Breast Implant Revision Surgery
The CCG policy has been reviewed and developed by the Treatment Policies Clinical Development Group in line with the groups guiding principles which are:

1. CCG Commissioners require clear evidence of clinical effectiveness before NHS resources are invested in the treatment;
2. CCG Commissioner require clear evidence of cost effectiveness before NHS resources are invested in the treatment;
3. The cost of the treatment for this patient and others within any anticipated cohort is a relevant factor;
4. CCG Commissioners will consider the extent to which the individual or patient group will gain a benefit from the treatment;
5. CCG Commissioners will balance the needs of each individual against the benefit which could be gained by alternative investment possibilities to meet the needs of the community
6. CCG Commissioners will consider all relevant national standards and take into account all proper and authoritative guidance;
7. Where a treatment is approved CCG Commissioners will respect patient choice as to where a treatment is delivered; AND
8. All policy decision is considered within the wider constraints of the CCG’s legally responsibility to remain fiscally responsible.
Breast Implant Revision Surgery

Breast implant revision surgery is defined as “Any consequence of an implant that would require an operative approach to managing it (e.g. removal)".

This can be subdivided into breast implant removal (Policy A) and breast implant removal and replacement (Policy B).

The population who may require breast revision surgery includes:
- Women with existing breast implants funded through the NHS
- Women who have had NHS funded breast augmentation as part of gender reassignment surgery.
- Women who have existing breast implants (Privately funded).

Indications for breast implant revision surgery

- Capsular contracture
  Capsular contracture is an unavoidable complication of breast implant surgery. After having a breast implant, the body will create a capsule of fibrous scar tissue around the implant as part of the healing process. This is a natural reaction that occurs when any foreign object is surgically implanted into the body. Over time the scar tissue will begin to shrink. The shrinkage is known as capsular contraction. The rate and extent at which the shrinkage occurs varies from person to person. In some people, the capsule can tighten and squeeze the implant, making the breast feel hard and patients may also experience pain and discomfort.
  Individual studies have published incidence rates of capsular contracture ranging from 2.8% to 20.4%. A 2013 systematic review published a combined overall rate of 3.6% following augmentation surgery. A literature review in 2016 indicated an incidence of between 8% and 15%.
- Rupture
  A rupture is a split that occurs in the implant’s casing. A rapid review of breast prosthesis implantation for reconstructive and cosmetic surgery reported Kaplan-Meier estimates of rupture at six years with a range of 1.5 to 9.3 per cent.
- Wrinkling and rippling
  Wrinkling and rippling during follow-up was estimated to occur in approximately 10% of cases over 10 years for silicone implants and 24.6% over 5 years for saline implants.
- Implant rotation
  Very occasionally teardrop-shaped implants can rotate behind the breast. The patient will notice a marked shape change, usually evident on waking in the morning. The implant will usually rotate back to its correct position by itself or can be gently pushed back in to position.
- Nerve problems in nipples
  A systematic review of nerve injuries in aesthetic breast surgery found the risk of any nerve injury after breast augmentation ranged from 13.57% to 15.44%.x for Mastectomy patients, nipples may not be preserved due to the original surgery.
- Problems with lactation
  Surgery to the breasts may impact on or prevent the ability of patients to breast feed.
- Scarring
After breast surgery, all patients will have some degree of scarring. In most cases, the scarring is relatively mild. However, in approximately 1 in 20 women, the scarring is more severe. For these women, their scars may be red or highly coloured, lumpy, thick and/or painful.

- **Seroma**
  Seroma refers to a build-up of fluid around the breast which normally resolves without aspiration.

- **Anaplastic Large Cell Lymphoma (ALCL)**
  ALCL is a rare type of non-Hodgkin's lymphoma and most cases occur in the capsule surrounding the implant and it is thought to be potentially associated with prolonged inflammatory states, similar to the theoretical pathogenesis of capsular contracture. A 2014 review found the absolute risk of ALCL remains low, ranging from 1: 500,000 to 1: 3,000,000.

**PIP implant removal**

The NHS offer detailed by the government regarding PIP implants is as follows:

- All women who have received an implant from the NHS will be contacted to inform them that they have a PIP implant and to provide relevant information and advice. If in the meantime NHS patients seek information about the make of their implant, then this will be provided free of charge.
- Women who wish to will able to seek a consultation with their GP, or with the surgical team who carried out the original implant, to seek clinical advice on the best way forward.
- If the woman chooses, this could include an examination by imaging to see if there is any evidence that the implant has ruptured.

The NHS will support removal of PIP implants if, informed by an assessment of clinical need, risk or the impact of unresolved concerns, a woman with her doctor decides that it is right to do so. The NHS will replace the implants if the original operation was done by the NHS

**Policy A – Breast Implant Revision Surgery – Implant Removal**

**Eligibility Criteria:**

| Removal of breast implants are commissioned where there is a clinical indication for removal (Rupture or Capsular contracture which is defined as grades III and IV capsular contracture), whether the implant was initially inserted by the NHS or privately funded. |

This means **(for patients who DO NOT meet the above criteria)** the CCG will **only** fund the treatment if an Individual Funding Request (IFR) application proves exceptional clinical need and that is supported by the CCG.

Eligibility criteria

Removal AND replacement of breast implants are commissioned where there is:

1. Clinical indication for removal (Rupture or Capsular contracture which is defined as grades III and IV capsular contracture), AND

2. The implant was initially inserted by the NHS under the previously or currently commissioned CCG / NHSE commissioned criteria which is outlined as follows:
   - Previous mastectomy or other excisional breast surgery undertaken due to a cancer diagnosis.
   - Trauma to the breast during or after development
   - Congenital amastia (total failure of breast development)
   - Endocrine abnormalities
   - Developmental asymmetry and severe hypoplasia.
   - Gender Reassignment Surgery

N.B. Lipofilling is a procedure not covered under this policy. Lipofilling will be reviewed under a future workflow by the CCG.
Guidance:

NHS Choices. (2016) Breast enlargement (implants)
https://www.nhs.uk/conditions/cosmetic-treatments/breast-enlargement/

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