

# Clinical Commissioning Policy

## CMICB\_Clin081

### Breast symmetrisation surgery for breast asymmetry

**Category 2 Intervention - Only routinely commissioned when specific criteria are met**

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### Last Reviewed: TBC

*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 Breast symmetrisation surgery is not routinely commissioned for cosmetic purposes alone.
- 1.2 Breast symmetrisation surgery will be commissioned in women if ALL the following criteria are met:
  - 1.2.1 the woman is aged at least 18 years  
**AND**
  - 1.2.2 BMI is <30kg/m<sup>2</sup> and stable for at least 12 months  
**AND**
  - 1.2.3 breast asymmetry (with an estimated difference of at least 3 cup sizes, (approximately 300g in weight) has been confirmed by a breast specialist  
**AND**
  - 1.2.4 the asymmetry is thought to have resulted from (but not limited to): macromastia, Poland Syndrome, tuberous breast, unilateral or asymmetric hypoplasia, amazia (unilateral/bilateral), congenital symmastia.
- 1.3 If there are less than 3 cups sizes difference between the breasts, symmetrisation breast surgery will only be offered if there is a clear tubular deformity of one breast. In these cases, the breast base diameter of the tubular breast must measure less than 50% of the contralateral breast.
- 1.4 NHS specialist breast surgeons in Cheshire and Merseyside will NOT offer aesthetic breast surgery in smokers due to the associated increased risk of complications. Referring clinicians are requested to ensure the patient is a non-smoker or has stopped smoking for at least 6 months before referral (this includes all nicotine-based products e.g. cigarettes, vapes, e-cigarette, nicotine replacement).

## 2. Exclusions

- 2.1 Breast symmetrisation, which is being performed as part of an oncoplastic reconstructive procedure, is outside the scope of 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 criteria; or the procedure or treatment is not routinely commissioned.
- 3.2 These core clinical eligibility criteria are as follows:
  - 3.2.1 Any patient who needs 'urgent' treatment will always be treated.
  - 3.2.2 All NICE Technology Appraisals Guidance (TAG), for patients that meet all the eligible criteria listed in a NICE TAG will receive treatment.
  - 3.2.3 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.
  - 3.2.4 Reconstructive surgery post cancer or trauma including burns.
  - 3.2.5 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.

- 3.2.6 Tissue degenerative conditions requiring reconstruction and/or restoring function e.g. leg ulcers, dehisced surgical wounds, necrotising fasciitis.
- 3.2.7 For patients expressing gender incongruence, further information can be also be found in the current ICB gender incongruence policy and within the [NHS England gender services programme](https://www.england.nhs.uk/commissioning/spec-services/npc-crg/gender-dysphoria-clinical-programme/).  
<https://www.england.nhs.uk/commissioning/spec-services/npc-crg/gender-dysphoria-clinical-programme/>

## 4. Rationale behind the policy statement

- 4.1 Breast symmetrisation is regarded as a cosmetic procedure unless the asymmetry is due to medical reasons (e.g. congenital breast development).
- 4.2 Breast symmetrisation as part of cancer treatment is considered outside this policy.

## 5. Summary of evidence review and references

- 5.1 Breast enlargement (or augmentation) or *augmentation mammoplasty* is a surgical procedure to increase the size of the breast, and this usually can be achieved using 2 main techniques. The first type of reconstructive surgery is implant-based, and the 2<sup>nd</sup> is autologous/free flap reconstruction. A nationwide survey indicated that whichever technique women receive varies throughout the country and between 55% – 70% of women undergo an implant-based procedure. The variation seems to be accounted for depending on availability of a free flap service.<sup>1</sup>
- 5.2 In 2017, it was reported that 15.6% of all cosmetic procedures worldwide were for breast augmentation.<sup>2</sup> In the USA, it has also been reported there has been a 41% increase in breast augmentations over the last 20 years.<sup>3</sup> However, the recently published “Getting it Right First Time” (GIRFT) review of breast surgery makes the distinction between cosmetic breast surgery (alteration of breast appearance for personal preference) and aesthetic breast surgery (alteration of breast appearance to support recovery from breast cancer or for a recognised medical problem such as failure of breast development).<sup>1</sup> The cited reasons for recognised medical problems were congenital breast development resulting in minimal breast growth or significant asymmetry<sup>4</sup> and hyperplasia (breast overgrowth). Such conditions are frequently labelled as “procedures of limited clinical value” and across the country there is an apparent 10-fold variation in CCGs which permit this surgery.
- 5.3 Congenital breast conditions include a wide range of rare conditions where the young person’s breast or underlying chest wall (e.g. Poland syndrome<sup>5</sup>) do not develop normally. Problems become apparent at puberty, and this can have a major psychological effect which can impact on quality-of-life, social integration and long-term mental health.
- 5.4 In addition, of the 55,000 women diagnosed every year in the UK with breast cancer (half of whom aged < 60 years), up to two thirds of these have concerns over changes in body image which is especially true in younger women.<sup>6</sup> Modern breast cancer surgery is now referred to as *oncoplastic breast surgery* which is cancer removal combined with plastic surgery techniques to maintain or adjust the breast shape. It could involve using implants or autologous/free flap reconstruction or a combination as above. In 2017, a freedom of information request from Breast Care Now (BCN) revealed that over three quarters of CCGs had no formal policy restrictions on oncoplastic surgery. However, a small proportion of CCGs did have formal policies which were restrictive and unclear. This raises concerns and may suggest a lack of understanding of the potential complexity of oncoplastic/reconstructive surgery and the vital importance of this surgery to the recovery and welfare of many women being treated for breast cancer.  
Around 17% of all breast surgery admissions are to complete a planned programme of reconstruction which could include “balancing surgery” of the opposite (sometimes healthy) breast.<sup>1</sup>

- 5.5 Aesthetic breast surgery is not without its risks. Complications have been reported such as bleeding/haematoma (1%), infection (<1%), capsular contracture (10% chance at 10 years), implant loss (<5%) and leakage of silicone. A very rare condition called Breast Implant Associated Anaplastic Large Cell Lymphoma (BIA – ATCL) has also been reported. This is a rare type of T cell non-Hodgkin lymphoma related to breast implants; to date there have been 800 cases confirmed worldwide with 33 deaths.<sup>2</sup> It is likely to be caused by textured (as opposed to smooth) implants.<sup>3</sup> In addition, “breast implant associated illness” occurs in women with breast implants who describe a variety of symptoms including fatigue, chest pain, hair loss, chronic pain, body odour, anxiety, brain fog, sleep disturbances or depression. This association is controversial.
- 5.6 In terms of national guidance, the NHS Modernisation Agency (2005) recommended that breast enlargement should not be carried out on small but normal breasts.<sup>7</sup> It may be carried out in exceptional circumstances in women with an absence of breast tissue or with a significant degree of asymmetry. The Agency highlighted the fact that implants will require replacement in the future and that not all patients demonstrate improvement in psychosocial outcomes following the procedure.
- 5.7 The British Association of Plastic Reconstructive and Aesthetic Surgeons concur that cosmetic breast augmentation is not available on the NHS although, as above, there may be exceptional circumstances when this could occur such as significant asymmetry, no breast tissue at all or as part of a breast reconstruction care plan.<sup>8</sup> The Academy of Medical Royal Colleges ran a consultation (in January 2022) on NHS England’s Evidence-Based Interventions (EBIs) List 3 proposals. This proposed corrective surgery for congenital breast asymmetry.<sup>9</sup> EBI 3 confirms that surgery is not funded on the NHS for cosmetic purposes, but it should be available in women with significant asymmetry and a BMI <27 kg/m<sup>2</sup> for congenital conditions which may include macromastia, Poland syndrome, tuberous breast, unilateral or asymmetric hyperplasia, and amazia/complete absence of breast tissue.
- 5.8 A maximum BMI ceiling is applied because of the surgical risks which are more apparent when operating on clinically obese patients. The value of this “ceiling” is debatable but there is some evidence that patients with BMIs of 27 – 29 kg/m<sup>2</sup> can safely be operated on.<sup>10-13</sup> Local specialists strongly support a BMI threshold of <30 kg/m<sup>2</sup> without fear of appreciable adverse effects.
- 5.9 Although currently there is no established agreement on how best to manage developmental breast asymmetry, reconstructive surgeons have a variety of options at their disposal such as implants, augmentation (see above), lipo-transfer, mammoplasty and mastopexy. Certain individuals may require other procedures, for example, to address abnormalities in breast connective tissue and even correction of chest wall deformities.<sup>14</sup> Correction of asymmetry could involve any one or a combination of these techniques and may also require an operation on the contralateral breast in the same person to achieve symmetry.<sup>15</sup> In addition, apart from addressing breast size, nipple position (or malposition) is also an important factor.<sup>16</sup>
- 5.10 Consistent with the concept of individual patients requiring more than one type of procedure for asymmetry is the now withdrawn (May 2023) EBI 3 policy proposal (above) which promoted “corrective” surgery for breast asymmetry as opposed to any specific procedure such as augmentation, mastopexy reduction etc. Thus, the term symmetrisation (or symmetrising) surgery is now more commonly used in this context.
- 5.11 In summary, the majority of breast procedures are performed purely for cosmetic reasons, and these are not usually funded by the NHS. However, there are some medical reasons where addressing asymmetry may be valid. These are conditions which are mostly associated with congenital breast development. A variety of techniques is available (e.g. augmentation, reduction or mastopexy) and possible surgery on the contralateral breast.

Breast symmetrisation encompasses all these aspects and generally is now the preferred term.

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## 6. Advice and Guidance

### 6.1 Aim and Objectives

- 6.1.1 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.
- 6.1.2 This policy relates to the commissioning of interventions which optimise clinical effectiveness and represent value for money.

- 6.1.3 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.
- 6.1.4 At the time of publication, the evidence presented per procedure/treatment was the most current available.
- 6.1.5 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.
- 6.1.6 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

- 6.2.1 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)

- 6.3.1 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.
- 6.3.2 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

- 6.4.1 Cosmetic surgery is often carried out to change a person's appearance to achieve what a person perceives to be a more desirable look.

6.4.2 Cosmetic surgery/treatments are regarded as procedures of low clinical priority and therefore not routinely commissioned by the ICB Commissioner.

6.4.3 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

6.5.1 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.

6.5.2 Where a General Practitioner/Optometrlist/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/Optometrlist/Dentist, in order for them to make a decision on future treatment.

## 6.6 Clinical Trials

6.6.1 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.

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 OPCS-4 Procedure Codes

Any in the primary position

B301	Insertion of prosthesis for breast
B312	Augmentation mammoplasty
B375	Lipofilling of breast
B301	Insertion of prosthesis for breast
B302	Revision of prosthesis for breast
B303	Removal of prosthesis for breast
B304	Renewal of prosthesis for breast
B308	Other specified prosthesis for breast
B309	Unspecified prosthesis for breast

9.2 **ICD-10 diagnosis code(s)**

Excluding  
All C\* (cancers)

With or without

Q83.8 Other congenital malformations of breast Hypoplasia of breast

Q83.9 Congenital malformation of breast, unspecified

## Document Control

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<b>Version History</b>
Version 0.2 DRAFT - 21/04/2022 Title change; Aligned to NHS England's EBI 3 recommendations
Version 0.3 DRAFT - 08/08/2023 <ol style="list-style-type: none"> <li>1. Policy amended following consultation with local breast surgeons and also takes into account the withdrawn EBI 3 policy statement</li> <li>2. Title is now “breast symmetrisation” which thus permits a range of techniques (e.g. augmentation/reduction) and procedures on a contralateral breast.</li> <li>3. Maximum BMI is &lt;math&gt;&lt;30\text{kg/m}^2&lt;/math&gt; (and not &lt;math&gt;&lt;27\text{kg/m}^2&lt;/math&gt;) as clinically this is considered “safe” to operate on and there is published evidence to support this.</li> <li>4. A statement is included on women with asymmetry who do not satisfy the 3-cup size difference if there is a tubular deformity of one breast where the breast base diameter of the tubular breast is measured less than 50% of the contralateral breast. This statement was developed in conjunction with a wide range of specialist surgeons in the northwest.</li> <li>5. Statement on smoking also added after consultation with a wide range of specialist surgeons in the northwest</li> </ol>