

BREAST IMPLANT SURGERY CRITERIA BASED ACCESS (CBA) POLICY

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Application Form	EBI Generic application form if appropriate to apply

**BREAST IMPLANT SURGERY
CRITERIA BASED ACCESS (CBA) POLICY**

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VERSION CONTROL

Document Status:	Current policy
Version:	2425.V3b

DOCUMENT CHANGE HISTORY

Version	Date	Comments
2324.v2	November 2023	Inclusion within 2.4 Implant removal and replacement routinely commissioned & criterion wording to include capsular contracture. Wording amended for private treatment 2.6
2324.v3	May 2024	Amendment of numbering within section 2 (2.3 - 2.11). Amendment to website link 3.6
2425.v3a	October 2024	Breast Surgery for Females policy separation for breast surgeries. Implant surgery separated into a single treatment policy due to pathway change

Equality Impact Assessment (EIA)	N/A
Quality Impact Assessment QIA	N/A
Sponsoring Director:	Dr Bernie Marden
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1 GENERAL PRINCIPLES (CBA)

- 1.1 Treatment should only be given in line with these general principles.
- 1.2 Clinicians should assess their patients against the criteria within this policy AND ENSURE that compliance to the policy criteria is met by the patient PRIOR TO a referral to treatment or surgery
- 1.3 Treatment should ONLY be undertaken where there is evidence that the treatment requested is effective and the patient has the potential to benefit from the proposed treatment
- 1.4 The ICB may approve funding for an ASSESSMENT ONLY to enable the Clinician to obtain further clinical evidence to help determine compliance to policy criteria by the patient.

In such cases, patients should be made aware that an assessment DOES NOT mean that they will automatically receive the treatment or surgery. The patient should be advised that, to effectively manage patient safety and ensure efficacy of the treatment/ surgery for the patient, they will only receive treatment or surgery if they meet policy criteria

- 1.5 Patients MUST CONSENT to receiving treatment/ surgery prior to treatment being undertaken
- 1.6 This policy does not apply to patients with suspected malignancy who should continue to be referred under the NHS '2 week wait pathway' rules for assessment and testing as appropriate
- 1.7 Patients with an elevated BMI of 30 or more MAY experience more post-surgical complications including post-surgical wound infection and should be encouraged to lose weight further prior to seeking surgery

<https://www.sciencedirect.com/science/article/pii/S1198743X15007193>
(Thelwall, 2015)

- 1.9 Patients who are smokers should be referred to smoking cessation services to reduce the risk of surgery and improve healing
- 1.10 Where patients are unable to meet the specific treatment criteria set out in this policy, funding approval MAY be sought by submission of a Generic EBI application form to the Evidence Based Interventions (EBI) team on grounds of 'clinical exceptionality'

2 BREAST IMPLANT SURGERY CRITERIA BASED ACCESS (CBA)

- 2.1 Breast surgery post cancer please refer to the Breast Reconstruction Post Cancer Policy

2.2 Breast surgery (for males) please refer to the Breast Reduction Gynaecomastia Policy

2.3 Breast surgery for patients on the gender dysphoria pathway is the commissioning responsibility of NHS England and is not subject to this policy

2.4 **PIP Breast Implants**

Pip Breast Implants: <https://www.nhs.uk/conditions/pip-implants/>

- If the removal of a pip implant is to be undertaken by the NHS, please refer to point 3 and follow the EBI pathway to apply for funding
- Please clearly state if the original surgery was undertaken by the NHS or in the private sector

2.5 **Breast Implant Removal and Replacement**

Breast Implant Removal and Replacement is routinely commissioned for both breast implants to be removed **OR** removed and replaced during the same surgery for the following clinical indications with the patients consent:

- a) Initial procedure was funded by the NHS.
- b) One OR both implants have ruptured.
- c) One OR both implants have grade 3 or 4 capsular contracture.
- d) One OR both implants are complicated by recurrent implant infection OR Seroma.
- e) The patient develops Breast Implant Associated Anaplastic Large Cell Lymphoma (BIA-ALCL)

2.6 In line with current guidance, patients eligible to have their implant replaced must be informed of the potential risk of BIA-ALCL.

2.7 Patients whose initial procedure was **privately funded** should seek assurance from their private provider in the first instance.

If, however, the patient meets one of the clinical indications detailed in point 2.5 above, and the private provider is unable to offer the patient surgery, a funding application can be put forward for an NHS referral for breast implant **removal only** but not for replacement.

2.8 Pre and postoperative photographs **MUST** be recorded for audit purposes. All eligible patients **MUST** be entered into the Breast and Cosmetic Implant Registry (BCIR) for audit purposes.

2.9 The removal of breast implants due to symptoms termed as Breast Implant Illness (BII) or Autoimmune Syndrome Induced by Adjuvants (ASIA) on social media, or due to the risk of developing Breast Implant Associated Anaplastic Large Cell Lymphoma (BIA-ALCL) is not currently recommended.

2.10 Patients who are not eligible for treatment under this policy, please refer to section 3 EVIDENCE BASED INTERVENTIONS APPLICATION PROCESS on how to apply for funding with evidence of clinical exceptionality

EBI applications put forward for patients who do not fulfil the above criterion for the CBA pathway must evidence

- Clinical exceptionality
- Are 18 years of age
- Have attained full breast development
- Has not smoked/used nicotine replacement therapy over preceding 3 months
- Has a BMI of 19 to 27 sustained for a minimum of 6 months

3 EVIDENCE BASED INTERVENTIONS APPLICATION PROCESS

3.1 Patients who are not eligible for surgery under this policy may be considered for surgery on an individual basis where the 'CLINICIAN BEST PLACED' believes exceptional circumstances exist that warrant deviation from the rule of this policy

'THE CLINICIAN BEST PLACED' is deemed to be the GP or Consultant undertaking a medical assessment and/or a diagnostic test/s to determine the health condition of the patient

3.2 Completion of a **Generic EBI Funding Application Form** must be sent to the EBI team by the 'clinician best placed' on behalf of the patient

Note. applications CANNOT be considered from patients personally

3.3 Only electronically completed EBI applications emailed to the EBI Team will be accepted

3.4 It is expected that clinicians will have ensured that the patient, on behalf of whom they are forwarding the funding application, has given their consent to the application and are made aware of the due process for receiving a decision on the application within the stated timescale

3.5 Generic EBI Funding Applications are considered against '**clinical exceptionality**'. To eliminate discrimination for patients, social, environmental, workplace, and non-clinical personal factors CANNOT be taken into consideration.

For further information on 'clinical exceptionalism' please refer to the NHS Somerset ICB EBI webpage [Evidence Based Interventions - NHS Somerset ICB](#) and click on the section titled **Generic EBI Pathway**

3.6 Where appropriate photographic supporting evidence can be forwarded with the application form

4 ACCESS TO POLICY

4.1 If you would like further copies of this policy or need it in another format, such as Braille or another language, please contact the Patient Advice and Liaison Service on Telephone number: 08000 851067

4.2 **Or write to us:** NHS Somerset ICB, Freepost RRKL-XKSC-ACSG, Yeovil, Somerset, BA22 8HR or **Email** us: somicb.pals@nhs.net

5 REFERENCES

The following sources have been considered when drafting this policy:

- 5.1 British Association of Plastic Reconstructive Aesthetic Surgeons. (2015). Congenital Breast and Chest Conditions. Retrieved 04 26, 2016, from British Association of Plastic Reconstructive and Aesthetic Surgeons: <http://www.bapras.org.uk/public/patient-information/surgery-guides/congenital-breast-and-chest-conditions>
- 5.2 NHS Choices. (2014,07 09). Breast Implants – Complications. Retrieved 04 26, 2016, from NHS Choices: <http://nhs.uk/Conditions/Breast-implants/Pages/Complications.aspx>
- 5.3 British Association of Plastic Reconstructive and Aesthetic Surgeons. (2015). Breast Augmentation. Retrieved 04 26, 2016, from British Association of Plastic Reconstructive and Aesthetic Surgeons: https://baaps.org.uk/patients/procedures/1/breast_augmentation
- 5.4 British Association of Plastic Reconstructive and Aesthetic Surgeons. (2015). *Risks and complications?* Retrieved 23 07 2024, from British Association of Plastic Reconstructive and Aesthetic Surgeons: [Risks and complications | BAPRAS](#)
- 5.5 NHS Choices. (2014, 07 09). Breast implants - complications. Retrieved 04 26, 2016, from NHS Choices: <http://www.nhs.uk/Conditions/Breast-implants/Pages/Complications.aspx>
- 5.6 Nuffield Health. (2016). *Inverted Nipple Surgery*. Retrieved 04 28, 2016, from Nuffield Health: <http://www.nuffieldhealth.com/treatments/inverted-nipple-surgery>
- 5.7 British Association of Plastic Reconstructive and Aesthetic Surgeons. (2015). Breast Reduction. Retrieved 04 14, 2016, from British Association of Plastic Reconstructive and Aesthetic Surgeons: <http://www.bapras.org.uk/public/patient-information/surgery-guides/breast-reduction>
- 5.8 NHS Choices. (2014, 01 07). Breast Reduction. Retrieved 04 14, 2016, from NHS Choices: <http://www.nhs.uk/conditions/Breast-reduction/pages/introduction.aspx>
- 5.9 Science Direct <https://www.sciencedirect.com/science/article/pii/S1198743X15007193>
- 5.10 NHS England EBI List 3 https://ebi.aomrc.org.uk/wp-content/uploads/2023/03/EBI_Guidance_List3_0523.pdf
- 5.11 NHS England AoMRC <https://ebi.aomrc.org.uk/interventions/breast-prosthesis-removal/>