



BlueShield
of Northeastern New York

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Protocol

Reconstructive Breast Surgery/Management of Breast Implants (Formerly Breast Implants Removal) (70122)

Effective January 1, 2006

Contracts Affected:
All Community Blue HMO
Senior Blue/Medicare PPO
Traditional Blue

*The following protocol contains medical necessity criteria for Reconstructive Breast Surgery/Management of Breast Implants services rendered on or after January 1, 2006 for BlueShield of Northeastern New York (BlueShield) contracts. If these criteria are not met, reimbursement will be denied and the patient cannot be billed. **Prior approval is required.** Please note that payment for covered services is subject to the limitations noted in the above-referenced contracts and the patient's eligibility at the time the services are rendered.*

Description

Reconstructive breast surgery is defined as surgical procedures that are designed to restore the normal appearance of the breast after surgery, accidental injury, or trauma. 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.

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. Contracture is the most common local complication of breast implants. Contractures have been 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

The following policy 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.

Corporate Medical Guideline

Explantation of a *silicone* gel-filled breast implant may be considered **medically appropriate** 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 appropriate** 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.

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

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

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

- 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.

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

Reconstructive breast surgery may be considered **medically appropriate** after a medically necessary mastectomy, accidental injury, or trauma. (See also policy called Cosmetic/Reconstructive Services for additional clarification, especially in regards to functional impairment requirements.) Medically necessary mastectomies are most typically done as treatment for cancer.

Policy Guidelines

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 appropriate**, 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
<i>Systemic Illness</i>				
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
<i>Patient Anxiety</i>	no	no	no	no
<i>Absolute Medical Indications</i>				
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

Indication for Explantation	Reconstruction/silicone	Reconstruction/saline	Cosmetic/silicone	Cosmetic/saline
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Other Indications

Baker class III contractures	yes	yes	no	no
Pain**	no	no	no	no

Post-Explantation Procedures

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.

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.

See also policy called Cosmetic/Reconstructive Services.

Prior approval is required. BlueShield fully expects that only appropriate and medically necessary services will be rendered. BlueShield reserves the right to conduct prepayment and postpayment reviews to assess the medical appropriateness of the above-referenced procedures.

References

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7. Gabriel SE, O'Fallon WM, Kurland LT, et al. Risk of connective-tissue diseases and other disorders after breast implantation. *N Engl J Med* 1994; 330(24):1697-702.
8. Hennekens CH, Lee IM, Cook NR, et al. Self-reported breast implants and connective-tissue disease in female health professionals. A retrospective cohort study. *JAMA* 1996; 275(8):616-21.

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10. Silverman BG, Brown SL, Bright RA, et al. Reported complications of silicone gel breast implants: an epidemiologic review. Ann Intern Med 1996; 124(8):744-56.
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Last Review Date

Reviewed with literature search/February 2008

Next Review Date

Review with literature search/February 2009