Clinical Policy Bulletin:
Breast Implant Removal

Number: 0142

Policy

Aetna considers the removal of breast implants medically necessary for members who meet the following selection criteria.

For members who have undergone either cosmetic augmentation mammoplasty or breast reconstruction following a medically necessary mastectomy (e.g., mastectomy for breast cancer or a prophylactic mastectomy (see CPB 0227 - BRCA Testing, Prophylactic Mastectomy, and Prophylactic Oophorectomy)), removal of a breast implant and capsulectomy or capsulotomy is considered medically necessary for any of the following indications:

1. Extrusion of implant through skin, or
2. Implants complicated by recurrent infections, or
3. Implants with Baker Class IV contracture associated with severe pain, or
4. Implants with severe contracture that interferes with mammography, or
5. Intra- or extra-capsular rupture of silicone gel-filled implants, or
6. Breast cancer in the implanted breast or remnant, or in the contralateral breast, where implant removal is necessary to excise the breast cancer.

For members whose breast reconstruction followed a medically necessary mastectomy (i.e., mastectomy for breast cancer or a prophylactic mastectomy), removal of a breast implant and capsulectomy or capsulotomy is also considered medically necessary for these additional indications:

1. Baker Class III contracture, or
2. Extra-capsular rupture of saline implant if the rupture compromises the cosmetic outcome of the implant.

Removal of ruptured saline-filled breast implants is not considered medically necessary for members who have previously undergone cosmetic breast augmentation mammoplasty.
If any of the above criteria for removal of a breast implant is met unilaterally, Aetna also considers medically necessary removal of the implant and capsulectomy or capsulotomy in the other breast if both implants are removed at the same time.

Requests for the removal of breast implants for any of the following indications is subject to medical review:

1. Baker Class III contracture that does not follow a medically necessary mastectomy; or
2. Implant removal for biopsy of breast mass that has not been proven to be cancerous; or
3. Implant removal for a mastectomy or lumpectomy that can be performed with the implant in place.

Silicone Implant Removal for Autoimmune Disease:

Aetna does not consider either of the following medically necessary:

1. IgG testing in connection with silicone implants (the development of IgG antibodies is neither specific to silicone implants nor indicative of autoimmune disorders); or
2. Removal of silicone implants for autoimmune disease unless the member meets at least one of the selection criteria listed above (e.g., rupture of silicone-gel filled implant, etc.).

Reinsertion of Breast Implants:

Although Aetna considers the removal of breast implants medically necessary for medical indications even if the implants were originally inserted for cosmetic purposes, Aetna considers the re-insertion of new breast implants cosmetic in this situation. Aetna considers medically necessary the insertion of initial breast implants and the replacement of breast implants inserted following a medically necessary mastectomy (i.e., mastectomy for breast cancer or a prophylactic mastectomy) or for women with Poland's syndrome meeting the criteria in CPB 0272 - Pectus Excavatum and Poland's Syndrome: Surgical Correction.

Baker Classification:

| Class I | Augmented breast feels soft as a normal breast. |
| Class II | Augmented breast is less soft and implant can be palpated, but is not visible. |
| Class III | Augmented breast is firm, implant is palpable and the implant (or distortion) is visible. |
| Class IV | Augmented breast is hard, painful, cold, tender, and distorted. |
See also CPB 0185 - Breast Reconstructive Surgery.

**Background**

At the time of the Food and Drug Administration (FDA) hearing on silicone breast implants in February of 1992, the FDA advised that ruptured silicone implants should be removed since the health risks of extruded silicone are not known. At the same time, the FDA panel acknowledged that asymptomatic rupture may be present in up to 4% of women with silicone implants, but the FDA specifically did not recommend screening for asymptomatic ruptures.

Rupture of silicone implants can be subdivided into 2 categories: (i) intra-capsular and (ii) extra-capsular. After implantation, a reactive fibrous capsule is formed around the implant. If the extruded silicone is contained by this fibrous capsule the rupture is termed intra-capsular. If the silicone gel is extruded beyond the capsule, the rupture is termed extra-capsular. Extra-capsular silicone can induce granulomatous reaction and can occasionally migrate to the axillary lymph nodes, producing a lymphadenopathy, which can mimic cancer. Clinically, extra-capsular ruptures are often associated with a change in size and consistency of the breast. Extra-capsular ruptures can usually be identified on mammography or other imaging studies. Explantation of these implants is clearly indicated.

The health consequences of intra-capsular ruptures are uncertain since theoretically the silicone is contained within the fibrous capsule. Furthermore it is known that intact implants routinely “bleed” microscopic silicone particles, which are also contained within the fibrous capsule. Nevertheless, an intra-capsular rupture can evolve to an extra-capsular rupture and the FDA has indicated that ruptured implants, whether intra-capsular or extra-capsular, should be explanted as well.

**CPT Codes / HCPCS Codes / ICD-9 Codes**

**CPT codes covered if selection criteria are met:**

- 19328  Removal of intact mammary implant
- 19330  Removal of mammary implant material
- 19370  Open periprosthetic capsulotomy, breast
- 19371  Periprosthetic capsulectomy, breast

**Other CPT codes related to the CPB:**

- 19120 - 19126  Breast, excision of cyst, fibroadenoma, or other benign or malignant tumor, aberrant breast tissue, duct lesion, nipple or areolar lesion (except 19300), open, male or female, one or more lesions
19316 - Breast, repair and/or reconstruction procedures
19380

Other HCPCS codes related to the CPB:
L8020 - Breast prostheses
L8039
L8600 - Implantable breast prosthesis, silicone or equal

ICD-9 codes covered if selection criteria are met:
174.0 - 175.9 Malignant neoplasm of breast
611.71 Mastodynia
996.54 Mechanical complication due to breast prosthesis
996.69 Infection and inflammatory reaction due to other internal prosthetic device, implant, or graft

Other ICD-9 codes related to the CPB:
279.4 Autoimmune disease, not elsewhere classified
238.3 Neoplasm of uncertain behavior of breast
611.72 Lump or mass in breast
V10.3 Personal history of malignant neoplasm of breast
V16.3 Family history of malignant neoplasm of breast
V45.71 Acquired absence of breast

The above policy is based on the following references: