

Clinical Commissioning Policy

CMICB_Clin100Liposuction

Category 1 Intervention - Not routinely commissioned

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Last Reviewed: March 2024

This policy statement will be reviewed 5 years from the date of the last review unless new evidence or technology is available sooner.

1. Policy statement

- 1.1 Liposuction is not routinely commissioned for cosmetic purposes.
- 1.2 Liposuction is not routinely commissioned in the treatment of lymphoedema or lipoedema.

2. Exclusions

2.1 Patients undergoing oncoplastic reconstruction surgery are excluded from this policy.

3. Core Eligibility Criteria

- 3.1 There are several circumstances where a patient may meet a 'core eligibility criterion' which means they are eligible to be referred for this procedure or treatment, regardless of whether they meet the policy statement criteria, or the procedure or treatment is not routinely commissioned.
- 3.2 These core clinical eligibility criteria are as follows:
 - Any patient who needs 'urgent' treatment will always be treated.
 - All NICE Technology Appraisals Guidance (TAG), for patients that meet all the eligible criteria listed in a NICE TAG will receive treatment.
 - In cancer care (including but not limited to skin, head and neck, breast and sarcoma)
 any lesion that has features suspicious of malignancy, must be referred to an
 appropriate specialist for urgent assessment under the 2-week rule.
 NOTE: Funding for all solid and haematological cancers are now the responsibility of
 NHS England.
 - Reconstructive surgery post cancer or trauma including burns.
 - Congenital deformities: Operations on congenital anomalies of the face and skull are
 usually routinely commissioned by the NHS. Some conditions are considered highly
 specialised and are commissioned in the UK through the National Specialised
 Commissioning Advisory Group (NSCAG). As the incidence of some cranio-facial
 congenital anomalies is small and the treatment complex, specialised teams, working in
 designated centres and subject to national audit, should carry out such procedures.
 - Tissue degenerative conditions requiring reconstruction and/or restoring function e.g. leg ulcers, dehisced surgical wounds, necrotising fasciitis.
 - For patients expressing gender incongruence, further information can be also be found in the current ICB gender incongruence policy and within the <u>NHS England gender</u> <u>services programme</u> - https://www.england.nhs.uk/commissioning/spec-services/npc-crg/gender-dysphoria-clinical-programme/

4. Rationale behind the policy statement

- 4.1 Liposuction is generally considered to be a cosmetic procedure.
- 4.2 The evidence base for use in lymphoedema and lipoedema is limited and most of the studies are low quality with low patient numbers and short-term outcomes.
- 4.3 There are significant concerns about safety particularly when used for lipoedema.

5. Summary of evidence review and references

- 5.1 *Liposuction* is normally deemed to be a cosmetic procedure to remove unwanted body fat. However, it can also be used for medical reasons for both lymphoedema and lipoedema.¹
- 5.2 *Lymphoedema* is the abnormal accumulation of subcutaneous fat and fluid in body tissues. This leads to chronic swelling which can cause disability, pain and cosmetic issues. It occurs most commonly in the arms and legs ² and arises as a result of damage to the lymphatic vessels. Primary lymphoedema is congenital and over time appears with a gradual occlusion of the lymphatics. Secondary lymphoedema results from damage to the lymphatic system through surgery, radiation, infection or injury. One of the most common types of chronic lymphoedema is secondary lymphoedema in the arm following breast cancer treatment.³ It has been estimated that up to 38% of women will develop lymphoedema of the arm following treatment for breast cancer.⁴
- 5.3 Current conservative treatments for lymphoedema include:
 - Manual lymphatic drainage (MLD) which stimulates the movement of lymph away from the affected limb and
 - Decongestive lymphatic therapy (DLT) which combines the above technique with compressive bandaging, skincare and decongestive exercises.
 - On completion of the above, patients are fitted with custom-made compression garments which are worn every day.
- 5.4 Lipoedema is characterised by an abnormal, usually symmetrical, accumulation of fat in the legs, hips, buttocks and occasionally the arms. It is different to lymphoedema and although the aetiology is unknown, hormonal changes, weight gain and genetics are thought to be involved. ^{5,6} Clinically, it can be characterised as a chronic disease which begins in puberty and takes a progressive course. In contrast to primary lymphoedema, the lymphatic system remains unimpaired in the initial stages.⁵ The condition is said to occur in 10% 11% of women and pubertal girls.⁷⁻⁹ Treatment involves healthy lifestyle changes, conservative therapy (compression and manual lymphatic drainage as above) and for chronic cases, surgery (mainly liposuction).⁶
- 5.5 Adverse effects (although uncommon) of liposuction are bleeding, infection, seroma and pulmonary complications. Fat embolism and necrotising fasciitis have rarely been reported. A large systematic review on the safety of liposuction also reported the overall incidence of major effects was 3.35%. The overall incidence of minor complications was 11.62% (with seroma being the most common). 10

Efficacy

- 5.6 Over the last few years, a handful of studies has been published on the efficacy of liposuction for lipoedema. A 2022 paper acknowledged that to date, the evidence for liposuction was limited to 5 peer-reviewed publications and then goes on to describe its retrospective, single centre, noncomparative study of 106 patients (with lipoedema) who experienced a reduction in symptom severity and need for conservative treatment after a median follow-up of 20 months. The authors concluded that liposuction is effective, especially if it is performed in patients with a BMI <35 kg/m² and at an early stage of the disease.^{8,11}
- 5.7 An open, noncomparative single centre study which reported a longer term follow-up (12 years) in 2021 of 60 patients observed the positive effects of liposuction. The same authors had reported similar positive effects, 4 years previously. However, it is important to highlight that the earlier study was based on 85 patients which implies that 29% of the original study cohort had been lost to follow-up (i.e. after 12 years).

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- 5.8 Two other open, single centre studies observed a positive effect in quality-of-life following liposuction in 20 ¹⁴ and 25 ⁵ patients after 6 months and 37 months respectively. It is interesting to note that all of the above studies were performed in Germany and none in the UK. It is concluded that the most recent evidence to support liposuction in lipoedema is based on low quality studies which involved low patient numbers and short-term follow-up periods.
- 5.9 Very little (if any) data on efficacy of liposuction for lymphoedema have been published within the last few years. A retrospective chart review of 21 patients undergoing liposuction in one institution concluded that patients with predominantly nonpitting oedema could benefit from liposuction (followed by lymphovenous anastomosis or vascularised lymph node transfer) to maximise removal of fibroadipose tissue and optimisation of post-operative compression.¹⁵

National and other guidelines

- 5.10 According to the NHS modernisation agency (2005), liposuction "will not be commissioned simply to correct the distribution of fat" i.e. for cosmesis. However, the Agency also states that liposuction may be useful for areas of localised fat atrophy or pathological hypertrophy (e.g. multiple lipomatosis & lipodystrophies). It may also be used as an adjunct to other surgical procedures e.g. abdominoplasty.¹⁶
- 5.11 For lymphoedema, the strongest piece of evidence is provided by NICE's interventional procedure guidance on liposuction for chronic lymphoedema. IPG 588 (2017) recommends that current evidence on safety and efficacy is adequate to support the use of the procedure provided that standard arrangements are in place for clinical governance and audit. However, patient selection should only be done by a multidisciplinary team as part of a lymphoedema service.³ The studies which IPG 588 included comprised low patient numbers and very short-term outcomes. It has to be noted that the interventional procedure guidelines from NICE do not carry the same weight as technology appraisals or clinical guidelines.
- 5.12 In the same year, a systematic review of the surgical treatment of extremity lymphoedema concluded that conservative management remained the first-line approach. The authors reviewed the literature to develop a treatment algorithm which included lymphovenous anastomosis and vascularised lymph node transfer in addition to liposuction. The algorithm recommends use of liposuction as a 2nd or 3rd line intervention in combination with other modes of treatment.¹⁷ What is not explicit in the review is that its data on liposuction were based on 105 patients only.
- 5.13 For lipoedema, in 2017, 2 key guidelines were issued. The first was produced by Wounds UK whose best practice guidelines in the management of lipoedema were developed by a group of clinicians during a meeting in September 2016. The meeting recognised the general paucity of clinical evidence relating to the management of lipoedema. Where evidence was lacking, expert opinion was used to inform the guideline which recommends liposuction for patients with moderate to severe lipoedema after 6 12 months of conservative management. Despite this, the guideline group acknowledged that access to liposuction within the NHS is limited.
- 5.14 The 2nd guideline was the "2017 First Dutch guideline" which was based on a systematic review and experience of the task force which acknowledged there was little consistent information concerning either diagnosis or treatment in the literature. ¹⁸ Irrespective of this, the guideline recommends tumescent liposuction is the treatment of choice for patients with a suitable health profile and/or inadequate response to conservative and supportive measures. The recommendations did not report the level of evidence or strength of recommendation.

- 5.15 Finally, an international conference consensus suggested that lymph sparing liposuction using tumescent local anaesthesia was currently the only effective treatment for lipoedema. No rigorous evaluation of the literature is apparent but the authors do mention "multiple studies from Germany" as discussed above.
- 5.16 In the UK, the Academy of Medical Royal Colleges are currently running a consultation exercise on the 3rd tranche of NHS England's Evidence-Based Interventions (EBIs).²⁰ This recommends liposuction in patients with a clear symptomatic or functional requirement who have chronic lymphoedema and/or lipoedema. The proposed recommendation for lymphoedema specifies the request must be from a multidisciplinary team as part of a lymphoedema service, there is evidence for functional impairment (not defined) and conservative management has failed after a minimum of 6 months.
- 5.17 Much of the evidence cited in the EBI 3 consultation document has already been discussed above. The underpinning "evidence" is a list of 8 references and provides no critical appraisal of the literature. Of particular note, however, is one key reference (not discussed above) from the Canadian Agency for Drugs and Technologies in Health (CADTH) ²¹ This found that the evidence base was of limited quality from 5 uncontrolled studies and these findings had to be interpreted with caution because they were from single arm, nonrandomised, based on patient self-assessments and using tools which haven't been validated in this context.
- 5.18 In summary, although liposuction is normally considered a cosmetic procedure, it can be used for medical reasons such as lymphoedema and lipoedema. The evidence base for both of these indications is limited. Most of the available studies are low quality with low patient numbers and short-term outcomes. To the author's knowledge, there are no health economics evaluations.
- 5.19 Various reviews have been written based on available information and it appears that liposuction is being recommended according to expert opinion rather than robust data. In the UK, the main driving force for recommendation is NICE interventional procedures guidance on lymphoedema. On its own, an IPG is simply an indication of the safety and efficacy of an intervention, it is not a cast-iron recommendation because of the rapid methods which NICE uses in its production. There are no cost effectiveness data. In addition, NICE are currently reviewing IPG 588 on lymphoedema and are developing an IPG for liposuction in lipoedema. It is understood that both of these reviews have been instigated following a regulation 28 letter from a coroner.
- 5.20 At the time of this review, the CCGs from Shropshire, North Staffordshire and Mersey do not routinely fund liposuction. The situation is further complicated by the EBI 3 consultation on liposuction which is indicated for both lymphoedema and lipoedema. The underpinning data for this EBI 3 recommendation do not appear very robust and it remains to be seen whether the recommendation stands when the consultation has been completed.
- 5.21 **Addendum**: Since writing this review, NICE have published an interventional procedure guideline on liposuction for chronic lipoedema which found that the evidence on efficacy to be inadequate with major concerns around safety. The intervention should only be used in the context of research.²²

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6. Advice and Guidance

6.1 Aim and Objectives

- This policy aims to ensure a common set of criteria for treatments and procedures across the region. This is intended to reduce variation of access to NHS services in different areas and allow fair and equitable treatment for all patients.
- This policy relates to the commissioning of interventions which optimise clinical effectiveness and represent value for money.
- This document is part of a suite of policies which the Integrated Care Board (ICB) uses to
 drive its commissioning of healthcare. Each policy is a separate public document in its
 own right but should be considered alongside all the other policies in the suite as well as
 the core principles outlined.
- At the time of publication, the evidence presented per procedure/treatment was the most current available.
- The main objective for having healthcare commissioning policies is to ensure that:
 - Patients receive appropriate health treatments
 - · Treatments with no or a very limited evidence base are not used; and
 - Treatments with minimal health gain are restricted.
- Owing to the nature of clinical commissioning policies, it is necessary to refer to the biological sex of patients on occasion. When the terms 'men' and 'women' are used in this document (unless otherwise specified), this refers to biological sex. It is acknowledged that this may not necessarily be the gender to which individual patients identify.

6.2 Core Principles

- Commissioning decisions by ICB Commissioners are made in accordance with the commissioning principles set out as follows:
 - Commissioners require clear evidence of clinical effectiveness before NHS resources are invested in the treatment.
 - Commissioners require clear evidence of cost effectiveness before NHS resources are invested in the treatment.
 - Commissioners will consider the extent to which the individual or patient group will gain a benefit from the treatment.
 - Commissioners will balance the needs of an individual patient against the benefit which could be gained by alternative investment possibilities to meet the needs of the community.
 - Commissioners will consider all relevant national standards and consider all proper and authoritative guidance.
 - Where a treatment is approved Commissioners will respect patient choice as to where a treatment is delivered, in accordance with the 'NHS Choice' framework.
 - Commissioning decisions will give 'due regard' to promote equality and uphold human rights. Decision making will follow robust procedures to ensure that decisions are fair and are made within legislative frameworks.

6.3 Individual Funding Requests (Clinical Exceptionality Funding)

- If any patients are excluded from this policy, for whatever reason, the clinician has the option to make an application for clinical exceptionality. However, the clinician must make a robust case to the Panel to confirm their patient is distinct from all the other patients who might be excluded from the designated policy.
- The ICB will consider clinical exceptions to this policy in accordance with the Individual Funding Request (IFR) Governance Framework consisting of: IFR Decision Making Policy; and IFR Management Policy available on the C&M ICB website: https://www.cheshireandmerseyside.nhs.uk/your-health/individual-funding-requests-ifr/

6.4 Cosmetic Surgery

- Cosmetic surgery is often carried out to change a person's appearance to achieve what a
 person perceives to be a more desirable look.
- Cosmetic surgery/treatments are regarded as procedures of low clinical priority and therefore not routinely commissioned by the ICB Commissioner.
- A summary of Cosmetic Surgery is provided by NHS Choices. Weblink: http://www.nhs.uk/conditions/Cosmetic-surgery/Pages/Introduction.aspx and http://www.nhs.uk/Conditions/Cosmetic-surgery/Pages/Procedures.aspx

6.5 Diagnostic Procedures

- Diagnostic procedures to be performed with the sole purpose of determining whether or
 not a restricted procedure is feasible should not be carried out unless the eligibility criteria
 are met, or approval has been given by the ICB or GP (as set out in the approval process
 of the patients responsible ICB) or as agreed by the IFR Panel as a clinically exceptional
 case.
- Where a General Practitioner/Optometrist/Dentist requests only an opinion the patient should not be placed on a waiting list or treated, but the opinion given and the patient returned to the care of the General Practitioner/Optometrist/Dentist, in order for them to make a decision on future treatment.

6.6 Clinical Trials

The ICB will not fund continuation of treatment commenced as part of a clinical trial. This
is in line with the Medicines for Human Use (Clinical Trials) Regulations 2004 and the
Declaration of Helsinki which stipulates that the responsibility for ensuring a clear exit
strategy from a trial, and that those benefiting from treatment will have ongoing access to
it, lies with those conducting the trial. This responsibility lies with the trial initiators
indefinitely.

7. Monitoring and Review

- 7.1 This policy remains in force until it is superseded by a revised policy or by mandatory NICE guidance or other national directive relating to this intervention, or to alternative treatments for the same condition.
- 7.2 This policy can only be considered valid when viewed via the ICB website or ICB staff intranet. If this document is printed into hard copy or saved to another location, you must check that the version number on your copy matches that of the one published.

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- 7.3 This policy may be subject to continued monitoring using a mix of the following approaches:
 - · Prior approval process
 - · Post activity monitoring through routine data
 - · Post activity monitoring through case note audits
- 7.4 This policy will be kept under regular review, to ensure that it reflects developments in the evidence base regarding effectiveness and value.

8. Quality and Equality Analysis

8.1 Quality and Equality Impact Analyses have been undertaken for this policy at the time of its review.

9. Clinical Coding

- 9.1 Office of Population Censuses and Surveys (OPCS)
 None
- 9.2 International classification of diseases (ICD-10)
 None



Document Control

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