

	<p>Therapeutic and Reconstructive Breast Procedures Guideline</p>	
<p>Guideline # 6203</p>	<p>Categories Clinical → Care Management CM, TCHP Guidelines, Utilization Management UM</p>	<p>This Guideline Applies To: Texas Children's Health Plan</p>
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GUIDELINE STATEMENT:

Texas Children's Health Plan (TCHP) performs authorization of all Surgical Breast Procedures, including prosthesis.

DEFINITIONS:

- Reconstructive Breast Procedures rebuild the normal contour of the affected or the contralateral unaffected breast to produce a more normal appearance. They can include any or all of the following:
 - Reconstructive surgery and implant insertion;
 - Procedures where muscle tissue is transposed from another site;
 - Reconstruction of the contralateral breast to achieve symmetry with reduction mammoplasty, augmentation mammoplasty with implants, or mastopexy;
 - Revision or removal of pre-existing breast implants placed for cosmetic purposes.

PRIOR AUTHORIZATION GUIDELINE

1. All requests for prior authorization for Therapeutic and Reconstructive Breast Procedures are received via online submission, fax, phone or mail by the Utilization Management Department and processed during normal business hours.
2. To request prior authorization for Surgical Breast Procedures or breast prostheses, the requesting provider must
 - 2.1. Submit clinical documentation of medical necessity for the requested date of service.
 - 2.1.1. For mastectomy for pubertal gynecomastia – the documentation must also include:
 - 2.1.1.1. Client’s history and treatment plan including planned surgical procedure and timelines.
 - 2.1.1.2. Identification of which breast or breasts, require mastectomy.
 - 2.1.2. For members over the age of 40 requesting a reduction mammoplasty, requesting physician should provide documentation of a mammogram that is negative for cancer within the past year
 - 2.2. Identify the location or facility where the services will be provided if applicable
 - 2.3. Prior authorization is required for members who are 17 years of age and younger

3. Establishing Medical Necessity for Therapeutic and Reconstructive Breast Procedures:
 - 3.1. Mastectomy or partial mastectomy is considered medically necessary when:
 - 3.1.1. It is medically necessary to remove a breast or portion of a breast for any of the following:
 - 3.1.1.1. Developmental abnormality
 - 3.1.1.2. Congenital defect
 - 3.1.1.3. Trauma or injury to the chest wall
 - 3.1.1.4. Primary or secondary malignancy of the breast
 - 3.1.1.5. Carcinoma in situ of the breast
 - 3.1.2. It is prophylactic for members who are at moderate to high risk for the development of breast cancer as evidenced by:
 - 3.1.2.1. Current or previous diagnosis of breast cancer
 - 3.1.2.2. Family history of breast cancer in mother, sister, or daughter, especially before the age of 50
 - 3.1.2.3. Presence of any of the following genetic mutations:
 - 3.1.2.3.1. Breast cancer gene 1 (BRCA1)
 - 3.1.2.3.2. Breast cancer gene 2 (BRCA2)
 - 3.1.2.3.3. Tumor protein 53 (TP 53)
 - 3.1.2.3.4. Phosphatase and tensin homolog (PTEN)
 - 3.1.2.4. Lobular carcinoma in situ (LCIS)
 - 3.1.2.5. Radiation therapy to the chest before a client reaches 30 years of age
 - 3.1.3. As treatment for gynecomastia when the member meets all the following criteria:
 - 3.1.3.1. Gynecomastia classification (grade II, III, or IV) as defined by the American Society of Plastic Surgeons classification.
 - 3.1.3.2. Member is a male over the age of 18 or has evidence that puberty is near completion, as indicated by the following:
 - 3.1.3.2.1. 95 percent of adult height based on bone age
 - 3.1.3.2.2. Tanner stage V has been achieved
 - 3.1.3.3. Evidence that the client has been off gynecomastia inducing drugs or other substances for a minimum of one year when this has been identified as the cause of the gynecomastia.
 - 3.1.3.4. Evidence of resolution as supported by appropriate test results and treatment for hormonal causes, including hyperthyroidism, estrogen excess, prolactinomas, and hypogonadism, for a minimum of one year when identified as the cause of the gynecomastia.
 - 3.1.3.5. Evidence of a psychiatric assessment performed by a psychiatrist or psychologist
 - 3.1.3.6. History and treatment plan including planned surgical procedure and timeline
 - 3.2. Reconstructive breast procedures are considered medically necessary in the following situation:
 - 3.2.1. Breast surgery of one or both breasts following the mastectomy of one or both breasts.
 - 3.2.2. Breast surgery to alter the contour of the breast when there are significant abnormalities related to trauma, congenital defects, infection or other non-malignant disease. A specific example of this is Poland's syndrome which may be diagnosed when all of the following are present:
 - 3.2.2.1. Congenital absence or hypoplasia of pectoralis major and minor muscles; and

- 3.2.2.2. Breast hypoplasia; and
- 3.2.2.3. Congenital partial absence of the upper costal cartilage.
- 3.2.3. Removal of an implant (any type) with or without reimplantation when an implant, originally placed in an individual with a history of mastectomy, lumpectomy or treatment of breast cancer develops a visible distortion (Baker Class III contracture).
- 3.2.4. Removal of a saline-filled or "Alternative" implant with or without reimplantation when originally placed in an individual with a history of mastectomy, lumpectomy or treatment of breast cancer if it ruptures, becomes infected or when there is an inflammatory reaction to the implant.
- 3.2.5. Surgery on the contralateral breast to produce a symmetrical appearance after removal of an implant and reimplantation when the implant was originally placed in an individual with a history of mastectomy, lumpectomy or treatment of breast cancer.

3.3. Reduction Mammoplasty is considered medically necessary when current applicable Interqual criteria are met. In the event that the Interqual criteria are not met, the following indications will be used to determine medical necessity:

- 3.3.1. Individuals meet BOTH of the following criteria:
 - 3.3.1.1. Presence of one or more of the following that has persisted for at least one year:
 - 3.3.1.1.1. A cervical or thoracic pain syndrome (upper back and shoulder pain); or
 - 3.3.1.1.2. Submammary intertrigo that is refractory to conventional medications and measures used to treat intertrigo, or shoulder grooving with ulceration unresponsive to conventional therapy; or
 - 3.3.1.1.3. Thoracic outlet syndrome (to include ulnar paresthesias from breast size) that has not responded to at least three (3) months of adequate conservative treatment.
 - 3.3.1.2. The preoperative evaluation by the surgeon concludes that an appropriate amount of breast tissue, per breast, will be removed and based upon the body surface area of the patient and that there is a reasonable prognosis of symptomatic relief. The request for surgery must include: the individual's height and weight; the size and shape of the breast(s) causing symptoms; the anticipated amount of breast tissue to be removed.
 - 3.3.1.2.1. The minimum weight of tissue expected to be removed from a single breast with consideration to body surface area is as follows, based on the Schnur Sliding Scale Chart:

Body Surface Area (m ²)	<u>Average grams of tissue per breast to be removed</u>
1.35	199
1.40	218
1.45	238
1.50	260
1.55	284
1.60	310
1.65	338
1.70	370
1.75	404

1.80	441
1.85	482
1.90	527
1.95	575
2.00	628
2.05	687
2.10	750
2.15	819
2.20	895
2.25	978
2.30	1068

3.3.1.2.2. Any member who is anticipated to have at least 1 kg of breast tissue removed from each breast qualifies as having an expected appropriate amount of tissue to be removed.

3.4. External breast prostheses are considered medically necessary for any female member with a history of a medically necessary mastectomy.

4. Requests that do not meet the criteria established by this guideline will be referred to a TCHP Medical Director/Physician Reviewer for review and the Denial Policy will be followed.
5. Preauthorization is based on medical necessity and not a guarantee of benefits or eligibility. Even if preauthorization is approved for treatment or a particular service, that authorization applies only to the medical necessity of treatment or service. All services are subject to benefit limitations and exclusions. Providers are subject to State and Federal Regulatory compliance and failure to comply may result in retrospective audit and potential financial recoupment.

REFERENCES:

Government Agency, Medical Society, and Other Publications:

- Holland-Hall C . Chapter 132- Adolescence Physical and Social development. In: Kliegman RM, St. Geme J, Editors. Nelson Textbook of Pediatrics. 21th Ed. St. Louis, MO: WB. Saunders, Inc. 2020.
- Townsend. Sabiston Textbook of Surgery, 16th edition. W. B. Saunders Company, 2001:559, 1567.
- Williams Textbook of Endocrinology, 9th Edition. Copyright 1998, W. B. Saunders Company; Disorders of Breasts in Men Gynecomastia.
- American Society of Plastic Surgeons (ASPS). Evidence-Based Clinical Practice Guideline: Breast Reconstruction with Expanders and Implants. 2013. Available at: <https://www.plasticsurgery.org/documents/Health-Policy/Guidelines/guideline-2013-breast-recon-expanders-implants.pdf> . Accessed on January 29, 2021.
- Centers for Medicare and Medicaid Services (CMS). National Coverage Determination: Breast reconstruction following mastectomy. NCD #140.2. Effective January 1, 1997; revised October 3, 2003. Available at: <https://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?ncdid=64>. Accessed on January 29, 2021.

- Chung KC. Discussion: Managing late periprosthetic fluid collections (seroma) in patients with breast implants: a consensus panel recommendation and review of the literature. *Plast Reconstr Surg.* 2011; 128(1):13-16.
- Klifto KM, Aravind P, Major M, et al. Differences between Breast Cancer Reconstruction and Institutionally Established Normative Data Using the BREAST-Q Reconstruction Module: A Comparative Study. *Plast Reconstr Surg.* 2020;145(6):1371-1379.
- Dvoracek LA, Gusenoff JA, Rubin JP, Manders EK. Quick Calculation of Breast Resection Mass Using the Schnur Scale. *Ann Plast Surg* 2019;82(3):316-319.
- NCCN Clinical Practice Guidelines in Oncology™. © 2015. National Comprehensive Cancer Network Clinical Practice guidelines in Oncology. For additional information visit the NCCN website: <http://www.nccn.org/index.asp>. Breast Cancer (V3.2015). Revised July 16, 2015.
- The Women's Health and Cancer Rights Act (WHCRA), §713; October 21, 1998. Available at: http://www.cms.gov/Regulations-and-Guidance/Health-Insurance-Reform/HealthInsReformforConsume/downloads/WHCRA_Statute.pdf.
- U.S. Food and Drug Administration (FDA). Center for Devices and Radiological Health (CDRH). Update on the Safety of Silicone Gel-Filled Breast Implants. June 2011. Available at: <http://www.fda.gov/downloads/MedicalDevices/ProductsandMedicalProcedures/ImplantsandProsthetics/BreastImplants/UCM260090.pdf>.
- U.S. Food and Drug Administration (FDA). Guidance for industry and FDA staff: saline, silicone gel, and alternative breast implants. November 17, 2006. Available at: <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm071228.htm>.
- U.S. Food and Drug Administration (FDA). Center for Devices and Radiological Health (CDRH). Executive Summary: Silicone Gel-Filled Breast Implants General Issues Panel. August 30-31, 2011. Available at: <http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/MedicalDevices/MedicalDevicesAdvisoryCommittee/GeneralandPlasticSurgeryDevicesPanel/UCM269639.pdf>.
- U.S. Food and Drug Administration (FDA). Labeling for approved breast implants. Updated 2014. Available at: <http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/ImplantsandProsthetics/BreastImplants/ucm063743.htm>.
- U.S. Food and Drug Administration (FDA). Information on breast implants and anaplastic large B-cell lymphoma. June 22, 2011. Available at: <http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/ImplantsandProsthetics/BreastImplants/ucm239995.htm>.
- American Society of Plastic Surgeons. Reduction mammoplasty Recommended Criteria for Third-Party Payer Coverage from the American Society of Plastic Surgeons (ASPS). May 2011. Available at: http://www.plasticsurgery.org/Medical_Professionals/Health_Policy_and_Advocacy/Health_Policy_Resources/Recommended_Insurance_Coverage_Criteria.html.
- American Society of Plastic Surgeons. Reduction Mammoplasty Practice Guidelines. May 2011. Available at: http://www.plasticsurgery.org/Documents/medical-professionals/health-policy/evidence-practice/Reduction%20Mammoplasty_%20Evidence%20Based%20Guidelines_v5.pdf.

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http://www.tmhp.com/Manuals_HTML1/TMPPM/Current/index.html#t=TMPPM%2F2_Med_Specs_and_Phys_Srvs%2F2_Med_Specs_and_Phys_Srvs.htm&rhsearch=breast%20reconstruction&rhhlterm=breast%20reduction&rhsyns=%20&ux=search

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