Guidelines for Medical Necessity Determination for Breast Reconstruction and Breast Implant Removal

These Guidelines for Medical Necessity Determination (Guidelines) identify the clinical information that MassHealth needs to determine medical necessity for breast reconstruction and breast implant removal surgeries. These Guidelines are based on generally accepted standards of practice, review of the medical literature, and federal and/or state policies and laws applicable to Medicaid programs. Other breast surgeries are covered in other MassHealth Guidelines.

Providers should consult MassHealth regulations at 130 CMR 415.000: *Acute Inpatient Hospital Services*, 130 CMR 433.000: *Physician Services*, 130 CMR 410.000: *Outpatient Hospital Services*, 130 CMR 450.000: *Administrative and Billing Regulations*, Subchapter 6 of the *Physician Manual*, and Subchapter 6 of the *Acute Outpatient Hospital Manual* for information about coverage, limitations, service conditions, and other prior-authorization (PA) requirements.

Providers serving members enrolled in a MassHealth-contracted accountable care partnership plan (ACPP), managed care organization (MCO), One Care Organization, Senior Care Organization (SCO), or Program of All-inclusive Care for the Elderly (PACE) should refer to the ACPP's, MCO's, One Care Organization's, SCO's, or PACE's medical policies for covered services.

MassHealth requires PA for breast reconstruction and breast implant removal. MassHealth reviews requests for PA on the basis of medical necessity. If MassHealth approves the request, payment is still subject to all general conditions of MassHealth, including member eligibility, other insurance, and program restrictions.

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SECTION I. GENERAL INFORMATION

Reconstructive breast surgery is defined as a surgical procedure that is designed to restore the shape of the breast after surgery, accidental injury, or trauma. It is often considered after a mastectomy or lumpectomy for the purposes of correcting deformity or reestablishing symmetry caused by previous surgery and/or the effects of therapeutic treatments, including radiation. Additionally, breast reconstruction is considered to correct congenital anomalies/chest wall deformities, including those seen in Poland Syndrome**;** amazia (absence of breast tissue when the nipple is present); nipple inversion, causing chronic bleeding, discharge, scabbing, or infection**;** chronic and severe fibrocystic breast disease unresponsive to medical therapy; *as well as for accidental injury, burns,* and trauma. Breast reconstruction may also be covered as a part of treatment for gender dysphoria. For additional details, please refer to MassHealth's *Guidelines for Medical Necessity Determination for Gender Affirming Surgery*, available at https://www.mass.gov/guides/masshealth-guidelines-for-medical-necessity-determination-for-gender-affirming-surgery.

Reconstruction procedures may involve multiple techniques and stages to recreate the breast mound through the use of either silicone gel-filled or saline-filled prosthetic implants, tissue expanders, and/or

acellular dermal matrices, versus using autologous tissue transfers from either the abdomen, back, or buttocks. In addition, breast reconstruction can also include nipple areola reconstruction and tattooing of the nipple area. Breast reconstruction may require multiple surgeries, revision surgery involving the breast and/or donor site, and surgery on the nondiseased/unaffected/contralateral breast to establish symmetry.

Although implantable breast prostheses may be inserted for either reconstructive or cosmetic reasons, clinically significant post-implant complications may occur, necessitating removal of the implants. Breast implant removal may be considered in instances of leakage or rupture; implant extrusion; infection; tissue necrosis; development of breast implant-associated anaplastic large cell lymphoma (BIA-ALCL); development of certain classifications of capsular contracture that either causes pain and/or interferes with mammography; cutaneous hypersensitivity-like reactions associated with breast implants that are resistant to conventional treatments; or if the implant interferes with breast cancer diagnosis or treatment. *An intact implant may also be removed in the unaffected/contralateral breast to maintain symmetry and reduce breast implant-associated conditions.*

MassHealth considers approval for coverage of breast reconstruction and breast implant removal on an individual, case-by-case basis, in accordance with 130 CMR 433.000, 130 CMR 415.000, 130 CMR 410.000, and 130 CMR 450.204.

SECTION II. CLINICAL GUIDELINES

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A. CLINICAL COVERAGE

MassHealth bases its determination of medical necessity for *breast reconstruction surgery* on clinical data including, but not limited to, indicators that would affect the relative risks and benefits of the procedure, including post-operative recovery. These criteria include, but are not limited to, the following:

1. A comprehensive medical history and physical exam has been conducted by the surgeon to evaluate the need for breast reconstruction surgery.

2. The breast reconstruction surgery is intended to correct, restore, or improve anatomical and/or functional impairments that have resulted from congenital anomalies; accidental injury; trauma; previous surgery, including mastectomy or lumpectomy; therapeutic interventions (for example, radiation); or condition/disease of the breast.

3. A surgical treatment plan that outlines the type of techniques and stages of the procedure(s) that will be performed has been developed.

4. When the proposed surgery follows a mastectomy that has been performed to remove a malignant neoplasm or carcinoma in situ of the breast or has been performed prophylactically to reduce the risk of breast cancer in high-risk members, breast reconstruction in connection with a mastectomy may include:

    a. Reconstruction by an implant-based approach or through the use of autologous tissue, as well as nipple reconstruction, to restore shape of the affected breast.

b. Surgery for the nondiseased/unaffected/contralateral breast, which may involve augmentation mammoplasty, reduction mammoplasty, and/or mastopexy to achieve breast symmetry.

MassHealth bases its determination of medical necessity for *breast implant removal* on clinical data including, but not limited to, indicators that would affect the relative risks and benefits of procedure, including post-operative recovery. These criteria include, but are not limited to, the following:

1. A comprehensive medical history and physical exam has been conducted by the surgeon to evaluate the need for breast implant removal.

2. Breast implant removal with or without capsulectomy is considered medically necessary if

   a. intended to correct, restore, or improve anatomical and/or functional impairments that result from leakage/rupture of a silicone gel-filled implant, extrusion of the implant through skin, implant infections refractory to medical management, tissue necrosis secondary to the implant, and cutaneous hypersensitivity-like reactions associated with breast implants that are refractory to conventional treatments;

   b. the implant interferes with diagnostic evaluation of a suspected breast cancer or interferes with a medically necessary treatment of a known breast cancer;

   c. the member has developed a symptomatic capsular contracture that (1) qualifies as either grade III or IV according to the Baker classification for capsular contracture, and (2) limits movement, leading to an inability to perform tasks that involved reaching or abduction.

3. A surgical treatment plan that outlines the type of techniques and stages of the procedure(s) that will be performed has been developed.

4. if any of the preceding criteria for removal of a breast implant is met unilaterally, MassHealth also considers the medically necessity of removal of the implant and capsulectomy or capsulotomy in the other unaffected/contralateral breast if both implants are removed at the same time.

B. NONCOVERAGE

MassHealth does not consider *breast reconstruction surgery* to be medically necessary under certain circumstances. Examples of such circumstances include, but are not limited to, the following:

1. Breast reconstruction that is performed for the exclusive purpose of altering appearance and is unrelated to physical disease, defect, or traumatic injury.

2. Breast reconstruction after prophylactic mastectomy performed to reduce risk of breast cancer in members who are not high risk.

3. Replacement of breast implants placed for cosmetic purposes or reconstruction following removal of breast implant originally placed for cosmetic purposes, when performed in the absence of breast cancer or other covered indications.

MassHealth does not consider *breast implant removal* to be medically necessary under certain circumstances. Examples of such circumstances include, but are not limited to, the removal of asymptomatic, intact breast implants except for cases of cancer diagnosis and treatment as described previously.

SECTION III. SUBMITTING CLINICAL DOCUMENTATION

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A. Requests for PA for breast reconstruction surgery or breast implant removal must be accompanied by clinical documentation that supports the medical necessity for this procedure, including, but not limited to, documentation demonstrating that the member meets the clinical criteria for coverage of the intended procedure, as described in Section II

B. Documentation of medical necessity must include all of the following:

1. The primary diagnosis name and ICD-CM codes for the condition requiring either reconstruction or implant removal;
2. The secondary diagnosis name(s) and ICD-CM code(s) pertinent to comorbid condition(s);
3. The most recent medical evaluation, including a summary of the medical history and last physical exam;
4. Results from diagnostic imaging and laboratory tests pertinent to the diagnosis;
5. Risk factors or comorbid conditions;
6. Previous surgeries and hospitalizations;
7. The surgical treatment plan (including any contralateral breast treatment); and
8. Other pertinent information that MassHealth may request.

Clinical information must be submitted by the MassHealth-enrolled qualified health professional performing the procedure. Providers are strongly encouraged to submit requests electronically. Providers must submit the request for PA and all supporting documentation using the Provider Online Service Center (POSC) or by completing a MassHealth Prior Authorization Request form (using the PA-1 paper form found at https://www.mass.gov/prior-authorization-for-masshealth-providers) and attaching all supporting documentation. The PA-1 form and documentation should be mailed to the address on the back of the form. Questions about POSC access should be directed to the MassHealth Customer Service Center at (800) 841-2900.

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These Guidelines are based on review of the medical literature and current practice in breast reconstruction and breast implant removal. MassHealth reserves the right to review and update the contents of these Guidelines and cited references as new clinical evidence and medical technology emerge.

This document was prepared for medical professionals to assist them in submitting documentation supporting the medical necessity of the proposed treatment, products, or services. Some language used in this communication may be unfamiliar to other readers; in this case, those readers should contact their health care provider for guidance or explanation.

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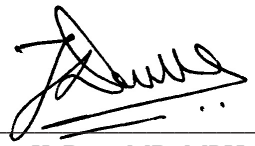
Approved by: 

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Supersedes policy dated March 12, 2018