

## Medical Coverage Policy | Breast Implant Removal



**EFFECTIVE DATE:** 08|17|1998

**POLICY LAST UPDATED:** 06|12|2013

### OVERVIEW

Breast implants complications are common and may require removal of the implant. Determining the medical necessity and coverage of removal requires documentation of the type of implant and whether it was used for reconstructive, restorative or cosmetic indications.

### PRIOR AUTHORIZATION

Prior authorization is required for BlueCHiP for Medicare and recommended for all other products for the removal of breast implant(s). Removal and reinsertion is considered medically necessary for patients who meet the above medical criteria.

### POLICY STATEMENT

Prior authorization is required for BlueCHiP for Medicare and recommended for all other products for the removal of breast implant(s). Removal and reinsertion is considered medically necessary for patients who meet the above medical criteria.

Reconstructive breast surgery after removal and reinsertion of an implant is considered medically necessary only in those patients who originally had breast implantation for reconstructive purposes. For all other indications, insertion of a new implant or other surgery to restore appearance is considered cosmetic and a contract exclusion.

### MEDICAL CRITERIA

Removal of a silicone gel-filled breast implant may be considered medically necessary for any of the following indications:

- A documented implant rupture, or
- in cases of infection; or
- extrusion; or
- Baker class III, Note this is only for patients who originally had breast implantation for reconstructive purposes; or
- Baker class IV contracture; or
- surgical treatment of breast cancer in the affected breast; or
- as part of covered reconstructive surgery for the opposite breast

Removal of a saline-filled breast implant may be considered medically necessary for any of the following indications:

- a documented implant rupture only in those patients who originally had breast implantation for reconstructive purposes; or
- in cases of infection; or
- extrusion; or
- Baker class IV contracture; or
- surgical treatment of breast cancer in the affected breast; or
- as part of covered reconstructive surgery on the opposite breast.

## BACKGROUND

Complications of breast implants are common and may require removal of the implant. Determining the medical necessity and coverage of removal requires documentation of the type of implant and whether it was used for reconstructive, restorative or cosmetic indications.

### **Reconstructive breast surgery:**

Reconstructive breast surgery is defined as a surgical procedure designed to restore the normal appearance of the breast after surgery, accidental loss, or trauma. The most common indication for reconstructive breast surgery is a prior mastectomy

Although breast reconstruction following a mastectomy does not meet the functional impairment requirement of a reconstructive procedure, The Women's Health and Cancer Rights Act (WHCRA) of 1998, mandates coverage of reconstructive surgery following mastectomy for all health plans providing medical and surgical benefits.

### **Cosmetic procedures:**

Cosmetic procedures are performed primarily to refine or reshape body structures that are not functionally impaired, to improve appearance or self-esteem, or for other psychological, psychiatric, or emotional reasons. Reduction mammoplasty is a common example of cosmetic breast surgery, but surgery to alter the appearance of a congenital abnormality of the breasts, such as tubular breasts, would also be considered cosmetic in nature.

Complications may be subdivided into local or systemic complications. Local complications include implant contracture, rupture, extrusion (implant is visible through the surgical wound or skin), or infection. Extrusion or infection are considered medical indications for removal in all cases, whether the implant was originally cosmetic or not. Documented rupture of a silicone gel-filled implant is considered an absolute indication for removal in all cases. Rupture of a saline implant poses no health threat, therefore, removal would not be considered medically necessary in patients with cosmetic implants. However, a ruptured saline implant compromises the esthetic outcome and removal may be considered appropriate in cases of reconstructive implants.

Rupture of the breast implant may be difficult to document, but physical exam, mammography, ultrasonography, or magnetic resonance imaging may be used. Although it has been suggested that older implants are associated with a higher incidence of rupture, there is no consensus that screening implants for rupture is warranted. Instead, work-up for a potential rupture is typically initiated at the onset of local symptoms, such as sudden change in the size or consistency of an implant, or the development of local pain.

The most common type of reconstructive breast surgery is insertion of a silicone gel-filled or saline-filled breast implant, either inserted immediately at the time of mastectomy or sometime afterward in conjunction with the previous use of a tissue expander. Local complications of breast implants are frequent and may require removal of the implant. Capsular contracture happens when the scar tissue or capsule that normally forms around the implant tightens and squeezes the implant. It can happen to one or both of the implanted breasts. Contracture is graded according to the Baker classification as follows:

- Grade I: Augmented breast feels as soft as a normal breast
- Grade II: Breast is less soft and the implant can be palpated but is not visible
- Grade III: Breast is firm, palpable, and the implant (or its distortion) is visible
- Grade IV: Breast is hard, painful, cold, tender, and distorted

Grade IV contractures interfere with adequate mammography screening and thus their presence constitutes a health risk. Therefore, removal may be considered medically necessary in all cases, regardless of whether the implant was originally inserted for cosmetic or reconstructive purposes. Grade III contractures, which describe firm, palpable implants, do not interfere with mammography; therefore, removal of these implants is not considered an indication for removal. Additionally, Grade III contractures have no significant probability of being the cause of pain, and therefore symptoms would not warrant removal. However, since grade III contractures have an impact on the normal appearance of the breast, removal may be appropriate in implants inserted for reconstructive purposes, since the goal of restoration of the normal appearance of the breast was not achieved.

## COVERAGE

Benefits may vary between groups and contracts. Please refer to the appropriate Evidence of Coverage, Subscriber Agreement for the applicable surgery services Not Medically Necessary benefits/coverage.

## CODING

The following codes require preauthorization:

**19328**

**19330**

This code is not covered unless it is being reinserted as the result of a previous mastectomy. Please see the Breast Reconstruction policy for additional information

**L8600**

## RELATED POLICIES

Breast Reconstruction And Applicable Mandates

## PUBLISHED

Provider Update Oct 2013

Provider Update May 2012

Provider Update May 2011

Provider Update Jun 2010

Provider Update Jul 2009

Provider Update May 2008

Policy Update Jun 2007

Policy Update Jul 2006

Policy Update July 2005

## REFERENCES

Blue Cross and Blue Shield Association National policy 7.01.22 Reconstructive Breast Surgery/ Management of Breast Implants. Last review: July 2003.

US Food and Drug Administration. FDA Breast Implant Consumer Handbook – 2004. Accessed 02/24/05:<http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/ImplantsandProsthetics/BreastImplants/default.htm>.

Gabriel SE, Woods JE, O'Fallon WM, et al. Complications leading to surgery after breast implantation. *NEJM*. 1997; 336:677-682.

Janowsky EC, Kupper LL, Hulka BS. Meta-analyses of the relation between silicone breast implants and the risk of connective-tissue diseases. *New England Journal of Medicine*;2000;342:781-90.

Mathes SJ. Breast implantation: The quest for safety and quality. *New England Journal of Medicine*;1997;336(10):718-719.1.

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