BSC7.12	Breast Implant Management		
Original Policy Date:	May 16, 2008	**Effective Date:**	June 1, 2022
Section:	7.0 Surgery	**Page:**	Page 1 of 10

Policy Statement

The California Reconstructive Surgery Act (Health & Safety Code Section 1367.63 and the Insurance Code Section 10123.88) defines "reconstructive surgery" as surgery performed to correct or repair abnormal structures of the body caused by congenital defects, developmental abnormalities, trauma, infection, tumors, or disease to do **either** of the following (see also Blue Shield of California Medical Policy: Reconstructive Services):

I. Create a normal appearance to the extent possible
II. Improve function

In interpreting whether a proposed procedure meets the definition of reconstructive surgery, as defined by law, the procedure may be denied as **not medically necessary** under **any** of the following conditions:

I. The procedure is likely to result in only minimal improvement in appearance, in accordance with the standard of care as practiced by physicians specializing in reconstructive surgery
II. The treating surgeon cannot or will not provide sufficient documentation, including (when appropriate) medical quality color photographs, which accurately depicts the extent of the clinical problem (see Policy Guidelines and Documentation for Clinical Review sections)
III. There is alternative approved medical or surgical intervention with equal or superior clinical outcomes
IV. The procedure is for cosmetic purposes only

Breast Implant Removal

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

I. Infection
II. Implant exposure/extrusion through skin
III. Baker Class IV capsular contracture (See Policy Guidelines)
IV. Surgical treatment of breast disease in close proximity to the implant
V. Intra- or extra-capsular rupture of a silicone gel-filled or combination silicone/saline-filled implant documented by imaging studies (e.g., mammography, ultrasound, or magnetic resonance imaging)

Removal of a breast implant may be considered **medically necessary** for any type of breast implant (including saline-filled) originally inserted for reconstructive purposes (e.g., after mastectomy, lumpectomy, or other surgical treatment of breast disease) and **one** of the following:

I. Persistent structural abnormality (e.g., distortion) for which removal (and subsequent augmentation) will result in more than minimal improvement in appearance
II. Chronic clinically significant symptoms that can be attributed to a local/regional reaction to the breast implant

Breast Implant Reimplantation

Breast implant reimplantation may be considered **medically necessary** for an individual with **both** of the following:

I. When a subsequent disease process (e.g., infection with necrosis) has resulted in a clinically significant structural abnormality of the adjacent native breast tissue
II. Breast implant was originally inserted for reconstructive purposes (e.g., after mastectomy, lumpectomy, or other surgical treatment of breast disease)

Removal of breast implant is considered **not medically necessary** for cosmetic purposes.

NOTE: Refer to Appendix A to see the policy statement changes (if any) from the previous version.

Policy Guidelines

Note: Quality color photographs or imaging reports showing the extent of the problem should be included with the medical records sent to support medical necessity.

For the purpose of this policy, the qualified reviewer will differentiate a normal structure from an abnormal one based on **any** of the following elements:

- The availability of published normative data for specific anatomic measurements (e.g., cephalometric data for orthognathic surgery)
- The normal structures wide range of accepted variations in diverse populations (e.g., nasal size and shape)
- The presence of a cosmetic implant, in the absence of adjacent native tissue structural pathology, does not constitute an abnormal structure (e.g., cosmetic unilateral, bilateral or asymmetrical saline breast implants)

In determining whether or not a procedure is likely to result in more than minimal improvement in appearance, the qualified reviewer will consider both the size and location of the structural abnormality.

"Cosmetic surgery" means surgery that is performed to alter or reshape normal structures of the body in order to improve appearance. Under existing California statutes, medically necessary services to treat complications from a non-covered service (e.g., cosmetic surgery) are a covered benefit as addressed below.

Baker Classification for Grading of Contractures

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

MRIs done to look for implant rupture are done without contrast (CPT 77046 unilateral or 77047 bilateral). An MRI done to look for cancer would be done with contrast.

Description

Breast implants are prosthetic devices used to augment, reshape, and/or reposition a woman's breast. Breast implants are most commonly used for primary cosmetic augmentation in order to improve breast appearance. However, they are also used in the primary reconstruction or revision reconstruction of structurally abnormal breasts resulting from congenital defects, developmental abnormalities, trauma, tumors, or other disease.

Occasionally, complications (e.g., infection, extrusion, rupture) may necessitate removal of a breast implant and/or reimplantation. Women with breast implant complications may present with breast contour irregularities, localized pain or mass, or a change in breast size.

Related Policies

- Reconstructive Services

Benefit Application

Benefit determinations should be based in all cases on the applicable contract language. To the extent there are any conflicts between these guidelines and the contract language, the contract language will control. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

Some state or federal mandates (e.g., Federal Employee Program [FEP]) prohibits plans from denying Food and Drug Administration (FDA)-approved technologies as investigational. In these instances, plans may have to consider the coverage eligibility of FDA-approved technologies on the basis of medical necessity alone.

Regulatory Status

The United States Food and Drug Administration (FDA)-approved saline-filled and silicone gel-filled breast implants are listed as follows[1]:

Saline-Filled:

- Ideal Implant Saline-Filled Breast Implant (Ideal Implant , Dallas, TX)
- Mentor Corporation Saline-Filled and Spectrum (R) Mammary Prostheses (Mentor Worldwide LLC, Irvine, CA)
- Natrelle Saline Breast Implants (Allergan [formerly Inamed], Irvine, CA)

The above saline-filled implants were approved for breast augmentation in women 18 years or older and for breast reconstruction in women of any age.

Silicone Gel-Filled:

- Mentor MemoryShape Breast Implants (Mentor Worldwide LLC, Irvine, CA)
- Memory Gel Silicone Gel-filled Breast Implants (Mentor Corp., Irvine, CA)
- Natrelle Silicone-Filled Breast Implants (Allergan [formerly Inamed], Irvine, CA)
- Natrelle Highly Cohesive Silicone-Filled Breast Implants (Allergan [formerly Inamed], Irvine, CA)
- Sientra Silicone Gel Breast Implants (Sientra, Inc., Santa Barbara, CA)

The above silicone gel-filled implants were approved for breast augmentation in women 22 years or older and for breast reconstruction in women of any age.

The FDA restricts the marketing of breast implants for augmentation in women of a minimum age because young women's breasts continue to develop through their late teens and early 20's. Also, a young woman may lack the maturity to make an informed decision about potential risks. The age restrictions are different for saline and silicone gel-filled implants because the risks are different for the two products. However, there is no age restriction on the marketing of these products for reconstruction.

Rationale

Background
Decision-making related to coverage for surgical insertion or removal of breast implants begins with knowledge of the applicable laws related to the members' coverage and benefits. The California Reconstructive Surgery Act (Health & Safety Code Section 1367.63 and the Insurance Code Section 10123.88) defines both reconstructive and cosmetic surgery, and mandates benefits for reconstructive surgery under certain conditions (See Blue Shield of California Medical Policy: Reconstructive Services). Medical Necessity is not a factor in meeting coverage criteria under this law. Additionally, there are both state and federal statutes under the Employee

Retirement Income Security Act of 1974 specifically related to coverage for breast reconstruction following mastectomy. These laws include the coverage for the provision of implants at both the disease site and the contralateral (non-diseased) breast to improve symmetry.

The use of breast implants in cosmetic surgery is considered not medically necessary. However, the existing California Knox-Keene Health Care Service Plan Act of 1975 mandates coverage for medically necessary services to treat the complications of non-covered services. This may include the removal (or explantation) of a cosmetic implant when it is determined the implant is likely to cause or worsen a known medical condition.

Literature Review
Basic to all breast implants is a silicone rubber (elastomer) shell, which can be single or double lumen, smooth or textured, and filled with saline, silicone gel, or alternative.

Surgery for implant insertion is normally performed as an outpatient procedure under local or general anesthesia. The incision for cosmetic insertion is most commonly made along the lower edge of the areola, in the axilla, or in the inframammary fold. For postmastectomy reconstruction, the existing surgical scar usually is used for access. A generous pocket is made for the implant in a plane either deep to the breast on the pectoral fascia (submammary) or beneath the pectoralis major and/or serratus fascia (submuscular). The implant is then inserted and the incision closed.[2]

Complications can be subdivided as local or systemic. Local complications include implant contracture (most common), rupture, extrusion, or infection. Extrusions, infections or documented rupture of a silicone gel-filled implant are considered absolute indications for removal. Removal of a ruptured saline implant is not considered medically necessary, since normal saline is physiologic, and rupture poses no health threat. However, a ruptured saline implant may compromise the aesthetic outcome and thus removal may be considered appropriate in cases of originally placed reconstructive breast implants (i.e., after mastectomy, lumpectomy, injury, or treatment of breast cancer).

Rupture
Breast implants are not lifetime devices. Breast implants rupture when the shell develops a hole or a tear which may allow migration of the contents outside the shell; however, the majority occur inside the shell and are grossly contained by the scar capsule. Ruptured implants may result in hard knots in the breast, an uneven breast appearance, pain or tenderness, tingling, swelling, numbness, burning, changes in breast sensation, or loss of breast size or shape.[3] However, there may be no symptoms or breast changes ("silent rupture"). Some implants may rupture in the first few months after being implanted, and others may rupture after several years. Rupture of the breast implant may be difficult to document, but physical exam, mammography, ultrasonography, or magnetic resonance imaging have been used.[4,5] There is no consensus on which method affords the best sensitivity and specificity. 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, the hearings on breast implants by the FDA in 1992 did not recommend screening for possible ruptures without signs or symptoms. Instead, work-up for a potential rupture is typically initiated at the onset of local symptoms or breast changes in size or consistency of the implant.

Infection
Infection of a breast implant is suspected when the surrounding skin is warm or red, or the patient is febrile and has pain around the implant. Late breast implant infections can occur at any time from a month to many years after the implant surgery. Late infections may result from secondary bacteremia or an invasive procedure in a location other than the breast, as well as from the breast ducts, and trauma.[6]

Exposure/Extrusion
Lack of adequate tissue coverage or infection may result in exposure and extrusion of the implant through the skin. Tissue breakdown or necrosis has been reported with the use of steroid drugs, after chemotherapy/radiation to breast tissue, and excessive heat or cold therapy. In some cases, incision sites fail to heal normally. The implant may become visible at the surface of the breast as a result of the device pushing through layers of the skin. If tissue breakdown occurs and the implant becomes exposed, implant removal may become necessary.

Capsular Contracture
Capsules of tightly-woven collagen fibers form as an immune response around a foreign body (e.g., breast implants, prosthetics, pacemakers) tending to wall it off. Capsular contracture occurs when the capsule tightens and squeezes the implant and may be more common following infection, hematoma, seroma, or subglandular breast implant placement. Contracture is a more subjective finding, which is graded according to the Baker classification (see Policy Guidelines). Symptoms may include mild firmness and mild discomfort to severe pain, distorted shape, palpability of the implant, and/or movement of the implant.[3] Grade IV contractures interfere with adequate mammography screening, and thus their presence constitutes a health risk. Therefore, removal is 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 removal. However, since Grade III contractures have an impact on the normal appearance of the breast, removal may be appropriate in implants inserted originally for reconstructive purposes, since the goal of restoration of the normal appearance of the breast is not achieved.

Systemic Complications
Potential systemic complications of implants, most prominently various connective tissue diseases, autoimmune diseases, fibromyalgia, and cancer have been debated for many years. In particular, it has been hypothesized leakage of silicone, due either to an implant rupture or "bleeding" of silicone through an intact capsule, may incite an autoimmune response with the development of systemic symptoms. Silicone breast implants were initially banned by the FDA in 1992 because of this concern and a possible association between these implants and connective tissue diseases. After extensive study and analysis, the FDA deemed the device safe for all augmentation and reconstruction, but continued to require tracking of patients.[7] Meta-analyses and retrospective studies have shown no statistical correlation between leakage of silicone implants and autoimmune diseases.[8-12] Large epidemiologic studies have not demonstrated women with breast implants are over-represented among all those with connective tissue disease.[13-16] Additionally, there are inadequate empiric studies to demonstrate that removal of breast implants is associated with resolution of systemic symptoms.

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

Summary of Evidence
Breast implant prostheses may be inserted for cosmetic or reconstructive reasons. Medically necessary implant removal may be required after complications of breast implant insertion. Peer-reviewed scientific literature and professional societies have not concluded there is a correlation between breast implants and the development of connective tissue disease, autoimmune disease, or increased breast cancer risk.

References

1. U.S. Food and Drug Administration (FDA). Labeling for Approved Breast Implants. Dec 3, 2021. http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/ImplantsandProsthetics/BreastImplants/ucm063743.htm. Accessed March 4, 2022.
2. Brody GS, et al. Silicone Breast Implant Safety and Efficacy. 2017. http://emedicine.medscape.com/article/1275451-overview. Accessed January 28, 2019.
3. U.S. Food and Drug Administration (FDA). Risks of Breast Implants. 2018. http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/ImplantsandProsthetics/BreastImplants/ucm064106.htm#Rupture_. Accessed January 28, 2019.
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6. Pittet B, Montandon D, Pittet D. Infection in Breast Implants. Lancet Infect Dis. 2005;5(2):94-106.
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9. Brown SL, Pennello G, Berg WA et al. Silicone gel breast implant rupture, extracapsular silicone, and health status in a population of women. J Rheumatol. 2001;28(5):996–1003.
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13. 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.
14. Hennekens CH, Lee IM, Cook NR et al. Self-reported breast implants and connective-tissue diseases in female health professionals. A retrospective cohort study. JAMA 1996;275(8):616- 21.
15. Sanchez-Guerrero J, Colditz GA, Karlson EW et al. Silicone breast implants and the risk of connective-tissue diseases and symptoms. N Engl J Med 1995;332(25):1666-70.
16. 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.

Documentation for Clinical Review

Please provide the following documentation:

- History and physical and/or consultation notes including:
  - Clinical indication for removal including Baker class if applicable
  - Reason for original insertion of the breast implant
  - Type of implant being removed
- Operative report(s) (if applicable)
- Radiological reports (if applicable)

Post Service (in addition to the above, please include the following):

- Breast implant related operative report(s)

Coding

This Policy relates only to the services or supplies described herein. Benefits may vary according to product design; therefore, contract language should be reviewed before applying the terms of the Policy.

The following codes are included below for informational purposes. Inclusion or exclusion of a code(s) does not constitute or imply member coverage or provider reimbursement policy. Policy Statements are intended to provide member coverage information and may include the use of some codes for clarity. The Policy Guidelines section may also provide additional information for how to interpret the Policy Statements and to provide coding guidance in some cases.

Type	Code	Description
CPT®	19328	Removal of intact breast implant
	19330	Removal of ruptured breast implant, including implant contents (e.g., saline, silicone gel)
	19340	Insertion of breast implant on same day of mastectomy (i.e., immediate)
	19342	Insertion or replacement of breast implant on separate day from mastectomy
	19370	Revision of peri-implant capsule, breast, including capsulotomy, capsulorrhaphy, and/or partial capsulectomy
	19371	Peri-implant capsulectomy, breast, complete, including removal of all intracapsular contents
HCPCS	C1789	Prosthesis, breast (implantable)
	L8030	Breast prosthesis, silicone or equal, without integral adhesive
	L8033	Nipple prosthesis, custom fabricated, reusable, any material, any type, each
	L8039	Breast prosthesis, not otherwise specified
	L8600	Implantable breast prosthesis, silicone or equal

Policy History

This section provides a chronological history of the activities, updates and changes that have occurred with this Medical Policy.

Effective Date	Action
05/16/2008	New Policy Adoption
10/28/2009	Coding Update
07/01/2011	Policy revision with position change
03/30/2015	Policy clarification
07/31/2015	Coding update
12/04/2015	Policy revision without position change
07/01/2016	Policy revision without position change
07/01/2017	Policy revision without position change
06/01/2018	Policy revision without position change
07/01/2018	Policy statement clarification
03/01/2019	Policy revision without position change
03/01/2020	Coding update
04/01/2020	Annual review. Policy statement and guidelines updated.
01/01/2021	Coding update

Effective Date	Action
04/01/2021	Annual review. No change to policy statement.
04/01/2022	Annual review. No change to policy statement. Policy guidelines and literature updated.
06/01/2022	Administrative update.

Definitions of Decision Determinations

Medically Necessary: Services that are Medically Necessary include only those which have been established as safe and effective, are furnished under generally accepted professional standards to treat illness, injury or medical condition, and which, as determined by Blue Shield, are: (a) consistent with Blue Shield medical policy; (b) consistent with the symptoms or diagnosis; (c) not furnished primarily for the convenience of the patient, the attending Physician or other provider; (d) furnished at the most appropriate level which can be provided safely and effectively to the patient; and (e) not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of the Member's illness, injury, or disease.

Investigational/Experimental: A treatment, procedure, or drug is investigational when it has not been recognized as safe and effective for use in treating the particular condition in accordance with generally accepted professional medical standards. This includes services where approval by the federal or state governmental is required prior to use, but has not yet been granted.

Split Evaluation: Blue Shield of California/Blue Shield of California Life & Health Insurance Company (Blue Shield) policy review can result in a split evaluation, where a treatment, procedure, or drug will be considered to be investigational for certain indications or conditions, but will be deemed safe and effective for other indications or conditions, and therefore potentially medically necessary in those instances.

Prior Authorization Requirements (as applicable to your plan)

Within five days before the actual date of service, the provider must confirm with Blue Shield that the member's health plan coverage is still in effect. Blue Shield reserves the right to revoke an authorization prior to services being rendered based on cancellation of the member's eligibility. Final determination of benefits will be made after review of the claim for limitations or exclusions.

Questions regarding the applicability of this policy should be directed to the Prior Authorization Department at (800) 541-6652, or the Transplant Case Management Department at (800) 637-2066 ext. 3507708 or visit the provider portal at www.blueshieldca.com/provider.

Disclaimer: This medical policy is a guide in evaluating the medical necessity of a particular service or treatment. Blue Shield of California may consider published peer-reviewed scientific literature, national guidelines, and local standards of practice in developing its medical policy. Federal and state law, as well as contract language, including definitions and specific contract provisions/exclusions, take precedence over medical policy and must be considered first in determining covered services. Member contracts may differ in their benefits. Blue Shield reserves the right to review and update policies as appropriate.

Appendix A

POLICY STATEMENT	
BEFORE	**AFTER** **Blue font: Verbiage Changes/Additions**
Breast Implant Management BSC7.12 **Policy Statement:** **Breast Implant Removal** Removal of a breast implant may be considered **medically necessary** for **any** of the following indications: I. Infection II. Implant exposure/extrusion through skin III. Baker Class IV capsular contracture (See Policy Guidelines)	**Breast Implant Management BSC7.12** **Policy Statement:** The California Reconstructive Surgery Act (Health & Safety Code Section 1367.63 and the Insurance Code Section 10123.88) defines "reconstructive surgery" as surgery performed to correct or repair abnormal structures of the body caused by congenital defects, developmental abnormalities, trauma, infection, tumors, or disease to do **either** of the following (see also Blue Shield of California Medical Policy: Reconstructive Services): I. Create a normal appearance to the extent possible II. Improve function In interpreting whether a proposed procedure meets the definition of reconstructive surgery, as defined by law, the procedure may be denied as **not medically necessary** under **any** of the following conditions: I. The procedure is likely to result in only minimal improvement in appearance, in accordance with the standard of care as practiced by physicians specializing in reconstructive surgery II. The treating surgeon cannot or will not provide sufficient documentation, including (when appropriate) medical quality color photographs, which accurately depicts the extent of the clinical problem (see Policy Guidelines and Documentation for Clinical Review sections) III. There is alternative approved medical or surgical intervention with equal or superior clinical outcomes IV. The procedure is for cosmetic purposes only **Breast Implant Removal** Removal of a breast implant may be considered **medically necessary** for **any** of the following indications: I. Infection II. Implant exposure/extrusion through skin III. Baker Class IV capsular contracture (See Policy Guidelines)

POLICY STATEMENT	
BEFORE	**AFTER** **Blue font: Verbiage Changes/Additions**
IV. Surgical treatment of breast disease in close proximity to the implant V. Intra- or extra-capsular rupture of a silicone gel-filled or combination silicone/saline-filled implant documented by imaging studies (e.g., mammography, ultrasound, or magnetic resonance imaging) Removal of a breast implant may be considered **medically necessary** for any type of breast implant (including saline-filled) originally inserted for reconstructive purposes (e.g., after mastectomy, lumpectomy, or other surgical treatment of breast disease) and **one** of the following: I. Persistent structural abnormality (e.g., distortion) for which removal (and subsequent augmentation) will result in more than minimal improvement in appearance II. Chronic clinically significant symptoms that can be attributed to a local/regional reaction to the breast implant **Breast Implant Reimplantation** Breast implant reimplantation may be considered **medically necessary** for an individual with **both** of the following: I. When a subsequent disease process (e.g., infection with necrosis) has resulted in a clinically significant structural abnormality of the adjacent native breast tissue II. Breast implant was originally inserted for reconstructive purposes (e.g., after mastectomy, lumpectomy, or other surgical treatment of breast disease) Removal of breast implant is considered **not medically necessary** for cosmetic purposes.	IV. Surgical treatment of breast disease in close proximity to the implant V. Intra- or extra-capsular rupture of a silicone gel-filled or combination silicone/saline-filled implant documented by imaging studies (e.g., mammography, ultrasound, or magnetic resonance imaging) Removal of a breast implant may be considered **medically necessary** for any type of breast implant (including saline-filled) originally inserted for reconstructive purposes (e.g., after mastectomy, lumpectomy, or other surgical treatment of breast disease) and **one** of the following: I. Persistent structural abnormality (e.g., distortion) for which removal (and subsequent augmentation) will result in more than minimal improvement in appearance II. Chronic clinically significant symptoms that can be attributed to a local/regional reaction to the breast implant **Breast Implant Reimplantation** Breast implant reimplantation may be considered **medically necessary** for an individual with **both** of the following: I. When a subsequent disease process (e.g., infection with necrosis) has resulted in a clinically significant structural abnormality of the adjacent native breast tissue II. Breast implant was originally inserted for reconstructive purposes (e.g., after mastectomy, lumpectomy, or other surgical treatment of breast disease) Removal of breast implant is considered **not medically necessary** for cosmetic purposes.