Anthem

Medical Policy

Subject: Breast Procedures; including Reconstructive Surgery, Implants and Other Breast Procedures
Document #: SURG.00023 **Publish Date:** 01/03/2024
Status: Revised **Last Review Date:** 11/09/2023

Description/Scope

This document addresses the following three areas: reconstructive breast surgery, cosmetic surgeries designed to enhance the appearance of the breast and management of breast implants.

Reconstructive breast surgery refers to surgical procedures to rebuild the contour of the breast, along with the nipple and areola if desired. Typically, breast reconstruction is performed following a mastectomy (that is, the breast has been removed because of breast cancer) or lumpectomy (that is, removal of the breast tumor and tissue surrounding it), but occasionally techniques of breast reconstruction are used to treat individuals who have an abnormal development of one or both breasts.

Note: Please see the following related document(s) for additional information:

- SURG.00011 Allogeneic, Xenographic, Synthetic, Bioengineered, and Composite Products for Wound Healing and Soft Tissue Grafting
- CG-SURG-71 Reduction Mammaplasty

Note: This document does not address gender affirming surgery or procedures. Criteria for gender affirming surgery or procedures are found in applicable guidelines used by the plan.

For autologous fat grafting and other soft tissue augmentation procedures of the breast see:

- MED.00132 Adipose-derived Regenerative Cell Therapy and Soft Tissue Augmentation Procedures

Note: The Women's Health and Cancer Rights Act of 1998 (WHCRA) is federal legislation that provides that any individual, with insurance coverage who is receiving benefits in connection with a mastectomy covered by their benefit plan (whether or not for cancer) who elects breast reconstruction, must receive coverage for the reconstructive services as provided by WHCRA. This includes reconstruction of the breast on which the mastectomy has been performed, surgery and reconstruction of the other breast to produce a symmetrical appearance and prostheses and treatment of physical complications of all stages of the mastectomy including lymphedemas. If additional surgery is required for either breast for treatment of physical complications of the implant or reconstruction, surgery on the other breast to produce a symmetrical appearance is reconstructive at that point as well. The name of this law is misleading because: 1) cancer does not have to be the reason for the mastectomy; and 2) the mandate applies to men, as well as women. WHCRA does not address lumpectomies. Some states have enacted similar legislation, and some states include mandated benefits for reconstructive services after lumpectomy.

Medically Necessary: In this document, procedures are considered **medically necessary** if there is a significant functional impairment, AND the procedure can be reasonably expected to improve the functional impairment.

Reconstructive: In this document, procedures are considered **reconstructive** when intended to address a significant variation from normal related to accidental injury, disease, trauma, treatment of a disease or congenital defect.

Note: Not all benefit contracts include benefits for reconstructive services as defined by this document. Benefit language supersedes this document.

Cosmetic: In this document, procedures are considered **cosmetic** when intended to change a physical appearance that would be considered within normal human anatomic variation. Cosmetic services are often described as those that are primarily intended to preserve or improve appearance.

Position Statement

Medically Necessary:

Removal of implants *partially or completely filled with* ***Silicone Gel*** is considered **medically necessary** when there is documented implant rupture (that is, using mammography, ultrasound, or MRI).

Removal of a ***Silicone Gel filled, Saline filled or "Alternative"*** implant is considered **medically necessary** for any of the following:

A. **I**nfection of the implant or surrounding tissue; **or**
B. Implant exposure/extrusion; **or**
C. Pain related to Baker Class IV capsular contracture;**or**
D. Confirmed cases of breast implant-associated anaplastic large cell lymphoma;**or**
E. Elective removal in individuals with an increased risk of breast implant-associated anaplastic large cell lymphoma (BIA-ALCL) due to use of Allergan BIOCELL textured breast implants and tissue expanders; **or**
F. Prior to surgical treatment of breast cancer. (Note: Implant explantation is routinely performed at the time of mastectomy. In individuals treated with breast conserving surgery [that is, lumpectomy], a breast implant may or may not interfere with subsequent treatment, and thus explantation at the time of lumpectomy is at the discretion of the treating physician and the treated individual).

Reconstructive:

Breast surgery is considered **reconstructive** to rebuild the normal contour of the affected and the contralateral *unaffected* breast to produce a more normal appearance following a mastectomy, lumpectomy, or other breast surgery for breast cancer.

Surgical procedures, such as reduction mammaplasty, may be considered **reconstructive** when done *in advance of* mastectomy or lumpectomy for breast cancer in order to produce improved cosmesis and prevent postoperative complications.

Breast surgery of *both* breasts is considered **reconstructive** following the mastectomy of both breasts.

Breast surgery to alter the contour of the breast is considered **reconstructive** when there are significant abnormalities related to trauma, congenital defects, infection or other non-malignant disease. A specific example of this is Poland syndrome which may be diagnosed when all of the following are present:

A. Congenital absence or hypoplasia of pectoralis major and minor muscles; **and**
B. Breast hypoplasia; **and**
C. Congenital partial absence of the upper costal cartilage.

Removal of an implant (any type) with or without reimplantation is considered **reconstructive** when:

A. An implant, originally placed **in an individual with a history of mastectomy, lumpectomy or treatment of breast cancer** for reconstructive purposes as defined above; **and**
B. There has been development of a visible distortion (Baker Class III contracture).

Removal of a ruptured saline-filled or "Alternative" implant with or without reimplantation is considered **reconstructive** when originally placed **in an individual with a history of mastectomy, lumpectomy or treatment of breast cancer** for reconstructive purposes, as defined above.

Surgery on the contralateral breast to produce a symmetrical appearance after removal of an implant and reimplantation is considered reconstructive when the implant was originally placed for reconstructive purposes **in an individual with a history of mastectomy, lumpectomy or treatment of breast cancer.**

Not Medically Necessary:

Removal of a ruptured saline-filled or "Alternative" implant is considered **not medically necessary** since the potential adverse medical consequences of implant rupture are related to silicone gel implants *only.*

Removal of ***ANY TYPE*** of breast implant is considered **not medically necessary** for any of the following:

A. Systemic symptoms attributed to connective tissue disease, autoimmune diseases, etc.; **or**
B. Personal anxiety; **or**
C. Pain not related to contractures or rupture; **or**
D. The medically necessary or reconstructive criteria listed above have not been met.

Cosmetic and Not Medically Necessary:

Reimplantation of an implant inserted for cosmetic purposes only (that is, for reasons other than a history of mastectomy, lumpectomy, treatment of breast cancer, significant abnormalities related to trauma, congenital defects, infection or other non-malignant disease) and *removed as part of a medically necessary or reconstructive surgery (see above)* is considered **cosmetic and not medically necessary.**

Other breast procedures, (including augmentation mammaplasty/breast lift, implant repositioning, repair of inverted nipples, mastopexy) are considered **cosmetic and not medically necessary** except when performed as part of a covered breast reconstruction service.

Rationale

The Women's Health and Cancer Rights Act of 1998 (WHCRA) mandated that reconstructive breast surgery for individuals who have undergone mastectomy be covered by their benefits for those who have opted to have breast reconstruction. In individuals who have undergone a medically necessary lumpectomy, surgery to create a more normal anatomy is considered reconstructive.

Removal of silicone-filled implants has been shown to be necessary when due to infection, implant exposure, or pain related to capsular contracture. In addition, Grade IV contractures interfere with adequate mammography screening and thus, their presence has potential medical implications. Therefore, removal may be considered medically necessary. Grade III contractures do not interfere with mammography; therefore, Grade III contractures are not considered an absolute indication for removal. However, since Grade III contractures do have an impact on the normal appearance of the breast, removal may be appropriate for implants *originally placed for reconstructive purposes*, since the goal of restoration of the normal appearance of the breast is not achieved. Contracture is the most common local complication of breast implants. Contractures have been graded according to the Baker Classification which is outlined below:

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 FDA labeling of silicone implants recommends removal of ruptured silicone implants. Intact silicone implants are all associated with leakage of small amounts of silicone, and there has been concern that this leakage is associated with various autoimmune diseases. The data from multiple studies is inadequate to support an association between silicone implants and autoimmune disease (Janowsky, 2000).

In 2011, the FDA published preliminary findings and analyses of breast implant-associated anaplastic large cell lymphoma (BIA-ALCL) in individuals with breast implants. As part of its analysis, the FDA conducted a thorough review of scientific literature published from January 1997 through May 2010. From this review, the FDA identified 34 unique cases of BIA-ALCL in women with breast implants throughout the world. This number is difficult to verify because not all cases were published in the scientific literature. Some cases have been identified through the FDA's contact with other regulatory authorities, scientific experts, and breast implant manufacturers, and it is not clear how many of these are duplicates of the ones found in the literature. The number of identified cases is small compared to the estimated 5-10 million individuals who have received breast implants worldwide. Based on these data:

> The FDA believes that women with breast implants may have a very small but increased risk of BIA-ALCL. Because the risk of BIA-ALCL appears very small, the FDA believes that the totality of evidence continues to support a reasonable assurance that FDA-approved breast implants are safe and effective when used as labeled (FDA, 2011; Kim, 2011).
>
> As of September 30, 2017, the FDA had received a total of 414 medical device reports (MDRs) of BIA-ALCL, including the death of nine patients. Of these, 272 of the 414 reports included information on the surface of the implant at the time of the report, including 242 with textured surfaces and 30 with smooth surfaces. Also noted, 413 of the 414 reports

> included information on the type of implant fill. Of these, 234 reported implants filled with silicone gel and 179 reported implants filled with saline. This further clarifies that saline implants are also reported to be associated with BIA-ALCL (FDA, 2017).

The FDA continues to collect and evaluate information about BIA-ALCL associated with breast implants. In collaboration with the American Society of Plastic Surgeons and the Plastic Surgery Foundation (ASPS/PSF), the FDA has developed a registry of BIA-ALCL cases, known as the PROFILE Registry (Patient Registry and Outcomes For breast Implants and anaplastic large cell Lymphoma [ALCL] etiology and Epidemiology), to prospectively track and collect scientific data on ALCL in individuals with breast implants. The primary goal of this ongoing collaboration is to better understand the role of breast implants in the etiology of primary ALCL in individuals with breast implants. The research will also focus on identifying potential risk factors and criteria detection for the identification of at-risk individuals and the management of BIA-ALCL. Based on global data sharing, at the present time, the ASPS claims to be aware of 573 cases of BIA-ALCL worldwide with 33 disease-related deaths over 30 countries. From the current total of 573 confirmed cases of BIA-ALCL, 481 are reported to have had Allergan breast implants at the time of diagnosis. Information from the PROFILE registry about breast implants and treatment for BIA-ALCL will be available for practitioners and individuals with implants or considering breast implants. Registry data on confirmed cases of primary ALCL in individuals with breast implants will also be available for analytical epidemiological studies. The current status of the PROFILE registry is listed as collecting cases; additional information is available at: https://www.thepsf.org/research/registries/profile.

In 2016, the World Health Organization (WHO) provisionally designated BIA-ALCL as a unique form of T-cell lymphoma that can develop in some breast implant recipients. The following is noted:

> The exact number of cases remains difficult to determine due to significant limitations in world-wide reporting and lack of global breast implant sales data. At this time, most data suggest that BIA-ALCL occurs more frequently following implantation of breast implants with textured surfaces rather than those with smooth surfaces (WHO, 2016).

In October of 2019, researchers from Memorial Sloan Kettering Cancer Center presented preliminary evidence from a prospective cohort study of individuals who received reconstructive textured implants from a single surgeon between April 1993 and December 2017. The study followed 3546 women from a prospective database who received 6023 implants; 8 of these recipients developed BIA-ALCL after a median of 11.2 years of exposure. This equates to a risk of 0.294 cases per 1000 person-years (1 case per 443 women). Although the full study has not been published to date, this finding indicates that the risk of BIA-ALCL following implantation of a textured implant may be significantly higher than previously estimated (Ghione, 2019).

On July 24, 2019, the FDA announced the voluntary recall of specific models of textured breast implants manufactured by Allergan (Irvine, CA) from the U.S. market, due to the risk of BIA-ALCL. Following the FDA request, Allergan has notified the FDA that it is moving forward with a worldwide recall of their BIOCELL® textured breast implant products, including: Natrelle Saline-Filled breast implants, Natrelle Silicone-Filled breast implants, Natrelle Inspira Silicone-Filled breast implants, and Natrelle 410 Highly Cohesive Anatomically Shaped Silicone-Filled breast implants. However, the FDA has recommended against removal of breast implants in individuals who have no symptoms due to the low risk of developing BIA-ALCL (FDA, 2019). On September 29, 2020, the FDA issued its final Guidance for Industry and FDA Staff for saline, silicone gel, and alternative breast implants, which is intended to guide implant manufacturers about labeling requirements and other necessary information for any future pre-market applications for breast implants. It includes detailed instructions about post-approval core studies to be conducted for 10 years to include data about complications and implant extractions to be reported to the FDA.

It has been noted in recent studies reporting on incidence of BIA-ALCL associated with breast implants that risk estimates of ALCL vary widely, prompting different responses from regulatory authorities around the world. Given the strong association between textured implants and ALCL, the rising incidence may be associated with both the increasing use of textured implants in the U.S. and increased recognition of the disease but may also reflect an increase in the incidence of all breast lymphomas. These updated risk estimates should increase the accuracy of epidemiological studies and support continued surveillance of breast ALCL by government and regulatory agencies (Kinslow, 2022).

On October 27, 2021, the FDA issued new labeling requirements for all legally marketed breast implants due to ongoing concerns about the possible risk of systemic illness or BIA-ALCL in individuals with silicone gel-filled breast implants. Also, the sale and distribution of breast implants will be restricted only to health care providers and facilities “That provide information to patients using the Patient Decision Checklist.” The manufacturers are required to post the following updated device labeling to their websites:

- Boxed warning;
- Patient decision checklist, which must be reviewed with the prospective patient by the health care provider to help ensure the patient understands the risks, benefits and other information about the breast implant device. The patient must be given the opportunity to initial and sign the patient decision checklist and it must be signed by the physician implanting the device;
- Updated silicone gel-filled breast implant rupture screening recommendations;
- Device description with a list of specific materials in the device;
- Patient device card.

In addition to BIA-ALCL, saline-filled implants have also been associated with infection, implant exposure, or pain related to capsular contracture, all requiring implant removal. Ruptured saline-filled implants have not been shown to pose any health risks due to the physiologic nature of saline, and their removal does not meet medical necessity criteria, except in the case of confirmed BIA-ALCL.

There is no medical evidence that supports the removal of breast implants for systemic symptoms, anxiety, or pain not related to contractures or rupture. The placement or removal of an implant in a healthy person is not considered to have any medically necessary justification and is considered cosmetic.

Note: Before considering the medical necessity for the removal of breast implants, the following questions must be answered:

1. **Was the original insertion of breast implant(s) considered *reconstructive* or *cosmetic* in nature?**
   Removal of a breast implant is considered **reconstructive** if the breast implant, originally inserted for reconstructive purposes, is associated with a significantly altered appearance, such that the goals of reconstruction (that is, to return the individual to a whole) are not reached.
2. **What signs or symptoms are present?**
   The presence of signs and symptoms related to the breast implant (for example, painful capsular contracture or rupture) may be used to establish the medical necessity for implant removal. Certain signs or symptoms (see medical necessity criteria) will establish the medical necessity of implant removal, *regardless of whether the implant was originally implanted for reconstructive or cosmetic reasons.*
3. **What type of implant is being removed?**
   The medical necessity criteria for explantation may depend on the type of implant. For example, the medical consequences of rupture of a silicone gel-filled implant differ from rupture of a saline-filled implant. The following implants are available:

- Silicone gel-filled
- Saline-filled
- Combination implants, that is, double lumen implants, consisting of an inner silicone-gel filled lumen surrounded by a saline-filled lumen

Background/Overview

Description of Technology

Reconstructive breast surgery is a surgical procedure that is designed to restore the normal appearance of a breast after a medically necessary mastectomy for breast cancer or other medical condition, injury or congenital abnormality. In contrast, cosmetic breast surgery is defined as surgery designed to alter or enhance the appearance of a breast that has not undergone a medically necessary surgery, an accidental injury/trauma, congenital defect, infection or other non-malignant disease.

Breast reconstruction following a mastectomy can be done immediately after, or some time following, a procedure to remove a breast. In an immediate procedure, after removal of the breast tissue, the surgeon will place a breast implant in the location where the breast was removed. This is referred to as a one-stage procedure and has no impact on the outcome of any chemotherapy treatments. A delayed reconstruction procedure may be necessary if radiation therapy following the surgery is needed, since implants may interfere with such treatment. In some circumstances, it is necessary to do a two-stage procedure, which involves the placement of a tissue expander to stretch the skin where an implant will be inserted as the second-stage procedure. Placement of the expander will be followed several months later by placement of an implant. This type of procedure may be done either immediately or sometime after the breast removal surgery. In some cases of breast cancer, reconstructive surgery (that is, reduction mammaplasty) is performed before the mastectomy or lumpectomy, in order to produce improved cosmesis and also to prevent postoperative complications following the mastectomy or lumpectomy. Regardless of the timing and which procedure(s) are done, the reconstruction will not interfere with the doctor's ability to detect any disease recurrence.

Another technique used in breast reconstruction involves a two-phase procedure. In the first phase, the breast mound is created, using either an implant with or without a tissue expander, or an autologous tissue reconstruction procedure with a transverse rectus abdominus musculocutaneous flap (that is, TRAM flap), and allowed to heal. In the second phase, which begins 3 to 6 months after the first stage is completed, the breast shape is refined and the nipple-areola is created. Tattooing of the nipple and/or areola is the final stage of reconstruction, and in some cases may be delayed up to 2 years.

Another surgical option that has gained some favorable feedback from individuals who have had a mastectomy is called aesthetic flat chest closure. This involves contouring of the chest wall after mastectomy without traditional breast reconstruction. The surgeon removes extra skin, pockets of fat or excess tissue, and tightens and smooths out the remaining tissue to create a flat chest wall contour. This procedure is considered reconstructive following a mastectomy for breast cancer and can be done immediately following the mastectomy or delayed until a few months later. In most cases individuals opt for removal of the contralateral breast and flat closure of that side also, in order to create a symmetrical appearance. A team of plastic surgeons from New York University noted that, to date, "There is no plastic surgery literature on specific techniques to achieve an aesthetic flat closure after mastectomy" (Morrison, 2022).

The National Cancer Institute (NCI) defines aesthetic flat closure as the following:

> A type of surgery that is done to rebuild the shape of the chest wall after one or both breasts are removed. An aesthetic flat closure may also be done after removal of a breast implant that was used to restore breast shape. During an aesthetic flat closure, extra skin, fat, and other tissue in the breast area is removed. The remaining tissue is then tightened and smoothed out so that the chest wall appears flat (NCI, 2011).

Baker and colleagues described results of a satisfaction survey of 931 women who had a history of uni- or bilateral mastectomy for treatment of breast cancer or elevated breast cancer risk without current breast mound reconstruction. Satisfaction with outcomes and surgeon support for the individual's experience were characterized using 5-level scaled scores. Mastectomy alone was the first choice for 73.7% of the respondents. The top two reasons for choosing flat closure were a desire for a faster recovery and avoidance of foreign body placement. Overall, the mean scaled satisfaction score was 3.72 ± 1.17 out of 5. In the multivariable analysis, low levels of surgeon support for the choice of flat closure were the strongest predictor of having a satisfaction score lower than 3 (odds ratio [OR], 3.85; 95% confidence interval [CI], 2.59–5.72; p<0.001). The authors noted that dissatisfaction was more likely among respondents reporting a body mass index (BMI) of 30 kg/m2 or higher (OR, 2.74; 95% CI, 1.76–4.27; p<0.001) and those undergoing a unilateral procedure (OR, 1.99; 95% CI, 1.29–3.09; p=0.002). Greater satisfaction was associated with a perception of having received adequate information about surgical options (OR, 0.48; 95% CI, 0.32–0.69; p<0.0001) and having a surgeon with a specialized breast surgery practice (OR, 0.56; 95% CI, 0.38–0.81; p=0.002). The authors concluded that the majority of individuals who had undergone a mastectomy alone were satisfied with their surgical outcome. They noted that surgeons may optimize the individual's experience by recognizing and supporting the choice of flat closure.

Description of Chest Wall Deformities

Congenital chest wall deformities include, but are not limited to, Poland syndrome, pectus excavatum (also referred to as sunken chest or funnel chest), and pectus carinatum (referred to as pigeon breast or chicken breast). Poland syndrome is a rare, congenital disorder which is associated with a wide range of malformations of the ribs on one or both sides of the sternum. This condition is characterized by absence or hypoplasia of the pectoralis major and minor muscles, absence of costal cartilages, hypoplasia of the breast and subcutaneous tissue, and a variety of hand and upper-extremity anomalies. In general, the severity of congenital chest wall deformities is dependent upon the depth, symmetry and width of the deformity which is evaluated by chest radiographs. In more severe cases where cardiac and/or pulmonary compression and cardiac displacement may be involved, the clinical evaluation may include chest computed tomography (CT) or magnetic resonance imaging (MRI), in addition to echocardiography and pulmonary function testing. Surgical repair may be necessary in some severe cases where cardiopulmonary function is impaired.

Concepts of Medical Necessity, Reconstructive and Cosmetic

The coverage eligibility of medical and surgical therapies to treat breast conditions is often based on a determination of whether repair of the abnormality is considered medically necessary, reconstructive, or cosmetic in nature. In many instances, the concept of reconstructive overlaps with the concept of medical necessity. For example, breast surgery to address pain related to Baker Class IV capsular contracture will be considered medically necessary and thus eligible for coverage, regardless of the contract language pertaining to reconstructive services, unless some other exclusion applies. Generally, reconstructive is often taken to mean that the service "returns the person to whole" as a result of a congenital anomaly, disease, or other condition, including post trauma or post therapy. Cosmetic generally describes changing a physical appearance that would be considered within normal human anatomic variation. Categories of conditions without associated functional impairment that may be included as reconstructive definitions, include or may be due to the following: surgery, accidental trauma or injury, diseases, congenital anomalies (including Poland syndrome),

severe anatomic variants, and chemotherapy or radiation therapy.

Choice of Breast Reconstruction Procedure

Breast reconstruction can play a pivotal part in recovery from breast cancer surgery. Reconstruction has been shown to improve quality of life in several domains including psychological, emotional, sexual, and social well-being. The choice and timing of breast reconstruction depends on a variety of factors that may be unique to each individual. Such factors include personal preference, degree of resection, prior surgeries or radiation treatments, body habitus including the amount of tissue available from donor sites, ongoing cancer treatment plans, and coexisting medical conditions. Common reconstructive techniques may include, but are not limited to, implant insertion, revision or removal of pre-existing implants (including implants placed for cosmetic purposes), reduction mammaplasty, surgery to the contralateral breast to achieve symmetry (which may include reduction mammaplasty, augmentation mammaplasty, mastopexy, or other procedures), tissue transfer, or chest wall reconstruction with flat chest closure.

Timing of Procedures

The number and timing of reconstructive breast procedures varies, depending on the individualized treatment plan developed by the treating physician(s) and the individual. These plans may be impacted by the overall treatment plan for the breast cancer itself.

Definitions

Alternative breast implants (also called combination implants): A type of breast implant that has two compartments that contain both silicone and saline. Some of these implants have silicone as the inner compartment and saline as the outer compartment. The saline compartment is filled at the time of surgery. Other implants in this category contain saline in the inner compartment and silicone in the outer compartment.

Augmentation mammaplasty (also referred to as augmentation mammoplasty): A surgical procedure in which the purpose is to enlarge the breast or breasts.

Breast implant-associated anaplastic large cell lymphoma (BIA-ALCL): This is a rare form of T-cell lymphoma (that is, Non-Hodgkin lymphoma) which is associated with breast implants. ALCL is characterized by abnormal growth of T-lymphocytes (T-cells) and strong expression of a protein, cytokine receptor CD30. ALCL can involve many parts of the body, including the lymph nodes and skin. There are currently two major variants of ALCL recognized in the literature, one of which expresses the protein anaplastic lymphoma kinase (ALK-positive) and a second which does not (ALK-negative). Reports in the scientific community have suggested a possible association between ALK-negative ALCL and silicone- and saline-filled breast implants. Optimum treatment is complete removal of the breast implants.

Contracture: A condition where scar tissue forms internally around the breast implant, tightens and makes the breast round, firm, and possibly painful. This excessive firmness of the breasts can occur soon after surgery or years later.

Contralateral: Pertaining to the opposite side which, in the case of breasts, refers to the breast not being medically treated.

Extrusion: A condition, where the lack of adequate tissue coverage, infection, or other conditions where skin may be weakened, that results in exposure of the implant through the skin.

Mastectomy: The surgical removal of a breast.

Mastopexy: A surgical procedure designed to elevate sagging breasts to a normal position, often with some improvement in shape.

Poland Syndrome: A condition where an individual is born missing some of their chest muscles and cartilage and did not develop a breast on one side of the chest during puberty.

Prophylactic mastectomy: A surgical procedure to remove a breast or both breasts with the purpose of reducing the risk of breast cancer in women determined to be at intermediate or high risk for developing breast cancer.

Reconstructive breast surgery: Surgical procedures performed to correct or repair abnormal structures of the breast that are designed to restore the normal appearance of one or both breasts.

Reduction mammaplasty (also referred to as reduction mammoplasty): A surgical procedure to decrease breast size.

Rupture: A condition where a liquid or gel-filled breast implant bursts, allowing leakage of its contents into the surrounding tissue.

Coding

The following codes for treatments and procedures applicable to this document are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. 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.

Reconstructive Breast Procedures before or after Breast Surgery
When services may be Reconstructive when criteria are met:

CPT	
11920-11922	Tattooing, intradermal introduction of insoluble opaque pigments to correct color defects of skin, including micropigmentation; 6.0 sq cm or less [when specified for nipple/areola reconstruction after breast surgery; includes codes 11920, 11921, 11922]
15877	Suction assisted lipectomy; trunk [when specified as a breast reconstruction procedure related to breast surgery]
17999	Unlisted procedure, skin, mucous membrane and subcutaneous tissue [when specified as aesthetic flat chest closure or chest wall reconstruction after breast surgery]
19316	Mastopexy
19318	Breast reduction
19325	Breast augmentation with implant
19340	Insertion of breast implant on same day of mastectomy (ie, immediate)
19342	Insertion or replacement of breast implant on separate day from mastectomy
19350	Nipple/areola reconstruction [when specified as a breast reconstruction procedure following breast surgery]
19355	Correction of inverted nipples

19357	Tissue expander placement in breast reconstruction, including subsequent expansion(s)
19361	Breast reconstruction; with latissimus dorsi flap
19364	Breast reconstruction; with free flap (eg, fTRAM, DIEP, SIEA, GAP flap)
19367	Breast reconstruction; with single-pedicled transverse rectus abdominis myocutaneous (TRAM) flap
19368	Breast reconstruction; with single-pedicled transverse rectus abdominis myocutaneous (TRAM) flap, requiring separate microvascular anastomosis (supercharging)
19369	Breast reconstruction; with bipedicled transverse rectus abdominis myocutaneous (TRAM) flap
19380	Revision of reconstructed breast (eg, significant removal of tissue, re-advancement and/or re-inset of flaps in autologous reconstruction or significant capsular revision combined with soft tissue excision in implant-based reconstruction)
19396	Preparation of moulage for custom breast implant

HCPCS

C1789	Prosthesis, breast (implantable)
L8600	Implantable breast prosthesis, silicone or equal
S2066	Breast reconstruction with gluteal artery perforator (GAP) flap, including harvesting of the flap, microvascular transfer, closure of donor site and shaping the flap into a breast, unilateral
S2067	Breast reconstruction of a single breast with “stacked” deep inferior epigastric perforator (DIEP) flap(s) and/or gluteal artery perforator (GAP) flap(s), including harvesting of the flap(s), microvascular transfer, closure of donor site(s) and shaping the flap into a breast, unilateral
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

ICD-10 Procedure

0H0T07Z-0H0V0ZZ	Alteration of breast [right, left or bilateral, with or without tissue or synthetic substitute, by approach; includes codes 0H0T07Z, 0H0T0JZ, 0H0T0KZ, 0H0T0ZZ, 0H0U07Z, 0H0U0JZ, 0H0U0KZ, 0H0U0ZZ, 0H0V07Z, 0H0V0JZ, 0H0V0KZ, 0H0V0ZZ]
0HHT0NZ-0HHV0NZ	Insertion of tissue expander into breast, open approach [right, left or bilateral; includes codes 0HHT0NZ, 0HHU0NZ, 0HHV0NZ]
0HPT0NZ-0HPU8NZ	Removal of tissue expander from breast [right or left, by approach; includes codes 0HPT0NZ, 0HPT3NZ, 0HPT7NZ, 0HPT8NZ, 0HPU0NZ, 0HPU3NZ, 0HPU7NZ, 0HPU8NZ]
0HRT075-0HRV075	Replacement of breast using latissimus dorsi myocutaneous flap, open approach [right, left or bilateral; includes codes 0HRT075, 0HRU075, 0HRV075]
0HRT076-0HRV076	Replacement of breast using transverse rectus abdominis myocutaneous flap, open approach [right, left or bilateral; includes codes 0HRT076, 0HRU076, 0HRV076]
0HRT077-0HRV077	Replacement of breast using deep inferior epigastric artery perforator flap, open approach [right, left or bilateral; includes codes 0HRT077, 0HRU077, 0HRV077]
0HRT078-0HRV078	Replacement of breast using superficial inferior epigastric artery flap, open approach [right, left or bilateral; includes codes 0HRT078, 0HRU078, 0HRV078]
0HRT079-0HRV079	Replacement of breast using gluteal artery perforator flap, open approach [right, left or bilateral; includes codes 0HRT079, 0HRU079, 0HRV079]
0HRT07Z-0HRV07Z	Replacement of breast with autologous tissue substitute, open approach [right, left or bilateral; includes codes 0HRT07Z, 0HRU07Z, 0HRV07Z]
0HRT0JZ-0HRV0JZ	Replacement of breast with synthetic substitute, open approach [right, left or bilateral; includes codes 0HRT0JZ, 0HRU0JZ, 0HRV0JZ]
0HRT0KZ-0HRV0KZ	Replacement of breast with nonautologous tissue substitute, open approach [right, left or bilateral; includes codes 0HRT0KZ, 0HRU0KZ, 0HRV0KZ]
0HRW07Z-0HRXXKZ	Replacement of nipple [right or left, by type of substitute and approach; includes codes 0HRW07Z, 0HRW0JZ, 0HRW0KZ, 0HRW37Z, 0HRW3JZ, 0HRW3KZ, 0HRWX7Z, 0HRWXJZ, 0HRWXKZ, 0HRX07Z, 0HRX0JZ, 0HRX0KZ, 0HRX37Z, 0HRX3JZ, 0HRX3KZ, 0HRXX7Z, 0HRXXJZ, 0HRXXKZ]
0HST0ZZ-0HSV0ZZ	Reposition breast, open approach [right, left or bilateral; includes codes 0HST0ZZ, 0HSU0ZZ, 0HSV0ZZ]
0HUT07Z-0HUV0KZ	Supplement breast, open approach [right, left or bilateral with tissue or synthetic substitute; includes codes 0HUT07Z, 0HUT0JZ, 0HUT0KZ, 0HUU07Z, 0HUU0JZ, 0HUU0KZ, 0HUV07Z, 0HUV0JZ, 0HUV0KZ]
0J060ZZ-0J063ZZ	Alteration of chest subcutaneous tissue and fascia [by approach, includes codes 0J060ZZ, 0J063ZZ]
0JD60ZZ-0JD63ZZ	Extraction of chest subcutaneous tissue and fascia [by approach; includes codes 0JD60ZZ, 0JD63ZZ]
0KXK0Z6-0KXL0Z6	Transfer abdomen muscle, transverse rectus abdominis myocutaneous flap, open approach [right or left; includes codes 0KXK0Z6, 0KXL0Z6]

ICD-10 Diagnosis

C50.011-C50.929	Malignant neoplasm of breast
C79.81	Secondary malignant neoplasm of breast
D05.00-D05.92	Carcinoma in situ of breast
N65.0-N65.1	Deformity and disproportion of reconstructed breast
T81.40XA-T81.40XS	Infection following a procedure, unspecified
T85.41XA-T85.49XS	Mechanical complication of breast prosthesis and implant
T85.79XA-T85.79XS	Infection and inflammatory reaction due to other internal prosthetic devices, implants and grafts
Z42.1	Encounter for breast reconstruction following mastectomy
Z85.3	Personal history of malignant neoplasm of breast
Z90.10-Z90.13	Acquired absence of breast and nipple

Reconstructive Breast Procedures for Other Indications:

When services may also be Reconstructive when criteria are met:
For the procedure codes listed above; for the following diagnoses:

ICD-10 Diagnosis	
N64.82	Hypoplasia of breast
Q67.6-Q67.7	Pectus excavatum, pectus carinatum
Q79.8	Other congenital malformations of musculoskeletal system (Poland syndrome)
Q83.0	Congenital absence of breast with absent nipple
Q83.2	Absent nipple
S21.001A-S21.009S	Unspecified open wound of breast
S21.011A-S21.019S	Laceration without foreign body of breast
S21.021A-S21.029S	Laceration with foreign body of breast
S28.211A-S28.229S	Traumatic amputation of breast

When services are Cosmetic and Not Medically Necessary:
For the procedure codes listed above when criteria are not met, or when the code describes a procedure indicated in the Position Statement section as cosmetic and not medically necessary.

Breast Implant Removal or Revision
When services may be Medically Necessary or Reconstructive when criteria are met:

CPT	
19328	Removal of intact breast implant
19330	Removal of ruptured breast implant, including implant contents (eg, saline, silicone gel)

ICD-10 Procedure	
0H2TXYZ-0H2UXYZ	Change other device in breast, external approach [right or left; includes codes 0H2TXYZ, 0H2UXYZ]
0HPT0JZ-0HPU0JZ	Removal of synthetic substitute from breast, open approach [right or left; includes codes 0HPT0JZ, 0HPU0JZ]
0HPT0KZ-0HPU0KZ	Removal of nonautologous tissue substitute from breast, open approach [right or left; includes codes 0HPT0KZ, 0HPU0KZ]
0HWT0JZ-0HWU0JZ	Revision of synthetic substitute in breast, open approach [right or left; includes codes 0HWT0JZ, 0HWU0JZ]
0HWT0KZ-0HWU0KZ	Revision of nonautologous tissue substitute in breast, open approach [right or left; includes codes 0HWT0KZ, 0HWU0KZ]

ICD-10 Diagnosis	
C50.011-C50.929	Malignant neoplasm of breast
C79.81	Secondary malignant neoplasm of breast
C84.60-C84.69	Anaplastic large cell lymphoma, ALK-positive
C84.70-C84.7A	Anaplastic large cell lymphoma, ALK-negative
C86.6	Primary cutaneous CD30-positive T-cell proliferations
D05.00-D05.92	Carcinoma in situ of breast
T81.40XA-T81.40XS	Infection following a procedure, unspecified
T85.41XA-T85.49XS	Mechanical complication of breast prosthesis and implant
T85.79XA-T85.79XS	Infection and inflammatory reaction due to other internal prosthetic devices, implants and grafts
Z40.8-Z40.9	Encounter for other/unspecified prophylactic surgery
Z42.1	Encounter for breast reconstruction following mastectomy
Z42.8	Encounter for other plastic and reconstructive surgery following medical procedure or healed injury
Z45.811-Z45.819	Encounter for adjustment or removal of breast implant
Z85.3	Personal history of malignant neoplasm of breast
Z98.82	Breast implant status

When services are Not Medically Necessary:
For the procedure and diagnosis codes listed above when criteria are not met, for all other diagnoses not listed; or when the code describes a procedure indicated in the Position Statement section as not medically necessary.

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Reduction Mammaplasty

The use of specific product names is illustrative only. It is not intended to be a recommendation of one product over another, and is not intended to represent a complete listing of all products available.

Document History

Status	Date	Action
Revised	11/09/2023	Medical Policy & Technology Assessment Committee (MPTAC) review. Revised formatting of Position Statement. Revised reconstructive statement related to procedures done in advance of mastectomy or lumpectomy. Moved reconstructive text related to procedure timing to Background section. Revised Position Statement section with text updates. Updated Rationale, Background, References, and Websites for Additional Information sections.

Revised	11/10/2022	MPTAC review. Chest wall reconstruction with flat chest closure was added to the list of surgical procedures considered 'Reconstructive' following surgery for breast cancer. The Rationale, Background, Index and References were updated. Updated Coding section to add CPT 17999 NOC code.
Revised	11/11/2021	MPTAC review. A cross-reference was added to the Scope for MED.000132 Adipose-derived Regenerative Cell Therapy and Soft Tissue Augmentation Procedures to direct the reader for fat grafting and other soft tissue augmentation procedures of the breast. The language of the Reconstructive statement was reformatted for clarification with no change to stance or criteria. The References were updated.
	10/01/2021	Updated Coding section with 10/01/2021 ICD-10-CM changes; added C84.7A.
	04/07/2021	Revised MN definition text in the Description section.
Reviewed	11/05/2020	MPTAC review. The Rationale and References sections were updated. Updated Coding section with 01/01/2021 CPT descriptor changes; codes 19324, 19366 deleted 12/31/2020.
	04/01/2020	Updated Coding section; corrected ICD-10 diagnosis codes T81.40XA-T81.40XS.
Revised	11/07/2019	MPTAC review. The MN indications for implant removal were expanded to add elective removal of Allergan BIOCELL textured breast implants and tissue expanders due to risk for BIA-ALCL. The Rationale, Coding, References and Index sections were updated.
Revised	06/06/2019	MPTAC review. Reduction mammaplasty done in advance of mastectomy or lumpectomy for breast cancer was added to the covered reconstructive procedures. The Background, References and Index sections were updated.
Revised	07/26/2018	MPTAC review. Breast implant-associated anaplastic large cell lymphoma (BIA-ALCL) was added to the medically necessary indications for implant removal. The Rationale, Coding, Definitions and References sections were updated.
	05/01/2018	The document header wording updated from "Current Effective Date" to "Publish Date."
Reviewed	08/03/2017	MPTAC review. Coding and References sections were updated.
Reviewed	08/04/2016	MPTAC review. References were updated. Removed ICD-9 codes from Coding section.
Reviewed	08/06/2015	MPTAC review. References were updated.
Reviewed	08/14/2014	MPTAC review. The Background, Coding and References sections were updated.
Reviewed	08/08/2013	MPTAC review. References were updated.
Revised	08/09/2012	MPTAC review. Position statements section was reformatted for clarification. Position statement for other procedures (including augmentation mammaplasty/breast lift, implant repositioning, repair of inverted nipples, mastopexy) was revised to state that these procedures are considered cosmetic and not medically necessary except when performed as part of a covered breast reconstruction service. The Rationale, Coding and References were updated.
	07/01/2012	Updated Coding section to recategorize CPT 19355.
Reviewed	08/18/2011	MPTAC review. The Definitions and References were updated.
Reviewed	08/19/2010	MPTAC review. References were updated.
	04/21/2010	Updated Coding section to add CPT 11921, 11922.
Revised	08/27/2009	MPTAC review. The language of the criteria under each category has been reformatted for clarification with no substantial revisions. References were updated.
Revised	08/28/2008	MPTAC review. The Reconstructive and medically necessary language for implant removal and replacement was clarified. Cosmetic language was also clarified. References were updated. Updated coding section with 10/01/2008 ICD-9 changes.
	02/21/2008	The phrase "cosmetic/not medically necessary" was clarified to read "cosmetic and not medically necessary." This change was approved at the November 29, 2007 MPTAC. meeting. A NOTE was added after the Reconstructive Definition to clarify that not all benefit contracts include a reconstructive services benefit.
Revised	08/23/2007	MPTAC review. Information was added to the Description and to the statements under Reconstructive Surgery and Management of Breast Implants sections regarding the definitions of "Reconstructive," "Medically Necessary" and "Cosmetic" for clarification. References were also updated.
	07/01/2007	Updated Coding section with 07/01/2007 HCPCS changes.
Reviewed	09/14/2006	MPTAC review. References were updated.
	11/17/2005	Added reference for Centers for Medicare and Medicaid Services (CMS) – National Coverage Determination (NCD).
Revised	09/22/2005	MPTAC review. Revision based on Pre- merger Anthem and Pre-merger WellPoint Harmonization.

Pre-Merger Organizations	Last Review Date	Document Number	Title
Anthem, Inc.	04/27/2004	SURG.00023	Breast Procedures; including Prophylactic Mastectomy; Reconstructive Surgery, including implants; Reduction Mammaplasty; Mastectomy for Gynecomastia
WellPoint Health Networks, Inc.	06/24/2004	3.01.09	Reconstructive Breast Surgery
	12/02/2004	Clinical Guidelines	Removal of Breast Implants
	12/02/2004	Clinical Guidelines	Reimplantation of Breast Implants

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Applicable to Commercial HMO members in California: When a medical policy states a procedure or treatment is investigational, PMGs should not approve or deny the request. Instead, please fax the request to Anthem Blue Cross Grievance and Appeals at fax # 818-234-2767 or 818-234-3824. For questions, call G&A at 1-800-365-0609 and ask to speak with the Investigational Review Nurse.

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 eligibility for coverage. The member's contract benefits in effect on the date that services are rendered must be used. Medical Policy, which addresses medical efficacy, should be considered before utilizing medical opinion in adjudication. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.