NHS
Vale of York
Clinical Commissioning Group

Minor Skin Surgery for Skin Lesions Commissioning Policy

Interventions	**Minor Surgery for Skin Lesions**
Policy Criteria	Skin Lesions must meet at least ONE of the following criteria to be removed[3]: • 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 • The lesion bleeds in the course of normal everyday activity • The lesion is obstructing an orifice or impairing visual access. The lesion significantly impacts on function eg: restricts joint movement • If left untreated, more invasive intervention would be required for removal • Facial viral warts that have not resolved with an appropriate trial of topical treatment. • Facial spider naevi in children causing significant psychological impact
Background	NHS Scarborough and Ryedale CCG and NHS Vale of York CCG are responsible for commissioning activity in secondary care, and this policy sets out the criteria for referral to secondary care for minor surgery, as this is not always routinely commissioned. As well as the lesions specifically detailed in the policy, the policy also applies to the benign lesions listed below[3]: Please note: This list is not exclusive: • Solar comedones • Corn/callous • Dermatofibroma • Milia • Epidermoid & Pilar Cysts (sometimes incorrectly called sebaceous cysts) • Seborrheic keratosis (basal cell papillomata) • Spider naevi (telangiectasia) • Xanthelasmata • Neurofibromata

Commissioning Position	**Treatment of any condition for purely cosmetic reasons 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 re-excision 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).*** o Removal by accredited GP Minor Surgeon (either in-house or through Practice-to-Practice referral via LES scheme o 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 Click Here) **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

	• 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: • for ano-genital warts in adults that have failed treatment in the Primary Care setting or Genito-Urinary (GUM) Clinic • for viral warts in immunosuppressed patients • if there is doubt about the diagnosis and concern about possible malignancy • Facial viral warts that have not resolved with an appropriate trial of topical treatment. 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

	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: • 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. • failure of 2 different treatments • Immuno-compromised patients
Pigmented Naevi (moles)	Refer if there is clinical suspicion of malignancy or diagnostic 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 benign (clinically OR radiologically OR histologically following biopsy). Surgery is ONLY funded • 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. 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

	approval See detailed clinical guidance, published on the RSS under General Surgery here. Diagnosis is usually clinical **– USS is 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 evidence / rationale	Minor surgery should only be carried out when clinically 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[1] 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[2]
Date effective from	14th April 2022
Review date	30th April 2025
Approved by	Vale of York Executive Committee
Responsible officer	Michelle Carrington, Executive Director of Quality and Nursing

References:

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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. http://www.journalslibrary.nihr.ac.uk/__data/assets/pdf_file/0006/64905/FullReport-hta12230.pdf
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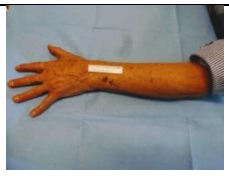
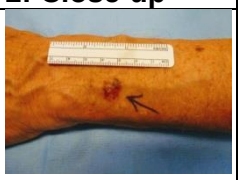
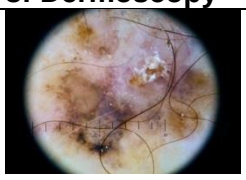
NHS
Scarborough and Ryedale
Vale of York
Clinical Commissioning Groups

Dermatology Referrals Commissioning Statement

<table>
<tr><td>Background</td><td>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 dermatology referrals.</td></tr>
<tr><td>Definition</td><td>It is the policy of NHS Vale of York and NHS Scarborough and Ryedale CCG that <u>three</u> specific photograph views (an overview, a close up and a dermatoscopic picture as detailed below) must be attached to <u>all</u> dermatology referrals, unless exceptions apply.

The <u>three</u> 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.</td></tr>
<tr><td>Essential Information to include with the referral letter</td><td>
<table>
<tr><td colspan="4">All <u>three</u> photographs must be high-quality: Sharp and In-Focus</td></tr>
<tr><td>Device</td><td colspan="2">Camera</td><td>Dermatoscope</td></tr>
<tr><td>Views</td><td>1: Overview</td><td>2: Close-up</td><td>3: Dermoscopy</td></tr>
<tr><td>Examples</td><td>  </td><td>  </td><td>  </td></tr>
<tr><td>Aim</td><td>Enables correct anatomical location</td><td>Facilitate diagnosis by naked-eye</td><td>Facilitate diagnosis by Dermatoscope</td></tr>
<tr><td>Tips</td><td>Entire limb, Head or Torso should be visable</td><td>Lesion centrally located & detail eg: scaling/crusting in focus</td><td>Use alcohol gel (or lubricating jelly if near eye or on mucosal surface). Vary pressure until vessels and pigment in sharp focus.</td></tr>
</table>

Dermatoscopy helps to enable accurate diagnosis, but <u>only</u> if the image</td></tr>
</table>

	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 here. Please note, rashes require only the first two photographs **overview** and **close-up** 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	• An area the patient deems too sensitive to photograph (e.g. genitalia, breasts) • Dermatoscopic equipment is broken (normal overview and close up photos should still be sent) • Dermatoscopic equipment is unavailable for other reason (normal photos should still be sent) 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) Any exceptions and the reason for them **must** be included in the referral.
Effective from	July 2019
Review Date	July 2021
Contact for this policy	Scarborough & Ryedale CCG: scrccg.rssifr@nhs.net Vale of York CCG: VOYCCG.RSS@nhs.net

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

NHS
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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: 1. When it is being performed to correct a nasal deformity secondary to congenital cleft lip and/or palate; 2. Upon individual case review, to correct chronic non-septal nasal airway obstruction from vestibular stenosis (collapsed internal valves) due to trauma, disease, or congenital defect, when all of the following criteria are met: • Airway obstruction which will not respond to septoplasty and turbinectomy alone AND • Nasal airway obstruction is causing significant symptoms (e.g. chronic rhinosinusitis, difficulty breathing) AND • Obstructive symptoms persist despite conservative management for three months or greater, which includes, where appropriate, nasal steroids or immunotherapy AND • Photos demonstrate an external nasal deformity AND • There is an average 50% or greater obstruction of 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 There are, however, exclusions that need to be addressed such as: • Unstable mental health • Unrealistic patient expectations • Previous rhinoplasty within the last 9-12 months (applies only to major rhinoplasties) • Poor perioperative risk profile • History of too many previous rhinoplasties, resulting in an atrophic skin–soft tissue envelope and significant scarring • Nasal cocaine users
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

	'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.

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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[14] and ensure patients are fully informed about options for treatment it is recommended that the RightCare inguinal-hernia shared decision-making aid[4] is discussed with patients prior to surgery. **For referral please use the referral form** **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. • Patient information leaflets – general NHS hernia advice; inguinal hernias inguinal hernias; NHS inguinal hernia repair inguinal hernia repair • 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*[1] *(*Level 1B evidence) and by a number of RCTs, concluding that it is an acceptable option for men with minimally symptomatic inguinal hernias[2]. 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[3]. The RightCare shared decision-making aid for surgical repair of inguinal hernia[4] states that 1. 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[5] (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[6] (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)[7, 8]
- 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**'[9, 10]
- 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[11]. 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[12]. 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[13]. 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 **not routinely commissioned** 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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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: 1. When it is being performed to correct a nasal deformity secondary to congenital cleft lip and/or palate; 2. Upon individual case review, to correct chronic non-septal nasal airway obstruction from vestibular stenosis (collapsed internal valves) due to trauma, disease, or congenital defect, when all of the following criteria are met: • Airway obstruction which will not respond to septoplasty and turbinectomy alone AND • Nasal airway obstruction is causing significant symptoms (e.g. chronic rhinosinusitis, difficulty breathing) AND • Obstructive symptoms persist despite conservative management for three months or greater, which includes, where appropriate, nasal steroids or immunotherapy AND • Photos demonstrate an external nasal deformity AND • There is an average 50% or greater obstruction of 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 There are, however, exclusions that need to be addressed such as: • Unstable mental health • Unrealistic patient expectations • Previous rhinoplasty within the last 9-12 months (applies only to major rhinoplasties) • Poor perioperative risk profile • History of too many previous rhinoplasties, resulting in an atrophic skin–soft tissue envelope and significant scarring • Nasal cocaine users
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

	'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

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Intervention	Gamete harvesting and storage (Cryopreservation)
For the treatment of:	Harvesting and storage of viable gametes in patients undergoing NHS 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: • That the planned treatment is likely to affect future fertility (and document this for the commissioners' audit purposes) • That the impact of the treatment on fertility has been discussed with the patient • 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 • That the patient is aware that funding for gamete harvesting and cryopreservation does not guarantee future funding of assisted conception treatment **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

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.

	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.
Summary of evidence / rationale	Following notification of a recent legal challenge[1] 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: • *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;* • *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;* • *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.* 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

References:

[1]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) VoYCCG Executive Committee	Dec 18 Jan 19

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

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: • One funded cycle of IVF available where the female is aged 40-43 (to 43rd birthday) • One funded cycle of IVF available where the female is aged 18 – 23yrs. Subject to meeting existing eligibility criteria.
Commissioning position	The Executive Committee agreed to implement a policy of immediate access to **one cycle of IVF for couples who meet the following criteria:** • Female age: 18 – 43rd birthday (at the time of treatment) • Female BMI: 19 to 29 female for six months prior to a referral • Smoking status: Non-smoking couple for six months prior to a referral • Existing children: To not have living or adopted children • Relationship: To be in a stable relationship for at least two years (including same sex couples) and currently cohabiting **Other criteria:** • 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 • 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 • 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

Frequently Asked Questions
A copy of a list of Frequently Asked Questions can be found here.

For Frequently Asked Questions specifically for same sex couples click here.

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 43rd 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.
Summary of evidence / rationale	The CCG Access to Infertility Treatment Commissioning 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 valeofyork.contactus@nhs.net

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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 2003[1] and is the subject of multi-agency guidelines from the Department of Health[2]. 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[3]. 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)

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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[4, 5]. 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[4]. 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[6]. 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[7]. 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 Executive 16.03.17
Responsible officer	Shaun O'Connell, GP Lead valeofyork.contactus@nhs.net

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2. Female genital mutilation: multi-agency practice guidelines. Dept of Health, February 2011 https://www.gov.uk/government/publications/female-genital-mutilation-multi- agency-practice-guidelines
3. Interim Clinical Commissioning Policy: Labiaplasty, vaginoplasty and hymenorrhaphy Nov 2013 http://www.england.nhs.uk/wp-content/uploads/2013/11/N-SC023.pdf
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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[1]. 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[1]. 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 here
Commissioning position	Treatment is **not indicated** where there is no contracture or it is mild (less than 20^{o}) or not progressing and does not impair function[1] 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 **only** be considered (and IFR approval is not required), when the patient meets **at least one** of the following functional difficulties. • finger contractures causing loss of finger extension of 30° or more at the metacarpophalangeal joint or 20° at the proximal interphalangeal joint. See here on how to measure the angles using a goniometer **OR** • thumb contractures which interfere with function **AND** • There is a current material impairment of hand function **AND** • 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.**

	NICE concluded that collagenase treatment (Xiapex) should only be used for[2]: 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[3]. 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

	of the condition. 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[3] 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. **To justify the risks of surgery a flexion deformity must be present.** Recent developments have been towards outpatient procedures, percutaneous needle fasciotomy (PNF) and collagenase injection (CCH) (more experimental, but supported by NICE TA459[2]). NICE guidance for PNF only exists as an IPG from 2004[4]. 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[5]. 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[6]. 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	22nd February 2020
Review date	2022

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2. NICE TA459 Collagenase clostridium histolyticum for treating Dupuytren's contracture. July 2017. https://www.nice.org.uk/Guidance/TA459
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5. 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 https://journals.lww.com/jbjsjournal/Fulltext/2018/07050/Percutaneous_Needle_Fasciotomy_Versus_Collagenase.1.aspx
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 Improvement Manager	Approval of threshold	NY Joint Business Executive VoY Executive Committee	Jan 20 Dec 19

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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 position	This commissioning policy is needed to provide a commissioning position for 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. 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 week[1]), 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 **delayed union** 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.

	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[2.] 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)[2.] NICE published guidance for Exogen® in January 2013[2]. 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 non-union 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 valeofyork.contactus@nhs.net

Reference:

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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 Prevention and Better Health strategy[1] 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	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[3], 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[4]).
- 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[3]

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[2] 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[4] 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[2] for those patients within a BMI range that is >30 but <35 • 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[5]. 20% of adults over 50 and 40% over 80 years report disability from knee pain secondary to osteoarthritis[6]. 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 non-surgical measures, as outlined by NICE[3]. Symptoms progress in 15% of patients with hip pain within 3 years and 28% within 6 years[5]. 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[6]. 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[7] stated that joint surgery is less successful in obese patients because 1. **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). 2. 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) 3. 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); 4. 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) 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[8]. 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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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[1]. 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. In particular, both diagnostic and therapeutic arthroscopy are **NOT** routinely commissioned: • for diagnostic purposes for investigation of knee pain • 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**)[2, 3]

	• 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[3]), ○ **lifestyle advice, including exercise or rest** ○ **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[4].

Partial meniscectomy surgery showed no advantage over sham in one RCT of patients aged 35-65 years with degenerative meniscal tears without osteoarthritis[5] and no advantage over physical therapy in two RCTs of older patients (>45 years) with osteoarthritis[6, 7]. 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[8]. 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[9].

Although rates of post-operative complications are generally low higher rates have been observed in children and young people[10,11]. There may also be future knee damage associated with arthroscopic procedures[12, 13] 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[14]. 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[14].
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[1]."

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[16, 17]. 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[14, 18].

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[19]. 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[20].

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[17, 21]. 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[5]. 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%)[5,6] 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[15]. 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[2, 3, 24-26] and NICE does not recommend lavage[2]. NICE recommends knee meniscus replacement with biodegradable scaffold only with special arrangements for clinical governance, consent and audit or research[27]. NICE currently recommends that mosaicplasty should not be used without special arrangements for consent and audit or research[28.] 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[29]. NICE recommends that arthroscopic trochleoplasty for patellar instability should only be used with special arrangements for clinical governance, consent and audit or research[30]. There is some evidence that debridement is ineffective[3, 24, 25], but NICE recommends that debridement may be appropriate in cases where there is mechanical locking[3]. **Restricted use of MRI** MRI is a good diagnostic tool[22], but may be inaccurate when used by less experienced staff[23] 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[32]. 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[33]. 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	Gamete harvesting and storage (Cryopreservation)
For the treatment of:	Harvesting and storage of viable gametes in patients undergoing NHS 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: • That the planned treatment is likely to affect future fertility (and document this for the commissioners' audit purposes) • That the impact of the treatment on fertility has been discussed with the patient • 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 • That the patient is aware that funding for gamete harvesting and cryopreservation does not guarantee future funding of assisted conception treatment **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

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.

	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.
Summary of evidence / rationale	Following notification of a recent legal challenge[1] 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: • *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;* • *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;* • *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.* 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

References:

[1]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) VoYCCG Executive Committee	Dec 18 Jan 19