Clinical Treatment Policies

December 2018
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Policy for the Treatment of Snoring with Uvulopalato, Uvulopalatopharyngoplasty, Palate Implants and Radiofrequency Ablation of Soft Palate.
The CCG policy has been reviewed and developed by the Treatment Policies Clinical Development Group in line with the groups guiding principles which are:
1. CCG Commissioners require clear evidence of clinical effectiveness before NHS resources are invested in the treatment;
2. CCG Commissioners require clear evidence of cost effectiveness before NHS resources are invested in the treatment;
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8. All policy decision are considered within the wider constraints of the CCG’s legally responsibility to remain fiscally responsible.
Category: Not Routinely Commissioned

The 5 procedures outlined below, which may be used to treat snoring are Not Routinely Commissioned due to the poor success rates or the lack of long-term data regarding the efficacy of these procedures.

Snoring

Snoring is caused by the tongue, mouth, throat, or airways in the nose, vibrating, as the patient breathes. It happens because these parts of the body relax and narrow when the patient is asleep.

There are five basic surgical procedures:

- Uvulopalatopharyngoplasty (UPPP)
- Laser-assisted uvulopalatoplasty (LAUP)
- Palatal stiffening operations (CAPSO)
- Palate Implants
- Radio-frequency ablation (Somnoplasty)

Uvulopalatopharyngoplasty (UPPP)

UPPP usually involves removing the uvula and pharyngeal arches, partial removal of the soft palate and sometimes the tonsils. This procedure is performed under general anaesthetic. Research indicates that UPPP is often complicated by severe post-operative pain. Additionally, there may be some long-term complications such as nasopharyngeal regurgitation, persistent palatal dryness, long-term voice changes and a partial loss of taste. UPPP is the only procedure that increases the width of the oropharynx. It has been shown that this could be useful in patients who palatal obstruction is caused by the side walls collapsing against each other.

Laser-Assisted Uvulopalatoplasty (LAUP)

LAUP is performed under local or general anaesthetic and is considered to be a safer, more economical and a more comfortable alternative to UPPP. It involves vaporising the free edge of the soft palate and uvula using a laser. Unlike UPPP, LAUP can be repeated in order to obtain the desired effect. The number of procedures needed varies with some patients requiring up to four sessions. The tonsils are not removed with this procedure. Although laser surgery is associated with fewer complications than UPPP, post-operative pain is still reported as being severe.

Because of the severe post-operative pain LAUP negatively affects the patient compliance and unlike UPPP patients who undergo the procedure only once, LAUP patients often have to undergo the post-operative severe pain several times. As with UPPP the success rate from this type of surgery is not high and research indicates that 2 years after the surgery only 55% if patients report that their bed partner is satisfied with the outcome. One disadvantage of LAUP is that it is difficult to perform on patients who have a strong gag reflex.
Palatal Stiffening (CAPSO)

CAPSO or electrical cautery, burns the palate causing fibrosis and consequent stiffening of the soft palate. It is also used a means to remove a longitudinal strip of mucosa along the soft palate or uvula. This procedure is performed during a single out-patient visit under local anaesthetic. Because this procedure is less invasive than UPPP or LAUP there are generally fewer complications, however post-operative pain is similar to the other surgical methods. Data now available shows that the short-term efficacy is also similar to that of UPPP and LAUP. As with LAUP, CAPSO can be repeated until the desired effect on the snoring is gained.

Soft Palate Implants

Under local anaesthesia, a hollow introducer needle containing the implant is used to pierce the soft palate close to the junction with the hard palate, into its muscle layer. The needle is then withdrawn, leaving the implant in position. Mirror examination or nasal endoscopy may be used to check that the implant has not penetrated the nasal surface of the soft palate. Typically, two or three implants are inserted in a single procedure, at the midline of the soft palate or parallel to it. The aim of the procedure is to stiffen the soft palate over subsequent weeks as a result of fibrosis. The implants may be removed with forceps if necessary.

NICE reviewed this procedure in 2007 and published the following guidance: Current evidence on soft-palate implants for simple snoring raises no major safety concerns. However, the evidence on efficacy is based on small case series only and there is a lack of well-controlled and comparative data. Therefore, this procedure should only be used in the context of research.

Radio-Frequency Ablation (Somnoplasty)

Radiofrequency ablation aims to stiffen the soft palate. It may be combined with other techniques (such as removal of the uvula or tonsillectomy) to reduce airflow obstruction and vibration in the airway.

The procedure is usually done using local anaesthesia in outpatients. An electrode delivery device is introduced into the mouth and directed upwards towards the soft palate. A needle tip makes a series of very shallow punctures in the underlying muscle. Radiofrequency energy is delivered at each puncture site, commonly in the mid-portion of the palate from the uvular base to the posterior nasal spine. Alternatively, 2 lateral applications can be given at a lower energy setting and to several areas on either side. The intention is to scar and tighten the soft palate. If necessary, the procedure can be repeated several weeks later: it is often carried out 2 or 3 times.

In 2014 NICE published the following guidance on the use of Radio-Frequency Ablation:
- short-term efficacy of the procedure is adequate, although uncertainties remain about its efficacy in the longer term. NICE encourages further research into radiofrequency ablation of the soft palate for snoring.
Eligibility Criteria:

UPPP, LAUP, CAPSO, Radio-frequency Ablation & Soft palate Implants Are Not Routinely Commissioned due to the poor success rates or the lack of long-term data regarding the efficacy of these procedures.

This means (for patients who DO NOT meet the above criteria) the CCG will only fund the treatment if an Individual Funding Request (IFR) application proves exceptional clinical need and that is supported by the CCG.

Guidance:

https://www.nhs.uk/conditions/snoring/

https://www.nice.org.uk/guidance/ipg240

NICE (2014) Radiofrequency ablation of the soft palate for snoring. Interventional procedures guidance 
https://www.nice.org.uk/guidance/ipg476

British Snoring and Sleep Apnoea Association. (2017) 
http://www.britishsnoring.co.uk/

PLEASE NOTE: The CCG does not endorse sales or marketing information contained in the weblink above.
Policy for the Investigation of Rectal Bleeding
The CCG policy has been reviewed and developed by the Treatment Policies Clinical Development Group in line with the groups guiding principles which are:

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Rectal Bleeding

Rectal bleeding (loss of blood from the anus) is a very common and usually intermittent and self-limiting symptom in people of all ages. Sudden heavy blood loss, requiring emergency hospital admission and intervention, can occur, but is uncommon. Most cases of painless rectal bleeding are due to benign (non-cancerous) anal conditions (e.g. haemorrhoids or anal fissure).

Colorectal Cancer

Only a small minority of cases have significant pathology, and the risk of such pathology (particularly colorectal cancer) is dependent of the presence of other symptoms and age. Colorectal cancer is the third most common cancer in the UK after breast and lung cancer and the second most common cause of death, with approximately 41,265 new cases diagnosed in 2014 in the UK (Cancer Research UK). Occurrence of colorectal cancer is strongly related to age, with almost three-quarters of cases occurring in people aged over 65 years, although people under 40 with a strong family history of colorectal cancer have an increased risk of developing the disease. Patients with long standing inflammatory diseases of the bowel, such as Crohn’s disease or ulcerative colitis, may also have an increased risk of developing colorectal cancer. People who have a rare genetic condition known as familial adenomatous polyposis (FAP) or adenomatous polyposis coli, in which benign tumours called polyps are found in the lining of the colon, have an increased risk of developing bowel cancer.

NICE NG12 (2015) states adults should be referred using a suspected cancer pathway referral (for an appointment within 2 weeks) for colorectal cancer if:

- they are aged 40 and over with unexplained weight loss and abdominal pain or
- they are aged 50 and over with unexplained rectal bleeding or
- they are aged 60 and over with:
  - iron-deficiency anaemia or
  - changes in their bowel habit, or
- tests show occult blood in their faeces.

Clinicians should consider a suspected cancer pathway referral (for an appointment within 2 weeks) for colorectal cancer in adults with a rectal or abdominal mass.
Clinicians should also consider a suspected cancer pathway referral (for an appointment within 2 weeks) for colorectal cancer in adults aged under 50 with rectal bleeding and any of the following unexplained symptoms or findings:

- abdominal pain
- change in bowel habit
- weight loss
- iron-deficiency anaemia

In cases of patient presenting with an unexplained anal mass or unexplained anal ulceration clinicians should consider a suspected cancer pathway referral (for an appointment within 2 weeks) for anal cancer.

<table>
<thead>
<tr>
<th>Symptom and specific features</th>
<th>Possible cancer</th>
<th>Recommendation</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Rectal bleeding</strong> (unexplained), 50 and over</td>
<td>Colorectal</td>
<td>Refer adults using a suspected cancer pathway referral (for an appointment within 2 weeks)</td>
</tr>
<tr>
<td><strong>Rectal bleeding</strong> with abdominal pain or change in bowel habit or weight loss or iron-deficiency anaemia in adults under 50</td>
<td>Colorectal</td>
<td>Consider a suspected cancer pathway referral (for an appointment within 2 weeks)</td>
</tr>
</tbody>
</table>

**Eligibility Criteria.**

The commissioner will therefore fund further investigation of rectal bleeding with either flexible sigmoidoscopy and / or colonoscopy in the following circumstances:

- The patient is 50 years old or older and has unexplained rectal bleeding.
- The patient is UNDER the age of 50 years, has rectal bleeding AND
  - Abdominal Pain OR
  - Change in bowel habit OR
  - Weight Loss OR
  - Iron-deficiency anaemia

This means for patients who DO NOT meet the specified criteria the CCG will only fund the treatment if an Individual Funding Request (IFR) application proves exceptional clinical need and that is supported by the CCG.

**For the purposes of this guidance, the following defines unexplained:**
Unexplained: Symptoms or signs that have not led to a diagnosis being made by the healthcare professional after initial assessment (including history, examination and any primary care investigations).
For example, if a patient has been reviewed by primary care and blood results have shown a raised faecal calprotectin, then the patient should be reviewed in line with the IBD care pathway and falls outside the scope of this policy.

Guidance:

https://www.nice.org.uk/guidance/ng12


Cancer Research UK 2017 Bowel Cancer Statistics.
http://www.cancerresearchuk.org/

NHS Choices. 2015. Rectal Bleeding.
https://www.nhs.uk/conditions/bleeding-from-the-bottom-rectal-bleeding/
Policy for Lithotripsy to treat Renal Calculi (Kidney Stones).
The CCG policy has been reviewed and developed by the Treatment Policies Clinical Development Group in line with the groups guiding principles which are:

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Category: Restricted

Renal Calculi (Kidney Stones)

Epidemiological data suggests that the prevalence of renal calculi (kidney stones) is increasing. The number of hospital episodes increased by 70% over a 15-year period between 2000 and 2015, from 51,035 episodes to 86,742 episodes (HES). The lifetime prevalence of renal (kidney) stone disease is 13%. Consequently, the direct costs of treatment are increasing as well as the indirect socioeconomic burdens on reduced quality of life, sickness leave and medical follow-up (NICE, 2015).

Treatment for Renal Calculi (Kidney Stones)

Extracorporeal Shockwave Lithotripsy is a non-invasive outpatient treatment that focuses ultrasound shock waves on renal stones to fragment them and facilitate spontaneous passage. (NICE, 2015). The complete treatment takes about 45 to 60 minutes (National Kidney Foundation, 2015)

Lithotripsy can have some side effects and most patients have some blood in the urine for a few days. The shattered stone fragments may also cause discomfort as they pass through the urinary tract. Sometimes, the stone is not completely shattered, and additional treatments may be needed (National Kidney Foundation, 2015).

Evidence review of treatment options.

There is good evidence that small stones <5mm in diameter usually pass spontaneously, and require little medical intervention other than simple analgesia. Larger stones, 5-10mm, become increasingly difficult to pass, and are less likely to be expelled without active stone removal. In these cases, however, where there is no clinical risk or indication for stone removal such as obstruction, infection, severe pain etc., and patients are asymptomatic, there remains debate on whether active stone management is necessary, as many stones that do not pass will not necessarily result in any long term symptoms and may remain stable.

Therefore, the European Association of Urology suggests a range of indications for which active stone removal in patients with kidney stones could be considered, and suggests that in the absence of these indications there is no strong evidence to confirm that lithotripsy is preferable to observation. Even though lithotripsy confers a greater chance of stone clearance for stones approaching 10mm compared to observation, complications of the technique may not justify an approach in asymptotic and uncomplicated patients with small stones.

Eligibility Criteria:

NICE are due to publish guidance on the use of lithotripsy for patients with renal calculi in 2019, therefore whilst awaiting this guideline, the CCG will commission the use of lithotripsy for renal calculi in the following circumstances:

- The renal calculus (kidney stone) must be 5mm or larger
- The patient is symptomatic (obstruction, infection, severe pain)
This means (for patients who DO NOT meet the above criteria) the CCG will only fund the treatment if an Individual Funding Request (IFR) application proves exceptional clinical need and that is supported by the CCG.

Guidance:


Breast Implant Revision Surgery
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Breast Implant Revision Surgery

Breast implant revision surgery is defined as “Any consequence of an implant that would require an operative approach to managing it (e.g. removal”).

This can be subdivided in to breast implant removal (Policy A) and breast implant removal and replacement (Policy B).

The population who may require breast revision surgery includes:
- Women with existing breast implants funded through the NHS
- Women who have had NHS funded breast augmentation as part of gender reassignment surgery.
- Women who have existing breast implants (Privately funded).

Indications for breast implant revision surgery

- Capsular contracture
  Capsular contracture is an unavoidable complication of breast implant surgery. After having a breast implant, the body will create a capsule of fibrous scar tissue around the implant as part of the healing process. This is a natural reaction that occurs when any foreign object is surgically implanted into the body. Over time the scar tissue will begin to shrink. The shrinkage is known as capsular contraction. The rate and extent at which the shrinkage occurs varies from person to person. In some people, the capsule can tighten and squeeze the implant, making the breast feel hard and patients may also experience pain and discomfort. Individual studies have published incidence rates of capsular contracture ranging from 2.8% to 20.4%. A 2013 systematic review published a combined overall rate of 3.6% following augmentation surgery. A literature review in 2016 indicated an incidence of between 8% and 15%.
- Rupture
  A rupture is a split that occurs in the implant’s casing. A rapid review of breast prosthesis implantation for reconstructive and cosmetic surgery reported Kaplan-Meier estimates of rupture at six years with a range of 1.5 to 9.3 per cent.
- Wrinkling and rippling
  Wrinkling and rippling during follow-up was estimated to occur in approximately 10% of cases over 10 years for silicone implants and 24.6% over 5 years for saline implants.
- Implant rotation
  Very occasionally teardrop-shaped implants can rotate behind the breast. The patient will notice a marked shape change, usually evident on waking in the morning. The implant will usually rotate back to its correct position by itself or can be gently pushed back in to position.
- Nerve problems in nipples
  A systematic review of nerve injuries in aesthetic breast surgery found the risk of any nerve injury after breast augmentation ranged from 13.57% to 15.44%. For Mastectomy patients, nipples may not be preserved due to the original surgery.
- Problems with lactation
  Surgery to the breasts may impact on or prevent the ability of patients to breast feed.
• Scarring
After breast surgery, all patients will have some degree of scarring. In most cases, the scarring is relatively mild. However, in approximately 1 in 20 women, the scarring is more severe. For these women, their scars may be red or highly coloured, lumpy, thick and/or painful.

- Seroma
Seroma refers to a build-up of fluid around the breast which normally resolves without aspiration.

- Anaplastic Large Cell Lymphoma (ALCL)
ALCL is a rare type of non-Hodgkin's lymphoma and most cases occur in the capsule surrounding the implant and it is thought to be potentially associated with prolonged inflammatory states, similar to the theoretical pathogenesis of capsular contracture. A 2014 review found the absolute risk of ALCL remains low, ranging from 1: 500,000 to 1: 3,000,000.

PIP implant removal

The NHS offer detailed by the government regarding PIP implants is as follows:

- All women who have received an implant from the NHS will be contacted to inform them that they have a PIP implant and to provide relevant information and advice. If in the meantime NHS patients seek information about the make of their implant, then this will be provided free of charge.
- Women who wish to will able to seek a consultation with their GP, or with the surgical team who carried out the original implant, to seek clinical advice on the best way forward.
- If the woman chooses, this could include an examination by imaging to see if there is any evidence that the implant has ruptured.

The NHS will support removal of PIP implants if, informed by an assessment of clinical need, risk or the impact of unresolved concerns, a woman with her doctor decides that it is right to do so. The NHS will replace the implants if the original operation was done by the NHS.

Policy A – Breast Implant Revision Surgery – Implant Removal

Eligibility Criteria:

Removal of breast implants are commissioned where there is a clinical indication for removal (Rupture or Capsular contracture which is defined as grades III and IV capsular contracture), whether the implant was initially inserted by the NHS or privately funded.

This means (for patients who DO NOT meet the above criteria) the CCG will only fund the treatment if an Individual Funding Request (IFR) application proves exceptional clinical need and that is supported by the CCG.

Eligibility criteria

Removal AND replacement of breast implants are commissioned where there is:

1. Clinical indication for removal (Rupture or Capsular contracture which is defined as grades III and IV capsular contracture), AND

2. The implant was initially inserted by the NHS under the previously or currently commissioned CCG / NHSE commissioned criteria which is outlined as follows:
   - Previous mastectomy or other excisional breast surgery undertaken due to a cancer diagnosis.
   - Trauma to the breast during or after development
   - Congenital amastia (total failure of breast development)
   - Endocrine abnormalities
   - Developmental asymmetry and severe hypoplasia.
   - Gender Reassignment Surgery

N.B. Lipofilling is a procedure not covered under this policy. Lipofilling will be reviewed under a future workflow by the CCG.
Guidance:

NHS Choices. (2016) Breast enlargement (implants)
https://www.nhs.uk/conditions/cosmetic-treatments/breast-enlargement/

L Martina, J M O’Dohnogheub, K Horganc, S Thrushd, R Johnson, A Gandhie
Joint Guidelines from the Association of Breast Surgery and the British Association of
Plastic, Reconstructive and Aesthetic Surgeons. Acellular dermal matrix (ADM) assisted
breast reconstruction procedures.
http://www.bapras.org.uk/docs/default-source/commissioning-and-policy/acellular-dermal-
matrix-doc-for-ejso--with-abs.pdf?sfvrsn=0

https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4579163/

Royal Australasian College of Surgeons. (2013) Breast Prosthesis Implantation for
reconstructive and cosmetic surgery: A rapid review.
https://www.surgeons.org/media/20844776/rpt_2014-02-
04_rr_breast_implantation_2_.pdf

British Association of Plastic Reconstructive and Aesthetic Surgeons. (2014) Your guide
to Breast Surgery.
http://www.bapras.org.uk/docs/default-source/Patient-Information-
Booklets/rcs_bapras_guide_breast_augmentation.pdf?sfvrsn=4

Ducic I¹, Zakaria HM², Felder JM 3rd², Fantus S . (2014) Nerve Injuries in Aesthetic Breast
Aug;34(6):841-56.

Breast Augmentation: An Update for Clinical Practice. Arch Plast Surg. 2015 Sep; 42(5):
532–543.
https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4579163/

Department of Health (2012) Department of Health statement on breast implants and
response to expert group report.
https://www.gov.uk/government/news/department-of-health-statement-on-breast-
implants-and-response-to-expert-group-report

Policy for the Reversal of Male Sterilisation
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Category: Not Routinely Commissioned

Reversal of Male Sterilisation

Sterilisation is a procedure by which a person is rendered permanently unable to produce children – made infertile. This is called Vas Occlusion in men (vasectomy): the tubes that carry sperm from a man's testicles to the penis are cut, blocked or sealed with heat. Sperm is then prevented from reaching the semen ejaculated from a man's penis during sex. Reversal of sterilisation is a surgical procedure that involves the reconstruction of the vas deferens in men but does not guarantee a return of fertility.

Reversal of Male Sterilisation is not normally available on the NHS (NHS Choices 2015). NICE (2016) deem vasectomy to be a permanent method of contraception and the British Association of Urological Surgeons (2017) state clinicians on gaining consent for a vasectomy, should ensure that it is made clear to the patient that the procedure is irreversible.

Eligibility Criteria

<table>
<thead>
<tr>
<th>Reversal of Male Sterilisation is not routinely commissioned.</th>
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Guidance

NHS Choices. 2015 Can I get a sterilisation reversal on the NHS?  
https://www.nhs.uk/Conditions/contraception-guide/Pages/sterilisation-reversal-NHS.aspx

https://www.nice.org.uk/guidance/qs129

Policy for the Reversal of Female Sterilisation
Document Details:

<table>
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<tr>
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<tbody>
<tr>
<td>Ratified by (name and date of Committee):</td>
<td>Treatment Policy Clinical Development Group 22nd February 2018</td>
</tr>
<tr>
<td>Date issued for Public Consultation:</td>
<td>14th May 2018</td>
</tr>
<tr>
<td>Equality &amp; Diversity Impact Assessment</td>
<td>19th March 2018</td>
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<tr>
<td>Birmingham and Solihull CCG Governing Body</td>
<td>2nd October 2018</td>
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<tr>
<td>Sandwell and West Birmingham CCG Governing Body</td>
<td>5th December 2018</td>
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<tr>
<td>Birmingham and Solihull Joint Health Overview and Scrutiny Committee</td>
<td>29th November 2018  Approved – 11th December 2018</td>
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<tr>
<td>Sandwell and West Birmingham Health Overview and Scrutiny Committee</td>
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Category: Not Routinely Commissioned.

Reversal of Female Sterilisation

Sterilisation is a procedure by which a person is rendered permanently unable to produce children – made infertile. In women, it is called operative occlusion of the fallopian tubes: cutting, sealing or blocking the fallopian tubes to prevent eggs from reaching the uterus (womb) where they could become fertilised.

Reversal of sterilisation is a surgical procedure that involves the reconstruction of the fallopian tubes in women but does not guarantee the return of a woman’s fertility.

Female Sterilisation is deemed to be a permanent method of contraception by NICE (2016). In guidance to clinicians the Royal College of Obstetrics and Gynaecologists (2016) state that when gaining consent from a woman for a sterilisation procedure, the patient should be informed that reversal of sterilisation is not available on the NHS.

Eligibility Criteria

Reversal of Female Sterilisation is not routinely commissioned.

This means (for patients who DO NOT meet the above criteria) the CCG will only fund the treatment if an Individual Funding Request (IFR) application proves exceptional clinical need and that is supported by the CCG.

Guidance


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4. CCG Commissioners will consider the extent to which the individual or patient group will gain a benefit from the treatment;
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6. CCG Commissioners will consider all relevant national standards and take into account all proper and authoritative guidance;
7. Where a treatment is approved CCG Commissioners will respect patient choice as to where a treatment is delivered; AND
8. All policy decision are considered within the wider constraints of the CCG’s legally responsibility to remain fiscally responsible.
Category: Restricted

Upright / Open MRI Scanners

Magnetic resonance imaging (MRI) is a type of scan that uses strong magnetic fields and radio waves to produce detailed images of the inside of the body. A standard MRI scanner is a large tube that contains powerful magnets. The patient lies inside the tube during the scan.

An MRI scan can be used to examine almost any part of the body, including the:

- brain and spinal cord
- bones and joints
- breasts
- heart and blood vessels
- internal organs, such as the liver, womb or prostate gland

The results of an MRI scan can be used to help diagnose conditions, plan treatments and assess how effective previous treatment has been.

Conventional MRI

Conventional MRI is established as the most sensitive imaging test of choice of the spine in routine clinical practice. MRI imaging of the spine is performed to:

- Assess the spinal anatomy;
- Visualize anatomical variations and diseased tissue in the spine;
- Assist in planning surgeries on the spine such as decompression of a pinched nerve or spinal fusion;
- Monitor changes in the spine after an operation, such as scarring or infection;
- Guide the injection of steroids to relieve spinal pain;
- Assess the disks, (i.e. bulging, degenerated or herniated intervertebral disk, a frequent cause of severe lower back pain and sciatica);
- Evaluate compressed (or pinched) and inflamed nerves;
- Explore possible causes in patients with back pain (compression fracture for example);
- Image spinal infection or tumours that arise in, or have metastasized to, the spine;
  - Assess children with daytime wetting and an inability to fully empty the bladder.

The absence of axial loading and lumbar extension results in a maximization of spinal canal dimensions, which may in some cases, result in failure to demonstrate nerve root compression. Attempts have been made to image the lumbar spine in a more physiological state, either by imaging with flexion–extension, in the erect position or by using axial loading.

Axially Loaded MRI

A modification of conventional MRI, known as axially loaded MRI, has been developed. The axial loading refers to the application of a force on a subject’s body to simulate weight-bearing. For this technique, patients put on a special harness that compresses the spine
while they lie in the MRI scanner but this procedure may not accurately reproduce the weight-bearing state. **Positional MRI (Upright MRI)**

Positional MRI has been developed to provide images of the spine under true weight-bearing conditions. This technique relies on a vertically open configuration MRI scanner in which the circular magnets have been turned on end. The patient sits or stands between the magnets during image collection and can adopt various positions such as flexion or extension of the neck or back, allowing imaging of the spine under conditions that occur in daily life.

Standing or sitting MRIs may be performed with patients in different positions (eg. extension, flexion, neutral) for comparison of anatomy in various positions.

Current Upright MRI scanners generally use medium field magnets of 0.5T or 0.6T. By comparison, the most advanced standard MRI scanners have magnet strength of at least 1.0T and up to 3.0T allowing for the greatest resolution generally in a shorter amount of time. With 0.6T magnets, Upright MRI requires more time to obtain images with lower resolution.

Slower imaging times with uMRI (Upright MRI) may create difficulty for the following groups of patients:

- patients who are unable to remain still while in a standing or sitting position;
- discomfort patients who experience pain or discomfort whilst in an upright position
- patients who are unstable in such upright positions.

Longer exam times may also decrease the overall patient flow and volume of patients that can be accommodated.

The proposed advantages of uMRI are based on the ability to scan the spine (or joints) in different positions (including the position where clinical symptoms are more pronounced) and assess the effects of weight bearing, position and dynamic movement.
**Eligibility Criteria**

Referral for open MRI scanning of at least 0.5T as an alternative to conventional MRI in is commissioned only for:

- patients who suffer from claustrophobia where an oral prescription sedative has not been effective (flexibility in the route of sedative administration may be required in paediatric patients as oral prescription may not be appropriate)

**OR**

- patients who are obese and cannot fit comfortably in conventional MRI scanners as determined by a Consultant Radiologist/Radiology department policy

**OR**

- patients who cannot lie properly in conventional MRI scanners because of severe pain despite adequate analgesia provision

**OR**

- patients whom require load bearing MRI images to be undertaken

**AND**

- There is a clear diagnostic need consistent with supported clinical pathways

**IN ADDITION,** The CCG will only fund uMRI of the specific anatomy requested.

This means *(for patients who DO NOT meet the above criteria)* the CCG will **only** fund the treatment if an Individual Funding Request (IFR) application proves exceptional clinical need and that is supported by the CCG.
Guidance

NHS Choices. 2015. MRI Scan. 
https://www.nhs.uk/conditions/mri-scan/


ACR practice parameter for performing and interpreting magnetic resonance imaging (MRI), Amended 2014

ACR–ASNR–SCBT-MR Practice guideline for the performance of magnetic resonance imaging (MRI) of the adult spine, Revised 2012


Adult obesity, Health Survey for England (HSE) 2014
NHS Imaging and Radiodiagnostic activity 2013/14 (NHS England and National Statistics)
Policy for Carpal Tunnel Syndrome (CTS)
The CCG policy has been reviewed and developed by the Treatment Policies Clinical Development Group in line with the groups guiding principles which are:

1. CCG Commissioners require clear evidence of clinical effectiveness before NHS resources are invested in the treatment;
2. CCG Commissioner require clear evidence of cost effectiveness before NHS resources are invested in the treatment;
3. The cost of the treatment for this patient and others within any anticipated cohort is a relevant factor;
4. CCG Commissioners will consider the extent to which the individual or patient group will gain a benefit from the treatment;
5. CCG Commissioners will balance the needs of each individual against the benefit which could be gained by alternative investment possibilities to meet the needs of the community
6. CCG Commissioners will consider all relevant national standards and take into account all proper and authoritative guidance;
7. Where a treatment is approved CCG Commissioners will respect patient choice as to where a treatment is delivered; AND
8. All policy decisions are considered within the wider constraints of the CCG’s legally responsibility to remain fiscally responsible.
CARPAL TUNNEL SYNDROME

Carpal tunnel syndrome (CTS) is a condition where the median nerve is compressed as it passes through a short tunnel at the wrist. The main symptoms are pain and altered feeling (often tingling and/or numbness) in the hand, affecting the thumb, index, middle and ring fingers; it is unusual for the little finger to be involved. Symptoms are often worse at night but can also be present in the daytime. Symptoms are often worse with driving or holding a book, newspaper, or telephone. In the early stages symptoms occur intermittently. As the condition worsens, the altered feeling may become continuous, with numbness in the fingers and thumb together with weakness and wasting of the muscles at the base of the thumb. Sufferers often describe a feeling of clumsiness and drop objects easily. CTS may also be associated with pain in the wrist and forearm.

The reported prevalence of CTS is between 1% and 7% in European population studies, and most studies cite a figure of around 5%. It has been found to be three times more common in women than in men and commonly affects women in middle age but can occur at any age in either sex. CTS is more likely among people with conditions such as pregnancy, diabetes, thyroid problems and rheumatoid arthritis, but most CTS sufferers have none of these. CTS may be associated with swelling in the tunnel which may be caused, for example, by inflammation of the tendons, a fracture of the wrist or wrist arthritis, although in most cases, the cause is not identifiable.

Treatments are directed at both the relief of symptoms and the prevention of future deterioration. Non-surgical (conservative) treatments include lifestyle modification, the use of splints, especially at night, and corticosteroid injection into the carpal tunnel or - a combination of any of these. CTS occurring in pregnancy often resolves after the baby is born.

Surgery is frequently performed. The operation involves opening the roof of the tunnel to reduce the pressure on the nerve. The most common method involves an incision over the tunnel at the wrist, opening the roof under direct vision. In an alternative keyhole method (endoscopic release) the roof is opened with instruments inserted through one or two small incisions. The outcomes of the two techniques are similar. The surgery may be performed under local anaesthesia, regional anaesthesia (injected at the shoulder to numb the entire arm) or general anaesthesia.
Eligibility Criteria

Surgical treatment for carpal tunnel syndrome can be undertaken where the patient meets **ALL** of the following criteria:

- Symptoms persisting longer than three months despite conservative treatment in primary care (by injection and/or wrist splint); **AND**
- Positive Clinical Signs OR Positive Nerve Conduction Studies

**N.B.** It is appropriate to proceed straight to decompression surgery if severe symptoms are present at presentation i.e. constant numbness or pain, wasting or weakness of the thumb muscles. Referral to a specialist should also be considered if the diagnosis is unclear, a serious alternative diagnosis is suspected, or symptoms recur following surgery.

For the purposes of this guidance:
Positive Clinical Signs are defined as the following (NICE 2016):

- Sensory loss in the distribution of the median nerve.
- Atrophy of the muscles of the thenar eminence.
- Reduced strength of thumb abduction.
- Dry skin on the thumb, index, and middle fingers compared to elsewhere—trophic ulcers at the tips of the digits may be present.

Nerve Conduction Studies are appropriate in the following circumstances:
- Equivocal clinical examination and history
- Persistent or recurrent carpal tunnel syndrome
- An unclear diagnosis suggesting peripheral neuropathy
- NCS may be undertaken in the OPD at the time of assessment by the specialist clinician or NCS may be requested by the GP prior to referral. The former is suggested as the most efficient process as physical examination by a specialist may mean that NCS is not required OR NCS can be undertaken at the same OPD appointment as the clinical assessment.

This means (**for patients who DO NOT meet the above criteria**) the CCG will **only** fund the treatment if an Individual Funding Request (IFR) application proves exceptional clinical need and that is supported by the CCG.
Guidance

https://cks.nice.org.uk/carpal-tunnel-syndrome#lscenario


The British Society of Surgery for the Hands (BSSH). Carpal Tunnel Syndrome 2016 http://www.bssh.ac.uk/patients/conditions/21/carpal_tunnel_syndrome

NHS Choices - 2016 Carpal Tunnel
https://www.nhs.uk/conditions/Carpal-tunnel-syndrome/
Policy for Arthroscopic Hip Surgery for Femoral Acetabular Impingement (FAI)
The CCG policy has been reviewed and developed by the Treatment Policies Clinical Development Group in line with the groups guiding principles which are:

1. CCG Commissioners require clear evidence of clinical effectiveness before NHS resources are invested in the treatment;
2. CCG Commissioner require clear evidence of cost effectiveness before NHS resources are invested in the treatment;
3. The cost of the treatment for this patient and others within any anticipated cohort is a relevant factor;
4. CCG Commissioners will consider the extent to which the individual or patient group will gain a benefit from the treatment;
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6. CCG Commissioners will consider all relevant national standards and take into account all proper and authoritative guidance;
7. Where a treatment is approved CCG Commissioners will respect patient choice as to where a treatment is delivered; AND
8. All policy decisions are considered within the wider constraints of the CCG’s legally responsibility to remain fiscally responsible.
FEMORAL-ACETABULAR IMPINGEMENT (FAI)

Hip or femoro-acetabular impingement (FAI) (mismatch between the hip ball and socket) results from abnormalities of the femoral head or the acetabulum (mismatch between the hip ball and socket). There are two main types of hip impingement depending on whether the anatomical abnormality lies in the femur (cam impingement) or the acetabulum (pincer impingement). The presence of both types is referred to as mixed impingement. Not all radiologic deformities are symptomatic. It is unknown what proportion of people with asymptomatic cam or pincer deformity, develop FAI symptoms.

Symptoms of FAI include restriction of movement, ‘clicking’ of the hip joint, and pain. Symptoms may occur or be exacerbated during hip flexion activities resulting from sporting activity, although many patients experience pain whilst sitting.

Cam impingement typically occurs in young, athletic males whilst symptomatic pincer impingement is more commonly seen in middle aged females.

Management of hip impingement usually includes a trial of conservative measures, including activity modification to reduce excessive motion and loading on the hip.

In patients who are refractory to conservative treatment, surgical management to improve range of movement and reduce pain may be required. Tears to the acetabular labrum may be debrided and/or re-fixed.

The three surgical approaches commonly used are:

- Open dislocation surgery involving dislocation of the hip joint;
- Arthroscopy;
- Arthroscopy with a limited open approach (mini-open).

Clinical Effectiveness

There are no published randomised controlled trials which directly compare open surgery with arthroscopic surgery for FAI. Evidence from three systematic reviews of low quality studies indicates that arthroscopic surgery for FAI is at least as clinically effective as open surgical techniques with regard to:

- Pain improvement at six months to one year and at two to three years
- non-arthritic hip scores (NAHS) at three and twelve-month follow-up for activities of daily living function and sport function (using various hip outcome score instruments) at all-time points between three months and three years after surgery
- Quality of life improvements at three to six months (no comparator)
• Open surgical dislocation resulted in a significantly improved hip shape (alpha angle).

Safety

Compared with open hip dislocation surgery, hip arthroscopy was associated with:

• Significantly lower time for reoperation rate (relative risk [RR]: 0.40, 95% CI 0.17 to 0.95, p= 0.04).
• No significant difference in complication rates (RR: 0.76, 95% CI 0.12 to 4.63, p= 0.76)
• No difference in conversion to total hip arthroplasty (p=0.06)

Cost effectiveness

• A Canadian study suggests that on a per patient basis, the costs associated with performing a hip arthroscopy are approximately 41% of surgical hip dislocation. This may not be directly generalisable to the NHS in England.

• A small UK cost analysis study based on two years’ data indicated that hip arthroscopy for FAI may be cost-effective with the cost per QALY after one, two and ten years being £19,335, £10,118 and £2,677 per QALY respectively.

Treatment Policy Recommendation

Prior to surgery for FAI, all patients with FAI should be assessed by an MDT experienced in providing both open and arthroscopic procedures.

Where surgery is appropriate following a multi-disciplinary team (MDT) assessment, arthroscopic surgery for hip impingement should be promoted as the treatment of choice.

Compared to open surgery, there is evidence that arthroscopic surgery is similarly effective for reducing pain and improving function and quality of life for patients. It is also associated with lower reoperation rates, as well as increased cost effectiveness.
Eligibility Criteria

Surgical treatment for Arthroscopic Hip Surgery for Femoral Acetabular Impingement can be undertaken where the provider meets **ALL** of the following criteria:

- A provider has a verifiable MDT assessment process to decide the appropriate surgery modality: open dislocation surgery involving dislocation of the hip joint, or arthroscopy or arthroscopy with a limited open approach (mini-open). **AND**

- Patients are offered the choice of modality of surgery: open dislocation surgery involving dislocation of the hip joint, or arthroscopy or arthroscopy with a limited open approach (mini-open), **AND**

- There is a clear and verifiable shared decision making process in place that can be evidenced.

- Commissioners for each provider that meets the above conditions require the provider to confirm:
  - The provider’s local clinical coding for each surgery modality: open dislocation surgery involving dislocation of the hip joint, or arthroscopy or arthroscopy with a limited open approach (mini-open).
  - The relative volumes undertaken against each procedure by named consultant for 2017/18.
  - All surgical episodes should be submitted and registered with the following: [https://www.britishhipsociety.com/main?page=NAHR](https://www.britishhipsociety.com/main?page=NAHR)

This ensures continued mid and long term monitoring of outcomes and is a driver for clinical effectiveness and quality.
Guidance

Policy for Knee Arthroscopy for Degenerative Knee Disease
The CCG policy has been reviewed and developed by the Treatment Policies Clinical Development Group in line with the groups guiding principles which are:

1. CCG Commissioners require clear evidence of clinical effectiveness before NHS resources are invested in the treatment;
2. CCG Commissioner require clear evidence of cost effectiveness before NHS resources are invested in the treatment;
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6. CCG Commissioners will consider all relevant national standards and take into account all proper and authoritative guidance;
7. Where a treatment is approved CCG Commissioners will respect patient choice as to where a treatment is delivered; AND
8. All policy decisions are considered within the wider constraints of the CCG’s legally responsibility to remain fiscally responsible.
Category: Not Routinely Commissioned.

DEGENERATIVE KNEE DISEASE

The most common cause of generalised knee pain is osteoarthritis (OA). OA is the result of progressive degeneration of the cartilage of the joint surface. Meniscal tears and other structural changes including osteophytes, cartilage and bone marrow lesions are common characteristics of knee osteoarthritis. The condition is also known as degenerative knee disease.

The relationship between degradation of the joint surfaces and knee osteoarthritis is unclear. Imaging abnormalities of the knee surfaces are common and are known to exist in pain-free knees as well as symptomatic patients.

Degenerative knee disease is an inclusive term, which many consider synonymous with osteoarthritis. The term degenerative knee disease is used to explicitly include patients with knee pain, particularly if they are >35 years old, with or without:

- Imaging evidence of osteoarthritis
- Meniscus tears
- Locking, clicking, or other mechanical symptoms except persistent objective locked knee
- Acute or subacute onset of symptoms

Symptoms include pain and stiffness, and may include mechanical giving way, clicking or locking. These may impair a patient’s ability to perform activities of daily living and recreational activities. Conservative treatments aimed at reducing the symptoms include patient information (https://www.arthritisresearchuk.org/arthritis-information.aspx), weight loss and physical therapy. NICE advises that pain relief medication, physiotherapy, arthrocentesis and intra-articular corticosteroid injections may also be beneficial if the pain is moderate to severe.

Arthroscopic Knee Surgery

Arthroscopic knee surgery is an established and common treatment option and may include arthroscopic lavage (also called ‘arthroscopic washout’), arthroscopic debridement (in combination with lavage) and arthroscopic partial meniscectomy (APM) which may be performed singly or in combination with debridement and lavage. An arthroscopic knee washout involves flushing the joint with fluid, which is introduced through small incisions in the knee. The procedure is often done with debridement, which is the removal of loose debris around the joint.
The meniscus is a piece of cartilage that provides a cushion between your femur (thighbone) and tibia (shinbone). There are two menisci in each knee joint. They can be damaged or torn during activities that put pressure on or rotate the knee joint. Meniscectomy is the surgical removal of all (total meniscectomy) or part (partial meniscectomy) of a torn meniscus.

NICE recommends that arthroscopic lavage and debridement should not be used in knee OA without a ‘clear history of mechanical locking’.

APM is the most common knee procedure performed in the UK (151.2 procedures per 100,000 population).

**Clinical effectiveness**

There is published evidence showing that arthroscopic debridement with or without partial meniscectomy is not superior to conservative management.

The systematic review and meta-analysis by Brignardello-Petersen et al (2017) found that there was a short term improvement in pain and function at 3 months but this benefit was not sustained at 12 and 24 months. The short term benefit in pain and function did not translate to an improvement in Quality of Life (QoL).

The outcomes from the meta-analysis of low quality studies are reinforced by the findings from the FIDELITY randomised controlled trial (Sihvonen R, Paavola M, Malmivaara A, et al.) which compared surgery with sham surgery for degenerative medial meniscus tear. This study design corrects for the inherent bias and preferences of patients and carers who may have an initial preference for surgery (and consider non-surgical interventions to be inferior). Nearly half of the subjects in each group reported ‘catching or locking symptoms’. Two years after surgery, there was no difference between the APM and sham surgery groups for any outcomes including:

- Composite knees scores including pain, function, disability and psychological outcomes
- Patient satisfaction
- Proportion of improved patients
- Reoperations (arthroscopy, tibial osteotomy or total knee replacement)
- Return to normal activity
- Adverse events
- Mechanical symptoms
- Meniscal tests
- The baseline presence of mechanical symptoms or meniscal tear did not result in APM being more favourable.
Safety

Knee arthroscopy carries a low risk of adverse events. These include:

- Venous thromboembolism (VTE) occurring in 5 per 1,000 procedures and
- Infection occurring in 2 per 1,000 procedures.
- It is not clear that the short term benefits associated with APM outweigh the low risks.

Cost Effectiveness

The most reliable study available concludes that the procedure is not cost effective despite including some indirect costs and only assessing costs effectiveness up to two years after surgery. Since the cost effectiveness of knee arthroscopy treatment is highly dependent upon the clinical effectiveness, it is not possible for the procedure to be regarded as cost effective if it is only marginally clinically effective, especially in view of the evidence that it may, in a very small proportion of cases, be harmful.

Activity and finance

Across the BSOL CCGs area, there were 2,036 elective admissions for knee arthroscopy for patients with a diagnosis of degenerative knee disease (April 2015 - June 2017 inclusive). This excluded admissions where the procedures were part of a more complex knee operation such as ligament repair. The most commonly performed knee arthroscopy procedure was ‘W822: endoscopic resection of semilunar cartilage NEC’. This accounted for 1,617 (79%) of the 2,036 admissions and cost £4,496,357.
INTERIM Eligibility Criteria

Knee arthroscopic lavage and debridement, with or without partial meniscectomy, will not be routinely commissioned for patients with degenerative knee disease (with or without radiographic and other symptoms of osteoarthritis, meniscus tears and mechanical symptoms).

Degenerative knee disease is an inclusive term, which many consider synonymous with osteoarthritis. The term degenerative knee disease is used to explicitly include patients with knee pain, particularly if they are >35 years old, with or without:

- Imaging evidence of osteoarthritis
- Meniscus tears
- Locking, clicking, or other mechanical symptoms except persistent objective locked knee
- Acute or subacute onset of symptoms

This means (for patients who DO NOT meet the above criteria) the CCG will only fund the treatment if an Individual Funding Request (IFR) application proves exceptional clinical need and that is supported by the CCG.
Guidance.


Policy for Dupuytren’s Contracture
The CCG policy has been reviewed and developed by the Treatment Policies Clinical Development Group in line with the groups guiding principles which are:

1. CCG Commissioners require clear evidence of clinical effectiveness before NHS resources are invested in the treatment;
2. CCG Commissioner require clear evidence of cost effectiveness before NHS resources are invested in the treatment;
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8. All policy decision are considered within the wider constraints of the CCG’s legally responsibility to remain fiscally responsible.
Category: Restricted

Dupuytren's Contracture

Dupuytren's contracture is a fairly common condition that causes one or more fingers to bend into the palm of the hand. The condition often occurs in later life, and is most common in men who are aged over 40. Around one in six men over the age of 65 are affected in the UK.

The symptoms of Dupuytren's contracture are often mild and painless and do not require treatment. The condition most often starts with a firm nodule in the skin of the palm and may stay the same for months or years. In some patients, however, it may progress to the next stage in which cords of fibrous tissue form in the palm and run into the fingers or thumb, eventually, pulling them into a permanently flexed position, making it difficult to perform activities of daily living. In about 50% of cases the condition affects both hands, and in rare cases it can also affect the soles and toes of the feet.

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. However, patients should be advised that probably 40% of people will have a recurrence following surgery. Dupuytren’s contracture can return to the same spot on the hand or may reappear somewhere else. Recurrence is more likely in younger patients; if the original contracture was severe; or if there is a strong family history of the condition.

Treatment

In July 2017 the National Institute for Health and Care Excellence (NICE) published guidance on the most appropriate treatments available for Dupuytren’s contracture and when these treatments should be used. This guidance approved the use of injections of collagenase clostridium histolyticum (CCH); limited surgical fasciotomy and percutaneous needle fasciotomy (PNF) for treating Dupuytren's contracture in certain clinical circumstances.
Eligibility Criteria

For patients requiring treatment with collagenase clostridium histolyticum (CCH) limited surgical fasciotomy or percutaneous needle fasciotomy (PNF), the patient must meet the following clinical criteria:

- Evidence of at least moderate disease
- For patients choosing treatment with collagenase clostridium histolyticum (CCH):
  - one injection should be given per treatment session,
  - the injection should be undertaken in an outpatient setting,
  - the injection should be performed by a suitably qualified clinician who has advanced knowledge of the anatomy of the hand and has completed the company's training.
  - For patient who meet the inclusion criteria for the ongoing clinical trial (HTA-15/102/04), comparing collagenase clostridium histolyticum (CCH) with limited fasciectomy, should participate in the study.

For the purposes of this guidance the baseline for 'moderate disease' is classified as:

- Functional problems AND
- moderate metacarpo-phalangeal joint contracture (at least 30 degrees) OR
- any proximal inter-phalangeal joint contracture OR
- First web contracture

For patients NOT taking part in the ongoing clinical trial, CCH is recommended as an option for treating Dupuytren's contracture with a palpable cord in adults only if all of the following eligibility criteria are met:

- 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 2 affected joints.
- Percutaneous needle fasciotomy (PNF) is not considered appropriate, but limited 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.
Note: Indicative Pathway Change

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<tr>
<th>Pathway item</th>
<th>Existing Pathway for Dupuytrens - Surgery</th>
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<td>New Consultant led OPA</td>
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<td>Palmar Fasciectomy Surgery (HN93Z)</td>
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<td>OT Application of Hand Splint</td>
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<td>6 OT Contacts</td>
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<td>OPA Dressing Clinic</td>
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<td>2 Consultant led Follow Ups</td>
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<tr>
<th>Pathway item</th>
<th>Proposed Injection Treatment Pathway</th>
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<tr>
<td></td>
<td>New OPA</td>
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<td></td>
<td>Outpatient Procedure for Injection OPCS T55.8 (HN93Z)</td>
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<td>Outpatient Procedure for Manipulation OPCS T578</td>
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<td>OT Application of Hand Splint</td>
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<td>1 OT Contact</td>
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Patient Choice and Shared Decision Making

- 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.
- For patient who meet the inclusion criteria for the ongoing clinical trial (HTA-15/102/04), comparing collagenase clostridium histolyticum (CCH) with limited fasciectomy, should be encouraged to participate in the study.

This means for patients who **DO NOT** meet the specified criteria the CCG will only fund the treatment if an Individual Funding Request (IFR) application proves exceptional clinical need and that is supported by the CCG.

Guidance

National Institute for Health and Care Excellence (NICE) 2017 - Collagenase clostridium histolyticum for treating Dupuytren’s contracture. Technology appraisal guidance # 459.
http://www.nice.org.uk/guidance/ta459

http://www.bssh.ac.uk/patients/conditions/25/Dupuytren’sdisease
Policy for the treatment of Chronic Fatigue Syndrome (CFS)/Myalgic Encephalomyelitis (ME)
The CCG policy has been reviewed and developed by the Treatment Policies Clinical Development Group in line with the groups guiding principles which are:

1. CCG Commissioners require clear evidence of clinical effectiveness before NHS resources are invested in the treatment;
2. CCG Commissioner require clear evidence of cost effectiveness before NHS resources are invested in the treatment;
3. The cost of the treatment for this patient and others within any anticipated cohort is a relevant factor;
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6. CCG Commissioners will consider all relevant national standards and take into account all proper and authoritative guidance;
7. Where a treatment is approved CCG Commissioners will respect patient choice as to where a treatment is delivered; AND
8. All policy decision are considered within the wider constraints of the CCG’s legally responsibility to remain fiscally responsible.
Chronic Fatigue Syndrome (CFS) / Myalgic Encephalomyelitis (ME)

Chronic Fatigue Syndrome (CFS) is also referred to as Myalgic Encephalomyelitis (ME) or Post Viral Fatigue Syndrome, it is characterised by long term tiredness that affects everyday life and does not go away with sleep or rest. It can encompass both physical (eg. fatigue) and psychological difficulties (eg. muddled thinking).

Although Chronic Fatigue Syndrome can sometimes follow a viral infection, quite often the trigger is unclear.

Symptoms may include:

- Fatigue for four months or more
- Feeling unusual tiredness, made worse by activity
- Impaired concentration or memory
- Unrested/disturbed sleep
- Aching joints/muscles
- Sore throat
- Headaches
- Tender/sore lymph nodes
- Hypersensitivity reactions (light, smells, noise)
- Post-exertional malaise
- Symptoms similar to IBS
- Autonomic symptoms

CFS/ME is a clinically defined syndrome with a characteristic pattern of symptoms but no consistent abnormalities on physical examination or on imaging/laboratory evaluation. It is often called a “diagnosis of exclusion" but in practice the symptomatology is frequently consistent enough to allow a fairly confident positive clinical diagnosis to be made.

NICE (2007) recommends that a small number of investigations are carried out to exclude conditions that potentially could be confused with CFS/ME. The following tests should usually be done:

- urinalysis for protein, blood and glucose
- full blood count
- urea and electrolytes
- liver function
- thyroid function
- erythrocyte sedimentation rate or plasma viscosity
- C-reactive protein
- HbA1c
- serum creatinine
- screening blood tests for gluten sensitivity
- serum calcium
- creatine kinase
- assessment of serum ferritin levels (children and young people only). Clinical judgement should be used when deciding on additional investigations to exclude other diagnoses.

Tests for serum ferritin in adults should not be carried out unless a full blood count and other haematological indices suggest iron deficiency.

Tests for vitamin B₁₂ deficiency and folate levels should not be carried out unless a full blood count and mean cell volume show a macrocytosis.

The following tests should NOT be done routinely to aid diagnosis:
- the head-up tilt test
- auditory brainstem responses
- electrodermal conductivity.

Serological testing should NOT be carried out unless the history is indicative of an infection.

Depending on the history, tests for the following infections may be appropriate:
- chronic bacterial infections, such as borreliosis
- chronic viral infections, such as HIV or hepatitis B or C
- acute viral infections, such as infectious mononucleosis (use heterophile antibody tests)
- latent infections, such as toxoplasmosis, Epstein–Barr virus or cytomegalovirus.
As indicated above, CFS/ME is a characteristic set of symptoms with no consistently identifiable pathology. Asymptomatic CFS/ME by definition cannot exist. Therefore, in addition to referral for definitive therapy patients with CFS/ME may need symptomatic remedies to help with specific symptoms whilst waiting for definitive therapy to become available and/or to become effective.

Prevalence

Adults

In 2011 the London School of Hygiene and Tropical Medicine conducted a cross-sectional study in three English regions on the primary care clinical presentation, prevalence and incidence of CFS/ME. The estimated minimum prevalence was found to be 0.2% in adults aged 18-64 (40 per 10,000 patients). Estimated minimal yearly incidence for this age group was 0.015% and the regions were found to have consistently higher prevalence in women than men. A Norwegian study also identified an incidence rate ratio of 3.1 for women compared to men_vi

Children

Less information is available on paediatric prevalence of CFS/ME. A review paper from 2013 reported variable North American prevalence estimates for 12-17 years olds ranging from 0.002%-0.116%.vii Studies have also consistently shown a female-to-male ratio of 3:1.

Evidence of clinical effectiveness of interventions for CFS/ME.

Based upon the evidence identified there is some evidence to show that cognitive behavioural therapy has a positive impact on patients with CFS/ME through reducing symptoms of fatigue. There was also moderate quality evidence that Exercise therapy was more effective at reducing fatigue compared to ‘passive’ treatment or no treatment and had a positive effect on people’s daily physical functioning, sleep and self-ratings of overall health.

There was no evidence identified on the clinical effectiveness of inpatient therapy or residential settings.

Current NICE guidelines highlight the importance of shared decision making and any decision to refer a person to specialist CFS/ME care should be based on their needs, the type, duration, complexity and severity of their symptoms, and the presence of comorbidities.
Eligibility Criteria:

<table>
<thead>
<tr>
<th>Eligibility Criteria</th>
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<tbody>
<tr>
<td>In patient care or therapy in a residential setting are NOT routinely commissioned for the treatment of CFS / ME due to the lack of clinical evidence to support this intervention.</td>
</tr>
</tbody>
</table>

CBT in the form of a PACE Programme or an individualised care package which combines CBT and exercise therapy as required to support the individual patient will be funded in an out-patient / community setting through the currently commissioned provider in the following circumstances:

1. The patient has a confirmed diagnosis of mild or moderate CFS / ME

AND

2. The patient has undergone a holistic assessment with a CFS / ME treatment specialist team and either a group or individualised programme has been deemed by the specialist clinical team the most appropriate intervention for the patient in their individual circumstances.

All referrals for assessment of CFS/ME or treatment plans should be undertaken in a process of shared decision making and any decision to refer a person to specialist CFS/ME care should be based on their needs, the type, duration, complexity and severity of their symptoms, and the presence of comorbidities.

This means (for patients who DO NOT meet the above criteria) the CCG will only fund the treatment if an Individual Funding Request (IFR) application proves exceptional clinical need and that is supported by the CCG.
Definitions of ME


VERY SEVERE

100% DISABLED: Severe symptoms – often on a continual basis. Cognitive function (i.e. short-term memory, concentration, attention span) is likely to be very poor. Bedridden and incapable of living independently. Requires a great deal of supervision and practical support – including disability aids such as a hoist or a stair lift – with all aspects of personal care (i.e. feeding, dressing, washing) on a 24-hour basis.

90% DISABLED: Severe symptoms, often including marked cognitive dysfunction, for much or all of the time. Bedridden and housebound for much or all of the time. Has considerable difficulties with all aspects of personal care. Unable to plan or prepare meals. Requires practical support and supervision on a 24-hour basis.

SEVERE

80% DISABLED: Moderate to severe symptoms for most or all of the time. Only able to carry out a very limited range of physical activities relating to personal care without help. Requires help with meal planning and preparation. Frequently unable to leave the house and may be confined to a wheelchair when up, or spends much of the day in bed. Unable to concentrate for more than short periods of time. Usually requires daytime and night-time supervision.

70% DISABLED: Moderate to severe symptoms for most or all of the time. Confined to the house for much or all of the time. Normally requires help with various aspects of personal care and meal planning and preparation, possibly on a 24-hour basis. Very limited mobility. May require wheelchair assistance.

MODERATE

60% DISABLED: Moderate symptoms for much or all of the time. Significant symptom exacerbation follows mental or physical exertion. Not usually confined to the house but has significant restrictions on mobility when outside and may require wheelchair assistance. Likely to require help with aspects of personal care and meal preparation – but not necessarily on a full-time basis. Requires regular rest periods during the day. Unable to resume any meaningful regular employment or education.
50% DISABLED: Moderate symptoms for much or all of the time. Symptom exacerbation follows mental or physical exertion. Not usually confined to the house, but mobility restricted to walking up to a few hundred yards at best. May require help with some aspects of personal care. May require help with meal planning and preparation. Requires regular rest periods during the day. Able to carry out light activities (i.e. housework, desk work) linked to normal daily living for short periods but not able to resume regular employment or education.

40% DISABLED: Moderate symptoms for some or much of the time. Normally able to carry out most activities linked to personal care and normal daily living, but may require assistance with meal preparation. May be able to cope with some work-related tasks for short periods – provided they are not mentally or physically strenuous – but not able to resume regular work or education.

MODERATE TO MILD

30% DISABLED: Fluctuating level of mild to moderate symptoms. Normally able to carry out all aspects of personal care and to plan and prepare meals. Able to walk short distances on a regular basis. May be able to return to work on a flexible or part-time basis – provided adjustments are made to cope with physical activity or cognitive problems. May have to stop leisure or social pursuits to resume work or education.

20% DISABLED: Normally only mild symptoms at rest but exacerbation will follow activity. Able to carry out all aspects of personal care and to plan and prepare meals. Able to walk short to medium distances (i.e. up to half a mile) on a regular basis. Normally able to return to flexible or part-time work or education.

10% DISABLED: Generally, well with only occasional mild symptoms. No problems with personal care or daily living. Mobility and cognitive functions may still be restricted but almost back to previous levels. May be able to return to full-time work or education.

0% DISABLED: Fit and well for at least the past three months. No symptoms at rest or after exertion. Capable of full-time work or education.
Guidance

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

Colin, S.m; Nuevo, R.; Van de Putte, E.M.; Nijhof, S.L.; Crawley, E. (2015) Chronic fatigue syndrome (CFS) or myalgic encephalomyelitis (ME) is different in children compared to in adults: a study of UK and Dutch clinical cohort. BMJ Online. 5(10)
http://bmjopen.bmj.com/content/5/10/e008830

NICE (expected publication 2020) Myalgic encephalomyelitis (or encephalopathy)/chronic fatigue syndrome: diagnosis and management
https://www.nice.org.uk/guidance/indevelopment/gid-ng10091

http://europepmc.org/articles/PMC3170215

https://link.springer.com/content/pdf/10.1186/s12916-014-0167-5.pdf

https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3856907/

Birmingham and Solihull Mental Health NHS Foundation Trust. The Chronic fatigue Syndrome Service.
http://www.bsmhft.nhs.uk/our-services/specialist-services/neuropsychiatry/the-chronic-fatigue-syndrome-service/


Policy for the Management of Port Wine Stains
The CCG policy has been reviewed and developed by the Treatment Policies Clinical Development Group in line with the groups guiding principles which are:

1. CCG Commissioners require clear evidence of clinical effectiveness before NHS resources are invested in the treatment;
2. CCG Commissioner require clear evidence of cost effectiveness before NHS resources are invested in the treatment;
3. The cost of the treatment for this patient and others within any anticipated cohort is a relevant factor;
4. CCG Commissioners will consider the extent to which the individual or patient group will gain a benefit from the treatment;
5. CCG Commissioners will balance the needs of each individual against the benefit which could be gained by alternative investment possibilities to meet the needs of the community
6. CCG Commissioners will consider all relevant national standards and take into account all proper and authoritative guidance;
7. Where a treatment is approved CCG Commissioners will respect patient choice as to where a treatment is delivered; AND
8. All policy decision are considered within the wider constraints of the CCG’s legally responsibility to remain fiscally responsible
Category: Not Routinely Commissioned.

Port Wine Stains

A port wine stain is a vascular birthmark caused by abnormal development of blood vessels in the skin. A port wine stain is sometimes referred to as a capillary malformation. The change in the blood vessels is caused by a mutation (change in a gene) occurring early in pregnancy while the baby is developing in the womb. This change in the gene is not inherited (passed on from one generation to the next) and is not known to be related to anything that happened during pregnancy.

A port wine stain is a flat, red or purple mark on the skin that is present at birth. Very occasionally, over time, the port wine stain may become thicker, darken and develop a ‘cobblestone’ appearance with raised bumps and ridges.

Port wine stains can appear anywhere on the body, in most cases on one side of the body only, but occasionally on both sides. About 65 per cent of port wine stains are on the head and neck. About three in every 1000 children has a port wine stain. Girls are twice as likely to have a port wine stain as boys, but we do not know why.

Port wine stains are clearly noticeable and quite different to other types of birthmark so no special diagnostic tests are usually needed. Generally, port wine stains do not need any special treatment. However, they do need protection from the sun. The patient should use a high factor sun cream on all areas of exposed skin, and use a hat to protect the patient’s face and/or an umbrella over the buggy or pushchair.

Port wine stains involving the upper part of the face can be linked to the following conditions:

**Glaucoma:** Patients with a port wine stain around the eye have an increased risk of glaucoma. Glaucoma is raised pressure within the eye, which can lead to blindness if it is not treated. Treatment is usually by eye drops and occasionally an operation. A specialist eye doctor (ophthalmologist) should examine the patient's eyes to check for glaucoma.

When comparing to the normal eye, the eye on the port wine side may look different. If the pupil looks larger, the eyelids are open further or the eye itself looks larger or more prominent than the other, the patient’s eyes should be checked by an ophthalmologist (specialist eye doctor).

**Sturge-Weber syndrome:** If the port wine stain is on the skin around the eye, forehead or scalp, there is a chance that the patient may have a condition called
Sturge-Weber syndrome. As well as the port wine stain affecting the skin, it may also involve blood vessels over the surface of the brain, which can cause seizures (fits or convulsions). If there is any suspicion the patient is at risk of Sturge-Weber syndrome, the patient will need to be reviewed by a neurologist.

Klippel Trenaunay syndrome: A large port wine stain on the arm or leg might be associated with extra growth of that limb and is referred to as Klippel Trenaunay syndrome. This may need a multidisciplinary review by dermatologists, and general, orthopaedic and vascular surgeons.
Treatment Options for Port Wine Stains

There are 2 options for treatment of port wine stain:

1. **Camouflage Makeup**
2. **Laser Treatment**

1. **Camouflage makeup**

Skin camouflage products effectively cover the affected area. Changing Faces provides education by trained volunteer practitioners on the use and application of cosmetic camouflage creams and powders, and people may self-refer.

Details of the nearest skin camouflage service can be found at [www.changingfaces.org.uk](http://www.changingfaces.org.uk).

Cosmetic camouflage creams can be used on any part of the body. The aim is to provide natural-looking cover. They are waterproof, and may remain on the body for up to 4 days, and on the face for 12–18 hours.

Three brands of camouflage product, in a range of shades, are included in the Birmingham, Sandwell and Solihull APC Formulary, and the prescription must be endorsed 'ACBS':

- Covermark classic foundation (10 shades) and Covermark finishing powder.
- Dermacolor camouflage cream (100 shades) and Dermacolor fixing powder.
- Keromask masking cream (9 shades) and Keromask finishing powder.

2. **Laser treatment**

Laser treatment for a port wine stain, may lighten the affected area of skin. NICE IPG90 (2004) states the following: Laser treatment is often recommended for lesions near the eyes or orifices, or if lesions bleed, ulcerate or become infected. However, external laser treatment of these vascular abnormalities may not be effective because the laser beam does not penetrate far beneath the skin.

There are multiple laser modalities, each having different settings that can be used for port wine stain. The pulse dye laser is considered the current gold standard. The evidence review produced for the CCG policy review (please see CCG website for full evidence review) suggests that the pulse dye laser is clinically effective in reducing the colour of port wine stains in the short term. The evidence review also suggests that other laser modalities may show clinical effectiveness in reducing the colour of port wine stains within trial settings, and
combinations of laser and other adjunctive may augment the action of pulse dye lasers, although there is no strong systematic review/guidance in this area.

The pulse dye laser was generally considered safe, although long term outcomes are not well studied. Short term adverse effects are common which vary from pain, skin crusting and bullae.

There was limited evidence investigating quality of life after treatment. One qualitative study found that the majority of patients felt that pulse dye laser therapy improves PWS colour over time with just under half of them feeling satisfied with treatment, but questionnaire response rates were around 50%. Most patients believed that the laser treatment did not improve their social interaction but it did help reduce their worry about their appearance.

There was no evidence found investigating the cost effectiveness for the treatment of port wine stains. The overall application of these findings to clinical practice is limited and further research and investigation is warranted, especially around long term outcomes, quality of life and cost effectiveness.

**Eligibility Criteria.**

| Patients with port wine stains involving the upper part of the face should be appropriately referred for further investigation to ensure complications of port wine stain, as outlined above, are identified and managed appropriately. |
|Patient may access camouflage make-up through their GP as described above. |

**Laser treatment is not routinely commissioned for the treatment of port wine stains.**

This is because there is insufficient clinical evidence to support the use of laser treatment as an effective intervention for port wine stain, further research is warranted, particularly around long term outcomes, quality of life and cost effectiveness.

This means the CCG will only fund the treatment if an Individual Funding Request (IFR) application proves exceptional clinical need and that is supported by the CCG.
Guidance


Kelly KM1, Choi B, McFarlane S, Motosue A, Jung B, Khan MH, Ramirez-San-Juan JC, Nelson JS.OI Description and analysis of treatments for port-wine stain birthmarks.


Berit C. Carlsen, MD, PhD et al. (2017) A Randomized Side-by-Side Study Comparing Alexandrite Laser at Different Pulse Durations For Port Wine Stains Department of Dermatology, Bispebjerg University Hospital, 2400 Copenhagen, NV, Denmark, Boom Laser Clinic, 2850 Boom, Belgium (2017)


Policy for Assisted Conception
The CCG policy has been reviewed and developed by the Treatment Policies Clinical Development Group in line with the groups guiding principles which are:

1. CCG Commissioners require clear evidence of clinical effectiveness before NHS resources are invested in the treatment;
2. CCG Commissioner require clear evidence of cost effectiveness before NHS resources are invested in the treatment;
3. The cost of the treatment for this patient and others within any anticipated cohort is a relevant factor;
4. CCG Commissioners will consider the extent to which the individual or patient group will gain a benefit from the treatment;
5. CCG Commissioners will balance the needs of each individual against the benefit which could be gained by alternative investment possibilities to meet the needs of the community
6. CCG Commissioners will consider all relevant national standards and take into account all proper and authoritative guidance;
7. Where a treatment is approved CCG Commissioners will respect patient choice as to where a treatment is delivered; AND
8. All policy decision are considered within the wider constraints of the CCG’s legally responsibility to remain fiscally responsible.
1. Introduction

Infertility is when a couple cannot conceive (get pregnant) despite having regular unprotected vaginal sexual intercourse. A woman of reproductive age who has not conceived after 1 year of unprotected vaginal sexual intercourse, in the absence of any known cause of infertility, should be offered further clinical assessment and investigation along with her partner. Infertility can be primary, in people who have never conceived, or secondary, in people who have previously conceived. It is estimated that infertility affects one in six heterosexual couples in the UK.

The causes of primary infertility in the UK occur in the following approximate proportions:

- unexplained infertility (no identified male or female cause), 25%
- ovulatory disorders, 20%
- tubal damage, 15%
- factors in the male causing infertility, 30%
- uterine or peritoneal, 10%.

In about one third of cases, disorders are found in both the man and the woman.

Other factors may play a role, including uterine or endometrial factors, gamete or embryo defects, and any other pelvic condition such as endometriosis.

Over 80% of heterosexual couples in the general population will conceive within 1 year if:

- the woman is aged under 40 years and
- they do not use contraception and have regular sexual intercourse.

Of those who do not conceive in the first year, about half will do so in the second year (cumulative pregnancy rate over 90%).
2. Scope of the Policy

This policy applies to all patients for whom the Birmingham and Solihull Clinical Commissioning Group (CCG) has responsibility, if a couple are requesting assisted conception treatment, then **BOTH partners in the couple must be registered with a Sandwell & West Birmingham GP or BOTH partners in the couple must be registered with a Birmingham and Solihull GP.**

Where a patient’s clinical presentation does not clearly meet the requirements for secondary care referral within the context of this policy, and where a GP is uncertain or concerned about the appropriate treatment/management pathway, a GP Advice & Guidance request should be considered as an alternative to a referral for clinical assessment.

There may be occasions when a GP referral is made for specialist assessment which appears to meet the policy requirements, but which on specialist clinical examination either does not meet the clinical criteria or is not considered clinically suitable for intervention. Such patients should be discharged without intervention.

For patients who do not fall within the eligibility criteria set out in the policy (Sections 3 & 4 with reference to Appendix 1), but where there is demonstrable evidence that the patient has exceptional clinical circumstances, an Individual Funding Request may be submitted for consideration.

The policy applies to patients experiencing difficulty with conception who are being managed on an NHS pathway of care.

**Funding for Military Serving Personnel**

Assisted conception services for current serving personnel and their partners is contained with the specific NHS England policy at: [https://www.england.nhs.uk/commissioning/policies/ssp/](https://www.england.nhs.uk/commissioning/policies/ssp/) as NHS England are the responsible commissioner.

Veterans who are in receipt of compensation for loss of fertility (received as a result of service/partner of same) and require access to assisted conception treatments, are also the commissioning responsibility of NHS England [https://www.england.nhs.uk/commissioning/wp-content/uploads/sites/12/2016/10/armed-forces-comms-intent-1617-1819.pdf](https://www.england.nhs.uk/commissioning/wp-content/uploads/sites/12/2016/10/armed-forces-comms-intent-1617-1819.pdf)

Veterans without relevant injury impacting on fertility are the commissioning responsibility of CCGs and the content of this policy applies.

**Pre-Implantation Genetic Diagnosis** (PiGD) is not covered by this commissioning policy as it is the commissioning responsibility of NHS England. Patients should be referred to the Genetic Centre at Birmingham Women’s & Children’s Hospital. Definitions are to be found in Appendix 1.
3. Patient Eligibility Criteria (Summary: Appendix 2)

1. Age
   a. Age of Female Partner wishing to conceive
      - The age of the female partner at the time of treatment must be under 40 years of age.
      - If infertility is clinically identified in a female from the age of 20 years old - NHS infertility treatment should be offered without delay.
      - Where the woman is aged 38 - 39 years of age, the couple/single female should be offered referral to a specialist NHS infertility centre for assessment without further delay.
      - Referrals for NHS infertility treatment should be made on or before the females 39th birthday (i.e. at least 12 months before her 40th birthday) to ensure relevant investigations can be completed, and treatment must have commenced prior to the females 40th birthday.
      - The rationale for referral and treatment prior to a woman’s 40th birthday is due to the high quality evidence from the 2013 NICE Clinical Guideline, more recently published evidence and the HFEA, all of which confirm that increasing maternal age is a key predictor of failure to have a live birth following IVF treatment.
      - One large observational cohort study (Smith et al (2015)) reported the live birth rate (LBR) for a full cycle of autologous IVF initiated between 2003 and 2010, for 156,947 women in the UK. After one full cycle (defined as an initial ovarian stimulation and all subsequent fresh and frozen embryos) the live birth rate (LBR) were:
         o For women <40 years: 32.3% (95%CI 32.0 to 32.5)
         o For women 40-42 years: 12.3% (95%CI 11.8 to 12.8)
         o For women >42 years: 3.7% (95% CI 3.2 to 4.3)
      - More recently, the HFEA reported LBR for women of different age bands who had an autologous IVF cycle which was initiated in 2013. There is a noticeable decline in LBR for women aged 38 years and older when compared to women up to and including 37 years.

<table>
<thead>
<tr>
<th>Maternal age</th>
<th>Live birth rate per treatment cycle started using patients’ fresh eggs in 2013 (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>All ages</td>
<td>26.5</td>
</tr>
<tr>
<td>18-34</td>
<td>32.8</td>
</tr>
<tr>
<td>35-37</td>
<td>29.5</td>
</tr>
<tr>
<td>38-39</td>
<td>21.8</td>
</tr>
<tr>
<td>40-42</td>
<td>13.7</td>
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</table>
b. **Age of Male Partner wishing to conceive**
   i. The age of the male partner at the time of treatment must be under 55 years of age.
   ii. HFCA regulations enable men to donate sperm to assist infertile people and recommend that sperm donors should be aged under 41 years; the possible effect of a donor’s age on assisted conception success is considered on a case by case basis.
   iii. There is limited evidence that IVF success decreases in men over the age of 40. Men aged over 40 are half as likely to conceive with IVF compared to 30-year-old men when their female partner is aged 35-39 years (de La Rochebrochardet al, 2006). However, male age does not impact on the success of other infertility treatment such as ICSI (Spandorfer et al, 1998).
   iv. In light of some evidence that male age does impact on infertility, and may have an impact on IVF outcomes, and keeping in line with other CCG areas which stipulate a male age restriction of 55 years, we have included this as a criterion for eligibility.

2. **Childlessness**
   a. NHS infertility treatment will NOT be funded if either partner has living children of any age; this includes an adopted child or a child (biological or adopted) from either the present or a previous relationship. Once accepted for treatment, should a child be adopted or a pregnancy leading to a live birth occur, the couple / individual will no longer be considered childless and will not be eligible for NHS funded treatment.

3. **Previous Infertility Treatment**
   a. NHS infertility treatment will not be offered to people where either partner within the couple has already undertaken any previous infertility treatment (IVF/ICSI) for fertility problems, regardless of whether the treatment was funded by the NHS or privately funded.

4. **Sterilisation**
   a. NHS infertility treatment will not be available if either partner within the couple has received a sterilisation procedure or has undertaken a reversal of sterilisation procedure.
   b. Sterilisation is offered within the NHS as an irreversible method of contraception. Protocols for sterilisation include counselling and advice that NHS funding will not be available for reversal of the procedure or any fertility treatment consequently to this.

5. **Body Mass Index**
   a. Females who have a body mass index (BMI) of 30 or over should be informed that they are likely to take longer to conceive.
   b. The female wishing to conceive must have a BMI of <30kg/m² at the time of referral AND commencement of treatment. Females wishing to
conceive must be informed of this criterion at the earliest opportunity and offered the support of local NHS services to optimise their BMI.

6. Smoking / Vaping Status
   a. Only non-smoking (including non-vaping) females/couples will be eligible for fertility treatment; smoking (including vaping) must have ceased by both partners three months prior to referral for infertility treatment.
   b. Females who smoke (including vaping) should be informed that this is likely to reduce their fertility, should be offered referral to a smoking cessation programme to support their efforts in stopping smoking (including vaping), and informed that passive smoking is likely to affect their chance of conceiving. Men who smoke (including vaping) should be informed that there is an association between smoking and reduced semen quality (although the impact of this on male fertility is uncertain), and that stopping smoking (including vaping) will improve their general health.
   c. Maternal and paternal smoking can adversely affect the success of infertility treatment and smoking during the antenatal period can lead to increased risk of adverse pregnancy outcomes. Females should be informed that passive smoking is likely to affect their chance of conceiving. There is an association between smoking and reduced semen quality. The impact of vaping on conception, pregnancy and the passive impact of vaping is uncertain and without further evidence of the safety of vaping in conception / pregnancy / childhood, this cannot be currently recommended as an alternative to smoking.

Once all of the above eligibility criteria have been met by the couple / single woman, Section 4 defines the clinical circumstances in which IVF / ICSI may be commissioned.

4: Definition of patients who may access Assisted Reproduction Treatments for the Management of Infertility.

   4.1 For all couples / single women
      o The presence of known reproductive pathology as defined in Appendix 1.

   4.2 For heterosexual couples:
      4.2.a. The failure to conceive after regular unprotected sexual intercourse for a period of 2 years.
      AND
      the absence of known reproductive pathology.
      OR
      4.2.b The failure to conceive after regular unprotected sexual intercourse for a period of one year.
AND
Known reproductive pathology (identified in tests run by GP after 1 year of failure to conceive – Male: semen analysis and Female: Female Stimulating Hormone (FSH) & Progesterone Level).
OR
4.3. Known reproductive pathology which would prevent natural conception.

4.3 For female same-sex couples / single women:
4.3.1. the failure to conceive after a minimum of six rounds of self-funded donor insemination via IUI
AND
the absence of any known reproductive pathology.

4.4 For Male same-sex couples / single men
The commissioner does not fund surrogacy arrangements or any associated treatments (including fertility treatments) related to those in surrogacy arrangements.

4.5 For couples where one partner has a known permanent physical disability
4.5.1 The permanent disability must prevent natural conception as defined by the following clinical situations:
• Permanent physical disability which prevents sexual intercourse
• an infection requiring sperm washing,
AND
the couple have failed 6 rounds of CCG funded IUI / DI
OR
4.5.2. IUI/DI is not clinically appropriate, e.g. one or both of the couple have known reproductive pathology which would prevent or significantly reduce the chance of conception using IUI/DI.

For the purposes of this policy disability is defined as: a permanent physical impairment which prevents sexual intercourse.
4. Commissioned Treatment

Providing that all eligibility criteria detailed in Section 3 are met, for females/couples in whom IVF/ICSI is clinically indicated, the Commissioner will fund 1 fresh cycle of In Vitro Fertilisation (IVF) or Intra-Cytoplasmic Sperm Injection (ICSI).

Definition of a cycle of IVF / ICSI

The definition of a single treatment cycle for the purpose of this policy is as follows:

The replacement of a fresh embryo(s) derived from the initial cycle.

Frozen Embryo Transfers

Embryos that are not used during the fresh transfer should be quality graded using the UK NEQAS embryo morphology scheme and may be frozen for subsequent use. Cryopreservation and storage of any suitable surplus embryos following a completed NHS funded cycle is for a period of 12 months, in line with Human Fertilisation and Embryology Authority (HFEA) guidelines and is funded by the specialist tertiary treatment provider. Following this period, the woman/couple may self-fund continued storage of the embryos. The CCG does NOT commission transfer of further frozen embryos.

Failed or Abandoned Cycles

It is acknowledged, that rarely, a cycle could fail at any time after commencement due to a number of reasons. For example; ovarian stimulation failure, failure to retrieve an egg, failure to fertilise or a failure of embryos to develop, all of which may result in embryo transfer to the uterus NOT taking place. These are known risks of infertility treatment and will be fully explained to the patient along with the likelihood of success. Should any such issue arise, the cycle will have failed and the Commissioner will not fund further cycles of IVF or ICSI.

Part-funding of cycles

The Commissioner will not part-fund or co-fund assisted conception/infertility treatment for individuals or couples that are ineligible or eligible for NHS-funded services under this policy.

Use of previously stored gametes.

Where cryopreserved gametes are available in line with the current CCG policy on gamete retrieval and cryopreservation, this policy will allow the use of cryopreserved gametes for infertility treatment in line with specialist clinical input where patients meet all other eligibility criteria (Section 3 & 4).
IUI and DI
IUI and DI is separate from IVF treatment, however, the couple / woman may then access IVF treatment if failure of IUI / DI has evidenced reproductive pathology.

IUI / DI is commissioned for patients in the following circumstances:
- Permanent physical disability which prevents sexual intercourse
- An infection requiring sperm washing,

Where a medical condition exists (such as permanent physical disability which prevents sexual intercourse or after sperm washing to prevent infectious disease transmission,). IUI for up to 6 cycles will be commissioned for patients who meet the criteria set out in Section 3 & 4, followed by further IVF / ICSI if reproductive pathology is established and the woman/couple continue to meet the criteria set out in Section 3.

IUI and DI in same-sex relationships:
6 cycles of IUI/DI must be SELF –FUNDED as a treatment option for people in same-sex relationships.

However, if 6 cycles of IUI /DI are unsuccessful and reproductive pathology has been established, further IVF / ICSI if clinically appropriate will be commissioned for patients who meet the criteria set out in Section 3 &4.

Donor Gametes

- **Donor Sperm**
Up to six cycles of donor insemination (dependent on availability of donor sperm) will be commissioned for heterosexual couples with azoospermia or oligospermia via donor Sperm.
If donor sperm is required for IVF, in the case of azoospermia, ICSI must NOT be clinically indicated in the couple’s individual circumstance.

**Pre-Implantation Genetic Diagnosis** (PiGD) is not covered by this commissioning policy as it is the commissioning responsibility of NHS England. Patients should be referred to the Genetic Centre at Birmingham Women’s & Children’s Hospital.

- **Donor Eggs**
Donor eggs will be funded where the patient is eligible for treatment with donor eggs, in line with NICE recommendations:

  - The patient has experienced premature ovarian failure (For the purposes of this policy premature ovarian failure is defined as a woman below the age of 35 years; with an absence of external factors / pathology where cessation of ovulation and menstruation has occurred and ovarian failure is confirmed by measurement of the ovarian reserve)
Pre-Implantation Genetic Diagnosis (PiGD) is not covered by this commissioning policy as it is the commissioning responsibility of NHS England. Patients should be referred to the Genetic Centre at Birmingham Women’s & Children’s Hospital.

In vitro Maturation (IVM)
IVM is not routinely commissioned due to the lack of currently available clinical evidence to demonstrate the effectiveness of this technique.

HIV/HEP B/ HEP C
People undergoing IVF treatment should be routinely offered testing for HIV, Hepatitis B and Hepatitis C (NICE 2013).
People found to test positive for one or more of HIV, Hepatitis B, or Hepatitis C should be offered specialist advice and counselling and appropriate clinical management (NICE 2013).

Surrogacy
The commissioner does not fund surrogacy arrangements or any associated treatments (including fertility treatments) related to those in surrogacy arrangements.

Single Embryo Transfer
Multiple births are associated with greater risk to mothers and children and the HFEA therefore recommends that steps are taken by providers to minimize multiple births. The CCG supports the HFEA guidance on single embryo transfer and will be performance monitoring commissioned tertiary providers to ensure that HFEA targets are met. All providers are required to have a multiple births minimisation strategy. The target for multiple births should now be an upper limit of 10% of all pregnancies.

- The patient has received cytotoxic therapy which has caused ovarian failure
- The patient has a diagnosed chromosomal abnormality e.g. Turner’s syndrome
- The patient’s ovaries have been removed

Unfortunately, the availability of suitably matched donor eggs remains variable due to the characteristics of the recipient. There is, therefore, no guarantee that eligible patients will be able to proceed with treatment. The average waiting time is as little as 18months, but will be much longer for some patients. Patients who require donor eggs will be placed on the waiting list for an initial period of 1 year, after which they will be reviewed annually to assess whether the assisted conception policy eligibility criteria are still met.
5. **Treatment Abroad under the European Union Cross Border Team.**
The commissioner has commissioned a local tertiary specialist fertility pathway which they expect patients within their commissioning area of responsibility to follow. If the patient would like to make an application to the EU Cross Border team for treatment abroad, then the patient must meet all of the eligibility criteria set out in this policy and this must be evidenced to the EU Cross Border team in writing by the commissioned fertility treatment provider with a supporting letter from the commissioned specialist fertility centre, detailing the clinical reasons why treatment abroad is recommended for the individual patient / couple. Prior approval for an EU Cross Border application must be sought by the specialist fertility centre from the commissioner and the commissioner must be satisfied that the proposed EU provider meets the HFEA standards for treatment, for example, the proposed EU infertility service provider must have a multiple births minimisation strategy. The target for multiple births should now be an upper limit of 10% of all pregnancies. – All applications and consent for funding must be delivered in accordance with and not deviate from the Birmingham and Solihull CCG’s Assisted Conception Policy.
6. Principles of care

Couples who experience problems in conceiving should be seen together because both partners are affected by decisions surrounding investigation and treatment.

Both partners, or the individual if the individual alone is requesting infertility treatment, must have Birmingham and Solihull CCG as their responsible commissioner.

People should have the opportunity to make informed decisions regarding their care and treatment via access to evidence-based information. These choices should be recognised as an integral part of the decision-making process.

Information should be provided in the following formats:

☐ Face to face discussions with couples
☐ Written information and advice
☐ Culturally sensitive
☐ Be sensitive to those with additional needs e.g. physical or cognitive, or sensitive disabilities, or those who do not speak English.

☐ As infertility and infertility treatments have a number of psycho-social effects on couples, once referred to a specialist tertiary centre for fertility treatment, access to counselling prior to and during treatment should be considered as integral to the care pathway.

☐ Providers of specialist fertility services are expected to deliver appropriate interventions to support lifestyle behaviour changes which are likely to have a positive impact on the outcome of assisted conception techniques and resulting pregnancies. Recommendations covering screening, brief advice and onward referral are outlined in NICE Public Health Guidance (PH49) and, specifically in relation to fertility and pre-conception, smoking (PH 26, PH48), weight management (PH27, PH53), healthy eating and physical activity (PH11, NG7) and alcohol (PH24).

☐ Use any appointment or meeting as an opportunity to ask women and their partners about their general lifestyle including smoking, alcohol consumption, physical activity and eating habits. If they practice unhealthy behaviours, explain how health services can support people to change behaviour and sustain a healthy lifestyle.

In a heterosexual couple trying to conceive, if primary care interventions (i.e. lifestyle advice) are not effective following one year of unprotected regular sexual inter-course in the absence of known reproductive pathology or disability, then the couple should be offered the following initial assessments in primary care:

☐ Semen analysis
☐ Female Follicle Stimulating Hormone & Progesterone Levels

It would also be appropriate at this stage for the primary care clinician to discuss the care pathway and potential eligibility for fertility treatment with the couple.
Following these initial primary care diagnostics, if all results are within normal parameters then the couple (as long as the woman is below the age of 38 years) should be advised to continue with regular unprotected intercourse for a further year.

If, after a further year, conception has not taken place, then the couple should be referred to secondary care services for further investigations.

If initial diagnostic test results are abnormal then the couple should be referred to secondary care where further investigation and potential treatments will be carried out, such as hormonal therapies to stimulate ovulation. The couple should be advised again at this stage of the care pathway and potential eligibility criteria for IVF/ICSI treatment. It may also be appropriate for healthy lifestyle interventions to be reiterated.

If secondary care interventions are not successful and the couple fulfils the eligibility criteria, they may then be referred through to tertiary care for assessment for assisted conception techniques where clinically appropriate if the couple meets the eligibility criteria set out in Sections 3 & 4, such as, DI, IUI, IVF and ICSI.

IUI involves:

- High quality sperm are separated from sperm that is sluggish or non-moving.
  - This sperm is then injected directly into the womb. IUI may be undertaken either with the woman’s partner’s sperm or donor sperm (known as donor insemination).
- It may be used in the treatment of:
  - People who need donated sperm but have no female fertility problems, including single women and same sex couples.
  - Couples who are unable (or would find it very difficult) to have vaginal intercourse, for example because of a permanent physical disability. Those who have a condition which means they need specific help to get pregnant (for example, men who are HIV positive and have had sperm washing to reduce the risk of passing on the disease to their partner and potential child).

DI involves:

- The use of donor sperm or eggs to try and achieve a pregnancy.
- It may be used in the treatment of:
  - Patients who are not producing sperm or eggs of their own
  - Patients where their own sperm or eggs are unlikely to result in a pregnancy
  - Patients who have a high risk of passing on an inherited disease
  - Patients in a same sex couple, or
  - Patients who are single.
**IVF involves:**
- The use of drugs to switch off the natural ovulatory cycle.
- Induction of ovulation with other drugs
- Monitoring the development of the eggs in the ovary
- Ultrasound guided egg collection from the ovary
- Processing of sperm
- Production of a fertilized embryo from sperm and egg cells in the laboratory
- Use of progesterone to make the uterus receptive to implantation
- Transfer of selected embryos and freezing of those suitable but not transferred

**ICSI involves:**
- Exactly the same treatment as with IVF for the female partner.
- The only difference is that instead of mixing the sperm with the eggs and leaving them to fertilise, a skilled embryologist (embryo specialist) will inject a single sperm into the egg.
- This maximises the chance of fertilisation taking place as it bypasses any potential problems the sperm will have in actually getting to the egg.
- The doctor may recommend ICSI if:
  - The man has a very low sperm count
  - The man’s sperm are abnormally shaped (poor morphology) or they don’t move normally (poor motility)
- The man requires sperm to be collected surgically from the testicles or epididymis (a narrow tube inside the scrotum where sperm are stored and matured); for example because the man does not ejaculate sperm, or because the man has an extremely low sperm count
  - The man is using frozen sperm in the treatment which isn’t of the highest quality
- The couple require embryo testing for a genetic condition
Guidance

NICE 2018. Fertility Overview


NICE 2017 Fertility problems CG 156
https://www.nice.org.uk/guidance/cg156/ifp/chapter/egg-donation


http://guidance.nice.org.uk/CG156


https://www.nice.org.uk/guidance/ph49


https://www.nice.org.uk/guidance/ph26

NICE (2013) NICE Public Health Guidance (PH48) Smoking: acute, maternity and mental health services

https://www.nice.org.uk/guidance/ph48

NICE (2010) NICE Public Health Guidance (PH27) Weight management before, during and after pregnancy

https://www.nice.org.uk/guidance/ph27

NICE (2014) NICE Public Health Guidance (PH53) Weight management: lifestyle services for overweight or obese adults

https://www.nice.org.uk/guidance/ph53


https://www.nice.org.uk/guidance/ph11


https://www.nice.org.uk/guidance/ng7


https://www.nice.org.uk/guidance/ph24
Appendix 1 - Definitions

<table>
<thead>
<tr>
<th>Item</th>
<th>Definition</th>
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<tbody>
<tr>
<td>Assisted Conception</td>
<td>The collective name for all techniques used artificially to assist conception and pregnancy, including In vitro fertilisation (IVF), Intra-cytoplasmic sperm injection (ICSI), Intrauterine insemination (IUI) and donor insemination (DI). These techniques are referred to as Infertility Treatment.</td>
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<tr>
<td>Female/Partner/Couple</td>
<td>Any reference to a female/partner/couple could relate to any of the following:</td>
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<td></td>
<td>o Heterosexual couple; a male and a female in a relationship; same sex female couple. A single female</td>
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<td></td>
<td>o Transgender male; biologically born as a female, gender reassigned to male, retention of female reproductive organs</td>
</tr>
<tr>
<td></td>
<td>o Transgender female, biologically born as a male, gender reassigned to female, retention of male reproductive organs</td>
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<tr>
<td>Infertility</td>
<td>• A female of reproductive age, who has not conceived after 1 year of unprotected vaginal sexual intercourse, in the absence of any known cause of infertility, should be offered further clinical assessment (Follicle Stimulating Hormone &amp; Progesterone levels) and investigation along with her partner (sperm analysis).</td>
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<td>• Following the first year and clinical investigation: Where the cause of infertility is known, the couple should be referred to secondary care services without further delay for further investigation and treatment as clinically required.</td>
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<td></td>
<td>• In the absence of any known cause of infertility, and where the woman is below 38 years of age, the couple should be referred to secondary care services for further investigations and treatment after a further 1 year of regular unprotected vaginal sexual intercourse</td>
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<td></td>
<td>• A female who has a known cause of infertility, e.g. Turner Syndrome should be immediately referred for specialist assessment and where</td>
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<td>Reproductive Pathology</td>
<td>Diagnosis of a recognised condition that renders a patient infertile or reduces fertility, including confirmed diagnosis of:</td>
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<td>- Polycystic Ovarian Syndrome (PCOS, including amenorrhea and oligomenorrhea)</td>
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<td>- Early onset of menopause</td>
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<td>- Complete amenorrhea</td>
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<td>- Endometriosis which has previously been surgically treated</td>
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<td>- Clinically significant fibroids</td>
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<td>- Pelvic Inflammatory Disease</td>
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<td>- Ovarian Failure including Turner’s syndrome and other genetic abnormalities</td>
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<td>- Azoosperma</td>
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<td>- Undescended testes</td>
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<td>- Tubal disorders and/or damage as a result of disease or trauma (e.g. blocked fallopian tubes, blocked seminal tubes); this does not include patients who have chosen to receive sterilisation surgery.</td>
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<td>- A permanent physical disability preventing vaginal sexual intercourse</td>
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<td>- Certain types of treatment (e.g. cytotoxic therapy) which permanently prevents the individual producing gametes (eggs/sperm)</td>
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<tr>
<td></td>
<td>- Certain types of treatment (e.g. cytotoxic therapy) which permanently causes genetic abnormalities in the eggs/sperm. Oligozoospermia /Asthenozoospermia / Teratozoospermia, or any combination of these.</td>
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<td>- Chronic Anovulation</td>
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| One cycle of fertility treatment | A cycle will consist of ovulation induction, egg retrieval, fertilisation and one fresh embryo(s) transfer |
In vitro Maturation (IVM) | In the IVM process, eggs are removed from your ovaries when they are still immature. They are then matured in the laboratory before being fertilised.

| Sperm washing | Sperm washing has been developed for couples who wish to have a child where the male partner is HIV positive but the female is HIV negative (referred to as HIV discordant status). The aim is to reduce the risk of HIV transmission by attempting to achieve pregnancy through insemination of sperm washed free of HIV rather than through unprotected intercourse.

The technique used to do this is called **sperm washing**) and rests on the observation that HIV infective material is carried in the fluid around the sperm (seminal fluid) rather than by sperm itself. The technique involves separating the HIV infected seminal fluid from the sperm by centrifugation and ‘washing’. The ‘washed’ sperm is then combined with nutritional fluid, tested for HIV using a sensitive test called a ‘PCR’ assay and, provided this is negative, inseminated into the female partner when she is ovulating and most likely to become pregnant. In couples with fertility problems washed sperm can be used in other fertility treatments such as IVF.
**Appendix 2 – Eligibility Criteria**

| 1a. | Age of Female Partner wishing to conceive | In females aged under 40 years, offer NHS infertility treatment. If the woman reaches the age of 40 during treatment, complete the current full cycle but do not offer further full cycles. | The age of the female partner at the time of treatment must be under 40 years of age. - If infertility is clinically identified in a female from the age of 18 years old - NHS infertility treatment should be offered without delay. - Where the woman is aged 38 - 39 years of age, the couple should be offered referral to specialist NHS infertility centre for assessment without further delay. Referrals for NHS infertility treatment should be made on or before the females 39th birthday (i.e. at least 12 months before her 40th birthday) to ensure relevant investigations can be completed, and treatment must have commenced. Consistent with NICE Guideline. Fall off in treatment success with increasing maternal age. Increased maternal and child complication rate. Prevention of delays in treatment where appropriate. Whilst NICE recommend an extension of the female age to 42 where specific criteria are met, the success rates for this cohort of patients is relatively low. For females aged under 34, success rates are 41%; in females aged 40-42, this drops down to 21%. [HFEA Trends and Figures 2011] |
### 1b. Age of Male Partner

| Both female fertility and (to a lesser extent) male fertility decline with age. [CG 1.2.1] | The age of the male partner at the time of treatment must be under 55 years of age. | HFEA regulations enable men to donate sperm to assist infertile people and recommend that sperm donors should be aged under 41 years; the possible effect of a donor's age on assisted conception success is considered on a case by case basis. There is limited evidence that IVF success decreases in men over the age of the 40. Men aged over 40 are half as likely to conceive with IVF compared to 30-year-old men when their female partner is aged 35-39 years (de La Rochebrochardet al., 2006). However, male age does not impact on the success of other infertility treatment such as ICSI (Spandorfer et al, 1998). In light of some evidence that |
male age does impact on infertility, and may have an impact on IVF outcomes, and keeping in line with other CCG areas which stipulate a male age restriction of 55 years, we have included this as a criterion for eligibility.

| 2. | Childlessness | n/a | NHS infertility treatment will NOT be funded if either partner has living children of any age; this includes an adopted child or a child (biological or adopted) from either the present or a previous relationship. Once accepted for treatment, should a child be adopted or a pregnancy leading to a live birth occur, the couple / individual will no longer be considered childless and will not be eligible for NHS funded treatment. |
| 3. | Previous Infertility Treatment | n/a | NHS infertility treatment will not be offered to people where |

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| 103 | NHS Birmingham and Solihull Clinical Commissioning Group  
NHS Sandwell and West Birmingham Clinical Commissioning Group | either partner within the couple has already undertaken any previous infertility treatment (IVF/ICSI) for fertility problems, regardless of whether the treatment was funded by the NHS or privately funded. | optimal number of couples. |
| 4. | Sterilisation | n/a | NHS infertility treatment will not be available if either partner within the couple has received a sterilisation procedure or has undertaken a reversal of sterilisation procedure. |
|   |   |   | Sterilisation is offered within the NHS as an irreversible method of contraception. Protocols for sterilisation include counselling and advice that NHS funding will not be available for reversal of the procedure or any fertility treatment consequently to this. |
| 5. | Body Mass Index | Females who have a body mass index (BMI) of 30 or over should be informed that they are likely to take longer to conceive. | The female wishing to conceive must have a BMI of <30 kg/m² at the time of referral and commencement of treatment. Females wishing to conceive must be informed of this criterion at the earliest opportunity and offered the Consistent with NICE Guideline. |
| 6. Smoking / Vaping Status | Females who smoke/vape should be informed that this is likely to reduce their fertility, should be offered referral to a smoking cessation programme to support their efforts in stopping smoking/vaping, and informed that passive smoking is likely to affect their chance of conceiving. Men who smoke/vape should be informed that there is an association between smoking and reduced semen quality (although the impact of this on male fertility is uncertain), and that stopping smoking/vaping will improve their general health. | Only non-smoking females/couples will be eligible for fertility treatment; smoking must have ceased by both partners three months prior to referral for infertility treatment. | Maternal and paternal smoking can adversely affect the success of infertility treatment and smoking during the antenatal period can lead to increased risk of adverse pregnancy outcomes. Females should be informed that passive smoking is likely to affect their chance of conceiving. There is an association between smoking and reduced semen quality. The impact of vaping on conception, pregnancy and the passive impact of vaping is uncertain and without further evidence of the safety of vaping in conception / pregnancy / childhood, this cannot be currently recommended as an alternative to smoking. |
Policy for the Provision of NHS funded Gamete Retrieval and Cryopreservation for the Preservation of Fertility
The CCG policy has been reviewed and developed by the Treatment Policies Clinical Development Group in line with the groups guiding principles which are:

1. CCG Commissioners require clear evidence of clinical effectiveness before NHS resources are invested in the treatment;
2. CCG Commissioner require clear evidence of cost effectiveness before NHS resources are invested in the treatment;
3. The cost of the treatment for this patient and others within any anticipated cohort is a relevant factor;
4. CCG Commissioners will consider the extent to which the individual or patient group will gain a benefit from the treatment;
5. CCG Commissioners will balance the needs of each individual against the benefit which could be gained by alternative investment possibilities to meet the needs of the community
6. CCG Commissioners will consider all relevant national standards and take into account all proper and authoritative guidance;
7. Where a treatment is approved CCG Commissioners will respect patient choice as to where a treatment is delivered; AND
8. All policy decision are considered within the wider constraints of the CCG’s legally responsibility to remain fiscally responsible.
Category: Restricted

1. Gamete Retrieval and Cryopreservation.

This policy lays out the CCG commissioning intentions regarding the retrieval and storage of gametes for patients in certain clinical circumstances as outlined below.

Gametes are sex cells. The male gametes are the sperm, and the female gametes are the eggs. Conception (getting pregnant) happens when a man’s sperm fertilises a woman’s egg.

In certain circumstances, a man or a woman’s fertility may be compromised for a number of reasons:

- Certain types of treatment (e.g. cytotoxic therapy) which permanently prevents the individual producing gametes (eggs/sperm) or
- Certain types of treatment (e.g. cytotoxic therapy) which permanently causes genetic abnormalities in the eggs/sperm.
- The ovaries or testes may, in certain clinically required circumstances, (e.g. to prevent the spread of disease) need to be surgically removed which results in infertility.
- The patient has premature ovarian failure.

Gamete Retrieval is the extraction of gametes (by surgical or non-surgical methods) which can then be stored for future use.

Cryopreservation is the process of storing biological material at extreme temperatures; most common -196 °C/-321 °F in nitrogen (N₂) vapour. At these low temperatures, all biological activity stops, including the biochemical reactions that lead to cell death and DNA degradation.

Patients undergoing treatments such as chemotherapy for cancer or radical surgery may be made sterile by such treatments. Where there is a significant likelihood of making a patient permanently infertile as an unwanted side-effect of NHS funded treatment, including gender reassignment, those patients will be eligible, under the CCG commissioned pathway, for gamete retrieval and cryopreservation to preserve fertility, provided they meet the criteria described below. This may be done by storing gametes (eggs or sperm), prior to treatment. Following the completion of the NHS funded treatment, these gametes may be used to assist conception. If the patient
requires CCG funding for assisted conception, then the patient will be required to evidence how he/she meets the currently commissioned Assisted Conception Policy.

Patients may also experience infertility through chromosomal abnormalities, e.g. Turner’s syndrome or through premature ovarian Insufficiency, which is defined for the purposes of this policy as: a woman below the age of 40 years; with an absence of external factors / pathology which has caused the ovarian failure, where cessation of ovulation has occurred and ovarian failure is confirmed by measurement of the ovarian reserve). In such cases it may be possible to store some eggs before the ovaries stop functioning completely.

2. Eligibility Criteria:

2.1 The patient must be permanently registered with a Birmingham and Solihull CCG GP practice.

AND

2.2 The patient must have no living children.

The aim of this criterion is to give priority to individuals with no existing living children. An adopted child has the same status as an individual’s biological child. However, self-funding for gamete retrieval and storage is still possible.

AND

2.3 Age.

2.3.a Upper age restrictions for both men and women will be in line with those patients funded for fertility services under the Assisted Conception policy in place at the time of the funding request.

2.3.b At the time the Policy for the Provision of NHS funded Gamete Retrieval and Cryopreservation for the Preservation of Fertility 2018 was commissioned these limits were as follows:

- A woman must be under the age of 40
- A man must be under the age of 55 years.

There is clinical evidence which demonstrates that a women’s fertility falls with age, significantly dropping by the age of 40 years. Chromosomal abnormality increases with age in men and increases significantly after the age of 55 years. Gamete retrieval (surgical or non-surgical) will be offered to all women aged 39 or younger and all men aged 55 years or younger at the date of the procedure, when the patient also meets the other eligibility criteria set out in this policy.
There is no lower age limit applied in this policy however all patients including those aged under 16 years must be able to understand the procedure being carried out and considered competent to give informed consent.

AND

2.4 The patient must meet ONE of the following clinical criteria:

2.4.a The patient must be undergoing NHS funded treatment which is likely to render the patient permanently infertile e.g. cytotoxic therapy

OR

2.4.b The patient is at immediate risk of premature ovarian failure.

For the purposes of this policy premature ovarian failure is defined as:

- a woman below the age of 35 years;
- with an absence of external factors / pathology which have impacted on fertility, the patient is experiencing a cessation of ovulation and menstruation
- ovarian failure is confirmed by measurement of the ovarian reserve

OR

2.4.c The patient has a diagnosed chromosomal abnormality which is likely to render the patient permanently infertile.

e.g. Turner’s syndrome which carries a high risk of premature ovarian failure

OR

2.4.d The patient's ovaries/testes are going to be removed as part of NHS funded treatment.

e.g. to prevent the spread of disease in a cancer diagnosis or the patient is undergoing gender reassignment.

AND

2.5. The funding application must be supported by the NHS consultant providing their care.
AND

2.6 The patient has NOT undergone a previous sterilisation and/or reversal of sterilisation procedure.

Gamete retrieval and cryopreservation will not be funded where the patient has previously undergone elective sterilisation (vasectomy or the fallopian tubes are blocked or sealed to prevent the eggs from reaching the sperm and becoming fertilised).

2.7 Previous Assisted Conception

Access to NHS funded 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 currently commissioned Assisted Conception Policy at the time of any funding application.

3 Timescales for NHS Funding for Storage of Gametes

Where the eligibility criteria (Section 2) are met, NHS funding will be available as set out below from the date of the retrieval of the patient’s gametes.

The funding parameters set out below in Section 3.1 are ONLY for patients who have been assessed as eligible under the terms of Section 2 above, for the specific storage of eggs or sperm for the preservation of fertility and NOT as part of fertility treatment. Funding parameters for those patients undergoing fertility treatment are set out in Section 3.2.

3.1.a. The patient will give written consent for an initial storage term of 10 years. If the gametes are to be stored for longer than the initial 10 years for which consent was given, the patient’s consent must be reviewed and reacquired from the patient and the patient must continue to meet the medical criteria for premature infertility.

AND

3.1.b. i. If gamete storage is to be funded under the terms of this policy, the CCG will fund gamete storage for up to 5 years or until the patient’s 30th birthday, whichever arrives later.

OR

3.1.b. ii. If storage is to be funded under the terms of this policy, the CCG will fund gamete storage for up to 5 years or until the patient’s 39th birthday (female) or 55th birthday (male) whichever arrives sooner.

AND

3.1.c. The patient must have a valid written storage agreement with the provider in place.
AND

3.1.d. Beyond the above timescales for CCG funded storage, as long as the patient continues to meet the criteria for storage, i.e. medically confirmed infertility, if the patient wishes for cryopreservation of his/her gametes, then the patient will be solely responsible for the annual storage fee.

3.2. Patients having CCG funded fertility treatment - IVF or ICSI - Cryopreservation of Embryos.

3.2.a. Embryos which are not used during the CCG funded fresh transfer cycle should be quality graded using the UK NEQAS embryo morphology scheme and may be frozen for subsequent use.

3.2.b. Cryopreservation and storage of any suitable surplus embryos following a completed CCG funded cycle is for a period of 12 months, in line with Human Fertilisation and Embryology Authority (HFEA) guidelines and is funded by the specialist tertiary treatment provider.

3.2.c. The consent to storage completed by patients is for ten years.

3.2.d. Patients must use the embryos within the legally consented storage period, at the end of this time if the storage consent agreement is not renewed then the embryos will be removed from storage and will perish.

3.2.e. Funding - the CCG does not fund for storage of embryos resulting from IVF / ICSI. The clinic will offer storage for the first year free of charge. After the first year, if any embryos remain in storage, the patient will be sent a reminder letter detailing that gametes remain in storage, and if they wish to keep the gametes stored they will be invoiced the agreed annual fee to continue storage. They will pay this annually until used, or perished or up to ten years. No storage is allowed beyond ten years at present.

3.2.f. If the patient has undergone unsuccessful IVF/ICSI treatment and has stored embryos and then experiences a loss of fertility, and meets the eligibility criteria set out in section 2, then the CCG will fund cryopreservation of the embryos with the consent of both partners for 5 years or until the female partner’s 39th birthday, whichever comes sooner.

ALL funding renewals for gamete storage will be considered in line with the ages specified in the Assisted Conception Policy in place at the time of application.

Patients may choose to self-fund storage once NHS funding ceases within the terms of the Human Fertility and Embryology Act 1990.
Human Embryo and Fertility Act 1990

Cryopreservation of gametes or embryo’s must meet the current legislative standards.

The provider of the service must ensure the patient receives appropriate counselling and provides full consent.

In the case of embryo preservation, both partners must be made aware of the legal position regarding embryos which have been cryopreserved, should one partner remove consent to their ongoing storage or use.

Patients must also be 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.

The provider of the service should contact patients annually to confirm that they wish to continue storage. The patient will be responsible for ensuring the storage provider has up to date contact details.

The provider must ensure that material is only stored where there is valid consent in place.
## Appendix 1

### Definitions

<table>
<thead>
<tr>
<th>Item</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>Assisted Conception</td>
<td>The collective name for all techniques used artificially to assist conception and pregnancy, including In vitro fertilisation (IVF), Intra-cytoplasmic sperm injection (ICSI), Intrauterine insemination (IUI) and donor insemination (DI). These techniques are referred to as Infertility Treatment.</td>
</tr>
<tr>
<td>Female/Partner/Couple</td>
<td>Any reference to a female/partner/couple could relate to any of the following:</td>
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<tr>
<td></td>
<td>- Heterosexual couple; a male and a female in a relationship; same sex female couple; A single female</td>
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<tr>
<td></td>
<td>- Transgender male; biologically born as a female, gender reassigned to male, retention of female reproductive organs</td>
</tr>
<tr>
<td></td>
<td>- Transgender female, biologically born as a male, gender reassigned to female, retention of male reproductive organs</td>
</tr>
<tr>
<td>Infertility</td>
<td>A female of reproductive age, who has not conceived after 1 year of unprotected vaginal sexual intercourse, in the absence of any known cause of infertility, should be offered further clinical assessment (FSH &amp; progesterone levels) and investigation along with her partner (sperm analysis). Following the first year and clinical investigation:</td>
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<td>- Where the cause of infertility is known, the couple should be referred to secondary care services without further delay for further investigation and treatment as clinically required.</td>
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<tr>
<td></td>
<td>- In the absence of any known cause of infertility, and where the woman is below 38 years of age, the couple should be referred to secondary care services for further investigations and treatment after a further 1 year of regular unprotected vaginal sexual intercourse A female who has a known cause of infertility, e.g. Turner Syndrome should be immediately referred for specialist assessment and where clinically indicated infertility treatment without delay.</td>
</tr>
<tr>
<td></td>
<td>In circumstances where the above definition cannot be applied, for example females in a same sex relationship, a single female, or a transgender male, infertility is identified where the female has not conceived after 6 cycles of self-funded donor or partner insemination, undertaken at a Human Fertilisation and</td>
</tr>
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</table>
### Embryology Authority (HFEA) registered clinic, in the absence of any known medical cause of infertility.

<table>
<thead>
<tr>
<th>One cycle of fertility treatment</th>
<th>A cycle will consist of ovulation induction, egg retrieval, fertilisation and one fresh embryo(s) transfer to the uterus, including all appropriate diagnostic tests, scans and pharmaceutical therapy.</th>
</tr>
</thead>
</table>
| **Reproductive Pathology**       | Diagnosis of a recognised condition that renders a patient infertile or reduces fertility, including confirmed diagnosis of:  
- Polycystic Ovarian Syndrome (PCOS, including amenorrhea and oligomenorrhea)  
- Early onset of menopause  
- Complete amenorrhea  
- Endometriosis which has previously been surgically treated  
- Clinically significant fibroids  
- Pelvic Inflammatory Disease  
- Ovarian Failure including Turners syndrome and other genetic abnormalities  
- Azoospermia  
- Undescended testes  
- Tubal disorders and/or damage as a result of disease or trauma (e.g. blocked fallopian tubes, blocked seminal tubes); this does not include patients who have chosen to receive sterilisation surgery.  
- A physical disability preventing vaginal sexual intercourse  
- Planned/received treatment that has resulted in infertility eg. cancer treatment  
- Oligozoospermia /Asthenozoospermia /Teraotozoospermia, or any combination of these.  
- Chronic Anovulation |
| One cycle of fertility treatment | A cycle will consist of ovulation induction, egg retrieval, fertilisation and one fresh embryo(s) transfer to the uterus, including all appropriate diagnostic tests, scans and pharmaceutical therapy. |
| In vitro Maturation (IVM)         | In the IVM process, eggs are removed from your ovaries when they are still immature. They are then matured in the laboratory before being fertilised. |
| Sperm washing                    | Sperm washing has been developed for couples who wish to have a child where the male partner is HIV positive but the female is HIV negative (referred to as HIV discordant status). The aim is to reduce the risk of HIV transmission by attempting to achieve pregnancy |
through insemination of sperm washed free of HIV rather than through unprotected intercourse.

The technique used to do this is called **sperm washing** and rests on the observation that HIV infective material is carried in the fluid around the sperm (seminal fluid) rather than by sperm itself. The technique involves separating the HIV infected seminal fluid from the sperm by centrifugation and ‘washing’. The ‘washed’ sperm is then combined with nutritional fluid, tested for HIV using a sensitive test called a 'PCR' assay and, provided this is negative, inseminated into the female partner when she is ovulating and most likely to become pregnant. In couples with fertility problems washed sperm can be used in other fertility treatments such as IVF.
### Appendix 2 – Eligibility Criteria

|   | Age of Female Partner wishing to conceive | In females aged under 40 years, offer NHS infertility treatment. If the woman reaches the age of 40 during treatment, complete the current full cycle but do not offer further full cycles. | The age of the female partner at the time of treatment must be under 40 years of age.  
- If infertility is clinically identified in a female from the age of 18 years old - NHS infertility treatment should be offered without delay.  
- Where the woman is aged 38 - 39 years of age, the couple should be offered referral to specialist NHS infertility centre for assessment without further delay.  

Referrals for NHS infertility treatment should be made on or before the females 39th birthday (i.e. at least 12 months before her 40th birthday) to ensure relevant investigations can be completed, and treatment must have commenced prior to the females 40th birthday. | Consistent with NICE Guideline. Fall off in treatment success with increasing maternal age. Increased maternal and child complication rate. Prevention of delays in treatment where appropriate.  
Whilst NICE recommend an extension of the female age to 42 where specific criteria are met, the success rates for this cohort of patients is relatively low. For females aged under 34, success rates are 41%; in females aged 40-42, this drops down to 21%. [HFEA Trends and Figures 2011]. |
<table>
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<tbody>
<tr>
<td>1a.</td>
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<td>1b</td>
<td>Age of Male Partner</td>
<td>Both female fertility and (to a lesser extent) male fertility decline with age. [CG 1.2.1]</td>
<td>The age of the male partner at the time of treatment must be under 55 years of age.</td>
</tr>
<tr>
<td>2.</td>
<td>Childlessness</td>
<td>n/a</td>
<td>NHS infertility treatment will NOT be funded if either partner has living children of any age; this includes an adopted child or a child (biological or adopted) from either the present or a previous relationship.</td>
</tr>
</tbody>
</table>
Once accepted for treatment, should a child be adopted or a pregnancy leading to a live birth occur, the couple/individual will no longer be considered childless and will not be eligible for NHS funded treatment.

| 3. | Previous Infertility Treatment | n/a | NHS infertility treatment will not be offered to people where either partner within the couple has already undertaken any previous infertility treatment (IVF/ICSI) for fertility problems, regardless of whether the treatment was funded by the NHS or privately funded. | The ability of the commissioner to provide infertility treatment to the optimal number of couples. |
| 4. | Sterilisation | n/a | NHS infertility treatment will not be available if either partner within the couple has received a sterilisation procedure or has undertaken a reversal of sterilisation procedure. | Sterilisation is offered within the NHS as an irreversible method of contraception. Protocols for sterilisation include counselling and advice that NHS funding will not be available for reversal of the procedure or any fertility treatment consequently to this. |
| 5. | Body Mass Index | Females who have a body mass index (BMI) of 30 or over should be informed that they are | The female wishing to conceive must have a BMI of <30 kg/m² at the time of referral and commencement of treatment. | Consistent with NICE Guideline. |
| Smoking / Vaping Status | Females who smoke/vape should be informed that this is likely to reduce their fertility, should be offered referral to a smoking cessation programme to support their efforts in stopping smoking/vaping, and informed that passive smoking is likely to affect their chance of conceiving. Men who smoke/vape should be informed that there is an association between smoking and reduced semen quality (although the impact of this on male fertility is uncertain), and that stopping smoking/vaping will likely to take longer to conceive. | Females wishing to conceive must be informed of this criterion at the earliest opportunity and offered the support of local NHS services to optimise their BMI. Only non-smoking females/couples will be eligible for fertility treatment; smoking must have ceased by both partners three months prior to referral for infertility treatment. | Maternal and paternal smoking can adversely affect the success of infertility treatment and smoking during the antenatal period can lead to increased risk of adverse pregnancy outcomes. Females should be informed that passive smoking is likely to affect their chance of conceiving. There is an association between smoking and reduced semen quality. The impact of vaping on conception, pregnancy and the passive impact of vaping is uncertain and without further evidence of the safety of vaping in conception / pregnancy / childhood, this cannot be currently recommended as an alternative to smoking. |
improve their general health.
Policy for Acupuncture (for indications other than back pain)
The CCG policy has been reviewed and developed by the Treatment Policies Clinical Development Group in line with the groups guiding principles which are:

1. CCG Commissioners require clear evidence of clinical effectiveness before NHS resources are invested in the treatment;
2. CCG Commissioner require clear evidence of cost effectiveness before NHS resources are invested in the treatment;
3. The cost of the treatment for this patient and others within any anticipated cohort is a relevant factor;
4. CCG Commissioners will consider the extent to which the individual or patient group will gain a benefit from the treatment;
5. CCG Commissioners will balance the needs of each individual against the benefit which could be gained by alternative investment possibilities to meet the needs of the community
6. CCG Commissioners will consider all relevant national standards and take into account all proper and authoritative guidance;
7. Where a treatment is approved CCG Commissioners will respect patient choice as to where a treatment is delivered; AND
8. All policy decision are considered within the wider constraints of the CCG’s legally responsibility to remain fiscally responsible.
Category: Restricted

Acupuncture

Acupuncture is a treatment derived from ancient Chinese medicine. Fine needles are inserted at certain sites in the body for therapeutic or preventative purposes. Both traditional (‘Eastern’) and ‘Western’ approaches to acupuncture exist, and acupuncture can also be assisted through the use of electrical stimulation (electro-acupuncture).

Acupuncture is often seen as a form of complementary or alternative medicine (CAM). It involves stimulating sensory nerves under the skin and in the muscles of the body. This results in the body producing natural substances, such as pain-relieving endorphins.

Acupuncture is used in some general practices, as well as settings including pain clinics and hospices in the UK. Acupuncture practitioners – sometimes called acupuncturists – use acupuncture to treat a wide range of health conditions. However, the use of acupuncture is not always based on rigorous scientific evidence.

Currently, NICE only recommends considering acupuncture as a treatment option for:

- chronic tension-type headaches
- migraines

NICE in November 2016, recommended that acupuncture should not be used to treat back pain or radicular (sciatic) pain in NICE Guidance 59.

Acupuncture is also often used to treat other musculoskeletal conditions (of the bones and muscles) and pain conditions. However, in many conditions where acupuncture is used, there is insufficient high quality evidence to draw any clear conclusions over acupuncture’s effectiveness compared with other treatments.

Tension –Type Headaches (TTH)

TTH typically presents with attacks of headache (usually bilateral) which are pressing or tightening (non-pulsating) in quality and of mild to moderate intensity lasting minutes to days.

- The pain is not aggravated by routine activities of daily living and is not associated with nausea or autonomic symptoms — photophobia or phonophobia may occur in some cases.
- Neurological examination should be normal.
- Pericranial tenderness on manual palpation may be present.

There are different types of TTH as defined below:

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NHS Birmingham and Solihull Clinical Commissioning Group
NHS Sandwell and West Birmingham Clinical Commissioning Group
- **Infrequent episodic TTH** — At least 10 episodes of headache occurring on fewer than 1 day per month on average and fulfilling criteria:
  - Lasting from 30 minutes to 7 days.
  - At least two of: bilateral location; pressing or tightening (non-pulsating) quality; mild or moderate intensity; not aggravated by routine physical activity such as walking or climbing stairs.
  - No nausea or vomiting and no more than one of photophobia or phonophobia.
  - Not better accounted for by another cause.

- **Frequent episodic TTH** — at least 10 episodes of headache occurring on 1–14 days per month on average for more than 3 months and fulfilling criteria:
  - Lasting from 30 minutes to 7 days.
  - At least two of: bilateral location; pressing or tightening (non-pulsating) quality; mild or moderate intensity; not aggravated by routine physical activity such as walking or climbing stairs.
  - No nausea or vomiting and no more than one of photophobia or phonophobia.
  - Not better accounted for by another cause.

- **Chronic TTH** — headache occurring on 15 or more days per month on average for more than 3 months and fulfilling criteria:
  - Lasting hours to days, or unremitting.
  - At least two of: bilateral location; pressing or tightening (non-pulsating) quality; mild or moderate intensity; not aggravated by routine physical activity such as walking or climbing stairs.
  - No moderate or severe nausea or vomiting and no more than one of photophobia or phonophobia.
  - Not better accounted for by another cause.

---

**Migraine**

**Migraine with aura**

Suspect aura in people who present with or without headache and with neurological symptoms that:

- are fully reversible and
- develop gradually, either alone or in succession, over at least 5 minutes and
- last for 5–60 minutes.
Diagnose migraine with aura in people who present with or without headache and with one or more of the following typical aura symptoms that meet the criteria above.

- visual symptoms that may be positive (for example, flickering lights, spots or lines) and/or negative (for example, partial loss of vision)
- sensory symptoms that may be positive (for example, pins and needles) and/or negative (for example, numbness)
- speech disturbance.

Consider further investigations and/or referral for people who present with or without migraine headache and with any of the following atypical aura symptoms that meet the criteria in recommendation

- motor weakness
- double vision
- visual symptoms affecting only one eye
- poor balance
- decreased level of consciousness
Eligibility Criteria – Chronic Tension Type Headaches:

- **The patient must be diagnosed with Chronic Tension – Type Headaches** as defined by NICE:
  - Headache occurring on 15 or more days per month on average for more than 3 months and fulfilling criteria:
    - Lasting hours to days, or unremitting.
    - At least two of: bilateral location; pressing or tightening (non-pulsating) quality; mild or moderate intensity; not aggravated by routine physical activity such as walking or climbing stairs.
    - No moderate or severe nausea or vomiting *and* no more than one of photophobia or phonophobia.
    - Not better accounted for by another cause.
  - If the patient fulfills the above criteria, then the patient may be offered **ONE course of up to 10 sessions of prophylactic acupuncture over 5–8 weeks.**
Eligibility Criteria – Migraines with Aura

- The patient must be diagnosed with Migraine with Aura as per NICE guidance:
  - are fully reversible and
  - develop gradually, either alone or in succession, over at least 5 minutes and
  - last for 5–60 minutes.

AND
- the patient has exhausted ACUTE treatments as defined by NICE 2012:
  - Offer combination therapy with an oral triptan and an NSAID, or an oral triptan and paracetamol.
  - If monotherapy is preferred, offer an oral triptan, or NSAID, or aspirin (900 mg every 4–6 hours when necessary up to a maximum of 4 g daily), or paracetamol.
  - Consider adding an anti-emetic (such as metoclopramide, domperidone, or prochlorperazine) even in the absence of nausea and vomiting
  - Do NOT use ergots or opioids
  - If treatment has not been adequate, or was poorly tolerated, reconfirm diagnosis, reassess lifestyle advice, check that usage of treatment is correct, and rule out medication-overuse headache.
  - Consider prescribing a triptan that is more suitable for the patient
  - If the person has tried two or more triptans unsuccessfully, or treatment is successful but attacks are frequent, consider preventive treatment (see Preventive treatment).

AND
- medication overuse headache has been excluded from the patient’s presentation.

AND
- the patient has one of the following:
  - visual symptoms that may be positive (for example, flickering lights, spots or lines) and/or negative (for example, partial loss of vision)
  - sensory symptoms that may be positive (for example, pins and needles) and/or negative (for example, numbness)
  - speech disturbance.

If the patient fulfils the above criteria, then the patient may be offered ONE course of up to 10 sessions of prophylactic acupuncture over 5–8 weeks.
This means (for patients who DO NOT meet the above criteria) the CCG will **only** fund the treatment if an Individual Funding Request (IFR) application proves exceptional clinical need and that is supported by the CCG.
Guidance:

NICE Low back pain and sciatica in over 16s: assessment and management. NICE guideline [NG59] Published date: November 2016
https://www.nice.org.uk/guidance/ng59

NHS Choices 2016 Acupuncture. [page updated 22/08/2016)
https://www.nhs.uk/conditions/acupuncture/

NICE CG150 Headaches in over 12s: diagnosis and management (Nov 2015)
https://www.nice.org.uk/guidance/cg150


British Association for the Study of Headache 2010 Guidelines for all healthcare professionals in the diagnosis and management of migraine, tension-type, cluster and medication-overuse headache.

International Classification of Headache Disorders (2013) 3rd edition (beta version)
https://www.ichd-3.org/

International Classification of Headache Disorders 2013 Diagnosis and treatment of headache
https://www.ichd-3.org/

https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4541429/


Policy for the use of Mechanical Insufflator/Exsufflator (MI-E) - Cough Assist Machines
The CCG policy has been reviewed and developed by the Treatment Policies Clinical Development Group in line with the groups guiding principles which are:

1. CCG Commissioners require clear evidence of clinical effectiveness before NHS resources are invested in the treatment;
2. CCG Commissioner require clear evidence of cost effectiveness before NHS resources are invested in the treatment;
3. The cost of the treatment for this patient and others within any anticipated cohort is a relevant factor;
4. CCG Commissioners will consider the extent to which the individual or patient group will gain a benefit from the treatment;
5. CCG Commissioners will balance the needs of each individual against the benefit which could be gained by alternative investment possibilities to meet the needs of the community
6. CCG Commissioners will consider all relevant national standards and take into account all proper and authoritative guidance;
7. Where a treatment is approved CCG Commissioners will respect patient choice as to where a treatment is delivered; AND
8. All policy decision are considered within the wider constraints of the CCG’s legally responsibility to remain fiscally responsible.
Cough Assist Machines.

An effective cough is an essential protective mechanism against respiratory tract infections. Cough can become ineffective due to respiratory muscle weakness in neurological and neuromuscular conditions, prolonged inactivity (e.g. post intubation), nerve injury, tracheostomy and vocal cord pathology.

Patients who have an ineffective/weak cough due to neuromuscular and neurological conditions and cervical cord injury are unable to clear secretions and are therefore susceptible to respiratory tract infections including pneumonia which require antibiotics and hospital admission. Respiratory tract infections caused by respiratory muscle weakness is the most common cause of hospital admission for patients with neuromuscular conditions. These include patients with conditions such as muscular dystrophy, spinal muscular atrophy, motor neurone disease and spinal cord injury.

The mechanical insufflator/exsufflator (MI-E/ Cough Assist machine) assists the clearance of bronchopulmonary secretions in those patients with an ineffective cough by the use of both positive and negative pressure.

The MI-E (Cough Assist Machine) is a non-invasive therapy that safely and consistently removes secretions in patients with an ineffective ability to cough (measured by peak cough flow <270 l/m). The Cough Assist device clears secretions by gradually applying a positive pressure to the airway, then rapidly shifting to negative pressure. The rapid shift in pressure produces a high expiratory flow, creating an effective cough by significantly increasing peak cough flow, which improves airway clearance and removes bronchopulmonary secretions, thereby preventing and reducing respiratory tract infections.

Respiratory function should be assessed in people with more complex care needs by a Specialist Ventilation MDT that includes consultants with a special interest in ventilatory support / weaning, physiotherapists, specialist ventilation nurses. The MDT may include palliative care and speech and language clinicians.

All patients being considered for cough assist device should be discussed with the Local Respiratory Specialist Team, however ONLY the Specialist Ventilation MDT may assess and apply for funding for a cough assist machine for the patient however, once funding has been secured, the local Respiratory Specialist Team may provide assessment, equipment if clinically indicated and on-going monitoring and support to the patient. If annual funding renewal is required, then review with the Specialist Ventilation MDT will be required to ensure that use of the device remains clinically indicated in the patient.

N.B the Specialist Ventilation MDT will need to be ratified by the CCG as an appropriate centre, with an appropriately skilled MDT prior to funding applications being accepted by the CCG.
**Benefits of Cough Assist**

- Removes secretions from the lungs
- Reduces the occurrence of respiratory infections and the ensuing requirement for antibiotics
- Supports a patient to avoid hospitalisation and need for intubation and tracheostomy
- Recruits lung volume and prevents atelectasis
- Decreases the risk of patient mortality
- Safe, non-invasive alternative to suctioning
- Easy for patients and caregivers to operate
- Can be used with a face mask, mouthpiece or with an adapter to a patient's endotracheal or tracheostomy tube
- Approved for home use in adults and children
- Available in automatic and manual models
- Portable so patients can increase independence and clear secretions in community, thereby improving quality of life

In preparing this policy, an evidence review was commissioned to ascertain the strength of the available clinical evidence to support the use of cough assist machines. Clinical and public engagement was undertaken which highlighted a number of studies and clinical opinion, published since the evidence review was undertaken.

The CCG, noted in particular, the significant amount of clinical opinion, both, local, national and international, which supported the use of cough assist machines in certain clinical circumstances within the community. The support of the use of the device by NHS England within an in-patient setting in certain clinical circumstances was also taken into consideration and the support given to the use of the machines by NICE and the British Thoracic Society, despite the availability of often low quality evidence to support the use of cough assist machines. It was noted by the CCG that it may potentially be difficult for Randomised Control trials to be undertaken in this area due to ethical considerations and that each procedure / treatment which is reviewed in the policy pathway is reviewed in the specific and individual circumstances in which it is presented.
Eligibility Criteria

The patient must be diagnosed with one of the following conditions:

- Motor Neurone Disease
- Spinal Muscular Atrophy
- Muscular Dystrophy
- Myasthenia gravis
- Spinal cord injury
- Multiple Sclerosis
- Guillain-Barre Syndrome
- Post-polio syndrome with respiratory impairment
- Kypho-scoliosis
- Syringomyelia
- Other neuromuscular disease which is known to cause respiratory muscle weakness or upper airway functional impairment.

AND

In line with the above diagnosis the patient must also be unable to cough or clear secretions effectively:

- PCF (Peak Cough Flow) less than 160 L/min AND
- VC (vital capacity) below 1.1L in general respiratory muscle weakness, AND
- Reduced Peak Cough Flow (PCF) of 270 l/pm or < 270 l/pm and have clinical symptoms or a weak cough and therefore require intervention necessary to clear bronchial secretions or infection

AND

The patient must be assessed and continue to be monitored by a specialist ventilation team with expert clinical knowledge and experience in the use of Cough Assist machines.

AND

Prior approval for funding must be sought for a cough assist machine to be provided in the community prior to the patient being supplied with a Cough Assist machine. For each patient funded with a Cough Assist Machine the provider should provide a written annual update by the specialist ventilation team to evidence that continuation of treatment is clinically effective before the next year of funding will be continued.
Contraindications to treatment with a Cough Assist Machine

The specialist ventilation team will individually assess each patient prior to commencing treatment with a cough assist machine and consider all contraindications before use.

These could include:
- Any patient with a history of bullous emphysema
- Susceptibility to pneumothorax or pnuemo-mediastinum

This means (for patients who DO NOT meet the above criteria) the CCG will only fund the treatment if an Individual Funding Request (IFR) application proves exceptional clinical need and that is supported by the CCG.
Guidance:


35. Chatwin


52. Sivasothy P, Brown L, Smith IE, Shneerson JM. Effect of manually assisted cough and mechanical insufflation on cough flow of normal subjects, patients with chronic obstructive pulmonary disease (COPD), and patients with respiratory muscle weakness. Thorax 2001;56(6):438-44


https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2764727/


by people with neuromuscular disorders: effects on health service use and lifestyle benefits. Orphanet Journal of Rare Diseases 10: 54.
Policy for the Management of Ear Wax
The CCG policy has been reviewed and developed by the Treatment Policies Clinical Development Group in line with the groups guiding principles which are:

1. CCG Commissioners require clear evidence of clinical effectiveness before NHS resources are invested in the treatment;
2. CCG Commissioner require clear evidence of cost effectiveness before NHS resources are invested in the treatment;
3. The cost of the treatment for this patient and others within any anticipated cohort is a relevant factor;
4. CCG Commissioners will consider the extent to which the individual or patient group will gain a benefit from the treatment;
5. CCG Commissioners will balance the needs of each individual against the benefit which could be gained by alternative investment possibilities to meet the needs of the community
6. CCG Commissioners will consider all relevant national standards and take into account all proper and authoritative guidance;
7. Where a treatment is approved CCG Commissioners will respect patient choice as to where a treatment is delivered; AND
8. All policy decision are considered within the wider constraints of the CCG’s legally responsibility to remain fiscally responsible.
Ear Wax

Earwax is a normal physiological substance which is a combination of dead flattened cells, cerumen (a wax-like substance), sebum. The external auditory meatus may also contain residue from cosmetics and environmental dust.

Earwax cleans, lubricates, and protects the lining of the ear canal, trapping dirt and repelling water.

People are at risk of impacted earwax if they:

- Have narrow or deformed ear canals.
- Have excessive hairs in their ear canals.
- Have benign bony growths in the external auditory canal (osteomata).
- Have a dermatological disease (psoriasis or eczema) of the peri-auricular area or scalp.
- Produce hard wax, as this is more likely to become impacted.
- Are elderly (earwax tends to become drier in older people).
- Have a history of recurrent impacted wax.
- Have recurrent otitis externa.
- Have Down's syndrome.

The most common symptoms caused by impacted earwax are:

- Conductive hearing loss.
- Earache.
- Tinnitus.
- Vertigo.

Other conditions which should be excluded (ruled out) include:

- Otitis externa (inflammation of the auricle or external ear canal due to allergy, infection, or eczematous conditions).
- Foreign bodies (particularly in children).
NICE (2016) recommends earwax should be removed if it is totally occluding the ear canal AND one of the following:

- The person is symptomatic (conductive hearing loss; earache; tinnitus; vertigo).
- The tympanic membrane is obscured by wax but needs to be viewed to establish a diagnosis.
- The person wears a hearing aid and an impression needs to be taken for a mould, or wax is causing the hearing aid to whistle.

Consider ear irrigation using an electronic irrigator to remove earwax in adults, provided there are no contraindications:
- eardrum perforation
- ear infection
- Previous ear surgery.

When carrying out ear irrigation in adults:

- use pre-treatment wax softeners, either immediately before ear irrigation or for up to 5 days beforehand
- if irrigation is unsuccessful:
  - i. repeat use of wax softeners or
- If irrigation is unsuccessful after the second attempt, refer the person to a specialist ear care service or an ear, nose and throat service for removal of earwax.

Consider microsuction or other methods of earwax removal (such as manual removal using a probe) for adults in primary or community care only if:

- the practitioner (such as a community nurse or audiologist) has training and expertise in using these methods to remove earwax and
- the correct equipment is available.

**Do not offer adults manual ear syringing to remove earwax.**

Advise adults not to remove earwax or clean their ears by inserting small objects, such as cotton buds, into the ear canal. Explain that this could damage the ear canal and eardrum, and push the wax further down into the ear.

Anyone who has had earwax removed should be advised to return if they develop otalgia, itching, or discharge from the ear, or swelling of the external auditory meatus, as this may indicate infection.
Referral should be arranged to an Ear, Nose, and Throat specialist if the person has:

- A chronic perforation of the tympanic membrane.
- A past history of ear surgery.
- A foreign body in the ear canal.
- Used ear drops, which have been unsuccessful, and irrigation is contraindicated.
- Had unsuccessful irrigation.
- Eczema or psoriasis

Advice should be urgently sought from an Ear, Nose, and Throat specialist if:

- Severe pain, deafness, or vertigo occur during or after irrigation, or if a perforation is seen following the procedure.
- Infection is present and the external canal needs to be cleared of wax, debris, and discharge.
- If the person continues to experience hearing loss after wax removal arrange an audiogram.
Eligibility Criteria:

Ear irrigation as a management option for ear wax should be avoided whenever possible.

However, ear irrigation may be carried out in primary care by a specially qualified clinician in patients over the age of 6 months whom are concordant with the procedure and have a level of understanding required to enable the procedure to be carried out safely in the following circumstances:

- Patient must have used ear drops for at least 3-5 days before irrigation is undertaken AND the patient must have at least ONE of the following symptoms which has persisted despite ear drops.
- If earwax is totally occluding the ear canal and any of the following are present:
  - Hearing loss
  - Earache
  - Tinnitus
  - Vertigo
  - If the tympanic membrane is obscured by wax but needs to be viewed to establish a diagnosis
  - The person wears a hearing aid and an impression needs to be taken for a mould, or wax is causing the hearing aid to whistle.

Referral should be arranged to an Ear, Nose, and Throat specialist if the person has:

- A chronic perforation of the tympanic membrane.
- A past history of ear surgery.
- A foreign body in the ear canal.
- Used ear drops, which have been unsuccessful, and irrigation is contraindicated.
- Had unsuccessful irrigation.
- Eczema or psoriasis

N.B
The ear wax removal methods listed below are NOT commissioned by the CCG as per NICE recommendations:

- Manual ear syringing
- Advise people against inserting anything in the ear as cotton buds, matchsticks, self-irrigation or self-suction and hair pins can:
- Damage the wall of the canal and increase the likelihood of otitis externa.
- Cause the wax to become impacted by pushing it further into the canal.
- Perforate the tympanic membrane.
- Advise that the use of ear candles has no benefit in the management of earwax removal and may result in serious injury.

This means (for patients who DO NOT meet the above criteria) the CCG will only fund the treatment if an Individual Funding Request (IFR) application proves exceptional clinical need and that is supported by the CCG.
Please Note: Nurse Practitioners carrying out aural care, should ensure that they meet the competencies set out by the RCN (2018)
https://www.rcn.org.uk/professional-development/publications/pub-004266

Guidance:

NICE 2017 Hearing Loss. Hearing Loss in Adults: Diagnosis and Management. (currently in development, final document due for release May 2018)

https://cks.nice.org.uk/earwax
Policy for the Management of Umbilical, Para-Umbilical and Incisional Hernias.
The CCG policy has been reviewed and developed by the Treatment Policies Clinical Development Group in line with the groups guiding principles which are:

1. CCG Commissioners require clear evidence of clinical effectiveness before NHS resources are invested in the treatment;
2. CCG Commissioner require clear evidence of cost effectiveness before NHS resources are invested in the treatment;
3. The cost of the treatment for this patient and others within any anticipated cohort is a relevant factor;
4. CCG Commissioners will consider the extent to which the individual or patient group will gain a benefit from the treatment;
5. CCG Commissioners will balance the needs of each individual against the benefit which could be gained by alternative investment possibilities to meet the needs of the community;
6. CCG Commissioners will consider all relevant national standards and take into account all proper and authoritative guidance;
7. Where a treatment is approved CCG Commissioners will respect patient choice as to where a treatment is delivered; AND
8. All policy decision are considered within the wider constraints of the CCG’s legally responsibility to remain fiscally responsible.
Umbilical, Para-umbilical and Incisional Hernias

Umbilical, para-umbilical and incisional hernias are common abdominal hernias encountered in clinical practice, and involve the protrusion of intra-abdominal tissue through a defect in the abdominal wall. With umbilical and para-umbilical hernias, the defect is at or around the umbilicus, and with incisional hernias the defect is at the site of a previous operative incision.

Umbilical hernias are common at birth, but often resolve themselves over time; in adults these hernias are less likely to resolve spontaneously and may require surgical management. Umbilical/para-umbilical hernias are more common in women with multiple pregnancies and people who have a high BMI.

Incisional hernias emerge through defects at a previous incision site and are seen with 5 in 1,000 after laparoscopy and 150 in 1,000 after open abdominal wall incisions.

Management Options

Advances in laparoscopic approaches, prosthesis (‘mesh’ repairs), and operative care have resulted in research interest into the relative costs and benefits of alternatives to traditional ‘open repair’ approaches. Furthermore, there is increasing interest in watch and wait approaches, where previously surgery was routinely performed for asymptomatic presentations.

Success of surgical techniques can vary considerably based on surgical experience, equipment and technique used, nature of defect, patient characteristics and hospital/operative environment, making comparisons difficult. However, evidence reviewed showed a significantly reduced risk of surgical site infection following laparoscopic procedures.

Eligibility Criteria:

This policy is for the management of umbilical, para-umbilical and incisional hernias in adult patients.

- Strangulated umbilical, para-umbilical or incisional hernias should proceed to the most clinically appropriate surgery in a timely manner OR
- For non-urgent procedures, the patient must be diagnosed with a symptomatic umbilical, para-umbilical or incisional hernia AND
- The patient should be reviewed by the surgical clinician and in a shared decision making process, a decision should be reached as to the most clinically effective method of surgery for the individual patient, i.e. laparoscopic or open surgery. However, the evidence shows that laparoscopic surgery, where clinically appropriate, due to the significantly reduced rates of surgical site infection should be the preferred choice.
For the purposes of this policy symptomatic hernia is described as debilitating pain which impacts on activities of daily living, e.g. walking; sleeping; working

This means (for patients who DO NOT meet the above criteria) the CCG will only fund the treatment if an Individual Funding Request (IFR) application proves exceptional clinical need and that is supported by the CCG.
Guidance:


Policy for Complementary and Alternative Therapies
The CCG policy has been reviewed and developed by the Treatment Policies Clinical Development Group in line with the groups guiding principles which are:

1. CCG Commissioners require clear evidence of clinical effectiveness before NHS resources are invested in the treatment;
2. CCG Commissioners require clear evidence of cost effectiveness before NHS resources are invested in the treatment;
3. The cost of the treatment for this patient and others within any anticipated cohort is a relevant factor;
4. CCG Commissioners will consider the extent to which the individual or patient group will gain a benefit from the treatment;
5. CCG Commissioners will balance the needs of each individual against the benefit which could be gained by alternative investment possibilities to meet the needs of the community
6. CCG Commissioners will consider all relevant national standards and take into account all proper and authoritative guidance;
7. Where a treatment is approved CCG Commissioners will respect patient choice as to where a treatment is delivered; AND
8. All policy decision are considered within the wider constraints of the CCG’s legally responsibility to remain fiscally responsible.
Category: Not Routinely Commissioned

Complementary and Alternative Therapies

Complementary and Alternative therapies cover a wide range of therapies an evidence review undertaken on behalf of BSoI CCG, showed a lack of clinical evidence to support the clinical effectiveness of a variety of complementary and alternative therapies.

Acupuncture falls outside of this clinical review and is covered under a separate policy: ‘Acupuncture for Indications Other than Back Pain’.

Complementary and Alternative therapies are Not Routinely Commissioned due to a lack of evidence to support clinical effectiveness.

Homeopathy and herbal treatments are included in the NHS England Guidance to CCGs on Items which should not be routinely prescribed in Primary Care, this policy which reflects this guidance. The national guidance was subject to public consultation during autumn 2017, with local engagement running concurrently.
Eligibility Criteria:

**Complementary and Alternative Therapies Are Not Routinely Commissioned as stand-alone therapies.**

These include the following interventions:

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<tr>
<th>Active release technique</th>
<th>Flower essence</th>
<th>Mesotherapy</th>
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<tbody>
<tr>
<td>Acupressure</td>
<td>Fresh cell therapy</td>
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<td>Aimspro</td>
<td>Functional intracellular analysis</td>
<td>Moxibustion (except for fetal breech presentation) - see MTH-68 vaccine</td>
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<td>Auto urine therapy</td>
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<td>Aromatherapy</td>
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<td>Chelation therapy for Atherosclerosis</td>
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NHS Birmingham and Solihull Clinical Commissioning Group
NHS Sandwell and West Birmingham Clinical Commissioning Group
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<th>Chung Moo Doe therapy</th>
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<td>Craniosacral therapy</td>
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<tr>
<td>Cupping</td>
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<tr>
<td>Feldenkrais method of exercise therapy</td>
<td>Meridian therapy</td>
<td>Yoga</td>
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**N.B. The alternative and complimentary therapies/disciplines listed above are not exhaustive.**

This means (for patients who DO NOT meet the above criteria) the CCG will only fund the treatment if an Individual Funding Request (IFR) application proves exceptional clinical need and that is supported by the CCG.
Guidance


The full evidence review with references is available on the CCG website.
Policy for Vasectomy
The CCG policy has been reviewed and developed by the Treatment Policies Clinical Development Group in line with the groups guiding principles which are:

1. CCG Commissioners require clear evidence of clinical effectiveness before NHS resources are invested in the treatment;
2. CCG Commissioner require clear evidence of cost effectiveness before NHS resources are invested in the treatment;
3. The cost of the treatment for this patient and others within any anticipated cohort is a relevant factor;
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6. CCG Commissioners will consider all relevant national standards and take into account all proper and authoritative guidance;
7. Where a treatment is approved CCG Commissioners will respect patient choice as to where a treatment is delivered; AND
8. All policy decision are considered within the wider constraints of the CCG’s legally responsibility to remain fiscally responsible.
Vasectomy

A vasectomy is a surgical procedure performed on males in which the vas deferens (tubes that carry sperm from the testicles to the seminal vesicles) are cut, tied, cauterized (burned or seared) or otherwise interrupted. The semen no longer contains sperm after the tubes are cut, so conception cannot occur. The testicles continue to produce sperm, but they die and are absorbed by the body.

The purpose of this operation is to provide reliable contraception. Vasectomy is the most reliable method of contraception.

Vasectomy is the technique of interruption of the vas deferens with an intention to provide permanent contraception. The procedure can be performed under local or general anaesthesia. The traditional method involves making one or two incisions in the scrotal skin to expose the vas deferens. The vas deferens is then occluded and divided using various techniques.

A relatively new technique to expose the vas, the no-scalpel vasectomy (NSV), involves a puncture wound in the scrotal skin to access and occlude the vas. Following anaesthesia, a specially designed fixation clamp encircles and firmly secures the vas without penetrating the skin. Sharp-tipped dissecting forceps are then used to puncture the skin and vas sheath and to stretch a small opening in the scrotum. The vas is lifted and occluded, as with other vasectomy techniques. The same puncture hole can be used for the opposite vas or a separate puncture can be made. A number of NSV techniques are reported in the literature. It has been suggested that these techniques should not be referred to as NSV but instead be referred to as minimally invasive vasectomy (MIV). For the purposes of this policy, the term MIV will be used to encompass NSV and any modified versions of this technique where the skin opening is ≤10 mm, and the dissection area surrounding the vas deferens is minimised and does not require the use of skin sutures. MIV may include the use of a variety of surgical instruments, including a scalpel, to expose the vas.

Vasectomy should be performed under local anaesthesia wherever possible.

Post-vasectomy semen analysis (PVSA) should be carried out to identify early failure. Additional contraception should be used until azoospermia is confirmed or special clearance given. Evidence suggests that 12 weeks’ post-vasectomy is the optimal timing to schedule the first PVSA. Earlier or later testing is acceptable taking into account that earlier testing increases the probability of additional tests and later testing prolongs the need for additional contraception.

A routine second PVSA is not required if azoospermia is found in the first sample.
Eligibility Criteria

The CCG will fund vasectomy in the following circumstances:

- The man (and where possible his partner) have given fully informed consent for the permanent sterilisation procedure and have been informed that reversal of sterilisation is not available on the NHS and reversal of sterilisation has poor success rates. **AND**

- Minimally invasive vasectomy is the first choice of procedure under local anaesthetic in a commissioned community clinic setting. **AND**

- The patient has been fully informed of the postoperative follow-up and post procedure semen analysis

Vasectomy will be funded in an in-patient setting under general anaesthetic **ONLY** in the following circumstances:

- The patient is allergic to local anaesthetic **OR**
- The patient is taking anticoagulants or antiplatelet medications and risk of haemorrhage (bleeding) is high **OR**
- The patient has anatomic abnormalities, i.e. there is an inability to palpate and mobilize both vas deferens or large hydroceles or varicoceles **OR**
- There is past trauma which has resulted in scarring of the scrotum which would require surgery in an in-patient setting.

This means **(for patients who DO NOT meet the above criteria)** the CCG will **only** fund the treatment if an Individual Funding Request (IFR) application proves exceptional clinical need and that is supported by the CCG.

Guidance

NHS Choices. 2017. Vasectomy

[https://www.nhs.uk/Video/Pages/Vasectomy.aspx](https://www.nhs.uk/Video/Pages/Vasectomy.aspx)


Policy for Asymptomatic & Symptomatic Bunions
The CCG policy has been reviewed and developed by the Treatment Policies Clinical Development Group in line with the groups guiding principles which are:

1. CCG Commissioners require clear evidence of clinical effectiveness before NHS resources are invested in the treatment;
2. CCG Commissioners require clear evidence of cost effectiveness before NHS resources are invested in the treatment;
3. The cost of the treatment for this patient and others within any anticipated cohort is a relevant factor;
4. CCG Commissioners will consider the extent to which the individual or patient group will gain a benefit from the treatment;
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6. CCG Commissioners will consider all relevant national standards and take into account all proper and authoritative guidance;
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8. All policy decisions are considered within the wider constraints of the CCG’s legally responsibility to remain fiscally responsible.
HALLUX VALGUS

Hallux valgus is the deviation of the big toe (the hallux) away from the mid-line towards the lesser toes. The metatarsal head drifts towards the midline and this together with its overlying bursa and inflamed soft tissue is known as the bunion, which causes pain and rubbing on shoes.

Hallux rigidus is the development of arthritic changes within the joint causing stiffness, pain and deformity. Hallux valgus and rigidus are frequently accompanied by lesser toe changes such as hammer or claw toes and abnormal weight distribution under the lesser toes which can be painful (metatarsalgia).

Hallux valgus (deviation of the big toe)) is often accompanied with, or mistaken for, hallux interphalangeus, where the tip of the big toe is deviated laterally (moved to one side), although symptoms may be similar. Deformity may contribute to impaired balance, which can increase the incidence of falls.

Untreated hallux valgus deformity in patients with diabetes (and other causes of peripheral neuropathy) may lead to ulceration, deep infection and even below knee amputation.

BUNIONS

Bunions are common, and more so in advanced age and in females. Prevalence has been estimated at 23% in adults aged 18-65 years and 35.7% in those aged over 65 years. Footwear often contributes to this problem. Patients with hallux valgus and rigidus have worse pain than the general population. Surgery can improve the quality of life in this group.

Overall satisfaction rates following surgery are good (more than 80% in most studies), but studies are small and follow up short.

The exact cause of bunions is unknown, but they tend to run in families. Wearing badly fitting shoes is thought to make bunions worse. It's also thought that bunions are more likely to occur in people with unusually flexible joints, which is why bunions sometimes occur in children. In some cases, certain health conditions, such as rheumatoid arthritis and gout, may also be responsible.

There are a number of treatment options for hallux vagus (bunions). Non-surgical treatments include painkillers, orthotics (insoles) and bunion pads.

While surgery is usually effective (symptoms are improved in 85% of cases), bunions can sometimes return. Complications occur after bunion surgery. These will depend on the type of surgery the patient has had and can include:

- stiffness in the toe joints
- a delay or failure of the bone to heal or the bone healing in the wrong position
• pain under the ball of the foot
• damage to the nerves in the foot
• prolonged swelling and continued pain
• the need for further surgery

The best way to reduce the patient’s chances of developing bunions is to wear shoes that fit properly. Shoes that are too tight or have high heels can force the patient’s toes together.

Primary Care Assessment

• The diagnosis of a bunion is usually based on clinical findings. Not all people with bunions have symptoms.
• Examine the person both sitting down and standing (standing up may exaggerate the deformity). Look for:
  o Lateral deviation of the first toe at the metatarsophalangeal (MTP) joint.
  o Movement of the first toe towards the second toe.
  o Prominence of the first metatarsal head.
  o Medial bursitis over the first MTP joint (as a result of irritation from shoes).
• Rule out alternative diagnoses, such as:
  o Hallux rigidus (arthritis of the metatarsophalangeal joint).
  o Gout.
  o Sesamoiditis.
  o Fractures.
  o Rheumatological disease.
  o Neurological pain (may be related to diabetes).
  o Infection.

Assessment

• Establish the reason for consultation.
  • The person may:
    o Require symptomatic relief only.
    o Have difficulty in fitting into footwear (resulting in skin trauma).
    o Have no symptoms but dislike the look of their foot or the type of footwear that must be worn to accommodate the foot.

• Assess the severity of the bunion(s).
  • Ask about: The duration of pain and the presence of paraesthesia (not all people with bunions are symptomatic). The patient may report medial first
metatarsophalangeal (MTP) joint or plantar foot pain, which is often worse when wearing shoes, may occur on weight bearing, and may be described as deep and aching if associated with joint degeneration. The effect of symptoms on the patient's lifestyle and activities.

- **Assess the degree of deformity.**
  - This depends on the extent of lateral deviation of the proximal phalanx from the first metatarsal (this can be formally measured using weight-bearing X-ray images, usually done in secondary care if referral is necessary). Also check for involvement of the second toe (may be at risk of dislocation).

- **Assess for degenerative joint disease** (which may develop in people with long-standing or severe bunions).
  - Ask the person to stand on tiptoe if they are able (stiffness of the first MTP joint may indicate osteoarthritis).

- **Enquire about a medical history of diabetes, vascular disease, or neuropathy,** and check for:
  - Skin quality (foot ulceration can occur if there are areas of skin breakdown).
  - Calluses or corns (indicate points of overload).
  - Pulses and sensation.

- **Assess footwear,** and ask what types of shoes are normally worn and whether there has been any recent change in footwear.

- **Enquire about treatments that have already been tried,** such as bunion pads or over-the-counter analgesics

**Management**

- Advise patients presenting with bunions that:
  - They should wear low-heeled, wide shoes with a soft sole.
  - Bunions can be progressive.
  - Non-surgical treatments (for example medication, bunion pads, orthoses) may relieve symptoms but do not limit progression.

- If the patient is symptomatic:
  - Offer oral analgesia (for example paracetamol or a nonsteroidal anti-inflammatory drug, such as ibuprofen).
  - Advise self-care treatments for symptomatic relief, such as bunion pads (available over-the-counter) or ice packs.
  - Consider referral to podiatry for footwear advice or consideration of a night splint or orthosis.
• Offer written information, i.e. CCG patient information leaflet.
• If analgesia and self-care measures are not effective, consider referral.
  o Advise the person that:
    ▪ Referral for bunion surgery is indicated for symptomatic bunions (see eligibility criteria below) and is not routinely commissioned for cosmetic purposes.
    ▪ Conservative treatment may be more appropriate than surgery for some older people, or people with severe neuropathy or other comorbidities affecting their ability to undergo surgery.
  o Refer for orthopaedic or podiatric surgery consultation according to local policy and service provision. Situations where referral may be of benefit include if:
    ▪ The deformity is painful and worsening.
    ▪ The second toe is involved.
    ▪ The person has difficulty obtaining suitable shoes.
    ▪ There is significant disruption to lifestyle or activities.
  o If the patient is referred for consideration of surgery, advise that:
    ▪ Surgery is usually done as a day case.
    ▪ Bunion surgery is one of the most commonly-performed foot and ankle procedures. It may help relieve pain and improve the alignment of the toe in most people (85%–90%); however, there is no guarantee that the foot will be perfectly straight or pain-free after surgery.
    ▪ Complications after bunion surgery may include infection, joint stiffness, transfer pain (pain under the ball of the foot), hallux varus (overcorrection), bunion recurrence, damage to the nerves, and continued long-term pain.
• Refer to a diabetic foot protection service if the person has diabetes.
Intermediate Care – Community Foot Health Service

- Commissioned services must be integrated into a multidisciplinary network and include the skills for example:
  - Musculoskeletal (MSK) physiotherapy
  - Podiatry (non-surgical and surgical)
  - Orthotics
  - Rheumatology
  - Orthopaedic surgery

Assessment:
- History - as above
- Examination: As above
  - Examine for metatarsalgia
  - Lesser toe deformity
  - Overall lower leg alignment
  - Presence of tibialis posterior dysfunction
  - Investigation - weight bearing X-rays (only if indicated, such as to guide injection; if to be undertaken include: Weight bearing X-rays Anteroposterior (AP), Lateral & Oblique)

Management:
- Providers must adopt a shared decision making model, define treatment goals and take into account personal circumstances.
- Patient information should be provided.
- Footwear assessment and provision of offloading orthotics as appropriate.
- Physiotherapy:
  - Balance, proprioception, and core stability, calf muscle stretches, and to treat features of tibialis posterior tendon dysfunction.
- Injections:
  - Only indicated if inflammation or arthritis is suspected or if patient unfit for surgery.
  - Contraindicated if infection is suspected.
  - Radiographs (X-rays - Weight bearing X-rays - Anteroposterior (AP), Lateral & Oblique) should be performed prior to procedure.

Refer for surgery:
- Deteriorating symptoms.
- Failure of appropriate conservative measures after three months.
- Persistent pain and disability not responding to up to 12 weeks of non-surgical treatments; this time to include any treatment received in primary care.
- Patient must be prepared to undergo surgery understanding that they will be out of sedentary work for 2-6 weeks and physical work for 2-3 months and they will be unable to drive for 6-8 weeks (2 weeks if left foot and driving automatic car).
- Age, gender, smoking, obesity and co-morbidity should not be barriers to referral.
- Patients with significant co-morbidities [systemic or local] should have treatment which optimises these before referral.
- For clarification, co-morbidities must be managed through a shared decision making process with the patient, enabling patients to make joint decisions on referral and treatment.
- Patients who are not suitable for surgery should be referred for a complex care package.
Secondary Care Assessment:
- History - as above, diagnosis confirmed.
- Examination - as above, other pathologies excluded.

Investigations:
- Weight bearing X-rays - Anteroposterior (AP), Lateral & Oblique and;
- Further imaging (e.g.: Ultrasound, MRI) as indicated.

Management:
- Providers must adopt a shared decision making model, define treatment goals and take into account personal circumstances, all alternatives MUST be discussed.
- Patient information should be provided.

Surgery:
Criteria for intervention are the same as the criteria for referral.
- MUST NOT be undertaken for prophylactic or cosmetic reasons.
- Should be undertaken by orthopaedic surgeons trained in foot and ankle surgery or Health and Care Professions Council registered podiatric surgeons (CCPST), integrated into a multi-disciplinary network.
- Is usually day case or 23-hour admission, unless clinical or social circumstances dictate otherwise.
- A minimum of 3 outpatient follow up appointments by appropriately experienced foot and ankle clinicians.
- Review of standing radiographs within 8 weeks by surgeon.
- It is recommended that PROM (Patient Reported Outcome Measures) scores be recorded at least 12 months following surgical episode.
- There are a number of surgical options. The procedure selected will depend on: patient symptoms/signs and patient choice having considered with the surgeon the risk and benefits of each. These require appropriate facilities. There is no conclusive evidence for the superiority of one operation over another.
- Surgery is simpler and more successful in the earlier stages of deformity.
- Recurrence of deformity after bunion surgery occurs in 8 - 15% of patients.
- Non-union of fusion for hallux rigidus occurs in up to 10% of cases.
- Complex surgery (e.g. complex revision infection with bone loss avascular necrosis and neurological deformity) must be undertaken by surgeons with a recorded interest in complex foot and ankle surgery working in high volume centre with appropriate facilities.
- Minimal access techniques must only be undertaken as part of a research project or where special arrangements for audit are in place (NICE IPG 332).
- In cases of post-operative complications, primary care should ideally be able to refer the patient back to the same surgical team, should the patient want this.

Patients should be informed that the decision to have surgery can be a dynamic process and a decision to not undergo surgery does not exclude them from having surgery at a future time point.
Eligibility Criteria:

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<tr>
<th>Surgery for Asymptomatic Hallux Valgus (Bunions) is not routinely commissioned.</th>
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<tr>
<td>If the patient has diagnosed diabetes and presents with an asymptomatic bunion the patient should be referred to a community foot health service.</td>
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<tr>
<th>Surgery for Symptomatic Hallux Valgus (Bunions) will be funded in the following circumstances:</th>
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<tr>
<td>• The patient has a confirmed diagnosis of a bunion AND</td>
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<td>• The patient has deteriorating symptoms AND</td>
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<td>• ALL Conservative measures have failed after three months AND</td>
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<td>• The patient is experiencing persistent pain and disability due to the hallux valgus, which is causing functional impairment and has not responded following 12 weeks of conservative measures AND</td>
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<td>• The patient must be prepared to undergo surgery, understanding that they will be out of sedentary work for 2-6 weeks and physical work for 2-3 months and they will be unable to drive for 6-8 weeks (2 weeks if left foot and driving automatic car) AND</td>
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<td>• Weight bearing X-rays - Anteroposterior (AP), Lateral &amp; Oblique have been undertaken prior to surgery. AND</td>
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<tr>
<td>• The provider has adopted a shared decision making model, with defined treatment goals and has taken into account personal circumstances, with ALL alternatives discussed with the patient AND the procedure will be undertaken by orthopaedic surgeons trained in foot and ankle surgery or Health and Care Professions Council registered podiatric surgeons (CCPST), integrated into a multi-disciplinary network.</td>
</tr>
</tbody>
</table>

Deteriorating symptoms are defined for the purposes of this policy as the following:

- moderate or severe pain AND functional impairment AND redness/soreness OR
- Bigger demormation, 2nd toe affected/lifting OR
- Callus under 2nd MTPJ.

Conservative measures are defined for the purposes of this policy as the following:

- Ensure footwear is appropriate (lower heels; wider fitting shoes; moulded shoes) AND
- the patient has been advised on and has trialled patient directed approach (bunionpads, over the counter analgesia, ice to relieve pain and inflammation) AND
- the use of offloading orthotics has been exhausted AND
- the patient has been provided with the patient leaflet.

Functional impairment is defined as interfering with activities of daily living, i.e. sleeping; eating; walking.
N.B.: Current evidence on the efficacy of surgical correction of hallux valgus using minimal access techniques is limited and inconsistent. In addition, the evidence relates to a range of different surgical techniques. The evidence on safety is inadequate. (NICE 2010). Therefore, surgical correction of hallux valgus using minimal access techniques is Not Routinely Commissioned in any circumstances.

This means (for patients who DO NOT meet the above criteria) the CCG will only fund the treatment if an Individual Funding Request (IFR) application proves exceptional clinical need and that is supported by the CCG.

Information regarding clinical outcomes and patient reported outcome measures following surgery were submitted during the engagement period and demonstrated good outcomes at 1, 2, 4 and 9.5 years’ post-surgery.
Guidance:


*JBJS*: October 2000 - Volume 82 - Issue 10 - p 1373-1373


NICE 2010. Surgical correction of hallux valgus using minimal access techniques. Interventional procedures guidance. IPG332. nice.org.uk/guidance/ipg332


