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
Medical Necessity shall mean a service or benefit that is compensable under the Medical Assistance Program and if it meets any one of the following standards:

(i) The service or benefit will, or is reasonably expected to, prevent the onset of an illness, condition or disability.
(ii) The service or benefit will, or is reasonably expected to, reduce or ameliorate the physical, mental or development effects of an illness, condition, injury or disability.
(iii) The service or benefit 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 unrelated to reconstruction following cancer surgery, removal of breast implants is considered medically necessary for any of the following indications:
- Breast cancer (new onset) or chest wall tumors in proximity to the implant; or
- Intra- or extra-capsular rupture of silicone gel implant; or
- Implants with 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

For members who have undergone reconstruction following a medically necessary mastectomy (due to malignancy or prophylactic mastectomy), removal of implants will be considered medically necessary for the following indications:
- Breast cancer (recurrent disease) or chest wall tumors in proximity to the implant; or
- Intra- or extra-capsular rupture of silicone gel implant; or
- Implants with severe contracture that interferes with mammography; or
- Extra-capsular rupture of saline implant if cosmetic outcome is compromised
- 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

*Baker’s Classification of Capsular Contracture

<table>
<thead>
<tr>
<th>Grade I (Absent)</th>
<th>Grade II (Minimal)</th>
<th>Grade III (Moderate)</th>
<th>Grade IV (Severe)</th>
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<tbody>
<tr>
<td>The breast is soft with no palpable capsule and looks natural.</td>
<td>The breast is a little firm with a palpable capsule but looks normal.</td>
<td>The breast is firm with an easily palpated capsule and is visually abnormal.</td>
<td>The breast is hard, cold, painful, and markedly distorted.</td>
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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 cosmetic 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.
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:
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.

19328 Removal of intact mammary implant
19330 Removal of mammary implant material


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 PA Medicaid Business segment, this policy applies as written.

REFERENCES:


Michael SG Bell, MD FRCSC, Gaby D Doumit, MD MSc FRCSC, and Brian R Buinewicz, MD FACS. "Removal of silicone breast implants and review of literature". 2009. Accessed Dec 2015.

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

Reviewed: 2/05, 2/06, 2/07, 2/08, 2/09, 2/10, 3/12, 1/14, 1/15, 1/16, 1/17