*Extract from -* [*EBI\_Guidance\_List3\_0523.pdf (aomrc.org.uk)*](https://ebi.aomrc.org.uk/wp-content/uploads/2023/03/EBI_Guidance_List3_0523.pdf)

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**Breast prosthesis removal**

Surgery to remove breast implants is only carried out by the NHS in specific situations when criteria are met. All patients should be aware when having implant surgery that due to capsular contracture and less frequently rupture they will need to be replaced at some point.

**Clinical overview**

Breast implants may be inserted during reconstructive surgery for treatment or prevention of breast cancer or for cosmetic purposes. Surgery to remove a breast implant may be used to treat the complications of breast implants inserted for reconstructive or cosmetic purposes.

**Guidance**

This guidance applies to those 18 years and over. This proposal does not cover the following: — Gender reassignment surgery — Implants inserted 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.

Surgery to remove breast implants should only be considered for the following clinical indications:

— After implant leakage or rupture

OR

— There is severe capsular contracture (grade III/IV on the Baker classification). This will need to be confirmed by a specialist opinion.

OR

* Implants are complicated by recurrent implant infection or seroma

OR

— The patient develops Breast Implant Associated Anaplastic Large Cell Lymphoma (BIA-ALCL).

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.

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 above clinical indications, and the private provider is unable to offer the patient surgery, the patient can be offered an NHS referral for breast implant removal but not for replacement.

Where a patient is eligible for implant removal due to a problem associated with a single implant, bilateral implant removal should be offered.

Only implant removal should be performed, and no other subsequent cosmetic procedure e.g. mastopexy.

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.

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.

As per guidance NG180 from the National Institute for Health and Care Excellence (NICE), 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. See NICE guidance NG180 on Perioperative care in adults for more information.

Please note that this guidance is intended as a standard threshold for access. However, if you/ your patient falls outside of these criteria, the option to apply for an Individual Funding Request is still available to you

**Rationale for recommendation**

Patients should be informed at the time of initial surgery that implants are likely to need replacement and further surgery may be required.

In the case of implant rupture, severe capsular contracture, recurrent infection, breast disease and BIA-ALCL the benefit of removing an implant outweighs the risk of keeping the implant in place.

It is accepted that the NHS has a duty of care to patients who require their implant to be removed for a listed clinical indication, but only if their private provider is unable to offer this care. As the NHS does not routinely commission breast implants for cosmetic reasons, removal but not replacement is considered appropriate in these cases.

Concerns have been expressed about the potential side effects of breast implants including the development of BIA-ALCL and BII or Autoimmune Syndrome Induced by Adjuvants (ASIA). The BIA-ALCL is uncommon and in the UK is currently estimated to be 1 per 15,000 implants sold. The most recent guidance from the Medicines and Healthcare products Regulatory Agency (MHRA) states that based on the current available evidence people with breast implants do not need to have them removed in the absence of symptoms of ALCL. The MHRA states this position is consistent with international regulators and they will continue to collect data on ALCL in patients with breast implants and review the guidance in light of any new evidence.

BII/ASIA is used by some to describe a constellation of symptoms felt to be associated with their breast implants. However, BII/ASIA is not a World Health Organization recognised disease. The MHRA states there is no single disease which could explain the reported symptoms and it is currently unknown whether there is a link between breast implants and the reported health problems.

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