in GPs' ability to recognise malignant lesions, and there may be differences in completeness of excision when compared with hospital doctors <sup>2</sup>
Date effective from	14 <sup>th</sup> April 2022
Review date	30 <sup>th</sup> April 2025
Approved by	Vale of York Executive Committee
Responsible officer	Michelle Carrington, Executive Director of Quality and Nursing

### References:

- 1. Primary Care Dermatology Society Skin Surgery Guidelines 2007 http://www.pcds.org.uk/images/downloads/skin\_surgery\_guidelines.pdf
- 2. S George, et al. (2008) A prospective randomised comparison of minor surgery in primary and secondary care. The MiSTIC trial. Health Technology Assessment 2008; Vol. 12: No. 23. <a href="http://www.journalslibrary.nihr.ac.uk/">http://www.journalslibrary.nihr.ac.uk/</a> <a href="http://www.journalslibrary.nihr.ac.uk/">data/assets/pdf</a> file/0006/64905/FullRep ort-hta12230.pdf
- 3. NHSE/I.(2018) Evidence-Based Interventions: Consultation Document. Available at: <a href="https://www.england.nhs.uk/wp-content/uploads/2018/06/04-b-pb-04-07-2018-ebi-consultation-document.pdf">https://www.england.nhs.uk/wp-content/uploads/2018/06/04-b-pb-04-07-2018-ebi-consultation-document.pdf</a>. Accessed:18/12/2018



**Clinical Commissioning Groups** 

## **Dermatology Referrals Commissioning Statement**

Background	NHS Scarborough and Ryedale CCG (SRCCG) & NHS Vale of York CCG (VOYCCG) are responsible for commissioning activity in secondary care and for enabling rapid review of patients with suspected cancer. This policy sets out the referral criteria for dermatology referrals.  The CCGs want to support acute providers manage demand for dermatology services so that patients who need specialist support are not subject to longer waits. In particular the CCGs are keen that patients referred in to 2WW clinics only receive 2WW appointments if there is good evidence that they may have skin cancer. This should increase the identification of skin cancer in such clinics. To support these aims this commissioning statement defines the expectations of all primary care dermatology referrals into secondary care.  In order to standardise the approach to dermatology referrals there is an expectation that three photographs should be attached with all			
Definition  Essential	It is the policy of NHS Vale of York and NHS Scarborough and Ryedale CCG that <a href="three">three</a> specific photograph views (an overview, a close up and a dermatoscopic picture as detailed below) must be attached to <a href="all">all</a> dermatology referrals, unless exceptions apply.  The <a href="three">three</a> photograph technique with high quality images should enable accurate triage and diagnosis. This means that patients can be triaged to the right place at the right time and some of the benign lesions can be confidently diagnosed as such with advice provided to the GP, saving patients from unnecessary hospital visits and other patients waiting longer than necessary.			
Information to	All three	photographs must b	e high-guality: Sha	rp and In-Focus
include with	Device	Camera	c mgm-quanty. Ona	Dermatoscope
the referral	Views	1: Overview	2: Close-up	3: Dermoscopy
letter	Exampl es		A STATE OF THE PARTY OF THE PAR	
	Aim	Enables correct anatomical location	Facilitate diagnosis by naked-eye	Facilitate diagnosis by Dermatoscope
	Tips	Entire limb, Head or Torso should be visable	Lesion centrally located & detail eg: scaling/crusting in focus	Use alcohol gel (or lubricating jelly if near eye or on mucosal surface). Vary pressure until vessels and pigment in sharp focus.
	Dermatoscopy helps to enable accurate diagnosis, but only if the image			

Responsible GP – Drs Shaun O'Connell and Dan Cottingham – York CCG	Approved: 05/06/2019 (VOY) 03/07/2019 (S&R)
Responsible Consultant – Drs Julia Stainforth and Kathryn Thompson	Review date: 04/06/2021
Responsible Pharmacist – n/a	NHS Scarborough & Ryedale Clinical Commissioning Group

	is high quality and this requires the use of either alcohol get or a lubricating jelly. A video on use of Schuco Handyscope dermatoscopes provided by York Against Cancer is <a href="here">here</a> .  Please note respect require only the first two photographs everyions and		
	Please note, rashes require only the first two photographs <b>overview</b> and <b>close-up</b> and exceptions are noted below.		
	Where photos are not attached GPs should detail which exception applies or referrals will be returned to GPs to clarify.		
	Further details of the requirements can be found here.		
Exceptions	<ul> <li>An area the patient deems too sensitive to photograph (e.g. genitalia, breasts)</li> <li>Dermatoscopic equipment is broken (normal overview and close up photos should still be sent)</li> <li>Dermatoscopic equipment is unavailable for other reason (normal photos should still be sent)</li> <li>Patient declines to have photographs taken even when referrer has explained the benefits to them and other patients of doing so. A patient leaflet on medical photography is available here. (LINK NEEDS ADDING)</li> <li>Any exceptions and the reason for them must be included in the referral.</li> </ul>		
Effective from	July 2019		
Review Date	July 2021		
Contact for this policy	Scarborough & Ryedale CCG: <a href="mailto:scrccg.rssifr@nhs.net">scrccg.rssifr@nhs.net</a> Vale of York CCG: <a href="mailto:VOYCCG.RSS@nhs.net">VOYCCG.RSS@nhs.net</a>		

Responsible GP – Drs Shaun O'Connell and Dan Cottingham – York CCG	Approved: 05/06/2019 (VOY) 03/07/2019 (S&R)
Responsible Consultant – Drs Julia Stainforth and Kathryn Thompson	Review date: 04/06/2021
Responsible Pharmacist – n/a	NHS Scarborough & Ryedale Clinical Commissioning Group

New Version	Created by	Nature of Amendment	Approved by	Date
1.0	S Bennett	Initial drafts		
1.2	S O'Connell	Amendments to initial draft		
2.0	S O'Connell	Consultation Draft		
3.0	S Bennett/S O'Connell	Near Final draft for Executive	Executive Committee	05/06/2019
4.0		Final draft for Governing Body		
5.0	S Bennett/S O'Connell	Final version for publication to providers	Scarborough & Ryedale Business Committee	03/07/2019

Responsible GP – Drs Shaun O'Connell and Dan Cottingham – York CCG	Approved: 05/06/2019 (VOY) 03/07/2019 (S&R)	
Responsible Consultant – Drs Julia Stainforth and Kathryn Thompson	Review date: 04/06/2021	
Responsible Pharmacist – n/a	NHS Scarborough & Ryedale Clinical Commissioning Group	

## **Adult Snoring Surgery Commissioning Policy**

Intervention	Adult Snoring Surgery (in the absence of OSA)
OPCS codes	F324; F325; F326
Description	In two systematic reviews of 72 primary research studies, there was no evidence that surgery to the palate to improve snoring provides any additional benefit compared to non-surgical treatments. The surgery has up to 16% risk of severe complications (bleeding, airway compromise, death). A number of alternatives to surgery can improve snoring. These include lifestyle changes (weight loss, smoking cessation and reducing alcohol intake) and medical treatment of nasal congestion.
Summary of intervention	Snoring is a noise that occurs during sleep that can be caused by vibration of tissues of the throat and palate. It is very common and as many as one in four adults snore, as long as it is not complicated by periods of apnoea (temporarily stopping breathing) it is not usually harmful to health, but can be disruptive, especially to a person's partner.  This guidance relates to surgical procedures in adults to remove, refashion or stiffen the tissues of the soft palate (Uvulopalatopharyngoplasty, laser assisted Uvulopalatoplasty & Radiofrequency ablation of the palate) in an attempt to improve the symptom of snoring. Please note this guidance only relates to patients with snoring in the absence of Obstructive Sleep Apnoea (OSA) and should not be applied to the surgical treatment of patients who snore and have proven OSA who may benefit from surgical intervention as part of the treatment for OSA.  It is important to note that snoring can be associated with multiple other causes such as being overweight, smoking, alcohol or blockage elsewhere in the upper airways (e.g. nose or tonsils) and often these
	other causes can contribute to the noise alongside vibration of the tissues of the throat and palate.
Commissioning position	NHS Scarborough & Ryedale and Vale of York CCGs do not commission adult snoring surgery in the absence of evidence of OSA.
	The CCGs do not commission surgery in the presence of OSA unless Continuous Positive Airway Pressure (CPAP) and other lifestyle changes (e.g. weight loss, reduction in alcohol consumption where needed) have failed to improve symptoms.
	All requests for funding should be submitted to the CCG IFR panel.
	This is on the basis of limited clinical evidence of effectiveness and the significant risks that patients could be exposed to, this procedure should no longer be routinely commissioned in the management of simple snoring.
	Alternative Treatments

### **Adult Snoring Surgery Commissioning Policy**

Summary of evidence / rationale	There are a number of alternatives to surgery that can improve the symptom of snoring. These include:  • Weight loss • Stopping smoking • Reducing alcohol intake • Medical treatment of nasal congestion (rhinitis) • Mouth splints (to move jaw forward when sleeping) In two systematic reviews of 72 primary research studies there is no evidence that surgery to the palate to improve snoring provides any additional benefit compared to other treatments. While some studies demonstrate improvements in subjective loudness of snoring at 6-8 weeks after surgery; this is not longstanding (>2 years) and there is no long term evidence of health benefit. This intervention has limited to no clinical effectiveness and surgery carries a 0-16% risk of severe complications (including bleeding, airway compromise and death). There is also evidence from systematic reviews that up to 58-59% of patients suffer persistent side effects (swallowing problems, voice change, globus, taste disturbance and nasal regurgitation). It is on this basis the interventions should no longer be routinely commissioned.
Date effective from	April 2019
Date published	March 2019
Review date	2021

### References

- 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 a systematic review. Sleep. 2009 Jan. 32 (1): 27-36
- Main C, Liu Z, Welch K, Weiner G, Jones SQ, Stein K. Surgical procedures and nonsurgical 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

Version	Created /actioned by	Nature of Amendment	Approved by	Date
v1	Senior Service	Implementation of NHSE/I EBI policy	CCG Clinical Leads	Nov 18
	Improvement Manager			
V2	Senior Service	Circulated to stakeholders for comments	No amendments required	Jan 18
	Improvement Manager			
FINAL	CCG Committees	Final policy	SRCCG Business Committee	Feb 18
			VoYCCG Executive Committee	Feb 18



# **Pinnaplasty Commissioning Statement Statement number: 35**

Treatment	Pinnaplasty
For the treatment of	Prominent ears
Background	Pinnaplasty is performed for the correction of prominent ears or bat ears.  Prominent ears are a condition where one's ears stick out more than normal
Commissioning position	Pinnaplasty is NOT routinely commissioned.
Summary of evidence / rationale	Ears are one of the first parts of the body to reach full size, which is why protruding ears can be more noticeable in children.
	Prominent ears may affect up to 5% of children. They may lead to significant psychosocial dysfunction for children and adolescents and impact on the education of young children as a result of teasing and truancy, although this can often be helped with school and other support. Children under the age of 5 rarely experience teasing and referrals may reflect concerns expressed by the parents rather than the child (1).
	Examples of restricted policies from other CCGs are available (2). Conservative management with psychosocial support from school or mental health services (if required) is recommended. Requests on the grounds of clinical exceptionality would need to include evidence that such support has been obtained and fully utilised.
Date effective from	September 2016
Date published	September 2016
Review date	September 2018
Author	Catherine Lightfoot, Clinical Triage Lead, Yorkshire and Humber Commissioning Support
Responsible officer	Shaun O'Connell, GP Lead valeofyork.contactus@nhs.net

### References:

- 1. Information for Commissioners of Plastic Surgery Services Referrals and Guidelines in Plastic Surgery (NHS Modernisation Agency)
- 2. South West CSU (Bristol area CCGs) policy on elective external ear and lobe repair <a href="http://www.swcsu.nhs.uk/media/12095/Exernal-Ear-Pinna-and-Lobe-Repair-Policy.pdf">http://www.swcsu.nhs.uk/media/12095/Exernal-Ear-Pinna-and-Lobe-Repair-Policy.pdf</a>



# Rhinoplasty Commissioning Statement Statement number: 38

Treatment	Rhinoplasty / Septorhinoplasty	
For the treatment of	Nasal deformities	
Background	Rhinoplasty/septoplasty for nasal deformities is a surgical procedure performed on the nose to change its size or shape or both. People usually ask for this procedure to improve self-image	
Commissioning position	All cases require prior approval. Consideration will not be given to cosmetic rhinoplasty.	
	Rhinoplasty may be considered medically necessary only in limited circumstances and where the clinical rationale fits with the evidence base as follows:	
	When it is being performed to correct a nasal deformity secondary to congenital cleft lip and/or palate;	
	<ol> <li>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:</li> </ol>	
	<ul> <li>Airway obstruction which will not respond to septoplasty and turbinectomy alone AND</li> </ul>	
	<ul> <li>Nasal airway obstruction is causing significant symptoms (e.g. chronic rhinosinusitis, difficulty breathing) AND</li> </ul>	
	<ul> <li>Obstructive symptoms persist despite conservative management for three months or greater, which includes, where appropriate, nasal steroids or immunotherapy AND</li> </ul>	
	<ul> <li>Photos demonstrate an external nasal deformity AND</li> <li>There is an average 50% or greater obstruction of nostrils (e.g. 50% obstruction of both nostrils; or 75% one nostril and 25% of other; or 100% obstruction of one nostril), documented by endoscopy, CT scan or other appropriate imaging modality</li> </ul>	
	There are, however, exclusions that need to be addressed such as:  • Unstable mental health	
	<ul> <li>Unrealistic patient expectations</li> <li>Previous rhinoplasty within the last 9-12 months (applies only to major rhinoplasties)</li> </ul>	
	<ul> <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>	
Summary of evidence / rationale	Rhinoplasty is an operation whereby the shape of the nose is changed by modifying the underlying bone and / or cartilage of the nose. In addition to altering the external appearance of the nose, the cartilage inside the nose can be straightened to improve the nasal airways. This procedure is called a septorhinoplasty.	
	Guidance on commissioning is provided by the Modernisation Agency Document	



Clinical	Commiss	ioning	Group	
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	'Information for Commissioners of Plastic Surgery Services', which was prepared by the British Association of Plastic and Reconstructive Surgery.
Date effective from	September 2016
Date published	September 2016
Review date	September 2018
Author	Dr Alison Forrester, Healthcare public health advisor, CYC and NYCC
Responsible officer	Dr Shaun O'Connell, GP Lead ValeofYork.contactus@nhs.net

### References:

- 1. 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.
- 2. NHS Modernisation Agency: Action on Plastic, Information for Commissioners of Plastic Surgery Services: Referrals and Guidelines in Plastic Surgery 2004.
- 3. Prasa, S., Kappor, P.K.D., Kumar, A., Reddy, V., Kumar, B.N Waiting list prioritization in the NHS. Journal of Laryngology and Ontology 2004,118(1):39-45.

## NHS Scarborough & Ryedale and Vale of York Clinical Commissioning Groups

## **Tonsillectomy Commissioning Policy**

Intervention	Tonsillectomy for recurrent tonsillitis in adults and children
OPCS codes	F34 Excision of tonsil
	F341 Bilateral dissection tonsillectomy
	F342 Bilateral guillotine tonsillectomy F343 Bilateral laser tonsillectomy
	F343 Bilateral laser tonsillectomy F344 Bilateral excision of tonsil NEC
	F345 Excision of remnant of tonsil
	F346 Excision of lingual tonsil
	F347 Bilateral coblation tonsillectomy
	F348 Other specified excision of tonsil
	F349 Unspecified excision of tonsil
For the treatment of:	Recurrent tonsillitis
Exclusions to	NHS Scarborough & Ryedale and Vale of York CCGs routinely
policy	commission treatment for Red Flag conditions (see clinical
	management).
	Please note this guidance only relates to patients with recurrent tonsillitis. It does not apply to other conditions where tonsillectomy should continue to be normally funded, these include:  Obstructive Sleep Apnoea / Sleep disordered breathing in Children
	Suspected Cancer (e.g. asymmetry of tonsils)  Parameter Chicago (alega asymmetry of tonsils)
	Recurrent Quinsy (abscess next to tonsil)  Francisco V. Proceedations (a.g. transferred of page 1 and page 2)
	<ul> <li>Emergency Presentations (e.g. treatment of parapharyngeal abscess)</li> <li>Severe immune deficiency that would make episodes of recurrent tonsillitis dangerous</li> </ul>
	Acute and chronic renal disease resulting from acute bacterial tonsillitis
	As part of the treatment of severe guttate psoriasis
	Metabolic disorders where periods of reduced oral intake could be
	dangerous to health
	PFAPA (Periodic fever, Apthous stomatitis, Pharyntitis, Cervical
	adenitis)
Commissioning	Referral criteria for possible tonsillectomy
position	The CCGs do not routinely commission tonsillectomy. Tonsillectomy will only be commissioned in accordance with the criteria specified below for recurrent acute sore throat in adults and children in the following circumstances:
	Sore throats are due to acute tonsillitis where
	The episodes are disabling and prevent normal functioning i.e. there has been significant severe impact on quality of life and normal functioning, as indicated by documented objective evidence (e.g. absence from school, failure to thrive)
	AND THERE HAS BEEN
	<ul> <li>Seven or more, well documented, clinically significant*, adequately treated sore throats in the preceding year OR</li> <li>Five or more well documented, clinically significant*, adequately treated sore throats in each of the preceding two years OR</li> </ul>

### **Tonsillectomy Commissioning Policy**

• Three or more well documented, clinically significant\*, adequately treated sore throats in each of the preceding three years.

#### **AND**

 There has been a discussion with patient/parents or carers in relation to the benefits and risks of tonsillectomy vs watchful waiting, as emphasised by the Royal College of Surgeons guidance<sup>3</sup>. Information should be provided (see patient leaflet section below) and reassurance given if no further treatment or referral for tonsillectomy is deemed necessary at this stage. This discussion should be documented.

\*preferably demonstrated by FeverPAIN or Centor scores (see below)

The impact of recurrent tonsillitis on a patient's quality of life must be taken into consideration. A fixed number of episodes, as described above, may not be appropriate for adults with severe symptoms and an application can be made to IFR for earlier surgery.

Tonsillectomy for the treatment of halitosis associated with tonsillar debris is NOT routinely commissioned.

The CCGs will also consider funding via IFR in **children (aged <16) with sleep disordered breathing** if **ANY ONE** of the following applies:

- A positive sleep study
- Significant impact on quality of life (daytime behaviour/sleepiness)

Within secondary care, there should be

- Confirmation of primary care assessment, fulfilment of the criteria for tonsillectomy and impact on quality of life and ability to work/attend school
- Management options –tonsillectomy, or referral back to primary care for ongoing monitoring

Patients who are not eligible for treatment under this policy can be considered on an individual basis, where their GP or consultant believes exceptional circumstances exist that warrant deviation from this policy.

Individual cases will be considered by the Individual Funding Request panel.

# Clinical management

### Red flag conditions – consider need for admission or urgent referral<sup>1, 2, 9</sup>

- Epialottitis
- Peritonsillar abscess (quinsy)
- Persistent sore throat for > 6 weeks
- Current or a history of excessive drooling (inability to swallow saliva) with acute inflammation/infection.
- Retropharyngeal abscess which can cause visible neck swelling and trismus (inability to open the mouth)
- Unilateral facial swelling
- Dysphagia
- Dyspnoea
- Immunosuppressant medication such as carbimazole
- Is immunosuppressed HIV, steroid use, post-transplant, leukaemia,

### NHS Scarborough & Ryedale and Vale of York Clinical Commissioning Groups

### **Tonsillectomy Commissioning Policy**

asplenia, aplastic anaemia

- Persistent unilateral tonsillar enlargement consider malignancy
- Signs of Meningitis Neck stiffness, Photophobia, Non-blanching rash
- Lemierre syndrome thrombophlebitis of the jugular vein
- Severe oral mucositis
- Adult obstructive sleep apnoea with tonsillar enlargement (if trials of continuous positive airway pressure (CPAP) and the use of mandibular advancement devices are unavailable or unsuccessful).
- Severe neck infection
- Witnessed episodes in children of apnoea exceeding 10 seconds OR choking episodes during sleep
- Patients with sore throat who have stridor, progressive dysphagia, bleeding, increasing pain or severe systemic symptoms (may require hospital admission)
- Tonsil bleeding

### **Acute Management of Sore Throats**

NICE CKS states:

- Studies have shown that use of antibiotics for streptococcal sore throat decrease symptom duration by less than 1 day.
- The threshold for prescribing antibiotics should be lower in people at risk of rheumatic fever (such as people with a previous history of rheumatic fever and those living in South Africa, Australian indigenous communities, Maori communities of New Zealand, the Philippines, and many developing countries), and vulnerable groups of people who are being managed in primary care, (such as infants, very old people, and those who are immunosuppressed or immunocompromised).
- Antibiotics should not be withheld if the person has very severe symptoms and there is concern about their clinical condition.
- For people not in a vulnerable group, and without severe symptoms, or who have a FeverPAIN score of 2 or3 consider a delayed antibiotic prescribing strategy.
- Acute Group A streptococcal (GAS) pharyngitis/tonsillitis is common in children and adolescents aged 5 to 15 years and is more common in the winter (or early spring) in temperate climates. Streptococcal infection is suggested by fever > 38.5°C, exudate on the pharynx/tonsils, anterior neck lymphadenopathy, and absence of cough. A scarlatiniform rash may be present, especially in children."

### FeverPAIN score

The FeverPAIN clinical score can help prescribers to determine if a sore throat is more likely to be caused by bacteria. Higher scores suggest more severe symptoms and likely bacterial (streptococcal) cause. Each of the FeverPAIN criteria (below) score 1 point (maximum score of 5).

- Fever
- Purulence
- Attend rapidly (3 days or less)
- Severely Inflamed tonsils
- No cough or coryza

A score of 0 or 1 is associated with a 13% to 18% likelihood of isolating streptococcus. A score of 2 or 3 is associated with a 34% to 40% likelihood of isolating streptococcus. A score of 4 or 5 is associated with a 62% to 65% likelihood of isolating streptococcus

### **Tonsillectomy Commissioning Policy**

### Centor criteria Tonsillar exudate Tender anterior cervical lymphadenopathy or lymphadenitis History of fever (over 38°C) Absence of cough Each of the Centor criteria score 1 point (maximum score of 4). A score of 0, 1 or 2 is thought to be associated with a 3 to 17% likelihood of isolating streptococcus. A score of 3 or 4 is thought to be associated with a 32 to 56% likelihood of isolating streptococcus. **Patient** Adult Tonsil Surgery – from ENT UK – click here Information Childrens Tonsil Surgery – from ENT UK – click here Tonsillitis - NHS Choices - Patient information on tonsillitis Leaflets The literature on surgery for recurrent tonsillitis is limited. Most published Summary of evidence / studies refer to a paediatric population. The quality of the evidence for rationale tonsillectomy in children is poor, but it suggests that surgery may be beneficial in selected cases. The small amount of information about adult sore throat and the effect of tonsillectomy is not scientifically robust but suggests that surgery can be beneficial for recurrent sore throats. The benefits of surgery compared to non-surgical treatment was the subject of a Cochrane Collaboration review (since updated) which provided additional evidence for the SIGN guidance<sup>4, 5</sup>. The consensus is that these criteria help to identify patients most likely to gain benefit from surgical intervention but the evidence level is low at 3/4 and clinical judgement is needed to identify patients where exceptionality applies. The Cochrane review found no randomised trials in adults and found that the evidence in children was limited by the lack of studies. Two randomised trials were found, but it was not possible to draw conclusions because many of the children also underwent adenoidectomy [Burton and Glasziou, 2009]. The authors of the Scottish Intercollegiate Guidelines Network (SIGN) quidance commented on<sup>5</sup>: 1. Four randomised clinical trials. One trial (which was included in the Cochrane review) found that there was no significant difference between the group that had a tonsillectomy and the group who did not. The other three studies had all taken place before 1972 and no conclusions could be drawn because of methodological flaws. 2. Three additional non-controlled studies. These suggested benefit of tonsillectomy for both reducing the number of sore throats, and improving general health. The evidence on referral criteria for sore throats is based on evidence from a paediatric population. At the time that the referral criteria were written there were no randomised controlled trials concerning the management of recurrent sore throats in adults<sup>3</sup>. A randomised trial in adults (people over 15 years of age) compared tonsillectomy (n = 36) with watchful waiting (n = 34) [Alho et al, 2007]: Criteria for entry to the trial were three or more episodes of pharyngitis in 6 months, or four or more episodes in 12 months.

### NHS Scarborough & Ryedale and Vale of York Clinical Commissioning Groups

### **Tonsillectomy Commissioning Policy**

	The primary end point was the proportion of people with an acute episode of group A streptococcal pharyngitis during the 90 days' follow up, as determined by signs and symptoms of acute pharyngitis and a positive result of throat culture.
	At 90 days streptococcal pharyngitis had recurred in 24% (8/34) of the control group and in 3% (1/36) of the tonsillectomy group (difference 21%, 95% CI 6 to 36).
	The number of people needing to undergo tonsillectomy to prevent one recurrence of streptococcal pharyngitis during the few months after tonsillectomy was five (NNT = 5).  The authors concluded that tonsillectomy is an effective alternative for adults
Date effective	with a documented history of recurrent episodes of pharyngitis.
from	May 2019
Date published	May 2019
Review date	2021

#### References:

- Baugh, R.F., Archer, S.M., Mitchell, R.B. et al. (2011) Clinical practice guideline: tonsillectomy in children. Otolaryngology - Head and Neck Surgery 144(1 Suppl), S1-S30. [Abstract]
- 2. NICE (2005) Referral for suspected cancer (NICE guideline) Clinical guideline 27. National Institute for Health and Clinical Excellence.www.nice.org.uk [Free Full-text]
- 3. Royal College of Surgeons Commissioning guide: Tonsillectomy Sept 2013
- 4. Cochrane Review of Tonsillectomy or adeno-tonsillectomy versus non-surgical treatment for chronic/recurrent acute tonsillitis (Cochrane Review) Nov 2014
- 5. Scottish Intercollegiate Guideline Network (SIGN) guideline: Management of sore throat and indications for tonsillectomy, a national clinical guideline [SIGN, 2010 report number 117] and the Centor clinical prediction score [Centor et al, 1981; Aalbers et al, 2011; ESCMID Sore Throat Guideline Group et al, 2012].
- 6. NICE CKS Management of acute sore throat July 2018 (https://cks.nice.org.uk/sore-throat-acute)
- 7. Royal College of Surgeons. National prospective tonsillectomy audit: final report of an audit carried out in England and Northern Ireland between July 2003 and September 2004. London: Royal College of Surgeons of England; 2005.
- 8. Burton MJ, Glasziou PP, Burton MJ, Glasziou PP. Tonsillectomy or adeno-tonsillectomy versus non-surgical treatment for chronic/recurrent acute tonsillitis. [Review] [20 refs][Update of Cochrane Database Syst Rev. 2000;(2):CD001802; PMID: 10796824]. Cochrane Database of Systematic Reviews 2009;(1):CD001802.
- 9. Red Flag symptoms https://www.gponline.com/red-flag-symptoms-pharyngitis/ear-nose-and-throat/article/1379827
- 10. NHSE/NHSI Evidence Based Interventions Policy published November 2018

Version	Created /actioned by	Nature of Amendment	Approved by	Date
1.0	Lead Clinician and Senior Service Imp Manager	Re-drafting of STP and SR/VoY policies	n/a	
2.0	Senior Service Improvement Manager	Share of new draft internally and circulation for consultation	Lead Clinicians – VoY and SR CCGs	Oct 18
2.1 – 2.5	Senior Service Improvement Manager	Update of statement following comments from consultation	Lead Clinicians – VoY and SR CCGs	Jan 19

## NHS Scarborough & Ryedale and Vale of York Clinical Commissioning Groups

## **Tonsillectomy Commissioning Policy**

3.0	Senior Service	Approval by CCG Committees	SRCCG Business Committee	March 19
	Improvement Manager		VoYCCG Executive Committee	March 19



# **Abdominoplasty / Apronectomy Commissioning Statement Commissioning Statement: 03**

Treatment	Abdominoplasty / Apronectomy and removal of excessive skin from other areas of the body
For the treatment of	Removal of excessive skin
Background	Abdominoplasty (also known as tummy tuck) is a surgical procedure performed to remove excess fat and skin from the mid and lower abdomen. Many people develop loose abdominal skin after pregnancy or substantial weight loss. However, surgery is not part of the usual response to these normal, physiological processes.
Commissioning position	NHS Vale of York CCG does not routinely commission Abdominoplasty / Apronectomy or removal of excessive skin from other areas of the body.
	Minimum requirements for requests for body contouring following bariatric surgery would be 1:
	<ul> <li>Starting BMI above 40 ( or above 35 with co-morbidities) AND</li> <li>Current BMI of less than or equal to 28.0 AND</li> <li>At least 24 months since surgery AND</li> </ul>
	Weight stability of at least 12 months AND
	<ul> <li>Significant functional disturbance. (This includes severe intertrigo,</li> </ul>
	disability, and evidence of significant interference with activities of daily life)
	In addition, there should be exceptional clinical circumstances.
	The clinician needs to submit an application to the CCG's Individual Funding Request Panel (IFR).
Summary of evidence / rationale	Any operation involving a general anaesthetic should be approached with caution, especially if for cosmetic reasons. Generally, the more extensive the procedure, the higher the risk. Cosmetic procedures are regarded as low priority.
Date effective from	September 2016
Date published	September 2016
Review date	September 2018
Author	Dr Alison Forrester, Healthcare public health advisor, CYC and NYCC Catherine Lightfoot, Clinical Triage Lead, Yorkshire and Humber Commissioning Support
Responsible Officer	Shaun O'Connell, GP Lead
	valeofyork.contactus@nhs.net

### References:

- 1. Royal College of Surgeons Commissioning guide: Massive Weight Loss Body Contouring March 2014 <a href="http://www.rcseng.ac.uk/healthcare-bodies/docs/massive-weight-loss-body-contouring">http://www.rcseng.ac.uk/healthcare-bodies/docs/massive-weight-loss-body-contouring</a>
- Information for Commissioners of Plastic Surgery Services Referrals and Guidelines in Plastic Surgery (NHS Modernisation Agency) London <a href="http://filesdown.esecure.co.uk/NorthLancsPCT/Modernisation\_Agency\_Plastic\_surgery\_Services.pdf\_29072008-1722-24.pdf">http://filesdown.esecure.co.uk/NorthLancsPCT/Modernisation\_Agency\_Plastic\_surgery\_Services.pdf\_29072008-1722-24.pdf</a>



## Ganglion Surgery Commissioning Statement

**Commissioning Statement: 19** 

Treatment	Ganglion Surgery
	The removal of ganglia
Background	Ganglia are benign fluid filled, firm and rubbery lumps attached to the adjacent underlying joint capsule, ligament, tendon or tendon sheath. They occur most commonly around the wrist, but also around fingers, ankles and the top of the foot.
Commissioning position	NHS Vale of York CCG does not routinely commission surgical removal of ganglia and surgical excision will not be commissioned for cosmetic reasons.  GPs must obtain prior approval from the IFR Panel before referring to secondary care. The CCG does commission the routine aspiration of ganglions in primary care within the local enhanced service contract.  Funding will only be considered on the grounds of clinical exceptionality if they meet the threshold below:
	<ul> <li>There is doubt about the diagnosis (if there is any concern about possible malignancy, patients should be referred via the 2 week wait route)         OR     </li> <li>The ganglion is causing significant functional impairment AND/OR</li> <li>The patient is experiencing considerable pain as a result of the ganglion's size or position despite the use of analgesics (e.g. inability to fit shoes or walk)</li></ul>
	Referral for soft tissue ultrasound can be made where there is diagnostic uncertainty. Where access to soft tissue ultrasound is not available, referral for a surgical opinion can be made to provide diagnostic support. However, in these situations, even where a diagnosis of ganglion is made clinically, excision will not be funded unless deemed an exceptional clinical circumstance by the Individual Funding Request Panel.  The clinician needs to submit an application to the CCG's IFR panel. The following information with examples of significant functional impairment should be provided:  • Precise location of ganglion e.g. flexor tendon • Size in cm/inches (length and width)
	<ul> <li>How is functioning of the area impaired? (What is the patient unable to do?)</li> <li>Impact on quality of life e.g. is the patient unable to fulfill any essential activities such as cooking, dressing, washing etc.?</li> <li>Degree of pain</li> <li>How long it has existed and treatments tried to date</li> </ul>
Summary of evidence / rationale	Most ganglia are symptom free, but some give pain, weakness, mobility disorders or pressure neuropathy. Many disappear spontaneously and many others cause little trouble.  For ganglion cysts in general, the possibilities for treatment are:

	<ul> <li>Explanation, reassurance, wait to see if the cyst disappears spontaneously</li> <li>Removal of the liquid contents of the cyst with a needle (aspiration) under local anesthetic</li> <li>Surgical removal of the cyst</li> <li>The Trent regional audit (which reviewed the progress of 729 ganglions up to 10 years from attendance) indicated that 33% of dorsal ganglions and 45% of volarwrist ganglia would resolve spontaneously in six years (1). The recurrence rate after excision of wrist ganglia is between 10- 45%.</li> <li>For any individual cyst, the recommendations for treatment will depend on the location of the cyst and on the symptoms that it is causing. Many occur in young adults and often disappear spontaneously. Problems after surgery include persistent pain, loss of wrist movement and trapping of nerve branches in the scar. For these reasons, many surgeons advise against operation for these cysts.</li> </ul>
Date effective from	September 2016
Date published	September 2016
Review date	September 2018
Author	Dr Alison Forrester, Healthcare public health advisor, CYC and NYCC
Responsible Officer	Shaun O'Connell, GP Lead
	valeofyork.contactus@nhs.net

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Useful website: http://www.nlm.nih.gov/medlineplus/tutorials/ganglioncysts/op089106.pdf

## Haemorrhoidectomy (and Haemorrhoidopexy) Commissioning Policy

## **General Commissioning Policy**

Treatment	Haemorrhoidectomy (and Haemorrhoidopexy)
OPCS Codes	H51 Excision of haemorrhoid H511 Haemorrhoidectomy H512 Partial internal sphincterotomy for haemorrhoid H513 Stapled haemorrhoidectomy H518 Other specified excision of haemorrhoid H519 Unspecified excision of haemorrhoid H521 Cryotherapy to haemorrhoid H522 Infrared photocoagulation of haemorrhoid H523 Injection of sclerosing substance into haemorrhoid H524 Rubber band ligation of haemorrhoid H528 Other specified destruction of haemorrhoid H529 Unspecified destruction of haemorrhoid
	H53 Other operations on haemorrhoid H531 Evacuation of perianal haematoma H532 Forced manual dilation of anus for haemorrhoid H533 Manual reduction of prolapsed haemorrhoid H538 Other specified other operations on haemorrhoid H539 Unspecified other operations on haemorrhoid
Background	Haemorrhoids are enlarged vascular cushions in the anal canal and may be external or internal. They are the commonest cause of rectal bleeding  Definition of degrees of haemorrhoids:  • First grade: the haemorrhoids remain inside at all times • Second grade: the haemorrhoids extend out of the rectum during a bowel movement but return on their own
	<ul> <li>Third grade: the haemorrhoids extend out during a bowel movement but can be pushed back inside</li> <li>Fourth grade: the haemorrhoid is always outside</li> </ul>
Commissioning position	NHS Scarborough & Ryedale and Vale of York CCGs will only commission haemorrhoidectomy (and haemorrhoidopexy) in the following circumstances:  • Grade I or II haemorrhoids with severe symptoms which include blooding faceal soiling, itching or pain which have failed to
	<ul> <li>bleeding, faecal soiling, itching or pain which have failed to respond to conservative management for 6 months.</li> <li>Grade III or IV haemorrhoids (i.e. prolapsed)</li> </ul>
	Treatment in all other circumstances is not routinely commissioned and should not be referred unless clinical exceptionality is demonstrated and approved by the Individual Funding Request

	Panel prior to referral
Summary of evidence / rationale  Grade I or II haemorrhoids may be managed by diet modification, laxatives or treated by topical applications. Interventional treatment include rubber band ligation, sclerosant injections, infra-red coagulation using diathermy.	
	Treatment for Grade III and IV haemorrhoids include bipolar electrocoagulation using diathermy, stapled haemorrhoidopexy or haemorrhoidal artery ligation (IPG 525)
	There is some evidence of longer term efficacy of conventional haemorrhoidectomy over stapled procedure.
<b>5</b>	Short term efficacy and cost effectiveness is similar.
Date effective from	September 2018
Date published	September 2018
Review Date	2020

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 04710

Version	Created /actioned by	Nature of Amendment	Approved by	Date
1.0	Lead Clinician and	Initial draft of new policy and	Lead Clinicians – VoY	May 2018
	Senior Service	circulation to internal GP Leads	and SR CCGs	
	Improvement Manager			
2.0	Senior Service	No requirement for consultation – no	Lead Clinicians – VoY and	June 2018
	Improvement Manager	significant change in thresholds	SR CCGs	
FINAL	Senior Service	Approval of threshold	SRCCG Business	04.07.18
	Improvement Manager		Committee	
			VoY Clinical Executive	04.07.18



## 22. Hernia Repair Commissioning Statement

Treatment	Hernia repair - inguinal (in men), umbilical, incisional	
Background	Hernia repair refers to a surgical operation for the correction of a hernia (a	
_	bulging of internal organs or tissues through the wall that contains it.) Hernias	
	can occur in many places, including the abdomen, groin, diaphragm, brain, and	
	at the site of a previous operation.	
	This statement covers surgical treatment of inguinal hernias in adult men, and umbilical or incisional hernias in all adults	
	It EXCLUDES suspected femoral hernias, inguinal hernias in women, and any irreducible hernias.	
Commissioning position	Repair of suspected femoral hernias, inguinal hernias in women, or any irreducible hernias is commissioned and should be referred urgently due to the increased risk of incarceration/strangulation	
	Hernia repair for cosmetic reasons or for asymptomatic or minimally symptomatic hernias in adults is NOT routinely commissioned. An approach of watchful waiting is recommended for small painless hernias and supported by the evidence base; delaying repair is considered safe. Conservative management should be encouraged first e.g. to lose weight or try support from surgical appliances or suitable underwear.	
	Surgical treatment should only be offered when one of the following criteria are met:	
	Pain/discomfort interfering significantly with activities of daily living     OR	
	The hernia is difficult to reduce OR	
	Comorbidity which does not make the patient unfit for surgery at present but is like to significantly increase the risks associated with future surgery AND	
	Where patients are willing to undergo surgery and are aware of the risks and benefits of surgery. To meet professional standard expectations <sup>14</sup> and ensure patients are fully informed about options for treatment it is recommended that the <a href="RightCare">RightCare</a> inguinal-hernia shared decision-making aid <sup>4</sup> is discussed with patients prior to surgery.	
	For referral please use the <u>referral form</u>	
	NHS Vale of York CCG does NOT routinely commission elective interventions on patients who have a BMI of 30 or above (classified as obese) or patients who are recorded as a current smoker – see commissioning statement <a funding="" href="Otto:Otto:Otto:Otto:Otto:Otto:Otto:Otto&lt;/th&gt;&lt;/tr&gt;&lt;tr&gt;&lt;th&gt;&lt;/th&gt;&lt;th&gt;Treatment in all other circumstances is not normally funded and should not be referred unless there is prior approval by the &lt;a href=" individual="" panel"="" request="">Individual Funding Request Panel</a> . Patients who are not eligible for treatment under this policy may be considered on an individual basis where their GP or consultant believes	



there is an exceptional clinical need that justifies deviation from the rule of this
policy. Individual cases will be considered by the individual funding request
panel.

- Patient information leaflets general NHS <u>hernia advice</u>; inguinal hernias <u>inguinal hernias</u>; NHS inguinal hernia repair <u>inguinal hernia repair</u>
- RightCare shared decision-making aid RightCare inguinal-hernia

## Summary of evidence / rationale

Watchful waiting (WW) is regarded as an acceptable option for men with minimally symptomatic or asymptomatic inguinal hernias by the *European Hernia Society guidelines on the treatment of inguinal hernia in adult patients*<sup>1</sup> (Level 1B evidence) and by a number of RCTs, concluding that it is an acceptable option for men with minimally symptomatic inguinal hernias<sup>2</sup>. Delaying surgical repair until symptoms increase is safe because acute hernia incarcerations occur rarely. More recently, the European Hernia Society has developed World Guidelines for Hernia Management which also supports this approach<sup>3</sup>.

The RightCare shared decision-making aid for surgical repair of inguinal hernia<sup>4</sup> states that

- Most people with inguinal hernia are free of symptoms by two weeks after surgical repair. But about 30% continue to feel pain and discomfort at the site of the repair.
- 2. The main short-term possible complications of surgical repair are bruising, swelling and numbness, difficulty passing urine and infection of the wound. Just over **22% of people get complications after surgery**.
- 3. The main long-term possible health problems are: chronic pain that may last for several years, and recurrence of the hernia.
- 4. Quality of life after surgical repair depends on whether or not symptoms persist. People left with chronic pain and discomfort report a lower quality of life than those who are symptom-free.
- 5. Both types of surgery for inguinal hernia can be done as day surgery without needing to stay overnight in hospital. People who have complications may need to stay longer. It can take between three and four weeks to recover completely.
- 6. People usually need about seven days off work and 14 days before they can return to strenuous leisure activities. About 7% of people can't return to work and 17% can't go back to strenuous leisure activities after 30 days either because of pain or problems with the wound.

NICE CKS guidance<sup>5</sup> (last revised in February 2010) states that, although European guidelines on the treatment of inguinal hernia in adults recommend that repair is not necessary for men with asymptomatic and reducible inguinal hernias, they recommend referral for repair where the hernia extends into the scrotum and the person is medically fit on the basis that:

- The risk of strangulation for all inguinal hernias is estimated to be 0.3– 3.0% per year
- If an inguinal hernia extends into the scrotum, it is almost always indirect
  The risk of strangulation is thought to be 10 times higher for indirect
  hernias than for direct inguinal hernias



- An emergency operation to treat a strangulated inguinal hernia has a higher mortality (higher than 5%) compared with an elective operation for a non-strangulated inguinal hernia (lower than 0.5%)
- Repair is recommended in a narrative review for people with asym ptomatic inguinal hernia if they are medically fit

The Royal College of Surgeons 2013 - High Value Care Pathway for groin hernia<sup>6</sup> (which includes a useful flow chart) states that GPs should refer:

- all patients with an overt or suspected inguinal hernia to a surgical provider except for patients with minimally symptomatic inguinal hernias who have significant comorbidity AND do not want to have surgical repair (after appropriate information provided)<sup>7,8</sup>
- irreducible and partially reducible inguinal hernias, and all hernias in women as 'urgent referrals'9, 10
- patients with suspected strangulated or obstructed inguinal hernia as 'emergency referrals'<sup>9, 10</sup>
- all children <18 years with inguinal hernia to a paediatric surgical provider

Analysis of 336 patients randomised to watchful waiting in the American College of Surgeons Watchful Waiting Hernia Trial found readily identifiable patient characteristics can predict those patients with minimally symptomatic inguinal hernia who are likely to "fail" watchful waiting hernia management<sup>11</sup>. These included pain with strenuous activities, chronic constipation and prostatism. Higher levels of activity reduced the risk of this combined outcome but there is no mention of BMI, although appropriate weight reduction is likely to help. Consideration of these factors will allow surgeons to tailor hernia management optimally.

Another study found that with follow up over 10 years, a total of 68% of men had had elective surgery, more commonly men older than 65 years, with pain<sup>12</sup>. They conclude that, although WW is a reasonable and safe strategy, symptoms are likely to progress and an operation will be needed eventually.

More recently a study concluded that a commissioning policy restricting funding for elective hernia repairs (but notably across all types) had led to a significant increase in emergency hernia repairs<sup>13</sup>. They carried out a retrospective cohort study on around 2550 patients who underwent repair of inguinal, umbilical, incisional, femoral or ventral hernias over a 3 year period.

The number of elective hernia repairs reduced from 857 over 12 months before the funding restrictions to 606 in the same period afterwards (p < 0.001). Over the same time period, however, a significant rise in total emergency hernia repairs was demonstrated, increasing from 98 to 150 (p < 0.001). 30-day readmission rates also increased from 5.1 % before the policy introduction to 8.5 % afterwards (p = 0.006). They concluded that the funding restrictions introduced in 2011 were followed by a statistically significant and unintended increase in emergency hernia repairs in their trust, with associated increased risks to patient safety.

A "watchful waiting" approach is also supported by other CCGs, including the



	Leeds CCGs. Their clinical guidelines commissioning position is that hernia repair is <b>not routinely commissioned</b> for:  Men with an asymptomatic or a minimally symptomatic inguinal hernia (discomfort or pain that does not restrict daily activity - adopt watchful waiting)  Men with groin pain and an ultrasound detected, but clinically impalpable, hernia (consider musculo-skeletal referral)  Post-operative follow up for low risk cases (eg no evidence of clinically significant haematoma, injury to the bowel or major blood vessels, deep infection, ischaemic orchitis, recurrence) is not required.	
Date effective from	April 2017	
Date published	April 2017	
Review date	April 2019	
Author	Dr Alison Forrester, Healthcare public health advisor, VOYCCG	
Approved by	Clinical Research and Effectiveness Committee 07.03.17 / Clinical Executive 27.04.17	
Responsible officer	Shaun O'Connell GP Lead valeofyork.contactus@nhs.net	

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- 12. Long-term results of a randomised controlled trial of a nonoperative strategy (watchful waiting) for men with minimally symptomatic inguinal hernias Fitzgibbon et all Annals of Surgery 2013 <a href="http://onlinelibrary.wiley.com/o/cochrane/clcentral/articles/697/CN-00962697/frame.html">http://onlinelibrary.wiley.com/o/cochrane/clcentral/articles/697/CN-00962697/frame.html</a>
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## Rhinoplasty Commissioning Statement Statement number: 38

Treatment	Rhinoplasty / Septorhinoplasty		
For the treatment of	Nasal deformities		
Background	Rhinoplasty/septoplasty for nasal deformities is a surgical procedure performed on the nose to change its size or shape or both. People usually ask for this procedure to improve self-image		
Commissioning position	All cases require prior approval. Consideration will not be given to cosmetic rhinoplasty.		
	Rhinoplasty may be considered medically necessary only in limited circumstances and where the clinical rationale fits with the evidence base as follows:		
	When it is being performed to correct a nasal deformity secondary to congenital cleft lip and/or palate;		
	<ol> <li>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:</li> </ol>		
	<ul> <li>Airway obstruction which will not respond to septoplasty and turbinectomy alone AND</li> </ul>		
	<ul> <li>Nasal airway obstruction is causing significant symptoms (e.g. chronic rhinosinusitis, difficulty breathing) AND</li> </ul>		
	<ul> <li>Obstructive symptoms persist despite conservative management for three months or greater, which includes, where appropriate, nasal steroids or immunotherapy AND</li> </ul>		
	<ul> <li>Photos demonstrate an external nasal deformity AND</li> <li>There is an average 50% or greater obstruction of nostrils (e.g. 50% obstruction of both nostrils; or 75% one nostril and 25% of other; or 100% obstruction of one nostril), documented by endoscopy, CT scan or other appropriate imaging modality</li> </ul>		
	There are, however, exclusions that need to be addressed such as:  • Unstable mental health		
	<ul> <li>Unrealistic patient expectations</li> <li>Previous rhinoplasty within the last 9-12 months (applies only to major rhinoplasties)</li> </ul>		
	<ul> <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>		
Summary of evidence / rationale	Rhinoplasty is an operation whereby the shape of the nose is changed by modifying the underlying bone and / or cartilage of the nose. In addition to altering the external appearance of the nose, the cartilage inside the nose can be straightened to improve the nasal airways. This procedure is called a septorhinoplasty.		
	Guidance on commissioning is provided by the Modernisation Agency Document		



Clinical	Commiss	ioning	Group	
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	'Information for Commissioners of Plastic Surgery Services', which was prepared by the British Association of Plastic and Reconstructive Surgery.	
Date effective from	Pate effective from September 2016	
Date published	September 2016	
Review date	September 2018	
Author	Dr Alison Forrester, Healthcare public health advisor, CYC and NYCC	
Responsible officer	Dr Shaun O'Connell, GP Lead ValeofYork.contactus@nhs.net	

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- 2. NHS Modernisation Agency: Action on Plastic, Information for Commissioners of Plastic Surgery Services: Referrals and Guidelines in Plastic Surgery 2004.
- 3. Prasa, S., Kappor, P.K.D., Kumar, A., Reddy, V., Kumar, B.N Waiting list prioritization in the NHS. Journal of Laryngology and Ontology 2004,118(1):39-45.

## **Dilatation and Curettage (D&C) Commissioning Policy**

Intervention	Dilatation and Curettage (D&C)
OPCS codes	Q10 Curettage of uterus
	Q101 Dilation of cervix uteri and curettage of products of conception
	from uterus
	Q103 Dilation of cervix uteri and curettage of uterus NEC
	Q108 Other specified curettage of uterus
For the	Q109 Unspecified curettage of uterus
treatment of:	Menorrhagia or for Diagnostic purposes
Background	Dilation and Curettage (D&C) is a procedure performed under general anaesthetic in which the lining of the uterus (the endometrium) is biopsied (diagnostic D&C) or removed (therapeutic D&C) by scraping with a sharp metal instrument (curette) in a systematic fashion.
	This commissioning policy is needed because these surgical procedures are of limited clinical value and are currently not routinely commissioned. Such requests therefore have to be made on the grounds of clinical exceptionality via the Individual Funding Request Panel (IFR).
Commissioning	NHS Scarborough & Ryedale and Vale of York CCGs do NOT
position	commission D&C:
	<ul> <li>As a diagnostic tool for uterine bleeding disorders</li> <li>As a treatment for heavy menstrual bleeding</li> <li>As a therapeutic treatment for other uterine bleeding disorders</li> <li>As a method of removing unwanted tissue, endometrial polyps or benign tumours from the womb or an IUD that has become embedded in the wall of the womb</li> <li>All requests for D&amp;C should be submitted to the IFR Panel.</li> </ul>
Summary of evidence / rationale	Diagnostic D&C: Ultrasound (1st line) or hysteroscopy (with or without biopsy) (2nd line) are recommended as diagnostic techniques to investigate uterine bleeding disorders. Hysteroscopy and biopsy is also the preferred technique to remove polyps and other benign lesions, as it allows targeted removal. If a tissue sample is required and there is no lesion visible on a scan then an endometrial biopsy may be done.
	Therapeutic D&C: There is limited evidence on the effectiveness of D&C in the management of menorrhagia. The one study that was identified by NICE showed that any effect was temporary. NICE guidance states that D&C should not be used as a therapeutic treatment.

#### NHS Scarborough & Ryedale and Vale of York Clinical Commissioning Groups

#### Dilatation and Curettage (D&C) Commissioning Policy

	Evacuation of retained products of conception (ERPC): where surgical evacuation after incomplete miscarriage or delivery is clinically indicated over medical management and watchful waiting, vacuum aspiration has superseded D&C as it is quicker, safer, easier and less painful.  Gestational trophoblastic disease: Suction/vacuum curettage is the preferred method of evacuation irrespective of uterine size in patients with suspected hydatidiform mole who want to preserve fertility
Date effective from	26 <sup>th</sup> March 2018
Date published	March 2018
Review date	March 2020

- 1. Investigation of Post-Menopausal Bleeding. SIGN Publication No.61; 2002
- 2. National Institute for Health and Clinical Excellence. Heavy Menstrual Bleeding. Investigation and Treatment. London: NICE; 2007
- 3. NICE. Heavy Menstrual Bleeding. January 2007. Do Not Do D&C alone should not be used as a diagnostic tool
- 4. NICE. Heavy Menstrual Bleeding. January 2007. Do Not Do D&C alone should not be used as a therapeutic treatment.

Version	Created /actioned by	Nature of Amendment	Approved by	Date
1.0	Lead Clinician and Senior	Re-drafting of STP and SR/VoY policies. No	n/a	01.02.18
	Service Imp Mngr	changes to previous commissioning positions		
		highlighted. No consultation required.		
2.0	Senior Service	Share of new draft internally	Lead Clinicians – VoY and SR	01.02.18
	Improvement Manager		CCGs	
FINAL	n/a	Approval of threshold	SRCCG Business Committee	07.03.18
			VoY Clinical Executive	21.03.18

**Gamete harvesting and storage (Cryopreservation) Commissioning Policy** 

Intervention	Gamete harvesting and storage (Cryoproservation)		
For the	Gamete harvesting and storage (Cryopreservation)  Harvesting and storage of viable gametes in patients undergoing NHS		
treatment of:	funded medical treatment(s) that cause infertility		
Background	To date, Scarborough and Ryedale and Vale of York CCGs have not had a formal policy on gamete harvesting and preservation for patients undergoing medical treatments that may leave them infertile.		
	Cryopreservation is the process of freezing and storing sperm, oocytes and embryos so that they can potentially be used at a later date, typically in an attempt to conceive a pregnancy. The CCGs have a comprehensive fertility policy available on their website which covers the commissioning of cryopreservation for routine infertility treatment.		
	One circumstance which is not covered by the fertility policy is the provision of cryopreservation for an individual who is expected to undergo NHS funded medical treatment(s) that cause infertility.		
Commissioning position	NHS Scarborough & Ryedale and Vale of York CCGs agree to fund the harvesting and subsequent storage (cryopreservation) of viable gametes, for an initial period of 10 years, for patients undergoing NHS funded medical treatment that may leave them infertile.		
	If after the initial 10 year period storage is still required, an IFR application should be made as an exceptional request, provided the patient wishes to keep their sample for potential future use. Each case will be considered on its own merit and in line with the HFEA legislation.		
	Approval for harvesting and cryopreservation does not guarantee future funding of assisted conception or fertility treatment – in this instance the specific CCG policy for assisted conception should be applied.		
	Prior to fertility preservation, the secondary care clinician at the organisation providing the fertility service must confirm:		
	<ul> <li>That the planned treatment is likely to affect future fertility (and document this for the commissioners' audit purposes)</li> <li>That the impact of the treatment on fertility has been discussed with the patient</li> </ul>		
	<ul> <li>That the patient is able to make an informed choice to undertake gamete harvesting and cryopreservation of semen, oocytes or embryos for an initial period of 10 years</li> <li>That the patient is aware that funding for gamete harvesting and cryopreservation does not guarantee future funding of assisted conception treatment</li> </ul>		
	Cryopreservation in males In general, it is recommended that at least two semen samples are collected over a period of one week. The CCGs will commission a maximum of three samples of semen; this is considered sufficient to		

**Gamete harvesting and storage (Cryopreservation) Commissioning Policy** 

provide future fertility.

Testicular tissue freezing is considered experimental and will not be funded.

Note: testicular sperm retrieval is commissioned by NHS England and not by the CCGs.

#### **Cryopreservation in Females**

The CCG will normally fund one cycle of egg retrieval, with or without fertilisation. If fewer than 10 eggs are retrieved following this first cycle of egg retrieval, then one further cycle can be offered.

Ovarian tissue storage is considered experimental and will not be funded.

#### Age

There are no specific age limits to this policy for males or females. The decision to attempt to preserve fertility is a clinical decision.

#### **Previous sterilisation**

Gamete retrieval and cryopreservation will not be funded where the patient has previously been sterilised.

#### **NHS Funded Assisted Conception**

Access to NHS funded harvesting and cryopreservation will not be affected by previous attempts at assisted conception. However, funding for further assisted conception attempts will be subject to the criteria stated in the CCG's IVF policy at the time of any funding application.

#### **Expectations of Providers**

Cryopreservation of gametes or embryos must meet the current legislative standards, i.e. under Human Embryo and Fertility Act 1990

The provider of the service must ensure the patient receives appropriate counselling and provides full consent. The patient and their partner must be made aware of the legal position on embryo ownership should one partner remove consent to their ongoing storage or use.

The provider of the service must ensure patients are aware of legal issues on posthumous use of gametes and embryos should they wish a partner to be able to use these should their treatment not be successful.

Patients will need to provide annual consent for continued storage.

The provider must ensure appropriate consent to storage is in place and that the patient understands the need for on-going consent and has outlined the purposes for which they can be used. Gamete harvesting and storage (Cryopreservation) Commissioning Policy

Summary of evidence / rationale	Expectation of the Patient The patient will be responsible for ensuring the storage provider has up to date contact details. Failure to provide on-going consent may result in the destruction of stored materials.  Following notification of a recent legal challenge <sup>1</sup> having been brought against NHS England by the Equality and Human Rights Commission (EHRC), the CCG wishes to ensure that all patients undergoing medical treatments that may affect fertility, including transgender treatments, have the same access to gamete preservation services as patients undergoing cancer treatment.			
	The challenge relates to the commissioning and provision of gamete retrieval and storage services for transgender patients. The EHRC argues that:			
	<ul> <li>NHS England wrongly interprets the words "Gender Identity Disorder Services" at paragraph 57, Schedule 4 of the NHS Commissioning Board and Clinical Commissioning Groups (Responsibilities and Standing Rules) Regulations 2012 ("the 2012 Regulations") as not including gamete retrieval and storage, and has thereby misdirected itself as to its obligation to provide that service to transgender patients;</li> <li>NHS England has unlawfully failed to exercise its power under s.2 of the National Health Service Act 2006 ("the 2006 Act"), in the light of its obligations under domestic and European equalities provisions, to provide gamete retrieval and storage to transgender patients;</li> <li>NHS England has unlawfully failed to exercise its power to issue guidance to clinical commissioning groups ("CCGs") to discourage them from unlawfully failing to arrange for the provision of gamete retrieval and storage to transgender patients.</li> </ul>			
	NHS England's position is that the commissioning of gamete retrieval and storage services is appropriately the commissioning responsibility of CCGs. Responsibility for developing clinical commissioning policy in this area extends as much to trans patients as it does to patients, for example, undergoing chemotherapy. When formulating clinical commissioning policy in this, and indeed all areas of commissioning responsibility, CCGs are under a number of legal duties including the Public Sector Equality Duty. NHS England's position is that no additional statutory guidance on this issue is required.			
	NHS England advised CCGs: 'in light of this challenge, [CCGs] may wish to review any commissioning policies in place in this area and how they apply to different groups of patients.			
Date effective from	January 2019			
Date published	January 2019			
Review date	2021			

#### NHS Scarborough & Ryedale and Vale of York Clinical Commissioning Groups

#### **Gamete harvesting and storage (Cryopreservation) Commissioning Policy**

#### References:

<sup>1</sup>NHE England CCG Bulletin - Issue 247 - 25 October 2018, Review of clinical commissioning policies for gamete retrieval and preservation

- NICE (CG156 Fertility Problems: assessment and management)
- Human Fertilisation and Embryology Act (1990) guidelines https://www.hfea.gov.uk/
- Human Tissue Authority guidelines https://www.hta.gov.uk/
- Leeds CCG Gynaecology and Urology Commissioning Policy

Version	Created /actioned by	Nature of Amendment	Approved by	Date
V1	GP Clinical Lead	Draft of initial statement	n/a	n/a
FINAL	GP Clinical Lead and Senior Service Improvement Manager	Final statement for approval	SRCCG Business Committee (via email)	Dec 18
			VoYCCG Executive Committee	Jan 19

# Invitro Fertilisation (IVF) and Intracytlopasmic Sperm Injection (ICSI) Commissioning Statement Statement number: 28

	I				
Treatment	Invitro Fertilisation (IVF) and Intracytlopasmic Sperm Injection (ICSI)				
Background	In December 2014 the CCG agreed to implement a policy of immediate access to one cycle of IVF for couples who met the agreed criteria.				
	Following a review of its Access to Infertility Treatment Policy, in July 2020, the CCG updated the policy to reflect the recent review of the Yorkshire and Humber Fertility Policy. The changes to the NHS Vale of York CCG policy makes:				
	<ul> <li>One funded cycle of IVF available where the female is aged 40-43 (to 43<sup>rd</sup> birthday)</li> <li>One funded cycle of IVF available where the female is aged 18 – 23yrs.</li> </ul>				
	Subject to meeting existing eligibility criteria.				
Commissioning position	The Executive Committee agreed to implement a policy o immediate access to one cycle of IVF for couples who mee the following criteria:				
	<ul> <li>Female age: 18 – 43rd birthday (at the time of treatment)</li> <li>Female BMI: 19 to 29 female for six months prior to a referral</li> <li>Smoking status: Non-smoking couple for six months prior to a referral</li> <li>Existing children: To not have living or adopted children</li> <li>Relationship: To be in a stable relationship for at least two years (including same sex couples) and currently cohabiting</li> </ul>				
	<ul> <li>Other criteria:</li> <li>For heterosexual couples: to have had regular unprotected intercourse (attempts to conceive) for at least two years prior to referral within the same stable relationship, in the absence of any known reproductive pathology</li> <li>For same-sex couples and where a medical condition exists (such as physical disability, an infection requiring sperm washing, or a psychosexual disorder prevents natural conception), IUI for up to 6 cycles may be funded, followed by further assisted conception if required</li> <li>Couples who have previously self-funded treatment are eligible for one NHS funded cycle as long as they have not received more than two self-funded cycles</li> </ul>				

#### **Frequently Asked Questions**

A copy of a list of Frequently Asked Questions can be found <u>here</u>.

For Frequently Asked Questions specifically for same sex couples <u>click here</u>.

Careful consideration will be given to previously eligible couples currently seeking IVF services. To ensure this process is fair and as effective as possible, the CCG is working closely with local Assisted Conception Units to develop a pathway into services.

#### **Access Criteria**

- Female age years at the time of treatment The age of women at the time of treatment must be less than 43<sup>rd</sup> birthday and over 18 years
- Female BMI 19 to 29 for 6 months prior to a referral Body Mass Index within the range 19 to 29 kg/m2 (this means that a BMI of 29.1 is outside the criteria). GPs should advise patients regarding weight loss support if they meet all other criteria. Assisted conception treatments will only be provided when BMI is within the range stipulated and has been maintained within 19 to 29 kg/m2 for the previous 6 months.
- Partners: both must be:-
  - Non-smokers for 6 months prior to a referral
    - Both partners must be non-smokers for 6 months prior to a referral. Non-smoking status for both partners will be tested with a carbon monoxide breath test prior to commencement of any treatment. GPs should refer any smokers who meet all other criteria, to a smoking cessation programme to support their efforts in stopping smoking. Previous smokers must be non smoking for 6 months prior to being put forward for assisted conception treatment and register below 5 on the Carbon Monoxide test.
  - Existing children
    - Neither partner should have any living children from either current or any previous relationships. The adoption of children confers the legal status of parent to the adoptive parents; this will apply to both adoptions in and out of the family. If any fertility treatment results in a live birth (and the child is still alive), then the couple will

	not be eligible for further fertility treatments, including the implantation of any stored frozen embryos.  Stable 2 year relationship  To be in a stable relationship for at least two years (including same sex couples) and currently cohabiting.  Having regular unprotected intercourse for the 2 years prior to referral within the same stable relationship  Couples must have been having regular unprotected intercourse for a 2 year period, reported to and documented by GP. Attempts to conceive should be based upon using recognised ovulation indicators at the appropriate time in the cycle.  Couples who conceive naturally and who subsequently miscarry up to twice within 2 years will be investigated for recurrent miscarriages. These women will not automatically received assisted conception treatment unless clinically appropriate as they are able to conceive naturally.  Previous treatment history  Any previous NHS funded IVF treatment will be an exclusion criterion. Couples who have previously self-funded treatment are eligible	
	for 1 NHS funded cycle as long as they have not received more than 2 self-funded cycles.  The CCG Access to Infertility Treatment Commissioning	
Summary of evidence / rationale	Policy reflects the latest guidelines from the National Institute for Clinical Excellence (https://www.nice.org.uk/guidance/cg156).	
Date effective from	July 2020	
Date published	October 2020	
Review date	July 2022	
Author	Dr Emma Broughton Clinical Lead Women's & Children NHS Vale of York Clinical Commissioning Group, Sarah Kocinski Commissioning & Transformation Manager, NHS Vale of York Clinical Commissioning Group	
Approved by	CCG Executive Committee, July 2020	
Responsible officer	Dr Shaun O'Connell GP Lead <u>valeofyork.contactus@nhs.net</u>	



## 43. Labiaplasty /vaginoplasty Commissioning Statement

Treatment	Labiaplasty /vaginoplasty
Background	This commissioning policy is needed as cosmetic procedures are not routinely commissioned.  Labiaplasty is a surgical procedure where the folds of the labia minora are partially removed, usually for cosmetic reasons alone to change appearance. Non-reconstructive vaginoplasty or "vaginal rejuvenation" is another cosmetic procedure used to restore vaginal tone and appearance  Note:  Female circumcision is prohibited in law by the Female Genital Mutilation Act 2003¹ and is the subject of multi-agency guidelines from the Department of Health².  Patients who have undergone female genital mutilation should be referred to a specialist female genital mutilation clinic via NHS England.
Commissioning position	The CCG will ONLY routinely commission reconstructive labiaplasty/ vaginoplasty:  • Following surgery for cancer; • vaginal repair following delivery; • for dyspareunia caused by scarring from vaginal delivery (including Fenton's procedure); • for scarring caused by underlying dermatology condition such as Lichen Sclerosis  NHS Vale of York CCG does not routinely commission labiaplasty/vaginoplasty, for cosmetic reasons, as these procedures are considered to be of limited clinical value. This is in line with the Interim Clinical Commissioning Policy produced by NHS England <sup>3</sup> .  Requests for labiaplasty will be considered, via a request to the IFR Panel, for the following indication:  • Where the labia are directly contributing to recurrent disease or infection  Requests for vaginoplasty will be considered, via a request to the IFR Panel, for the following indication:  • Congenital absence or significant developmental/endocrine abnormalities of the vaginal canal,  The clinician needs to submit an application to the CCG's Individual Funding Request Panel (IFR)



Summary of evidence /rationale	The number of requests for this procedure and the number of surgeons offering it has dramatically increased in recent years. Reasons for requesting labiaplasty are often to alleviate functional discomfort, improve appearance and increase self-esteem. Many women seeking labial reduction opt for the procedure because they feel stigmatised by social norms about how they should look and may have unrealistic expectations of the surgery <sup>4, 5</sup> . Recent work has demonstrated there is a wide range of what is regarded as "normal" and satisfaction at the cosmetic outcome of surgical attempts to create normative feminine genital appearance tends to be poor, with up to 80% requiring further reconstructive surgery <sup>4</sup> .
	Surgery to the labia minora is being promoted as an effective treatment for complaints such as recurrent urinary tract infections (UTIs) or to enhance sexual functioning. There is no good evidence for clinical effectiveness so it can be considered as medically non-essential surgery and thus not routinely commissioned <sup>6</sup> . In one large multicentre study, the author noted that although over 90% of patients were satisfied with the results of their surgery in the short-term, sexual dysfunction before surgery and enhancement after surgery is highly subjective and difficult to quantify <sup>7</sup> .
	Some case series also point to re-operation rates following labiaplasty of up to 7% for reasons such as wound dehiscence, infection and dissatisfaction with appearance. None of the studies found in a literature review looked at the potential for long-term obstetric complications after such surgery.
Date effective from	March 2017
Date published	March 2017
Review date	March 2019
Author	Dr Emma Broughton, GP Lead for Women's Health VOYCCG
Approved by	Clinical Research & Effectiveness Committee 07.03.17 / VOYCCG Clinical
Posponsible officer	Executive 16.03.17
Responsible officer	Shaun O'Connell, GP Lead <u>valeofyork.contactus@nhs.net</u>

- 1. Female Genital Mutilation Act 2003 <a href="http://www.legislation.gov.uk/ukpga/2003/31">http://www.legislation.gov.uk/ukpga/2003/31</a>
- 2. Female genital mutilation: multi-agency practice guidelines. Dept of Health, February 2011 <a href="https://www.gov.uk/government/publications/female-genital-mutilation-multi-guidelines">https://www.gov.uk/government/publications/female-genital-mutilation-multi-guidelines</a>
- 3. Interim Clinical Commissioning Policy: Labiaplasty, vaginoplasty and hymenorrhaphy Nov 2013 http://www.england.nhs.uk/wp-content/uploads/2013/11/N-SC023.pdf
- 4. Lloyd J, et al (2005) Female genital appearance: 'normality' 'unfolds'. BJOG An International Journal of Obstetrics and Gynaecology 2005; 112:643-646. http://onlinelibrary.wiley.com/doi/10.1111/j.1471-0528.2004.00517.x/pdf
- 5. Bramwell R, et al (2007) Expectations and experience of labial reduction: a qualitative study. BJOG An International Journal of Obstetrics and Gynaecology 114:1493-1499. http://onlinelibrary.wiley.com/doi/10.1111/j.1471-0528.2007.01509.x/pdf
- 6. Liao LM, et al (2010) Labial surgery for well women: a review of the literature. BJOG An international Journal of Obstetrics and Gynaecology 2010;117: 20-25



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

7. Goodman MP, 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



### 37. Reversal of Sterilisation in Men and Women Commissioning Statement

Treatment	Reversal of sterilization in men and women		
rreatment	Reversal of sternization in men and women		
Background	Reversal of female sterilisation is a surgical procedure that involves the reconstruction of the fallopian tubes.		
	Reversal of male sterilisation is a surgical procedure that involves the reconstruction of the vas deferens		
Commissioning position	NHS Vale of York CCG does not routinely commission the Reversal of sterilisation for men or women		
	Reversal of female sterilisation Sterilisation procedure is available on NHS and couples seeking sterilisation should be fully advised and counselled (in accordance with RCOG guidelines) that the procedure is intended to be permanent. Policy: Reversal of female sterilisation will not be routinely funded.		
	Reversal of male sterilisation Sterilisation procedure is available on the NHS and couples seeking sterilisation should be fully advised and counselled (in accordance with RCOG guidelines) that the procedure is intended to be permanent. Policy: Reversal of male sterilisation will not be routinely funded.		
Summary of evidence / rationale	The Faculty of Sexual & Reproductive Healthcare Clinical Guidance Male and Female Sterilisation Clinical Effectiveness Unit, September 2014¹ provides evidence-based recommendations and good practice points for health professionals on elective male sterilisation (vasectomy) and female sterilisation (tubal occlusion) in the UK. It is intended for any health care professional or service that undertakes or refers individuals for either procedure. This guidance has been jointly developed with the Royal College of Obstetricians and Gynaecologists (RCOG). On the reversals of both male and female sterilization it states the following:  It is important to note that at present female sterilisation reversal and vasectomy reversal is not routinely offered by the NHS.  Reversal of female sterilisation (pg 45)  Fallopian tube re-anastomosis following sterilisation can result in high postoperative patency rates, but may not result in pregnancy or a return to fertility  Reversal of male sterilisation (pg 22)  Vasectomy reversal involves complex surgery that can result in high postoperative patency rates, but may not result in pregnancy or a return to fertility		
Date effective from	November 2016		
Date published	November 2016		
Review date	November 2018		
Author	Dr Emma Broughton Clinical Lead Women's & Children NHS Vale		
	of York Clinical Commissioning Group. Julie Ryan, Innovation &		



	Improvement Manager, NHS VOYCCG		
Approved by			
Responsible officer	Dr Shaun O'Connell, GP Lead valeofyork.contactus@nhs.net		

#### References:

 Faculty of Sexual & Reproductive Healthcare Clinical Guidance Male and Female Sterilisation Clinical Effectiveness Unit, September 2014 <a href="http://www.fsrh.org/documents/cec-ceu-guidance-sterilisation-cpd-sep-2014/">http://www.fsrh.org/documents/cec-ceu-guidance-sterilisation-cpd-sep-2014/</a>

## NHS Vale of York Clinical Commissioning Group

## **Arthroscopic Sub acromial Decompression surgery**

Treatment	Arthroscopic Sub acromial Decompression of Shoulder			
OPCS Codes	029.1 Sub acromial decompression W84.4 Endoscopic decompression of joint + Shoulder W88.9 Unspecified diagnostic endoscopic examination of other Joint + shoulder			
For the treatment of	Sub acromial shoulder pain			
Background	Evidence published suggests that arthroscopic sub acromial decompression for sub acromial shoulder pain offers little benefit over a non-operative approach.			
	<ul> <li>This statement does not apply to those with any of the following: <ul> <li>Acute rotator cuff tears</li> <li>Sub acromial impingement pain for whom a combined rotator cuff repair and sub acromial decompression may be appropriate</li> <li>Calcific tendonitis</li> <li>Large Sub acromial spur</li> <li>Post fracture complications</li> <li>Post traumatic sub acromial bursitis</li> </ul> </li> <li>OR <ul> <li>Those with any clinical suspicion of infection, malignancy, unreduced dislocation or inflammatory arthritis, for whom appropriate local urgent pathways should be followed</li> </ul> </li> </ul>			
Commissioning position	NHS Vale of York CCG <b>DO NOT</b> routinely commission arthroscopic sub acromial decompression shoulder surgery for the treatment of sub acromial impingement pain.  Patients should be managed conservatively as outlined in the MSK pathway for conservative management:  • Rest/activity modification • Appropriate oral analgesia including NSAIDs • Lifestyle factors considered, such as BMI/smoking/exercise status, and discussed as risk factors for MSK ill health/tendon pain • At least six months active physiotherapy including, rotator cuff and scapular muscle strengthening, manual therapy and motor control retraining including class based exercise. If appropriate, six month programme can include patient self-directed continuation of exercises.  • No more than two sub acromial steroid injections, if appropriate and only considered in conjunction with			

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	physiotherapy as high recurrence rates in cases managed with injection alone
	Treatment is not normally funded and should not be referred unless there is prior approval by the Individual Funding Request panel
Summary of evidence / rationale  Local data suggests that this procedure has become of practised within Vale of York CCG. RightCare data for identified that the CCG was an outlier, against their identified that	
	The benefits of surgery are unclear, however, with some conflicting evidence. A recent randomised, placebo-controlled study compared outcomes following sub acromial decompression surgery, arthroscopy only, and no treatment for patients with sub acromial shoulder pain <sup>2</sup> . It concluded that "surgical groups had better outcomes for shoulder pain and function compared with no treatment, but this difference was not clinically important and decompression appeared to offer no advantage over arthroscopy only The findings question the value of this operation for these indications."
	In response to these results, the British Elbow and Shoulder Society (BESS) and the British Orthopaedic Association (BOA) have issued a position statement announcing that they will be recruiting a multidisciplinary group to update the 2014 BOA commissioning guidelines for sub acromial pain <sup>3</sup> .
	Wider questions have since also been raised about distinguishing between the effects of elective surgery and those of time, rest, graduated rehabilitation and the placebo effect – "the reported outcomes of many elective orthopaedic surgical procedures may be attributed to these responses" <sup>4</sup> . The condition is a long-term one and fluctuations in symptoms are to be expected.
	Further studies are being carried out. This statement has a review date and future publications will be taken into account upon review.
Date effective from	11 <sup>th</sup> February 2019
Review date	2021
Author	Dr Alison Forrester (Public Health England Advisor), Annette Wardman (Commissioning & Transformation manager)
Approved by	Executive Committee
Responsible officer	Dr Shaun O'Connell (GP Lead for Acute Service Transformation)
	Dr Shaun O'Connell (GP Lead for Acute Service Transformation)

- 1. Public Health England, NHS RightCare Commissioning for value focus pack Musculoskeletal conditions: trauma and injuries May 2016
- 2. Beard et al Lancet 391: 329-338 January 2018 Arthroscopic subacromial decompression for subacromial shoulder pain (CSAW): a multi-centre, pragmatic parallel group, placebo-controlled, three-group, randomised surgical trial CSAW Trial
- 3. Statement in response to recent studies regarding subacromial decompression BESS (2017) <u>Bess/boa statement</u>
- 4. Lewis J Journal of Orthopaedic and sports physical therapy 48:127-129 March 2018 The end of an era?

Version	Created /actioned by	Nature of Amendment	Approved by	Date
1.0	Lead Clinician and	Draft of new policy and circulation to	Lead Clinicians – VoY and	May 2018
	Commissioning &	internal GP Leads	SR CCGs	
	Transfomation Manager			
2.0	Senior Service	Share of threshold with stakeholders		June
	Improvement Manager	for consultation		2018
FINAL		Approval of threshold	VoY Clinical Executive	Jan 2019

### **Carpal Tunnel Syndrome Commissioning Policy**

Intervention	Treatment for Carpal tunnel syndrome may be called carpal tunnel release (CTR) or carpal tunnel decompression surgery.
For the treatment of	Carpal tunnel syndrome
Commissioning position	Nerve conduction studies (NCS) are NOT available from primary care (see commissioning statement). The need for NCS to confirm and predict positive surgical outcome in specific cases is a matter for surgeons and neurophysiologists consideration.
	NHS Scarborough & Ryedale and Vale of York CCGs will commission surgical decompression under local anaesthetic, for the treatment of carpal tunnel syndrome only in the following circumstances. For classification of symptoms of CTS, please see Appendix 1.
	Moderate symptoms Patients are experiencing symptoms that are interfering with activities of daily living AND all of the following have been tried:
	<ul> <li>The patient has not responded to a minimum of 6 months of conservative management, including at least 8 weeks of night time use of well-fitting wrist splints and</li> <li>Appropriate analgesia has been tried and</li> </ul>
	<ul> <li>Corticosteroid injections (given at least once prior to referral, unless clinically contraindicated) and</li> <li>Lifestyle/workplace modification e.g. weight loss, if appropriate</li> </ul>
	OR
	<ul> <li>Severe symptoms</li> <li>Patient is experiencing advanced or severe, neurological symptoms of Carpal Tunnel Syndrome such as constant pins and needles, numbness, muscle wasting and prominent pain or</li> <li>Sudden or traumatic in origin</li> </ul>
	Surgery should only be undertaken under local anaesthetic. Fear of the procedure, or patient choice are <b>not</b> adequate reasons for requesting surgery under GA, unless supporting mitigating factors are submitted to the IFR panel by the requesting clinician.
	Patients who do not meet the criteria outlined above, can be considered on an individual basis where their GP or Consultant believes there is an exceptional clinical need that justifies deviation from this policy. In those instances an application should be made to the IFR panel.
	In all cases the patient should have been informed about the shared decision making tool for Carpal Tunnel Syndrome available here <a href="http://www.valeofyorkccg.nhs.uk/rss/data/uploads/shared-decision-making/sdm-carpal-tunnel-syndrome.pdf">http://www.valeofyorkccg.nhs.uk/rss/data/uploads/shared-decision-making/sdm-carpal-tunnel-syndrome.pdf</a>

#### NHS Scarborough and Ryedale and Vale of York Clinical Commissioning Groups

#### **Carpal Tunnel Syndrome Commissioning Policy**

	Both splinting and steroid injection produce improvement in the majority of patients at least temporarily and should both be tried for patients with less severe symptoms and findings who are likely to include the 35% of patients who will not need further intervention.
Summary of evidence / rationale	Overall, patients whose CTS symptoms are significantly troublesome and who have mild or moderate impairment of the median nerve function should be offered splinting and local steroid injection.
	Patients failing such conservative management and those who present at a later stage with objective neurological signs or delayed motor conduction on nerve conduction systems should be offered the option of surgical decompression.
	All should be advised of the potential risks of the different treatments.
	An estimated 35% of patients with carpal tunnel syndrome will improve without surgical intervention. This is more likely when the patient is younger, when the symptoms are unilateral and/or of shorter duration or when Phalen's test is negative.
	A survey of over 4,000 patients having surgery under usual NHS circumstances found that about two years after surgery, only 75% considered the operation an unqualified success and 8% thought that they were worse off.
Date effective from	22 <sup>nd</sup> February 2020
Review Date	2022

- 1. NICE CKS Carpal tunnel syndrome
- 2. Clinical Evidence Carpal Tunnel Syndrome updated August 2014
- 3. Bland JDP. Carpal tunnel syndrome. Curr Opin Neurol 2005;18:581-5. [PubMed]
- 4. Bland J (2007) Clinical Review: Carpal tunnel syndrome. BMJ 2007;335;p343-346
- 5. BSSH Evidence for Surgical Treatment 1 CTS 2010
- 6. Royal College of Surgeons Commissioning Guide: Treatment of painful tingling fingers (November 2013)
- 7. NHS Choices Carpal tunnel syndrome Treatment
- 8. Evidence Based Intervention Policy NHSE published November 2018

Version	Created /actioned by	Nature of Amendment	Approved by	Date
FINAL	Senior Service	Approval of threshold	SRCCG Business Committee	14.01.20
	Improvement Manager		VoY Clinical Executive	Dec 2019

#### NHS Scarborough and Ryedale and Vale of York Clinical Commissioning Groups

#### **Carpal Tunnel Syndrome Commissioning Policy**

#### Appendix 1 – Classification of Carpal Tunnel Syndrome (CTS) Symptoms

CTS is a condition that involves pain and tingling in the first three or four fingers of one or both hands, which usually occurs at night. It is caused by pressure on the median nerve as it passes under the strong ligament that lies across the front of the wrist. Mild or moderate symptoms often resolve within 6 months.

There are a variety of treatment options which may be applied to the syndrome, depending on the severity of symptoms which can be mild, moderate or severe. An indication of each classification is detailed below:-

Assessment and Management in Primary Care		
	Symptoms	Treatment
Mild CTS	The sensory symptoms occur:  No more than once during the day  Once or twice a week during the night  Lasting for up to 10 minutes	Explanation of condition and that it may improve spontaneously  Lifestyle advice
	> Pain is not present	
Moderate CTS	The sensory symptoms occur:  > Two or three times during the day  > Once most nights  > Last for more than 10 minutes  > Pain may be present	Lifestyle advice  Well fitted nocturnal wrists splints if waking at night is troublesome  Appropriate analgesia
		Corticosteroid injection
Severe CTS	The sensory symptoms occur:  > Frequently each day and can last for more than an hour at a time  > Can be continuous  > Sleep is disturbed with more than two wakings every night  > Pain can be prominent  > Wasting and weakness of the thenar muscles may be present, together with sensory loss in the median supplied digits.	Consider early or immediate referral for surgery

## **Dupuytren's Contracture Commissioning Policy**

Intervention	Surgical Treatment for Dupuytren's Contracture
For the treatment of:	Dupuytren's contracture
Background	Dupuytren's contracture is a progressive disorder that affects the palmar fascia, causing the fibrous tissue to shorten and thicken, which may prevent full extension of the fingers and limit function.  All treatments aim to straighten the finger/s to restore and retain hand function, but none cure the condition - which can recur after any intervention so that further interventions are required <sup>1</sup> .
	Several treatments are available: percutaneous needle fasciotomy and collagenase injections are outpatient procedures whereas fasciectomy and dermatofasciectomy are open surgical procedures. No procedure is entirely satisfactory with some having slower recovery periods, higher complication rates or higher need for further surgery (for recurrence) than others <sup>1</sup> . It is unclear which intervention is best for restoring and maintaining hand function and which are the most cost-effective in the long term. Research studies are trying to address these questions and patients should discuss the latest understanding with surgeons. A Patient information leaflet can be found <a href="https://example.com/here">here</a>
Commissioning position	Treatment is <b>not indicated</b> where there is no contracture or it is mild (less than 20°) or not progressing and does not impair function <sup>1</sup>
	NHS Scarborough & Ryedale and Vale of York CCG's will commission surgical treatment for Dupuytren's Contracture only in the following circumstances.
	An intervention (collagenase injections; needle fasciotomy; fasciectomy and dermofasciectomy) should <b>only</b> be considered (and IFR approval is not required), when the patient meets <b>at least one</b> of the following functional difficulties.
	<ul> <li>finger contractures causing loss of finger extension of 30° or more at the metacarpophalangeal joint or 20° at the proximal interphalangeal joint. See <a href="here">here</a> on how to measure the angles using a goniometer</li> <li>OR</li> </ul>
	<ul> <li>thumb contractures which interfere with function AND</li> </ul>
	<ul> <li>There is a current material impairment of hand function AND</li> </ul>
	Surgery is likely to restore function
	Treatment in all other circumstances is not routinely commissioned and should not be referred unless clinical exceptionality is demonstrated and approved by the Individual Funding Request panel.

#### **Dupuytren's Contracture Commissioning Policy**

NICE concluded that collagenase treatment (Xiapex) should only be used for<sup>2</sup>:

- a. Participants in the ongoing clinical trial (HTA-15/102/04) or
- b. Adult patients with a palpable cord if all of the following apply:
- there is evidence of moderate disease (functional problems and metacarpophalangeal joint contracture of 30° to 60° and proximal interphalangeal joint contracture of less than 30° or first web contracture) plus up to two affected joints; and
- percutaneous needle fasciotomy is not considered appropriate, but limited open fasciectomy is considered appropriate by the treating hand surgeon.
- The choice of treatment (CCH or limited fasciectomy) is made on an individual basis after discussion between the responsible hand surgeon and the patient about the risks and benefits of the treatments available.
- One injection is given per treatment session by a hand surgeon in an outpatient setting.

## Summary of evidence / rationale

Dupuytren's disease is a benign, slowly progressive condition of unknown origin, characterised by connective tissue thickening in the palm of the hand, forming nodules and cords, which leads to difficulty in extending the fingers<sup>3</sup>. Early symptoms are usually often mild and painless and do not require treatment but can include reduced range of motion, reduced hand function and pain. Most patients are affected in both hands.

Most patients do neither need treatment nor a referral to secondary care but do need explanation and reassurance. They do not require monitoring. It is important to emphasise that contractures can progress and only need treatment if symptomatic (usually 20 – 30 degrees) Contractures that do impact on function are better treated earlier as they can pull the joints into a permanently flexed position, making it difficult to straighten fully with any treatment if allowed to progress too far. The condition often occurs in later life, and is most common in men aged over 40. Around one in six men over the age of 65 are affected by early, asymptomatic disease in the UK. It can be associated with diabetes, liver disease and alcohol excess.

Although there is great variation in the rate of progress, it is usually possible to distinguish the more aggressive form of the disease early on by its rapid progression.

Recurrence following treatment is more likely in younger patients if the original contracture was severe or if there is a strong family history

## **Dupuytren's Contracture Commissioning Policy**

	of the condition
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	Intervention is almost exclusively surgical, but surgery is not curative, complications and recurrence rates can be high (an overall complication rate of 26% has been reported for fasciectomy and fasciotomy <sup>3</sup> of which 4% have infection, numbness and stiffness). The evidence base provides no clarity about the best approach, which has to be judged for the individual patient. <b>To justify the risks of surgery a flexion deformity must be present.</b>
	Recent developments have been towards outpatient procedures, percutaneous needle fasciotomy (PNF) and collagenase injection (CCH) (more experimental, but supported by NICE TA459 <sup>2</sup> ). NICE guidance for PNF only exists as an IPG from 2004 <sup>4</sup> . CCH is a potential (but more expensive) option if PNF is not considered appropriate by the clinician. Although NICE TA459 suggests it in defined circumstances (including access to the ongoing clinical trial), its cost-effectiveness has not yet been demonstrated.
	A recent Swedish RCT, with institutional not industry funding and high internal validity, randomised around 150 patients (with involvement of only one finger and no earlier treatments) between PNF and collagenase treatment <sup>5</sup> . They found no significant differences between the two methods with regard to any outcome measurement at any time during the 2 year follow up. Most (around 75%) retained a straight finger although there was a significant recurrence rate of palpable cords.
	They point out that in the US, the introduction of CCH has increased the percentage of Dupuytren's contractures that are treated with minimally invasive techniques from 14% (2007) to 39% (2013), while the number of PNFs remains steady (and the number of open surgical procedures has declined). There is a substantial difference in cost, with CCH treatment almost 3 times more expensive. Another study has reported a significantly inferior outcome for CCH at 2 years <sup>6</sup> .
	Patient selection therefore has to be made carefully according to agreed criteria, with a preference for PNF while the benefits of CCH (in particular its cost-effectiveness) remain unproven.
OPCS codes	T521, T522, T525, T526, T528, T529, T541, T549, T561 T562 ICD code: M720
Date effective from	22 <sup>nd</sup> February 2020
Review date	2022

#### **NHS Scarborough & Ryedale and Vale of York Clinical Commissioning Groups**

#### **Dupuytren's Contracture Commissioning Policy**

- Evidence-Based Interventions: Guidance for CCGs N. Dupuytren's contracture release in adults. NHSE/NHSI Nov 2018, updated Jan 2019 <a href="https://www.england.nhs.uk/wp-content/uploads/2018/11/ebi-statutory-guidance-v2.pdf">https://www.england.nhs.uk/wp-content/uploads/2018/11/ebi-statutory-guidance-v2.pdf</a>
- 2. NICE TA459 Collagenase clostridium histolyticum for treating Dupuytren's contracture. July 2017. https://www.nice.org.uk/Guidance/TA459
- 3. NICE Clinical Knowledge Summaries (CKS) 2015 <a href="https://cks.nice.org.uk/dupuytrens-disease#!scenario">https://cks.nice.org.uk/dupuytrens-disease#!scenario</a>
- National Institute for Health and Clinical Excellence (NICE). Needle fasciotomy for Dupuytren's contracture. IPG43. London: NICE; 2004 <a href="https://www.nice.org.uk/quidance/ipg43">https://www.nice.org.uk/quidance/ipg43</a>
- Percutaneous Needle Fasciotomy Versus Collagenase Treatment for Dupuytren Contracture: A Randomized Controlled Trial with a Two-Year Follow-up Stromberg et al al J Bone and Joint Surgery July 2018 <a href="https://journals.lww.com/jbjsjournal/Fulltext/2018/07050/Percutaneous Needle\_Fasciotomy Versus Collagenase.1.aspx">https://journals.lww.com/jbjsjournal/Fulltext/2018/07050/Percutaneous Needle\_Fasciotomy Versus Collagenase.1.aspx</a>
- 6. Injectable collagenase versus percutaneous needle fasciotomy for Dupuytrens contracture in PIP joints: an RCT Skov et al J Hand Surg Am 2017

Version	Created /actioned by	Nature of Amendment	Approved by	Date
FINAL	Senior Service	Approval of threshold	NY Joint Business Executive	Jan 20
	Improvement Manager		VoY Executive Committee	Dec 19



## 16. Exogen Ultrasound Bone Healing Commissioning Statement

Treatment	Exogen® Ultrasound Bone Healing
Background	From April 2013, NHS England took over responsibility for commissioning
	activity in primary care, where initial conservative treatment takes place. NHS
	Vale of York CCG is responsible for commissioning activity in secondary care.
	The Exogen® ultrasound bone healing system delivers ultrasound waves with
	the aim of stimulating bone healing. Long bone fractures with non-union (most
	commonly tibia) are suitable for treatment if the fracture is stable and well
	aligned. Tibial fractures also appear to have the best healing rates and
	outcomes. Exogen® is not indicated for use in fractures of the skull or
	vertebrae or in children or adolescents because of their skeletal immaturity.
Commissioning	This commissioning policy is needed to provide a commissioning position for
position	the use of Exogen.
	The use of the Exogen® system to treat long bone fractures with delayed union
	or any other indications is NOT commissioned.
	(NB: NHS Vale of York CCG does NOT routinely commission an elective
	intervention on patients who have a BMI of 30 or above (classified as
	obese) or patients who are recorded as a current smoker - see
	commissioning statement 01. Optimising Outcomes from All Elective
	Surgery**)
	NHS Vale of York Clinical Commissioning Group will fund the use of the
	Exogen® system to treat long bone fractures with non-union, in accordance
	with defined clinical criteria as follows:
	Patient age > 18 years
	Non-union of fracture > 9 months
	Not to be used in cases of unstable surgical fixation, not well aligned or
	where inter-fragment gap is > 10mm
	Not to be used in cases with infection
	Not to be used in pregnancy, patients with pacemakers or vertebral/skull
	fractures
	Only when lifestyle factors addressed**
	**Note: patients with lifestyle factors which are known to delay fracture
	healing rates e.g. smoking and excess alcohol intake (i.e. men and
	women should not drink more than 14 units of alcohol each week1), will
	be appropriately counselled and required to eliminate these risks before
	determining non-union status and ultimately eligibility for Exogen®.
	Where appropriate, referrals to specific support services should be
	arranged e.g. smoking cessation service.
	NHS Vale of York Clinical Commissioning Group will NOT fund the use of the
	Exogen® system to treat long bone fractures with <b>delayed union</b> or any other
	indications for use of Exogen®.
	These criteria will be reviewed on publication of new evidence in the form of
	relevant trial data, updated national guidance, or national or local audit
	outcomes.



Clinical Commissioning Group

Any identified new indications for use of the Exogen® system requiring additional funding will only be considered in exceptional circumstances through the Individual Funding Request Panel.

## Summary of evidence / rationale

The Exogen® device consists of a main operating unit with a permanently connected transducer and a separate fixture strap. The strap is placed around the fractured bone and the transducer is secured directly over the fracture site. The transducer generates an acoustic wave pattern specific to Exogen®. If the patient's limb is immobilised in a cast then a hole is cut to allow access to the skin. It is thought that healing is promoted by stimulating the production of growth factors and proteins that increase the removal of old bone, increase the production of new bone and increase the rate at which fibrous matrix at a fracture site is converted to mineralised bone<sup>2</sup>.

The device is programmed to deliver ultrasound in 20-minute sessions and these are self-administered by the patient each day, generally over several months. It is intended to be used in the patient's home. The only type of device shown to be cost-effective in treating non–union (one can deliver more than 6 months' treatment) is the Exogen 4000+, cost around £2500 (price 2013; excludes VAT)<sup>2.</sup>

NICE published guidance for Exogen® in January 2013<sup>2</sup>. This states that the technique is cost-saving over traditional surgery when used for treatment of long bone fractures with non-union.

The NICE MTG states that:

- The case for adopting the Exogen® system to treat long bone fractures with non-union (failure to heal after 9 months) is supported by the clinical evidence, which shows high rates of fracture healing.
- About one third of non-union tibial fractures might be suitable for treatment with Exogen and thereby avoid surgery
- The Exogen® 4000+ system to treat long bone fractures with nonunion is associated with an estimated cost saving of £1164 per patient compared with current management, through avoiding surgery. (Note: this level of cost-saving has not been established locally)
- There is some radiological evidence of improved healing when the Exogen® system is used for long bone fractures with delayed healing (no evidence of healing after about 3 months). There are substantial uncertainties, however, about the rate at which bone healing progresses without adjunctive treatment between 3 and 9 months after fracture, and about whether or not surgery would still be necessary. These uncertainties result in a range of cost consequences, some cost-saving and others that are more costly than current management.

It should be noted that all the evidence associated with Exogen® when used for long-bone fracture with non-union is from observational studies with limited outcomes but with good clinical results, with healing rates ranging from 75% to 100% (depending on the long bone involved and duration of non-healing) over a period of 4.6 to 7.3 months. This is the reason for support from NICE.

Comparative evidence with surgery is limited. Healing rates from surgical intervention as identified in case series/cohort studies range from 62 to 100% over a period of 9 to 24 weeks.

	The evidence for use of Exogen® when used for long bone fracture and delayed healing is more limited and the outcomes varied. Uncertainties about the rate at which healing progresses after fracture, both with and without Exogen®, and about whether surgery would still be required, are outlined in the MTG as mentioned above. This therefore raises many uncertainties about the cost savings Some of the delayed healing studies include a significant number of patients (50%) considered to be non-union, with no sub-group analysis.
	Adverse events associated with use of Exogen® appear to be minimal. None of the clinical studies reported device-related events and no safety concerns were identified by the external assessment centre in relation to Exogen®.
	Reports on surgical treatment of non-union and delayed healing fractures documented adverse events including postoperative wound infection, osteomyelitis and pain.
Date effective from	November 2016
Date published	November 2016
Review date	November 2018
Author	Dr Alison Forrester, Healthcare Public Health Advisor CYC & NYCC
Approved by	Clinical Research & Effectiveness Committee 22.11.16
Responsible officer	Dr Shaun O'Connell, GP Lead <u>valeofyork.contactus@nhs.net</u>

#### Reference:

- 1. New alcohol guidelines show increased risk of cancer. Department of Health: Updated alcohol consumption guidelines give new advice on limits for men and pregnant women. 8 January 2016.
  - https://www.gov.uk/government/news/new-alcohol-guidelines-show-increased-risk-of-cancer
- NICE: EXOGEN ultrasound bone healing system for long bone fractures with non-union or delayed healing. Medical Technology Guidance 12 January 2013 <a href="https://www.nice.org.uk/guidance/mtg12">https://www.nice.org.uk/guidance/mtg12</a>

### **Bunions and Hallux Valgus Commissioning Policy**

Intervention	Bunion Surgery
OPCS codes	W79 Soft tissue operations on joint of toe
	W791 Soft tissue correction of hallux valgus
	W792 Excision of bunion NEC
	W793 Syndactylisation of lesser toes
	W798 Other specified soft tissue operations on joint of toe
	W799 Unspecified soft tissue operations on joint of toe
	W15 Division of bone of foot
	W151 Osteotomy of neck of first metatarsal bone
	W152 Osteotomy of base of first metatarsal bone
	W153 Osteotomy of first metatarsal bone NEC
	W154 Osteotomy of head of metatarsal bone
	W155 Osteotomy of midfoot tarsal bone
	W156 Cuneiform osteotomy of proximal phalanx with resection of head of
	first metatarsal
	W157 Osteotomy of bone of foot and fixation HFQ
	W158 Other specified division of bone of foot
	W159 Unspecified division of bone of foot
	W59 Fusion of joint of toe
	W591 Fusion of first metatarsophalangeal joint and replacement of lesser
	metatarsophalangeal joint
	W592 Fusion of first metatarsophalangeal joint and excision of lesser
	metatarsophalangeal joint
	W593 Fusion of first metatarsophalangeal joint NEC
	W594 Fusion of interphalangeal joint of great toe
	W595 Fusion of interphalangeal joint of toe NEC
	W596 Revision of fusion of joint of toe
	W598 Other specified fusion of joint of toe
	W599 Unspecified fusion of joint of toe
For the	Hallux valgus (bunion) surgery for the treatment of a deformity of the
treatment of:	joint connecting the big toe to the foot
Commissioning	NHS Scarborough & Ryedale and Vale of York CCGs do not routinely
position	commission surgery for asymptomatic hallux valgus (bunion), regardless of
•	cosmetic appearance. Concerns about cosmetic appearance should not be
	referred to secondary care. These procedures will not be funded.
	All patients should be referred to local podiatry services prior to referral to secondary care. (This does not affect the existing diabetic foot pathway)
	URGENT referral to Podiatry required if patient has a skin ulcer not
	, · · · · · · · · · · · · · · · · · · ·
	healing.
	Requests for the removal of symptomatic bunions will <b>ONLY</b> be considered
	where:
	Appropriate conservative measures have been trialled for 3 months and
	have failed <sup>(2)</sup> (these include trying accommodative footwear, considering
	orthoses as advised by podiatry and using appropriate analgesia). OR
	In the view of the podiatrist, three months of conservative treatment is
	futile
	AND the patient suffers from either
	Pain on walking (not relieved by appropriate analgesia) that causes
	significant functional impairment <b>OR</b>
	Deformity (with or without lesser toe deformity) that causes significant
	functional impairment or prevents them from finding adequate footwear
	OR
	I UN

### **Bunions and Hallux Valgus Commissioning Policy**

	Recurrent or chronic ulceration or infection
	The clinician needs to ensure that the patient fulfils <b>all</b> the criteria before they are referred to secondary care.
	<ul> <li>Before referral patients must be informed that</li> <li>They will be unable to drive for 6-8 weeks</li> <li>It will take at least a further 2 months to regain full function</li> <li>They will be out of sedentary work for up to 6 weeks and out of physical work for up to 3 months</li> <li>The prognosis for treated and untreated Hallux Valgus is very variable</li> <li>Recurrence of deformity occurs in 8-15% patients</li> <li>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<sup>(2)</sup></li> <li>Treatment in all other circumstances is not routinely commissioned and should not be referred unless clinical exceptionality is demonstrated and approved by the Individual Funding Request panel prior to referral.</li> </ul>
	and approved by the individual i unding nequest patiel prior to felerial.
Patient Information	NHS Bunion patient advice
Leaflets	Patient information leaflet
Summary of evidence / rationale	NICE CKS makes clear that referral for bunion surgery is indicated for pain and is not routinely performed for cosmetic purposes <sup>(1)</sup> Conservative treatment may be more appropriate than surgery for some older
	people, or people with severe neuropathy or other comorbidities affecting their ability to undergo surgery.
	Referral for orthopaedic or podiatric surgery consultation may be of benefit if the deformity is painful and worsening; the second toe is involved; the person has difficulty obtaining suitable shoes; or there is significant disruption to lifestyle or activities.
	If the person is referred for consideration of surgery, advise that surgery is usually done as a day case. Bunion surgery may help relieve pain and improve the alignment of the toe in most people (85%–90%); but there is no guarantee that the foot will be perfectly straight or pain-free after surgery.
	Complications after bunion surgery may include infection, joint stiffness, transfer pain (pain under the ball of the foot), hallux varus (overcorrection), bunion recurrence, damage to the nerves, fractures, metalwork removal and continued long-term pain.  There is very little good evidence with which to assess the effectiveness of either conservative or operative treatments or the potential benefit of one over the other.
	Untreated Hallux valgus in patients with diabetes (and other causes of peripheral neuropathy) may lead to ulceration, deep infection and even amputation <sup>(2)</sup>
Date effective from	September 2018
Date published	September 2018

#### NHS Scarborough and Ryedale and Vale of York Clinical Commissioning Groups

#### **Bunions and Hallux Valgus Commissioning Policy**

Review date	2020
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#### References

- 1. NICE Clinical Knowledge Summaries (2016)
- 2. Royal College of Surgeons Commissioning guide: Painful deformed great toe in adults.(2017)
- 3. Abhishek A; Roddy E; Zhang W; Doherty M. Are hallux valgus and big toe pain associated with impaired quality of life? A cross-sectional study. Osteoarthritis Cartilage 2010 Jul;18(7):923-6
- 4. Nix S; Smith M; Vicenzino B. Prevalence of hallux valgus in the general population: a systematic review and meta-analysis. J Foot Ankle Res 2010;3:21
- 5. NICE Surgical correction of hallux valgus using minimal access techniques. 332. London: National Institute for Health and Clinical Excellence; 2010.
- 6. Ferrari J; Higgins JP; Prior TD. Interventions for treating Hallux Valgus (abductovalgus) and bunions. Cochrane Database Syst Rev 2009;(1):CD000964
- 7. Saro C; Jensen I; Lindgren U; Fellander-Tsai L. Quality-of-life outcome after hallux valgus surgery. Qual Life Res 2007 Jun;16(5):731-8

Version	Created /actioned by	Nature of Amendment	Approved by	Date
1.0	Lead Clinician and	Re-drafting of STP and SR/VoY	n/a	27.04.18
	Commissioning &	policies		
	Transformation			
	Manager	No changes to previous		
		commissioning positions highlighted.		
		No consultation required.		
2.0	Senior Service	Share of new draft internally	Lead Clinicians – VoY and	May 18
	Improvement Manager		SR CCGs	
3.0	Senior Service	Minor changes following feedback	Lead Clinician – VoY	June 18
	Improvement Manager	from Clinical Director		
FINAL	Senior Service	Approval of threshold	SRCCG Business Committee	
	Improvement Manager		VoY Clinical Executive	04.07.18



### 24. Hip and Knee Replacement Commissioning Statement

Treatment	Hip and knee replacement for hip & knee arthritis - referral to secondary care	
Background	This commissioning policy is needed in order to clarify the criteria for referral to secondary care for hip and knee replacement. The CCG is facing severe financial constraints and has decided to tighten thresholds for elective joint replacement surgery, particularly in relation to BMI.  The Prevention and Better Health strategy¹ has been developed to demonstrate how focusing our efforts on prevention, self-care and shared decision making can support a shift in the way health care resources are valued, and to empower patients in the Vale of York to become more active participants in shaping their health outcomes	
Commissioning position	NHS Vale of York CCG does NOT routinely commission referral to secondary care for hip or knee replacement for patients whose BMI is 35 or above.	
	Exceptions to this threshold:	
	<ul> <li>Revision hip surgery which is clinically urgent AND where delay could lead to significant deterioration/acute hospital admission. Includes infection, recurrent dislocations, impending peri-prosthetic fracture, gross implant loosening or implant migration.</li> <li>Revision knee surgery which is clinically urgent AND where delay could lead to significant deterioration/acute hospital admission. Includes infection, impending peri-prosthetic fracture, gross implant loosening/migration, severe ligamentous instability.</li> <li>Primary hip or knee surgery which is clinically urgent because there is rapidly progressive or severe bone loss that would render reconstruction more complex.</li> <li>Orthopaedic procedures for chronic infection</li> </ul> Please note: As part of the <a href="Prevention and Better Health strategy">Prevention and Better Health strategy</a> ,	
	patients with a BMI range of 30 to 35 will be covered by the  Optimising Outcomes from All Elective Surgery Commissioning  Statement <sup>2</sup> Also note that any patient who is a current smoker will also be covered by this statement, regardless of their BMI.	
	Funding will ONLY be considered where criteria are met (see section 3). The clinician needs to ensure that the patient fulfils all the criteria and provides evidence of any of the clinical indications before they are referred to secondary care.	



All other cases need to be referred for consideration by the Individual Funding request panel (IFR). For further information see IFR policies and guidance (including the referral form)

In line with NICE CG177 Care and Management in Osteoarthritis<sup>3</sup>, patients should be offered advice on the following core treatments. (All conservative options should have been tried for at least 3 months.)

#### 1. Non pharmacological management

- Agree individualised self-management strategies. Ensure that
  positive behavioural changes, such as paced activity / exercise,
  weight loss, use of suitable footwear and, are appropriately
  targeted
- Activity and exercise should be encouraged, irrespective of age, comorbidity, pain severity or disability. Exercise should include local muscle strengthening and general aerobic fitness.
- All patients must have taken part in regular tier 2 exercise, with support as available from any appropriate service eg local authority exercise trainers, NHS services where available or private gyms and personal coaches
- All patients must have undertaken a programme of physiotherapy, including manipulation and stretching as an adjunct to core treatments.
- Interventions to achieve weight loss must be offered if the person is overweight or obese (see NICE CG 43<sup>4</sup>).
- People with osteoarthritis who have biomechanical joint pain or instability should be considered for assessment for bracing/joint supports/insoles. Assistive devices (e.g. walking sticks) should be considered for people who have specific problems with activities of daily living. Referral to occupational therapy or podiatry may be appropriate
- TENS should be considered as option for pain relief
- DO NOT offer glucosamine or chondroitin products, or acupuncture, for the management of osteoarthritis

#### 2. Pharmacological management

Arthritic pain is chronic nociceptive pain and drug management is covered in the RSS pathway guidance for pain relief.

#### This includes:

- Oral analgesia (eg regular paracetamol, cocodamol)
- Topical NSAIDs
- Oral NSAIDs eg ibuprofen 400mg tds or naproxen 500mg bd, with PPI cover.

At least three different types should be tried. Diclofenac and Cox2 inhibitors are not recommended because of the increased cardiovascular risk



- Intra-articular corticosteroid injections can be considered as an adjunct to core treatments, if appropriate, for the relief of moderate to severe pain in people with osteoarthritis<sup>3</sup>
- 3. Before any referral for surgery, patients also have to meet the following criteria:
- Experiencing moderate-to-severe persistent pain not adequately relieved by an extended course of non-surgical management. Pain is at a level at which it interferes with activities of daily living e.g. washing, dressing, lifestyle and sleep

#### **AND**

- Troubled by clinically significant functional limitation resulting in diminished quality of life AND
- Patients with a BMI range that is >30 but <35 meet the criteria covered by the Optimising Outcomes from All Elective Surgery commissioning statement<sup>2</sup> AND
- The patient has been a non-smoker for at least 8 weeks
   AND
- Evidence that regular paced tier 2 activity/exercise has been undertaken, with physiotherapy support if appropriate

#### AND

- A simple x-ray to confirm diagnosis has been carried out AND
- Evidence that PROMS data have been explained and discussed (see link http://www.valeofyorkccg.nhs.uk/rss/index.php?id=proms
- Evidence that the patient has had their options discussed via a shared decision-making tool

#### **Patient Information**

Further information for patients can be found the following website http://www.valeofyorkccg.nhs.uk/rss/index.php?id=prevention

#### 4. Referring Clinician

Therefore the referring clinician must:

- Ensure patients are signposted to the most appropriate support required for their lifestyle changes
- Ensure that patients are advised to seek review by their GP or other appropriate health care professional should their condition change during the period for lifestyle changes
- Ensure patients who continue to smoke and are not able to reduce their BMI must be allowed to access clinically appropriate elective care after specified periods of time.
- Ensure patients who receive interventions contrary to this
  policy statement may still be able to access support post
  procedure to improve their lifestyles to minimise any
  disadvantage to their health.
- Vulnerable patients / patients with mental illness, learning



disabilities or cognitive impairment will need to be clinically assessed to ensure that where they may be able to benefit from opportunities to improve lifestyle that are offered. (Please note that deferring elective interventions may be appropriate for some vulnerable patients based on clinical assessment of their ability to benefit from an opportunity to stop smoking/reduce their BMI/improve pre-operative fitness.)

## 5. The MSK service must refer all requests via the RSS and demonstrate that

- Patients with clinically urgent need do not experience avoidable delay
- The recommended hierarchy of management within NICE CG177 Care and Management in Osteoarthritis<sup>4</sup> has been followed: non-pharmacological treatments first, then drugs, for at least 3 months
- Adherence to the Optimising Outcomes from All Elective Surgery commissioning statement<sup>2</sup> for those patients within a BMI range that is >30 but <35</li>
- Confirmation that patients have been made aware of the options available as an alternative to surgery and the risks associated with surgery, and have considered the PROMs data and used shared decision-making tools during the patient care pathway
- Patients' fitness for surgery has been properly assessed and this is evidenced AND
- Ensure that patients with significant co-morbidities [systemic or local] have appropriate investigations and treatment to optimise their condition before referral

## Summary of evidence / rationale

Around 450 patients per 100,000 population will present to primary care with hip pain each year. Of these, 25% will improve within three months and 35% at twelve months; this improvement is sustained<sup>5</sup>.

20% of adults over 50 and 40% over 80 years report disability from knee pain secondary to osteoarthritis<sup>6</sup>. The majority of patients present to primary care with symptoms of pain and stiffness, which reduces mobility and with associated reduction in quality of life.

Osteoarthritis may not be progressive and most patients will not need surgery, with their symptoms adequately controlled by nonsurgical measures, as outlined by NICE<sup>3</sup>. Symptoms progress in 15% of patients with hip pain within 3 years and 28% within 6 years<sup>5</sup>.

When patient's symptoms are not controlled by up to 3 months of non-operative treatment they become candidates for assessment for joint surgery. The decision to have joint surgery is based on the



	patient's pre-operative levels of symptoms, their capacity to benefit, their expectation of the outcome and attitude to the risks involved. Patients should make shared decisions with clinicians, using decision support such as the NHS Decision Aid for knee osteoarthritis <sup>6</sup> .
	Obesity is an increasing problem in the population and also a significant risk factor for osteoarthritis. It is often associated with comorbidities such as diabetes, IHD, HT and sleep apnoea. Some years ago, an Arthritis Research Campaign Report <sup>7</sup> stated that joint surgery is less successful in obese patients because
	<ol> <li>Obese patients have a significantly higher risk of a range of short-term complications during and immediately after surgery (eg longer operations, excess blood loss requiring transfusions, DVT, wound complications including infection).</li> <li>The heavier the patient, the less likely it is that surgery will bring about an improvement in symptoms (eg they are less likely to regain normal functioning or reduction in pain and stiffness)</li> <li>The implant is likely to fail more quickly, requiring further surgery (eg within 7 years, obese patients are more than 10 times as likely to have an implant failure);</li> <li>People who have joint replacement surgery because of obesity-related osteoarthritis are more likely to gain weight post-operatively (despite the new opportunity to lose weight through exercise following reduction in pain levels)</li> </ol>
	It also concluded that "Weight loss and exercise combined have been shown to achieve the same level of symptom relief as joint replacement surgery". A study of obese patients with knee osteoarthritis found that those who dropped their weight by 10% after a combination of diet and exercise reported less pain, better knee function, improved mobility and enhanced quality of life <sup>8</sup> .
	A recent extensive literature review advises assessment of "timely weight loss as a part of conservative care"9. It confirms in detail the increased risk of many perioperative and postoperative complications associated with obesity (as well as increased costs and length of stay), such as wound healing/infections; respiratory problems; thromboembolic disease; dislocation; need for revision surgery; component malposition; and prosthesis loosening.
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# Clinical Commissioning Group 27. Ilizarov Technique / Taylor Spatial Frame (TSF) Commissioning Statement

Treatment	Elective use of the Ilizarov technique/Taylor Spatial Frame (TSF) in adults
Background	The <b>Ilizarov apparatus</b> is a type of external fixation used in orthopaedic surgery to lengthen or reshape limb bones; to treat complex and/or open bone fractures; and in cases of infected non-unions of bones that are not amenable with other techniques. The Taylor Spatial Frame (TSF) is more versatile and easier to use, but very costly.  The appropriate use of Ilizarov frames in <b>non-elective</b> traumatic injury is routinely commissioned; complex cases requiring specialist treatment are commissioned by NHS England <sup>1.</sup>
Commissioning position	This commissioning policy is needed to clarify under which circumstances the <b>elective</b> use of the Ilizarov technique is commissioned.
podulon	The use of the Ilizarov technique will NOT be commissioned where limb lengthening alone is the desired outcome as this would be deemed cosmetic and not medically necessary
	(NB: NHS Vale of York CCG does NOT routinely commission an elective intervention on patients who have a BMI of 30 or above (classified as obese) or patients who are recorded as a current smoker – see commissioning statement 01. Optimising Outcomes from All Elective Surgery**)
	NHS Vale of York CCG commissions the use of the Ilizarov technique/TSFs for elective use in orthopaedics in <b>individual carefully selected cases</b> which fulfill these criteria
	<ul> <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 osteoarthritis³.</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 8 weeks*</li> <li>The MDT should comprise at least two consultant orthopaedic surgeons, with input from specialist nursing, physiotherapy and musculoskeletal radiology.</li> </ul>
	* Smoking is a significant, potentially remediable risk factor for failure following Ilizarov reconstruction and cessation strategies are of paramount importance prior to initiating treatment <sup>14</sup> Thus, careful patient selection is important for determining the likelihood of success with Ilizarov (see risk factors for further details)



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Requests to use the Ilizarov technique outside these criteria must be submitted to the Vale of York CCG Individual Funding Request Panel (IFR) for consideration. Requests must include documented minutes from the MDT meeting at which the individual case was discussed.

# Summary of evidence / rationale

The Ilizarov technique is a method of bone fixation using an external fixator (eg the Ilizarov fixator or the Taylor Spatial Frame) for lengthening limbs, correcting deformities, and assisting the healing of otherwise hopeless traumatic or pathological fractures and infections. The TSF fixator is a computer software-controlled circular external fixator using six struts, allowing correction of lower limb deformities, fractures and limb lengthening with great accuracy<sup>4</sup>. The main drawback with this technique is the long duration of external fixation required with marked patient discomfort, thus good patient understanding and compliance is required.

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<sup>5, 6</sup>.

#### Non-union cases: 7 - 12

- The Ilizarov technique appears useful in the management of non-union of the long bones when internal devices have failed, though outcome results are varied
- Infected non-unions have a higher risk of failure than non- infected cases so the bone infection should be treated first.
- Outcomes appear to worsen with repeated surgical procedures
- Complications appear more frequent in lower leg non-union than in the femur or upper arm. Residual pain and secondary surgery are a frequent complication of tibial non-unions
- When bony union is achieved after Ilizarov the scores for bone function and the overall physical and mental health scores of the patient improves
- The greatest improvements may be seen 6-12 months after frame removal
- Early removal of the Ilizarov external fixation frame and replacement with internal fixation after bone graft appears to produce no difference in functional outcome on follow up of tibial non-union
- Patients with infected nonunion of tibia and femur treated by Ilizarov methods had a low rate of "poor" bone and functional results, suggesting that these methods may be a good choice for the treatment of infected nonunion of tibia and femur.

### Leg length discrepancy<sup>13</sup> (not routinely commissioned - via IFR only):

- Limb-length discrepancies greater than 2cm often result in pelvic slanting, scoliosis, alterations in normal walking pattern and abnormal loading of the hip and knee joints on the long side, with the attendant risks of premature arthrosis
- Speedier tibial lengthening may be achieved by using the Ilizarov fixator in conjunction with secondary internal fixation.
- The greater the leg length discrepancy the higher the risk for complications

	Risk factors:  Smoking is a significant, potentially remediable risk factor for failure following Ilizarov reconstruction and cessation strategies are of paramount importance prior to initiating treatment <sup>14</sup> . Thus, careful patient selection is important for determining the likelihood of success with Ilizarov especially regarding factors such as:  Smoking status BMI Length of bone defect Presence of infection Time from original trauma Number of previous operations The particular bone affected  All patients should understand the long duration of external fixation, the likelihood of marked patient discomfort and possible complications. Thus good patient understanding and compliance is paramount.
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Responsible	Shaun O'Connell GP Lead <u>valeofyork.contactus@nhs.net</u>
officer	

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### 29. Knee Arthroscopy Commissioning Statement

Treatment	Knee arthroscopy for diagnostic or therapeutic reasons
Background	Knee arthroscopy is a surgical procedure for inspection and treatment of problems arising in the knee joint such as inflammation or an injury. It can include repair or removal of any damaged tissue or cartilage. It has been used extensively in the past to diagnose knee problems but this is no longer appropriate due to the invasive nature of the procedure and the increasing access to less invasive diagnostic methods such as MRI.
	Recent analysis of the RightCare Commissioning for Value Focus Pack for Vale of York CCG shows that the CCG appears to have a much higher rate of elective knee arthroscopy than demographically similar CCGs.
	One of the main measures of knee arthroscopy* is the third commonest procedure carried out on the CCG population under elective MSK, after knee and hip joint replacement. The CCG is identified as an outlier, with over 60% more procedures than age and sex matched populations in similar CCGs, involving around £5M expenditure. The reasons for this are being explored (see RightCare data)
	With such a common procedure, it is all the more important to ensure that the evidence base is robust so that patients are not exposed to the risks without good evidence of benefit. It is important for the NHS to optimise the safety and cost-effectiveness of procedures to ensure maximum benefit for the risks and costs involved. The figures suggest that this could represent an area of improvement in cost-effectiveness and possible cost saving.
	The most recent Royal College of Surgeons commissioning guide states that knee arthroscopy, lavage and debridement should NOT be offered to patients with non-mechanical symptoms of pain and stiffness <sup>1</sup> . This approach is supported by many CCGs in England, including ones local to Vale of York, which do not support the routine funding of diagnostic knee arthroscopy.
	* (W822 Endoscopic resection of semilunar cartilage - not elsewhere classified)
Commissioning position	NHS Vale of York CCG does NOT routinely commission referral to secondary care for knee arthroscopy.
	NB: NHS Vale of York CCG also does NOT routinely commission an elective intervention on patients who have a BMI of 30 or above (classified as obese) or patients who are recorded as a current smoker – see commissioning statement Optimising Outcomes from All Elective Surgery)
	<ul> <li>In particular, both diagnostic and therapeutic arthroscopy are NOT routinely commissioned:</li> <li>for diagnostic purposes for investigation of knee pain</li> <li>to provide washout treatment (lavage) or debridement as a treatment for knee pain or arthritis (in line with NICE guidance, this should not be offered as part of a treatment for osteoarthritis unless the person has a clear documented history of mechanical locking)<sup>2, 3</sup></li> </ul>



 for symptoms of "giving way" or X-ray evidence of loose bodies without true locking

NB If clinical assessment suggests the patient might have a **red flag** condition (e.g.trauma, infection, carcinoma, bony fracture, avascular necrosis, or constant progressive non-mechanical pain, particularly at night), refer without delay **OR** if there has been knee trauma causing fracture or ligament avulsion and arthroscopy is needed urgently.

The CCG will ONLY commission therapeutic knee arthroscopy in adults where:

• the patient has clear mechanical features of true locking, or symptoms that worsen with conservative treatment,

#### **AND**

 conservative treatment has been tried over a 3 month period (This needs to include exercise, weight loss where appropriate, physiotherapy and maximal analgesic medication)

#### OR

- for patients with chronic knee pain, up to 6 months of comprehensive conservative treatment should be tried, including
  - efforts to lose weight if BMI over 25, (as outlined in NICE guidance<sup>3</sup>),
  - o lifestyle advice, including exercise or rest
  - o optimum pharmacological treatments
  - self or physiotherapy guided mobilisation and strengthening exercises.

NB: Referral for MRI scans should only be made by secondary care consultants or specialists working in CCG commissioned MSK services.

Investigation of knee pain with locking within the MSK service (tier 2) should start with less invasive MRI scanning to identify meniscal tears and loose bodies, in line with RSS guidance Radiology for knee pain with locking. The only exception is when there are contraindications to MRI (eg a pacemaker) or diagnostic uncertainty following a MRI scan **OR** if the patient has an anterior cruciate ligament reconstruction with metal screws affecting the MRI image quality.

Treatment in all other circumstances is not normally funded and should not be referred unless there is prior approval by the Individual Funding Request Panel.

Patients who are not eligible for treatment under this policy may be considered on an individual basis where their GP or consultant believes there is an exceptional clinical need that justifies deviation from the rule of this policy. Individual cases will be considered by the individual funding request panel (IFR request)

Providers will not be reimbursed for procedures on patients that do not have IFR approval.

## Summary of evidence / rationale

For patients with non-traumatic knee injury, evidence shows that, on average, conservative treatment is as effective as arthroscopic knee surgery for some



procedures. As long ago as 2002, a controlled trial addressing knee arthroscopy, using placebo or "sham" surgery as a comparator, showed no benefit<sup>4</sup>.

Partial meniscectomy surgery showed no advantage over sham in one RCT of patients aged 35-65 years with degenerative meniscal tears without osteoarthritis<sup>5</sup> and no advantage over physical therapy in two RCTs of older patients (>45 years) with osteoarthritis<sup>6, 7</sup>. In a systematic review of RCTs of young patients (mean age ~20 years) with a first occurrence of patellar dislocation, there was no conclusive advantage of surgical treatments compared with non-surgical treatments<sup>8</sup>. In an RCT of patients with patellarfemoral pain syndrome (18-40 years), mixed arthroscopic procedures and exercise resulted in equivalent improvements compared with exercise alone<sup>9</sup>.

Although rates of post-operative complications are generally low higher rates have been observed in children and young people<sup>10,11</sup>. There may also be future knee damage associated with arthroscopic procedures<sup>12,13</sup> and a recent meta-analysis showed that the small benefit from arthroscopic knee surgery seen in middle aged or older patients with knee pain and degenerative knee disease was absent one to two years after surgery and was associated with an increase in significant harms such as deep vein thrombosis, pulmonary embolism, infection and death<sup>14.</sup> The paper concludes

"The small inconsequential benefit seen from interventions that include arthroscopy for the degenerative knee is limited in time and absent at one to two years after surgery. Knee arthroscopy is associated with harms. Taken together, these findings do not support the practice of arthroscopic surgery for middle aged or older patients with knee pain with or without signs of osteoarthritis<sup>14</sup>.

The Royal College of Surgeons/British Orthopaedic Association commissioning guide points out that "osteoarthritis may not be progressive and most patients will not need surgery, with their symptoms adequately controlled by non-surgical measures as outlined by NICE<sup>1</sup>."

Regarding knee arthroscopy, it states that lavage and debridement should be considered in patients:

- With clear history of mechanical symptoms e.g. locking that have not responded to at least 3 months of non-surgical treatment
- Where a detailed understanding of the degree of compartment damage within the knee is required, above that demonstrated by imaging, when considering patients for certain surgical interventions (e.g. high tibial osteotomy)

The RCS/BOA guidance also states (in line with NICE guidance) that "Knee arthroscopy, lavage and debridement should NOT be offered for patient with non-mechanical symptoms of pain and stiffness."

More recently, the BMJ has published two editorials about arthroscopic surgery for degenerative knee or knee pain<sup>16, 17</sup>. They both explore the evidence for benefit and harm and point out that, although this is one of the most common surgical procedures, there is no convincing evidence for the procedure being



beneficial beyond the placebo effect.

A series of rigorous trials summarised in two recent systematic reviews and meta-analyses provide clear evidence that arthroscopic knee surgery offers little benefit for most patients with knee pain<sup>14, 18</sup>.

The most recent linked paper is a comparison between exercise therapy alone and arthroscopic partial meniscectomy alone (without any postoperative rehabilitation) in adults with a degenerative meniscal tear<sup>19</sup>. The authors found no between group differences in patient reported knee function at the two year follow-up, but greater muscle strength in the exercise group at three months.

Over time, the indications have extended from locked knees in young patients to all patients of all ages with knee pain and meniscus tears of any sort; tears which, on magnetic resonance imaging, have proved poorly associated with symptoms<sup>20</sup>.

Essentially, the editorials say, good evidence has been widely ignored. The most recent editorial comments that arthroscopic surgery for knee pain continues unabated, as disinvestments in ineffective treatments are generally slow<sup>17, 21</sup>. It calls for local commissioners to respond appropriately to the evidence, because "system level measures that result in more appropriate use of scarce medical resources are urgently required".

In addition, it says that "in a world of increasing awareness of constrained resources and epidemic medical waste, what we should not do is (...) ignore the results of rigorous trials and allow continuing widespread use of procedures for which there has never been compelling evidence".

## Rationale for up to 12 months of conservative treatment in chronic knee pain

This policy therefore specifies that conservative treatment should primarily be used but, when this fails, referral for surgery is an option. In the trial of meniscal surgery compared with conservative treatment in patients without osteoarthritis, at earlier time points, outcomes favoured surgery, but by 12 months of conservative treatment, outcomes were equivalent<sup>5</sup>. Therefore, to allow sufficient time for benefits of conservative treatment to be gained, and to allow for any potential natural healing of joint derangements, a minimum 12 months restriction has been selected for which conservative treatment should be attempted before any referral.

In this trial, cross-over from the conservative group to surgery over 12 months was low (7%). However, in other trials cross-over has been higher (around 30%)<sup>5,6</sup> suggesting that some patients will require more urgent surgery. There may be some cases where symptoms re-occur on conservative management and these patients may benefit from surgery<sup>15</sup>. Therefore, this policy allows for patients with mechanical locking or worsening symptoms to be referred before the 12 month period of conservative management.

#### Restricted procedures

For some interventions, the evidence identifies a lack of effect or there is insufficient evidence to warrant their use. There is currently no NICE guidance on the use of many procedures but, for the procedures that have been assessed, those not recommended by NICE will not be funded without IFR



approval.

There is evidence (including from a Cochrane systematic review) that lavage does not improve patient outcome compared to sham<sup>2, 3, 24-26</sup> and NICE does not recommend lavage<sup>2</sup>. NICE recommends knee meniscus replacement with biodegradable scaffold only with special arrangements for clinical governance, consent and audit or research<sup>27</sup>. NICE currently recommends that mosaicplasty should not be used without special arrangements for consent and audit or research<sup>28</sup>.

NICE does not currently recommend autologous chondrocyte implantation for the treatment of articular cartilage defects of the knee joint except in the context of on-going or new clinical studies<sup>29</sup>. NICE recommends that arthroscopic trochleoplasty for patellar instability should only be used with special arrangements for clinical governance, consent and audit or research<sup>30</sup>. There is some evidence that debridement is ineffective<sup>3, 24, 25</sup>, but NICE recommends that debridement may be appropriate in cases where there is mechanical locking<sup>3</sup>.

#### Restricted use of MRI

MRI is a good diagnostic tool<sup>22</sup>, but may be inaccurate when used by less experienced staff<sup>23</sup> and its use is, therefore, restricted to secondary care or specialists working in CCG commissioned MSK services for this indication.

Adapted (and updated) from evidence review in Knee arthroscopy for chronic knee pain Cambridgeshire and Peterborough CCG31, with thanks to Dr Raj Lakshman, Consultant Lead in Healthcare

#### Shared decision-making

A letter following the recent BMJ editorial suggests that the overtreatment of knee pain with arthroscopy could be solved through the use of shared decision making<sup>32</sup>. The NHS/BMJ aid for knee arthritis clearly states that arthroscopy for lavage and/or debridement doesn't make much difference to pain, increase mobility around or stop symptom progression<sup>33</sup>. The British Orthopaedic Association recently claimed that GPs were over-diagnosing patients with non-arthritic complaints and referring them on for surgery (instead of prescribing exercise) with the expectation that the keyhole procedure would 'cure' the problem, so that too many patients were undergoing needless arthroscopy. Easy access to MRI is also likely to be leading to overdiagnosis of meniscal tears and subsequent overtreatment.

"Shared decision making for the management of knee pain should begin in the GP surgery and continue through the patient's treatment. Given the research findings, it would be difficult to see why patients who are adequately supported in the decision making process would be choosing surgery over physiotherapy."

Deciding what to do about osteoarthritis of the knee; SDM guide - OA knee

Patient information leaflets available Arthroscopy Knee cartilage injuries

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Intervention	Therapeutic and diagnostic injections for the treatment of spinal pain
For the treatment of:	Spinal pain - Cervical, Thoracic & Lumbar.
Background	This policy sets out the commissioning position and threshold for therapeutic and diagnostic injections for the treatment of spinal pain.
	This commissioning policy is needed because the clinical and cost effectiveness of therapeutic injections for back pain is not proven.
	There is a threshold in place for diagnostic injections for back pain prior to surgery and also for patients who are on an acute back pain pathway.
Commissioning position	NHS Vale of York CCG <b>DO NOT</b> routinely commission therapeutic spinal injections for cervical, thoracic or Lumbar spine pain. This includes:
	<ul> <li>Spinal Epidural Injections         (transforaminal/interlaminar) and nerve root blocks</li> <li>Spinal Facet Joint Injections (FJI)/Medial branch blocks</li> <li>Spinal Radiofrequency Nerve Denervation         (rhizolysis/medial branch block/nerve root pulsed denervation)</li> <li>Therapeutic trigger point injections for the management of spinal pain</li> </ul>
	There are five exceptions which <u>are</u> commissioned:
	<ol> <li>During an acute episode of severe spinal pain with radicular pain of up to 16 weeks duration, as part of the acute back pain pathway, to help with mobilisation, one independent episode of epidural or transforaminal or medial branch block injections will be commissioned within an acute back pain service.</li> </ol>
	<ol> <li>For the treatment of chronic severe spinal pain with radicular pain for diagnostic purposes that guides surgical decision making, up to 2 independent episodes of transforaminal injections are commissioned to guide surgical decision making in patients.</li> </ol>
	<ol> <li>Facet joint medial branch block injections for diagnostic purposes: For patients with spinal pain AND/OR radicular pain up to 2 independent episodes of diagnostic facet medial branch block injections will be commissioned for diagnostic purposes to help define further management in line with the National Back Pain Pathway¹ (NBPP).</li> </ol>



- 4. Facet nerve radiofrequency denervation can be offered at no less than 16 month intervals to those with chronic low back pain who have (in the opinion of the specialist pain team), engaged in an MDT approach and have a positive response to a diagnostic facet joint medial nerve block (in line with National Back and Radicular Pain Pathway).
- 5. Spinal injections required to treat spinal pain caused by cancer.

ALL OTHER requests now must be made via an Individual Funding Request (IFR) application:

VOY CCG IFR

All patients with low back pain and/or sciatica should be assessed and managed in line with NICE guidance NG59<sup>1</sup>. This MUST initially include:

- Consider alternative diagnoses e.g. injury, malignancy
- Risk assessment and risk stratification (e.g. <u>STarTBack</u> risk assessment tool at first point of contact with a healthcare professional).

Based on risk stratification, consider simpler support (e.g. self-management - exercise, weight loss etc.) or more complex intensive support (e.g. pain management programmes with physical and psychological elements), optimised pharmacological interventions.

## Summary of evidence / rationale

#### History of evidence base

The previous NICE clinical guideline on low back pain (CG88; May 2009²) recommended that injection therapy should not be offered for back pain lasting greater than 6 weeks and less than 1 year. It specifically states "Do not offer injections of therapeutic substances into the back for non-specific low back pain".

#### **Current evidence base**

The new NICE guidance NG59<sup>3</sup> maintains the current position not to offer spinal injections for managing low back pain and to consider epidurals only in people with acute and severe sciatica.

It does however include a new recommendation to "consider" referral for assessment for radiofrequency denervation (RFD) for people with chronic low back pain when:

- non-surgical treatment has not worked for them and
- the main source of pain is thought to come from structures supplied by the medial branch nerve and
- they have moderate or severe levels of localised back pain (rated as 5 or more on a visual analogue scale, or



equivalent) at the time of referral.

Only to be performed in people with chronic low back pain (i.e. over 12 weeks) and after a positive response to a diagnostic medial branch block.

The most commonly used injection for the management of sciatica is corticosteroid, with or without local anaesthetic. Although performed widely since the 1950s, the administration of steroids into the epidural space remains unlicensed. Currently there are areas of uncertainty beyond the effectiveness of epidural injections to be considered, including the ideal route of administration, the use of imaging to improve accuracy, the timing of injection and the safety profile.

The fuller NICE guideline (methods, evidence and recommendations) covers the evidence base in detail<sup>4</sup>. The quality of evidence is low to moderate in strength and comes from populations with chronic pain for more than 2 years who had failed to respond to conservative treatment<sup>5</sup>. It comments that the duration of pain relief following RFD is uncertain. Data from randomised controlled trials suggests relief is maintained for at least 6-12 months but no study has reported longer term outcomes. Some trials show adverse event (allodynia) rates higher than expected with RFD.

The economic model built for the guideline showed that RFD is "cost effective" but the results were sensitive to the duration of the intervention; it suggested that the treatment is likely to be cost effective provided the duration of effect exceeds 16 months. When this was less than 16 months, RFD was not cost effective as the ICER would go above the £20,000 per QALY threshold. This is, in itself, the upper limit of what is considered an acceptable threshold and takes no account of affordability. Given the relatively low cost of RFD (around £750 per procedure) it also suggests the impact is rather limited.

The guideline development group considered the various limitations of the model together with the main results and concluded that although RFD is a cost effective intervention, there was not enough confidence for a strong ('offer') recommendation for this intervention.

In addition, if RFD is repeated, there is no evidence to show whether the outcomes and duration of these outcomes are similar to the initial treatment.

#### What NICE mean by the terms 'Offer' and 'Consider'

Some NICE recommendations are made with more certainty than others. NICE word their recommendations to reflect this. For example NICE use 'offer' to reflect a strong recommendation, usually where there is clear evidence of



benefit. NICE use 'consider' to reflect a recommendation for which the evidence of benefit is less certain. See Making decisions using NICE guidelines:

https://www.nice.org.uk/about/what-we-do/our-programmes/nice-guidance/nice-guidelines/making-decisions-using-nice-guidelines

#### **Back pain injections glossary**

#### Spinal injections include all of the following:

#### Facet joint injections (FJI).

These involve injection of substances (local anaesthetic, steroid or other agents) into the facet joint itself. Facet joints are small stabilizing joints located between and behind adjacent vertebrae in the spine and are believed to contribute to spinal pain in some cases. Facet joint injections can be used as a diagnostic procedure intended to establish whether the pain originates entirely or largely from the facet joint and may also be used as a therapeutic procedure for short-term pain relief in patients who have such significant degenerative change it is difficult to identify the location of the medial branch nerve

#### **Facet Medial branch Blocks**

Injection of the same substances as above around the primary nerve innervating the facet joint (the medial branch of the posterior primary ramus) is termed a medial branch block. It can be used as a more specific diagnostic procedure for considering future radiofrequency and is intended to establish whether pain originates from the facet joint. It can also sometimes be used as a therapeutic procedure.

## Radiofrequency denervation (RFD) (requires a positive response to a diagnostic medial branch block

For people with low back pain who experience significant but short term relief with facet joint nerve block, this can be followed by a neurodestructive procedure called radiofrequency denervation (RFD) in an attempt to achieve longer term pain relief. RFD has evolved as a treatment for spinal pain over the last 40 years and is a minimally invasive and percutaneous procedure. Radiofrequency energy is delivered along an insulated needle in contact with the target nerves and denatures them. This process may allow axons to regenerate with time requiring the repetition of the radiofrequency procedure. Radiofrequency denervation is not an appropriate treatment of people who have sciatica without back pain.

## Transforaminal Epidurals/ Nerve root injections/ Dorsal root ganglion block

The epidural space lies within the spinal canal, outside the dura mater, and contains the spinal nerve roots. A transforaminal



epidural injection is an injection of a therapeutic substance into this canal around a single nerve root with the aim of a more regional response.
Inter-laminar Epidurals This may be a caudal injection at the base of the spine or in the midline between the vertebral laminae (NICE recommends against use of epidural injections for patients with central spinal canal stenosis). This is usually only the injection of steroid with no local anaesthetic component to prevent the chance of accidental spinal injection.
Trigger point injections Trigger points are specific sites in a muscle that cause pain. In back pain this can occur either locally or refer more widely throughout the back. For the purpose of this policy Trigger point injections refers to those into painful muscles causing spinal pain.

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### 42. Trigger Finger Commissioning Statement

Treatment	Surgery for trigger finger
Background	Trigger finger is a condition that affects one or more of the hand's tendons, making it difficult to bend the affected finger or thumb. If the tendon becomes swollen and inflamed it can 'catch' in the tunnel it runs through (the tendon sheath). This can make it difficult to move the affected finger or thumb and can result in a clicking sensation.  Conservative management includes  • rest and NSAID medication for pain relief,  • splinting (to reduce movement)  • steroid injections
Commissioning position	NHS Vale of York CCG does not routinely commission surgery for trigger finger but will consider funding (via the referral form) if the following criteria are met  • Significant symptoms which have failed to respond to conservative measures including at least 2 corticosteroid injections (NB: if a patient refuses steroid injections IFR will need to consider this case on an individual basis)  • Fixed deformity that cannot be corrected  • Co-existing inflammatory or degenerative disorders of the hand  • Co-existing nerve entrapment syndromes or Dupuytren's disease  If patients do not meet the above criteria then any request has to be submitted via the IFR Panel.  Patient information leaflets trigger finger and BSSH trigger finger
Summary of evidence / rationale	One systematic review (2007) looked at 4 RCTs - two trials were placebo- controlled, one compared corticosteroid alone with percutaneous release with corticosteroid, and the fourth compared intra-sheath corticosteroid with subcutaneous corticosteroid. The conclusion was that corticosteroids were effective in relieving pain in 57% of patients <sup>1</sup> .  A Cochrane systematic review (2009) found that the effectiveness of local corticosteroid injections was studied in only two small RCTs of poor methodological quality. Both studies showed better short-term effects of corticosteroid injection combined with lidocaine compared to lidocaine alone on the treatment success outcome <sup>2</sup> . In one study the effects of corticosteroid injections lasted up to four months. No adverse effects were observed.  It concluded that corticosteroid injections can be an effective treatment of trigger finger; this and other appropriate non-invasive interventions e.g. splinting should precede consideration of surgery.  Key clinical practice recommendations from the British Society for Surgery of the Hand (evidence based management of adult trigger digits, 2016) <sup>3</sup> :  In the absence of contraindication and with patient's agreement, the first



	<ul> <li>line of adult trigger digit should be a single steroid and local anaesthetic injection.</li> <li>If the patient prefers percutaneous or open release, referral to secondary care should be made.</li> <li>A referral to secondary care for surgical treatment (percutaneous or open depending on the available expertise) should be made if symptoms fail to resolve, or if there is recurrence.</li> <li>Another systematic review found that the frequencies of treatment failure and complications were no different between percutaneous release surgery and open surgery for trigger digit in adults. Patients treated with percutaneous releases were less likely to have treatment failure than patients treated with corticosteroid injections<sup>4</sup>.</li> </ul>
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#### References

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- 3. British Society for Surgery of the Hand (2011) BSSH Evidence for Surgical Treatment (BEST): Trigger Finger (Thumb) http://www.bssh.ac.uk/education/guidelines/trigger.pdf
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## **Functional Electrical Stimulation Commissioning Statement**

**Commissioning Statement: 18** 

Treatment	Functional Electrical Stimulation Implantable Device
	Functional Electrical Stimulation for "drop foot" of central neurological origin
Background	Functional electrical stimulation (FES) is a treatment that uses the application of small electrical charges to improve mobility. It is particularly used as a treatment for drop foot. Drop foot is caused by disruption in the nerve pathway to and from the brain, rather than in nerves within the leg muscles.
	This commissioning policy is needed because, although requests for the standard skin-surface PACE FES device for drop foot are routinely commissioned, requests for wireless and implantable devices are only considered in exceptional clinical circumstances via referral to the Individual Funding Request Panel (IFR).
	Details of costs
	<b>Standard FES device</b> – All potential patients need to attend an initial assessment appointment. The following costs cover the load of the stimulation devices, consumables and clinician time.
	The cost of the initial assessment is £140. The cost of each further follow up appointment is £300. There are usually five appointments in the first year - £1640 in total, and one or two appointments in subsequent years (£ 300 - £ 600). No prior authorisation required
	<b>Implantable FES device</b> (STIMuSTEP) – cost of implant £6,442; ongoing costs £351 per year.
	The cost of treatment for each patient is subject to inflation rises.
Commissioning position	NHS Vale of York CCG routinely commission Functional Electrical Stimulation for drop foot, with the non-implantable device, in line with NICE IPG278 <sup>1</sup> , provided normal arrangements are in place for clinical governance, consent and audit.
	The CCG do <b>not</b> routinely commission the wireless or implantable device. Funding will only be considered where there are exceptional clinical circumstances. The clinician needs to submit an application to the CCG's Individual Funding Request Panel (IFR).
Summary of evidence / rationale	Drop foot is inability to lift the foot and toes in the swing phase of the gait when walking. This can cause abnormal gait, reduced walking speed and an increased risk of falls. This condition is present in around 20% of patients surviving a stroke. It is also associated with multiple sclerosis (MS) and other neurological conditions.
	FES involves the application of electrical pulses to the common peroneal nerve. The pulses are produced by a stimulator unit worn externally and delivered via skin surface (or implanted electrodes). The aim is to produce muscle contractions that mimic normal voluntary movement lifting the foot so that it does not drag on the ground, and so improve gait.
	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 <sup>2</sup> .

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<sup>2</sup>.

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

A recent UK economic model showed FES in addition to usual physiotherapy care, compared with usual physiotherapy care alone in patients who have suffered a stroke, had a conservative base case cost per QALY of approximately £20,000 (or over £50,000 for the first year and dropping to around £10,000)<sup>3</sup>. No cost effectiveness evidence was identified for other patient groups.

#### Recommendations

Functional electrical stimulation can be used for drop foot of central neurological origin, in line with NICE IPG 278, provided normal arrangements are in place for clinical governance, consent and audit. Patient selection for implantable FES for drop foot of central neurological origin should involve a multidisciplinary team specialising in rehabilitation.

The IPG also suggests that further publication on the efficacy of FES would be useful, specifically including patient-reported outcomes, such as quality of life and activities of daily living, and these outcomes should be examined in different ethnic and socioeconomic groups

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associated with more serious adverse events<sup>2</sup>.

#### References:

- NICE IPG 278 Functional Stimulation for drop foot of central neurological origin (March 2009) <a href="http://publications.nice.org.uk/functional-electrical-stimulation-for-drop-foot-of-central-neurological-origin-ipg278">http://publications.nice.org.uk/functional-electrical-stimulation-for-drop-foot-of-central-neurological-origin-ipg278</a>
- Evidence note 46 The use of functional electrical stimulation (FES) in adults with dropped foot (This evidence note updates evidence note 25 published in October 2008.)
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## **Cataract Commissioning Policy**

Treatment	Cataract Surgery			
Background	NHS North Yorkshire CCG and NHS Vale of York CCG responsible for commissioning activity in secondary care. policy defines the commissioning position for cataract surgand aims to:			
	<ul> <li>Ensure cataract surgery is commissioned where there is acceptable evidence of clinical benefit and cost-effectiveness.</li> <li>Reduce variation in access.</li> <li>Prioritise on the basis of surgical need.</li> <li>Ensure that patients are aware of the implications of surgery and confirms their wish to proceed.</li> </ul>			
Commissioning Position	NHS North Yorkshire CCG and NHS Vale of York CCG do not routinely commission cataract surgery based purely on the presence of a cataract. There will be a need to demonstrate that a patient's condition, in terms of visual acuity and impact on lifestyle/activities of daily living, exceeds the commissioning threshold for referral.			
	First Eye			
	The presence of a cataract in itself does not indicate a need for surgery. It is intended that all patients should be fully assessed and counselled as to the risk and benefits of surgery.			
	Where both eyes are affected by cataract, the first eye referred for cataract surgery is expected to be the eye cataract that has caused the greatest reduction in visual acuity.			
	Referral of patients with cataracts to Ophthalmologists should be based on the following indications:			
	<ul> <li>Visual acuity and impact on lifestyle/activities of daily living exceeding the commissioning threshold for referral as identified in the direct cataract referral form (See Appendix 1).</li> </ul>			
	AND			
	There has been a discussion on the risks and benefits of cataract surgery.			
	AND			





• The patient has understood what a cataract surgical procedure involves and wishes to have surgery.

#### **Second Eye**

Second eye surgery referred at a time after first eye surgery has been completed will follow the same criteria as the first eye, see above.

#### **Exclusions**

The following categories of patient or ophthalmic conditions are exempt from application of the access criteria and may be referred directly for possible cataract surgery:

- There is resultant significant optical imbalance (anisometropia - difference in refractive error) where the difference between the two eyes is more than 2.50 dioptres) AND which causes poor binocular vision (VA 6/12 or worse) or diplopia affecting daily living.
- Patients with diabetes in whom the removal of cataract is considered necessary to facilitate effective digital retinopathy;
- Patients with narrow angle glaucoma where removal of cataract (s) will prevent angle closure and blindness;

#### Exceptionality

Patients who do not meet any of the above indications nor exclusions, can still be referred to the CCG Individual Funding Request (IFR) panel for consideration of exceptional circumstances.

## Summary of evidence / rationale

With the current volume of cataract surgery and the likely increases in the future, it is critical to be able to optimise the safety and cost effectiveness of this procedure and to prioritise use of limited NHS resources. Whilst patients with mild visual impairment due to cataracts may want surgery their need, in terms of health gain and function, may not be significant.

Most cataracts are age-related and therefore surgeries are performed on older individuals with correspondingly high systemic and ocular comorbidities. It is therefore more important to ensure the right balance of risk to benefit<sup>7</sup>. Cataract surgery does not always result in an improvement in visual acuity or patient satisfaction with visual function<sup>8</sup>.





The judgement of when to offer surgery depends both upon the risks of surgery and the impact of the cataract on the patient's quality of life. NICE Guidance (NG77), published in October 2017, advises that the decision to refer, a person with a cataract, for surgery should be based on a discussion with them that includes: how the cataract affects the person's vision and quality of life; whether one or both eyes are affected; what cataract surgery involves, including possible risks and benefits; how the person's quality of life may be affected if they choose not to have cataract surgery and whether the person wants to have cataract surgery. NG77 also emphasises that the offer for second-eye cataract surgery should be done using the same criteria as for the first-eye surgery.

It is well known that patients with bilateral cataracts are at greater risk of falls and their quality of life is impaired.

In the NHS locally there are long waits for surgery following diagnosis and this creates a longer period of risk for patients. Cataracts can reduce the ability to socialise, to drive and have confidence in normal living.

The CCGs are keen to minimise the risk to as many patients, as fast as possible and treat at least one eye in all patients with bilateral cataracts. Whilst many patients will benefit from second eye surgery, the CCGs want to prioritise treating the first eye before those who have already had benefit from one cataract operation.

Patients may have falsely raised expectations that having the second eye is either routine, imperative or necessary for other reasons. The rate at which cataracts progress is unpredictable. Reading glasses are usually needed after cataract surgery. Some people may require glasses for distance vision who did not previously require them<sup>6</sup>.

Whilst in most patients having second eye surgery should give a better result, all surgery carries some risk. The need to take that risk depends on patient satisfaction, the degree of function after first eye surgery and any continuing imbalance with the second eye. Some may have a satisfactory return to function after just one operation and decide they can live with mild impairment. As a result their discussion, about the risks and benefits of a second operation, may lead to the conclusion not to undertake surgery.

Patients with poor vision due to other ophthalmic conditions may achieve limited improvement after surgery to the first eye





and may not get much better improvement after second eye surgery.

After first eye surgery good refraction may achieve good vision with an up-to-date pair of spectacles after the first surgery. Second eye surgery may not benefit the patient a lot more in terms of their functional needs.

Some CCGs require second eye surgery to meet the same criteria as first eye (Rotherham 2019), Dorset 2019). Note these follow NICE [NG77] guidance that the offer for second-eye cataract surgery should be done using the same criteria as for the first-eye surgery.

Cambridgeshire and Peterborough CCG's policy (July 2018) states: "NICE [NG77] used four studies to explore what should be the optimal clinical thresholds, in terms of severity and impairment for referral for cataract surgery, and did not find any tool was suitable to set a threshold for surgery<sup>1,2</sup>. For the cost-effectiveness analysis NICE used a [newly developed] economic model with "potentially serious limitations" [as it is] based on a cohort of patients already triaged for surgery with policy criteria that might vary depending on their CCG location<sup>2</sup>."

Significant improvements in visual symptoms and visual function may occur following first eye cataract surgery even where the preoperative visual acuity is better than 6/12 but the RCOphth guidance also recognises that "the risk of worse visual acuity after surgery increases where the preoperative visual acuity is very good so surgery should be considered only where the patient is experiencing significant symptoms attributable to cataract"<sup>3</sup>.

There is good evidence (as stated in the RCOphth guidance and confirmed by two systematic reviews) of significant improvement following first eye surgery, including a reduction in the rate of falls in older people receiving expedited cataract surgery for the first eye - but receiving second cataract surgery does not improve the risk of falling<sup>4</sup>. At least 5 studies have reported less visual function gain with second eye surgery compared with first, although this could be attributed to worse pre-operative VAs<sup>5</sup>.

There are risks associated with cataract surgery, some common and many very rare. With such a common procedure, it is all the more important to select the patients most likely to benefit. There is no set level of vision for which an operation is essential<sup>6</sup>.





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- 2. Cataracts Cambridge and Peterborough CCG Surgical Threshold Policy July 2018
- Royal College of Ophthalmologists January 2018 Commissioning Guide: Adult Cataract Surgery <a href="https://www.rcophth.ac.uk/wp-content/uploads/2018/02/Cataract-Commissioning-Guide-January-2018.pdf">https://www.rcophth.ac.uk/wp-content/uploads/2018/02/Cataract-Commissioning-Guide-January-2018.pdf</a>
- 4. Foss et al Falls and health status in elderly women following second eye cataract surgery: an RCT Age and Ageing 2006;35(1) 66-71
- 5. London Choosing Wisely (guidance for all London CCGs); Healthy London Sept 2018 Cataract Surgery Appx 9a <a href="https://www.healthylondon.org/wp-content/uploads/2018/10/Appendix-9a-Cataract-Surgery-Policy.pdf">https://www.healthylondon.org/wp-content/uploads/2018/10/Appendix-9a-Cataract-Surgery-Policy.pdf</a> (ref to RCOphth 2010 guidelines)
- 6. NICE Clinical Knowledge Summaries: Cataracts 2015 https://cks.nice.org.uk/cataracts#!scenario
- 7. Routine pre-operative medical testing for cataract surgery Cochrane database 2012 <a href="http://www.cochrane.org/CD007293/EYES">http://www.cochrane.org/CD007293/EYES</a> routine-preoperative-medical-testing-for-cataract-surgery
- **8.** 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 <a href="http://www.nature.com/eye/journal/v29/n4/full/eye20153a.html">http://www.nature.com/eye/journal/v29/n4/full/eye20153a.html</a>

Version	Created /actioned by	Nature of Amendment	Approved by	Date
1.0	Lead Clinicians and Head of	New policy covering VoY & NY CCGs	n/a	April 20
	Transformation & Delivery			
1.1	Head of Transformation &	Encompass suggested amendments.	n/a	April 20
	Delivery			





## **Appendix 1: Cataract Referral Form**

#### **DIRECT CATARACT REFERRAL FORM**

Please note that referrals relevant to this form should go via the Choice Office reflecting the requirements of the North Yorkshire/Vale of York CCGs Cataract Commissioning Statement and not be for the identified excluded patients.

Patient Choice Office Referral Management Service

West Offices, Station Rise York, YO1 6GA Telephone: 0300 3030060

Patient	t Name			DOE	3 /				Practice Sta	ımp
Addres	SS									
Teleph GP Na	none ame and Surger	у	١	NHS Nui	mber					
	rgery required o	on: Tick ap	propriate	boxes -	First ey	e Se	econd eye	Rig	ht eye	Left eye
VISUA	L ACUITY Unaided VA	Sphere	Cyl	Axis	Prism	Base	New VA	Add	Near VA	Previous
	Onalded VA	Оргісто	- Oyi	AXIS	1 113111	Dasc	NOW VA	Add	Near VA	Corrected VA:
RE										Date:
LE										
than 6/18= '10')  LIFESTYLE QUESTIONS TO THE PATIENT  Does the patient have any difficulty with mobility (including all aspects of travel, e.g. driving, using buses)?  Score '2' for 'yes' and '0' for 'no'  Is the patient affected by glare in sunlight or at night (e.g. car headlights)?  Score '1' for 'yes' and '0' for 'no'										
Is the patient's quality of life affected by vision difficulties (e.g. car driving, watching TV, doing hobbies, etc)?  Score '3' for 'very much', '2' for 'moderately', '1' for 'slightly', '0' for 'not at all'										
Is the patient's 'social functioning' affected by vision difficulties (e.g. crossing roads, recognising people, recognising coins, etc)?  Score '3' for 'very much', '2' for 'moderately', '1' for 'slightly', '0' for 'not at all'										
Is the patient's vision affecting their ability to carry out daily tasks?  Score '2' for 'yes' and '0' for 'no'										
TOTAL ASSESSMENT SCORE (VA SCORE PLUS LIFESTYLE SCORE)										
Important A patient with a total assessment score of 10 and over should be referred, unless you have indicated reasons below for not referring. Please provide description of cataract and any known co-morbidities below.  A patient with a total assessment score of under 10 should be advised that a referral for a cataract operation is not essential at this time – the patient should be advised to have a follow-up assessment in 6 months. If the patient has a score of less than 10 but you feel a referral is still required, please state why.										

I claim payment as per the Direct Cataract Referral Scheme. To be completed by the contractor or authorised signatory:



# **Chalazion Commissioning Statement Commissioning Statement: 48**

Treatment	Removal of chalazion		
For the treatment of			
	Chalazion/Meibomian cyst  A chalazion is a slowly developing lump that forms due to blockage and swelling		
Background	of an oil gland in the eyelid.		
	<ul> <li>Initial Treatment</li> <li>Initial treatment should include:         <ul> <li>massage through a hot flannel for 30 seconds first thing (at least twice a day) in the morning and last thing at night and any other times that are possible.</li> <li>Treatment of any blepharitis present with lid hygiene advice</li> <li>Given patients information such as that at <a href="http://patient.info/health/chalazion-leaflet">http://patient.info/health/chalazion-leaflet</a></li> </ul> </li> <li>There is no place for the use of topical antibiotics to treat chalazia per se though topical Chloroman parised sixtement may treat minor infortions.</li> </ul>		
	topical Chloramphenicol ointment may treat minor infections.		
Commissioning	Removal of chalazion is not routinely commissioned.		
position	Cases may be referred for excision if:  • the chalazion has been present for 3 months without spontaneous resolution  AND  • the chalazion is distressing the patient  AND  • the patient is willing to undergo excision under local anaesthetic  OR  • the chalazion is symptomatic —		
	<ul> <li>AND</li> <li>the patient is willing to undergo excision under local anaesthetic OR</li> <li>there is for diagnostic uncertainty OR</li> <li>primary care clinicians are suspicious of malignancy in which case a specialist opinion can be sought (under the 2WW rule as appropriate).</li> </ul>		

Clinical	Commissioning	Group	0

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	Excision should only be undertaken if one of the criteria above apply.		
	If the above criteria are not met clinicians can make an application to the independent funding review panel with details on why the patient may fulfil exceptional grounds for funding to be approved.		
Summary of evidence / rationale	Three studies quoted on BMJ Best practice detail that most chalazion (46%, 58% and 80%) resolve spontaneously over a four week period.		
	<ol> <li>NICE Clinical Knowledge Summary states 'if the meibomian cyst does not improve or resolve after 4 weeks with conservative treatment offer the following options (depending on clinical judgment and the person's preference):         <ul> <li>a. No treatment — for example, if the meibomian cyst is small and asymptomatic.</li> <li>b. Referral to an ophthalmologist'.</li> </ul> </li> </ol>		
	3. Moorfields Eye Hospital information for health professionals says: 'Unless acutely infected, it is harmless and nearly all resolve if given enough time'		
	Chalazia will often disappear without further treatment within a few months and virtually all will re-absorb within two years.  If conservative therapy fails, chalazia can be treated by surgical incision into the tarsal gland followed by curettage of the retained secretions and inflammatory material under local anesthetic.		
Date effective from	September 2016		
Date published	September 2016		
Review date	September 2018		
Author	Contributions to this policy have been received from Emma Broughton, James Green (local GP with interest in ophthalmology), Nicola Topping, (CD YHFT), and Nabil El-Hindy (YHFT consultant)		
Responsible Officer	Shaun O'Connell, GP Lead		
	valeofyork.contactus@nhs.net		



# **Surgery for Refractive Error Commissioning Statement Statement number: 40**

T 4	Occupit to Occupit the Involution of House Treatment
Treatment	Corrective Surgery, Lens Implants and Laser Treatment
For the treatment of	\ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \
Background	Corrective surgery for refractive error is widely available in the private sector but is not performed as an NHS procedure unless indicated for therapeutic reasons e.g. a specific clinical indication or the inability to wear spectacles due to disability.
Commissioning position	NHS Vale of York CCG does not routinely commission non- essential corrective surgery or lens implants for focusing (refractive) errors such as short-sightedness (myopia), astigmatism, and long- sightedness (hyperopia) because these conditions are usually corrected by wearing spectacles or contact lenses.  All requests for corrective surgery, lens implants and laser treatment for refractive error must be considered via the NHS Vale of York CCG Individual Funding Request (IFR) process and a clear clinical
	case of need must be evidenced, such as treatment for keratoconus (a rare eye condition where the cornea is conical shaped) that cannot be corrected by other means.
Summary of evidence / rationale	Corrective surgery includes either corneal or lens techniques. Corneal techniques include:
	<ul> <li>LASIK (Laser in-situ keratomileusis). Most common procedure in the UK, performed since the mid-1990s. Not suitable for high degree of myopia.</li> <li>Wavefront guided LASIK. Reduces the natural irregularities of the eye (which can cause light rays to focus incorrectly), and improves the visual result of the surgery.</li> <li>PRK (Photo refractive keratectomy). Used since the 1980s, but now mainly used for correcting low degree myopia.</li> <li>LASEK (Laser-assisted sub-epithelial keratectomy). Similar to PRK but the surface layer of the cornea is retained as a flap which helps prevent complications and speeds up healing.</li> </ul>
	Laser refractive surgery is generally effective for up to 10 dioptres of myopia, 6 dioptres of hyperopia and 4 dioptres of astigmatism, though the predictability of correction tends to diminish towards the extremes of these ranges. Current evidence suggests that laser surgery for the correction of refractive errors is safe and efficacious for use in appropriately selected patients, including when used to correct refractive error resulting from other forms of ophthalmic surgery (1, 2). The Royal College of Ophthalmologists issued a statement on Standards for Laser Refractive Surgery in 2012 (3).
	However corrective surgery is considered a cosmetic treatment and

Clinical Commissioning Group

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, with prices varying from approx £500-£1500 per eye depending on the prescription and the type of surgery involved.

Complications of laser refractive surgery include infection, bleeding, over/under correction, corneal haze, glare, halo or starburst, corneal damage, retinal detachment and dry eye. However risks which have the potential to cause permanent damage are very rare.

A 2005 review (4) of the efficacy of laser treatment found a broadly similar performance for PRK, LASEK and LASIK. People with a milder degree of myopia were more likely to achieve the intended refractive correction. Treatment of hyperopia was less successful than treatment of myopia.

#### Intraocular lens implants

For correction of large myopic refractive errors and moderate or large hyperopic refractive errors, a more predictable correction may be achieved by insertion of an intraocular lens (IOL) implant of the appropriate power. Lens techniques include:

- Insertion of corneal implants
- Intraocular lens insertion with preservation of the natural lens.
   (eg. phakic intraocular lens implants)

Current evidence from NICE on the efficacy of corneal implants for the correction of refractive error shows limited and unpredictable benefit. In addition, there are concerns about the safety of the procedure for patients with refractive error. Therefore, corneal implants should only be used for the treatment of refractive error when there is other ocular pathology present eg. keratoconus (5).

There is good evidence for the short term efficacy and safety of phakic IOL insertion, but the long term risks of cataract, corneal damage or retinal detachment remain uncertain and require ongoing audit. (6). Other complications of IOL implantation are similar to those of cataract surgery and include infection, poor night vision, glare and eye damage. Eyes with higher refractive errors have a greater risk

Date effective from	August 2016
Date published August 2016	
Review date August 2018	
Author  Dr Alison Forrester, Healthcare public health advisor, CYC and Note that Catherine Lightfoot, Clinical Triage Lead, Yorkshire and Humber Commissioning Support	
Responsible Officer	Shaun O'Connell, GP Lead valeofyork.contactus@nhs.net



#### References:

- 1. 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).
- 2. NICE IPG385 Laser correction of refractive error following non-refractive ophthalmic surgery (March 2011)
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- 4. 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. <a href="http://www.nice.org.uk/guidance/index.jsp?action=download&o=31559">http://www.nice.org.uk/guidance/index.jsp?action=download&o=31559</a>
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- 6. NICE IPG 289 (2009) Intraocular lens insertion for correction of refractive error, with preservation of the natural lens <a href="http://guidance.nice.org.uk/IPG289/Guidance/pdf/English">http://guidance.nice.org.uk/IPG289/Guidance/pdf/English</a>

#### **Acknowledgements**

Hull CCG Refractive Error Policy



# Oculoplastic Eye Problems Commissioning Statement Commissioning Statement: 32

Treatment	Oculoplasty (eyelid surgery)
For the treatment	Oculoplastic Eye Problems: Watery Eyes
of	Occiopiastic Lye i Tobiettis. Watery Lyes
Background	Oculoplasty is a branch of ophthalmology that focuses on plastic surgery procedures relating to the eyes, as well as the structures that surround it. This pertains to cosmetic or reconstructive surgery on areas around the eyes, such as the eyelids and orbit (eye socket). Droopy upper eyelids, tumors around the orbit, and thyroid disease, are some of the conditions that may require oculoplastic surgery eyelid surgery  Epiphora is a symptom, which may represent an underlying eye problem, which should be addressed. The commonest cause is blepharitis and blocked nasolacrimal ducts
Commissioning position	Oculoplastic procedures are not routinely commissioned as many are for cosmetic reasons. However there are a number of conditions which affect vision and functionality affecting activities of daily living and quality of life which may be considered via IFR for surgical correction.  The following eyelid surgery procedures will NOT be commissioned unless there is any diagnostic uncertainty:  Removal of eyelid papilloma's or skin tags Surgery for cyst of moll Surgery for cyst of zeis Surgery for pingueculum Excision of other lid lumps Surgery for cosmetic reasons  The following conditions are NOT routinely commissioned but there are specified criteria which may be considered by IFR for referral and treatment in secondary care:  Ectropion  Background: Ectropion is a condition, typically a consequence of advanced age, in which the eyelid is turned outwards away from the eyeball.  Policy: Ectropion is not routinely commissioned unless: Conservative management has been exhausted and there is evidence of significant impairment of the punctum There is recurrent infection in surrounding skin.  Epiphora  Background: Epiphora is an overflow of tears onto the face. A clinical sign or condition that constitutes insufficient tear film drainage from the eyes in that tears will drain down the face rather than through the nasolacrimal system.

Clinical Commissioning G
conservative management, the patient is experiencing a daily impact of significant watering of the eyes indoors and outdoors affecting visual function and / or interfering markedly with quality of life.
Chalazion/Meibomian cyst

Background: A chalazion is a slowly developing lump that forms due to blockage and swelling of an oil gland in the eyelid.

Policy: Removal of chalazion is not routinely commissioned. Cases may be considered by the IFR if:

 the chalazion has been present for 6 months and conservative management has been exhausted

OR

- the chalazion is symptomatic painful and has recurrent infection treated with antibiotics
- · there is significant impact on vision affecting functionality

N.B. for diagnostic uncertainty or suspicious symptoms to be referred under the 2 week wait.

#### **Blepharitis**

Background: Blepharitis is a common condition where the edges of the eyelids (eyelid margins) become red and swollen (inflamed).

Policy: Referral to secondary care for Blepharitis is NOT routinely commissioned. Refer to IFR if symptoms are persistent and have exhausted antibiotic therapy. If lids persistently swollen consider alternative diagnosis e.g. malignancy and refer under the 2 week referral wait.

Summary of	Patient information:
evidence /	http://patient.info/health/watering-eyes-epiphora
rationale	
Date effective	
from	
Date published	
Review date	
Author	Catherine Lightfoot, Clinical Triage Lead, North of England Commissioning Support
Approved by	
Responsible Officer	Shaun O'Connell, GP Lead <u>valeofyork.contactus@nhs.net</u>

#### References:

1. http://www.patient.co.uk/doctor/Epiphoria-(Watering-Eyes).htm



# Alternative and Complementary Therapies Commissioning Statement Commissioning Statement: 11

Treatment	Alternative and Complementary Therapies	
For the treatment of	Various medical conditions	
Background	From April 2013, NHS England took over responsibility for commissioning activity in primary care, where initial conservative treatment takes place. NHS Vale of York CCG is responsible for commissioning activity in secondary care.	
	This commissioning policy is needed in order to clarify the criteria for the use of alternative and complementary therapies.	
Commissioning position	This commissioning policy is needed because alternative and complementary therapies are not routinely commissioned by NHS Vale of York CCG due to a paucity of information on clinical effectiveness.	
	All requests for such treatments must be made on the grounds of clinical exceptionality to the NHS Vale of York CCG Individual Funding Request Panel. The therapies covered by this policy include:	
	Alternative therapies (professionally organised)     Acupuncture	
	Chiropractic	
	Herbal medicine	
	Homeopathy	
	Osteopathy	
	Neutralising Antigens	
	2. Complementary therapies	
	Alexander Technique	
	Yoga	
	Pilates	
	Aromatherapy	
	Bach and other flower remedies	
	Massage     Maditation	
	<ul><li>Meditation</li><li>Reflexology</li></ul>	
	Shiatsu	
	Healing Nutritional medicine	
	Hypnotherapy	
	3. Alternative disciplines	
	Anthroposophical medicine	
	Maharishi Ayurvedic medicine  Okina a kashada a dikida a	
	Chinese herbal medicine     Factors medicine	
	<ul><li>Eastern medicine</li><li>Naturopathy</li></ul>	
	Traditional Chinese medicine	
	Traditional Crimicolo modicino	
	4. Other alternative disciplines	

	Crystal therapy
	Dowsing
	• Iridology
	Kinesiology
	<ul> <li>Radionics and all other alternative and complementary therapies.</li> </ul>
	N.B. The alternative and complementary therapies/disciplines listed above are not exhaustive.
	However, in certain circumstances some of the procedures are occasionally commissioned as part of a broader contract with a mainstream provider (for example specialist pain management, oncology, palliative care and musculoskeletal [MSK] services) in a multidisciplinary approach to symptom control.
	On existing available evidence NHS Vale of York CCG would not commission referral outside the NHS for these services.
	The IFR Panel will only consider cases where exceptionality has been demonstrated and will require robust scientific evidence of clinical and cost effectiveness of the therapy, supported by published, peer-reviewed trials; outcomes of conventional treatments tried; and assurance concerning the training and qualifications of the proposed provider practitioners.
Summary of evidence / rationale	While some evidence of effectiveness exists for therapies in Group 1, there is a lack of conclusive evidence for the effectiveness of the majority of these therapies as obtained through properly established scientific trials; and as such NHS Vale of York CCG has to prioritise mainstream treatments for which there is evidence of clinical and cost- effectiveness.
	Some NHS professionals use a selection of these therapies in their practice and with effective regulatory mechanisms in place for individual professionals and under NHS clinical governance arrangements the use of such therapies is acceptable.
Date effective from	September 2016
Date published	September 2016
Review date	September 2018
Author	Dr Alison Forrester, Healthcare public health advisor, CYC and NYCC, Catherine Lightfoot, Clinical Triage Lead, Yorkshire and Humber Commissioning Support
Responsible Officer	Shaun O'Connell, GP Lead
	valeofyork.contactus@nhs.net

#### References:

- House of Lords Select Committee (House of Lords Select Committee on Science and Technology (2000): Complementary and Alternative Medicine. The Stationery Office, London) <a href="http://www.publications.parliament.uk/pa/ld199900/ldselect/ldsctech/123/12304">http://www.publications.parliament.uk/pa/ld199900/ldselect/ldsctech/123/12304</a>. htm
- 2. Bandolier review of complementary and alternative therapies. [no date given]



#### http://www.medicine.ox.ac.uk/bandolier

- 3. NICE (May 2009) Low back pain: early management of persistent non-specific low back pain <a href="http://www.nice.org.uk/guidance/cg88">http://www.nice.org.uk/guidance/cg88</a>
- 4. Lewith GT, Breen A, Filshie J, et al; Complementary medicine: evidence base, competence to practice and regulation. Clin Med. 2003 May-Jun;3(3):235-40.
- 5. Ernst E. Massage therapy for low back pain: A systematic review. Journal of Pain & Symptom Management 1999;17:56-69.
- 6. Dennis J, Cates C. Alexander technique for chronic asthma. The Cochrane Database of Systematic Reviews: Reviews 2000; 2.
- 7. Thorgrimsen L, Spector A, Wiles A, Orrell M. Aroma therapy for dementia. The Cochrane Database of Systematic Reviews: Reviews 2003, Issue 3.
- 8. de Izquierdo Santiago A, Khan M. Hypnosis for schizophrenia. The Cochrane Database of Systematic Reviews: Reviews 2004 Issue 3.

# **Endoscopic Thoracic Sympathectomy for Hyperhidrosis Commissioning Policy**

Intervention	Endoscopic Thoracic Sympathectomy
OPCS codes	R61*
For the treatment of:	Primary hyperhidrosis of the upper limb
Background	Endoscopic thoracic Sympathectomy (ETS) is a surgical procedure in which a portion of the sympathetic nerve trunk in the thoracic region is destroyed. ETS is used to treat focal hyperhidrosis, facial blushing, Raynaud's disease and reflex sympathetic dystrophy. By far the most common complaint treated with ETS is palmar hyperhidrosis, colloquially known as 'sweaty palms'. The intervention is controversial and illegal in some jurisdictions. Like any surgical procedure, it has risks; the endoscopic sympathetic block (ESB) procedure and those procedures that affect fewer nerves have lower risks.
Commissioning position	NHS Scarborough & Ryedale and Vale of York CCGs do not routinely commission Endoscopic Thoracic Sympathectomy.
	Applications will only be considered by the individual Funding Request Panel (IFR) where exceptional clinical circumstances are demonstrated. All cases require prior approval.
	In view of the risk of side effects, this procedure should only be considered in patients suffering from severe and debilitating primary hyperhidrosis that has been refractory to other treatments. (These may include topical agents, oral medication, botulinum toxin injections and iontophoresis.)  Endoscopic Thoracic Sympathectomy does not work as well for those
	with excessive axillary (armpit) sweating.
Summary of evidence / rationale	Recent NICE guidance (IPG 487 May 2014) indicates that the evidence base for the efficacy and safety of this procedure is "adequate" but there is a risk of serious complications (including death from major intrathoracic bleeding); it is not always effective; and it can cause hyperhidrosis ("compensatory") elsewhere on the body (in around 80% of cases, of whom 33% reported symptoms that were "severe" or "incapacitating").
	The primary indication is palmar hyperhidrosis because it is less effective for axillary symptoms. It should only be considered in patients suffering from severe and debilitating primary hyperhidrosis that has been refractory to other treatments.
	Further research is required to establish good patient selection and to identify which patient characteristics might predict severe side-effects.
Date effective from	26 <sup>th</sup> March 2018
Date published	March 2018
Review date	March 2020

## NHS Scarborough & Ryedale and Vale of York Clinical Commissioning Groups

## **Endoscopic Thoracic Sympathectomy for Hyperhidrosis Commissioning Policy**

#### References

- 1. NICE Clinical Knowledge Summary Hyperhidrosis
- 2. NICE IPG 487 (May 2014) Endoscopic Thoracic Sympathectomy for primary hyperhidrosis of the upper limb: guidance

Version	Created /actioned by	Nature of Amendment	Approved by	Date
1.0	Lead Clinician and Senior	Re-drafting of STP and SR/VoY policies.	n/a	01.02.18
	Service Imp Manager			
		No changes to previous commissioning		
2.0	Senior Service	Share of new draft internally	Lead Clinicians – VoY and SR	01.02.18
	Improvement Manager		CCGs	
FINAL	Senior Service	Approval of threshold	SRCCG Business Committee	07.03.18
	Improvement Manager		VoY Clinical Executive	21.03.18



## 10. Circumcision for Adults and Children

Treatment	Circumcision for adults and children for medical conditions
Background	Circumcision is a surgical procedure that involves partial or complete removal of the foreskin of the penis. It is an effective procedure and confers benefit for a range of medical indications.  This commissioning policy is needed because male circumcision (defined as the surgical removal of all or part of the foreskin of the penis) may be done for certain medical reasons.  NB Female circumcision has no medical benefits and is illegal under the Female Genital Mutilation Act (2003)
Commissioning position	NHS Vale of York CCG does NOT routinely commission male circumcision for cultural or religious reasons; the procedure will only be considered where medically necessary.  NHS Vale of York CCG routinely commission circumcision IF there is evidence of one of the following clinical indications:  • Lichen sclerosus (chronic inflammation leading to a rigid fibrous foreskin) in males aged 9 years and over  • Potentially malignant lesions of the prepuce or those causing diagnostic uncertainty  • Congenital abnormalities with functional impairment  • Distal scarring of the preputial orifice (a short course of topical corticosteroids might help with mild scarring  • Painful erections secondary to a tight foreskin  • Recurrent bouts of infection (balanitis/balanoposthitis  • Redundant prepuce, phimosis (inability to retract the foreskin due to a narrow prepucial ring) sufficient to cause ballooning of the foreskin on micturition; and paraphimosis (inability to pull forward a retracted foreskin)  • Traumatic injury eg zipper damage  • Congenital urological abnormalities when skin is required for grafting  Otherwise, funding will ONLY be considered where criteria are met. In children ensure physiological phimosis has been excluded and consider a trial of topical steroids for up to 3 months.  The clinician needs to submit an application to the CCG's Individual Funding Request Panel (IFR), using the referral form to provide evidence of any of the following clinical indications:  • Interference with normal sexual activity in adult males  • Dermatological disorders unresponsive to treatment
Summary of evidence / rationale	Nearly all boys are born with non-retractable foreskins as they are still in the process of developing and are often non-retractable up to the age of 3 years old. During normal development, the foreskin gradually becomes retractable without the need for any intervention. The majority of boys will have a



retractable foreskin by 10 years of age and 95% by 16-17 years of age. Inability to retract the foreskin in boys up to at least the age of 16, in the absence of scarring, is, therefore, physiologically normal and does not require any intervention.

In children up to and including 18 years of age, pathological phimosis (non-retraction) must be distinguished from physiological adherence of the foreskin to the glans, which is normal<sup>1</sup>. Non-retractile ballooning of the foreskin and spraying of urine do not routinely need to be referred for circumcision although not all ballooning is related to physiological phimosis and spraying can be due to lichen sclerosus<sup>1</sup>.

Parents and patients should be made aware of the risks and benefits of circumcision. Referrals from primary care for physiological phimosis account for a significant clinical workload in consultation time that could be avoided<sup>1</sup>. Conservative management of the non-retractile foreskin is under-recognised and practised in some regions. This is of particular importance in the paediatric population where too many circumcisions are undertaken for physiological phimosis thereby incurring avoidable morbidity<sup>1</sup>.

When physiological phimosis is diagnosed in a primary care assessment of foreskin condition, consultation should focus on reassurance and education of parents and child. If there is concern that any pathology is evident, or if there is diagnostic uncertainty, referral to a regional centre undertaking paediatric surgery is indicated<sup>1</sup>.

Discrepancy between regional UK circumcision rates suggest a significant number of circumcisions are being unnecessarily performed and commissioning guidance is intended to provide the necessary information to identify and introduce conformity in the frequency of procedures undertaken though better understanding, and differentiation between disease and physiological change in the foreskin<sup>1</sup>.

Paraphimosis (where the foreskin becomes trapped behind the glans and cannot go forward again) can usually be reduced under local anaesthetic and recurrence avoided by not forcibly retracting the foreskin. It should not be regarded as a routine indication for circumcision. There are several alternatives to treating retraction difficulties before circumcision is carried out. The BMA has stated 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<sup>2</sup>.

Common risks of surgical circumcision include bleeding, local sepsis, oozing, discomfort >7 days, meatal scabbing or stenosis, removal of too much or too little skin, urethral injury, amputation of the glans and inclusion cyst<sup>3</sup>. 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)<sup>4</sup>. 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.		
Date effective from	November 2016		
Date published	November 2016		
Review date	November 2018		
Author	Catherine Lightfoot, Clinical Triage Lead, Yorkshire and Humber CSU		
	and Dr Alison Forrester, Healthcare Public Health Advisor CYC and NYCC		
Approved by	Clinical Research & Effectiveness Committee 22.11.16		
Responsible Officer	Shaun O'Connell, GP Lead <u>Valeofyork.contactus@nhs.net</u>		

#### References:

- 1. Royal College of Surgeons Commissioning guide: Foreskin conditions October 2013 http://www.rcseng.ac.uk/healthcare-bodies/docs/published-guides/foreskin-conditions
- 2. 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 Surgeons, The Royal College of Nursing, The Royal College of Paediatrics and Child Health, The Royal College of Surgeons of England and The Royal College of Anaesthetists. (2001) "Statement on Male Circumcision". <a href="http://www.cirp.org/library/statements/RCS2001/">http://www.cirp.org/library/statements/RCS2001/</a>
- 4. Siegfried N, Muller M, Deeks J, Volmink J. Male circumcision for prevention of heterosexual acquisition of HIV in men. Cochrane Database of Systematic Reviews 2009, Issue 2. <a href="http://www.mrw.interscience.wiley.com/cochrane/clsysrev/articles/CD003362/pdf\_fs.html">http://www.mrw.interscience.wiley.com/cochrane/clsysrev/articles/CD003362/pdf\_fs.html</a>
- 5. NHS Choices Information on Circumcision and medical reasons why it may be necessary. http://www.nhs.uk/Conditions/Circumcision/Pages/Introduction.aspx

**Gamete harvesting and storage (Cryopreservation) Commissioning Policy** 

Intervention	Gamete harvesting and storage (Cryoproservation)
For the	Gamete harvesting and storage (Cryopreservation)  Harvesting and storage of viable gametes in patients undergoing NHS
treatment of:	funded medical treatment(s) that cause infertility
Background	To date, Scarborough and Ryedale and Vale of York CCGs have not had a formal policy on gamete harvesting and preservation for patients undergoing medical treatments that may leave them infertile.
	Cryopreservation is the process of freezing and storing sperm, oocytes and embryos so that they can potentially be used at a later date, typically in an attempt to conceive a pregnancy. The CCGs have a comprehensive fertility policy available on their website which covers the commissioning of cryopreservation for routine infertility treatment.
	One circumstance which is not covered by the fertility policy is the provision of cryopreservation for an individual who is expected to undergo NHS funded medical treatment(s) that cause infertility.
Commissioning position	NHS Scarborough & Ryedale and Vale of York CCGs agree to fund the harvesting and subsequent storage (cryopreservation) of viable gametes, for an initial period of 10 years, for patients undergoing NHS funded medical treatment that may leave them infertile.
	If after the initial 10 year period storage is still required, an IFR application should be made as an exceptional request, provided the patient wishes to keep their sample for potential future use. Each case will be considered on its own merit and in line with the HFEA legislation.
	Approval for harvesting and cryopreservation does not guarantee future funding of assisted conception or fertility treatment – in this instance the specific CCG policy for assisted conception should be applied.
	Prior to fertility preservation, the secondary care clinician at the organisation providing the fertility service must confirm:
	<ul> <li>That the planned treatment is likely to affect future fertility (and document this for the commissioners' audit purposes)</li> <li>That the impact of the treatment on fertility has been discussed with the patient</li> </ul>
	<ul> <li>That the patient is able to make an informed choice to undertake gamete harvesting and cryopreservation of semen, oocytes or embryos for an initial period of 10 years</li> <li>That the patient is aware that funding for gamete harvesting and cryopreservation does not guarantee future funding of assisted conception treatment</li> </ul>
	Cryopreservation in males In general, it is recommended that at least two semen samples are collected over a period of one week. The CCGs will commission a maximum of three samples of semen; this is considered sufficient to

**Gamete harvesting and storage (Cryopreservation) Commissioning Policy** 

provide future fertility.

Testicular tissue freezing is considered experimental and will not be funded.

Note: testicular sperm retrieval is commissioned by NHS England and not by the CCGs.

#### **Cryopreservation in Females**

The CCG will normally fund one cycle of egg retrieval, with or without fertilisation. If fewer than 10 eggs are retrieved following this first cycle of egg retrieval, then one further cycle can be offered.

Ovarian tissue storage is considered experimental and will not be funded.

#### Age

There are no specific age limits to this policy for males or females. The decision to attempt to preserve fertility is a clinical decision.

#### **Previous sterilisation**

Gamete retrieval and cryopreservation will not be funded where the patient has previously been sterilised.

#### **NHS Funded Assisted Conception**

Access to NHS funded harvesting and cryopreservation will not be affected by previous attempts at assisted conception. However, funding for further assisted conception attempts will be subject to the criteria stated in the CCG's IVF policy at the time of any funding application.

#### **Expectations of Providers**

Cryopreservation of gametes or embryos must meet the current legislative standards, i.e. under Human Embryo and Fertility Act 1990

The provider of the service must ensure the patient receives appropriate counselling and provides full consent. The patient and their partner must be made aware of the legal position on embryo ownership should one partner remove consent to their ongoing storage or use.

The provider of the service must ensure patients are aware of legal issues on posthumous use of gametes and embryos should they wish a partner to be able to use these should their treatment not be successful.

Patients will need to provide annual consent for continued storage.

The provider must ensure appropriate consent to storage is in place and that the patient understands the need for on-going consent and has outlined the purposes for which they can be used. Gamete harvesting and storage (Cryopreservation) Commissioning Policy

Summary of evidence / rationale	Expectation of the Patient  The patient will be responsible for ensuring the storage provider has up to date contact details. Failure to provide on-going consent may result in the destruction of stored materials.  Following notification of a recent legal challenge having been brought against NHS England by the Equality and Human Rights Commission (EHRC), the CCG wishes to ensure that all patients undergoing medical treatments that may affect fertility, including transgender treatments, have the same access to gamete preservation services as patients undergoing cancer treatment.			
	The challenge relates to the commissioning and provision of gamete retrieval and storage services for transgender patients. The EHRC argues that:			
	<ul> <li>NHS England wrongly interprets the words "Gender Identity Disorder Services" at paragraph 57, Schedule 4 of the NHS Commissioning Board and Clinical Commissioning Groups (Responsibilities and Standing Rules) Regulations 2012 ("the 2012 Regulations") as not including gamete retrieval and storage, and has thereby misdirected itself as to its obligation to provide that service to transgender patients;</li> <li>NHS England has unlawfully failed to exercise its power under s.2 of the National Health Service Act 2006 ("the 2006 Act"), in the light of its obligations under domestic and European equalities provisions, to provide gamete retrieval and storage to transgender patients;</li> <li>NHS England has unlawfully failed to exercise its power to issue guidance to clinical commissioning groups ("CCGs") to discourage them from unlawfully failing to arrange for the provision of gamete retrieval and storage to transgender patients.</li> </ul>			
	NHS England's position is that the commissioning of gamete retrieval and storage services is appropriately the commissioning responsibility of CCGs. Responsibility for developing clinical commissioning policy in this area extends as much to trans patients as it does to patients, for example, undergoing chemotherapy. When formulating clinical commissioning policy in this, and indeed all areas of commissioning responsibility, CCGs are under a number of legal duties including the Public Sector Equality Duty. NHS England's position is that no additional statutory guidance on this issue is required.			
	NHS England advised CCGs: 'in light of this challenge, [CCGs] may wish to review any commissioning policies in place in this area and how they apply to different groups of patients.			
Date effective from	January 2019			
Date published	January 2019			
Review date	2021			

#### NHS Scarborough & Ryedale and Vale of York Clinical Commissioning Groups

#### **Gamete harvesting and storage (Cryopreservation) Commissioning Policy**

#### References:

<sup>1</sup>NHE England CCG Bulletin - Issue 247 - 25 October 2018, Review of clinical commissioning policies for gamete retrieval and preservation

- NICE (CG156 Fertility Problems: assessment and management)
- Human Fertilisation and Embryology Act (1990) guidelines https://www.hfea.gov.uk/
- Human Tissue Authority guidelines https://www.hta.gov.uk/
- Leeds CCG Gynaecology and Urology Commissioning Policy

Version	Created /actioned by	Nature of Amendment	Approved by	Date
V1	GP Clinical Lead	Draft of initial statement	n/a	n/a
FINAL	GP Clinical Lead and Senior Service Improvement Manager	Final statement for approval	SRCCG Business Committee (via email)	Dec 18
			VoYCCG Executive Committee	Jan 19



# Penile Implants Commissioning Statement Statement number: 34

Treatment	Penile Implants		
For the treatment of:	Erectile Dysfunction		
Background	A penile prosthesis is another treatment option for men with erectile dysfunction (ED). These devices are either malleable or inflatable. The simplest type of prosthesis consists of a pair of malleable (bendable) rods surgically implanted within the erection chambers of the penis.		
Commissioning position	NHS Vale of York CCG does not routinely commission penile implants (prostheses) for treating erectile dysfunction (ED).		
	Funding will only be considered by NHS Vale of York CCG Individual Funding Request Panel (IFR) where exceptional clinical circumstances are demonstrated. These might include men with sexual dysfunction after radical treatment for prostate cancer <sup>3</sup> .		
Summary of evidence / rationale	Erectile dysfunction (ED) is defined as the persistent inability to attain and maintain an erection sufficient to permit satisfactory sexual performance. It is more common in older men, affecting about half the male population of 40–70 years of age.		
	There is considerable evidence that adequate levels of testosterone are required for 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.		
	NICE CG 175 includes the following advice on managing sexual dysfunction following radical treatment for prostate cancer:		
	1.3.31 Ensure that men have early and ongoing access to specialist erectile dysfunction services		
	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		
	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.		
	A Cochrane Review from 2007 <sup>4</sup> mainly covered the effectiveness of PDE5 and did not mention penile implants.		
Date effective from	August 2016		
Date published	August 2016		
Review date	August 2018		
Author	Catherine Lightfoot, Clinical Triage Lead, Yorkshire and Humber Commissioning Support		
Responsible officer	Shaun O'Connell, GP Lead  valeofyork.contactus@nhs.net		



#### References:

- 1. NHS Evidence Clinical Knowledge Summaries ; Erectile Dysfunction http://cks.nice.org.uk/erectile-dysfunction
- 2. Guidelines on the management of erectile dysfunction, British Society for Sexual Medicine (BSSM) 2009. <a href="http://www.bssm.org.uk/downloads/BSSM">http://www.bssm.org.uk/downloads/BSSM</a> ED Management Guidelines 2009. <a href="pdf">pdf</a>
- 3. NICE CG 175 Prostate cancer: diagnosis and treatment January 2014 <a href="http://www.nice.org.uk/guidance/cg175/chapter/1-recommendations">http://www.nice.org.uk/guidance/cg175/chapter/1-recommendations</a>
- 4. Interventions for sexual dysfunction following treatments for cancer. Cochrane Review 2007 http://onlinelibrary.wiley.com/doi/10.1002/14651858.CD005540.pub2/abst\_ract



# 37. Reversal of Sterilisation in Men and Women Commissioning Statement

Treatment	Reversal of sterilization in men and women	
rreatment	Reversal of sternization in men and women	
Background	Reversal of female sterilisation is a surgical procedure that involves the reconstruction of the fallopian tubes.	
	Reversal of male sterilisation is a surgical procedure that involves the reconstruction of the vas deferens	
Commissioning position	NHS Vale of York CCG does not routinely commission the Reversal of sterilisation for men or women	
	Reversal of female sterilisation Sterilisation procedure is available on NHS and couples seeking sterilisation should be fully advised and counselled (in accordance with RCOG guidelines) that the procedure is intended to be permanent. Policy: Reversal of female sterilisation will not be routinely funded.	
	Reversal of male sterilisation Sterilisation procedure is available on the NHS and couples seeking sterilisation should be fully advised and counselled (in accordance with RCOG guidelines) that the procedure is intended to be permanent. Policy: Reversal of male sterilisation will not be routinely funded.	
Summary of evidence / rationale	Policy: Reversal of male sterilisation will not be routinely funded.  The Faculty of Sexual & Reproductive Healthcare Clinical Guidance Male and Female Sterilisation Clinical Effectiveness Unit, September 2014¹ provides evidence-based recommendations and good practice points for health professionals on elective male sterilisation (vasectomy) and female sterilisation (tubal occlusion) in the UK. It is intended for any health care professional or service that undertakes or refers individuals for either procedure. This guidance has been jointly developed with the Royal College of Obstetricians and Gynaecologists (RCOG). On the reversals of both male and female sterilization it states the following:  It is important to note that at present female sterilisation reversal and vasectomy reversal is not routinely offered by the NHS.  Reversal of female sterilisation (pg 45)  Fallopian tube re-anastomosis following sterilisation can result in high postoperative patency rates, but may not result in pregnancy or a return to fertility  Reversal of male sterilisation (pg 22)  Vasectomy reversal involves complex surgery that can result in high postoperative patency rates, but may not result in pregnancy or a return to fertility	
Date effective from	November 2016	
Date published	November 2016	
Review date	November 2018	
Author	Dr Emma Broughton Clinical Lead Women's & Children NHS Vale	
	of York Clinical Commissioning Group. Julie Ryan, Innovation &	



	Improvement Manager, NHS VOYCCG	
Approved by		
Responsible officer	Dr Shaun O'Connell, GP Lead valeofyork.contactus@nhs.net	

#### References:

 Faculty of Sexual & Reproductive Healthcare Clinical Guidance Male and Female Sterilisation Clinical Effectiveness Unit, September 2014 <a href="http://www.fsrh.org/documents/cec-ceu-guidance-sterilisation-cpd-sep-2014/">http://www.fsrh.org/documents/cec-ceu-guidance-sterilisation-cpd-sep-2014/</a>

# NHS Scarborough & Ryedale and Vale of York Clinical Commissioning Groups

## **Vasectomy Commissioning Policy**

Intervention Vasectomy under Local (LA) or General (GA) anaesthetic					
For the treatment of:	Male Fertility				
Exclusions to policy	Not applicable				
Background	Vasectomy is a surgical procedure for male sterilisation or permanent contraception. During the procedure, the male vas deferens are severed and then tied or sealed in a manner so as to prevent sperm from entering into the seminal stream (ejaculate) and thereby prevent fertilisation.				
Commissioning position	Vasectomy under Local Anaesthetic (LA)  NHS Scarborough & Ryedale and Vale of York CCGs routinely commission vasectomies carried out under LA in non-secondary care settings.				
	Vasectomy under General Anaesthetic (GA) NHS Scarborough & Ryedale and Vale of York CCGs do commission vasectomies under General Anaesthetic in secondary care only in the following circumstances:  • Previous documented adverse reaction to LA • Scarring or deformity from previous scrotal surgery or trauma that makes vasectomy under LA difficult to achieve • History of coagulation disorder, inguinal scrotal hernia or cryptorchidism • Large varicocele or hydrocele • Where patients have previously had vasectomy on the NHS, have subsequently had a reversal of vasectomy (privately or on the NHS) and again wish to undergo vasectomy  Fear of the procedure, or patient choice are not adequate reasons for requesting vasectomy under GA, unless supporting mitigating factors are				
	Patients who do not meet the criteria outlined above, can be considered on an individual basis where their GP or Consultant believes there is an exceptional clinical need that justifies deviation from this policy. In those instances an application should be made to the IFR panel				
Summary of evidence / rationale	It is recommended that men who request a vasectomy are fully assessed and counselled before the procedure is given; including taking the medical history of both partners to ascertain if the procedure is indeed the most appropriate intervention.  Men should be counselled about the permanency of the procedure and variable success rates for reversal. Additional counselling is recommended				
	for men under 30 years <sup>1</sup> . Advice should also be provided to men about the possibility of chronic testicular or scrotal pain after vasectomy.  Most vasectomies are carried out under local anaesthetic. This means only the scrotum and testicles will be numbed and the patient will be awake for the procedure. The procedure should not be painful but may feel slightly uncomfortable. Most men will only need a local anaesthetic.  The RCOG guidelines <sup>4</sup> recommend a general anaesthetic is used where:  • There is a history of allergy to local anaesthetic				

#### NHS Scarborough & Ryedale and Vale of York Clinical Commissioning Groups

#### **Vasectomy Commissioning Policy**

	<ul> <li>Surgery has been carried out before on the scrotum or genital area</li> <li>The RCOG guidelines also recommend: <ul> <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<sup>5</sup></li> </ul> </li> </ul>
OPCS codes	N17 Excision of vas deferens N171 Bilateral vasectomy N172 Ligation of vas deferens NEC N178 Other specified excision of vas deferens N179 Unspecified excision of vas deferens
Date effective from	August 2019
Review date	2021

#### References:

- 1. RCOG Faculty of Sexual & Reproduction Health Care. UK Medical Eligibility Criteria for Contraceptive Use. 2009. (section on male surgical sterilisation pp101-104)
- 2. NICE Clinical Knowledge Summaries. Contraception management. Male sterilisation (last revised June 2012) <a href="http://cks.nice.org.uk/contraception-sterilization">http://cks.nice.org.uk/contraception-sterilization</a>
- 3. Cook LA, et al. Scalpel versus no-scalpel incision for vasectomy. Cochrane database Syst Rev. 2007 Apr 18 (2); CD004112 https://www.cochrane.org/CD004112/FERTILREG\_scalpel-or-no-scalpel-approach-vas
- 4. 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 <a href="https://www.aspc-uk.net/wp-content/uploads/2014/03/VasectomyLogbook.pdf">https://www.aspc-uk.net/wp-content/uploads/2014/03/VasectomyLogbook.pdf</a>
- 6. FPA factsheet on male and female sterilisation (Nov 2012) http://www.fpa.org.uk/sites/default/files/male-and-female-sterilisation-your-guide.pdf

Version	Created /actioned by	Nature of Amendment	Approved by	Date
1.0	Lead Clinicians and	Re-drafting of STP and SR/VoY policies	n/a	Mar 19
	Senior Service Imp			
	Manager			
2.0	Senior Service	Share of new draft internally and circulation	Lead Clinicians – VoY and SR	Mar 19
	Improvement Manager	for consultation	CCGs	
2.1 – 2.5	Senior Service	Update of statement following comments	Lead Clinicians – VoY and SR	
	Improvement Manager	from consultation	CCGs	
3.0	Senior Service	Approval by CCG Committees	SRCCG Business Committee	July 19
	Improvement Manager		VoYCCG Executive Committee	July 19

# NHS Scarborough and Ryedale and Vale of York Clinical Commissioning Groups

## **Varicose Vein Treatments Commissioning Policy**

Intervention	Interventional treatments in the management of Varicose Veins			
OPCS Codes	32 – Subfascial ligation of perforating vein of leg 41 – Combined operations on primary long saphenous vein 42 – Combined operations on primary short saphenous vein 43 – Combined operations on primary long and short saphenous vein 44 – Combined operations on recurrent long saphenous vein 45 – Combined operations on recurrent short saphenous vein 46 – Combined operations on recurrent long and short saphenous vein 46 – Combined operations on recurrent long and short saphenous vein 47 – Other specified ligation of varicose vein of leg 48 – Other specified ligation of varicose vein of leg 49 – Unspecified ligation of varicose vein of leg 40 – Incision of varicose vein of leg 41 – Percutaneous transluminal operations on varicose vein of leg 42 – Sample of transluminal operations on varicose vein of leg 43 – Percutaneous transluminal laser ablation of long saphenous vein 49 – Unspecified combined operations on varicose vein of leg 40 – Percutaneous transluminal laser ablation of long saphenous vein 41 – Percutaneous transluminal laser ablation of long saphenous vein 42 – Stripping of long saphenous vein 43 – Stripping of long saphenous vein 44 – Stripping of varicose vein of leg NEC 45 – Ligation of long saphenous vein 46 – Injection of sclerosing substance into varicose vein of leg NEC 46 – Avulsion of varicose vein of leg			
For the treatment of	Varicose Veins			
Background	This commissioning policy clarifies the care pathway and the criteria that must be met before interventional treatment or surgery is commissioned.  The policy takes into account NICE Clinical Guideline CG168 (July 2013)  Varicose Veins in the legs – Diagnosis and Management¹ and NICE  Surveillance report 2016 – Varicose veins in the legs (2013) NICE guideline  CG168²  The NICE Clinical Guideline is only a recommendation and in this statement the CCG has defined the grading / severity of varicose veins for what is felt to be an appropriate use of NHS resources.  Requests for surgical treatment outside the criteria outlined below and outside the pathway must be considered via the Individual Funding  Request (IFR) Panel.			
Commissioning position	The NHS does not routinely commission treatment in secondary care for varicose veins.			
	The NHS does not commission treatment for			
	<ul> <li>telangiectasia,</li> <li>reticular veins,</li> <li>asymptomatic varicose veins,</li> </ul>			

- varicose veins without other clinical skin signs
- treatment for cosmetic or aesthetic reasons
- surgical treatment for varicose veins in pregnancy

# Clinicians should exclude Red Flag Symptoms which are not covered by this statement

- Deep vein thrombosis (DVT) should be excluded in any patient presenting with a red, hot swollen leg with use of the Well's criteria and d-dimer testing.
- Superficial vein thrombosis above the knee should be discussed
  with the vascular team as admission is sometimes indicated for
  high tie and/or anticoagulation as there is a significant potential for
  clot migration and pulmonary embolism.
- **Bleeding varicose vein** which has caused significant blood loss and/or will not stop with direct pressure may require admission.

NICE detail symptoms from varicose veins as pain, aching, discomfort, swelling, heaviness and itching. Patients along with their primary care clinicians and surgeons should be aware that these symptoms are subjective and not specific just to varicose veins. Other causes should be considered and excluded prior to referral to the secondary care vascular services.

# Clinical signs of varicose veins that <u>may</u> justify surgical treatment include

- oedema,
- changes in skin and subcutaneous tissue such as eczema, lipodermatosclerosis or atrophie blanche,
- healed or active ulceration of the skin in the absence of other causes of ulceration.

The severity of varicose vein induced skin damage or imminent risk to skin integrity and any subjective symptoms should be a guide for general practitioners and vascular surgeons in prioritizing patients for NHS surgery. Conservative management should still be encouraged to prevent or delay the need for, or support the success of, subsequent surgery.

In the **absence of** skin damage or an imminent risk to skin integrity, primary care clinicians should only refer for an opinion, and surgeons should only undertake surgery, where there is a clear justification for clinical benefit and use of NHS resources.<sup>3</sup>

In light of financial position and capacity issues within the local health economy in 2018 referral for, and surgery for, symptomatic varicose veins without skin damage is not regarded as a priority for use of NHS resources.

Where clinical signs are mild, conservative management should be undertaken for at least six months prior to referral into the hospital vascular team, where clinicians believe that such an approach is clinically appropriate, and in the patient's best interest, and that there is **no urgency for surgical intervention**. Patients should be advised

to report any worsening of their symptoms.

Conservative management in primary care should include advice on

- the causes of varicose veins,
- the likelihood of progression and possible complications (NICE in 2013 stated "the evidence review for the guideline showed a lack of high-quality evidence on the progression of varicose veins from [mild] (CEAP<sup>9</sup> stage C2 or C3) to more serious varicose veins disease<sup>1</sup>)
- Patient Reported Outcome Measures for Varicose Vein Surgery. In 2013/14 nationally only 52% of patients reported an improvement in their health status as measured by the EQ5D tool; although 84% reported improvement using the Aberdeen Varicose Vein Questionnaire, only 40% reported improvement using the EQ-VAS score.
- The following should be recommended for those who do not have signs of skin damage or those who do not wish to undergo surgery.
  - Increasing activity such as walking and more vigorous exercise when possible
  - Weight loss where needed, aiming to achieve a BMI of 20-25
  - Avoidance of activities that exacerbate symptoms e.g. prolonged sitting or standing
  - Elevation of the legs when sitting down to increase venous return
  - A trial of compression hosiery to relieve oedema (leg swelling) associated with varicose veins (especially in pregnancy). In 2013 NICE recommended research was needed to ascertain the clinical and cost effectiveness of compression hosiery versus no compression for the management of symptomatic varicose veins<sup>1</sup>.

Vale of York and Scarborough and Ryedale CCGs commission referral to a secondary care vascular service for patients with

Symptomatic primary or recurrent varicose veins <u>and</u> clinical signs such as oedema (in the absence of other causes), changes in skin and subcutaneous tissue: eczema, lipodermatosclerosis or atrophie blanche, healed or active venous ulcers

NHS Vale of York and Scarborough and Ryedale CCGs do not routinely commission Transilluminated Powered Phlebectomy or Endovenous Mechanochemical Ablation (NICE IPG37 and IPG435) to treat varicose veins, due to inadequate evidence on the safety and efficacy of these techniques<sup>4, 5</sup>.

NHS Vale of York and Scarborough and Ryedale CCGs commission surgical treatment for varicose veins as detailed above if

 the pathway has been clinically evidenced as being followed and there is justification for prioritising NHS resources for treatment and

 after clinical assessment including duplex ultrasound confirmation of the diagnosis of varicose veins and presence of truncal reflux (venous blood flowing backwards due to valves not working properly),

NHS Vale of York and Scarborough and Ryedale CCGs only commission the following surgical treatment:

- 1. First line: endothermal (radiofrequency) ablation **without** removal of varicosities<sup>6, 7</sup>.
- 2. Second line: Ultrasound guided foam sclerotherapy **without** removal of varicosities<sup>8</sup>.

Surgery to remove superficial varicosities (phlebectomies) is NOT routinely commissioned. NICE stated in 2013 'There is limited evidence on the use and timing of tributary treatments after truncal endothermal ablation. There is a need for practice to be based on empirical evidence from a large and sufficiently powered RCT comparing all 3 main intervention options (no tributary treatment, concurrent tributary treatment and delayed tributary treatment). NICE reviewed studies published between 2013 and 2016 and reported that none of the new evidence considered in surveillance of [the 2013] guideline was thought to have an effect on current recommendations<sup>1, 2</sup>.

Removal of varicosities (phlebectomies) are commissioned when:

- there has been a history of significant bleeding from the varicosities OR
- there is anterior thigh vein incompetence and the incompetent trunk is too tortuous for endothelial ablation. Where possible patients should have proximal ablation and sequential avulsions if skin complications are present OR
- large (>1cm) varicosities are present in association with truncal incompetence and perforator disease in the calf or thigh. Ultrasound measurement of varicosities, demonstration of truncal incompetence, and presence of perforators needs to be recorded and stored for medico-legal and audit purposes.

All patients are expected to be treated under **local anaesthetic** unless there are clinical reasons why this is not appropriate, e.g.

- Three or more truncal veins require treatment
- For high tie and stripping of a Saphena Varix or a large (>2cm)
   Greater Saphenous Vein where radiofrequency ablation and foam sclerotherapy are not suitable.
- Patients in whom a large number of phlebectomies are needed AND the phlebectomies are commissioned (as defined above) AND the use of local anaesthesia would risk toxicity.

	Treatment in all other circumstances is not routinely commissioned and should not be referred unless clinical exceptionality is demonstrated and approved by the Individual Funding Request panel.  Patient preference for general anaesthesia without exceptional factors, as agreed by IFR, is not an appropriate use of NHS resources	
Summary of evidence / rationale	Varicose veins are dilated superficial veins in the leg caused by incompetent venous valves. About a third of the population are affected by visible varicose veins in the legs; prevalence increases with age and they often develop during pregnancy.	
	Asymptomatic ones present as a few isolated, raised palpable veins with no associated pain, discomfort or any skin changes. Moderate varicose veins present as local or generalised dilatation of subcutaneous veins with associated pain or discomfort and slight ankle swelling.	
	Severe varicose veins may present with phlebitis, ulceration and haemorrhage. About 3-6% of people who have varicose veins will go on to develop ulcers.	
	There is some evidence that the clinical severity of venous disease is worse in obese persons so advice on weight loss may help reduce symptoms and would make any intervention safer.	
	Because most varicose veins do not cause serious health problems, treatment is not usually needed on medical grounds.	
Date effective from	September 2018	
Date published	September 2018	
Review Date	2020	

#### References:

- 1. NICE Clinical Guideline 168 (July 2013) Varicose veins in the legs: the diagnosis and management of varicose veins
- 2. Surveillance report 2016 Varicose veins in the legs (2013) NICE Guideline CG168 (published 4/2/16)
- 3. Paragraph 18 GMC Good Medical Practice, 2013
- 4. NICE IPG 37 (2004) Transilluminated powered phlebectomy for varicose veins
- 5. NICE IPG 435 (2013) Endovenous mechanochemical ablation for varicose veins
- 6. NICE IPG 8 (2003) Radiofrequency ablation of varicose veins

#### NHS Scarborough and Ryedale and Vale of York Clinical Commissioning Groups

#### **Varicose Vein Treatments Commissioning Policy**

- 7. NICE IPG 52. (2004) Endovenous laser treatment of the long saphenous vein.
- 8. NICE IPG 440. (2013) Ultrasound-guided foam sclerotherapy for varicose veins
- 9. HG.Beebe, J.J.Bergan, D.Bergqvist, B.Eklöf, I.Eriksson, M.P.Goldman et al. Classification and grading of chronic venous disease in the lower limbs: a consensus statement

Version	Created by	Nature of Amendment	Approved by	Date
1.0	CCG GP Lead	Redrafting of STP and VoY policy		11.01.18
2.0	CCG GP Lead	Share of new draft internally		
2.1	CCG GP Lead	Amendments after discussion with SRCCG	CCG GP Leads	
2.2	CCG GP Lead	Version sent out for consultation	CCG GP Lead	23.01.18
2.3	CCG GP Lead	Internal version sharing Mr Baroni's comments	CCG GP Lead	22.01.18
2.4	CCG GP Lead	Amendments made in light of Mr Baroni's comments	CCG GP Lead	28.02.18
2.5	CCG GP Lead	SO working document	CCG GP Lead	29.03.18
2.6	CCG GP Lead	Revision after comments from Vascular Team	CCG GP Lead	04.04.18
2.7	CCG GP Lead	Revision after comments from Alison Forrester	CCG GP Lead	06.04.18
FINAL	CCG GP Lead	Approval at CCG Committee	Executive Committee Business Committee	06.06.18 06.06.18