Geisinger

# Geisinger Health Plan Policies and Procedure Manual

**Policy: MP099**

**Section: Medical Benefit Policy**

**Subject: Breast Implants Removal**

**Applicable Lines of Business**

| | | | |
|---|---|---|---|
| **Commercial** | **X** | **CHIP** | **X** |
| **Medicare** | **X** | **ACA** | **X** |
| **Medicaid** | **X** | | |

**I. Policy:** Breast Implants – Removal

**II. Purpose/Objective:**

To provide a policy of coverage regarding Breast Implants – Removal

**III. Responsibility:**

A. Medical Directors
B. Medical Management

**IV. Required Definitions**

1. Attachment – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. Exhibit – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. Devised – the date the policy was implemented.
4. Revised – the date of every revision to the policy, including typographical and grammatical changes.
5. Reviewed – the date documenting the annual review if the policy has no revisions necessary.

**V. Additional Definitions**

Medical Necessity or Medically Necessary means Covered Services rendered by a Health Care Provider that the Plan determines are:

a. appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
b. provided for the diagnosis, and the direct care and treatment of the Member's condition, illness disease or injury;
c. in accordance with current standards of good medical treatment practiced by the general medical community.
d. not primarily for the convenience of the Member, or the Member's Health Care Provider; and
e. the most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

**Medicaid Business Segment**

Medically Necessary — A service, item, procedure, or level of care that is necessary for the proper treatment or management of an illness, injury, or disability is one that:

- Will, or is reasonably expected to, prevent the onset of an illness, condition, injury or disability.
- Will, or is reasonably expected to, reduce or ameliorate the physical, mental or developmental effects of an illness, condition, injury or disability.
- Will assist the Member to achieve or maintain maximum functional capacity in performing daily activities, taking

into account both the functional capacity of the Member and those functional capacities that are appropriate for Members of the same age

**DESCRIPTION:**
At the time of the FDA hearing on silicone breast implants in February of 1992, the FDA advised that ruptured silicone implants should be removed since the health risks of extruded silicone are not known. Rupture of silicone implants can be subdivided into two categories - intra and extra capsular. Extracapsular silicone can induce granulomatous reaction and can occasionally migrate to the axillary lymph nodes, producing a lymphadenopathy which can mimic cancer. The FDA has indicated that ruptured silicone implants, whether intracapsular or extracapsular, should be explanted.

**INDICATIONS:**
For members who have undergone cosmetic breast augmentation to treat gender dysphoria, or reconstruction following cancer surgery or prophylactic mastectomy, removal of breast implants is considered medically necessary for any of the following indications:

- Breast cancer (new onset or recurrent disease) or chest wall tumors in proximity to the implant; or
- Intra- or extra-capsular rupture of silicone gel implant; or
- Extra-capsular rupture of saline implant if post-cancer reconstruction cosmetic outcome is compromised

- Implants with severe contracture that interferes with mammography; or
- Implants with contracture associated with pain (Baker Class III or IV)*; or
- Implants complicated by persistent or recurrent local or systemic infection secondary to the breast implant and refractory to medical management, including antibiotics
- Erosion of the implant through the skin or scar
- Breast implant-associated anaplastic large cell lymphoma
- Elective removal in members at an increased risk of breast implant-associated anaplastic large cell lymphoma due to use of Allergan BIOCELL textured breast implants and tissue expanders
- Removal of ruptured silicone breast implant in members who have undergone cosmetic breast augmentation (not related to breast cancer or prophylactic mastectomy) is considered medically necessary based on increased risk of medical complications.

*Baker's Classification of Capsular Contracture

| Grade I (Absent) | Grade II (Minimal) | Grade III (Moderate) | Grade IV (Severe) |
|---|---|---|---|
| The breast is soft with no palpable capsule and looks natural. | The breast is a little firm with a palpable capsule but looks normal. | The breast is firm with an easily palpated capsule and is visually abnormal. | The breast is hard, cold, painful, and markedly distorted. |

**LIMITATIONS:**
If the criteria for breast implant removal is met unilaterally, removal of the contra-lateral implant is considered medically necessary if done at the same time.

The Plan will provide coverage for insertion of initial breast implants and for the replacement of breast implants inserted following a medically necessary mastectomy (i.e., mastectomy for breast cancer or a prophylactic mastectomy) as outlined in MP 64 Post Mastectomy Breast Reconstruction.

The Plan considers the removal of breast implants for the identified medical indications to be medically necessary even if the implants were originally inserted for non-medical cosmetic enhancement purposes. However, the Plan will consider the reinsertion of new breast implants in this situation to be **cosmetic** and **NOT COVERED.**

**EXCLUSIONS:**
Removal of ruptured saline –filled breast implant in members who have undergone cosmetic breast augmentation (not related to breast cancer or prophylactic mastectomy) is considered **cosmetic** and **NOT COVERED**.

There is no scientific evidence that intact silicone breast implants increase risk of connective tissue disease or autoimmune disease. Removal of an intact implant not meeting criteria for coverage indications is considered **not medically necessary** and **NOT COVERED.**

There is insufficient evidence that intact textured breast implants (silicone or saline) pose a greater than average risk of breast implant-associated anaplastic large cell lymphoma. Currently, the FDA is not recommending prophylactic breast implant removal in patients in the absence of signs or symptoms noted above. Removal of an intact implant not meeting criteria for coverage indications is considered **not medically necessary** and **NOT COVERED**.

There is no scientific evidence to support removal/replacement of intact implants based solely on the manufacturer's rated "lifespan" of the implant. Removal of an intact implant in the absence of meeting criteria for coverage indications is **considered not medically necessary** and **NOT COVERED.**

## Medicaid Business Segment:

Any requests for services, that do not meet criteria set in the PARP, may be evaluated on a case by case basis

**Note: A complete description of the process by which a given technology or service is evaluated and determined to be experimental, investigational or unproven is outlined in MP 15 - Experimental Investigational or Unproven Services or Treatment.**

**CODING ASSOCIATED WITH: Breast Implants Removal**

***The following codes are included below for informational purposes and may not be all inclusive. Inclusion of a procedure or device code(s) does not constitute or imply coverage nor does it imply or guarantee provider reimbursement. Coverage is determined by the member specific benefit plan document and any applicable laws regarding coverage of specific services. Please note that per Medicare coverage rules, only specific CPT/HCPCS Codes may be covered for the Medicare Business Segment. Please consult the CMS website at www.cms.gov or the local Medicare Administrative Carrier (MAC) for more information on Medicare coverage and coding requirements.***

19328 Removal of intact mammary implant
19330 Removal of mammary implant material
19340 Removal of ruptured breast implant, including implant contents (eg, saline, silicone gel)
19370 Open periprosthetic capsulotomy, breast
19371 Periprosthetic capsulectomy, breast



**LINE OF BUSINESS:**

**Eligibility and contract specific benefits, limitations and/or exclusions will apply. Coverage statements found in the line of business specific benefit document will supersede this policy. For Medicare, applicable LCD's and NCD's will supercede this policy. For PA Medicaid Business segment, this policy applies as written.**

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This policy will be revised as necessary and reviewed no less than annually.

**Devised:** 8/14/98 (Silicone breast implant removal)

**Revised:** 02/03 (format, title and criteria); 2/04 (criteria clarification); 2/11; 4/11 (revised indication), 1/13, 12/19 (added indication and exclusion); 12/23 ( consolidate and refine indications)

**Reviewed:** 2/05, 2/06, 2/07, 2/08, 2/09, 2/10, 3/12, 1/14, 1/15, 1/16, 1/17, 12/17, 12/18, 12/20, 12/21, 12/22