NHS Birmingham and Solihull CCG
NHS Sandwell and West Birmingham CCG

DRAFT
Policy Knee Arthroscopy for Acute Knee Injury

Document Details:

Version:	DRAFT v1.
Ratified by (name and date of Committee):	Treatment Policy Clinical Development Group
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Equality & Diversity Impact Assessment	

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.

Category: Restricted

The Knee

The 3 bones that meet in the knee are the:

- thigh bone (femur)
- shin bone (tibia)
- kneecap (patella)

These bones are connected by 4 ligaments – 2 collateral ligaments on the sides of the knee and 2 cruciate ligaments inside the knee.

Ligaments are tough bands of connective tissue. The ligaments in the knee hold the bones together and help keep the knee stable.

The menisci are thick pads of cartilage tissue within the knee which act as shock absorbers to absorb body weight and help improve smooth movement and stability of the knee.

The two main areas within the knee which may be damaged by an acute injury include:

1. Menisci (cartilage)
2. Ligaments

1. **Menisci.**

What is the knee meniscus?

The menisci are thick pads of cartilage tissue within the knee which act as shock absorbers to absorb body weight and help improve smooth movement and stability of the knee. Each knee joint contains a medial and lateral meniscus (inner and outer meniscus).

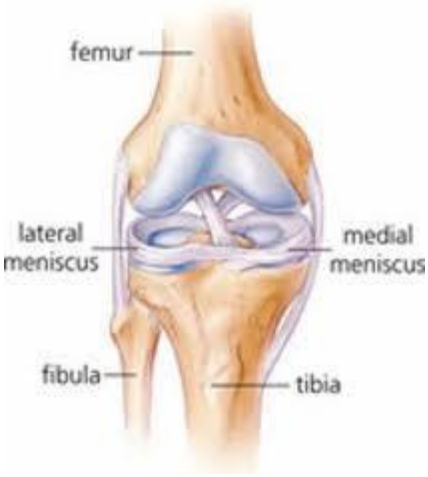

Figure 1. The Knee Joint

What is a meniscal injury?

There are varying degrees of damage a patient can do to the menisci. These range from bruising the menisci through to having large tears of the menisci. Meniscal tears can occur during sporting activities through twisting the knee whilst the foot is still in contact with the ground. In severe injuries, other parts of the knee may also be damaged in addition to a meniscal tear. For example, a patient may also sprain or tear a ligament. Meniscal cartilage does not always heal very well once it is torn. This is mainly because the central area of the meniscus does not have a good blood supply. The outer edge of each meniscus has some blood vessels, but the area in the centre has no direct blood supply.

Conservative Treatment

The PRICE protocol is effective for most sports-related injuries. PRICE stands for Protection, Rest, Ice, Compression, and Elevation.

- **Protection** – protect the affected area from further injury – for example, by using a support.
- **Rest** – avoid exercise and reduce your daily physical activity. Using crutches or a walking stick may help if you can't put weight on your ankle or knee. **Ice** – apply an ice pack to the affected area for 15-20 minutes every two to three hours. A bag of frozen peas, or similar, will work well. Wrap the ice pack in a towel so that it doesn't directly touch your skin and cause an ice burn.
- **Compression** – use elastic compression bandages during the day to limit swelling.
- **Elevation** – keep the injured body part raised above the level of your heart whenever possible. This may also help reduce swelling.

Non-steroidal anti-inflammatory medicines. Drugs like aspirin and ibuprofen reduce pain and swelling.

Physiotherapy for those whose symptoms do not resolve.

Surgical Treatment

Procedure. Knee arthroscopy is one of the most commonly performed surgical procedures. During a knee arthroscopy,, a miniature camera is inserted through a small incision (portal). This provides a clear view of the inside of the knee. The orthopaedic surgeon, then inserts miniature surgical instruments through other portals to trim or repair the tear.

- Partial meniscectomy. In this procedure, the damaged meniscus tissue is trimmed away.

- Meniscus repair. Some meniscus tears can be repaired by suturing (stitching) the torn pieces together. Whether a tear can be successfully treated with repair depends upon the type of tear, as well as the overall condition of the injured meniscus. Because the meniscus must heal back together, recovery time for a repair is much longer than from a meniscectomy.

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Risks of meniscal surgery

The knee may not be exactly like it was before the injury, and the patient may still have some pain and swelling.

This may be because of other injuries to the knee, such as tears or injuries to ligaments, which happened at the same time as or after the injury.

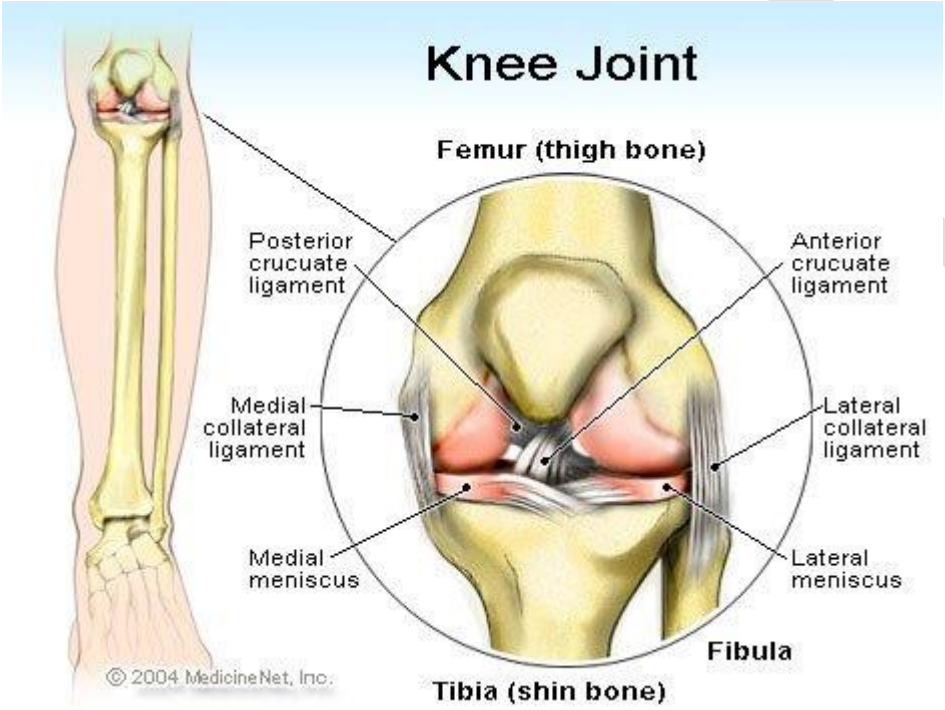
As with all types of surgery, there are some small risks associated with knee surgery, including infection, a blood clot, knee pain, and knee weakness and stiffness.

2. **Ligaments (Anterior Cruciate Ligament (ACL); Posterior Cruciate Ligament (PCL); Collateral Ligaments R/LCL)**

What are the Knee Ligaments?

The Ligaments found within the knee are tough bands of tissue joining the thigh bone to the shin bone at the knee joint.

The ligaments run diagonally through the inside of the knee and around each side which give the knee joint stability. It also helps to control the back-and-forth movement of the lower leg.



Ligament injuries

Knee injuries can occur during sports such as skiing, tennis, squash, football and rugby. Ligament injuries, in particular Anterior Cruciate Ligament (ACL) injuries are one of the most common types of knee injuries, accounting for around 40% of all sports injuries.

A patient may tear the knee ligaments if the lower leg extends forwards too much. It can also be torn if the knee and lower leg are twisted.

Common causes of a ligament injury include:

- landing incorrectly from a jump
- stopping suddenly
- changing direction suddenly
- having a collision, such as during a football tackle

Conservative management

The PRICE protocol is effective for most sports-related injuries. PRICE stands for Protection, Rest, Ice, Compression, and Elevation.

- **Protection** – protect the affected area from further injury – for example, by using a support.
- **Rest** – avoid exercise and reduce your daily physical activity. Using crutches or a walking stick may help if you can't put weight on your ankle or knee. A sling may help if you've injured your shoulder.
- **Ice** – apply an ice pack to the affected area for 15-20 minutes every two to three hours. A bag of frozen peas, or similar, will work well. Wrap the ice pack in a towel so that it doesn't directly touch your skin and cause an ice burn.
- **Compression** – use elastic compression bandages during the day to limit swelling.
- **Elevation** – keep the injured body part raised above the level of your heart whenever possible. This may also help reduce swelling.

Non-steroidal anti-inflammatory medicines. Drugs like aspirin and ibuprofen reduce pain and swelling.

Physiotherapy for those whose symptoms do not resolve.

Reconstructive Ligament surgery

A torn ligament cannot be repaired by stitching it back together, but it can be reconstructed by attaching (grafting) new tissue on to it.

The ligament, for example the ACL, may be reconstructed by removing what remains of the torn ligament and replacing it with a tendon from another area of the leg, such as the hamstring or patellar tendon.

The patellar tendon attaches the bottom of the kneecap (patella) to the top of the shinbone (tibia).

Risks of ligament surgery

The knee may not be exactly like it was before the injury, and you may still have some pain and swelling.

This may be because of other injuries to the knee, such as tears or injuries to the cartilage, which happened at the same time as or after the ligament injury.

As with all types of surgery, there are some small risks associated with knee surgery, including infection, a blood clot, knee pain, and knee weakness and stiffness.

Evidence Review

There was no NICE Guidance identified which reviewed this surgical intervention, and no systematic reviews were identified.

Utsaerts et al. (2016) produced a follow-up paper to their RCT, which is considered high quality with long follow-up. In this high quality randomised controlled trial, with minimal loss to follow-up, a strategy of rehabilitation plus early ACL reconstruction did not provide better results at five years than a strategy of initial rehabilitation with the option of having a later ACL reconstruction. Results did not differ between knees surgically reconstructed early or late and those treated with rehabilitation alone. These results should encourage clinicians and young active adult patients to consider rehabilitation as a primary treatment option after an acute ACL tear.

Frobell et al (2013) found there was no increased risk of osteoarthritis or meniscal surgery if the ACL injury was treated with physiotherapy alone compared with if it was treated with surgery. Neither was there any difference in patients' experiences of function, activity level, quality of life, pain, symptoms or general health.

Measures included Knee injury and osteoarthritis outcome score (KOOS), the Medical Outcomes Study 36-item short-form health survey (SF-36), short-form health survey (SF-36), and the Tegner activity scale. In the full analysis set, the mean change in KOOS4 score from baseline to five years was 42.9 points for patients assigned to rehabilitation plus early anterior cruciate ligament reconstruction and 44.9 points for those assigned to rehabilitation plus optional delayed reconstruction (between group difference 2.0 points, 95% confidence interval −8.5 to 4.5; P=0.54 after adjustment for the baseline score). No statistically significant differences in KOOS4, any of the five individual subscales of KOOS, SF-36, or Tegner activity scale between the two treatment strategies were identified at five years or in the change between two and five years.

In conclusion, the evidence does not support the use of surgical repair as a primary treatment immediately following injury. However, in cases where conservative treatment over 3 months has failed: physiotherapy; analgesia and PRICE, then the current evidence demonstrates that knee arthroscopy with ligament / menisci repair may be clinically appropriate.

Eligibility Criteria: Restricted

Knee Arthroscopy for Acute Knee injury is only commissioned in the following clinical circumstances:

- The patient does not have degenerative knee disease AND
- The patient has experienced an acute knee injury AND
- Following the acute knee injury, the patient has undergone clinician verified conservative treatment for at least 3 months with physiotherapy; analgesia and PRICE, which have all failed AND
- The patient continues to have mechanical symptoms which are causing functional impairment.

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 OR

– Acute or subacute onset of symptoms

N.B. Functional impairment is defined as interfering with activities of daily living, i.e. walking; sleeping; eating.

Investigations for suspected or proven malignancy are outside the scope of this policy and should be treated in line with the relevant cancer pathway.

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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NHS Birmingham and Solihull CCG
NHS Sandwell and West Birmingham CCG

DRAFT
Policy Adenoidectomy

Document Details:

Version:	DRAFT v1.
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Equality & Diversity Impact Assessment	

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Category: Restricted

Adenoids

Adenoids are small lumps of tissue at the back of the nose, above the roof of the mouth. You can't see a person's adenoids by looking in their mouth.

Adenoids are part of the immune system, which helps fight infection and protects the body from bacteria and viruses.

In most cases only children have adenoids. They start to grow from birth and are at their largest when a child is around three to five years of age.

By age seven to eight, the adenoids start to shrink and by the late teens, they're barely visible. By adulthood, in most people they will have disappeared completely.

Adenoids can be helpful in young children, but they're not an essential part of an adult's immune system.

Adenoids can sometimes become swollen or enlarged. This can happen after a bacterial or viral infection, or after a substance triggers an allergic reaction.

In most cases, swollen adenoids only cause mild discomfort and treatment isn't needed. However, for some, it can cause severe discomfort and interfere with their daily life.

Adenoidectomy

The adenoids can be removed during an adenoidectomy.

The operation is usually carried out by an ear, nose and throat (ENT) surgeon and takes around 30 minutes. Afterwards, the patient will need to stay in the recovery ward until the anaesthetic has worn off.

Adenoidectomies are sometimes day cases if carried out in the morning, in which case you / your child may be able to go home on the same day. However, if the procedure is carried out in the afternoon, you / your child may need to stay in hospital overnight.

Eligibility Criteria

Adenoids may be removed in the following clinical circumstances:

- Documented medical problems caused by obstruction of the airway by enlarged adenoids **AND** all conservative treatments have been exhausted.

For the purposes of this eligibility criteria, a medical problem is defined as a medical problem that continually impairs sleep and/or breathing, e.g.

- difficulty sleeping – the patient has problems sleeping and may start to snore; in severe cases, some patients may develop sleep apnoea (irregular breathing during sleep and excessive sleepiness during the day) due to enlarged adenoids
- recurrent or persistent problems with the ears – such as middle ear infections (otitis media) or glue ear (where the middle ear becomes filled with fluid)
- recurrent or persistent sinusitis – leading to symptoms such as a constantly runny nose, facial pain and nasal-sounding speech.

All clinical circumstances which meet the above eligibility criteria, must have failed conservative medical treatment, before being eligible for surgical intervention.

Conservative medical treatments include:

Topical nasal steroids.

Investigations for suspected or proven malignancy are outside the scope of this policy and should be treated in line with the relevant cancer pathway.

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

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NHS Birmingham and Solihull CCG
NHS Sandwell and West Birmingham CCG

DRAFT
Policy for the use of Biological Mesh.

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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

Surgical Mesh

Surgical mesh is a screen-like material that is used as a reinforcement for tissue or bone. It can be made of synthetic polymers or biopolymers.

Materials used for surgical mesh include:

- Non-absorbable synthetic polymers (polypropylene)
- Absorbable synthetic polymers (polyglycolic acid or polycaprolactone)
- Biologic (acellular collagen sourced from cows or pigs)
- Composite (a combination of any of the three previous materials e.g. Biosynthetic)

Mesh implants may be used in a number of surgical procedures to provide additional support when repairing weakened or damaged tissue.

Over recent years attention has increased on complications that can occur with the use of this mesh in urogynaecological procedures to treat pelvic organ prolapse (POP) and stress urinary incontinence (SUI). These complications may include persistent pain, sexual problems, mesh exposure through vaginal tissues and occasionally injury to nearby organs, such as the bladder or bowel. There has been an acknowledgement from the NHS England Mesh Working Group that there is a lack of comprehensive data on these complications. Work is ongoing to ensure that patients are encouraged to report complications and clinicians report adverse events.

Currently, the use of mesh in urogynaecological procedures to treat pelvic organ prolapse and stress urinary incontinence is not supported across the NHS and a wider NHS England review of the use of mesh in these clinical circumstances, means that at the current time in line with NHSE recommendation, the CCG does not support the use of mesh implants in these urogynaecological procedures.

However, surgical mesh implants (non-biological mesh) are routinely used across the NHS to address the clinical problem of hernia. A hernia may be inguinal, femoral; umbilical; para-umbilical or incisional. These implants typically restore structural domain to the abdominal/pelvic wall and prevent extrusion of visceral contents. Surgery takes place either as an open or laprascopic procedure.

Open surgery

The surgeon makes a single cut (incision) over the hernia. This incision is usually about 6 to 8cm long. The surgeon then places the lump of fatty tissue or loop of bowel back into your abdomen (tummy). A mesh is placed in the abdominal wall, at the weak spot where the hernia came through, to strengthen it. When the repair is complete, your skin will be sealed with stitches. These stitches usually dissolve on their own over the course of a few days after the operation.

If the hernia has become strangulated and part of the bowel is damaged, the affected segment may need to be removed and the 2 ends of healthy bowel rejoined. This is a bigger operation and you may need to stay in hospital for 4 to 5 days.

Laparoscopic (keyhole) surgery

During keyhole surgery, the surgeon usually makes 3 small incisions in your abdomen instead of a single larger incision. A thin tube containing a light source and a camera (laparoscope) is inserted through one of these incisions so the surgeon can see inside your abdomen. Special surgical instruments are inserted through the other incisions so the surgeon can pull the hernia back into place.

There are 2 types of keyhole surgery.

1. Transabdominal preperitoneal (TAPP)

Instruments are inserted through the muscle wall of your abdomen and through the lining covering your organs (the peritoneum).

A flap of the peritoneum is then peeled back over the hernia and a piece of mesh is stapled or glued to the weakened area in your abdomen wall to strengthen it.

2. Totally extraperitoneal (TEP)

This is the newest keyhole technique and involves repairing the hernia without entering the peritoneal cavity.

Once the repair is complete, the incisions in your skin are sealed with stitches or surgical glue.

Evidence Review

A review of the clinical evidence found mixed clinical review, with no strong basis for the use of biological mesh over standard mesh in standard or first line hernia repair operations (inguinal; umbilical; paraumbilical or incisional). The standard of the evidence reviewed comprised mainly of retrospective studies of low to moderate quality, but with hernia reoccurrence being slightly higher following the use of biological mesh, but no significant difference was determined in the occurrence of wound and mesh infection. It is possible due to the nature of the studies that the high rates of reoccurrence could be accounted for due to the more complex nature of the hernia repairs where biological mesh was utilised. Therefore, in light of the currently available low quality evidence, to support the use of biological mesh over standard mesh, in first line or standard hernia repair procedures, the use of biological or bio-synthetic mesh is not routinely commissioned.

However, the use of biological or biosynthetic mesh in hernia repair may be undertaken when first line hernia repair surgery with permanent synthetic mesh or conservative treatment has failed or is inappropriate to use synthetic mesh and the use of biological / biosynthetic mesh has been deemed the most clinically appropriate surgical intervention by a complex abdominal wall repair multidisciplinary team.

Eligibility Criteria: Restricted

The use of biological or biosynthetic mesh in standard hernia (inguinal; femoral; umbilical, para-umbilical and incisional) repair is Not Routinely Commissioned.

The use of biological or biosynthetic mesh in hernia repair is only to be undertaken when:

- first line hernia repair surgery with permanent synthetic mesh followed by conservative wound care management has failed

OR

- first line hernia repair surgery with permanent synthetic mesh followed by conservative wound care management is deemed inappropriate

In ALL surgical cases, where the use of biological / biosynthetic mesh is to be considered for use in hernia repair, the patient must be reviewed by a specialist complex abdominal wall repair MDT and the use of biological / biosynthetic mesh must be deemed the most clinically appropriate surgical intervention by a complex abdominal wall repair MDT.

Conservative wound care management is defined as follows:

- Wound care management plan developed for the individual patient by the specialist wound care management team has failed.

Investigations for suspected or proven malignancy are outside the scope of this policy and should be treated in line with the relevant cancer pathway.

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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NHS Birmingham and Solihull CCG
NHS Sandwell and West Birmingham CCG

DRAFT
Policy for use of domiciliary Continuous Positive Airway Pressure (CPAP) Devices.

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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.

Obstructive Sleep Apnoea Hypopnea Syndrome (OSAHS)

Apnoea is defined as a temporary absence or cessation of breathing. Obstructive Sleep Apnoea hypopnea syndrome (OSAHS) is a condition in which a person experiences repeated episodes of apnoea because of a narrowing or closure of the pharyngeal airway during sleep. This is caused by a decrease in the tone of the muscles supporting the airway during sleep. Complete closure (obstruction) stops airflow (apnoea) whereas partial obstruction decreases airflow (hypopnoea). OSAHS results in episodes of brief awakening from sleep to restore normal breathing.

Moderate to severe OSAHS can be diagnosed from patient history and a sleep study using oximetry or other monitoring devices carried out in the person's home. In some cases, further studies that monitor additional physiological variables in a sleep laboratory or at home may be required, especially when alternative diagnoses are being considered. The severity of OSAHS is usually assessed on the basis of both severity of symptoms (particularly the degree of sleepiness) and the sleep study, by using either the apnoea/hypopnoea index (AHI) or the oxygen desaturation index. OSAHS is considered mild when the AHI is 5–14 in a sleep study, moderate when the AHI is 15–30, and severe when the AHI is over 30. In addition to the AHI, the severity of symptoms is also important.

The symptoms of OSAHS include impaired alertness, cognitive impairment, excessive daytime sleepiness, snoring, nocturia, morning headaches and sexual dysfunction. The sleep quality of partners may also be affected. Excessive daytime sleepiness can adversely affect cognitive function, mood and quality of life. OSAHS is associated with high blood pressure, which increases the risk of cardiovascular disease and stroke. OSAHS has also been associated with an increased risk of road traffic accidents.

Major risk factors for developing OSAHS are increasing age, obesity and being male. OSAHS is also associated with certain specific craniofacial characteristics (such as retrognathia), enlarged tonsils and enlarged tongue. Use of alcohol or sedatives can also increase the risk or severity of the condition. OSAHS has been reported to affect up to 4% of middle-aged men and 2% of middle-aged women in the UK. It is estimated that 1% of men in the UK may have severe OSAHS.

The use of Continuous Positive Airway Pressure in OSAHS.

Treatment for OSAHS aims to reduce daytime sleepiness by reducing the number of episodes of apnoea/hypopnoea experienced during sleep. In the clinical management of sleep apnoea, continuous positive airway pressure (CPAP) is the most commonly use intervention for patients with moderate or severe diagnosis of OSAHS.

The potential alternative treatment to CPAP are:

- lifestyle management,
- dental devices
- surgery.

Lifestyle management involves helping people to lose weight, stop smoking and/or decrease alcohol consumption.

Dental devices are designed to keep the upper airway open during sleep. The efficacy of dental devices has been established in clinical trials, but these devices are traditionally viewed as a treatment option only for mild and moderate OSAHS.

Surgery involves resection of the uvula and redundant retrolingual soft tissue. However, there is a lack of evidence of clinical effectiveness, and surgery is not routinely used in clinical practice.

A CPAP device consists of a unit that generates airflow, which is directed to the airway via a mask. Positive pressure is generated by the airflow, which prevents upper airway collapse. For CPAP treatment to be effective the patient must always wear their device when they go to sleep.

Reasons for not adhering to CPAP treatment include poor mask fit, pressure intolerance and, more commonly, upper airway symptoms such as nasal dryness, nasal bleeding and throat irritation. Humidification devices are now commonly used in conjunction with CPAP devices in order to reduce these side effects. Masks should be replaced at least annually, and long-term follow-up of patients is critical to ensure adherence.

There are two types of CPAP devices. Fixed CPAP devices deliver air at constant pressure throughout the night, and the person will continue to receive this pressure until a further titration study is performed to determine whether the set pressure is still appropriate. Auto-titrating CPAP devices continually adjust the pressure delivered throughout the night, with the aim of improving comfort and thus adherence.

Eligibility Criteria: Restricted

1. Continuous positive airway pressure (CPAP) is commissioned as a treatment option for adults with moderate or severe symptomatic obstructive sleep apnoea/hypopnoea syndrome (OSAHS).

   OR

2. CPAP is only recommended as a treatment option for adults with mild OSAHS if:

   a. The OSAHS is causing severe functional impairment, which is impacting on the patient's ability to carry out activities of daily living

AND

   b. lifestyle advice and any other relevant treatment options have been unsuccessful or are considered inappropriate

The diagnosis and treatment of OSAHS, and the monitoring of the response, should always be carried out by a specialist service with appropriately trained medical and support staff.

N.B. The definition of OSAHS following a sleep study is as follows:
Mild OSAHS= Apnoea–Hypopnoea Index (AHI) 5–14.
Moderate OSAHS = AHI is 15–30.
Severe OSAHS = AHI is over 30.

Functional impairment is defined as preventing activities of daily living to be undertaken independently, i.e. sleeping; eating; walking, driving.

Exclusion criteria:

- Inability to remove mask independently (with no waking night carer)
- Cognitive / behavioural limitation affecting ability to comply safely with NIV
- Intolerance of acute NIV
- Multiple co-morbidities limiting utility of NIV

Funding will be provided for the following if the patient meets the above clinical criteria:

- One CPAP machine
- 1-2 lengths of tubing per year
- 1-2 masks per year

In a small proportion of OSA patients, CPAP proves insufficient to control apnoea and it becomes necessary to use bi-level NIV. If a patient has failed treatment with CPAP, but continues to meet the eligibility criteria outlined above, a further funding application will be considered for:

- One Bi-level NIV machine
- 1-2 lengths of tubing per year

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 - OSA

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NHS Birmingham and Solihull CCG
NHS Sandwell and West Birmingham CCG

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Policy for use of domiciliary Non-Invasive Ventilation.

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Category: Restricted

Why is Non-Invasive Ventilation (NIV) used and what is it?

When we breathe in, we take oxygen out of the air to keep us alive - this oxygen is transferred to our blood in our lungs. The body then uses the oxygen and produces a waste gas called carbon dioxide, which we breathe out. The process of this exchange is ventilation.

Some people with severe lung disease, have problems getting enough oxygen into the body, which results in hypoxaemia. If their oxygen level drops below a certain level, it is relatively easy to give extra oxygen for them to breathe, which is called oxygenation. However, in some severe cases of obstructive lung conditions, muscle weakness or neurological impairment, the extra effort of trying to keep the oxygen at a satisfactory level in the blood and to expel carbon dioxide results in the person tiring and leading to hypoventilation and hypercapnia causing respiratory failure.

Respiratory failure is more difficult to deal with. It is a particular problem with diseases that cause obstruction to our airways, such as chronic obstructive pulmonary disease (COPD). In COPD, the airways are narrowed, making it harder to get oxygen into the lungs and carbon dioxide out. Patients who have weak or denervated respiratory muscles in neuromuscular/neurological conditions are also unable to take in a sufficient volume of air to expel carbon dioxide. In all these conditions, a person can develop type 2 respiratory failure which cannot be corrected with oxygenation as the person needs help to ventilate to expel carbon dioxide. Type 2 respiratory failure can lead to high heart rate and cardiac complications.

The aim of using Non-Invasive ventilation (NIV) is not only to obtain satisfactory oxygen levels, but also to expire carbon dioxide. It is often first used at night when the patient is asleep and carbon dioxide levels increase, but as the patient's condition progresses, NIV may be required in the day when the patient has diurnal respiratory failure. It is also important to ease the work of breathing associated with respiratory failure as when a patient with respiratory failure becomes overly tired, this can lead to fatigue, further respiratory compromise and potential respiratory arrest. NIV also aims to take some of the effort out of breathing because the patient's chest muscles don't have to work as hard, so it helps to ease the feelings of breathlessness.

People receiving NIV need to wear a cushioned mask or use a mouthpiece, which is connected to an air pump machine. This mask fits either over the nose alone, or over both the nose and mouth; a strap holds the mask firmly in place, but it can be easily removed, to enable, for example, the patient to eat and drink.

Types of Non-Invasive Ventilation

Noninvasive ventilation (NIV) refers to the administration of ventilatory support without using an invasive artificial airway (endotracheal tube or tracheostomy tube). The use of noninvasive ventilation has markedly increased over the past three decades, and noninvasive ventilation has now become an integral tool in the management of both acute and chronic respiratory failure, in both the home setting and in critical care.

In its simplest terms, noninvasive ventilation differs from invasive ventilation by the interface between the patient and the ventilator. Invasive ventilatory support is provided via either an endotracheal tube or tracheostomy tube. Noninvasive ventilatory support uses a variety of interfaces, and these have continued to evolve with modifications based on patient comfort and efficacy. Many of the interfaces or masks were initially used in patients with obstructive sleep apnoea before they were adapted for use in patients to provide noninvasive ventilatory support.

Nasal masks and orofacial masks were the earliest interfaces, with subsequent development and use of full-face masks, mouthpieces, nasal pillows, and helmets. Hybrid masks and orofacial masks are still the most commonly used interfaces. Orofacial masks are used almost twice as frequently as nasal masks. Both have advantages and disadvantages in the application of noninvasive ventilation.

Noninvasive positive-pressure ventilation

Positive-pressure ventilation delivered through a mask, has become the predominant method of providing noninvasive ventilatory support. Early bedside physiological studies in healthy patients and in patients with respiratory conditions document successful ventilatory support (i.e., reduction in respiratory rate, increase in tidal volume, decrease in dyspnoea) with reduction in diaphragmatic electromyography (EMG), transdiaphragmatic pressures, work of breathing and improvement in oxygenation with a reduction in hypercapnia.

Ventilatory support can be achieved through a variety of interfaces (mouth piece or nasal, face, or helmet mask), using a variety of ventilatory modes (e.g., volume ventilation, pressure support, bilevel positive airway pressure [BiPAP], proportional-assist ventilation [PAV]) with either ventilators dedicated to noninvasive ventilation (NIV) or those capable of providing support through an endotracheal tube or mask. Older models of noninvasive ventilators required oxygen to be bled into the system, but current models incorporate oxygen blenders for precise delivery of the fraction of inspired oxygen (FIO_2).

Current use of Non-invasive Ventilation devices.

Bilevel positive airway pressure (BiPAP) is probably the most common mode of noninvasive positive pressure ventilation and provides for inspiratory positive airway pressure (IPAP) and expiratory positive airway pressure (EPAP). The difference between IPAP and EPAP reflects the amount of pressure support ventilation provided to the patient, and EPAP is synonymous with positive end-expiratory pressure (PEEP). Some noninvasive ventilation is provided using proportional-assist ventilation (PAV), which provides flow and volume assistance with each breath. Clinical trials have not demonstrated a significant difference between PAV and pressure-support ventilation with BiPAP. [5, 6] However, BiPAP is the most commonly available and more frequently used modality for noninvasive ventilation. PAV remains available on many ventilator models, but use is much less common than BiPAP.

National context

National Guidance for the provision of aspects of specialist non-ventilation services to patients exists for some individual patient groups e.g. Motor Neurone Disease (MND), Duchene's Muscular Dystrophy (DMD); and for broader categories of patients e.g. weaning guidance; and around specific technologies e.g. diaphragmatic pacing and tracheostomies. There are some national standards (NICE, 2010; 2016) available and some specialist society guidance (BTS/ICS 2016).

Provision of complex home ventilation services also falls within the NHS Outcomes Framework:
Domain 1 - preventing people from dying prematurely where Improvement Area 1a specifically identifies reducing mortality from respiratory disease,
Domain 2 – enhancing quality of life for patients with long term conditions
Domain 3 – helping patients to recover after an episode of acute illness, where post-acute admission, non-invasive ventilation has been shown to help people recover better in the community and reduce readmission rates.

Guidance supports delivery of care by respiratory specialists working within MDTs. For example, the National Institute for Health and Clinical Excellence (NICE) clinical guideline around the use of NIV in MND states that "multidisciplinary teams (MDT) should coordinate and provide on-going management and treatment for patients with MND, including regular respiratory assessment and provision of non-invasive ventilation. The team should include a neurologist, a respiratory physician, a MND specialist nurse, a respiratory specialist nurse, a specialist respiratory physiotherapist, a respiratory physiologist, a specialist in palliative care and a speech and language therapist". The guidance also outlines the support and training which need to be provided to the patient and their family and carers: "support and assistance to manage non-invasive ventilation which should include training on using non-invasive ventilation and ventilator interfaces, for example emergency procedures, night-time assistance if the patient is unable to use the equipment independently (for example, emergency removal or replacement of interfaces), how to use the equipment with a wheelchair or other mobility aids, if required, what to do if the equipment fails, assistance with secretion management, information on general palliative strategies, an offer of on-going emotional and psychological support for the patient and their family and carers".

Ensuring NIV is delivered by competent respiratory professionals is emphasised in NICE MND guidance and also in the National Patient Safety Agency (NPSA) alert which identified cases where problems with administering NIV were stated as causing at least moderate harm: key issues included shortage of staff skills or staff time to set up and monitor NIV.

Local context

The CCG, based on strong supporting evidence for the clinical effectiveness of the intervention, will commission the use of domiciliary non-invasive ventilation in the following clinical conditions where the patient's individual clinical circumstances meet the relevant clinical eligibility criteria outlined in Sections A & B respectively:

- Chronic Obstructive Pulmonary Disease (Section A)
- Neuro-muscular and Neurological Weakness Patients (Section B)

Please note the provision of treatment for patients with Cystic Fibrosis and patients with Spinal Muscular Atrophy are specialised services commissioned by NHSE.

Guidance

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9. National Institute for Health and Clinical Excellence (NICE). Motor neurone disease: assessment and management**.** NICE guideline [NG42] Published date: February 2016 Last updated: July 2019
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NIV – Section A – Chronic Obstructive Pulmonary Disease (COPD)

Chronic obstructive pulmonary disease (COPD) is the collective name for a group of lung conditions that may cause breathing difficulties.

It includes:

- **emphysema** – damage to the air sacs in the lungs
- **chronic bronchitis** – long-term inflammation of the airways

COPD is a common condition that mainly affects middle-aged or older adults who have a smoking history. The breathing problems tend to get gradually worse over time and can limit the patient's normal activities, although treatment can help keep the condition under control.

Symptoms of COPD

The main symptoms of COPD are:

- increasing breathlessness, particularly when the patient is active
- a persistent chesty cough with phlegm
- frequent chest infections
- persistent wheezing

Without treatment, the symptoms usually get slowly worse. There may also be periods when they get suddenly worse, known as a flare-up or exacerbation.

Causes of COPD

COPD occurs when the lungs become inflamed, damaged and narrowed. The main cause is smoking, although the condition can sometimes affect people who have never smoked.

The likelihood of developing COPD increases the more a patient smokes and the longer the patient has smoked. Some cases of COPD are caused by long-term exposure to harmful fumes, or dust or occur as a result of a rare genetic problem that means the lungs are more vulnerable to damage.

The damage to the lungs caused by COPD is permanent, but treatment can help slow down the progression of the condition.

Treatments include:

- smoking cessation – if a patient is diagnosed with COPD still smokes, stopping smoking is the most important thing a patient can do
- inhalers and medications
- pulmonary rehabilitation – a specialised programme of exercise and education
- surgery or a lung transplant –an option for a very small number of people

Chronic obstructive pulmonary disease (COPD) is characterized by recurrent exacerbations that can cause intermittent periods of severe clinical deterioration requiring hospitalisation and ventilator support. Although treating patients with COPD and acute respiratory failure with non-invasive ventilation improves outcomes, persistent hypercapnia after an exacerbation is associated with excess mortality and early rehospitalization. In 2013, the 28-day COPD readmission rate was around 20%, (Suh et al. 2015).

Eligibility Criteria: Restricted

For patients with COPD the CCG will commission the use of domiciliary non-invasive ventilation in the following clinical circumstances:

The patient has a diagnosis of COPD, identified by post bronchodilator Forced Expiratory Volume (FEV)1 / Forced Vital Capacity (FVC) <0.70

AND

4 weeks post-acute admission the patient has a paCO2 over 7 kPa.

AND

the patient must have ONE of the following:

- A reduction in Quality of life identified by symptoms consistent with Sleep Disordered Breathing Problems (see pg12 for definition)
    - If the patient has reduced quality of life, then overnight oximetry should be undertaken to demonstrate that the patient meets ONE of the following criteria:
        - An apnoea/hypopnoea index >10/hour on respiratory polysomnography or multi-channel respiratory sleep study
        - Four or more episodes of SpO2 <92%
        - Drops in SpO2 of at least 4% per hour of sleep

OR

- A co-morbidity secondary to hypoxemia
    - Pulmonary Hypertension
    - Heart Failure

If the patient has co-morbidities secondary to hypoxemia then the patient should also meet the following criteria:

- Recurrent NIV admissions (2 or more in a 12month period OR difficulty weaning / unable to tolerate weaning)
  AND
- Acute use of NIV has been well tolerated

N.B. Symptoms consistent with Sleep Disordered Breathing Problems are defined as:

- Excessive daytime somnolence (a state of strong desire for sleep, or sleeping for unusually long periods as per the Epworth Sleepiness Score)
- Headache
- Confusion
- Increased shortness of breath
- Resting tremor

Exclusion criteria:

- Inability to remove mask independently (with no waking night carer)
- Cognitive / behavioural limitation affecting ability to comply safely with NIV
- Intolerance of acute NIV
- Multiple co-morbidities limiting utility of NIV

Funding will be provided for the following if the patient with COPD meets the above clinical criteria:

- One NIV machine
- +/- Humidifier as required
- 1-2 lengths of tubing per year
- 1-2 masks per year

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.

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NIV – Section B –Patients with Neuro-muscular and Neurological weakness

A number of chronic neuromuscular disorders, for example muscular dystrophy and motor neurone disease lead to progressive respiratory muscle dysfunction, which in turn can lead to respiratory failure and death. Nocturnal and daytime Non-Invasive Ventilation (NIV) is the preferred method of treatment for these disorders[1].

Non-invasive ventilation as a treatment for neuromuscular disease has several benefits. It has been shown to:

- Improves lung mechanics and gas exchange
- Decrease work of breathing
- Improve symptoms of fatigue
- Reduce daytime sleepiness
- Improve survival in Duchenne Muscular Dystrophy (DMD) and Motor Neurone Disease (MND) patients.

Patients with one of the following conditions will be considered for funding when the patient also meets the eligibility criteria outlined below.

- Motor Neurone Disease
- Muscular Dystrophies including Duchenne Muscular Dystrophy
- Spinal cord injury
- Multiple Sclerosis
- Guillain-Barre Syndrome
- Post polio syndrome with respiratory impairment
- Syringomyelia
- Tuberculosis infection with residual respiratory insufficiency
- Other neuromuscular impairment which is known to cause respiratory muscle weakness or upper airway functional impairment which are the commissioning responsibility of the CCG.

Eligibility Criteria: Restricted

For patients diagnosed with a neuromuscular condition as outlined above, the patient must meet the following criteria for funding f non-invasive ventilation to be approved:

Nocturnal Ventilation

The patient must meet ONE of the following criteria:

- Signs (<50% predicted/<1l) or symptoms of hypoventilation
- MIP< 60cmH_2O
- A baseline SpO_2 <95%
- Blood or end tidal pCO2 >45mmHg whilst awake
- Four or more episodes of SpO2 <92%
- Drops in SpO2 of at least 4% per hour of sleep

Daytime Ventilation (in addition to meeting the above criteria the patient must also meet ONE of the following criteria):

- Abnormal deglutition due to dyspnoea, which is relieved by ventilatory assistance
- Inability to speak in full sentences without breathlessness
- Symptoms of hypoventilation with baseline SpO2 <95%
- Blood or end tidal pCO2 >45mmHG whilst awake
- Symptoms of awake dyspnoea are present

Exclusion criteria:

- Inability to remove mask independently (with no waking night carer)
- Cognitive / behavioural limitation affecting ability to comply safely with NIV
- Intolerance of acute NIV
- Multiple co-morbidities limiting utility of NIV

Funding will be provided for the following if the patient meets the above clinical criteria:

Below 14 hours of ventilation required.

- One NIV machine
- +/- Humidifier as required
- 1-2 lengths of tubing per year
- 1-2 masks per year

Above 14 hours / 24-hour period of ventilation required.

- Two NIV machines
- +/- ONE Humidifier as required
- 2-4 lengths of tubing per year
- 2-4 masks per year

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 for NMD

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Evidence Review

Knee Arthroscopy in Under 35 year olds in comparison to Conservative Management.

Questions to be addressed:

What is the evidence of clinical and cost effectiveness of Knee arthroscopy in under 35 year olds with Acute knee injury compared to conservative treatment?

Reason for review:

NHS Birmingham and Solihull CCG and Sandwell and West Birmingham CCG, requested a rapid evidence review of the clinical and cost effectiveness of knee arthroscopy in patients who are under 35 years and have had an acute meniscal or anterior cruciate ligament (ACL) tear. The review was requested because of the influx of prior approval requests for this cohort of patients following injury for instance while playing sports. This cohort of patients is not currently considered in the national policy for Knee Arthroscopy which covers the cohort of over 35 year olds with degenerative diseases of the knee.

Options for commissioners:

1. Due to insufficient quality of evidence demonstrating that Knee arthroscopy in cases of acute knee injury in under 35 year olds is no more effective than conservative treatment, develop a commissioning policy that clearly stipulates that the intervention is not routinely commissioned, until more evidence is available.
2. Due to the lack of evidence for the clinical effectiveness for Knee arthroscopy in acute knee injury compared to conservative treatment, develop a commissioning policy that considers that the cohort of patients with acute ACL tears should undergo a minimum of 12 weeks of conservative treatment following which, where symptoms persist should be considered for knee arthroscopy in line with restricted criteria.

Summary

The conditions relevant to this scope for acute meniscal tear and acute anterior cruciate ligament (ACL) tear.

Background

The 3 bones that meet in the knee are the:

- thigh bone (femur)
- shin bone (tibia)
- kneecap (patella)

(See Figure 1)

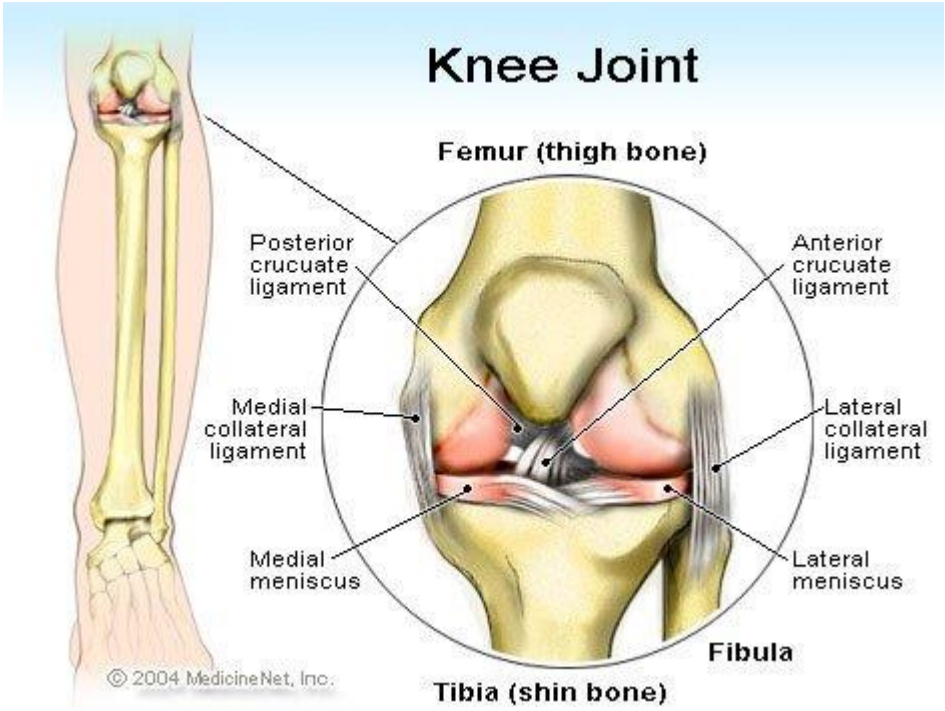

Fig 1: The Knee Joint (Source: https://www.emedicinehealth.com/torn_acl/article_em.htm#what_is_the_anatomy_of_the_knee)

These bones are connected by 4 ligaments – **2 collateral ligaments on the sides of the knee and 2 cruciate ligaments inside the knee.** Ligaments are tough bands of connective tissue. The ligaments in the knee hold the bones together and help keep the knee stable.

The menisci are thick pads of cartilage tissue within the knee which act as shock absorbers to absorb body weight and help improve smooth movement and stability of the knee.

The two main areas within the knee which may be damaged by an acute injury include:

1. Menisci (cartilage)
2. Ligaments

- **Menisci.**

What is the knee meniscus?

The menisci are thick pads of cartilage tissue within the knee which act as shock absorbers to absorb body weight and help improve smooth movement and stability of the knee. Each knee joint contains a medial and lateral meniscus (inner and outer meniscus).

What is a meniscal injury?

There are varying degrees of damage you can do to your menisci. These range from bruising them through to having large tears. Meniscal tears can occur with sport through twisting the knee whilst the foot is still in contact with the ground. In severe injuries, other parts of the knee may also be damaged in addition to a meniscal tear. For example, you may also sprain

or tear a ligament. Meniscal cartilage does not always heal very well once it is torn. This is mainly because the central area of the meniscus does not have a good blood supply. The outer edge of each meniscus has some blood vessels, but the area in the centre has no direct blood supply.

- **Ligaments - Anterior Cruciate Ligament (ACL); Posterior Cruciate Ligament (PCL); Medial Collateral Ligaments (MCL)**

What are the Knee Ligaments?

The Ligaments found within the knee are tough bands of tissue joining the thigh bone to the shin bone at the knee joint. The ligaments run diagonally through the inside of the knee and around each side to give the knee joint stability. They also help to control the back-and-forth movement of the lower leg.

What is an injury of the ligament?

Knee injuries can occur during sports such as skiing, tennis, squash, football and rugby. Ligament injuries, in particular Anterior Cruciate Ligament (ACL) injuries are one of the most common types of knee injuries, accounting for around 40% of all sports injuries.

You can tear your ligaments if your lower leg extends forwards too much. It can also be torn if your knee and lower leg are twisted.

Common causes of a ligament injury include:

- landing incorrectly from a jump
- stopping suddenly
- changing direction suddenly
- having a collision, such as during a football tackle

The intervention

Knee arthroscopy is one of the most commonly performed surgical procedures. In it, a miniature camera is inserted through a small incision (portal). This provides a clear view of the inside of the knee. Your orthopaedic surgeon inserts miniature surgical instruments through other portals to trim or repair the tear.

• Partial meniscectomy: In this procedure, the damaged meniscus tissue is trimmed away.

• Meniscus repair: Some meniscus tears can be repaired by suturing (stitching) the torn pieces together. Whether a tear can be successfully treated with repair depends upon the type of tear, as well as the overall condition of the injured meniscus. Because the meniscus must heal back together, recovery time for a repair is much longer than from a meniscectomy.

• Reconstructive Ligament surgery: A torn ligament cannot be repaired by stitching it back together, but it can be reconstructed by attaching (grafting) new tissue on to it. The ligament, for example the ACL can be reconstructed by removing what remains of the torn ligament and replacing it with a tendon from another area of the leg, such as the hamstring or patellar tendon. The patellar tendon attaches the bottom of the kneecap (patella) to the top of the shinbone (tibia).

Conservative Management

The RICE protocol is effective for most sports-related injuries. RICE stands for:

- **Rest:** Take a break from the activity that caused the injury. Your doctor may recommend that you use crutches to avoid putting weight on your leg.
- **Ice:** Use cold packs for 20 minutes at a time, several times a day. Do not apply ice directly to the skin.
- **Compression:** To prevent additional swelling and blood loss, wear an elastic compression bandage.
- **Elevation:** To reduce swelling, recline when you rest, and put your leg up higher than your heart.

Other conservative management includes Non-steroidal anti-inflammatory medicines which are drugs like aspirin and ibuprofen which assist by reducing pain and swelling.

1 Context

1.1 Introduction

A knee arthroscopy is a type of keyhole surgery used to diagnose and treat problems of the knee joint. Knee arthroscopy is usually done under a general anaesthetic, but a patient may be able to have it under local anaesthetic, depending on the anaesthetist or surgeon's advice.

With this procedure, the surgeon through a small incision that measures only few millimetres, introduces optics in the joints. It is a system of lenses, which usually measure 3-5mm in diameter, and are located in a metal tube in the dimension of a pencil, and allows concentrated artificial light to flow into the joint through this system.

There is a special camera attached to the optics that can monitor the interior part of the joint and transfers the image onto a high resolution monitor. In this way arthroscopy gives the surgeon a view of all joint structures, also of ones that cannot easily be seen in classical surgeries or are even inaccessible to examine. In addition to the incision, which is necessary for introducing the optics, there is normally also needed one or more extra, also only few millimeters small incisions, through which we can insert different operative instruments into the joint. These different sensors, tongs, clips, miniature motorized, and electric instruments are used for the surgical procedure performed in the interior part of the joint.

The procedure can take up to 2 hours depending on the clinical presentation and patients may be able to leave hospital within a few hours. Physiotherapy and pain management will be recommended as required by the surgeon.

1.2 Existing national policies and guidance

- No NICE Guidelines

2 Epidemiology

The knee is injured more frequently than any other joint in the body because it is part of a weight-bearing limb, and second, it does not have the stability procured by the joint congruity of the hip and ankle [10].

Meniscal tears are responsible for 750,000 arthroscopies per year in the US and are the most common soft tissue injury to the knee joint [8]. Traumatic meniscal tears most commonly occur in young, active people during twisting sports such as football and basketball.

3 Findings

3.1 Evidence of effectiveness

3.1.1 A high quality RCT [1] enrolled active adults, 18 to 35 years of age, with an acute anterior cruciate ligament tear occurring not more than four weeks. These were the highlights from the RCT:

- In this high quality randomised controlled trial with minimal loss to follow-up, a strategy of rehabilitation plus early ACL reconstruction did not provide better results at five years than a strategy of initial rehabilitation with the option of having a later ACL reconstruction.
- Results did not differ between knees surgically reconstructed early or late and those treated with rehabilitation alone. These results should encourage clinicians and young active adult patients to consider rehabilitation as a primary treatment option after an acute ACL tear [1].
- This RCT is considered high quality with long follow-up – moderate confidence that evidence reflect true effect in absence of other directly comparable evidence.
- After five years in this randomised controlled trial, it was found that there was no statistically significant differences in pain, symptoms, function in activities of daily living, function in sports and recreation, knee related quality of life, general physical or mental health status, current physical activity level, return to pre-injury activity level, radiographic osteoarthritis, or meniscus surgery between patients assigned to rehabilitation plus early anterior cruciate ligament reconstruction and those assigned to initial rehabilitation with the

option of having a later reconstruction if needed [1]. The results also showed no difference between early or late surgical reconstruction and rehabilitation alone.

- No evidence that arthroscopy improves quality of life compared to conservative treatment at five years. However, the intervention is normally performed on an otherwise young and healthy cohort of patients. Due to short duration nature of the injury, high health utility and low or moderate capacity of intervention to improve the health state the capacity of the intervention to improve quality of life is low. [1]

3.1.2 A systematic review of meniscal tear surgery types was considered including arthroscopic versus open surgery but not surgery versus conservative treatment. [2]

3.1.3 A further systematic review with patients where the mean age was 26.2 was considered. Though the review isn't specifically on patients under 35, the findings of this study suggested that there was no statistically significant difference in outcomes between those patients who underwent earlier compared to delayed ACL reconstruction [3].

3.2 Clinical effectiveness

1 randomised controlled trial (RCT) and 2 systematic reviews were highlighted from the search.

The RCT is high quality and clear, but both of the systematic reviews, although they agree with the RCT findings, do not fully reflect the evidence selection criteria (PICO – Population, Intervention, Comparator, Outcome) used. This means that overall there is moderate confidence that the evidence reflects the true effect of the defined intervention.

RANDOMISED CONTROLLED TRIAL

1. **Treatment for acute anterior cruciate ligament tear: five-year outcome of randomised trial [1]:**

ABSTRACT

Objective: To compare, in young active adults with an acute anterior cruciate ligament (ACL) tear, the mid-term (five year) patient reported and radiographic outcomes between those treated with rehabilitation plus early ACL reconstruction and those treated with rehabilitation and optional delayed ACL reconstruction.

Design Extended follow-up of prospective randomised controlled trial.

Setting Orthopaedic departments at two hospitals in Sweden.

Participants 121 young, active adults (mean age 26 years) with acute ACL injury to a previously uninjured knee. One patient was lost to five-year follow-up.

Intervention: All patients received similar structured rehabilitation. In addition to rehabilitation, 62 patients were assigned to early ACL reconstruction and 59 were assigned to the option of having a delayed ACL reconstruction if needed.

Main outcome measure: The main outcome was the change from baseline to five years in the mean value of four of the five subscales of the knee injury and osteoarthritis outcome score (KOOS4). Other outcomes included the absolute KOOS4 score, all five KOOS subscale scores, SF-36, Tegner activity scale, meniscal surgery, and radiographic osteoarthritis at five years.

Results: Thirty (51%) patients assigned to optional delayed ACL reconstruction had delayed ACL reconstruction (seven between two and five years). The mean change in KOOS4 score from baseline to five years was 42.9 points for those assigned to rehabilitation plus early ACL reconstruction and 44.9 for those assigned to rehabilitation plus optional delayed reconstruction (between group difference 2.0 points, 95% confidence interval −8.5 to 4.5; P=0.54 after adjustment for baseline score). At five years, no significant between group differences were seen in KOOS4 (P=0.45), any of the KOOS subscales (P≥0.12), SF-36 (P≥0.34), Tegner activity scale (P=0.74), or incident radiographic osteoarthritis of the index knee (P=0.17). No between group differences were seen in the number of knees having meniscus surgery (P=0.48) or in a time to event analysis of the proportion of meniscuses operated on (P=0.77). The results were similar when analysed by treatment actually received.

Conclusion: In this first high quality randomised controlled trial with minimal loss to follow-up, a strategy of rehabilitation plus early ACL reconstruction did not provide better results at five years than a strategy of initial rehabilitation with the option of having a later ACL reconstruction. Results did not differ between knees surgically reconstructed early or late and those treated with rehabilitation alone. These results should encourage clinicians and young active adult patients to consider rehabilitation as a primary treatment option after an acute ACL tear.

SYSTEMATIC REVIEWS:

1. **Surgical interventions for meniscal tears: a closer look at the evidence [2].**

ABSTRACT:

The aim of the present study was to compare the outcomes of various surgical treatments for meniscal injuries including (1) total and partial meniscectomy; (2) meniscectomy and meniscal repair; (3) meniscectomy and meniscal transplantation; (4) open and arthroscopic meniscectomy and (5) various different repair techniques. The Bone, Joint and Muscle Trauma Group Register, Cochrane Database, MEDLINE, EMBASE and CINAHL were searched for all (quasi) randomized controlled clinical trials comparing various surgical techniques for

meniscal injuries. Primary outcomes of interest included patient-reported outcomes scores, return to pre-injury activity level, level of sports participation and persistence of pain using the visual analogue score. Where possible, data were pooled and a meta-analysis was performed. A total of nine studies were included, involving a combined 904 subjects, 330 patients underwent a meniscal repair, 402 meniscectomy and 160 a collagen meniscal implant. The only surgical treatments that were compared in homogeneous fashion across more than one study were the arrow and inside-out technique, which showed no difference for re-tear or complication rate. Strong evidence-based recommendations regarding the other surgical treatments that were compared could not be made.This meta-analysis illustrates the lack of level I evidence to guide the surgical management of meniscal tears.Level I meta-analysis.

Introduction: The aim of the present study was to compare the outcomes of various surgical treatments for meniscal injuries including (1) total and partial meniscectomy; (2) meniscectomy and meniscal repair; (3) meniscectomy and meniscal transplantation; (4) open and arthroscopic meniscectomy and (5) various different repair techniques.

Materials and methods: The Bone, Joint and Muscle Trauma Group Register, Cochrane Database, MEDLINE, EMBASE and CINAHL were searched for all (quasi) randomized controlled clinical trials comparing various surgical techniques for meniscal injuries. Primary outcomes of interest included patient-reported outcomes scores, return to pre-injury activity level, level of sports participation and persistence of pain using the visual analogue score. Where possible, data were pooled and a meta-analysis was performed.

Results: A total of nine studies were included, involving a combined 904 subjects, 330 patients underwent a meniscal repair, 402 meniscectomy and 160 a collagen meniscal implant. The only surgical treatments that were compared in homogeneous fashion across more than one study were the arrow and inside-out technique, which showed no difference for re-tear or complication rate. Strong evidence-based recommendations regarding the other surgical treatments that were compared could not be made.

Conclusions: This meta-analysis illustrates the lack of level I evidence to guide the surgical management of meniscal tears.

Level of evidence: Level I meta-analysis.

2. **Early versus delayed surgery for anterior cruciate ligament reconstruction: a systematic review and meta-analysis [3].**

ABSTRACT:

There is no consensus in the literature regarding the optimal timing of surgical reconstruction of the ruptured anterior cruciate ligament (ACL). Previous authors have suggested that early reconstruction may facilitate an early return to work or sport but may increase the incidence

of post-operative complications such as arthrofibrosis. This study systematically reviewed the literature to determine whether ACL reconstruction should be performed acutely following rupture. Medline, CINAHL, AMED, EMBASE databases and grey literature were reviewed with a meta-analysis of pooled mean differences where appropriate. Six papers including 370 ACL reconstructions were included. Early ACL reconstructions were considered as those undertaken within a mean of 3 weeks post-injury; delayed ACL reconstructions were those undertaken a minimum of 6 weeks post-injury. We found there was no difference in clinical outcome between patients who underwent early compared to delayed ACL reconstruction. However, this conclusion is based on the current literature which has substantial methodological limitations.

3.3 Cost effectiveness

No studies were found to demonstrate the cost effectiveness of Knee arthroscopy in acute indications in under 35s.

3.4 Magnitude of Health Improvement Benefit

There was no increased risk of osteoarthritis or meniscal surgery if the ACL injury was treated with physiotherapy alone compared with if it was treated with surgery. Neither was there any difference in patients' experiences of function, activity level, quality of life, pain, symptoms or general health.

Measures included Knee injury and osteoarthritis outcome score (KOOS), the Medical Outcomes Study 36-item short-form health survey (SF-36), and the Tegner activity scale. In the full analysis set, the mean change in KOOS4 score from baseline to five years was 42.9 points for patients assigned to rehabilitation plus early anterior cruciate ligament reconstruction and 44.9 points for those assigned to rehabilitation plus optional delayed reconstruction (between group difference 2.0 points, 95% confidence interval −8.5 to 4.5; P=0.54 after adjustment for the baseline score). No statistically significant differences were found in KOOS4, any of the five individual subscales of KOOS, SF-36, or Tegner activity scale between the two treatment strategies at five years or in the change between two and five years. Knee stability at rest at five years was statistically significantly better in knees assigned to early anterior cruciate ligament reconstruction [1].

There is a small indication in favour of surgical intervention for multi-ligament injuries [1].

3.5 Safety

- Mild chondral injury often occurs at the time of ACL tearing, as the femur and tibia bang against each other [5].
- Increasing age, height, weight, and BMI may also increase the risk for meniscal and articular cartilage injury [6]. Over time, recurrent instability episodes may cause further cartilage damage. Although no method yet exists for fully restoring normal

articular cartilage, techniques can be combined with ACL reconstruction to address full-thickness chondral defects.

- Bone bruising may accompany ACL tears and is thought to set in motion a biochemical cascade, which, even in reconstructed knees, may lead to post-traumatic arthrosis [7].
- Risks of the surgery include infection, DVT/venous thrombo-embolism, neurovascular injury, loss of motion, patellofemoral pain, harvest site pain, patellar fracture, tendon rupture, and pain from hardware [8].
- More serious problems are much less common, occurring in less than 1 in 100 cases [9]. They include:
    - •a blood clot that develops in one of the limbs – known as deep vein thrombosis (DVT), it can cause pain and swelling in the affected limb
    - •infection inside the joint – known as septic arthritis, it can cause fever, pain and swelling in the joint
    - •bleeding inside the joint – which often causes severe pain and swelling
    - •accidental damage to the nerves near the joint – which can lead to temporary or permanent numbness and some loss of sensation

3.6 Equity issues

The prevalence of knee pain (lasting for more than 1 week in the past month) was 19% in a community-based survey of people 16 years of age or older registered with one of three general practices near Manchester [4]. Responses were received from 4515 people (78.5%).

The prevalence of knee pain increased with age in both sexes. The age-standardized prevalence of knee pain was equal for men and women, but prevalence was higher in older women than in older men. In people 75 years of age or older, the prevalence in women was 36% and in men was 27%. The prevalence of knee pain with disability was 6%, and the prevalence of moderate or severe knee pain was 12%. It was estimated (from a survey of a subset of initial responders) that 13% of people had consulted their GP for knee pain.

Limited information available particularly under the age of 35. However, no obvious inequalities have been identified in younger age group.

4. Activity and finance

At all levels, injury is a constant threat, and, of all injuries, those of the knee fulfil the athlete's greatest fear of spending a long time out of action. This is confirmed by a study from Sheffield, which showed the knee to have been the most commonly injured joint and soccer and rugby to have the highest risks [11].

Not only may a knee injury require surgery followed by months of rehabilitation, but permanent disability from both sport and work may be the outcome. Indeed, a large study from Scandinavia found that the most common cause of permanent disability following a sports injury was injury to the knee.

There is little work on the pattern of knee injuries in the United Kingdom [11], although a multicenter study is currently in progress. The work that has been carried out abroad, however, has produced some interesting information. It is not widely appreciated that ligament damage to the knee is more common than any other type of knee injury pathology.

Many medical students, general practitioners, and paramedics may be familiar with the story of a weight bearing, twisting injury producing a meniscal tear; however, there is generally a profound ignorance about the history and signs of the more common (and potentially more devastating) ligament injuries. The "miscellaneous injuries" category takes up a quarter of the total, and this is made up of a selection of pathologies such as contusions of the knee and traumatic bursitis. Projecting from American figures, a casualty department covering a population of 400 000 should expect to see about 500 significant knee injuries a year [11].

5.Summary of findings

- Absence of systematic review evidence which fits the specified PICO.
- Conservative management – such as rehabilitation shows as good outcomes if not better than arthroscopy, however there may be an indication in multiligament injuries.
- With reference to specific disease related to the knee, the review found no evidence that arthroscopy prevents further conditions such as osteoarthritis
- Not much evidence was available to form conclusive recommendations for knee arthroscopy following acute meniscal tear.
- No definite length of period for conservative management was evident in the review undertaken.

6.Search Strategy

The following databases are routinely searched: NICE Clinical Guidance and full website search; NHS Evidence and NICE CKS; SIGN; Cochrane; York; and the relevant Royal College and any other relevant bespoke sites. A Medline search was also undertaken and a general google search for key terms carried out.

The search identified publications with relating to acute knee injuries and the abstracts and titles were then sifted to select those that met the criteria in the PICO below. Where there was ambiguity in the PICO criteria, the reviewer also referred to the wording of the research question for this evidence review, which specified that the intervention of interest was knee arthroscopy.

6.1 PICO parameters:

Population: Under 35 years, Acute Meniscal Tear or Anterior Cruciate Ligament Tear
Intervention: Knee arthroscopy with repair of tear
Comparator / Control: Conservative management; physiotherapy, analgesia, steroid injections
Outcome: Improved knee function; pain; mobility

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Evidence Review

Non-Cosmetic Body Contouring Surgery following massive sustained weight loss.

Questions to be addressed:

What is the evidence of clinical and cost effectiveness of clinically indicated Body Contouring Surgery (BCS), following massive sustained weight loss in adults with a starting BMI of above 40kg/m2; or above 35kg/m2 with co-morbidities AND current BMI of less than 30.0kg/m2 AND weight stability of 12 months who are experiencing significant functional disturbance, in comparison to no surgical treatment?

Reason for review:

NHS Birmingham and Solihull CCG and Sandwell and West Birmingham CCG, requested a rapid evidence review of the clinical and cost effectiveness of clinically indicated Body contouring surgery. The review was requested to support policy development and to define the procedures to be considered within the policy for body contouring.

Options for commissioners:

1. Due to consistent and strong volume of evidence demonstrating that body contouring surgery (BCS) is clinically effective, develop a commissioning policy that details a restricted criterion and defines the exclusions to the policy.
2. Due to the strong evidence identified in the "Body Q" Systematic review develop a policy with criteria that defines the overarching themes: 1) Appearance; 2) Health related Quality of life; and 3) Patient experience.

Summary

Body contouring is a procedure that alters the shape of the human body. It includes procedures that eliminate or reduce excess skin and fat that remains after losing a significant amount of weight, in a variety of places including the torso, upper arms, chest, and thighs. Body contouring may also be requested by women who have excess abdominal skin following pregnancy or to treat excessive 'stretch marks'.

Massive weight loss is defined as loss of 50% or more of body weight [1].

Background

Individuals are increasingly suffering with excess skin after being encouraged to lose weight either through diet and exercise (often supported by community weight loss programs) or as a result of bariatric surgery undertaken either privately or on the NHS. Rapid, marked weight loss often results in large areas of loose skin. Patients have increasing expectations that

removal of this excess skin will be funded by the NHS especially if the bariatric surgery was NHS funded.

These surgical procedures can involve removing fat and excess loose skin and tightening the abdominal muscles. The aim is to remove excess skin that can't be removed through exercise - It is not a quick fix for losing weight.

The interventions

Body contouring covers a variety of requests to remove redundant skin usually following major weight loss, therefore NHS Birmingham and Solihull CCG and Sandwell and West Birmingham CCG have brought the following body contouring procedures together into one policy:

- **Surgery to improve the appearance of the abdomen where clinically indicated:**

There are a number of procedures available, for example, in abdominoplasty it may involve removing excess skin and fat and tightening the abdominal muscles. Panniculectomy / apronectomy is a limited abdominoplasty procedure and is performed to remove the excess skin only. Documented clinical evidence of severe impairment associated to the excess skin and a definition of how far down the excess skin hangs (panniculus) is required.

- **Full abdominoplasty:**

For patients who have significant skin laxity, excess fat and separation of the muscles, a classic tummy tuck is the most common procedure. Performed under general anaesthetic, this operation can require patients to be in hospital for two or three days.

During the operation, an incision is made from hip to hip and around the umbilicus. The excess skin and fat is excised from the umbilicus to just above the pubic hair. The muscles above and below the umbilicus are tightened. The skin is then sewn up to give a circular scar around the umbilicus and a long scar across the lower abdomen. Although this operation leaves a large scar, it does provide the greatest improvement in abdominal shape.

Patients who are thinking about becoming pregnant should not undergo this procedure, and should wait until they are sure they are not having any more children. All the skin and fat below the umbilicus can be removed in a standard abdominoplasty. This results in a scar across the lower abdomen and a scar around the umbilicus.

- **Mini abdominoplasty**

For patients with only a small amount of excess skin, a lesser abdominoplasty might be appropriate. A general anaesthetic is still needed.

During the operating, a wedge of skin and fat is excised from the lower tummy leaving a horizontal scar above the pubic hair. Sometimes the muscles will also be tightened. No scar is

left around the umbilicus, which may be stretched slightly to become a different shape. A mini abdominoplasty will give a smaller effect than a full abdominoplasty.

- **Extended abdominoplasty**

Surplus skin and fat of the loins and back are removed at the same time as the abdomen.

- **Endoscopic abdominoplasty**

Tightens the muscles of the abdominal wall. Skin is not removed but liposuction can be carried out at the same time.

- **Apronectomy (Panniculectomy)**

An Apronectomy is a modified mini-abdominoplasty, mainly for patients who have a large excess of skin and fat hanging down over the pubic area and only the surplus skin and fat is removed. A modification to an abdominoplasty might also be necessary when the patient has problems with scars from previous operations.

A panniculus is excess adipose tissue hanging downward from the abdomen and resembles an "apron of skin" overlying the front of the pelvic girdle. A large panniculus can interfere with normal activities such as walking, and lead to serious medical problems. The heavy overhanging tissue can cause chronic skin inflammation under the flap, and subsequently, skin breakdown and infection.

The panniculus hanging below the symphysis pubis when the individual is standing normally can cause significant functional impairment and other complications such as intertrigo.

Historically, panniculectomy/apronectomy has been considered primarily a cosmetic procedure; however, for some patients, surgery is the only option if a large panniculus causes debilitating symptoms that do not respond to conventional medical therapy.

- **Arm reduction and lift (Brachioplasty):**

Brachioplasty, or upper arm reduction or arm lift is a surgical procedure which removes and tightens loose skin and excess fat in the upper arm. It is usually performed under a general anaesthetic. The surgeon makes a long incision between the elbow and axilla. Segments of skin and fat are removed and the remaining skin and tissue lifted resulting in a tight, smooth look.

- **Buttock and/or Thigh lift (Thighplasty):**

Thighplasty is aesthetic reshaping surgery with the removal of excess skin and fat. Buttock or thigh lift surgery is performed to lift the excess skin to firm and tighten the skin around the buttocks and/or thighs. Liposuction may also be performed during this procedure. Sometimes a buttock lift is combined with this procedure.

- **Liposuction / Liposculpture / Suction Assisted Lipectomy**

Liposuction is also known as liposculpture or suction assisted lipectomy. It is a technique most commonly performed to remove unwanted fat deposits. Liposuction can be performed on other areas of the body, including the neck, arms, tummy, loins, thighs, inner side of the knees and the ankles.

Funding for procedures to remove excess skin from other areas of the body other than the abdomen has been deemed cosmetic with much greater risks than non-surgical procedures.

Other procedures that are not included within the Body Contouring Surgery policy are:

- Mastopexy/ Breast Lift, surgery for gynaecomastia other breast surgery procedures
- Liposuction for Lipoedema and Lymphoedema

Current Management

Weight loss surgery or bariatric surgery is commissioned nationally across England. In adults with a BMI of more than 40kg/m2 (or more than 35kg/m2 with co-morbidities) in whom surgical intervention is considered appropriate, bariatric surgery is recommended as a treatment option in the National Institute for Health and Clinical Excellence (NICE) guidelines [1].

Where body contouring interventions are required solely to improve the appearance, these are regarded as cosmetic surgery and so not normally available on the NHS. There are however, some clinical circumstances in which there is documented evidence of clinical benefit to be attained by undertaking such a procedure.

1 Context

1.1 Introduction

The resultant redundant skin presents new quality of life concerns in a range of areas such as mobility, decreased activity, body image dissatisfaction and depression. The excess skin causing physical discomfort, psychosocial problems, lost work days/productivity and concern about quality of life in general has led to an increasing uptake of body contouring surgery, to manage the complex problems that span multiple parts of the body after massive weight loss.

Research demonstrates significant improvements in patients' physical function, emotional wellbeing, stability in mood, body image satisfaction, identity shifts and identity transformation, sexual vitality, greater wellbeing and quality of life once they have undergone body contouring surgery following massive weight loss [1].

Body contouring surgery has been shown to have positive benefits, especially in relation to improved wellbeing, function and Quality of Life (QoL). However, adjustment to changing

body image following body contouring is both challenging and empowering and seems to be a transitional process [2].

The commissioning guide provides the overview of the types of health conditions that can be prevented if body contouring procedures are carried out after massive weight loss and/or post-bariatric surgery [1]. The purpose of the evidence review is to draw out the benefits of clinically indicated body contouring.

1.2 Existing national policies and guidance

- NICE have not currently issued guidance on this treatment.
- The Royal College of Surgeons in association with the British Association of Plastic Reconstructive and Aesthetic Surgeons (BAPRAS) have recently produced guidance on body contouring using a NICE accredited process. Those guidelines have been taken into account in the review of the evidence to support policy development.

2 Epidemiology

In 2010, 65.1% of all adults aged 16 years and over were overweight or obese. Morbid obesity rates (body mass index (BMI) ≥40kg/m2) increased from 1.2% in 1995 to 2.7% in 2003, and fluctuated between 2.2% and 2.7% between 2008 and 2010 [1].

3 Findings

3.1 Evidence of effectiveness

- The UK Commissioning Guide [1] highlights an expert interpretation of various papers to inform NICE and clinical commissioners in the UK health care sector. All results highlighted of the search strategy are also utilised within the commissioning guide.
- The commissioning guide [1] is a strong example of evidence of Body Contouring in the UK Health Sector.

3.1.1 Clinical effectiveness

3 systematic reviews, 1 economic systematic review and 4 clinical trials & guidance were highlighted from the search that directly informed 'Body Contouring' in reference to the effectiveness measurable by physical, physiological, and/or qualitative patient reported outcomes:

SYSTEMATIC REVIEWS:

1. **Measuring Quality of Life and Patient Satisfaction After Body Contouring [2]:**

ABSTRACT

Evidence-Based Background: In both cosmetic and post bariatric body contouring populations, the primary determinants of success are patient satisfaction and quality of life

(QOL). These patient-reported outcomes (PRO) are ideally measured with specially-designed, procedure- or condition-specific questionnaires.

Objective: The authors identify and appraise all patient-reported outcome (PRO) measures (questionnaires) developed for patients undergoing body contouring surgery.

Methods: MEDLINE, EMBASE, PsychINFO, Ebase, CINAHL, HAPI, Science Citation Index/Social Sciences Citation Index, Ovid Evidence Based Medicine databases were searched from the inception of each database through August 2010. Articles included in the study described the development and/or psychometric evaluation of a PRO measure developed for body contouring patients. Each measure was then appraised for adherence to internationally-recommended guidelines for item generation, item reduction, and psychometric evaluation.

Results: The following five PRO questionnaires were identified by our search: one liposuction (the Freiburg Questionnaire on Aesthetic Dermatology and Cosmetic Surgery, FQAD), one general plastic surgery (Derriford Appearance Scale, DAS-59/24), and three breast reduction measures (the Breast Reduction Assessed Severity Scale Questionnaire, BRASSQ; Breast Related Symptoms questionnaire, BRS; and the BREAST-Q reduction module. Detailed examination of these measures revealed that the FQAD, DAS-59, and BRS are limited by both their content range and psychometric properties. The BRASSQ and BREAST-Q both have strong psychometric properties, and the BREAST-Q is unique in its inclusion of items covering specific postoperative issues such as scarring.

Conclusions: While instruments are available for measuring outcomes in breast reduction patients, reliable, valid, and responsive PRO measures are lacking for the majority of body contouring procedures. To demonstrate the unique outcomes of body contouring surgery, future research to rigorously develop and validate new PRO measures in this population is necessary.

2. **Recommendations on the most suitable quality-of-life measurement instruments for bariatric and body contouring surgery [3]:**

ABSTRACT

Objective: The objective of this study is to systematically assess the quality of existing patient-reported outcome measures developed and/or validated for Quality of Life measurement in bariatric surgery (BS) and body contouring surgery (BCS).

Methods: We conducted a systematic literature search in PubMed, EMBASE, PsycINFO, CINAHL, Cochrane Database Systematic Reviews and CENTRAL identifying studies on measurement properties of BS and BCS Quality of Life instruments. For all eligible studies, we evaluated the methodological quality of the studies by using the COnsensus-based Standards for the selection of health Measurement INstruments checklist and the quality of the

measurement instruments by applying quality criteria. Four degrees of recommendation were assigned to validated instruments (A-D).

Results: Out of 4,354 articles, a total of 26 articles describing 24 instruments were included. No instrument met all requirements (category A). Seven instruments have the potential to be recommended depending on further validation studies (category B). Of these seven, the BODY-Q has the strongest evidence for content validity in BS and BCS. Two instruments had poor quality in at least one required quality criterion (category C). Fifteen instruments were minimally validated (category D).

Conclusion: The BODY-Q, developed for BS and BCS, possessed the strongest evidence for quality of measurement properties and has the potential to be recommended in future clinical trials.

3. **Quality of life among adults following bariatric and body contouring surgery: a systematic review [4]:**

ABSTRACT

Background: Weight loss following bariatric surgery is associated with significant improvements in obesity-related comorbidities, body satisfaction and psychosocial outcomes, at least in the short term. However, in the context of extreme weight loss, body image and appearance may worsen again because the “excess” or “loose” skin can lead to both functional and profound dissatisfaction with appearance. These concerns have led to an increasing uptake of post-bariatric surgery, “body-contouring” procedures but the implications for quality of life (QoL) have not been thoroughly considered.

Objective/purpose: The objective was to identify the best available evidence regarding the QoL outcomes for adults following bariatric and body contouring surgery.

Inclusion criteria - Types of participants: The review considered studies involving people aged 18 years and beyond who underwent bariatric surgery and body contouring surgery.

Types of interventions: The review considered studies that evaluated bariatric surgery as well as body contouring surgery.

Types of studies: The review considered both experimental and epidemiological study designs.

Outcomes: The primary outcomes were QoL as measured by validated tools at less than two years, two to five years and more than five years following body contouring surgery. The secondary outcomes were adverse events, unsatisfactory aesthetic appearance and weight gain.

Search strategy: Six databases were searched, including Cochrane Central, MEDLINE, Embase, Web of Science, PsycINFO and CINAHL. Studies published from 1954 to 2014 were considered.

Additional searches for unpublished studies were undertaken in BIOSIS citation index, Register of Current Controlled Trials and Global Health Observatory.

Methodological quality: The methodological quality of eligible studies was assessed independently by two reviewers using the Joanna Briggs Institute quality assessment tool.

Data extraction: Data extraction from the included studies was undertaken and summarized independently by two reviewers using the standardized Joanna Briggs Institute data extraction tool.

Data synthesis: Studies were too heterogeneous and could not be pooled in statistical meta-analysis. Therefore, the data results are presented as a narrative summary in relation to the outcomes of interest.

Results: Nine quantitative studies (four comparable cohort studies, including two group design and two four-group designs and five descriptive or case-series studies) were included in the review. The included studies reported significant clinical improvements in appearance, wellbeing and QoL. These included primary outcomes pointing to body image satisfaction, improved self-esteem and confidence, improved physical function/pain and improved social function. The secondary outcomes were related to adverse events in the early postoperative period and reported wound healing problems, including seromas, partial necrosis, dehiscence, hematoma and anaemia because of blood loss. Also, some data sets shed light on appearance-related distress and body dysphoria post-surgery associated with visible scars and contour deformities.

Conclusion: Body contouring surgery has been shown to have positive benefits, especially in relation to improved wellbeing, function and QoL. However, adjustment to changing body image following body contouring is both challenging and empowering and seems to be a transitional process.

ECONOMIC SYSTEMATIC REVIEWS:

1. **Diverse approaches to the health economic evaluation of bariatric surgery: a comprehensive systematic review [5]:**

ABSTRACT

Background: Health economic evaluations inform healthcare resource allocation decisions for treatment options for obesity including bariatric/metabolic surgery. As an important advance on existing systematic reviews, we aimed to capture, summarize and synthesize a diverse range of economic evaluations on bariatric surgery.

Methods: Studies were identified by electronic screening of all major biomedical/economic databases. Studies included if they reported any quantified health economic cost and/or consequence with a measure of effect for any type of bariatric surgery from 1995 to

September 2015. Study screening, data extraction and synthesis followed international guidelines for systematic reviews.

Results: Six thousand one hundred eighty-seven studies were initially identified. After two levels of screening, 77 studies representing 17 countries (56% USA) were included. Despite study heterogeneity, common themes emerged, and important gaps were identified. Most studies adopted the healthcare system/third-party payer perspective; reported costs were generally healthcare resource use (inpatient/shorter-term outpatient). Out-of-pocket costs to individuals, family members (travel time, caregiving) and indirect costs due to lost productivity were largely ignored. Costs due to reoperations/complications were not included in one-third of studies. Body-contouring surgery included in only 14%. One study evaluated long-term waitlisted patients. Surgery was cost-effective/cost-saving for severely obese with type 2 diabetes mellitus. Study quality was inconsistent.

Discussion: There is a need for studies that assume a broader societal perspective (including out-of-pocket costs, costs to family and productivity losses) and longer-term costs (capture reoperations/complications, waiting, body contouring), and consequences (health-related quality-of-life). Full economic evaluation underpinned by reporting standards should inform prioritization of patients (e.g. type 2 diabetes mellitus with body mass index 30 to 34.9 kg/m 2 or long-term waitlisted) for surgery.

GUIDANCE & CLINICAL STUDIES:

1. **Body image and quality of life in patients with and without body contouring surgery following bariatric surgery: a comparison of pre- and post-surgery groups [6].**

ABSTRACT

Background: Massive weight loss (MWL) following bariatric surgery frequently results in an excess of overstretched skin causing physical discomfort and negatively affecting quality of life, self-esteem, body image, and physical functioning.

Methods: In this cross-sectional study 3 groups were compared: (1) patients prior to bariatric surgery (n = 79), (2) patients after bariatric surgery who had not undergone body contouring surgery (BCS) (n = 252), and (3) patients after bariatric surgery who underwent subsequent BCS (n = 62). All participants completed self-report questionnaires assessing body image (Multidimensional Body-Self Relations Questionnaire, MBSRQ), quality of life (IWQOL-Lite), symptoms of depression (PHQ-9), and anxiety (GAD-7).

Results: Overall, 62 patients (19.2%) reported having undergone a total of 90 BCS procedures. The most common were abdominoplasties (88.7%), thigh lifts (24.2%), and breast lifts (16.1%). Post-bariatric surgery patients differed significantly in most variables from pre-bariatric surgery patients. Although there were fewer differences between patients with and without BCS, patients after BCS reported better appearance evaluation (AE), body area

satisfaction (BAS), and physical functioning, even after controlling for excess weight loss and time since surgery. No differences were found for symptoms of depression and anxiety, and most other quality of life and body image domains.

Discussion: Our results support the results of longitudinal studies demonstrating significant improvements in different aspects of body image, quality of life, and general psychopathology after bariatric surgery. Also, we found better AE and physical functioning in patients after BCS following bariatric surgery compared to patients with MWL after bariatric surgery who did not undergo BCS. Overall, there appears to be an effect of BCS on certain aspects of body image and quality of life but not on psychological aspects on the whole.

2. **The impact of reconstructive procedures following bariatric surgery on patient well-being and quality of life [7]:**

ABSTRACT

Background: Massive weight loss following bariatric surgery may lead to an excess of lax, overstretched skin, causing physical discomfort which may affect the patient's quality of life. Whereas the functional and aesthetic deformity is an expected result of massive weight loss, the role of the plastic surgeon in the multidisciplinary approach of the morbidly obese is still unclear. The purpose of the current study is to evaluate the results of reconstructive surgery following weight loss surgery, focusing on the impact on the physical and psycho-social well-being and quality of life of the patients.

Methods: Out of a group of 465 patients, 61 patients underwent reconstructive surgery following weight loss surgery. In 43 respondents, the quality of life after reconstructive surgery was measured by the Obesity Psychological State Questionnaire. Patient satisfaction was evaluated.

Results: Reconstructive surgery resulted in a significant improvement in quality of life in patients at a mean interval of 42 months between weight loss and reconstructive surgery. The most frequent procedures were abdominoplasty and breast reconstruction. The relative high complication rate of 27.9% was of no influence on quality of life and the majority of the patients (67%) were satisfied with reconstructive surgery.

Conclusions: This study shows that reconstructive surgery following weight loss after bariatric surgery results in a significant improvement in overall quality of life. Reconstructive surgery should be incorporated in the multidisciplinary care programme following weight loss surgery in the morbidly obese patient.

3. **The BODY-Q: A Patient-Reported Outcome Instrument for Weight Loss and Body Contouring Treatments [8]:**

ABSTRACT

Background: Body contouring performed for cosmetic purposes, or after weight loss, has the potential to improve body image and health-related quality of life (HRQL). The BODY-Q is a new patient-reported outcome (PRO) instrument designed to measure patient perceptions of weight loss and/or body contouring. In this article, we describe the psychometric properties of the BODY-Q scales after an international field-test.

Methods: Weight loss and body contouring patients from Canada, United States, and United Kingdom were recruited between November 2013 and February 2015. Data were collected using an iPad directly into a web-based application or a questionnaire booklet. Rasch measurement theory analysis was used for item reduction and to examine reliability, validity, and ability to detect change.

Results: The sample included 403 weight loss and 331 body contouring patients. Most BODY-Q items had ordered thresholds (134/138) and good item fit. Scale reliability was acceptable, i.e., Person separation index >0.70 for 16 scales, Cronbach α ≥0.90 for 18 of 18 scales, and Test-retest ≥0.87 for 17 of 18 scales. Appearance and HRQL scores were lower in participants with more obesity-related symptoms, higher body mass index, and more excess skin and in those pre- versus postoperative body contouring. The 134 weight loss patients who completed the BODY-Q twice, either 6 weeks (weight loss/nonsurgical body contouring program) or 6 months (bariatric program) later, improved significantly on 7 appearances and 4 HRQL scales.

Conclusion: The BODY-Q is a clinically meaningful and scientifically sound patient-reported outcome instrument that can be used to measure outcomes in patients who undergo weight loss and/or body contouring.

4. **Body-Q User Manual, Royal College of Surgeons [9]:**

The 'BODY-Q' systematic review is strong evidence to support the method in measuring the effectiveness of body contouring from patient-reported outcomes. 'BODY-Q' method is the framework of the BODY-Q scales, is comprised of three overarching themes as follows:

1) Appearance; 2) Health-Related Quality of Life; and 3) Patient Experience.

Under these domains, there are 18 independently functioning scales that measure important Concepts of Interest (COI). In addition to the 18 scales, there is 1 obesity-specific symptom checklist.

5. **Body Image and Quality of Life in Post Massive Weight Loss Body Contouring Patients [10]:**

ABSTRACT

Objective: Because post-bariatric surgery patients undergo massive weight loss, the resulting skin excess can lead to both functional problems and profound dissatisfaction with

appearance. Correcting skin excess could improve all these corollaries, including body image. Presently, few data are available documenting body image and weight-related quality of life in this population.

Research methods and procedures: Eighteen patients who underwent both bariatric surgery and body contouring completed our study. Both established surveys and new surveys designed specifically for the study were used to assess body perception and ideals, quality of life, and mood. Patients were surveyed at the following time-points: pre-body contouring (after massive weight loss) and both 3 and 6-month post-body contouring. Statistical testing was performed using Student's t test and ANOVA.

Results: The mean age of the patients was 46 +/- 10 years (standard deviation). Quality of life improved after obesity surgery and was significantly enhanced after body contouring. Three months after body contouring, subjects ascribed thinner silhouettes to both current appearance and ideal body image. Body image also improved with body contouring surgery. Mood remained stable over 6 months.

Discussion: Body contouring after surgical weight loss improved both quality-of-life measurements and body image. Initial body dissatisfaction did not correlate with mood. Body contouring improved body image but produced dissatisfaction with other parts of the body, suggesting that as patients become closer to their ideal, these ideals may shift. We further developed several new assessment methods that may prove useful in understanding these post-surgical weight loss patients.

3.1.2 Cost effectiveness

Studies were found in a systematic review that appeared to reference QALYs in relation to body contouring. On further review of the literature referenced these were in relation to gastric bypass surgery and similar. No QALYs relevant to body contouring specifically were found.

3.2 Magnitude of Health Improvement Benefit

- All studies [1], [2] and [7] highlight the psychological and physiological improvement post-body contouring surgery. [2] and [7] explore in various tables the score improvement in physical movement and psychological benefit as high as 74% of study population [7].
- The papers also highlight the importance of support during the process and post-body contouring procedure to deal with the transition which resulted in higher QoL from the study population. It is highly suggested a sound support package is beneficial for maximum health outcomes.
- Clinical Outcomes of Body Contouring have been highlighted as achieving statistically significant improvements in conditions such as Neck, Back and Abdominal pain and conditions such as Lymphedema.

Outcome	Pre Body Contouring Score	Post Body Contouring Score	p Value
Neck Pain	2.52	2.02	≤ 0.05
Back Pain	5.63	2.10	≤ 0.0001
Abdominal Pain	5.96	1.43	≤ 0.0001
Lymphedema	3.35	1.65	≤ 0.0001

Table 7 [2]: Wilcoxon-signed rank demonstrating statistical significant improvement in all clinical outcomes above.

- Complications are recognised as a 'relative high complication rate of 27.9%' however this is substantially outweighed by the high patient satisfaction and QoL improvement post-surgery with or without complications [7].
- Reconstructive surgery resulted in a significant improvement in quality of life in patients at a mean interval of 42 months between weight loss and reconstructive surgery. The most frequent procedures were abdominoplasty and breast reconstruction. The relative high complication rate of 27.9% was of no influence on quality of life and the majority of the patients (67%) were satisfied with reconstructive surgery [7].
- QoL of existing health conditions with large reductions in 'Pain during exercise' by 4.34 (P≤0.0001) and 'Lymphedema' by 1.70 (P≤0.0001) and others [4].

3.3 Supports people with existing health problems

- The commissioning guidelines [1] provide a clear narrative on how body contouring can support the QoL for patients with existing health problems.
- The systematic review [4] explores in greater detail with scoring on the improvement of QoL of existing health conditions with large reductions in 'Pain during exercise' by 4.34 (P≤0.0001) and 'Lymphedema' by 1.70 (P≤0.0001) and others - distant indirect health utility benefit.

3.4 Safety

- Complications recognised included post procedure hematomas, abscesses which required secondary intervention; and few complications such as seromas and focal

skin neuroses. It is also highlighted that complications and infections are higher within smokers than non-smokers who receive procedure [1], [2], [7].

- Body contouring surgery (BCS) creates large wounds. The current evidence favours this surgery when patients have 'fully deflated'. Performing BCS at higher BMI's is associated with higher risk of complications [1].
- The following were defined as exceptions to BCS within the Commissioning Guide [1]:
    - Current smoker
    - Active psychiatric or psychological condition that would benefit from diagnosis and treatment prior to referral for body contouring surgery or that would contraindicate surgery including:
        - patients who have had an episode of self-harm within the last two years;
        - patients with a previous diagnosis of body dysmorphic disorder;
        - patients with a disproportionate view of the problem following consultation with a consultant Plastic Surgeon;
        - patients who currently have on going alcohol or drug misuse problems.

  NB: General health, social and lifestyle issues should also be taken into account before offering body contouring surgery to patients.

3.5 Equity issues

- Patients requiring body contouring surgery after bariatric surgery have been described as a new and unique population that is difficult to manage, with 96% of post-bariatric surgery patients developing multiple redundant skin flaps [5].
- Study [11] shows that there exists a postcode lottery for bariplastic surgery in England. The PCTs act independently of each other while drawing up their guidelines for the purposes of rationing. This leads to variability in funding for procedures in different regions within the NHS. The study showed a variation in guidelines across Trusts in the UK, amounting to a “postcode lottery” and stated that it is also evident from our survey that majority (101/106, 95.3%) of PCTs have their own guidelines and individual cut-off points for referrals leading to a postcode lottery for bariplastic surgery.

4. Activity and finance

There are a number of co-morbidities linked to obesity such as Type 2 diabetes, heart disease, some cancers, arthritis etc. The evidence demonstrates that there are statistically significant health improvement benefits to be realised in the overall health economy from Body Contouring Surgery following massive weight loss.

A Statistical report published in England 2018 [12] details the following facts on obesity, physical activity and diet, drawn together from a variety of sources.:

- In 2016/17, there were 617,000 admissions in NHS hospitals where obesity was a factor. This is an increase of 18% from 2015/16.

- In 2016, 26% of adults were classified as obese. This has increased from 15% in 1993 but has remained at a similar level since 2010.
- In 2016, 26% of adults consumed 5 or more portions of fruit and vegetables a day.

5. Summary of findings

- Consistent evidence and high score relates to high confidence the evidence will not change and any change will not be substantial.
- As stated in the justification the method in which to measure the effectiveness clinically is currently investigating & researching under the BODY-Q Method.
- Statistically significant health improvement benefits both in relation to QoL and clinical outcomes of more than 30% improvement
- Body Contouring based on the evidence has the potential to prevent both primary and secondary prevention of future illness such as mobility, QoL concerns, infection, lymphedema and other illnesses.
- A high capacity to improve health and starting with a high baseline health utility.
- No relevant QALYs found
- There is evidence from the systematic review that there is a vulnerable group (post bariatric surgery) that are more in need of body contouring.
- Diabetes was noted as a local and national priority that is linked to reducing obesity

6. Search Strategy

The following databases were routinely searched: NICE Clinical Guidance and full website search; NHS Evidence and NICE CKS; SIGN; Cochrane; York; and the relevant Royal College and any other relevant bespoke sites. A Medline search was undertaken where indicated and a general google search for key terms also undertaken.

Most of the evidence relating to these procedures was non-specific and included in reviews of obesity management. Systematic reviews of quality of outcome measures found that the papers studied did not use robust measures of outcomes and more work was needed but that overall patients appeared satisfied with the outcomes (based on low grade evidence). Studies looking at complications following these procedures found relatively high rates of complications but these were confounded by high rates of comorbidity.

6.1 Clinical criteria & definition:

Age over 16 years. Starting BMI above 40kg/m2 or above 35kg/m2 with co-morbidities AND current BMI of less than 30.0kg/m2 AND weight stability of 12 months AND significant functional disturbance (both physical and psychological). Weight stability allows for a maximum of 5kg increase or a 5kg decrease in weight [1].

6.2 Exceptions to general criteria:

Starting BMI above 40kg/m2 or above 35kg/m2 with co-morbidities and 75% excess body weight lost– should be eligible for apronectomy only - if they are unable to slim down to a

BMI of less than 30.0g/m2. A BMI of up to 40kg/m2 can be considered here. Weight stability of 12 months and significant functional disturbance applies here too.

6.3 PICO parameters:

Population: Those who clinically need 'Body Contouring' due to massive sustained weight loss.
Intervention: 'Body Contouring' (All procedures that are include under 'Body Contouring')
Comparator / Control: No surgery
Outcome: Clinical Benefit, Wider Health Utility, Mental Health

7. Glossary

Term	Meaning
Bariatric Surgery	Surgery to reduce the size of the stomach in order to promote weight loss.
Intertrigo	A dermatitis occurring between juxtaposed folds of skin. The dermatitis is usually caused by retention of sweat, moisture, and warmth which results in an overgrowth of normal skin microorganisms.
The Symphysis Pubis	The area of junction of the pubic bones and lies at the centre-front of the pelvic girdle.

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Evidence Review

Liposuction for Lymphoedema and Lipoedema

Questions to be addressed:

What is the evidence of clinical and cost effectiveness of liposuction specifically in patients with lymphoedema or lipoedema, in comparison to conservative treatment?

Reason for review:

NHS Birmingham and Solihull CCG and Sandwell and West Birmingham CCG, requested a rapid evidence review of the clinical and cost effectiveness of liposuction in lymphoedema and lipoedema. The review was requested to support policy development.

Options for commissioners:

1. Due to consistent and strong volume of evidence demonstrating that liposuction in lymphoedema is clinically effective, develop a commissioning policy that details restricted criteria.
2. Due to there being a lack of evidence identified to directly compare liposuction in lipoedema with conservative management develop a policy that indicates that this procedure is not routinely commissioned in this indication. Should further evidence be available in future, the policy will be reviewed accordingly.

Summary

Liposuction is normally deemed to be a cosmetic procedure used to remove unwanted body fat. It involves sucking out small areas of fat that are hard to lose through exercise and a healthy diet. It is carried out on areas of the body where deposits of fat tend to collect, such as the buttocks, hips, thighs and tummy.

The aim is to alter body shape, and the results are generally long-lasting, providing you maintain a healthy weight. It works best in people who are a normal weight and in areas where the skin is tight.

Background

Liposuction carried out for cosmetic reasons is not normally available on the NHS. However, liposuction can sometimes be used by the NHS to treat certain health conditions.

The intervention

Liposuction for chronic lymphoedema is usually done under general anaesthesia, but regional nerve blockade is also possible. Small incisions are made in the target area and cannulas, connected to a vacuum pump are inserted and oedematous adipose tissue is removed by vacuum aspiration. Liposuction is done around and all the way along the limb.

Immediately after liposuction, a compression bandage is applied to the limb to control any bleeding and to prevent postoperative oedema. Antibiotics are typically prescribed after the operation. The limb is elevated during hospital stay for 3 to 7 days after the procedure.

From about 2 weeks after the procedure, a custom-made compression garment is worn. This garment is revised 3 or 4 times during the first year until the oedema volume has been reduced as much as possible and a steady state has been reached [9].

Safety:

Side effects to expect - It's common after liposuction to have:

- **bruising and swelling**, which may last up to six months
- **numbness**, which should go away in six to eight weeks
- **scars**
- **inflammation** of the treated area, or the veins underneath
- **fluid** coming from the cuts
- **swollen ankles** (if the legs or ankles are treated)

What could go wrong - Liposuction can occasionally result in:

- **lumpy and uneven results**
- **bleeding under the skin** (haematoma)
- **persistent numbness** that lasts for months
- **changes in skin colour** in the treated area
- **a build-up of fluid in the lungs** (pulmonary oedema) from the fluid injected into the body
- **a blood clot in the lungs** (pulmonary embolism)
- **damage to internal organs** during the procedure

Any type of operation also carries a small risk of:

- **excessive bleeding**
- **developing a blood clot** in a vein
- **infection**
- **an allergic reaction** to the anaesthetic

The surgeon should explain how likely these risks and complications are, and how they would be treated if they occurred.

Occasionally, people find the desired effect wasn't achieved and feel they need another operation.

PART I: LIPOSUCTION IN LYMPHOEDEMA

Current Management

1 Context

Lymphoedema is a long-term (chronic) condition that causes swelling in the body's tissues. It can affect any part of the body, but usually develops in the arms or legs.

It develops when the lymphatic system doesn't work properly. The lymphatic system is a network of channels and glands throughout the body that helps fight infection and remove excess fluid.

There are two main types of lymphoedema:

- **primary lymphoedema** – caused by faulty genes that affect the development of the lymphatic system; it can develop at any age, but usually starts during infancy, adolescence, or early adulthood

- **secondary lymphoedema** – caused by damage to the lymphatic system or problems with the movement and drainage of fluid in the lymphatic system; it can be the result of an infection, injury, cancer treatment, inflammation of the limb, or a lack of limb movement

1.1 Introduction

There's no cure for lymphoedema, but it's usually possible to control the main symptoms using techniques to minimize fluid build-up and stimulate the flow of fluid through the lymphatic system.

These include wearing compression garments, taking good care of your skin, moving and exercising regularly, having a healthy diet and lifestyle, and using specialised massage techniques.

1.1.1 Decongestive lymphatic therapy (DLT)

The recommended treatment for lymphoedema is decongestive lymphatic therapy (DLT).

DLT isn't a cure for lymphoedema, but it can help control the symptoms. Although it takes time and effort, the treatment can be used to bring lymphoedema under control. There are four components to DLT:

- **compression bandages** – to complement exercise by moving fluid out of the affected limb and minimise further build-up
- **skin care** – to keep the skin in good condition and reduce the chances of infection
- **exercises** – to use muscles in the affected limb to improve lymph drainage
- **specialised massage techniques** – known as manual lymphatic drainage (MLD); this stimulates the flow of fluid in the lymphatic system and reduces swelling

DLT is an intensive phase of therapy, during which you may receive daily treatment for several weeks to help reduce the volume of the affected body part.

This is followed by a second phase called the maintenance phase. You'll be encouraged to take over your care using simple self-massage techniques, wearing compression garments, and continuing to exercise.

This treatment phase aims to maintain the reduced size of the affected body part.

1.1.2 Surgery

In a small number of cases, surgery may be used to treat lymphoedema. There are three main types of surgery that may be useful for the condition:

- removal of sections of excess skin and underlying tissue (debulking)
- removal of fat from the affected limb (liposuction)
- restoration of the flow of fluid around the affected section of the lymphatic system – for example, by connecting the lymphatic system to nearby blood vessels (lymphaticovenular anastomosis)

These treatments may help reduce the size of areas of the body affected by lymphoedema, but some are still being evaluated – particularly lymphaticovenular anastomosis – and aren't in widespread use.

1.2 Existing national policies and guidance

- NICE Guideline (IPG588): Liposuction for chronic lymphoedema

2 Epidemiology

Lymphoedema is thought to affect more than 200,000 people in the UK. Primary lymphoedema is rare and is thought to affect around 1 in every 6,000 people. Secondary lymphoedema is much more common.

Secondary lymphoedema affects around 2 in 10 women with breast cancer, and 5 in 10 women with vulval cancer. About 3 in every 10 men with penile cancer get lymphoedema. In the UK, one of the most common types of chronic lymphoedema is secondary lymphoedema of the arm after breast cancer or its treatment [9].

People who have treatment for melanoma in the lymph nodes in the groin can also get lymphoedema. Research has shown around 20-50% of people are affected [1].

3 Findings

3.1 Evidence of effectiveness

Cochrane systematic review in 2015 (six randomised controlled trials, 208 patients) considered the effectiveness of combined manual lymph drainage and other treatments compared with other treatments alone for lymphoedema after breast cancer treatment. [3]

In a second systematic review, studies were scored for methodological quality using the methodological index for nonrandomized studies (MINORS) scoring system. A total of 69 articles met inclusion criteria and were assigned MINORS scores with a maximum score of 16 or 24 for non-comparative or comparative studies, respectively. The average MINORS scores using non-comparative criteria were 12.1 for excision, 13.2 for liposuction. Thirty-nine studies scoring > 12/16 or > 19/24 were considered high quality. [4]

Both of the systematic reviews show good quality evidence and support the same outcome; further studies are unlikely to change confidence in the effect of the intervention. It is however important to note that no direct comparisons with conservative management in published sources.

SYSTEMATIC REVIEWS:

1. **Which are the best conservative interventions for lymphoedema after breast cancer surgery? [3]:**

ABSTRACT

Background: Breast cancer-related lymphoedema can be a debilitating long-term sequela of breast cancer treatment. Several studies have investigated the effectiveness of different treatment strategies to reduce the risk of breast cancer-related lymphoedema.

Objectives: To assess the effects of conservative (non-surgical and non-pharmacological) interventions for preventing clinically-detectable upper-limb lymphoedema after breast cancer treatment.

Search methods: Searched the Cochrane Breast Cancer Group's (CBCG) Specialised Register, CENTRAL, MEDLINE, EMBASE, CINAHL, PEDro, PsycINFO, and the World Health Organization (WHO) International Clinical Trials Registry Platform in May 2013. Reference lists of included trials and other systematic reviews were searched.

Selection criteria: Randomised controlled trials that reported lymphoedema as the primary outcome and compared any conservative intervention to either no intervention or to another conservative intervention.

Data collection and analysis: Three authors independently assessed the risk of bias and extracted data. Outcome measures included lymphoedema, infection, range of motion of the

shoulder, pain, psychosocial morbidity, level of functioning in activities of daily life (ADL), and health-related quality of life (HRQoL). Where possible, meta-analyses were performed. Risk ratio (RRs) or hazard ratio (HRs) were reported for dichotomous outcomes or lymphoedema incidence, and mean differences (MDs) for range of motion and patient-reported outcomes.

Main results: Ten trials involving 1205 participants were included. The duration of patient follow-up ranged from 2 days to 2 years after the intervention. Overall, the quality of the evidence generated by these trials was low, due to risk of bias in the included trials and inconsistency in the results.

Manual lymph drainage: In total, four studies used manual lymph drainage (MLD) in combination with usual care or other interventions. In one study, lymphoedema incidence was lower in patients receiving MLD and usual care (consisting of standard education or exercise, or both) compared to usual care alone. A second study reported no difference in lymphoedema incidence when MLD was combined with physiotherapy and education compared to physiotherapy alone. Two other studies combining MLD with compression and scar massage or exercise observed a reduction in lymphoedema incidence compared to education only, although this was not significant in one of the studies. Two out of the four studies reported on shoulder mobility where MLD combined with exercise gave better shoulder mobility for lateral arm movement (shoulder abduction) and forward flexion in the first weeks after breast cancer surgery, compared to education only (mean difference for abduction 22°; 95% confidence interval (CI) 14 to 30; mean difference for forward flexion 14°; 95% CI 7 to 22). Two of the studies on MLD reported on pain, with inconsistent results. Results on HRQoL in two studies on MLD were also contradictory.

Exercise: early versus delayed start of shoulder mobilising exercises

Three studies examined early versus late start of postoperative shoulder exercises. The pooled relative risk of lymphoedema after an early start of exercises was 1.69 (95% CI 0.94 to 3.01, 3 studies, 378 participants). Shoulder forward flexion was better at one and six months' follow-up for participants who started early with mobilisation exercises compared to a delayed start (two studies), but no meta-analysis could be performed due to statistical heterogeneity. There was no difference in shoulder mobility or self-reported shoulder disability at 12 months' follow-up (one study). One study evaluated HRQoL and reported difference at one-year follow-up (mean difference 1.6 points, 95% CI -2.14 to 5.34, on the Trial Outcome Index of the FACT-B). Two studies collected data on wound drainage volumes and only one study reported higher wound drainage volumes in the early exercise group.

Exercise: resistance training

Two studies compared progressive resistance training to restricted activity. Resistance training after breast cancer treatment did not increase the risk of developing lymphoedema (RR 0.58; 95% CI 0.30 to 1.13, two studies, 358 participants) provided that symptoms are

monitored and treated immediately if they occur. One out of the two studies measured pain where participants in the resistance training group reported pain more often at three months and six months compared to the control group. One study reported HRQoL and found no significant difference between the groups.

Patient education, monitoring and early intervention.

One study investigated the effects of a comprehensive outpatient follow-up programme, consisting of patient education, exercise, monitoring of lymphoedema symptoms and early intervention for lymphoedema, compared to education alone. Lymphoedema incidence was lower in the comprehensive outpatient follow-up programme (at any time point) compared to education alone (65 people). Participants in the outpatient follow-up programme had a significantly faster recovery of shoulder abduction compared to the education alone group.

Authors' conclusions: Based on the current available evidence, we cannot draw firm conclusions about the effectiveness of interventions containing MLD. The evidence does not indicate a higher risk of lymphoedema when starting shoulder-mobilising exercises early after surgery compared to a delayed start (i.e. seven days after surgery). Shoulder mobility (that is, lateral arm movements and forward flexion) is better in the short term when starting shoulder exercises earlier compared to later. The evidence suggests that progressive resistance exercise therapy does not increase the risk of developing lymphoedema, provided that symptoms are closely monitored and adequately treated if they occur. Given the degree of heterogeneity encountered, limited precision, and the risk of bias across the included studies, the results of this review should be interpreted with caution.

2. **Systematic Review of the Surgical Treatment of Extremity Lymphedema [4]**

ABSTRACT

Background: Although conservative management of lymphedema remains the first-line approach, surgery is effective in select patients. The purpose of this study was to review the literature and develop a treatment algorithm based on the highest quality lymphedema research.

Methods: A systematic literature review was performed to examine the surgical treatments for lymphedema. Studies were categorized into five groups describing excision, liposuction, lymphovenous anastomosis (LVA), vascularized lymph node transfer (VLNT), and combined/multiple approaches. Studies were scored for methodological quality using the methodological index for nonrandomized studies (MINORS) scoring system.

Results: A total of 69 articles met inclusion criteria and were assigned MINORS scores with a maximum score of 16 or 24 for noncomparative or comparative studies, respectively. The average MINORS scores using noncomparative criteria were 12.1 for excision, 13.2 for liposuction, 12.6 for LVA, 13.1 for VLNT, and 13.5 for combined/multiple approaches. Loss to follow-up was the most common cause of low scores. Thirty-nine studies scoring > 12/16

or > 19/24 were considered high quality. In studies measuring excess volume reduction, the mean reduction was 96.6% (95% confidence interval [CI]: 86.2–107%) for liposuction, 33.1% (95% CI: 14.4–51.9%) for LVA, and 26.4% (95% CI: − 7.98 to 60.8%) for VLNT. Included excision articles did not report excess volume reduction.

Conclusion: Although the overall quality of lymphedema literature is fair, the MINORS scoring system is an effective method to isolate high-quality studies. These studies were used to develop an evidence-based algorithm to guide clinical practice. Further studies with a particular focus on patient follow-up will improve the validity of lymphedema surgery research.

CASE SERIES:

1. **Operative Treatment of Lymphedema Using Suction-Assisted Lipectomy [7].**

ABSTRACT

Surgical management of lymphedema includes removal of affected tissues (excisional procedures), or operations that create new lymphatic connections (physiologic procedures). The purpose of this study was to determine the efficacy of one type of excisional procedure, suction-assisted lipectomy, for extremity lymphedema. Patients treated in our Lymphedema Program between 2007 and 2015 with liposuction that had postoperative follow-up were reviewed. The diagnosis of lymphedema was made by history/physical examination and confirmed with lymphoscintigraphy. Patient sex, age, type of lymphedema (primary or secondary), location of disease, infection history, volume of lipoaspirate, and reduction of extremity volume were recorded. Fifteen patients were included, mean age was 45 years (range, 17-71). Six patients had secondary upper extremity lymphedema, and 9 patients had lower limb disease. Eight patients had a history of repeated cellulitis involving the lymphedematous extremity. Mean lipoaspirate volume was 1612 mL (range, 1200-2800) for the upper extremity and 2902 mL (range, 2000-4800) for the lower limb. Postoperative follow-up averaged 3.1 years. The mean reduction in excess extremity volume was 73% (range, 48% to 94%), and patients reported improvement in their quality of life. Suction-assisted lipectomy is an effective technique to reduce extremity volume for patients with lymphedema.

Background: Surgical management of lymphedema includes removal of affected tissues (excisional procedures), or operations that create new lymphatic connections (physiologic procedures). The purpose of this study was to determine the efficacy of one type of excisional procedure, suction-assisted lipectomy, for extremity lymphedema.

Methods: Patients treated in our Lymphedema Program between 2007 and 2015 with liposuction that had postoperative follow-up were reviewed. The diagnosis of lymphedema was made by history/physical examination and confirmed with lymphoscintigraphy. Patient

sex, age, type of lymphedema (primary or secondary), location of disease, infection history, volume of lipoaspirate, and reduction of extremity volume were recorded.

Results: Fifteen patients were included, mean age was 45 years (range, 17–71). Six patients had secondary upper extremity lymphedema, and 9 patients had lower limb disease. Eight patients had a history of repeated cellulitis involving the lymphedematous extremity. Mean lipoaspirate volume was 1612 mL (range, 1200–2800) for the upper extremity and 2902 mL (range, 2000–4800) for the lower limb. Postoperative follow-up averaged 3.1 years. The mean reduction in excess extremity volume was 73% (range, 48% to 94%), and patients reported improvement in their quality of life.

Conclusions: Suction-assisted lipectomy is an effective technique to reduce extremity volume for patients with lymphedema.

3.1.1 Cost effectiveness

No information available.

3.2 Magnitude of Health Improvement Benefit

No direct comparison in literature so indirect comparison made. Evidence shows a moderate to large health improvement using this procedure supported by long term follow up.

- In studies measuring excess volume reduction, the mean reduction was 96.6% (95% confidence interval [CI]: 86.2–107%) for liposuction [4]
- Findings support the use of an intensive course of compression bandaging to reduce lymphoedema volume. One year follow-up findings suggest better maintenance of reduction in limb volume in those who used compression hosiery. Manual lymph drainage was found to offer additional benefit when added to compression bandaging (mean difference in reduction of arm volume 7%, 95% confidence interval 1.75-12.47, P=0.009) [3]
- To determine the longer term outcomes of the technique, Schaverien et al published 21-year prospective data in 146 women with arm lymphedema. 11 Preoperative mean excess volume was 1,568 mL (range: 545–4,235), aspirate mean volume was 1,807 mL (range 650–3,850), and postoperative mean reduction was 103% (range 50–194) at 3 months and more than 100% during 21 years' follow-up. The preoperative mean volume ratio between the affected and unaffected arms was 1.5, declining to 1.0 at 3 months, and <1.0 after 1 year. This demonstrates the long-term effectiveness and stability of the technique. [5]

3.3 Supports people with existing health problems

The condition presents as a moderate health utility, and there is moderate capacity for improvement for the intervention (liposuction). Moderate health utility has been used because there is a wide range of severity and considerable variability for Lymphoedema.

- 3 Studies included in a Systematic Review reported improved well-being and decreased depression and anxiety postoperatively at 12- to 38-month follow-up after liposuction. [4]
- A consecutive cohort of 90 patients treated by liposuction for chronic lymphoedema responded to a SF-36 questionnaire before and at different points after the procedure. At 3-month follow-up the physical functioning, bodily pain, mental health and vitality dimensions were statistically significantly improved from baseline assessment, $p<0.05$. At 12-month follow-up the all of the above dimension plus social functioning were statistically significantly improved from baseline assessment, $p<0.05$. [6]

3.4 Prevention of Future illness

There is clear evidence that the intervention prevents future illness; due to the nature of the illness and the reduction in the likelihood of serious infections.

- In the case series of 15 patients (12 women, 3 men) treated by liposuction, all patients reported improved extremity function, reduction in episodes of cellulitis and better quality of life. [7]
- In the case series of 88 patients treated by liposuction, the rate of cellulitis was statistically significantly reduced from 8 (per limb per year) at baseline to 0.2 in the patients with primary lymphoedema and from 6 to 0.3 in the secondary lymphoedema group, at 24-month follow-up. [8]

3.5 Equity issues

There are indirect associations between lymphoedema and socioeconomic and population inequalities; lymphoedema is associated with obesity and cancer and these are both associated with socioeconomic inequalities [1]. A number of causes of secondary Lymphoedema [2] include:

- **Surgery.** Removal of or injury to lymph nodes and lymph vessels may result in lymphedema. For example, lymph nodes may be removed to check for spread of breast cancer, and lymph nodes may be injured in surgery that involves blood vessels in your limbs.

- **Radiation treatment for cancer.** Radiation can cause scarring and inflammation of your lymph nodes or lymph vessels.

- **Cancer.** If cancer cells block lymphatic vessels, lymphedema may result. For instance, a tumour growing near a lymph node or lymph vessel could enlarge enough to block the flow of the lymph fluid.

- **Infection.** An infection of the lymph nodes or parasites can restrict the flow of lymph fluid. Infection-related lymphedema is most common in tropical and subtropical regions and is more likely to occur in developing countries.

4.Activity and finance

The National Lymphoedema Tariff Guide recommended by BLS represents an average treatment schedule. The costing models are based on a 42-week year, staff cost and related service provision costs. The cost for simple/early to complex treatment ranges from £922.50 to £4551 [10].

5.Summary of findings

- Cochrane and Systematic Reviews show good quality of evidence, multiple Systematic Reviews supporting the same outcome therefore further studies unlikely to change confidence in the effect.
- No direct comparison with conservative management noted in literature so indirect comparisons have been made.
- Evidence shows that there is moderate to large health improvement of using this procedure supported by long term follow up.
- There is clear evidence of prevention of future illness, due to the nature of the illness and the reduction in the likelihood of serious infections.
- There is a high prevention benefit.
- Moderate health utility and moderate capacity of intervention to improve the health state
- Indirect socioeconomic associations for some of the main causes including obesity and cancer.

6.Search Strategy

PICO parameters:

Population: Patients with primary and secondary lymphoedema all limbs
Intervention: Liposuction +/- tourniquet +/- adrenaline
Comparator / Control: conservative management
Outcome: Clinical effectiveness including Pain, Function/mobility, Quality of Life score AE,

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PART II: LIPOSUCTION IN LIPOEDEMA

Current Management

1 Context

Lipoedema is a long-term (chronic) condition where there's an abnormal build-up of fat cells and usually only affects women, although in rare cases it can also affect men. This normally occurs in the legs, thighs and buttocks, and sometimes in the arms which are usually enlarged at the same time and to the same extent.

The feet and hands aren't affected, which creates a "bracelet" effect or "band-like" appearance just above the ankles and wrists. Leg and arm size can vary between individuals with lipoedema, and the condition can gradually get worse over time.

As well as becoming enlarged, affected areas of the body may:

- feel soft, "doughy" and cold
- bruise easily
- ache or feel painful or tender
- have small broken veins under the skin

Someone with lipoedema may eventually get fluid retention (lymphoedema) in their legs. This type of swelling can worsen by the end of the day and may improve overnight, whereas the fatty swelling of lipoedema is constant.

1.1 Introduction

There's been little research into lipoedema, so there's some uncertainty about the best way to treat the condition.

If you have lipoedema it's important to avoid significant weight gain and obesity because putting on weight will make the fatty swelling worse.

1.2 Treatments for lipoedema

1.2.1 Non-surgical treatments

These can sometimes help improve pain and tenderness, prevent or reduce lymphoedema, and improve the shape of affected limbs – although they often have little effect on the fatty tissue.

Several different treatments are designed to improve the flow and drainage of fluid in your tissues, such as:

- compression therapy – wearing bandages or garments that squeeze the affected limbs
- exercise – usually low-impact exercises, such as swimming and cycling
- massage – techniques that help encourage the flow of fluid through your body

Compression tights are helpful for some people because they support the fatty swelling and may reduce the pain.

1.2.2 Tumescent liposuction

Liposuction is the surgical option for the removal of fat.

Tumescent liposuction involves sucking out the unwanted fat through a tube. A liquid solution is first injected into the legs to help numb the area and reduce blood loss.

Fatty swelling of the legs may return after having the procedure if weight gain occurs.

Non-surgical treatments may also be needed for a long period after having tumescent liposuction. For example, you'll need to wear compression garments after surgery to prevent complications such as lymphoedema.

1.3 Treatments that don't work

Treatments used for some types of tissue swelling are generally unhelpful for lipoedema.

Lipoedema doesn't respond to:

- raising the legs
- diuretics (tablets to get rid of excess fluid)
- dieting – this tends to result in a loss of fat from areas not affected by lipoedema, with little effect on the affected areas

1.4 Causes of lipoedema

The cause of lipoedema isn't known, but in some cases there's a family history of the condition. It seems likely that the genes you inherit from your parents play a role.

Lipoedema tends to start at puberty or at other times of hormonal change, such as during pregnancy or the menopause, which suggests hormones may also have an influence.

Although the accumulation of fat cells is often worse in obese people, lipoedema isn't caused by obesity and can affect people who are a healthy weight. It shouldn't be mistaken for obesity, and dieting often makes little difference to the condition.

1.5 Existing national policies and guidance

There is currently no national policy or guidance around liposuction in lipoedema.

2 Epidemiology

Relatively little epidemiological research has been carried out on lipoedema and so it is unclear exactly how many people are affected and to what extent. The research so far has

produced widely varying figures. In the UK, the minimum prevalence of lipoedema has been estimated to be 1 in 72,000 which is also noted as likely to be an underestimate [5].

3 Findings

3.1 Evidence of effectiveness

There has been little research into lipoedema, so there's some uncertainty about the best way to treat the condition. If you have lipoedema it's important to avoid significant weight gain and obesity because putting on weight will make the fatty swelling worse. Compression tights are helpful for some people because they support the fatty swelling and may reduce the pain. The only treatment that appears to be effective in reducing the build-up of fatty tissue associated with lipoedema is a procedure called tumescent liposuction [1].

3.1.1 Quality and strength of evidence

No Randomised Controlled trials or systematic reviews were found during the evidence review; however, 3 relevant case series were considered and below is the summary of the evidence review. No studies directly compared liposuction to conservative treatment, but patients undergoing the intervention had previously received conservative management so any benefits stated for interventions were in addition to any benefits achieved by conservative management:

- Twenty-five patients [2] who received 72 liposuction procedures for the treatment of lipoedema completed a standardized questionnaire. Lipoedema-associated complaints and the need for combined decongestive therapy (CDT) were assessed for the preoperative period and during 2 separate postoperative follow-ups using a visual analogue scale and a composite CDT score. The mean follow-up times for the first postoperative follow-up and the second postoperative follow-up were 16 months and 37 months, respectively.
- Whereas conservative methods with combined decongestive therapy (manual lymphatic drainage, compression garments) have been well established over the past 50 years, surgical therapy with tumescent liposuction has only been used for about 10 years and long-term results are unknown. A total of 164 patients who had undergone conservative therapy over a period of years, were treated by liposuction under tumescent local anaesthesia with vibrating microcannulas. In a monocentric study, 112 could be re-evaluated with a standardized questionnaire after a mean of 3years and 8months (range 1year and 1month to 7years and 4months) following the initial surgery and a mean of 2years and 11months (8months to 6years and 10months) following the last surgery. [3]
- In a single-centre study, 85 patients with lipoedema had already been examined after 4 years. A mail questionnaire - often in combination with clinical controls - was

repeated after another 4 years (8 years after liposuction). Compared with the results after 4 years, the improvement in spontaneous pain, sensitivity to pressure, oedema, bruising and restriction of movement persisted. The same held true for patient self-assessment of cosmetic appearance, quality of life and overall impairment. Eight years after surgery, the reduction in the amount of conservative treatment (combined decongestive therapy, compression garments) was similar to that observed 4 years earlier. [4]

3.1.2 Clinical Effectiveness

CASE SERIES

1. **Liposuction in the Treatment of Lipoedema: A Longitudinal Study [2].**

ABSTRACT

Background: Lipoedema is a condition consisting of painful bilateral increases in subcutaneous fat and interstitial fluid in the limbs with secondary lymphedema and fibrosis during later stages. Combined decongestive therapy (CDT) is the standard of care in most countries. Since the introduction of tumescent technique, liposuction has been used as a surgical treatment option. The aim of this study was to determine the outcome of liposuction used as treatment for lipoedema.

Methods: Twenty-five patients who received 72 liposuction procedures for the treatment of lipoedema completed a standardized questionnaire. Lipoedema-associated complaints and the need for CDT were assessed for the preoperative period and during 2 separate postoperative follow-ups using a visual analogue scale and a composite CDT score. The mean follow-up times for the first postoperative follow-up and the second postoperative follow-up were 16 months and 37 months, respectively.

Results: Patients showed significant reductions in spontaneous pain, sensitivity to pressure, feeling of tension, bruising, cosmetic impairment, and general impairment to quality of life from the preoperative period to the first postoperative follow-up, and these results remained consistent until the second postoperative follow-up. A comparison of the preoperative period to the last postoperative follow-up, after 4 patients without full preoperative CDT were excluded from the analysis, indicated that the need for CDT was reduced significantly. An analysis of the different stages of the disease also indicated that better and more sustainable results could be achieved if patients were treated in earlier stages.

Conclusions: Liposuction is effective in the treatment of lipoedema and leads to an improvement in quality of life and a decrease in the need for conservative therapy.

2. **Tumescent liposuction in lipoedema yields good long-term results [3].**

ABSTRACT

Background: Lipoedema is a painful disease in women with circumscribed increased subcutaneous fatty tissue, oedema, pain and bruising. Whereas conservative methods with combined decongestive therapy (manual lymphatic drainage, compression garments) have been well established over the past 50years, surgical therapy with tumescent liposuction has only been used for about 10years and long-term results are unknown.

Objectives: To determine the efficacy of liposuction concerning appearance (body shape) and associated complaints after a long-term period.

Methods: A total of 164 patients who had undergone conservative therapy over a period of years, were treated by liposuction under tumescent local anaesthesia with vibrating microcannulas. In a monocentric study, 112 could be re-evaluated with a standardized questionnaire after a mean of 3years and 8months (range 1year and 1month to 7years and 4months) following the initial surgery and a mean of 2years and 11months (8months to 6years and 10months) following the last surgery.

Results: All patients showed a distinct reduction of subcutaneous fatty tissue (average 9846mL per person) with improvement of shape and normalization of body proportions. Additionally, they reported either a marked improvement or a complete disappearance of spontaneous pain, sensitivity to pressure, oedema, bruising, restriction of movement and cosmetic impairment, resulting in a tremendous increase in quality of life; all these complaints were reduced significantly (P<0·001). Patients with lipoedema stage II and III showed better improvement compared with patients with stage I. Physical decongestive therapy could be either omitted (22·4% of cases) or continued to a much lower degree. No serious complications (wound infection rate 1·4%, bleeding rate 0·3%) were observed following surgery.

Conclusions: Tumescent liposuction is a highly effective treatment for lipoedema with good morphological and functional long-term results.

3. **Long-term benefit of liposuction in patients with lipoedema: a follow-up study after an average of 4 and 8 years [4].**

ABSTRACT

Background: Long-term results following liposuction in patients with lipoedema are available only for an average period of 4 years.

Objective: To find out whether the improvement of complaints persists for a further 4 years.

Methods: In a single-centre study, 85 patients with lipoedema had already been examined after 4 years. A mail questionnaire - often in combination with clinical controls - was repeated after another 4 years (8 years after liposuction).

Results: Compared with the results after 4 years, the improvement in spontaneous pain, sensitivity to pressure, oedema, bruising and restriction of movement persisted. The same held true for patient self-assessment of cosmetic appearance, quality of life and overall impairment. Eight years after surgery, the reduction in the amount of conservative treatment (combined decongestive therapy, compression garments) was similar to that observed 4 years earlier.

Conclusion: These results demonstrate for the first time the long-lasting positive effects of liposuction in patients with lipoedema.

3.1.2 Cost effectiveness

No relevant studies identified.

3.2 Magnitude of Health Improvement Benefit

The health improvement benefits shown within the two trials, and are directly comparable with the benefits requested within the research parameters, are substantial.

The results suggest that there are both short and long-term sustained improvements in almost all dimensions around pain and Quality of Life (QoL), and one study substantiates this as over and above conservative treatment.

- Tumescent liposuction involves sucking out the unwanted fat through a tube. A liquid solution is first injected into the legs to help numb the area and reduce blood loss. The procedure can be effective and have good results, but several operations may be needed to remove the fat from different parts of your body. Fatty swelling of the legs may return after having the procedure if weight is gained. Non-surgical treatments may also be needed for a long period after having tumescent liposuction. For example, compression garments will need to be worn after surgery to prevent complications such as lymphoedema [1].
- Patients showed significant reductions in spontaneous pain, sensitivity to pressure, feeling of tension, bruising, cosmetic impairment, and general impairment to quality of life from the preoperative period to the first postoperative follow-up, and these results remained consistent until the second postoperative follow-up. Patients also reported substantial lipoedema-associated complaints preoperatively. Spontaneous pain was reported with a mean VAS score of 7.2 (standard deviation [SD], 1.46); the equivalent of “severe” to “very severe” spontaneous pain. Sensitivity to pressure and feeling of tension were reported with mean VAS scores of 7.38 (SD, 1.79) and 7.52 (SD, 1.36), respectively, falling within the “very severe” range. The reported cosmetic

impairment ranged from “severe” to “unbearable,” resulting in a mean VAS score of 8.98 (SD, 0.81). General impairment to quality of life was also reported as “very severe,” with a mean VAS score of 8.38 (SD, 1.06). The severity of all analysed complaints was significantly reduced over the course of liposuction treatment by the time of the first postoperative follow-up. All but 1 of the patients reported a reduction in spontaneous pain (the chief complaint in lipoedema), with a mean difference in VAS score of 3.5 (95% confidence interval [CI], 2.83–4.17). Furthermore, all but 1 of the patients reported a reduction in impairment of quality of life, with a mean difference in VAS score of 4.08 (95% CI, 3.12–5.04). The Bonferroni-corrected P-value was <0.001 for all 6 complaints. At the second postoperative follow-up, only the severity of cosmetic impairment significantly increased since the first postoperative follow-up, and there was significant improvement in all symptoms between the preoperative period and the second postoperative follow-up [2].

VAS - Is a visual system form scoring pain levels, 0=no pain, 5 is moderate, 10 is extreme pain/worst pain ever

- The patients reported either a marked improvement or a complete disappearance of spontaneous pain, sensitivity to pressure, oedema, bruising, restriction of movement and cosmetic impairment, resulting in a tremendous increase in quality of life; all these complaints were reduced significantly (P<0·001). Patients with lipoedema stage II and III showed better improvement compared with patients with stage I. Physical decongestive therapy could be either omitted (22·4% of cases) or continued to a much lower degree. No serious complications (wound infection rate 1·4%, bleeding rate 0·3%) were observed following surgery [3].
- The results of the studies suggest that there are both short and long-term sustained improvements in almost all dimensions relating to pain and quality of life.

3.3 Supports people with existing health problems

Baseline health utility living with the condition has been considered as high, with the capacity to benefit also being high (the results show almost universal improvement across patients).

- The combination of symptoms can lead to reduced mobility and psychological issues, such as low self-esteem [1].
- The condition is a major psychosocial burden for most patients, causing pain that often limits their capacity for exercise. In addition, standing for long periods of time and high temperatures are not tolerated well by those with lipoedema, and in severe cases, the condition may cause absence from work or lead to occupational disability [2].

3.4 Prevention of future illness

There are statements that suggest lipoedema may develop into lymphoedemia, which is a serious condition. However, there was no evidence how often this may occur and whether this intervention would mitigate such development, the minimum score has been awarded.

There is potential plausibility in such statements and if the evidence base became more robust there would be potential to modify this score.

- A person with lipoedema may eventually develop lymphoedema as well, if the build-up of fat affects lymphatic drainage. This combination of the two conditions is known as lipo-lymphoedema [1].
- Data published in a longitudinal study suggest that liposuction treatment for stage II lipoedema provides a more sustainable reduction in the impairment of quality to life and a larger decrease in the need for conservative therapy than liposuction treatment for stage III lipoedema. The authors state that due to the development of secondary lymphedema and the irreversible damage to the lymphatic system that occurs in later stages of the disease, liposuction should be implemented as part of the standard therapy for lipoedema at early stages. This will prevent disease progression, improve quality of life, and reduce the need for decongestive therapy [2].

3.5 Equity issues

Very strong direct associated between being female and the presentation of the condition, although no other associations are cited.

- The condition usually only affects women, although in rare cases it can also affect men [1].
- It almost exclusively affects women, and there are very few published case reports of men with lipoedema [2].

4 Activity and finance

Lipoedema is estimated to occur in 11% of the adult female population, meaning that millions of women worldwide are affected [5]. No further activity or finance data available.

5 Summary of findings

- There is no evidence available that directly compares the intervention with conservative management – where evidence testing the intervention is found it is applied to patient cohorts that have already received conservative management so any benefits reported for the intervention are in addition to any benefits already delivered by conservative treatment [1].
- The evidence [2] itself (consisting of three trials totalling 274 patients) along with the NHS website states that this is a relatively new and under researched condition. The study consisting of 164 patients clearly stated that they had “undergone conservative therapy over a period of years” and as such the benefits stated can be viewed as over and above those offered by conservative treatment.

- The studies [2] were consistent on their findings and provided moderate confidence that the research reflects the true effect, however the lack of RCTs (or direct comparison to no treatment on two of the studies) is noted.
- The health improvement benefits shown within the two trials, are directly comparable with the benefits requested within the PICO.
- The results suggest that there are both short and long-term sustained improvements in almost all dimensions around pain and Quality of Life (QoL), and one study substantiates this as over and above conservative treatment.
- There are statements that suggest lipoedema may develop into lymphoedemia, which is a serious condition. However, there was no evidence how often this may occur and whether this intervention would mitigate such development.
- Baseline health utility if living with the condition has been considered as high, with the capacity to benefit also being high (the results show almost universal improvement across patients).
- Very strong direct associated between being female and the presentation of the condition, although no other associations with socioeconomic factors are cited.

6 Search Strategy

The following databases were routinely searched: NICE Clinical Guidance and full website search; Cochrane; York; and the relevant Royal College and any other relevant bespoke sites. A Medline / Open Athens search was undertaken where indicated and a general google search for key terms was also undertaken.

6.1 PICO parameters:

Population: Patients with Lipoedema
Intervention: Liposuction
Comparator / Control: Conservative Treatment
Outcome: Clinical improvement in pain, Quality of Life (QoL)

7 References

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[3]Tumescent liposuction in lipoedema yields good long-term results (2017) - https://www.ncbi.nlm.nih.gov/pubmed/21824127

[4] Long-term benefit of liposuction in patients with lipoedema: a follow-up study after an average of 4 and 8 years (2015) - https://www.ncbi.nlm.nih.gov/pubmed/26574236

[5] Best Practice Guidelines (Wounds UK – 2017): The management of lipoedema https://www.lipoedema.co.uk/wp-content/uploads/2017/05/WUK_Lipoedema-BPS_Web.pdf

Evidence Review for Adenoidectomy

Question to be addressed

1. In patients with documented medical problems caused by obstruction of the airway by the adenoids and all conservative treatments have been exhausted is there evidence to support adenoidectomy?

Reason for review

NHS Birmingham and Solihull CCG, Sandwell and West Birmingham CCG, requested a rapid evidence review of the clinical and cost effectiveness of adenoidectomy for adults with a documented medical problem, caused by obstruction of the airway compared to alternative treatment options, to inform their decisions on commissioning policy development.

Options for commissioners:

1. The Committee considers that due to the limited quality of evidence of clinical and cost effectiveness for the use adenoidectomy compared to conservative treatment options, its use should be considered a low priority.
2. The Committee recommends that, due to the limited quality of evidence of its clinical and cost effectiveness, adenoidectomy should be offered ONLY to patients who have failed conservative treatment.
3. The Committee considers that there is sufficient evidence to suggest that the use of adenoidectomy in patients with enlarged adenoids which care causing documented medical probelms is at least as effective as alternative treatment options and the costs are comparable, therefore the decision about which approach to proceed with should be made after an informed discussion between the clinician and the individual person about the risks and benefits of each procedure.

Summary

Background

- Adenoids are small lumps of tissue at the back of the nose, above the roof of the mouth.
- Adenoids are part of the immune system, which helps fight infection and protects the body from bacteria and viruses.
- By age seven to eight, the adenoids start to shrink and by the late teens, they're barely visible. By adulthood, they should have disappeared completely.
- Adenoidectomy is the surgical procedure to remove enlarged adenoids

Clinical effectiveness

- There was a paucity of evidence available to determine the clinical effectiveness of adenoidectomy, however NICE IPG supports this intervention.

Safety

NICE supports the use of adenoidectomy and deems it a safe intervention.

Cost effectiveness

NICE deems adenoidectomy with suction diathermy to be cost effective.

Equity issues

None were identified within the course of this review.

Context

1.1 Introduction

- Adenoids are small lumps of tissue at the back of the nose, above the roof of the mouth. You can't see a person's adenoids by looking in their mouth.
- Adenoids are part of the immune system, which helps fight infection and protects the body from bacteria and viruses.
- In most cases only children have adenoids. They start to grow from birth and are at their largest when a child is around three to five years of age. By age seven to eight, the adenoids start to shrink and by the late teens, they're barely visible. By adulthood, in most people they will have disappeared completely.
- Adenoids can be helpful in young children, but they're not an essential part of an adult's immune system. This is why they shrink and eventually disappear.
- Adenoids can sometimes become swollen or enlarged. This can happen after a bacterial or viral infection, or after a substance triggers an allergic reaction.
- In most cases, swollen adenoids only cause mild discomfort and treatment isn't needed. However, for some, it can cause severe discomfort and interfere with their daily life.

Management

- The adenoids can be removed during an adenoidectomy.
- The operation is usually carried out by an ear, nose and throat (ENT) surgeon and takes around 30 minutes. Afterwards, the patient will need to stay in the recovery ward for up to an hour until the anaesthetic has worn off.
- Adenoidectomies are sometimes day cases if carried out in the morning, in which case you / your child may be able to go home on the same day. However, if the

procedure is carried out in the afternoon, you / your child may need to stay in hospital overnight.

1.2 Existing national policies and guidance

NICE Interventional procedures guidance [IPG328] Suction diathermy adenoidectomy Published date: December 2009

- Guidance was published in 2009 on suction diathermy adenoidectomy which states that this procedure should only be carried out by trained surgeons who perform the procedure regularly.
- The use of adenoidectomy is considered by NICE to be an 'Interventional Procedure', and therefore is not 'approved' as may be the case for a drug or procedure subject to technology appraisal. NICE do not examine interventional procedures which are considered established practice unless there are data demonstrating uncertainty about their efficacy or safety.

- **Epidemiology**

There was a lack of epidemiology data available relating to adenoidectomy in adults.

- **Findings**

.1 Evidence of effectiveness

NICE IPG 328 found clinical effectiveness of the suction diathermy procedure, however no systematic reviews were found of adenoidectomy in adults / adolescents.

.1.1 Clinical effectiveness

Adenoidectomy is an accepted intervention in children with medical problems caused by enlarged adenoids.

However, there is very little available evidence on the use of adenoidectomy in adults with adenoid hypertrophy.

4.1.2 Trials in progress

A search of clinicaltrials.gov found no clinical trials currently recruiting for a review of adenoidectomy vs conservative management in either adults or children.

4.1.3 Cost-effectiveness

NICE deems adenoidectomy with suction diathermy to be cost effective.

.2 Safety

- NICE IPG 328 found clinical effectiveness and safety of the suction diathermy procedure.

.1 Summary of findings

There is a significant paucity of evidence available to review the use of adenoidectomy fully. However, the available evidence along with clinical review, supports the use of adenoidectomy in certain clinical circumstances.

- Equity issues

There is a greater occurrence rates of adenoidectomy in children as most adenoids have resolved by the time a child has reached the age of 8 years old.

- Search Strategy

PubMed:

Publication types, MeSH terms

Publication types

- Meta-Analysis
- Review
- Systematic Review

MeSH terms

- Adenoids/abnormalities*
- Humans
- Hypertrophy/diagnosis
- Hypertrophy/epidemiology*
- Prevalence

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Evidence Review for the Use of Non-Invasive Ventilation in a Domiciliary Setting

Question to be addressed

1. In adults with respiratory failure in:
    a. Chronic obstructive pulmonary disease
    b. Neuro-muscular disease
    c. Obstructive Sleep Apnoea

is there evidence to support the use of non-invasive domiciliary ventilation and if so, in what clinical circumstances is the use of domiciliary NIV appropriate?

Reason for review

NHS Birmingham and Solihull CCG, Sandwell and West Birmingham CCG, requested a rapid evidence review of the clinical and cost effectiveness of the use of domiciliary non-invasive ventilation in reducing hospital admissions and preventing death to inform their decisions on commissioning policy development.

Options for commissioners:

1. The Committee considers that due to the limited quality of evidence of clinical and cost effectiveness for the use of domiciliary non-invasive ventilation compared to alternative treatment options, its use should be considered a low priority.
2. The Committee recommends that, due to the limited quality of evidence of its clinical and cost effectiveness, the use of domiciliary non-invasive ventilation should be offered ONLY to patients who have certain clinical diagnoses and have a certain degree of respiratory failure.
3. The Committee considers that there is sufficient evidence to suggest that the use of domiciliary NIV is at least as effective as alternative treatment options and the costs are comparable, therefore the decision to commence non-invasive ventilation should be made after an informed discussion between the clinician and the individual person about the risks and benefits.

Summary

Background

- Respiratory Failure can occur in a number of clinical circumstances and can impact on a patient's ability to carry out activities of daily living and can ultimately result in death.
- Non-invasive ventilation can be undertaken using positive or negative pressure, though the most commonly used form of non-invasive ventilation is positive pressure.
- Positive pressure ventilation can be undertaken through continuous positive airway pressure through to bi-level ventilation.

Clinical effectiveness

- Clinical effectiveness of non-invasive ventilation was clearly identified in number of clinical scenarios:

.1 Chronic Obstructive Pulmonary Disease

.2 Neuromuscular Diseases
.3 Obstructive Sleep Apnoea

- NICE clearly supports the use of this intervention in OSA & Motor Neurone Disease.
- There is strong evidence not only for the clinical effectiveness of the use of NIV in certain clinical circumstances but also for the cost-effectiveness of this intervention in preventing deterioration in patient symptoms, readmission to an acute care setting and death.

Safety

NICE & MHRA support the use of Non-invasive ventilation support in certain clinical circumstances.

Cost effectiveness

A. COPD

No QALY identified within the literature.

B. NMD

Cost-effectiveness of the use of Non-invasive ventilation was supported by NICE (NG 42) with certain cohorts of this patient population diagnosed with NMD

C. OSA

Cost-effectiveness of the use of Non-invasive ventilation was supported by NICE (2012 TA139) with certain cohorts of this patient population diagnosed with OSA.

Equity issues

None were identified within the course of this review for OSA or Neuro-

dependent patient, however COPD was associated with deprivation. Major risk factors for developing COPD are smoking, and occupation dust exposure in patients over the age of 40 years old. Ensuring good smoking cessation support in all ages may help to reduce any inequity issues. Due to the links to smoking and exposure to dust and chemicals more likely to be found in manual labour roles, this would indicate indirect links with deprivation.

Context

1.1 Introduction

A. COPD

Chronic obstructive pulmonary disease (COPD) is the collective name for a group of lung conditions that may cause breathing difficulties.

It includes:

- emphysema – damage to the air sacs in the lungs
- chronic bronchitis – long-term inflammation of the airways

COPD is a common condition that mainly affects middle-aged or older adults who have a smoking history. The breathing problems tend to get gradually worse over time and can limit the patient's normal activities, although treatment can help keep the condition under control.

Symptoms of COPD

The main symptoms of COPD are:

- increasing breathlessness, particularly when the patient is active
- a persistent chesty cough with phlegm
- frequent chest infections
- persistent wheezing

Without treatment, the symptoms usually get slowly worse. There may also be periods when they get suddenly worse, known as a flare-up or exacerbation.

Causes of COPD

COPD occurs when the lungs become inflamed, damaged and narrowed. The main cause is smoking, although the condition can sometimes affect people who have never smoked.

The likelihood of developing COPD increases the more a patient smokes and the longer the patient has smoked. Some cases of COPD are caused by long-term exposure to harmful fumes, or dust or occur as a result of a rare genetic problem that means the lungs are more vulnerable to damage.

The damage to the lungs caused by COPD is permanent, but treatment can help slow down the progression of the condition.

B. NMD

Neuromuscular disorder (NMD) is a very broad term encompassing a range of conditions that impair the functioning of the muscles, either directly, being pathologies of the voluntary muscle, or indirectly, being pathologies of the peripheral nervous system or neuromuscular junctions. Other spinal cord or brain diseases are not considered "neuromuscular" diseases.

NMD affect the nerves controlling voluntary muscles. Voluntary muscles are the ones that can be controlled such as those in arms and legs. Nerve cells, also called neurons, send the messages that control these muscles. When the neurons become unhealthy or die, communication between the nervous system and muscles breaks down. As a result, muscles weaken and waste away. The weakness can lead to twitching, cramps, aches and pains, and joint and movement problems. Sometimes it also affects heart function and the ability to breathe.

Examples of NMD include:

- Motor Neurone Disease
- Multiple sclerosis
- Myasthenia gravis
- Spinal muscular atrophy.

Many NMD are genetic, which means they run in families or there is a gene mutation for example in muscle dystrophies. Sometimes, an immune system disorder can cause them as in myasthenia.

C. OSA

Apnoea is defined as a temporary absence or cessation of breathing. Obstructive Sleep Apnoea hypopnea syndrome (OSAHS) is a condition in which a person experiences repeated episodes of apnoea because of a narrowing or closure of the pharyngeal airway during sleep. This is caused by a decrease in the tone of the muscles supporting the airway during sleep. Complete closure (obstruction) stops airflow (apnoea) whereas partial obstruction decreases airflow (hypopnoea). OSAHS results in episodes of brief awakening from sleep to restore normal breathing.

Moderate to severe OSAHS can be diagnosed from patient history and a sleep study using oximetry or other monitoring devices carried out in the person's

home. In some cases, further studies that monitor additional physiological variables in a sleep laboratory or at home may be required, especially when alternative diagnoses are being considered. The severity of OSAHS is usually assessed on the basis of both severity of symptoms (particularly the degree of sleepiness) and the sleep study, by using either the apnoea/hypopnoea index (AHI) or the oxygen desaturation index. OSAHS is considered mild when the AHI is 5–14 in a sleep study, moderate when the AHI is 15–30, and severe when the AHI is over 30. In addition to the AHI, the severity of symptoms is also important.

The symptoms of OSAHS include impaired alertness, cognitive impairment, excessive daytime sleepiness, snoring, nocturia, morning headaches and sexual dysfunction. The sleep quality of partners may also be affected. Excessive daytime sleepiness can adversely affect cognitive function, mood and quality of life. OSAHS is associated with high blood pressure, which increases the risk of cardiovascular disease and stroke. OSAHS has also been associated with an increased risk of road traffic accidents.

Major risk factors for developing OSAHS are increasing age, obesity and being male. OSAHS is also associated with certain specific craniofacial characteristics (such as retrognathia), enlarged tonsils and enlarged tongue. Use of alcohol or sedatives can also increase the risk or severity of the condition. OSAHS has been reported to affect up to 4% of middle-aged men and 2% of middle-aged women in the UK. It is estimated that 1% of men in the UK may have severe OSAHS.

Management

Noninvasive ventilation (NIV) refers to the administration of ventilatory support without using an invasive artificial airway (endotracheal tube or tracheostomy tube). The use of noninvasive ventilation has markedly increased over the past three decades, and noninvasive ventilation has now become an integral tool in the management of both acute and chronic respiratory failure, in both the home setting and in critical care.

In its simplest terms, noninvasive ventilation differs from invasive ventilation by the interface between the patient and the ventilator. Invasive ventilatory support is provided via either an endotracheal tube or tracheostomy tube. Noninvasive ventilatory support uses a variety of interfaces, and these have continued to evolve with modifications based on patient comfort and efficacy. Many of the interfaces or masks were initially used in patients with obstructive sleep apnea before they were adapted for use in patients to provide noninvasive ventilatory support.

Nasal masks and orofacial masks were the earliest interfaces, with subsequent development and use of full-face masks, mouthpieces, nasal pillows, and helmets. Nasal masks and orofacial masks are still the most commonly used interfaces. Orofacial masks are used almost twice as frequently as nasal masks. Both have advantages and disadvantages in the application of noninvasive ventilation.

1.2 Existing national policies and guidance

National Guidance for the provision of aspects of specialist non-ventilation services to patients exists for some individual patient groups e.g. Motor Neurone Disease (MND), Duchene's Muscular Dystrophy; and for broader categories of patients e.g. weaning guidance; and around specific technologies e.g. diaphragmatic pacing and tracheostomies. There are some national standards (NICE, 2010; 2016) available and some specialist society guidance (BTS/ICS 2016).

Provision of complex home ventilation services also falls within the NHS Outcomes Framework Domain 1 - preventing people from dying prematurely where Improvement Area 1a specifically identifies reducing mortality from respiratory disease, and Domain 2 – enhancing quality of life for patients with long term conditions.

Guidance supports delivery of care by respiratory specialists working within MDTs. For example, the National Institute for Health and Clinical Excellence (NICE) clinical guideline (CG) around use of NIV in MND states that "multidisciplinary teams (MDT) should coordinate and provide on-going management and treatment for patients with MND, including regular respiratory assessment and provision of non-invasive ventilation. The team should include a neurologist, a respiratory physician, an MND specialist nurse, a respiratory specialist nurse, a specialist respiratory physiotherapist, a respiratory physiologist, a specialist in palliative care and a speech and language therapist". The guidance also outlines the support and training which need to be provided to the patient and their family and carers: "support and assistance to manage non-invasive ventilation which should include training on using non-invasive ventilation and ventilator interfaces, for example emergency procedures, night-time assistance if the patient is unable to use the equipment independently (for example, emergency removal or replacement of interfaces), how to use the equipment with a wheelchair or other mobility aids if required, what to do if the equipment fails, assistance with secretion management, information on general palliative strategies, an offer of on-going emotional and psychological support for the patient and their family and carers".

Ensuring NIV is delivered by competent respiratory professionals is emphasised in NICE MND guidance and also in the National Patient Safety Agency (NPSA) alert which identified cases where problems with administering NIV were stated as causing at least moderate harm: key issues included shortage of staff skills or staff time to set up and monitor NIV.

2 Epidemiology

A. Chronic Obstructive Pulmonary Disease

An estimated 1.2 million people are living with diagnosed COPD (BLF, 2019) – considerably more than the 835,000 estimated by the Department of Health in 2011. In terms of diagnosed cases, this makes COPD the second most common lung disease in the UK, after asthma. Around 2% of the whole population – 4.5% of all people aged over 40 – live with diagnosed COPD.

The number of people who have ever had a diagnosis of COPD has increased by 27% in the last decade, from under 1,600 to nearly 2,000 per 100,000. This could mean that more undiagnosed cases are being found, or that the disease is becoming more common. Changes in record-keeping could also be a factor.

However, prevalence increased by 9% between 2008 and 2012, while record-keeping practices remained the same. Research has indicated that up to two-thirds of people with COPD remain undiagnosed.

In 2012, 29,776 people died from COPD (5.3 per cent of the total number of UK deaths and 26.1 per cent of deaths from lung disease). Of these, 15,245 were males and 14,531 were females. The total number of deaths was up from 28,344 in 2008.

B. Neuromuscular Disorders

Deenen et al 2015 found incidence rates for ten neuromuscular disorders, ranging from 0.05 to 9 per 100,000/yr. Most NMDs showed prevalence rates between 1 and 10 per 100,000 population, except for multifocal motor neuropathy,

C. Obstructive Sleep Apnoea

OSA is common, affecting an estimated 1.5 million adults in the UK, and yet up to 85% are undiagnosed, therefore untreated. Only an estimated 330,000 adults are currently being treated, out of an OSA population of 1.5 million. (BLF 2015)

3 The interventions

Noninvasive positive-pressure ventilation

Positive-pressure ventilation delivered through a mask, has become the predominant method of providing noninvasive ventilatory support. Early bedside physiologic studies in healthy patients and in patients with respiratory conditions document successful ventilatory support (ie, reduction in respiratory rate, increase in tidal volume, decrease in dyspnea) with reduction in diaphragmatic electromyography (EMG), transdiaphragmatic pressures, work of breathing and improvement in oxygenation with a reduction in hypercapnia.

Ventilatory support can be achieved through a variety of interfaces (mouth piece or nasal, face, or helmet mask), using a variety of ventilatory modes (eg, volume ventilation, pressure support, bilevel positive airway pressure [BiPAP], proportional-assist ventilation [PAV], continuous positive airway pressure [CPAP]) with either ventilators dedicated to noninvasive ventilation (NIV) or those capable of providing support through an endotracheal tube or mask. Older models of noninvasive ventilators required oxygen to be bled into the system, but current models incorporate oxygen blenders for precise delivery of the fraction of inspired oxygen (FIO_2).

Noninvasive negative-pressure ventilation

Negative-pressure ventilators provide ventilatory support using a device that encases the thoracic cage starting from the neck, and devices range from a whole-body tank to a cuirass shell. The general principal is the same with a vacuum device, which lowers the pressure surrounding the thorax, creating sub-atmospheric pressure and thereby passively expanding the chest wall with diaphragmatic descent, all leading to lung inflation. Exhalation occurs with passive recoil of the chest wall.

This was the predominant technology during the polio epidemics, but these devices were bulky and cumbersome to use. Upper airway obstruction was also a problem. These ventilators have been largely supplanted by the more widespread positive-pressure noninvasive ventilators; however, some patients continue to be treated with this modality. While the bulk of the experience lies in patients with chronic respiratory failure, specifically neuromuscular respiratory failure, reports described successful application in patients with acute respiratory failure.

Current use of Non-invasive Ventilation devices.

With respect to the two modes, positive-pressure ventilation has supplanted negative-pressure ventilation as the dominant mode of delivery of noninvasive ventilation. Positive-pressure ventilation is more effective than negative-pressure ventilation in unloading the respiratory muscles, at least under investigational conditions. The primary focus of this policy is domiciliary positive-pressure noninvasive ventilation, and the mention of "noninvasive ventilation" will refer to positive-pressure delivery.

Many patients who are assessed as requiring noninvasive ventilation are provided support with pressure ventilation, i.e. continuous positive airway pressure (CPAP), which is the most basic level of support. CPAP pumps a steady flow of air at constant pressure through the nose to prevent the narrowing or collapse of air passages or to help the lungs to expand. CPAP may be especially useful in patients with congestive heart failure or obstructive sleep apnea.

Bilevel positive airway pressure (BiPAP) is probably the most common mode of noninvasive positive pressure ventilation and requires provisions for inspiratory positive airway pressure (IPAP) and expiratory positive airway pressure (EPAP). The difference between IPAP and EPAP is a reflection of the amount of pressure support ventilation provided to the patient, and EPAP is synonymous with positive end-expiratory pressure (PEEP). Some noninvasive ventilation is provided using proportional-assist ventilation (PAV), which provides flow and volume assistance with each breath. Clinical trials have not demonstrated a significant difference between PAV and pressure-support ventilation with BiPAP. [5, 6] However, BiPAP is the most commonly available and more frequently used modality for noninvasive ventilation. PAV remains available on many ventilator models, but use is much less common than BiPAP.

4 Findings

4.1 Evidence of effectiveness

4.1.1 Clinical effectiveness

A. COPD

Murphy et al (2017), undertook a randomized clinical trial of patients with persistent hypercapnia (PaCO2 >53mmHg), a total of 116 patients (mean [SD] age of 67 [10] years, 53%female, mean BMI of 21.6 [IQR, 18.2-26.1], mean [SD] forced expiratory volume in the first second of expiration of 0.6 L [0.2 L], and mean [SD] PaCO2 while breathing room air of 59 [7]mmHg) were randomized. Sixty-four patients (28 in home oxygen alone and 36 in home oxygen plus home NIV) completed the 12-month study period. The median time to readmission or death was 4.3 months (IQR, 1.3-13.8 months) in the home oxygen plus home NIV group vs 1.4 months (IQR, 0.5-3.9 months) in the home oxygen alone group, adjusted hazard ratio of 0.49 (95% CI, 0.31-0.77; *P* = .002). The 12-month risk of readmission or death was 63.4%in the home oxygen plus home NIV group vs 80.4%in the home oxygen alone group, absolute risk reduction of 17.0%(95%CI, 0.1%-34.0%). At 12 months, 16 patients had died in the home oxygen plus home NIV group vs 19 in the home oxygen alone group. Among patients with persistent hypercapnia following an acute exacerbation of COPD, adding home noninvasive ventilation to home oxygen therapy prolonged the time to readmission or death within 12 months.

B. NMD

Very strong recent NICE guidance, and repeated studies which found clinically and statistically significant benefits. Radunovic et al 2017 stated that it would be unethical to have a control group in future RCTs, indicating that equipoise is no longer a question.

A systematic review by Radunovic et al 2017 found good basis for the use of non-invasive ventilation in certain Motor Neurone Disease cohorts of patients:

The conclusions of the review were based on a single RCT on 41 participants. The study provided modest quality evidence that overall median survival was significantly different between the group treated with NIV and the standard care group.
Low-quality evidence indicates that it improves or maintains quality of life in people with ALS.
Survival and quality of life were significantly improved in the subgroup of people with better bulbar function, but not in those with severe bulbar impairment. Adverse effects related to NIV should be systematically reported, as at present there is little information on this subject. More RCT evidence to support the use of NIV in ALS will be difficult to generate, as not offering NIV to the control group is no longer ethically justifiable.

This is also supported by D' Cruz et al. 2018

NIV has been shown to improve quality of life for patients with MND. In a randomised controlled trial, Bourke and colleagues randomised MND patients with orthopnoea, MIP <60% predicted or symptomatic daytime hypercapnia to NIV or standard care. NIV was associated with sustained improvements in quality of life, with the greatest improvements observed in the domains relating to sleep problems, despite an observed reduction in REM sleep. This supports the findings of smaller prospective studies which have demonstrated sustained improvements in patient-reported outcomes amongst MND patients, including sleep quality, duration and efficiency, reduced sleep disturbance and improved and daytime somnolence, following initiation of NIV.

Similar positive impacts have also been identified within the paediatric population by Katz et al 2004:

NPPV can decrease hospitalisations for children with neuromuscular disease and improves sleep related respiratory parameters. A prospective study is now needed to further delineate the role of NPPV in this population of children.

This was supported by Falsaperla et al. in 2014: We found a statistically significant improvement of the lowest oxygen desaturation (nadir SaO2), apnoea-hypopnoea index (AHI) and oxygen desaturation index (ODI) after NIV treatment in all patients. Mean SaO2 also improved, although this result was not statistical significant, while the percentage of episodes of desaturation with a SaO2 <90% and <80% decreased with a statistical significance (P < 0.0001). After NIV, only one patient showed an episode of desaturation lasting more than 5 min (10.6 min length), and we also found an improvement of daytime blood gas parameters with a normalization of these indexes.

C. OSA

Extensive NICE guidance (NICE 2007;2012; 2017) supported by meta-analyses, Cochrane review, and primary studies supports the use of Continuous Positive Airway pressure for the treatment of moderate to severe obstructive sleep apnoea and mild sleep apnoea with certain presenting symptoms. Alternative treatments to CPAP are discussed however the evidence of efficacy for surgery is, as yet, inconclusive.

In the NICE 2012 guidance 139, the Assessment Group identified 23 RCTS that compared CPAP with placebo or usual care using the Epworth Sleepiness Scale (ESS). A meta-analysis of these studies identified a statistically significantly greater reduction in daytime sleepiness with CPAP compared with placebo or usual care (weighted mean difference in ESS score −2.7; 95% confidence interval [CI] −3.5 to −2.0).

The NICE Assessment Group undertook a series of meta-analyses that compared the effect of CPAP on levels of daytime sleepiness in different populations. This showed a statistically significantly greater reduction in daytime sleepiness with CPAP compared

with placebo for moderate and severe categories of OSAHS. For mild OSAHS (meta-analysis of 3 studies; AHI = 5–14 episodes per hour) a weighted mean difference in ESS score of −1.5 (95% CI −3.4 to 0.4) was found. For moderate OSAHS (meta-analysis of 7 studies; AHI = 15–30 episodes per hour) a weighted mean difference in ESS score of −2.0 (95% CI −3.0 to −1.1) was found. For severe OSAHS (meta-analysis of 13 studies; AHI = over 30 episodes per hour) a weighted mean difference in ESS score of −3.4 (95% CI −4.6 to −2.3) was found.

4.1.2 Trials in progress

A search of clinicaltrials.gov using the search terms domiciliary non-invasive ventilation found the following trials currently recruiting:

Terms	Search Results*	Entire Database**
Synonyms		
domiciliary	11 studies	73 studies
non-invasive ventilation	10 studies	402 studies
ventilation	11 studies	6,696 studies
Respiration	6 studies	4,908 studies
breathing	--	894 studies
respiratory assist	--	6 studies
Respiratory function	--	144 studies
non-invasive	11 studies	2,231 studies

1. Assist Control Versus Pressure Support Modes for **Domiciliary Noninvasive Ventilation** in Chronic Respiratory Failure. ClinicalTrials.gov Identifier: NCT00189527
2. Impact of Early **Non Invasive Ventilation** in Amyotrophic Lateral Sclerosis (ALS) Patients
3. Effect of the Integrated Tele-monitoring Management of NIV Treatment
4. Autotitrating Versus Standard **Non-invasive Ventilation** (NIV) in Newly Diagnosed Patients
5. Trial of **Non-invasive Ventilation** for Stable COPD

6. Assesment of Muscular Unloading in Chronic Obstructive Pulmonary Disease (COPD) Patients With NIV
7. **on-invasive Ventilation** Versus Sham **Ventilation** in Chronic Obstructive Pulmonary Disease (COPD)
8. What do built-in Softwares in Home Ventilators Tell us?
9. Prospective Cohort of Respiratory Insufficiency Outcome
10. **Non-invasive** Ventilator Modems: a Qualitative Study
11. Tracheostomized COPD Patients and **Non Invasive** Mechanical **Ventilation**

4.1.3 Cost-effectiveness

A. COPD

None of the studies identified contained QALY measures, however reduction in repeated hospital admissions with the use of domiciliary NIV within this patient cohort was shown in a number of studies. (Murphy et al 2017)

B. NMD

None of the studies identified contained QALY measures so cost effectiveness could not be determined.

C. OSA

NICE assessment group (2012) identified four published economic evaluations all of which compared CPAP with a 'do nothing' alternative. The resulting incremental cost-effectiveness ratios (ICERs) were: (1) US $3354 (approximately £1688; currency conversions were calculated in August 2007) per quality-adjusted life year (QALY) gained from a third-party payer perspective and US $314 (£158) per QALY gained from a societal perspective; (2) €7861 (£5348) per QALY gained over a 5-year time horizon and €4938 (£3359) per QALY gained for a lifetime time horizon; (3) £8300 per QALY gained at 1 year and £5200 per QALY gained at 2 years; (4) Can $9809 (£4654) per QALY gained for the high-cost estimate and Can $3523 (£1672) per QALY gained for the low-cost estimate.

Only two of the NICE Assessment Group's subgroup and scenario analyses resulted in pronounced changes to the base-case ICERs. When the lifespan of the device was changed from 7 to 5 years and an auto-titrating device plus humidifier was used instead of a fixed-pressure device, the ICER was £16,362 per QALY gained. When cardiovascular events and road traffic accidents were excluded in the analysis for the total population (all severities of OHAHS), the ICER was approximately £8000 per QALY gained.

4.2 Safety

NICE
Support of use in: a subset of section B. patients with Motor Neurone Disease & C. OSA

Medicines and Healthcare Products Regulatory Authority (MHRA) support the use of a number of NIV devices.

5 Equity issue

A. COPD

Major risk factors for developing COPD are smoking, and occupation dust exposure in patients over the age of 40 years old. Ensuring good smoking cessation support in all ages may help to reduce any inequity issues. Due to the links to smoking and exposure to dust and chemicals more likely to be found in manual labour roles, this would indicate indirect links with deprivation.

B. NMD

None of the studies identified discussed health inequality measures.

C. OSA

Major risk factors for developing OSAHS are increasing age, obesity and being male. OSAHS is also associated with certain specific craniofacial characteristics (such as retrognathia), enlarged tonsils and enlarged tongue. Use of alcohol or sedatives can also increase the risk or severity of the condition. OSAHS has been reported to affect up to 4% of middle-aged men and 2% of middle-aged women in the UK. It is estimated that 1% of men in the UK may have severe OSAHS.

6 Discussion and conclusions

A. COPD

There is evidence to support the addition to patients with persistent hypercapnia following an acute exacerbation of COPD, of home non-invasive ventilation to home oxygen therapy prolonged the time to readmission or death within 12 months.

B. NMD

High quality evidence to support the use of non-invasive ventilation within certain patient groups within this cohort of patients. Clinical review should be ensured with patients with severely impaired bulbar function to ensure tolerance of the intervention.

C. OSA

Clinical and cost-effective use of CPAP in more moderate / severe instances of OSA are clearly demonstrated within the literature. Use in those with a mild diagnosis of OSA is demonstrated when the patient is symptomatic.

7 Search Strategy

A. COPD

Population: Person with COPD (and similar conditions) Breathing Impairment Having Experienced a Recent Exacerbation

Intervention: Self-Administered / Home-Based Routine Non-Invasive Ventilation / Continuous Positive Airway Pressure (excludes acute episodes and Long Term Oxygen Therapy)

Comparator / Control: No intervention / Alternative treatments
Outcome: Quality of Life and Survival Benefit

B. NMD

Population: Person with Neurologically Dependent Breathing Impairment
Intervention: Self-Administered / Home-Based Routine Non-Invasive Ventilation / Continuous Positive Airway Pressure (excludes acute episodes and Long Term Oxygen Therapy)
Comparator / Control: No intervention
Outcome: Quality of Life and Survival Benefit

C. OSA

Population: Persons with Sleep Apnoea
Intervention: Self-Administered / Home-Based Routine Non-Invasive Ventilation / Continuous Positive Airway Pressure (excludes acute episodes and Long Term Oxygen Therapy)
Comparator / Control: No intervention / Alternative treatments
Outcome: Quality of Life and Wider Health Benefits

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Evidence Review for the use of Hysteroscopy as a First Line Investigation

Question to be addressed

1. In female adults, are there clinical circumstances where the use of hysteroscopy would be clinically more effective than ultrasound as a first line investigation?

Reason for review

NHS Birmingham and Solihull CCG, Sandwell and West Birmingham CCG, requested a rapid evidence review of the clinical and cost effectiveness of the use of hysteroscopy as a first line investigation and identification of the clinical circumstances in which use as a first line investigative tool this intervention would be most clinically effective to inform their decisions on commissioning policy development.

Options for commissioners:

1. The Committee considers that due to the limited quality of evidence of clinical and cost effectiveness for the use hysteroscopy as a first line intervention, its use should be considered a low priority.
2. The Committee recommends that, due to the limited quality of evidence of its clinical and cost effectiveness in all clinical circumstances, the use of hysteroscopy as a first line intervention should ONLY be offered to patients who have suspected submucosal fibroids OR polyps OR endometrial pathology AND one of the following: persistent intermenstrual bleeding OR risk factors for endometrial pathology.
3. The Committee considers that there is sufficient evidence to suggest that the use of hysteroscopy as a first line treatment is at least as effective as alternative treatment options and the costs are comparable, therefore the decision about which approach to proceed with should be made after an informed discussion between the clinician and the individual person about the risks and benefits of each procedure.

Summary:

Background

- Heavy periods are common, but they can have a big effect on a woman's everyday life. HMB does not always have an underlying cause but can result from problems such as fibroids or endometriosis.
- Heavy menstrual bleeding is defined as losing 80ml or more in each period, having periods that last longer than 7 days, or both.
- A hysteroscopy is a procedure used to examine the inside of the womb (uterus).

Clinical effectiveness

- Evidence including the NICE review 2018 demonstrated clinically robust evidence to support the use of hysteroscopy as a first line intervention should ONLY be offered to patients who have suspected submucosal fibroids OR polyps OR endometrial

pathology AND one of the following: persistent intermenstrual bleeding OR risk factors for endometrial pathology.

- Evidence including the NICE evidence review 2018 enabled a review of the diagnostic tests to be used to direct treatment according to the woman's underlying pathology. In the NICE 2018 model, diagnostic test accuracy was used to estimate the proportion of women who would be correctly identified and receive the appropriate first line treatment.

Safety

- NICE supports the use of hysteroscopy as a first line intervention should ONLY be offered to patients who have suspected submucosal fibroids OR polyps OR endometrial pathology AND one of the following: persistent intermenstrual bleeding OR risk factors for endometrial pathology in NG 88.

Cost effectiveness

- A high quality economic evaluation from the UK (Cooper 2014) concluded that either outpatient hysteroscopy or outpatient hysteroscopy in combination with endometrial biopsy represented cost-effective strategies for HMB.
- NICE NG 88 established that whilst outpatient hysteroscopy was the most expensive diagnostic test but the least expensive diagnostic strategy. An important contributing factor to this is that hysteroscopy can facilitate a one stop 'see-and-treat' approach which reduces treatment cost.

Equity issues

NICE identified the following groups of women whom may require special consideration, but equity issues were not identified:

- women who have difficulties communicating in English
- women with learning difficulties
- women from some minority ethnic groups (because women from some minority ethnic group might find it difficult to talk about HMB with health care professionals)
- women from disadvantaged socio-economic groups.

Context

1.1 Introduction

In about half of women with heavy menstrual bleeding, no underlying reason is found. But there are several conditions and some treatments that can cause heavy menstrual bleeding.

Some conditions of the womb and ovaries can cause heavy bleeding, including:

- fibroids – non-cancerous growths that develop in or around the womb and can cause heavy or painful periods

- endometriosis – where the tissue that lines the womb (endometrium) is found outside the womb, such as in the ovaries and fallopian tubes (although this is more likely to cause painful periods)
- adenomyosis – when tissue from the womb lining becomes embedded in the wall of the womb; this can also cause painful periods
- pelvic inflammatory disease (PID) – an infection in the upper genital tract (the womb, fallopian tubes or ovaries) that can cause symptoms like pelvic or abdominal pain, bleeding after sex or between periods, vaginal discharge and fever
- endometrial polyps – non-cancerous growths in the lining of the womb or cervix (neck of the womb)
- cancer of the womb – the most common symptom is abnormal bleeding, especially after the menopause
- polycystic ovary syndrome (PCOS) – a common condition that affects how the ovaries work; it causes irregular periods, and periods can be heavy when they start again

Other conditions that can cause heavy periods include:

- blood clotting disorders, such as Von Willebrand disease
- an underactive thyroid gland (hypothyroidism) – where the thyroid gland does not produce enough hormones, causing tiredness, weight gain and feelings of depression
- diabetes

Medical treatments that can sometimes cause heavy periods include:

- an IUD (intrauterine contraceptive device, or "the coil") – this can make your periods heavier for the first 3 to 6 months after insertion
- anticoagulant medication – taken to prevent blood clots
- some medicines used for chemotherapy
- some herbal supplements, which can affect your hormones and may affect your periods – such as ginseng, ginkgo and soya

1.2 Management

A hysteroscopy is a procedure used to examine the inside of the womb (uterus). It is carried out using a hysteroscope, which is a narrow telescope with a light and camera at the end. Images are sent to a monitor so the doctor or specialist nurse can see inside the womb. The hysteroscope is passed into the womb through the vagina and cervix.

NICE Guideline 88 states:

In Women with suspected submucosal fibroids, polyps or endometrial pathology

1.3.4 Offer outpatient hysteroscopy to women with HMB if their history suggests submucosal fibroids, polyps or endometrial pathology because:

- they have symptoms such as persistent intermenstrual bleeding or

- they have risk factors for endometrial pathology

Women with possible larger fibroids

1.3.12 Offer pelvic ultrasound to women with HMB if any of the following apply:

- their uterus is palpable abdominally
- history or examination suggests a pelvic mass
- examination is inconclusive or difficult, for example in women who are obese.

Women with suspected adenomyosis

1.3.13 Offer transvaginal ultrasound (in preference to transabdominal ultrasound or MRI) to women with HMB who have:

- significant dysmenorrhoea (period pain) **or**
- a bulky, tender uterus on examination that suggests adenomyosis.

1.3.14 If a woman declines transvaginal ultrasound or it is not suitable for her, consider transabdominal ultrasound or MRI, explaining the limitations of these techniques.

1.3.15 Be aware that pain associated with HMB may be caused by endometriosis rather than adenomyosis (see NICE's guideline on endometriosis).

Other diagnostic tools

1.3.16 Do not use saline infusion sonography as a first-line diagnostic tool for HMB.

1.3.17 Do not use MRI as a first-line diagnostic tool for HMB.

1.3.18 Do not use dilatation and curettage alone as a diagnostic tool for HMB

1.3 Existing national policies and guidance

- National Institute for Health and Care Excellence (NICE) Guidance

Guidance was published in 2018 on the use of hysteroscopy as a first line treatment, which states that a hysteroscopy should be used as a first line treatment in women who have suspected submucosal fibroids OR polyps OR endometrial pathology AND one of the following: persistent intermenstrual bleeding OR risk factors for endometrial pathology.

2 Epidemiology

HMB is one of the most common reasons for gynaecological consultations in both primary and secondary care. About 1 in 20 women aged between 30 and 49 years consult their GP each year because of heavy periods or menstrual problems, and menstrual disorders comprise 12% of all referrals to gynaecology services.

The focus of this review is on women of reproductive age (after puberty and before the menopause) with HMB, including women with suspected or confirmed fibroids, and women with suspected or confirmed adenomyosis. The guideline does not primarily cover women with gynaecological bleeding other than HMB (for example, intermenstrual bleeding or postcoital bleeding) or with gynaecological conditions in which HMB is not the main symptom (such as endometriosis).

Since 2007, equipment and software for transvaginal ultrasound have improved. Outpatient hysteroscopy has become more widely available, and is more acceptable to women with the advent of modern equipment such as miniature hysteroscopes.
Therefore, the relative clinical and cost effectiveness of diagnostic strategies have changed. Improvements in diagnostic imaging in recent years have resulted in an increase in the reported prevalence of certain conditions, e.g. adenomyosis.

3 The interventions

3.1 Ultrasound scan

3.1.1 Abdominal

Ultrasound imaging involves sending high-frequency sound waves into the body. These waves reflect off of organs and other structures inside the body. A receiver then picks up these response signals.

It is possible to create images by analyzing the data that these signals create.

The abdominal ultrasound scan is undertaken with a probe moving over the stomach to identify structures within the abdominal and pelvic areas.

3.1.2 Transvaginal

The transvaginal (internal) ultrasound scan does not require a full bladder as the scan probe is placed inside the vagina and is closer to the pelvic organs being examined.
This type of scan is used to help provide clearer pictures of the womb, ovaries and surrounding structures.

3.2 Hysteroscopy

A hysteroscopy is a procedure used to examine the inside of the womb (uterus). It's carried out using a hysteroscope, which is a narrow telescope with a light and camera at the end. Images are sent to a monitor so that the inside the womb may be examined. The hysteroscope is passed into the womb through the vagina and cervix.

4 Findings

4.1 Evidence of effectiveness

In reviewing the evidence NICE 2018 considered the following requirements:

- that the correct identification of the cause of HMB is important as this can impact the treatment options offered to women.
- If a test is sensitive, it may help the clinicians to choose the right initial treatment to be offered to women.
- It is important to avoid false positives because unnecessary treatment, especially surgical treatment, can cause harm.
- The evidence on diagnostic accuracy was assessed using adapted GRADE methodology.
- The evidence on patient satisfaction or acceptability was assessed using Cochrane Collaboration's tool for assessing risk of bias.

NICE in their evidence review accepted that the quality of evidence in these reviews ranged from very low to moderate with most evidence being of very low quality. The NICE committee recognised that the evidence was fragmented and with several limitations. The NICE committee agreed that the quality of evidence was most often downgraded because of unclear sampling, unclear inclusion and exclusion criteria, unclear diagnostic criteria, and at times, considerable number of drop-outs.

4.1.1 Clinical effectiveness

It was noted that there was a lack of robust evidence to support the intervention.

The NICE committee agreed that many women presenting to primary care with symptoms of HMB can be offered treatment without the need for further examination or investigation. However, investigation via a diagnostic technique might be warranted for women for whom history or examination suggests a structural or endometrial pathology or for whom the initial treatment has failed.

The NICE committee considered outpatient hysteroscopy to be an efficient and safe technique with a low risk of complications, and acceptable to most women if done according to best practice guidance. It would also allow for services to be developed to offer women the option of see-and-treat by having submucosal fibroids or polyps identified and removed in one process when appropriate.

4.1.2 Trials in progress

Review of *clinicaltrials.gov* provided no current trials being undertaken to evaluate the use of hysteroscopy and the clinical circumstances in which hysteroscopy would be a first line treatment.

4.1.3 Cost-effectiveness

A high quality economic evaluation from the UK (Cooper 2014) compared a number of diagnostic strategies for HMB. This analysis took an NHS perspective and the setting was a 'one-stop' secondary care clinical setting. The study concluded that either outpatient hysteroscopy or outpatient hysteroscopy in combination with endometrial biopsy represented cost-effective strategies for HMB. Treatment effectiveness was estimated through patient satisfaction although the authors also derived a cost per QALY estimate based on this.

Outpatient hysteroscopy is a more expensive investigation than pelvic ultrasound but there are potential off-setting savings to treatment costs as the technique can allow a 'see and treat' approach.

4.2 Safety

National Institute for Health and Care Excellence (NICE) Guidance 88 supports the use of hysteroscopy as a first line investigation to patients who have suspected submucosal fibroids OR polyps OR endometrial pathology AND one of the following: persistent intermenstrual bleeding OR risk factors for endometrial pathology.

4.3 Summary of findings

The evidence identified in the NICE review and the paucity of reliable evidence which was found within this evidence review, appears to be a result of a lack of quality/ strong evidence, not evidence which does not support hysteroscopy as a first line intervention.

The safety and cost effectiveness of hysteroscopy as a first line treatment, particularly in a see and treat scenario are documented by NICE (2018).

5 Equity issues

This issue solely relates to women. However, further equity issues have not been identified.

6 Discussion and conclusions

A paucity of robust, current evidence, has meant that NICE Guidance 88 has been heavily relied on in reviewing this intervention. The guidance has identified that the most appropriate clinical circumstances in which hysteroscopy should be used is as a first line investigation. NICE recognise the limited evidence available and have used clinical experts to guide the development of this guidance.

Further research in this area, would be welcomed.

7 Search Strategy

- PubMed

("hysteroscopy"[MeSH Terms] OR "hysteroscopy"[All Fields]) AND first[All Fields] AND ("long interspersed nucleotide elements"[MeSH Terms] OR ("long"[All Fields] AND "interspersed"[All Fields] AND "nucleotide"[All Fields] AND "elements"[All Fields]) OR "long interspersed nucleotide elements"[All Fields] OR "line"[All Fields]) AND ("therapy"[Subheading] OR "therapy"[All Fields] OR "treatment"[All Fields] OR "therapeutics"[MeSH Terms] OR "therapeutics"[All Fields]) AND ("menorrhagia"[MeSH Terms] OR "menorrhagia"[All Fields] OR ("heavy"[All Fields] AND "menstrual"[All Fields] AND "bleeding"[All Fields]) OR "heavy menstrual bleeding"[All Fields])

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Evidence Review for the Use of Biological Mesh in hernia repair in comparison to synthetic surgical mesh.

Questions to be addressed

1. In adults with a non-healed wound following hernia repair surgery using synthetic surgical mesh, is there evidence to support the use of biological mesh?
2. In adults are there clinical circumstances where the use of biological mesh in hernia repair would be clinically more effective than the use of synthetic surgical mesh?

Reason for review

NHS Birmingham and Solihull CCG, Sandwell and West Birmingham CCG, requested a rapid evidence review of the clinical and cost effectiveness of biological surgical mesh for hernia repair compared to alternative treatment options, in particular synthetic surgical mesh to inform their decisions on commissioning policy development.

Options for commissioners:

1. The Committee considers that due to the limited quality of evidence of clinical and cost effectiveness for the use of biological mesh compared to alternative treatment options, its use should be considered a low priority.
2. The Committee recommends that, due to the limited quality of evidence of its clinical and cost effectiveness, the use of biological mesh should be offered ONLY to patients who have failed wound healing following hernia repair using standard surgical mesh.
3. The Committee considers that there is sufficient evidence to suggest that the use of biological mesh in surgical hernia repair is at least as effective as alternative treatment options and the costs are comparable, therefore the decision about which approach to proceed with should be made after an informed discussion between the clinician and the individual person about the risks and benefits of each procedure.

Summary

Background

- Hernia most frequently occurs when an organ or internal tissue pokes through a hole or weakness in the abdominal muscle wall.
- Hernia repair surgery is one of the most common surgeries to be performed.
- Different types of mesh can be used in hernia repair: standard surgical mesh and biological mesh.

Clinical effectiveness

- Clinical effectiveness of biological mesh above synthetic mesh was not identified within the literature.
- 2 systematic reviews demonstrated a lack of clinically robust evidence to support the use of biological mesh above the use of synthetic mesh.
- The currently available clinical evidence demonstrated a lack of blinding within the studies and often retrospective studies of low to moderate quality.

Safety

NICE & MHRA support the use of surgical synthetic mesh in hernia repair surgery.

Cost effectiveness

Synthetic mesh is not excluded from National Tariff and the cost of synthetic mesh is within tariff and not funded separately.

Biological Mesh is currently excluded from PbR tariff. This is because of the variable and often high cost associated with its use; the product can range in cost from £750 to in excess of £8,500 per patient, depending on intended use, size of wound and product choice. All items listed as PbR exclusions are subject to locally agree payments taking into consideration existing tariff charges.

Equity issues

None were identified within the course of this review.

Context

1.1 Introduction

- A hernia occurs when an internal part of a body pushes through a weakness in the muscle or surrounding tissue wall. It usually takes the form of a lump, or swelling with or without some discomfort that may limit daily activities, including the ability to work.

- There are different types of hernia, inguinal hernias are the most common and the majority of these (approximately 98%) are found in men due to their particular anatomical structure.

- Other types include femoral (also in the groin), umbilical and incisional (this type occurs following surgery in the upper abdomen where an incision has caused weakness in tissue)

- Hernias cannot be treated medically and often require surgical repair if the patient is fit enough. Without surgery, there are risks of strangulation, bowel obstruction and incarceration, which could require emergency surgical intervention.

Management

- Hernia repair is a very common surgical intervention and significantly more patients have undergone hernia mesh procedures than have undergone vaginal mesh

procedures [with approximately 70,000 inguinal hernia repairs performed every year in England and 6,000 each year in Wales].

- Until the 1950's, the repair took the form of a suture technique at the site of weakness or defect. The stitching of such weak areas did not result in long lasting repair which led to the recurrence of the hernia.

- The use of prosthetic mesh has become increasingly common since then as a 'tension-free' or patching method for strengthening and reinforcing weak tissue, resulting in longer lasting repair.

- There has been significant change in the design and manufacture of synthetic mesh over the years, with a move to larger pore, lighter weight mesh, with early data suggesting better tolerance of such implants by the patient.

- There are broadly two techniques for mesh hernia repair - open or laparoscopic.

    - In an open repair, the defect through which the hernia is protruding is identified and mesh placed over the defect and stitched in place, in effect creating a scaffold for the tissue to grow through to strengthen the weak area.

    - In a laparoscopic repair, a small incision is made near the umbilicus as well as two small incisions in the lower abdomen. Carbon dioxide is used to inflate the abdomen and a camera is inserted via one of the incisions so that the defect is viewed from the interior abdominal wall and mesh introduced.

- As with all types of surgery, there are associated risks. These include inter-operative complications such as bleeding or damage to surrounding structures as well as post-operative complications such as infection, pain (which can become chronic), thromboembolic complications as well as hernia recurrence.

There are 2 types of surgical mesh:

1. Standard Surgical Synthetic Mesh
2. Biological Mesh

Standard Surgical Synthetic mesh is made of either non-absorbable synthetic polymers (polypropylene) or absorbable synthetic polymers (polyglycolic acid or polycaprolactone).

A number of Biological Meshes are currently available on the market. Biological Meshes are derived from human (allograft) or animal (xenograft) dermis, pericardium or intestinal submucosa. These tissues are processed to remove any immunogenic material and, as a result, are rendered acellular. After processing, the extracellular matrix remains and is used as a scaffold by host tissues.

1.2 Existing national policies and guidance

National Institute for Health and Care Excellence (NICE) Guidance

- Guidance was published in 2004 on laparoscopic hernia repair which states that a laparoscopic repair should only be carried out by trained surgeons who perform the procedure regularly.

- The use of mesh in hernia repair is considered by NICE to be an 'Interventional Procedure', and therefore is not 'approved' as may be the case for a drug or procedure subject to technology appraisal. NICE do not examine interventional procedures which are considered established practice unless there are data demonstrating uncertainty about their efficacy or safety.

- The guidance with regard to laparoscopic repair was reviewed in 2016 but there was no new evidence to suggest a change in the guidelines was required.

Medicines and Healthcare Products Regulatory Authority (MHRA)

- It is understood that the MHRA broadly agrees with NICE's position outlined above and considers that the main determinant of success of an operation seems to be patient selection and surgical technique rather than choice of device. MHRA continues to encourage the reporting of adverse events following the use of surgical mesh.

2 Epidemiology

Groin hernia repairs are amongst the most commonly performed general surgical operations with over 71,000 inguinal and femoral hernias repairs carried out in England in 2014/15.

There is more than a 2-fold variation in the rate of inguinal hernia repair across the NHS. Patients and surgeons have the choice between various techniques and materials.
There is no national system of audit or follow-up, and the overall low reported recurrence rate following inguinal hernia repair makes it difficult to determine which procedure is best. However, outcomes should not be judged in only terms of hernia recurrence, but also wound complications, length of hospital stay, chronic pain, patient experience, quality of life and cost2.

The British Association of Day Surgery has suggested that 80% of inguinal hernia repairs should be carried out as day case procedures. In 2014/15 77.8% of primary inguinal hernia repairs (unilateral) were carried out as a day case, and rates varied from 67% to 88% across providers. (RCS, 2016).

Further data and analysis for England is yet to be undertaken, but Wales has undertaken a review of the use of surgical mesh and has found the following:

- In Wales between 2011/12 and 2017/18, 43,646 patients had a hernia repair
- Of those, 78.8% underwent a mesh-based technique
- A small number of patients will require removal of mesh due to complications, for example, chronic infection.
- The data showed that a very small minority of patients suffer complications that necessitates removal and those figures do not change dramatically on an annual basis
- Obviously some patients will have complications that do not warrant mesh removal but the interpretation is that those who undergo mesh removal suffer the most severe complications. The likelihood of the mesh being removed appears to be around 0.007%, consistent with international data and extremely low for any surgical complication. This is a rate which appears to have been largely consistent over the 5 year period of this review.

3 The interventions

Most hernias are found in the abdomen. Areas of weakness in the abdominal wall where hernias are commonly found include the groin, upper stomach, belly button and, where you have a surgical scar.

The most frequently seen types of hernia include:

• Inguinal hernias – the most common hernia, seen more in men, causes a bulge in your groin. The inguinal hernia appears through your inguinal canal, a narrow passage that blood vessels pass through in your abdominal wall and, may reach your scrotum.
• Femoral hernias – also a bulge in your groin, relatively uncommon and seen more in women. The femoral hernia happens at the hole in your abdominal wall where the femoral artery and vein pass from the abdomen into your leg.
• Hiatus hernias - occur in your upper chest area when part of your stomach pushes up into your chest by squeezing through a gap in your diaphragm called the hiatus.
• Umbilical/periumbilical hernias – occur at the umbilicus, a natural weakness in your abdominal wall, when fatty tissue or a part of your bowel pokes through your abdomen near your naval.
• Incisional hernia – occurs through a scar from past abdominal surgery as tissue pokes through the weak healed site in your abdominal wall.

Hernia surgery is a routine procedure, but as with all surgeries there are risks of complications. These may vary depending upon the exact hernia operation required and the individual patient' health.

Often the greatest complication risk is a reoccurrence of the hernia. Other hernia surgery side effects include: build-up of seroma or a fluid-filled sac under the surface of the skin, inability or difficulty urinating, organ or tissue damage, wound infection and, rejection of the mesh.

4 Findings

4.1 Evidence of effectiveness

- A Cochrane systematic review was published in 2018 comparing mesh procedures and non-mesh procedures for the repair of inguinal and femoral hernias (which included 6,293 participants)

- It found that mesh repairs are associated with a reduced rate of hernia recurrence (hence reduced amount of patients needing more surgery) as well as reduced risk of visceral and neurovascular damage but non-mesh procedures carried a lower risk of seroma (pocket of serous fluid) formation.

- In terms of chronic pain a large systematic review published in 2018 found no statistical difference in the rates of chronic pain between mesh and non-mesh procedures in the first post-operative year. There is no evidence that the use of mesh increases the risk of pain

    - There are reports that moderate-severe chronic pain can affect 10-12% post-operatively, but that the risk is less with mesh than non-mesh repair. Reports from England also noted that up to 5 % of those undergoing inguinal hernia repairs can experience long-term discomfort or pain, lasting for more than three months after their operations.

    - An original piece of research looked at the rate of chronic infection following mesh insertion with only 0.005% requiring mesh removal due to chronic infection.

There is good evidence to support the use of synthetic mesh in hernia repair operations. Further evidence was reviewed to ascertain the clinical and cost effectiveness of synthetic vs biological mesh.

4.1.1 Clinical effectiveness

Con et al undertook a systematic review in 2019, , which aimed to review potential bias in the literature which reviewed the use of biological mesh in hernia repair:

A literature search in PubMed, Embase and Cochrane databases of systematic reviews on biologic mesh for ventral hernia repair. The literature review was conducted using the Population, Intervention, Comparisons, Outcomes and Design approach. 40 studies were identified which matched the stringent criteria set. A 13-point instrument was set to assess for bias and applied on the primary studies that were analyzed.

Most primary studies are case series or case reports of patients undergoing abdominal hernia repair with biologic mesh, without any comparison group, and the inclusion of cases was only specified to be consecutive in 6 out of 40 cases. In terms of assessing outcomes, in none of the 40 articles were the outcome assessors blinded to the intervention or exposure status of participants.

The instrument that created could allow assessment of the risk of bias in different kind of studies. The assessment of the studies based on the criteria set up in the instrument clearly identified that further research needs to be done due to the lack of unbiased studies regarding the use of biologic meshes for abdominal hernia repair.

Other earlier systematic reviews also support the need for further research in this area.

2017 Systematic Review of synthetic vs biological mesh (Knappen et al 2017) found the following: Forty-four studies were included: 5 reporting biologic mesh repairs; 21, synthetic mesh repairs; and 18, prophylactic mesh repairs. Most of the studies were retrospective cohorts of low to moderate quality. The hernia recurrence rate was higher after undergoing biologic compared to synthetic mesh repair (24.0% vs 15.1%, P = 0.01). No significant difference was found concerning wound and mesh infection (5.6% vs 2.8%; 0% vs 3.1%). Open and laparoscopic techniques were comparable regarding recurrences and infections. Prophylactic mesh placement reduced the occurrence of a parastomal hernia (OR = 0.20,

P < 0.0006) without increasing wound infection [7.8% vs 8.2% (OR = 1.04, P = 0.91)] and without differences between the mesh types.

Further research in this area is required to identify the clinical circumstances in which the use of biological mesh would be clinically superior and cost effective.

4.1.2 Trials in progress

A search of clinicaltrials.gov found the following trials currently recruiting:

1. https://clinicaltrials.gov/ct2/show/NCT03034213?cond=biological+surgical+mesh&rank=2

The hypothesis for this study is complex incisional hernia repair using the separation of

components technique reinforced with retrorectus placement of Gentrix™ Surgical Matrix will lead to fewer incisional hernia recurrences and fewer wound complications compared to the same incisional hernia repair techniques reinforced with other prosthetic or biologically-derived mesh.

2. Performance of biological mesh materials in abdominal wall reconstruction: study rotocol for a randomised controlled trial

Carver DA, *et al*. *BMJ Open* 2019;9:e024091. doi:10.1136/bmjopen-2018-024091

3. Seedfelt et al (2019) BIOLAP: biological versus synthetic mesh in laparo-endoscopic inguinal hernia repair: study protocol for a randomized, multicenter, self-controlled clinical trial. Trials. 2019 Jan 16;20(1):55. doi: 10.1186/s13063-018-3122-5.

https://www.ncbi.nlm.nih.gov/pubmed/30651127

4.1.3 Cost-effectiveness

Biological meshes are excluded from National Tariff.

Biological Mesh is currently excluded from PbR tariff. This is because of the variable and often high cost associated with its use; the product can range in cost from £750 to in excess of £8,500 per patient, depending on intended use, size of wound and product choice. All items listed as PbR exclusions are subject to locally agree payments taking into consideration existing tariff charges.

For a device to be considered as an exclusion from PbR it must meet all 3 of the following criteria:
I. high cost and represent a disproportionate cost relative to the relevant HRG
II. used in a subset of cases within an HRG and/or used in a subset of providers delivering services under a specific HRG
III. relatively high cost in terms of volume and cost.

Synthetic mesh is not excluded from National Tariff and the cost of synthetic mesh is within tariff and not funded separately.

Synthetic Equivalents This wording was included within PbR exclusions and is intended to allow for the possibility that there are synthetic materials in use which may represent a similar disproportionate cost as biological mesh – synthetic equivalents to biologic mesh are therefore also excluded.

4.2 Safety

National Institute for Health and Care Excellence (NICE) Guidance

- Guidance was published in 2004 on laparoscopic hernia repair which states that a laparoscopic repair should only be carried out by trained surgeons who perform the procedure regularly.

- The use of mesh in hernia repair is considered by NICE to be an 'Interventional Procedure', and therefore is not 'approved' as may be the case for a drug or procedure subject to technology appraisal. NICE do not examine interventional procedures which are considered established practice unless there are data demonstrating uncertainty about their efficacy or safety.

- The guidance with regard to laparoscopic repair was reviewed in 2016 but there was no new evidence to suggest a change in the guidelines was required.

Medicines and Healthcare Products Regulatory Authority (MHRA)

- It is understood that the MHRA broadly agrees with NICE's position outlined above and considers that the main determinant of success of an operation seems to be patient selection and surgical technique rather than choice of device. MHRA continues to encourage the reporting of adverse events following the use of surgical mesh.

4.3 Summary of findings

There is a significant amount of evidence to currently support the use of surgical synthetic mesh in hernia repair surgery at the present time. However, there is a lack of evidence to support the use of biological mesh above standard synthetic mesh in hernia repair surgery. The evidence to support the use of biological mesh when standard surgical mesh has failed is also scant and the disproportionate higher cost of biological mesh is also a factor to be considered.

5 Equity issues

Whilst there is a greater occurrence rates of inguinal hernia in men, there is currently insufficient evidence to support a wider equity issue.

6 Discussion and conclusions

Systematic reviews of the use of biological mesh found that there were issues with many of the studies carried out in this area. Many studies had no comparison group, assessors were not blinded to either the intervention or exposure status of participants.

Further unbiased studies are required to identify the true clinical effectiveness of biological mesh and the most cost effective clinical circumstances for use should be identified.

7 Search Strategy

Medline:

Surgical mesh

Biological mesh

Hernia repair

Synthetic mesh

PubMed:

Surgical mesh

Biological mesh

Hernia repair

Synthetic mesh

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NHS Birmingham and Solihull CCG
NHS Sandwell and West Birmingham CCG

DRAFT
Policy for Hysteroscopy for Heavy Menstrual Bleeding.

Document Details:

Version:	DRAFT v1.
Ratified by (name and date of Committee):	Treatment Policy Clinical Development Group
Date issued for Public Consultation:	02.09.2019
Equality & Diversity Impact Assessment	

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.

Category: Restricted

Heavy Menstrual Bleeding (HMB/ Heavy Periods)

Heavy Menstrual Bleeding (HMB) is common but can have a big effect on a woman's everyday life. HMB does not always have an underlying cause but can result from problems such as fibroids or endometriosis.

It's difficult to define exactly what a heavy period is because it varies from woman to woman. Heavy for one woman may be normal for another.

Most women will lose less than 16 teaspoons of blood (80ml) during their period, with the average being around 6 to 8 teaspoons.

Heavy menstrual bleeding is defined as losing 80ml or more in each period, having periods that last longer than 7 days, or both.

However, it's not usually necessary to measure blood loss. Most women have a good idea of how much bleeding is normal for them during their period and can tell when this changes.

A good indication that your periods are heavy is if you:

- are having to change your sanitary products every hour or two
- are passing blood clots larger than 2.5cm (about the size of a 10p coin)
- are bleeding through to your clothes or bedding
- need to use two types of sanitary product together – for example, tampons and pads

In about half of women with heavy menstrual bleeding, no underlying reason is found. But there are several conditions and some treatments that can cause heavy menstrual bleeding.

Some conditions of the womb and ovaries can cause heavy bleeding, including:

- fibroids – non-cancerous growths that develop in or around the womb and can cause heavy or painful periods
- endometriosis – where the tissue that lines the womb (endometrium) is found outside the womb, such as in the ovaries and fallopian tubes (although this is more likely to cause painful periods)
- adenomyosis – when tissue from the womb lining becomes embedded in the wall of the womb; this can also cause painful periods
- pelvic inflammatory disease (PID) – an infection in the upper genital tract (the womb, fallopian tubes or ovaries) that can cause symptoms like pelvic or abdominal pain, bleeding after sex or between periods, vaginal discharge and fever

- endometrial polyps – non-cancerous growths in the lining of the womb or cervix (neck of the womb)
- cancer of the womb – the most common symptom is abnormal bleeding, especially after the menopause
- polycystic ovary syndrome (PCOS) – a common condition that affects how the ovaries work; it causes irregular periods, and periods can be heavy when they start again

Other conditions that can cause heavy periods include:

- blood clotting disorders, such as Von Willebrand disease
- an underactive thyroid gland (hypothyroidism) – where the thyroid gland does not produce enough hormones, causing tiredness, weight gain and feelings of depression
- diabetes

Medical treatments that can sometimes cause heavy periods include:

- an IUD (intrauterine contraceptive device, or "the coil") – this can make your periods heavier for the first 3 to 6 months after insertion
- anticoagulant medication – taken to prevent blood clots
- some medicines used for chemotherapy
- some herbal supplements, which can affect your hormones and may affect your periods – such as ginseng, ginkgo and soya

Hysteroscopy

A hysteroscopy is a procedure used to examine the inside of the womb (uterus).

It is carried out using a hysteroscope, which is a narrow telescope with a light and camera at the end. Images are sent to a monitor so your doctor or specialist nurse can see inside your womb.

The hysteroscope is passed into your womb through your vagina and cervix (entrance to the womb), which means no cuts need to be made in your skin.

In deciding whether to offer the woman a hysteroscopy or ultrasound scan NICE Guidance 88 should be taken into consideration:

Women with suspected submucosal fibroids, polyps or endometrial pathology
Offer outpatient hysteroscopy to women with HMB if their history suggests submucosal fibroids, polyps or endometrial pathology because:

- they have symptoms such as persistent intermenstrual bleeding or
- they have risk factors for endometrial pathology

Women with possible larger fibroids

Offer pelvic ultrasound to women with HMB if any of the following apply:

- their uterus is palpable abdominally
- history or examination suggests a pelvic mass
- examination is inconclusive or difficult, for example in women who are obese.

Women with suspected adenomyosis

Offer transvaginal ultrasound (in preference to transabdominal ultrasound or MRI) to women with HMB who have:

- significant dysmenorrhoea (period pain) or
- a bulky, tender uterus on examination that suggests adenomyosis.

If a woman declines transvaginal ultrasound or it is not suitable for her, consider transabdominal ultrasound or MRI, explaining the limitations of these techniques.

Be aware that pain associated with HMB may be caused by endometriosis rather than adenomyosis (see NICE's guideline on endometriosis).

Other diagnostic tools

Do not use saline infusion sonography as a first-line diagnostic tool for HMB.

Do not use MRI as a first-line diagnostic tool for HMB.

Do not use dilatation and curettage alone as a diagnostic tool for HMB

Evidence Review

In reviewing the evidence NICE 2018 considered the following requirements:

- that the correct identification of the cause of HMB is important as this can impact the treatment options offered to women.
- If a test is sensitive, it may help the clinicians to choose the right initial treatment to be offered to women.
- It is important to avoid false positives because unnecessary treatment, especially surgical treatment, can cause harm.
- The evidence on diagnostic accuracy was assessed using adapted GRADE methodology. GRADE is a systematic approach to rating the certainty of evidence in systematic reviews and other evidence syntheses.
- The evidence on patient satisfaction or acceptability was assessed using Cochrane Collaboration's tool for assessing risk of bias.

NICE in their evidence review accepted that the quality of evidence in these reviews ranged from very low to moderate with most evidence being of very low quality. The NICE committee recognised that the evidence was fragmented and with several limitations. The NICE committee agreed that the quality of evidence was most often downgraded because of unclear sampling, unclear inclusion and exclusion criteria, unclear diagnostic criteria, and at times, considerable number of drop-outs.

However, national clinical consensus under NG 88 has recommended the use of hysteroscopy as a first line intervention in a limited number of clinical circumstances:

The patient must have suspected submucosal fibroids OR polyps OR endometrial pathology

AND

The patient has one of the following symptoms:

- persistent intermenstrual bleeding OR
- risk factors for endometrial pathology

Due to this national clinical expertise, the use of hysteroscopy will be commissioned in specified clinical circumstances in line with the clinical consensus achieved through NICE NG 88.

Eligibility Criteria: Restricted

Hysteroscopy for Heavy menstrual Bleeding is commissioned as a first line investigation in the following clinical circumstances:

The patient must have suspected submucosal fibroids OR polyps OR endometrial pathology

AND

The patient has one of the following symptoms:

- persistent intermenstrual bleeding OR
- risk factors for endometrial pathology

Risk factors for endometrial pathology are defined as:

- the patient has persistent intermenstrual or persistent irregular bleeding, and the patient has infrequent heavy bleeding and is obese or has polycystic ovary syndrome
- the patient taking tamoxifen
- the patient for whom treatment for HMB has been unsuccessful.

In other clinical circumstances diagnostic hysteroscopy is commissioned in the following clinical circumstances:

- First -line investigation using ultrasound scan has provided inconclusive results. For example, hysteroscopy is clinically required to determine the exact location of a fibroid or the exact nature of the abnormality.

N.B. investigation for suspected or proven malignancy is outside the scope of this policy and should in investigated in line with the relevant cancer pathway.

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.

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NHS Birmingham and Solihull CCG
NHS Sandwell and West Birmingham CCG

DRAFT
Policy for the use of Liposuction in Lymphoedema

Document Details:

Version:	DRAFT v1.
Ratified by (name and date of Committee):	Treatment Policy Clinical Development Group
Date issued for Public Consultation:	2nd September 2019
Equality & Diversity Impact Assessment	

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.

Liposuction

Liposuction is normally deemed to be a cosmetic procedure used to remove unwanted body fat.

It involves sucking out small areas of fat that are hard to lose through exercise and a healthy diet. It's carried out on areas of the body where deposits of fat tend to collect, such as the buttocks, hips, thighs and tummy.

The aim is to alter body shape, and the results are generally long-lasting, providing you maintain a healthy weight.

It works best in people who are a normal weight and in areas where the skin is tight.

Liposuction carried out for cosmetic reasons is not normally available on the NHS. However, liposuction can sometimes be used by the NHS to treat certain health conditions.

Liposuction is usually carried out under general anaesthetic, although an epidural anaesthetic may be used to enable treatment on lower parts of the body.

The surgeon would mark on your body the area where fat is to be removed. He or she would then:

- **inject this area** with a solution containing anaesthetic and medication, to reduce blood loss, bruising and swelling
- **break up the fat cells** using high-frequency vibrations, a weak laser pulse or a high-pressure water jet
- **make a small incision (cut) and insert a suction tube attached to a vacuum machine** (several cuts may need to be made if the area is large)
- **move the suction tube back and forth** to loosen the fat and suck it out
- **drain** any excess fluid and blood
- **stitch up and bandage** the treated area

It usually takes one to three hours. Most people need to stay in hospital overnight.

After the procedure, you would be fitted with a compression garment. This helps to reduce swelling and bruising, and should be worn constantly for several weeks after the operation.

You may need to take antibiotics straight after the procedure to reduce the risk of infection. Most people also take mild painkillers to ease any pain and swelling.

Recovery

It may take up to 12 weeks to make a full recovery.

If you had a general anaesthetic, someone would need to drive you home and stay with you for the first 24 hours. You would not be able to drive for a few days.

The compression garment may be taken off while you shower.

You would need to avoid strenuous activity for up to four weeks (but walking and general movement should be fine).

The results of the procedure are not always noticeable until the swelling has gone down or depending on the care plan for the individual patient, it may take more than one surgical episode before results are visible. It can take up to six months for the area to settle completely.

After about a week: Stitches would be removed (unless you had dissolvable stitches).

At four to six weeks: You should be able to resume any contact sports or strenuous activities you would normally do.

- Side effects to expect

It is common after liposuction to have:

- **bruising and swelling**, which may last up to a couple of months
- **numbness**, which should go away in six months
- **scars**
- **inflammation** of the treated area, or the veins underneath
- **fluid** coming from the cuts
- **swollen ankles** (if the legs or ankles are treated)and it may require long-term compression garments to be worn.
- **Pain which may last for up to a month**
- **Skin laxity**

- What could go wrong

Liposuction can occasionally result in:

- **lumpy and uneven results, which is often due to skin laxity and cannot be resolved by further episodes of liposuction.**
- **Seroma which is a collection of fluid under the skin**
- **bleeding under the skin** (haematoma)
- **persistent numbness** that lasts for months
- **changes in skin colour** in the treated area

- **a build-up of fluid in the lungs** (pulmonary oedema) from the fluid injected into the body
- **a blood clot in the lungs** (pulmonary embolism)
- **damage to internal organs** during the procedure

Any type of operation also carries a small risk of:

- **excessive bleeding**
- **developing a blood clot** in a vein
- **infection**
- **an allergic reaction** to the anaesthetic

The surgeon should explain how likely these risks and complications are, and how they would be treated if they occurred.

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Liposuction in Lymphoedema: Category: Restricted

Lymphoedema

Lymphoedema is a long-term (chronic) condition that causes swelling in the body's tissues. It can affect any part of the body, but usually develops in the arms or legs.

It develops when the lymphatic system does not work properly. The lymphatic system is a network of channels and glands throughout the body that helps fight infection and remove excess fluid.

There are two main types of lymphoedema:

- **primary lymphoedema** – caused by faulty genes that affect the development of the lymphatic system; it can develop at any age, but usually starts during infancy, adolescence, or early adulthood
- **secondary lymphoedema** – caused by damage to the lymphatic system or problems with the movement and drainage of fluid in the lymphatic system; it can be the result of an infection, injury, cancer treatment, inflammation of the limb, or a lack of limb movement

Lymphoedema is thought to affect more than 200,000 people in the UK. Primary lymphoedema is rare and is thought to affect around 1 in every 6,000 people. Secondary lymphoedema is much more common.

Secondary lymphoedema affects around 2 in 10 women with breast cancer, and 5 in 10 women with vulval cancer. About 3 in every 10 men with penile cancer get lymphoedema.

People who have treatment for melanoma in the lymph nodes in the groin can also get lymphoedema. Research has shown around 20-50% of people are affected.

Treating lymphoedema

There is no cure for lymphoedema, but it's usually possible to control the main symptoms using techniques to minimise fluid build-up and stimulate the flow of fluid through the lymphatic system.

These include wearing compression garments, taking good care of your skin, moving and exercising regularly, and having a healthy diet and lifestyle.

The recommended treatment for lymphoedema is decongestive lymphatic therapy (DLT).

DLT isn't a cure for lymphoedema, but it can help control the symptoms. Although it takes time and effort, the treatment can be used to bring lymphoedema under control.

Decongestive lymphatic therapy (DLT)

There are four components to DLT:

- **compression garments** – to complement exercise by moving fluid out of the affected limb and minimise further build-up
- **skin care** – to keep the skin in good condition and reduce the chances of infection
- **exercises** – to use muscles in the affected limb to improve lymph drainage
- **specialized massage techniques** – known as manual lymphatic drainage (MLD); this stimulates the flow of fluid in the lymphatic system and reduces swelling however, this technique is only appropriate for patients with cancer-related or primary lymphoedema.

DLT is an intensive phase of therapy, during which you may receive treatment up to 3 times per week for several weeks to help reduce the volume of the affected body part.

This is followed by a second phase called the maintenance phase. You will be encouraged to take over your care using simple self-massage techniques, wearing compression garments, and continuing to exercise.

This treatment phase aims to maintain the reduced size of the affected body part.

Surgery

In a small number of cases, surgery may be used to treat lymphoedema. There are three main types of surgery that may be useful for the condition:

- removal of sections of excess skin and underlying tissue (debulking)
- removal of fat from the affected limb (liposuction)
- restoration of the flow of fluid around the affected section of the lymphatic system – for example, by connecting the lymphatic system to nearby blood vessels (lymphaticovenular anastomosis)
- Lymph node transfer

These treatments may help reduce the size of areas of the body affected by lymphoedema, but some are still being evaluated – particularly lymphaticovenular anastomosis – and aren't in widespread use.

This policy ONLY covers the use of Liposuction for Lymphoedema.

Liposuction

Liposuction is where a thin tube is inserted through small cuts (incisions) in the skin to suck fat out of tissue. It can be used to remove excess fat from an affected limb to help reduce its size.

After surgery, you'll have to wear a compression garment on the affected limb day and night for at least a year to help keep the swelling down.

Evidence Review

Searches in the Cochrane Database and the identification of a number of systematic reviews show, good quality of evidence, which support the use of liposuction in patient diagnosed with lymphoedema in certain clinical circumstances.

The evidence demonstrated clear prevention of future illness, due to the nature of lymphoedema and the reduction in the likelihood of serious infections.

Moderate to large health improvement using this procedure was supported within the evidence review by long term follow up which demonstrated on-going clinical benefit to patients.

Current evidence on the safety and efficacy of liposuction for chronic lymphoedema is adequate to support the use of this procedure provided that standard arrangements are in place for clinical governance, consent and audit.

However, patient selection should only be done by a specialist lymphoedema multidisciplinary team as part of a lymphoedema service pathway.

Eligibility Criteria: Restricted

For patients with either Primary or Secondary Lymphoedema who have failed conservative management in line with the currently commissioned patient pathway for the treatment of lymphoedema, patients will be eligible for treatment of their lymphoedema with liposuction.

AND

Patient selection should only be undertaken by a specialist lymphoedema multidisciplinary team as part of a lymphoedema service pathway.

Conservative management of lymphoedema is defined as:

Current conservative treatments for lymphoedema include decongestive lymphatic therapy (DLT). DLT combines MLD massage techniques with compressive bandaging, skin care and decongestive exercises. Once DLT sessions are stopped the patient is fitted with a custom-made compression garment, which is worn every day.

Investigations for suspected or proven malignancy are outside the scope of this policy and should be treated in line with the relevant cancer pathway.

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 request is supported by the CCG.

Guidance

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NHS Birmingham and Solihull CCG
NHS Sandwell and West Birmingham CCG

DRAFT
Policy for the use of Liposuction in Lipoedema

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Version:	DRAFT v2
Ratified by (name and date of Committee):	Treatment Policy Clinical Development Group
Date issued for Public Consultation:	2nd September 2019
Equality & Diversity Impact Assessment	

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.

Liposuction in Lipoedema: Category: Not Routinely Commissioned

Liposuction

Liposuction is normally deemed to be a cosmetic procedure used to remove unwanted body fat.

It involves sucking out small areas of fat that are hard to lose through exercise and a healthy diet. It is usually carried out on areas of the body where deposits of fat tend to collect, such as the buttocks, hips, thighs and tummy.

The aim is to alter body shape, and the results are generally long-lasting, providing a healthy weight is maintained.

It works best in people who are a normal weight and in areas where the skin is tight.

Liposuction carried out for cosmetic reasons is not normally available on the NHS. However, liposuction can sometimes be used by the NHS to treat certain health conditions.

Liposuction is usually carried out under general anaesthetic, although an epidural anaesthetic may be used to enable treatment on lower parts of the body.

The surgeon would mark on your body the area where fat is to be removed. He or she would then:

- **inject this area** with a solution containing anaesthetic and medication, to reduce blood loss, bruising and swelling
- **break up the fat cells** using high-frequency vibrations, a weak laser pulse or a high-pressure water jet
- **make a small incision (cut) and insert a suction tube attached to a vacuum machine** (several cuts may need to be made if the area is large)
- **move the suction tube back and forth** to loosen the fat and suck it out
- **drain** any excess fluid and blood
- **stitch up and bandage** the treated area

It usually takes one to three hours. Most people need to stay in hospital overnight.

Lipoedema

Lipoedema is a long-term (chronic) condition where there is an abnormal build-up of fat cells in the legs, thighs and buttocks, and sometimes in the arms.

The condition usually only affects women, although in rare cases it can also affect men.

In lipoedema, the thighs, buttocks, lower legs, and sometimes the arms, become enlarged due to a build-up of abnormal fat cells. Both legs and/or the arms are usually enlarged at the same time and to the same extent.

The feet and hands are not affected, which creates a "bracelet" effect or "band-like" appearance just above the ankles and wrists.

Leg and arm size can vary between individuals with lipoedema, and the condition can gradually get worse over time.

As well as becoming enlarged, affected areas of the body may:

- feel soft, "doughy" and cold
- bruise easily
- ache or feel painful or tender
- have small broken veins under the skin

Someone with lipoedema may eventually get fluid retention (lymphoedema) in their legs. This type of swelling can worsen by the end of the day and may improve overnight, whereas the fatty swelling of lipoedema is constant.

Treatments for lipoedema

There has been little research into lipoedema, so there is some uncertainty about the best way to treat the condition.

If you have lipoedema it is important to avoid significant weight gain and obesity because putting on weight will make the fatty swelling worse.

Compression tights are helpful for some people because they support the fatty swelling and may reduce the pain.

Liposcution is the surgical option for the removal of fat.

Tumescent liposuction

Tumescent liposuction involves sucking out the unwanted fat through a tube. A liquid solution is first injected into the legs to help numb the area and reduce blood loss.

Fatty swelling of the legs may return after having the procedure if you subsequently gain weight.

Non-surgical treatments may also be needed for a long period after having tumescent liposuction. For example, you'll need to wear compression garments after surgery to prevent complications such as lymphoedema.

Treatments to prevent lipoedema progression

Non-surgical treatments can sometimes help improve pain and tenderness, prevent or reduce lipoedema, and improve the shape of affected limbs – although they often have little effect on the fatty tissue.

Several different treatments are designed to improve the management of the lipoedema, such as:

- compression therapy – wearing bandages or garments that squeeze the affected limbs
- exercise – usually low-impact exercises, such as swimming and cycling
- massage – techniques that help relieve the aching and heaviness often felt by patients

Treatments that do not work

Treatments used for some types of tissue swelling are generally unhelpful for lipoedema.

Lipoedema doesn't respond to:

- raising the legs
- diuretics (tablets to get rid of excess fluid)
- dieting – this tends to result in a loss of fat from areas not affected by lipoedema, with little effect on the affected areas

Causes of lipoedema

The cause of lipoedema is not known, but in some cases, there is a family history of the condition. It seems likely that the genes you inherit from your parents play a role.

Lipoedema tends to start at puberty or at other times of hormonal change, such during pregnancy or the menopause, which suggests hormones may also have an influence.

Although the accumulation of fat cells is often worse in obese people, lipoedema is not caused by obesity and can affect people who are a healthy weight. It should not be mistaken for obesity and dieting often makes little difference to the condition.

Evidence Review

There is no evidence available which directly compares liposuction with conservative management – where evidence testing the intervention is found, it is applied to patient cohorts that have already received conservative management.

The evidence identified during the evidence review consisted of three trials (totalling 274 patients), along with the NHS website (https://www.nhs.uk/conditions/lipoedema/) which states that this is a relatively new and under researched condition.

The largest study consisting of 164 patients, clearly stated that they had “undergone conservative therapy over a period of years” and as such the benefits stated can be viewed as over and above those offered by conservative treatment.

The results from all of the identified studies, suggests that there are both short and long-term sustained improvements in almost all dimensions around pain and Quality of Life measurements, and one study substantiates this as over and above conservative treatment. However, the number of patients across the research areas are very low and no randomised control trials were identified.

Whilst the three studies seem consistent in their findings, the evidence identified within the review reflects the lack of RCTs (or direct comparison to no treatment on two of the studies) and the need for further research in this area.

Therefore, in light of the paucity of evidence to support this intervention, liposuction for this clinical indication cannot be supported at the present time.

Eligibility Criteria: Not Routinely Commissioned

For patients with Lipoedema, Liposuction is Not Routinely Commissioned in these clinical circumstances due to a lack of evidence to support this intervention.

Investigations for suspected or proven malignancy are outside the scope of this policy and should be treated in line with the relevant cancer pathway.

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

Lipoedema (2017) - https://www.nhs.uk/conditions/lipoedema/

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NHS Birmingham and Solihull CCG
NHS Sandwell and West Birmingham CCG

DRAFT
Policy for the use of Non-Cosmetic Body Contouring Surgery.

Document Details:

Version:	DRAFT v1.
Ratified by (name and date of Committee):	Treatment Policy Clinical Development Group
Date issued for Public Consultation:	02.09.2019
Equality & Diversity Impact Assessment	

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.

Category: Restricted

Body Contouring Surgery

The Surgical Procedures included in Body Contouring Surgery may including the following:

- **Full abdominoplasty:**

For patients who have significant skin laxity, excess fat and separation of the muscles, a classic tummy tuck is the most common procedure. Performed under general anaesthetic, this operation can require patients to be in hospital for two or three days.

During the operation, an incision is made from hip to hip and around the umbilicus. The excess skin and fat is excised from the umbilicus to just above the pubic hair. The muscles above and below the umbilicus are tightened. The skin is then sewn up to give a circular scar around the umbilicus and a long scar across the lower abdomen. Although this operation leaves a large scar, it does provide the greatest improvement in abdominal shape.

Patients who are thinking about becoming pregnant should not undergo this procedure and should wait until they are sure they are not having any more children. All the skin and fat below the umbilicus can be removed in a standard abdominoplasty. This results in a scar across the lower abdomen and a scar around the umbilicus.

- **Mini abdominoplasty**

For patients with only a small amount of excess skin a lesser abdominoplasty might be appropriate. A general anaesthetic is still needed.

During the operating, a wedge of skin and fat is excised from the lower tummy leaving a horizontal scar above the pubic hair. Sometimes the muscles will also be tightened. No scar is left around the umbilicus, which may be stretched slightly to become a different shape. A mini abdominoplasty will give a smaller effect than a full abdominoplasty.

- **Extended abdominoplasty**

Surplus skin and fat of the loins and back are removed at the same time as the abdomen.

- **Endoscopic abdominoplasty**

Tightens the muscles of the abdominal wall. Skin is not removed but liposuction can be carried out at the same time.

- **Apronectomy (Panniculectomy)**

An Apronectomy is a modified mini-abdominoplasty, mainly for patients who have a large excess of skin and fat hanging down over the pubic area and only the surplus skin and fat is removed. A modification to an abdominoplasty might also be necessary when the patient has problems with scars from previous operations.

A panniculus is excess adipose tissue hanging downward from the abdomen and resembles an "apron of skin" overlying the front of the pelvic girdle. A large panniculus can interfere with normal activities such as walking, and lead to serious medical problems. The heavy overhanging tissue can cause chronic skin inflammation under the flap, and subsequently, skin breakdown and infection.

The panniculus hanging below the symphysis pubis when the individual is standing normally can cause significant functional impairment and other complications such as intertrigo.

- **Arm reduction and lift (Brachioplasty):**

Brachioplasty, or upper arm reduction or arm lift is a surgical procedure which removes and tightens loose skin and excess fat in the upper arm. It is usually performed under a general anaesthetic. The surgeon makes a long incision between the elbow and axilla. Segments of skin and fat are removed and the remaining skin and tissue lifted resulting in a tight, smooth look.

- **Buttock and/or Thigh lift (Thighplasty):**

Thighplasty is aesthetic reshaping surgery with the removal of excess skin and fat. Buttock or thigh lift surgery is performed to lift the excess skin to firm and tighten the skin around the buttocks and/or thighs. Liposuction may also be performed during this procedure. Sometimes a buttock lift is combined with this procedure.

- **Liposuction / Liposculpture / Suction Assisted Lipectomy**

Liposuction is also known as liposculpture or suction assisted lipectomy. It is a technique most commonly performed to remove unwanted fat deposits. Liposuction can be performed on other areas of the body, including the neck, arms, tummy, loins, thighs, inner side of the knees and the ankles.

Evidence Review

The results from the search strategy found 3 systematic reviews, 1 economic systematic review and 4 clinical trials & guidance which directly informed 'Body Contouring' in reference to the effectiveness measurable by physical, physiological, and/or qualitative patient reported outcomes.

The BAPRAS UK Commissioning Guide 2017 highlights an expert interpretation of various papers to inform NICE and clinical commissioners in the UK health care sector. All results highlighted in the evidence review are also utilised within the commissioning guide.

The 'BODY-Q' systematic review provides strong evidence to support the method in measuring the effectiveness of body contouring from patient-reported outcomes (PRO. 'BODY-Q' method is the framework of the BODY-Q scales, presented below, is comprised of three overarching themes as follows: 1) Appearance; 2) Health-Related Quality of Life; and 3) Patient Experience. Under these domains, there are 18 independently functioning scales that measure important Central Obesity Index. In addition to the 18 scales, there is 1 obesity-specific symptom checklist.

Due to the statistically significant health improvement benefits both in relation to Quality of Life and clinical outcomes of more than 30%, and that the evidence has demonstrated the potential of removal of excess skin to prevent both 1st and 2nd prevention of future illness such as mobility, Quality of Life concerns, infection, lymphoedema and other illnesses, it was deemed within certain clinical circumstances that excess skin removal could be an effective surgical intervention.

Glossary

Term	Definition
Body mass index (BMI)	A measure for human body shape based on an individual's weight and height. BMI = body weight in kilograms / height in meters squared
Excess body weight	Calculation of change of BMI relative to a maximum normal BMI of 25kg/m_2
Massive weight loss	Loss of 50% or more excess body weight
BODY-Q	The Patient-Reported Outcome Instrument for Weight Loss and Body Contouring Treatments

Eligibility Criteria: Restricted

Removal of excess skin is commissioned in the following clinical circumstances:

The patient is 18 or over at the time of application

AND

The patient has lost at least 50% of their original excess weight and maintained their weight for at least two years, both of which have been recorded and documented by a clinician in the patient's medical notes

AND the patient has one of the following:

Skin folds are causing severe functional impairment which is impacting on the patient's ability to carry out activities of daily living.

OR

Recurrent skin infections are present in the patient's skin folds which fail to resolve, despite appropriate medical treatment for at least 6 months.

N.B. Functional impairment is defined as preventing activities of daily living to be undertaken independently, i.e. sleeping; eating; walking.
Each patient will have access to funding for one course of surgical treatment to remove excess skin. All surgical interventions for removal of the excess skin must be undertaken as part of the original treatment plan and in line with the above eligibility criteria. Further applications for body contouring surgery will not be routinely funded and revision surgery to improve the cosmetic appearance will not be accepted. Funding is for surgical procedures to remove excess skin from an area of the body, which is causing functional impairment / recurrent skin infections. Procedures to aid weight loss or muscle tightening e.g. full abdominoplasty are not commissioned under this policy.

Other procedures which are not included within the Body Contouring Surgery policy are:

- Breast Surgery
- Liposuction
- Cosmetic Surgery

Investigations for suspected or proven malignancy are outside the scope of this policy and should be treated in line with the relevant cancer pathway.

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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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