



Kansas City

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## Reconstructive Breast Surgery and Management of Breast Implants

**Policy Number:** 7.01.22

**Origination:** 3/1993

**Last Review:** 1/2014

**Next Review:** 1/2015

### **Policy**

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Blue Cross and Blue Shield of Kansas City (Blue KC) will provide coverage for reconstructive breast surgery and management of breast implants when it is determined to be medically necessary because the criteria shown below are met.

*Member contracts specifically exclude coverage for cosmetic procedures. Benefit language should be reviewed for revision or treatment of complications when the original surgery was performed for cosmetic purposes.*

### **When Policy Topic is covered**

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Reconstructive mammoplasty may be considered **medically necessary** for the correction of documented Poland Syndrome (see definition in Considerations section below) for patients meeting **ALL** of the following criteria:

- Chest muscle deformities - absence of the pectoralis minor and the breastbone part of the pectoralis major, **and**
- Underdevelopment\* or absence of breast or nipple on the affected side

Reconstructive breast surgery may be considered **medically necessary** after a medically necessary mastectomy, accidental injury, or trauma. Medically necessary mastectomies are most typically done as treatment for cancer. Reconstruction may be performed by an implant-based approach or through the use of autologous tissue. Reconstructive breast surgery may consist of any of the following procedures:

- Immediate or delayed insertion of breast prosthesis with or without associated tissue expansion;
- Autologous reconstruction using autologous tissue, e.g., latissimus dorsi flap, transverse rectus abdominis myocutaneous flap or free flap;
- Revision of reconstructed breast;
- Nipple/areola reconstruction and nipple tattooing when the breast reconstruction is considered eligible for coverage;
- Mastopexy or reduction mammoplasty on the contralateral breast to achieve symmetry.

Explantation of a breast implant associated with a Baker class III contracture may be considered **medically necessary** only in those patients who had originally undergone breast implantation for reconstructive purposes.

Reconstructive breast surgery after explantation of an implant is considered **medically necessary** only in those patients who had originally undergone breast implantation for reconstructive purposes.

Explantation of a *silicone* gel-filled breast implant may be considered **medically necessary** in all cases for a documented implant rupture, infection, extrusion, Baker class IV contracture, or surgical treatment of breast cancer.

Explantation of a ruptured *saline*-filled breast implant may be considered **medically necessary** only in those patients who had originally undergone breast implantation for reconstructive purposes. Otherwise, indications for the explantation of a saline-filled implant are similar to those of a silicone-filled implant.

**When Policy Topic is not covered**

\* Surgery to correct breasts that are unequal in shape or size; or failure of one breast to develop is considered **cosmetic**.

After reconstructive breast surgery on one side, insertion of an implant on the contralateral, normal side is rarely necessary to achieve symmetry.

The following indications for explantation of implants are considered **not medically necessary**:

- Systemic symptoms, attributed to connective tissue diseases, autoimmune diseases, etc.;
- Patient anxiety;
- Baker class III contractures in patients with implants for cosmetic purposes;
- Rupture of a saline implant in patients with implants for cosmetic purposes;
- Pain not related to contractures or rupture.

**Considerations**

**Poland syndrome** consists of a deficiency of subcutaneous fat and muscles on one side of the body. It may include underdevelopment of the arm, hand, and fingers on the same side, and may be associated with other conditions such as Moebius syndrome or Klippel-Feil syndrome. The right side of the body is affected twice as often as the left. Poland syndrome does seem to affect males more commonly than females. In addition to those listed in the criteria section, symptoms on the affected side may include:

- Underdeveloped or missing ribs
- Underdeveloped arm, hand, and fingers
- Abnormally short, webbed fingers
- Small, elevated scapula (shoulder bone), called Sprengel deformity
- Patchy absence of hair under the arm on the affected side

Rupture of implants requires documentation with an imaging study, such as mammography, magnetic resonance imaging, or ultrasonography. Lack of imaging confirmation of rupture in association with persistent local symptoms requires case by case consideration.

Pain as an isolated symptom is an inadequate indication for explantation. The pain should be related to the Baker classification or a diagnosis of rupture.

Application of the above policy regarding explantation of implants requires documentation of the original indication for implantation and the type of implant, either saline- or silicone gel-filled, and the current symptoms, either local or systemic. The following chart should facilitate determination of the medical necessity of explantation. Yes indicates that the explantation would be considered medically necessary, given the symptoms, type of implant, and original indication for implantation.

**Indication/Type of Implant**

Indication for Explantation	Reconstruction/ silicone	Reconstruction/ saline	Cosmetic/ silicone	Cosmetic/ saline
<b>Systemic Illness</b>				
Connective tissue disease	No	No	No	No
Autoimmune disease	No	No	No	No
Rheumatic conditions	No	No	No	No
Neurologic symptoms	No	No	No	No
Fibromyalgia	No	No	No	No

Chronic fatigue syndrome	No	No	No	No
Patient Anxiety	No	No	No	No
<b>Absolute Medical Indications</b>				
Rupture*	Yes	Yes	Yes	No
Baker class IV contracture	Yes	Yes	Yes	Yes
Recurrent infection	Yes	Yes	Yes	Yes
Extruded implant	Yes	Yes	Yes	Yes
Surgery for breast cancer	Yes	Yes	Yes	Yes
<b>Other Indications</b>				
Baker class III contractures	Yes	Yes	No	No
Pain**	No	No	No	No
<b>Post-Explantation Procedures</b>				
reimplantation of implants	Yes	Yes	No	No
autologous reconstruction	Yes	Yes	No	No

\*Rupture of implants requires documentation with an imaging study, such as mammography, magnetic resonance imaging, or ultrasonography. Lack of imaging confirmation of rupture in association with persistent local symptoms requires case by case consideration.

\*\* Pain as an isolated symptom is an inadequate indication for explantation. The pain should be related to the Baker classification or a diagnosis of rupture.

### **Description of Procedure or Service**

Reconstructive breast surgery is defined as a surgical procedure that is designed to restore the normal appearance of the breast after surgery, accidental injury, or trauma. Breast reconstruction is distinguished from purely cosmetic procedures by the presence of a medical condition, e.g., breast cancer or trauma, which leads to the need for breast reconstruction.

The most common indication for reconstructive breast surgery is a prior mastectomy; in fact, benefits for reconstructive breast surgery in these patients are a mandated benefit in many states. In contrast, cosmetic breast surgery is defined as surgery designed to alter or enhance the appearance of a breast that has not undergone surgery, accidental injury, or trauma. 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.

There is a broadening array of surgical approaches to breast reconstruction. The most common is insertion of a breast implant, either a silicone gel-filled or saline-filled prosthesis. The implant is either inserted immediately at the time of mastectomy (CPT code 19340) or sometime afterward in conjunction with the previous use of a tissue expander (19342, 19357).

The breast may also be reconstructed using autologous tissues, such as a free flap (19364), a latissimus dorsi flap (19361), or more commonly using a transverse rectus abdominis flap (TRAM procedure, 19367, 19369). Nipple areola reconstruction (19350) or nipple tattooing (11920) may also be considered reconstructive breast surgery. Since the purpose of reconstructive breast surgery is to restore the normal appearance of the breast, on some occasions procedures are performed on the contralateral, normal breast to achieve symmetry, such as mastopexy (19316) and reduction mammoplasty (19318). These procedures fall into the category of reconstructive breast surgery only when performed in conjunction with a contralateral mastectomy for cancer with associated

reconstruction. Except for medically necessary reduction mammoplasty, these procedures are considered cosmetic in other circumstances.

The following policy describes different types of reconstructive breast surgery and reviews the evidence on efficacy for the different approaches. It also establishes criteria for the explantation of breast implants based on whether the original implant was cosmetic or reconstructive in nature, and whether the implant is silicone gel-filled or saline-filled.

## **Rationale**

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This policy was created in 1995 and updated periodically since. The latest update with literature review covers the period of July 2003 through October 2011.

### **Breast Reconstruction Surgery**

The evidence on breast reconstruction surgery consists primarily of case series, the majority of which are retrospective. A smaller number of prospective cohort studies have also been published. There is a lack of clinical trials, including a very limited number of randomized controlled trials. The main outcomes that are important in breast reconstruction research are the cosmetic result, measures of psychosocial functioning, and rates of procedure-related morbidity.

Numerous case series have demonstrated improvements in psychosocial functioning for women undergoing breast reconstruction following mammography. For example, the Michigan Breast Reconstruction Outcomes Study (1), there were improvements in all subscales of the SF-36 health status questionnaire, and on the FACT-B scale, a breast-cancer specific health status instrument. These improvements were maintained for up to two years following surgery.

There is uncertainty in several areas of breast reconstruction. For women with breast cancer who are to receive radiotherapy post-mastectomy, the optimal timing and the preferred approach to breast reconstruction is controversial. Another important clinical question is the comparative effectiveness of different surgical approaches to reconstruction. The evidence for these two questions is reviewed below:

#### *What is the optimal timing and approach to breast reconstruction in patients receiving radiotherapy post-mastectomy?*

The potential advantages of immediate reconstruction are an improved cosmetic result, and avoiding the need to operate later on irradiated tissue. On the other hand, complications of reconstruction are higher if immediate reconstruction is followed by radiotherapy. Radiotherapy post-reconstruction has been shown to be an independent predictor of contractures, fat necrosis, and poor cosmetic outcomes. (2) Delayed reconstruction avoids the problem of radiation complications in the reconstructed breast. The disadvantages of this approach are the psychologic distress associated with waiting for reconstruction following mastectomy, and the difficulty of operating on previously irradiated tissue. (3, 4)

A Cochrane systematic review of immediate versus delayed breast reconstruction following mastectomy was published in 2011. (3) This review was confined to randomized controlled trials (RCTs) of immediate versus delayed surgery. Only one RCT from 1983 was identified, the results of which are probably not relevant to current clinical practice. As a result no conclusions could be drawn on immediate versus delayed reconstruction.

Winters et al. (5) published a systematic review that focused on the health-related quality of life outcomes following breast reconstruction surgery. These authors included articles that compared the outcomes of different types of reconstruction, or that compared immediate versus delayed reconstruction. They identified two RCTs, 11 prospective longitudinal studies, and 21 retrospective studies. The majority of the studies used general QOL instruments, such as the SF-36, rather than breast-specific QOL measures. The authors reported that the overall quality of the evidence was low. Most of the studies did not follow recommended methods for health-related quality of life research, and

there was a high degree of variability in the reported outcomes. Combined analysis was not performed due to variations in study methodology and outcomes. Conclusions from this systematic review were that limitations of methodology precluded any meaningful conclusions on whether immediate or delayed reconstruction is the preferred approach.

The Michigan Breast Reconstruction Outcomes Study (1) was a prospective longitudinal study from 12 centers, which followed patients who had undergone breast reconstruction following mastectomy for up to two years. The main outcomes that were evaluated were psychosocial measures, including the SF-36 and the Functional Assessment of Cancer Therapy – Breast (FACT-B). A total of 287 women completed baseline surveys, and 173 completed the two-year follow-up for a response rate of 60.3%. The authors classified patients into the categories of immediate (n=116) versus delayed (n=57) reconstruction, and by the type of reconstructive surgery performed: pedicle TRAM (n=91), free TRAM (n=40) or expander/implant (n=42).

There was an improvement in QOL for all groups following reconstruction. At two years, the magnitude of improvement was greater for the immediate reconstruction group. Statistically significant improvements compared to baseline were noted for the SF-36 subscales of vitality, general mental health, role emotional, and social functioning; and for the FACT-B social well-being scale. In the delayed reconstruction group, there was a significant improvement in the FACT-B social well being scale, but not for the subscales of the SF-36.

This study suggests that QOL outcomes may be better in immediate reconstruction versus delayed reconstruction. However, these conclusions are limited by the methodologic weaknesses of the study, which include a lack of formal comparisons between groups, a large number of dropouts at two years, and potential baseline differences in clinical characteristics of the groups that are compared.

#### *What is the comparative efficacy of different surgical techniques for breast reconstruction?*

There is a single RCT published comparing different techniques of breast reconstruction. (6) In this study, 87 women were randomized to one of three breast reconstruction techniques, and 75 women actually underwent one of the three procedures: Lateral thoracodorsal flap (n=16); Latissimus dorsi flap (n=30); or Transverse rectus abdominis muscle flap (TRAM) (n=29). At six months and one-year following surgery, patients were asked about their satisfaction with the cosmetic result and the impact of the surgery on important areas of their lives. In addition, patients completed the SF-36 health status survey. At six months there were 56 responses (75%) to the survey and at one-year there were 61 responses (81%). The majority of women reported a positive impact on major life areas and a positive change in overall health status. There were not significant differences among groups on any measure, except that the Latissimus dorsi group scored significantly lower on having problems with social situations compared to the other two groups. The results of this study support the conclusion that the benefit of breast reconstruction, in terms of cosmesis and quality of life, is roughly equivalent across different surgical techniques.

In the Barry et al. (4) systematic review, the authors evaluated whether implant-based approach or an autologous tissue approach led to better outcomes in patients receiving radiotherapy. Of all patients receiving radiotherapy (n=380), 216 underwent implant-based reconstruction and 164 underwent autologous reconstruction. There was no significant difference in overall morbidity between those receiving implant-based reconstruction and those receiving autologous reconstruction (odds ratio [OR] 0.87, 95% confidence interval [CI] 0.47-1.62). However, for the subset of women who underwent both radiotherapy and immediate breast reconstruction, overall morbidity was less common in women undergoing autologous reconstruction (OR 0.20, 95% CI 0.11-0.39).

The Michigan Breast Reconstruction Outcomes Study (1) compared outcomes among patients for most of the comparisons between types of surgeries, there were not significant differences noted. Patients who received delayed reconstruction with TRAM surgery had greater gains in body image compared with patients receiving implant-based reconstruction.

## Management of breast implants

Complications of breast implants are common and may require explantation. (7) Determining the medical necessity of explantation requires documentation of the type of implant and its original indication, i.e., whether reconstructive or cosmetic. The basic underlying principle is that cosmetic implants require explantation only for absolute medical indications that pose significant health consequences, while the criteria for explantation of reconstructive implants are broader. Since the purpose of reconstructive implants is the restoration of normal breast appearance, in a small subset of patients explantation may be warranted in cases of unsatisfactory aesthetic outcome.

Complications can be subdivided into local or systemic complications. Local complications include implant contracture, rupture, extrusion, or infection. Extrusion or infection are considered absolute medical indications for explantation 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 explantation in all cases. However, explantation of a ruptured saline implant is considered medically necessary only in the setting of prior reconstruction. Since normal saline is physiologic, rupture poses no health threat, and thus explantation would not be considered medically necessary in patients with cosmetic implants. However, a ruptured saline implant compromises the aesthetic outcome and thus explantation 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 has been used. There is no consensus on which method affords the best sensitivity and specificity. (8-10) 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. Specifically, in the hearings on breast implants by the U.S. Food and Drug Administration (FDA), held in 1992, the FDA did not recommend screening for asymptomatic ruptures. Instead, workup 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.

Local complications of breast implants are frequent and may require removal of the implant. Contracture is the most common local complication of breast implants. Contractures are somewhat subjective findings, and can be graded according to the Baker classification as follows: (11)

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 are the cause of local symptoms, and thus their presence constitutes a health risk. (12) Therefore, explantation 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, explantation of these implants is not considered an absolute indication for explantation. However, since Grade III contractures have an impact on the normal appearance of the breast, explantation may be appropriate in implants inserted for reconstructive purposes, since the goal of restoration of the normal appearance of the breast is not achieved.

Potential systemic complications of implants, most prominently various connective tissue diseases or chronic fatigue syndrome, has been controversial in the past. In particular, it had been hypothesized that leakage of silicone, due either to an implant rupture or to "bleeding" of silicone through an intact capsule, may incite an autoimmune response with the development of systemic symptoms. However, to date, large epidemiologic studies have not demonstrated that women with breast implants are overrepresented among all those with connective tissue disease. (13-16) In addition, there are inadequate empiric studies to demonstrate that removal of breast implants is associated with resolution of systemic symptoms. As a result of this evidence, there is not considered to be a relationship between silicone breast implants and systemic disease, particularly connective tissue disease.

Patients with cosmetic implants may develop breast cancer. While lumpectomy can be accomplished without removal of the implant, in general, explantation as an adjunct to surgical treatment for breast cancer would be considered medically necessary. However, explantation is not necessary in patients who are undergoing chemotherapy or radiation therapy for breast cancer.

Once an implant has been removed, patients who have originally undergone reconstructive implantation are candidates for additional reconstructive breast surgery, either insertion of another breast implant, or for autologous reconstruction of the breast, as described here. Patients who have originally undergone implantation of a cosmetic breast implant are not candidates for additional reconstructive breast surgery after explantation.

### **Clinical Input Received from Academic Medical Centers and Specialty Societies**

None

### **Summary**

Breast reconstruction is intended for patients undergoing mastectomy for breast cancer, or who have an injury or trauma to the breasts. For the general population of women undergoing mastectomy, the evidence supports the conclusion that breast reconstruction improves psychosocial outcomes, such as anxiety, social functioning, and perception of body image. Thus, breast reconstruction may be considered medically necessary when reconstruction is needed as a result of breast cancer, injury, or trauma.

Important clinical questions remain concerning the optimal timing of breast reconstruction in women undergoing radiotherapy, and concerning which of the surgical approaches leads to better outcomes. For women undergoing radiotherapy following mastectomy, the evidence is not sufficient to determine whether immediate or delayed surgery is preferred. The evidence is also not sufficient to determine the comparative efficacy of different procedures. There is some evidence that an autologous tissue approach leads to better cosmetic outcomes in patients receiving radiotherapy, but this is not from high-quality evidence and is not a consistent finding across studies.

Breast implants can be used as part of breast reconstruction, or for cosmetic reasons. Local complications of breast implants are common, and may lead to explantation. The medical necessity of implant explantation is dependent on the type of implant, the indication for removal, and the original indication for implantation (see Policy Guidelines).

### **Clinical Practice Guidelines and Consensus Statements**

The 2011 National Comprehensive Cancer Network (NCCN) guidelines (17) did not produce formal guidelines concerning breast reconstruction; however, they included a section in their breast cancer that was titled "Principles of Breast Reconstruction Following Surgery". The following summarizes the statements in this section:

- The breast can be reconstructed using breast implants, autologous tissue or a combination of the two.
- Breast reconstruction can be performed immediately following mastectomy or after a delay following mastectomy.
- Skin-sparing mastectomy is probably equivalent to standard mastectomy in terms of local and regional recurrence. Skin sparing mastectomy should be performed by an experienced breast surgery team.
- When post-mastectomy radiation is required:
  - Delayed reconstruction is generally preferred for autologous reconstruction
  - Immediate reconstruction is generally preferred for implant reconstruction
- Selection of type of reconstruction is dependent on cancer treatment, body habitus, smoking history, comorbidities, and patient preferences.
- An evaluation of the likely cosmetic outcome of lumpectomy should be performed prior to surgery.

- Women who are not satisfied with the cosmetic outcome following completion of breast cancer treatment should be offered a plastic surgery consultation.

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## **Billing Coding/Physician Documentation Information**

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| <b>11920</b> | Tattooing, intradermal introduction of insoluble opaque pigments to correct color defects of skin, including micropigmentation; 6.0 sq cm or less |
| <b>19316</b> | Mastopexy   |
| <b>19318</b> | Reduction mammoplasty   |

- 19324 Mammoplasty, augmentation; without prosthetic Implant
- 19325 Mammoplasty, augmentation; with prosthetic implant.
- 19328 Removal of intact mammary implant
- 19330 Removal of mammary implant material
- 19340 Immediate insertion of breast prosthesis following mastopexy, mastectomy or in reconstruction
- 19342 Delayed insertion prosthesis following mastopexy, mastectomy or in reconstruction.
- 19350 Nipple/areola reconstruction
- 19357 Breast reconstruction, immediate or delayed, with tissue expander, including subsequent expansion
- 19361 Breast reconstruction with latissimus dorsi flap, with or without prosthetic implant
- 19364 Breast reconstruction with free flap
- 19366 Breast reconstruction with other technique
- 19367 Breast reconstruction with transverse rectus abdominis myocutaneous flap (TRAM), single pedicle, including closure of donor site;
- 19368 Breast reconstruction with transverse rectus abdominis myocutaneous flap (TRAM), single pedicle, including closure of donor site; with microvascular anastomosis (supercharging)
- 19369 Breast reconstruction with transverse rectus abdominis myocutaneous flap (TRAM), double pedicle, including closure of donor site
- 19370 Open periprosthetic capsulotomy, breast
- 19371 Periprosthetic capsulectomy, breast
- 19380 Revision of reconstructed breast
- L8600 Implantable breast prosthesis, silicone or equal
- S2068 Breast reconstruction with deep inferior epigastric perforator (DIEP) flap or superficial inferior epigastric artery (SIEA) flap, including harvesting of the flap, microvascular transfer, closure of donor site and shaping the flap into a breast, unilateral

### **Additional Policy Key Words**

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N/A

### **Policy Implementation/Update Information**

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- 3/93 New policy. Added to surgery section, titled Breast Implants Criteria for Insertion or Removal
  - 4/1/00 No policy statement changes.
  - 1/1/01 Policy statement updated to include, "Reconstruction of the unaffected breast may also be allowed when necessary to create symmetry."
  - 1/1/02 Policy statement updated to include, "Concern over **possible future disease** occurring is considered not medically necessary in the absence of signs and symptoms."
  - 1/1/03 Policy statement updated to include indications for removal of implant: rupture, infection, extrusion, Baker Class III or IV contracture, surgical treatment of breast cancer
  - 1/1/04 Policy statement updated to include benefit language regarding exclusion of complications related breast implants.
  - 1/1/05 Title changed to: Reconstructive Breast Surgery and Management of Breast Implants. Policy statement re-written with discussion of reconstructive breast surgery, revised indications for removal of breast implants
  - 1/1/06 No policy statement changes.
  - 1/1/07 No policy statement changes.
  - 1/1/08 No policy statement changes.
  - 1/1/09 No policy statement changes.
  - 1/1/10 No policy statement changes.
  - 1/1/11 No policy statement changes.
  - 1/1/12 Policy statement revised to indicate both implant-based and autologous approaches to breast reconstruction are medically necessary.
  - 1/1/13 No policy statement changes.
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