

CLINICAL POLICY ADVISORY GROUP (CPAG)

Breast Prosthesis (Implant) Removal Policy

Statement

This policy applies to those aged 18 years and over.

Breast implant surgery is regarded as a procedure of low clinical priority and therefore is not routinely funded by the Commissioner.

NHS Derby and Derbyshire ICB (DDICB) has deemed that the removal of NHS or privately* funded breast implants should not be routinely commissioned unless the patient meets at least one of the following indications:

- Breast disease
- Implants complicated by recurrent infections or seroma
- Implants with severe capsular contracture (grade III/IV on the Baker classification)
- Implants with capsule formation that interferes with mammography
- Intra or extra capsular rupture of silicon gel-filled implants
- Breast Implant Associated Anaplastic Large Cell Lymphoma (BIA-ALCL)

*Privately Funded Breast Implants

Patients with privately funded breast implants should contact the clinic that fitted the implant(s) in the first instance. If the clinic is unable or unwilling to help then the patient will be considered for NHS funded implant removal.

For information on breast implant replacement, see the DDICB [Breast Prosthesis \(Implant\) Revision/Replacement Policy](#).

These commissioning intentions will be reviewed periodically. This is to ensure affordability against other services commissioned by the ICB.

1. Background

A Breast implant is a silicone rubber shell filled with either silicone gel or saline solution, which is used to enlarge the breast. Breast implants are fitted on the NHS, mostly for breast reconstruction following breast cancer. Breast implants do not last a lifetime and therefore will require replacement at some point in the patient's lifetime. The insertion of breast implants also carries a risk of number complications that may warrant the removal of the implants.

Capsular contracture is an example of such complications and involves the normal fibrous capsule that forms around the implant shrinking and squeezing the implant. This can alter the shape of the breast and make the breast hard and painful.

Implants can occasionally leak due to injury, a tight capsule or due to age. The leak is normally contained within the capsule but can cause a change in breast size, shape or consistency.

2. Recommendation

This policy applies to those aged 18 years and over.

NHSDDICB does not routinely commission the removal of NHS or privately* funded breast implants unless the patient meets at least one of the following indications:

- Breast disease
- Implants complicated by recurrent infections or seroma
- Implants with severe capsular contracture (grade III/IV on the Baker classification). This will need to be confirmed by a specialist opinion
- Implants with capsule formation that interferes with mammography
- Intra or extra capsular rupture of silicon gel-filled implants
- Breast Implant Associated Anaplastic Large Cell Lymphoma (BIA-ALCL)

As per NICE guidance NG180, discuss lifestyle modifications with people having surgery — for example stopping smoking and reducing alcohol consumption — in order to reduce the risk of post-operative complications.

Request for the removal of bilateral breast implants requires at least one of the breast implants to meet the above criteria. Only implant removal should be performed, and no other subsequent cosmetic procedure e.g. mastopexy.

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.

*Privately Funded Breast Implants

Patients with privately funded breast implants should contact the clinic that fitted the implant(s) in the first instance. If the clinic is unable or unwilling to help then the patient will be considered for NHS funded implant removal.

Only patients whose initial procedure was funded by the NHS should be considered for both implant removal and replacement. In line with current guidance, patients eligible to have their implant replaced must be informed of the potential risk of BIA-ALCA. For information on breast implant replacement, see the NHSDDICB [Breast Prosthesis \(Implant\) Revision/Replacement Policy](#).

Information to be Included with Referral

Smoking status and the details of condition, including history of implant insertion.

Exclusion Criteria

The following indications are excluded from this policy:

- Gender reassignment surgery
- Implants following surgery for breast cancer or breast cancer prevention performed under the NHS. In these cases, please refer to the Association of Breast Surgery (ABS) Guidance for the Commissioning of Oncoplastic Breast Surgery

3. Rationale for Recommendation

Breast implant surgery is regarded as a procedure of low clinical priority and therefore is not routinely funded by the Commissioner. 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.

4. Useful Resources

- Breast Implant Safety, British Association of Aesthetic Plastic Surgeons, 2022
https://baaps.org.uk/patients/safety_in_surgery/breast_implant_safety.aspx
- PIP Breast Implants, NHS, last reviewed 01/12/22, <https://www.nhs.uk/conditions/PIP-implants/>

5. References

- East Midlands Commissioning Policy for Cosmetic Procedures, version 2, 2014.
- NHS England Interim Clinical Commissioning Policy: Breast Implant Removal/Re-insertion (November 2013), last accessed 19/07/23,
<https://www.england.nhs.uk/commissioning/wp-content/uploads/sites/12/2013/11/N-SC004.pdf>
- PIP Breast Implants, NHS, last reviewed 01/12/22, last accessed 19/07/23,
<https://www.nhs.uk/conditions/PIP-implants/>
- British Association of Aesthetic Plastic Surgeons. Glossary, cited 2021 Dec 20, last accessed 19/07/23, <https://baaps.org.uk/patients/glossary>
- Breast prosthesis removal, Evidence based Interventions List 3 Guidance, Academy of Medical Royal Colleges, last accessed 19/07/23, [EBI_Guidance_List3_0523.pdf](https://aomrc.org.uk/EBI_Guidance_List3_0523.pdf)
(aomrc.org.uk)

6. Appendices

Appendix 1 - Consultation

All relevant providers/stakeholders will be consulted via a named link consultant/specialist. Views expressed should be representative of the provider/stakeholder organisation. CPAG will consider all views to inform a consensus decision, noting that sometimes individual views and opinions will differ.

Consultee	Date
Consultant Oncoplastic Breast Surgeon (CRHFT)	June 2023
Consultant Plastic and Reconstructive Surgeon (UHDBFT)	July 2023
Associate Specialist in Plastic Surgery (UHDBFT)	July 2023
Clinical Policy Advisory Group (CPAG)	August 2023

Appendix 2 - Document Update

Document Update	Date Updated
<p>Version 4.0</p> <p>Policy reviewed and updated to reflect the new EB13 recommendations. Updates include addition of:</p> <ul style="list-style-type: none">• Statement ' This policy applies to those aged 18 years and over'• Grading of capsular contracture along with the need for confirmation by specialist opinion• 'Seroma' criteria• Breast Implant Associated Anaplastic Large Cell Lymphoma (BIA-ALCL)• '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' under the 'Rationale for Recommendation' section of the policy• Statement ' 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'• Statement ' Only implant removal should be performed, and no other subsequent cosmetic procedure e.g. mastopexy'• Statement 'Only patients whose initial procedure was funded by the NHS should be considered for both implant removal and replacement. In line with current guidance, patients eligible to have their implant replaced must be informed of the potential risk of BIA-ALCL'• Statement ' As per NICE guidance NG180, discuss lifestyle modifications with people having surgery — for example stopping smoking and reducing alcohol consumption — in order to reduce the risk of post-operative complications'	August 2023

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| <ul style="list-style-type: none">• Addition of 'Exclusion Criteria' section | |
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Minor amendments to the policy include the addition of reference to EB13 guidance and policy rewording to reflect the new DDICB organisation.

Appendix 3 - OPCS Codes

- B303 (removal of prosthesis for breast)
- B374 (capsulectomy of breast)