

**BREAST SURGERY (FOR FEMALES)
BREAST ASYMMETRY
BREAST AUGMENTATION
BREAST IMPLANT
BREAST MASTOPEXY OR UPLIFT
BREAST REDUCTION**

EVIDENCE BASED INTERVENTIONS (EBI) POLICY

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Application Form	Generic EBI Application

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VERSION CONTROL

Document Status:	Current policy
Version:	2324.v3

DOCUMENT CHANGE HISTORY

Version	Date	Comments
V8e	April 2015	Remove from the Guidance for Clinicians Document as a separate policy
1617.v2	July 2017	Change the CSU template to a SCCG template
1617.v2a/ 1617.v2b/ 1819.v2b	December 2020	One overarching breast surgery policy, remains not routinely commissioned, removal of consideration for funding wording, removal of background data, rebranding from IFR to EBI
1920.v1a	September 2020	Include commissioned treatment of breast implant rupture, inclusion of non-smoker
1920.v1c	July 2022	Amendment from SCCG to NHS Somerset ICB. New PALS email address
2223.v1d	March 2023	Wording change 3.5
2223.v1e	July 2023	3-year review, inclusion of criterion and wording from NHS E EBI list 3 under implant section
2324.v2	November 2023	Inclusion within in 2.4 Implant removal and replacement routinely commissioned & criterion wording to include capsular contracture. Wording amended for private treatment 2.6

Equality Impact Assessment EIA	May 2016
Quality Impact Assessment QIA	N/A
Sponsoring Director:	Bernie Marden
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1 GENERAL PRINCIPLES (EBI)

- 1.1 Funding approval must be secured prior to a referral for an assessment and/or surgery. Referring patients to secondary care without funding approval having been secured not only incurs significant costs in out-patient appointments for patients that may not qualify for surgery, but inappropriately raises the patient's expectation of treatment
- 1.2 On limited occasions, we may approve funding for an assessment only in order to confirm or obtain evidence demonstrating whether a patient meets the criteria for funding. In such cases, patients should be made aware that the assessment does not mean that they will be provided with surgery and surgery will only be provided where it can be demonstrated that the patients meet the criteria to access treatment in this policy
- 1.3 Funding approval will only be given where there is evidence that the treatment requested is effective and the patient has the potential to benefit from the proposed treatment. Where it is demonstrated that patients have previously been provided with the treatment with limited or diminishing benefit, funding approval is unlikely to be agreed
- 1.4 Receiving funding approval does not confirm that they will receive treatment or surgery for a condition as a consent discussion will need to be undertaken with a clinician prior to treatment
- 1.5 The policy does not apply to patients with suspected malignancy who should continue to be referred under 2 week wait pathway rules for assessment and testing as appropriate
- 1.6 Patients with an elevated BMI of 30 or more may experience more post-surgical complications including post-surgical wound infection so should be encouraged to lose weight further prior to seeking surgery.
<https://www.sciencedirect.com/science/article/pii/S1198743X15007193>
(Thelwall, 2015)
- 1.7 Patients who are smokers should be referred to smoking cessation services in order to reduce the risk of surgery and improve healing

2 POLICY CRITERIA NOT ROUTINELY COMMISSIONED

- 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 Breast surgery (for females) to healthy tissue is not routinely commissioned, the procedures are considered cosmetic, this includes the following types of breast surgery:
- Breast Asymmetry
 - Breast Mastopexy or Uplift
 - Breast Reduction
 - Breast Augmentation

2.2 **EBI Funding Applications**

EBI applications put forward for any breast surgery under this policy on the grounds of clinical exceptionalty must evidence the patient.

- Is over 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

Please refer to point 3 of this policy for the EBI funding pathway.

2.3 **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

2.4 **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)
- 2.5 In line with current guidance, patients eligible to have their implant replaced must be informed of the potential risk of BIA-ALCL.
- 2.6 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 2.4, 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 but not for replacement.

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
- 2.7 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.
- 2.8 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.

3 **EVIDENCE BASED INTERVENTIONS APPLICATION PROCESS**

- 3.1 Patients who are not eligible for treatment under this policy may be considered on an individual basis where their GP or Consultant believes exceptional circumstances exist that warrant deviation from the rule of this policy
- 3.2 Completion of a **Generic EBI Application Form** by a patient's GP or Consultant is required
- 3.3 Applications cannot be considered from patients personally
- 3.4 Only electronically completed EBI applications will be accepted to the EBI Service
- 3.5 It is expected that clinicians will have ensured that the patient, on behalf of who they are forwarding the application for, is appropriately informed about the existing policies prior to an application to the EBI service. This will reassure the service that the patient has a reasonable expectation of the outcome of the application and its context

3.6 EBI applications are reviewed and considered against clinical exceptionality

For further information on 'clinical exceptionality' please refer to the NHS England information using the link below page 9-13;

<https://www.england.nhs.uk/wp-content/uploads/2017/11/comm-policy-individual-funding-requests.pdf>

Social, Emotional and Environmental factors *i.e.*, *income, housing, environmental pollution, access to services, family, friends, ethnicity, life experiences etc.* CANNOT be considered with an application

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

3.8 An application put forward for consideration must demonstrated some unusual or unique clinical factor about the patient that suggests they are exceptional as defined below:

- Significantly different to the general population of patients with the condition in question
- Likely to gain significantly more benefit from the intervention than might be expected from the average patient with the condition

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:

<http://www.bapras.org.uk/public-information/surgery-guides/breastenlargement>

5.4 British Association of Plastic Reconstructive and Aesthetic Surgeons. (2015). *What complications can occur?* Retrieved 04 26, 2016, from British Association of Plastic Reconstructive and Aesthetic Surgeons:

- <http://www.bapras.org.uk/public/patient-information/surgery-guides/breast-enlargement/what-complications-can-occur#Implant Failure>
- 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 <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 <https://ebi.aomrc.org.uk/interventions/breast-prosthesis-removal/>