


MEDICAL POLICY	Breast Implant Removal (All Lines of Business Except Medicare)
Effective Date: 7/1/2021	Medical Policy Number: 59
 7/1/2021	Medical Policy Committee Approved Date: 6/99; 6/00; 5/01; 10/01; 11/02; 10/03; 9/04; 11/06; 11/08; 10/12; 8/13; 10/14; 11/15; 12/16; 3/18; 8/19; 5/2020; 6/2021
Medical Officer	Date

See Policy CPT/HCPCS 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

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

Breast Implant Removal after Mastectomy or Lumpectomy

- I. Surgical removal and/or replacement of any type of breast implant after mastectomy or lumpectomy is considered **medically necessary and covered**.
- II. Surgical removal and/or replacement of any type of breast implant in the contralateral breast after mastectomy or lumpectomy in the affected breast is considered **medically necessary and covered**.

MEDICAL POLICY	Breast Implant Removal (All Lines of Business Except Medicare)
-----------------------	---

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

- III. Surgical removal of a cosmetically-placed breast implant with or without capsulectomy may be considered **medically necessary and covered** when **any** of the following conditions is present (A.-E.):
- A. A pre-operative imaging study demonstrates implant failure (i.e., rupture or silicone outside of implant) of a silicone gel-filled breast implant; **or**
 - B. Breast implant-related infection; **or**
 - C. Breast implant associated large cell lymphoma (BIA-ALCL); **or**
 - D. Extrusion/exposure of implant through skin; **or**
 - 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.
- IV. Surgical removal of a cosmetically-placed breast implant in the contralateral breast is considered **medically necessary and covered** when the affected breast meets criterion III. above.
- V. Surgical removal cosmetically-placed breast implant(s) is considered **not medically necessary and is not covered**, when criterion III. above is not met, including but not limited to the removal of a ruptured, saline-filled implant.

Link to [Policy Summary](#)

BILLING GUIDELINES

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

MEDICAL POLICY	Breast Implant Removal (All Lines of Business Except Medicare)
-----------------------	---

CPT CODES

All Lines of Business Except Medicare	
Prior Authorization Required	
19328	Removal of intact mammary implant
19330	Removal of mammary implant material
19340	Immediate insertion of breast prosthesis following mastopexy, mastectomy or in reconstruction
19342	Delayed insertion of breast prosthesis following mastopexy, mastectomy or in reconstruction
19370	Open periprosthetic capsulotomy, breast
19371	Periprosthetic capsulectomy, breast
19380	Revision of reconstructed breast

DESCRIPTION

Reconstructive Surgery

Reconstructive surgery refers to the use of surgery to restore the form and function of the body 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),¹ 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
- Prostheses
- Treatment of physical complications of the mastectomy, including lymphedema

MEDICAL POLICY	Breast Implant Removal (All Lines of Business Except Medicare)
-----------------------	---

REVIEW OF EVIDENCE

Breast Implant Removal Following Mastectomy/Lumpectomy

The Women’s Health and Cancer Rights Act of 1998 (WHCRA) provides protections for individuals who elect breast reconstruction after a mastectomy by requiring group health plans that offer mastectomy coverage to provide coverage for services relating to the mastectomy. This includes all stages of reconstruction of the breast on which the mastectomy was performed as well as surgery and reconstruction of the other breast to produce a symmetrical appearance, and provision of a prostheses.¹

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 April 2021.

- In 2016, deBoer and colleagues published a systematic review of existing literature regarding explantation of silicone breast implants in patients with complaints.² 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 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.³ 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

MEDICAL POLICY	Breast Implant Removal (All Lines of Business Except Medicare)
-----------------------	---

indolent and has a good prognosis, often requiring only a capsulectomy and implant removal and no further treatment to achieve complete remission.”⁴

CLINICAL PRACTICE GUIDELINES

No evidence-based clinical practice guidelines were identified regarding the surgical removal of breast implants.

POLICY SUMMARY

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.

MEDICAL POLICY CROSS REFERENCES

- Breast Reconstruction
- Breast Implant Removal (Medicare Only)

MEDICAL POLICY	Breast Implant Removal (All Lines of Business Except Medicare)
-----------------------	---

REFERENCES

1. Centers for Medicare & Medicaid Services. Women's Health and Cancer Rights Act (WHCRA). https://www.cms.gov/CCIIO/Programs-and-Initiatives/Other-Insurance-Protections/whcra_factsheet. Published 2013. Accessed 4/27/2021.
2. De Boer M, Colaris M, van der Hulst R, Tervaert JC. Is explantation of silicone breast implants useful in patients with complaints? *Immunologic research*. 2017;65(1):25-36
3. Leberfinger AN, Behar BJ, Williams NC, et al. Breast implant–associated anaplastic large cell lymphoma: a systematic review. *JAMA surgery*. 2017;152(12):1161-1168
4. Hayes Inc. Anaplastic Large Cell Lymphoma (ALCL) Associated With Textured Silicone Breast Implants. <https://evidence.hayesinc.com/report/crr.anaplastic3733>. Published 2018 (archived 2020). Accessed 4/27/2021.