MEDICAL POLICY

Breast Implant Removal
(All Lines of Business Except Medicare)

Effective Date: 6/1/2020

Medical Officer Date

Section: SUR Policy No: 163

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

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.
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Note:
- 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 Allergan BIOCELL textured breast implants and tissue expanders.

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.
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CPT CODES

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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
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 prosthesis.

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 February 2020.

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

**CLINICAL PRACTICE GUIDELINES**

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

**POLICY SUMMARY**

Peer-reviewed evidence and clinical practice guidelines assessing the medical necessity of breast implant explantation is limited in quality and quantity. 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, breast implant-associated large cell lymphoma or pain related to capsular contracture.

**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.

**MEDICAL POLICY CROSS REFERENCES**

- Breast Reconstruction, SUR162
- Breast Implant Removal (Medicare Only), SUR448
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REFERENCES