


MEDICAL POLICY	Breast Surgery: Reduction Mammoplasty, Reconstructive Surgery, and Implant Management (All Lines of Business Except Medicare)
Effective Date: 7/1/2022	Medical Policy Number: 58
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Medical Officer	Date

See Policy CPT CODE section below for any prior authorization requirements

SCOPE:

Providence Health Plan, Providence Health Assurance, Providence Plan Partners, and Ayin Health Solutions as applicable (referred to individually as “Company” and collectively as “Companies”).

APPLIES TO:

All lines of business except Medicare (unless otherwise directed by a Medicare medical policy. Note that investigational services are considered “not medically necessary” for Medicare members.)

BENEFIT APPLICATION

Medicaid Members

Oregon: Services requested for Oregon Health Plan (OHP) members follow the OHP Prioritized List and Oregon Administrative Rules (OARs) as the primary resource for coverage determinations. Medical policy criteria below may be applied when there are no criteria available in the OARs and the OHP Prioritized List.

POLICY CRITERIA

Policy Criteria Links

- [Breast Reconstruction](#)
- [Reduction Mammoplasty](#)
 - [Mammoplasty Related to Mastectomy or Lumpectomy](#)
 - [Mammoplasty to Treat Macromastia](#)
- [Breast Implant Removal](#)
 - [Breast Implant Removal after Mastectomy or Lumpectomy](#)
 - [Removal of Cosmetically Placed Breast Implant](#)

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Breast Reconstruction

Notes:

- The policy criteria below apply to any period of time after mastectomy, lumpectomy, injury, or trauma.
 - Other Medical Policies may apply to breast reconstruction services. Please see the [Medical Policy Cross References](#) section below for more information.
- I. Reconstructive breast surgery may be considered **medically necessary** when recommended by the treating physician and **any** of the following (A.-C.) criteria are met:
 - A. After a prophylactic or therapeutic mastectomy or lumpectomy; **or**
 - B. If traumatic injury or surgery of the affected breast results in an asymmetrical change in breast shape or development compared to the contralateral breast; **or**
 - C. To correct a congenital or developmental abnormality, which is known to affect normal breast growth. Examples of abnormalities may include, but are not limited to: Poland syndrome, absence, hypoplasia, unilateral hypertrophy/macromastia, or malformation of the pectoralis muscles, upper coastal cartilage, or breast.
 - II. In members who have a condition noted in criteria I.A-C. above, reconstructive breast surgery of the unaffected, contralateral breast may be considered **medically necessary** to achieve symmetry when recommended by the treating physician.
 - III. Skin substitutes approved for breast reconstruction may be considered **medically necessary** when criteria I. or II. above are met.
 - IV. Breast surgery is considered cosmetic when used strictly to reshape the breasts to improve appearance in the absence of a medically necessary indication. Therefore, breast reconstruction surgery is considered **cosmetic and not covered** if the patient does not meet any of criteria I.A. – I.C. above.

Reduction Mammoplasty

Notes:

- This policy does not address the use of reduction mammoplasty as a treatment of male gynecomastia (CPT 19300), which is addressed in the “Cosmetic and Reconstructive Surgery” medical policy.
- This policy does not address the use of reduction mammoplasty as a treatment of gender dysphoria, which is addressed in the “Gender Affirming Interventions” medical policy.

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Mammoplasty Related to Mastectomy or Lumpectomy

Note: The following criteria for mammoplasty related to mastectomy or lumpectomy apply to the affected and/or unaffected breast.

Staged Procedure

- V. A staged reduction mammoplasty as a *preparatory first stage procedure preceding a nipple-sparing mastectomy*, may be considered **medically necessary** to achieve symmetry or as deemed necessary by the provider for appropriate reconstruction.

Non-staged Procedure

- VI. A non-staged reduction mammoplasty may be considered **medically necessary** as a treatment related to mastectomy or deforming lumpectomy when **either** of the following criteria are met:
- A. To achieve symmetry; **or**
 - B. Reduction surgery is required to facilitate radiation therapy.

Mammoplasty to Treat Macromastia

Note: For all reduction mammoplasty requests for the treatment of macromastia, the following patient information/documentation must be submitted with the surgical request:

- History and physical with evidence of conservative treatment
 - Estimated amount of tissue to be removed
 - Bra size
 - Photographs showing macromastia and shoulder grooving
 - Height and Weight
- VII. For those who are 18 years and older, reduction mammoplasty may be considered **medically necessary** as a treatment of macromastia when **all** of the following criteria (A.-D.) are met:
- A. Documentation of a three-month trial of conservative management such as physical therapy, exercise, weight loss, and pain medication; **and**
 - B. Photographs must be submitted to demonstrate as clinical evidence of the medical need for reduction surgery; **and**
 - C. The clinical records indicate there is significant physiologic/symptomatology which

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are chronic and are refractory to conservative management which are documented by **both** of the following:

1. Symptoms are chronic and have existed for a minimum of one year; **and**
2. One or more of the following:
 - a. Shoulders, neck or back pain where there is high probability that the symptoms are due to macromastia; **or**
 - b. Nerve root compression where there is high probability that the symptoms are due to macromastia; **or**
 - c. Other pain syndrome due to bra straps where there is high probability that the symptoms are due to macromastia; **and**

- D. The amount of breast tissue removed from each breast is at least the minimum in grams per breast for the patient's body surface area* (see [Policy Guidelines](#) for body surface area/breast weight table). In the case of significant breast asymmetry, the combined total in grams must meet Schnur criteria for total grams of breast tissue removed.

VIII. For those who are less than 18 years of age, reduction mammoplasty may be considered **medically necessary** as a treatment of macromastia when **all** of the following criteria (A. – C.) are met:

- A. Criteria III (A. – D.) above are met; **and**
- B. Documentation of stability of breast size for at least one year; **and**
- C. Completion of puberty changes.

IX. Reduction mammoplasty be considered **medically necessary** as a treatment of unilateral hypertrophy/macromastia.

X. Reduction mammoplasty is considered **cosmetic and is not covered** when any of the criteria V-IX. above are not met.

Breast Implant Removal

Breast Implant Removal after Mastectomy or Lumpectomy

XI. Surgical removal and/or replacement of any type of breast implant (e.g., saline or silicone) after mastectomy or lumpectomy is considered **medically necessary**.

XII. Surgical removal and/or replacement of any type of breast implant (e.g., saline or silicone) in the contralateral breast after mastectomy or lumpectomy in the affected breast is considered **medically necessary**.

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Notes:

- If one breast implant ruptures, removal and/or replacement of both breast implants may be appropriate.
- Clinical documentation should indicate the original breast implant(s) were placed following a mastectomy or lumpectomy.
- Both breast implant and capsulectomy removal may be covered.

Removal of Cosmetically Placed Breast Implant

XIII. Surgical removal of a cosmetically placed silicone gel-filled breast implant with or without capsulectomy may be considered **medically necessary** when a pre-operative imaging study demonstrates implant failure (i.e., rupture or silicone outside of implant).

XIV. Surgical removal of any type of cosmetically placed breast implant (e.g., saline or silicone) with or without capsulectomy may be considered **medically necessary** when **any** of the following conditions is present:

- A. Breast implant-related infection; **or**
- B. Breast implant associated large cell lymphoma (BIA-ALCL); **or**
- C. Extrusion/exposure of implant through skin; **or**
- D. Implants with Baker Class IV contracture (see [Policy Guidelines](#) for Baker Classification) associated with severe pain
- E. Increased risk of breast implant-associated anaplastic large cell lymphoma due to use of textured breast implants and tissue expanders. Examples include, but are not limited to: Allergan BIOCELL, McGhan, and Natrelle.

XIII. Surgical removal of a cosmetically placed breast implant in the contralateral breast is considered **medically necessary** when the affected breast meets criterion XII or XIII above.

XIV. Surgical removal of cosmetically placed breast implant(s) is considered **not medically necessary and is not covered** when criterion XII or XIII above is not met, including but not limited to the removal of a ruptured, saline-filled implant.

Link to [Policy Summary](#)

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Policy Guidelines

*Body Surface Area Calculations

The estimate of amount of tissue to be removed must satisfy the minimum amounts of the Schnur criteria per breast as determined by body surface area.^{1,2}

*Body surface area is calculated using the following formula:

$$\text{Take the square root of: } \frac{\text{Ht. (inches)} \times \text{Wt. (lbs)}}{3,131} = \text{BSA m}^2$$

Body surface area (m²) and cutoff weight of breast tissue removed:

Body Surface Area m ²	Minimum Breast Tissue to be removed in grams per breast	Body Surface Area m ²	Minimum Breast Tissue to be removed in grams per breast
1.35	199	2.35	1167
1.40	218	2.40	1275
1.45	238	2.45	1393
1.50	260	2.50	1522
1.55	284	2.55	1662
1.60	310	2.60	1806
1.65	338	2.65	1972
1.70	370	2.70	2154
1.75	404	2.75	2352
1.80	441	2.80	2568
1.85	482	2.85	2804
1.90	527	2.90	3061
1.95	575	3.00	3343
2.00	628	3.05	3650
2.05	687	3.10	3985
2.10	750	3.15	4351
2.15	819	3.20	4750
2.20	895	3.25	5186
2.25	978	3.30	5663
2.30	1068	3.35	6182

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Baker Classification

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

BILLING GUIDELINES

Reimbursement for a non-covered procedure performed at the same operative session as a covered surgical procedure will not be allowed.

Free Flap Breast Reconstruction

HCPCS codes S2066-S2068 are not covered by the Company unless allowed under a provider contract exception, as indicated in the relevant Company coding policy (Coding Policy 22.0 HCPCS S-Codes and H-Codes). In addition, according to CPT Guidelines, “Code 19364 describes a microsurgical free tissue transfer of skin and subcutaneous fat and/or muscle for breast reconstruction. This code includes the flap harvest, microsurgical anastomosis of one artery and two veins with use of an operating microscope, flap inset as a breast mound, and donor-site closure. Typical free flaps include free transverse rectus abdominis myocutaneous (fTRAM), deep inferior epigastric perforator (DIEP), superficial inferior epigastric artery (SIEA), or gluteal artery perforator (GAP) flaps.” Therefore, CPT code 19364 is the appropriate code to use and HCPCS codes S2066-S2068 are not accepted.

CPT CODES

All Lines of Business Except Medicare	
Prior Authorization Required	
11920	Tattooing, intradermal introduction of insoluble opaque pigments to correct color defects of skin, including micropigmentation; 6.0 sq cm or less
11921	Tattooing, intradermal introduction of insoluble opaque pigments to correct color defects of skin, including micropigmentation; 6.1 to 20.0 sq cm

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11922	Tattooing, intradermal introduction of insoluble opaque pigments to correct color defects of skin, including micropigmentation; each additional 20.0 sq cm, or part thereof (List separately in addition to code for primary procedure)
19316	Mastopexy
19318	Breast reduction
19325	Breast augmentation with implant
19328	Removal of intact implant
19330	Removal of ruptured breast implant, including implant contents (eg, saline, silicone gel)
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
19355	Correction of inverted nipples
19357	Breast reconstruction, immediate or delayed, with tissue expander, including subsequent expansion
19361	Breast reconstruction with latissimus dorsi flap, without prosthetic implant
19364	Breast reconstruction; with free flap (eg, fTRAM, DIEP, SIEA, GAP flap)
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
19396	Preparation of moulage for custom breast implant
No Prior Authorization Required	
11970	Replacement of tissue expander with permanent prosthesis
11971	Removal of tissue expander(s) without insertion of prosthesis

DESCRIPTION

Breast Reconstruction

Breast reconstruction after mastectomy is covered for both the abnormal breast (flap reconstruction or prosthesis) and the normal breast (reduction for symmetry).

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Occasionally a lumpectomy (partial mastectomy) necessitates a wide resection and results in deformity of the affected breast. Surgical procedures to correct the defect and to achieve symmetry may be covered.

The medical necessity criteria within this policy are primarily based on the Women’s Health and Cancer Rights Act (WHCRA) of 1998. The WHCRA requires all insurance carriers that cover mastectomies to also cover the following in consultation with the attending physician and patient:³

“All stages of reconstruction of the breast on which the mastectomy was performed, surgery and reconstruction of the other breast to produce a symmetrical appearance, prostheses and treatment of physical complications of the mastectomy, including lymphedema.”⁴

The WHCRA law is not limited to cancer patients or women and applies to anyone who has had a mastectomy.

Reduction Mammoplasty

Coverage of reduction mammoplasty related to mastectomy due to suspected or confirmed malignancy is governed by the Women's Health and Cancer Rights Act of 1998 (WHCRA) in addition to applicable state and federal regulations.⁴⁻⁶

The medical necessity criteria within this policy that address mammoplasty related to mastectomy or lumpectomy are primarily based on the Women’s Health and Cancer Rights Act (WHCRA) of 1998. The WHCRA requires all insurance carriers that cover mastectomies to also cover the following in consultation with the attending physician and patient:

“All stages of reconstruction of the breast on which the mastectomy was performed, surgery and reconstruction of the other breast to produce a symmetrical appearance, prostheses and treatment of physical complications of the mastectomy, including lymphedema.”⁴

The WHCRA law is not limited to cancer patients or women and applies to anyone who has had a mastectomy.

Coverage for the surgical reduction of very large breasts (macromastia) is provided to relieve significant pain in the shoulders, neck and back. It is not covered for appearance improvement, breast ptosis, better fitting clothing or any other cosmetic reason.

Normal physiology promotes deposition of fat within the mammary structure. Any degree of obesity may be associated with disproportionate increase in breast size. Attainment of ideal body weight should be attempted prior to consideration of surgical intervention.

Breast Implant Removal

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Reconstructive Surgery

Reconstructive surgery refers to the use of surgery to restore the form and function of the body or to correct a deformity resulting from disease, injury, trauma, birth defects, congenital anomalies, infections, burns or previous medical treatment, such as surgery or radiation therapy. The most common type of reconstructive breast surgery is insertion of a silicone gel-filled or saline-filled breast implant, inserted either at the time of mastectomy or sometime afterward in conjunction with the use of a tissue expander prior to implant placement. Implants on the contralateral breast may be performed in order to achieve symmetry with the reconstructed breast.

Cosmetic Surgery

Cosmetic surgery refers to an elective surgery that is performed to reshape normal structures of the body with the goal of enhancing the patient’s “natural” appearance and self-esteem.

Women’s Health and Cancer Rights Act of 1998 (WHCRA)

Based on the Women’s Health and Cancer Rights Act of 1998 (WHCRA),³ services following a medically necessary (e.g., for trauma, breast cancer or a prophylactic mastectomy), coverage is required for:

- All stages of reconstruction of the breast on which the mastectomy was performed
- Surgery and reconstruction of the other breast to produce a symmetrical appearance
- Protheses
- Treatment of physical complications of the mastectomy, including lymphedema

REVIEW OF EVIDENCE

This policy is primarily based on the Women’s Health and Cancer Rights Act (WHCRA) of 1998. Therefore, an evidence review was only performed for cosmetic breast implant removal.

Cosmetic Breast Implant Removal

A review of the ECRI, Hayes, Cochrane, and PubMed databases was conducted regarding cosmetic breast implant removal. Below is a summary of the available evidence identified through May 2022.

- In 2016, deBoer and colleagues published a systematic review of existing literature regarding explantation of silicone breast implants in patients with complaints.⁷ The review included 23 studies which were assessed to determine if clinical manifestations and autoimmune diseases improved after explantation. In addition, authors examined the effect of explantation on laboratory findings. Studies which reported on implant removal due to rupture were not included in this review. In patients with silicone related complications (469 of 622 patients) a

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75% improvement of complications was reported. However, in patients with autoimmune diseases, only 16% (3 of 18 patients) improvement was reported. In addition, no documented influence on autoantibody testing, such as antinuclear antibody (ANA), was reported. Limitations of this analysis include the subjective nature of patient reporting of pain and other symptoms. In addition, the quality of studies included in the review was low with many retrospective case reports and case series articles included.

- In 2017, Leberfinger and colleagues published a systematic review of studies which evaluated the prevalence of large cell lymphoma (BIA-ALCL) in patients with breast implants.⁸ In all a total of 93 cases of large cell lymphoma have been reported and almost all have been associated with textured implants. The authors indicated that, “(t)he underlying mechanism is thought to be due to chronic inflammation from indolent infections, leading to malignant transformation of T cells that are anaplastic lymphoma kinase (ALK) negative and CD30 positive.” Time to presentation was estimated to be approximately 10 years from placement. Although an association of disease onset was suggested, causality was not assessed.
- A Hayes review (updated 2018; archived 2020) of ALCL associated with silicone breast implants indicated the following, “(b)ased on review of the abstracts and the FDA reports, the evidence suggests that, although the risk is very low and occurrence is extremely rare, ALCL may be associated with both silicone and saline breast implants. In situ breast implant associated–ALCL (BIA-ALCL), which is confined to the fibrous capsule and often identified by a seroma, is usually indolent and has a good prognosis, often requiring only a capsulectomy and implant removal and no further treatment to achieve complete remission.”⁹

CLINICAL PRACTICE GUIDELINES

National Comprehensive Cancer Network (NCCN)

In 2022, the NCCN published guidelines for the treatment of breast cancer (Version 3.2022), as part of which investigators addressed the principles of breast reconstruction following surgery.¹⁰ The guideline stated that:

“Breast reconstruction may be an option for any woman receiving surgical treatment for breast cancer. All women undergoing breast cancer treatment should be educated about breast reconstructive options as adapted to their individual clinical situation. However, breast reconstruction should not interfere with the appropriate surgical management of the cancer or the scope of appropriate surgical treatment for this disease...

Surgical options for breast reconstruction following mastectomy include:

- Procedures that incorporate breast implants (ie, tissue expander placement followed by implant placement, immediate implant placement)

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- Procedures that incorporate autologous tissue transplantation (ie, pedicled TRAM flap, fat grafting, various microsurgical flaps from the abdomen, back, buttocks, and thigh)
- Procedures that incorporate both breast implants and autologous tissue transplantation (eg, latissimus dorsi flaps).¹⁰

American Society of Plastic Surgeons (ASPS)

In 2011, the ASPS published clinical practice guidelines for reduction mammoplasty.^{11,12} The ASPS defines symptomatic breast hypertrophy as:

“a syndrome of persistent neck and shoulder pain, painful shoulder grooving from brassiere straps, chronic intertriginous rash of the inframammary fold, and/or frequent episodes of headache, backache, and upper extremity peripheral neuropathies caused by an increase in the volume and weight of breast tissue beyond normal proportions.”

The ASPS indicated that reduction mammoplasty is effective in reducing breast-related symptoms in patients with symptomatic breast hypertrophy. This was a strong recommendation; based on level I evidence (high-quality, multicenter or single-center, randomized controlled trials with adequate power; or systematic review of these studies).

The ASPS also indicated volume of breast tissue resection is not correlated to the degree of postoperative symptom relief and therefore should not be criteria for reduction mammoplasty. This was not a strong recommendation. Furthermore, if at least two out of seven breast-related physical symptoms are present all or most of the time, reduction mammoplasty is appropriate. However, these statements are primarily based on observational studies which lack randomized control groups and have a potential for selection bias.

American College of Obstetricians and Gynecologists (ACOG)

The ACOG published a consensus based expert Committee Opinion in 2017 (reaffirmed 2020) regarding adolescent breast and labial surgery.¹³ The recommendations include providing extensive patient education regarding nonsurgical alternatives, reassurance regarding normal variation in anatomy, growth, and development, screening for body dysmorphic disorder, and assessing the adolescent’s physical maturity and emotional readiness before surgical management or referral. The discussion section on breast reduction surgery notes that, “recommendations for timing of surgery include postponing surgery until breast maturity is reached, waiting until there is stability in cup size over 6 months, and waiting until the age of 18 years.” The authors also state there is “no one consensus on timing” and reiterate the need for the surgeon’s assessment of the adolescent’s total physical and emotional state.

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Reduction mammoplasty

Reduction mammoplasty related to mastectomy due to suspected or confirmed malignancy is governed by the Women's Health and Cancer Rights Act of 1998 (WHCRA) in addition to applicable state and federal regulations. For that reason, medical necessity criteria are primarily based on the Women's Health and Cancer Rights Act (WHCRA) of 1998. This law is not limited to cancer patients or women and applies to anyone who has had a mastectomy. The surgical reduction of very large breasts (macromastia) is provided to relieve significant pain in the shoulders, neck and back. It is not covered for appearance improvement, breast ptosis, better fitting clothing or any other cosmetic reason.

Implant Removal

There is a lack of high-quality published studies and clinical practice guidelines assessing the medical necessity of breast implant explantation. However, medical consensus holds that breast implant removal may be medically necessary following mastectomy or lumpectomy, or in the cases of implant failure, infection, extrusion, or breast implant- associated large cell lymphoma.

INSTRUCTIONS FOR USE

Company Medical Policies serve as guidance for the administration of plan benefits. Medical policies do not constitute medical advice nor a guarantee of coverage. Company Medical Policies are reviewed annually and are based upon published, peer-reviewed scientific evidence and evidence-based clinical practice guidelines that are available as of the last policy update. The Companies reserve the right to determine the application of Medical Policies and make revisions to Medical Policies at any time. Providers will be given at least 60-days' notice of policy changes that are restrictive in nature.

The scope and availability of all plan benefits are determined in accordance with the applicable coverage agreement. Any conflict or variance between the terms of the coverage agreement and Company Medical Policy will be resolved in favor of the coverage agreement.

REGULATORY STATUS

Mental Health Parity Statement

Coverage decisions are made on the basis of individualized determinations of medical necessity and the experimental or investigational character of the treatment in the individual case. In cases where medical necessity is not established by policy for specific treatment modalities, evidence not previously considered regarding the efficacy of the modality that is presented shall be given consideration to determine if the policy represents current standards of care.

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MEDICAL POLICY CROSS REFERENCES

- Cosmetic and Reconstructive Procedures (All Lines of Business Except Medicare),
- Cosmetic and Reconstructive Procedures (Medicare Only)
- Skin Substitutes
- Surgical Treatments for Lymphedema

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