Introduction

Gynecomastia is swelling of breast tissue in boys or men. It can happen in one or both breasts. This enlargement may be caused by fat deposits, glands that start growing, or the thickening or increased density of breast tissue. Aging, obesity, or use of certain prescribed and nonprescribed drugs can stimulate the growth of this tissue. Other health problems like an overactive thyroid gland, kidney disease, or cancer can also create other bodily changes that spur breast enlargement. If the enlargement is due to male breast cancer, surgery to remove the breast can be approved without trying other treatments. If the enlargement is due to reasons other than cancer, other treatments must be tried before surgery may be approved.

Note: The Introduction section is for your general knowledge and is not to be taken as policy coverage criteria. The rest of the policy uses specific words and concepts familiar to medical professionals. It is intended for providers. A provider can be a person, such as a doctor, nurse, psychologist, or dentist. A provider also can be a place where medical care is given, like a hospital, clinic, or lab. This policy informs them about when a service may be covered.
<table>
<thead>
<tr>
<th>Indication</th>
<th>Medical Necessity</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Malignant (cancer) indications for mastectomy</strong></td>
<td>Mastectomy surgery for gynecomastia may be considered medically necessary for diagnosed malignancy (cancer) of the breast(s) regardless of age.</td>
</tr>
</tbody>
</table>
| **Non-malignant (not cancer) indications for mastectomy in adults and adolescents** | Mastectomy surgery for gynecomastia may be considered medically necessary for non-malignant (not cancer) indications according to the criteria for adults and adolescents when ALL of the following criteria are met:  
  - Glandular (not fatty/adipose tissue) breast tissue is causing a physical functional impairment  
  - Unilateral or bilateral Grade III or Grade IV gynecomastia is present (per modified McKinney and Simon, Hoffman and Kohn scales - see Practice Guidelines and Position Statements)  
  - Persists 2 years after pathological causes (eg, hormonal, endocrine, or liver disease) are ruled out or treated  
  - Persists after 6-month discontinuation of medications, nutritional supplements, or substances that could be the underlying cause, when medically appropriate and applicable (eg, testosterone, marijuana, anabolic steroids, topical lavender oil/tea tree oil, anti-androgens, tricyclic antidepressants, cimetidine, digoxin, and calcium channel blockers)  
  - Pain and discomfort due to the distention and tightness from the hypertrophied breast(s) has not responded to medical management (eg, analgesics or anti-inflammatories).  

Mastectomy for gynecomastia is considered not medically necessary when the above criteria are not met. |

<table>
<thead>
<tr>
<th>Indication</th>
<th>Investigational</th>
</tr>
</thead>
<tbody>
<tr>
<td>Liposuction</td>
<td>Liposuction as a treatment of gynecomastia is considered investigational.</td>
</tr>
</tbody>
</table>

**Documentation Requirements**

The medical records submitted for review should document that medical necessity criteria are met. The record should include clinical documentation of ALL of the following:

- The tissue to be removed is glandular breast tissue and it interferes with normal physical
Documentation Requirements

- Severity of breast enlargement is considered moderate to marked according to the American Society of Plastic Surgeons (grade III or IV) and
- Persists for 2 years after no other possible medical causes were found
- Persists after 6-month discontinuation of medications, nutritional supplements, or substances that could be the underlying cause, when medically appropriate and applicable
- The pain and discomfort directly related to the breast tissue enlargement has not responded to medical management

Coding

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>19300</td>
<td>Mastectomy for gynecomastia</td>
</tr>
<tr>
<td>15877</td>
<td>Suction assisted lipectomy; trunk</td>
</tr>
</tbody>
</table>

Note: CPT codes, descriptions and materials are copyrighted by the American Medical Association (AMA). HCPCS codes, descriptions and materials are copyrighted by Centers for Medicare Services (CMS).

Related Information

One of the bases for medical necessity is the presence of a functional impairment. Typically, no functional impairment is associated with gynecomastia. Therefore, determination of coverage eligibility for the surgical treatment of gynecomastia may require consideration of whether or not such surgery would be considered reconstructive. (See Related Policies for further discussion of functional impairment, and general concepts of reconstructive and cosmetic services.)
Definition of Terms

When specific definitions are not present in a member’s plan, the following definition of terms will be applied:

**Cosmetic:** Cosmetic services are those which are primarily intended to preserve or improve appearance. Cosmetic surgery is performed to reshape normal structures of the body in order to improve the patient's appearance or self-esteem.

**Physical Functional Impairment:** This means a limitation from normal (or baseline level) of physical functioning that may include, but is not limited to, problems with ambulation, mobilization, communication, respiration, eating, swallowing, vision, facial expression, skin integrity, distortion of nearby body parts or obstruction of an orifice. The physical functional impairment can be due to structure, congenital deformity, pain, or other causes. Physical functional impairment excludes social, emotional and psychological impairments or potential impairments.

**Reconstructive Surgery:** This refers to surgeries performed on abnormal structures of the body, caused by congenital defects, developmental abnormalities, trauma, infection, tumors or disease. It is generally performed to improve function.

Benefit Application

Contractual definitions of the scope of reconstructive services that may be eligible for coverage vary. Categories of conditions, which may be included as part of the contractual definition of reconstructive services, include one or more of the following:

- Accidental trauma or injury
- Anatomic variants
- Congenital anomalies
- Diseases
- Post-chemotherapy
- Post-surgery

For example, adolescent gynecomastia may be considered an anatomic variant, while gynecomastia related to liver disease would be considered secondary to a disease process.
Determinations of whether a proposed intervention would be considered reconstructive should always be interpreted in the context of the specific benefits language. State or federal mandates may also dictate coverage decisions.

Evidence Review

Description

Gynecomastia is a benign enlargement of the male breast, either due to increased adipose tissue, glandular tissue, fibrous tissue, or a combination of all three. Surgical removal of the breast tissue, using either surgical excision or liposuction, may be considered if conservative therapies are not effective or possible.

Background

Gynecomastia is the benign enlargement of the male breast, either due to increased adipose tissue, glandular tissue, fibrous tissue, or a combination of all three. The condition can be bilateral or unilateral. Clinically defined, “true gynecomastia” is the presence of an abnormal development of glandular tissue that may appear as a palpable rubbery or firm mass extending concentrically from the nipples. The condition known as pseudo-gynecomastia, or lipomastia, is characterized by fat deposition (adipose tissue) without glandular proliferation.\(^1\) Pathological gynecomastia is breast enlargement due to a pathological process. The following are examples and are not all inclusive:

- An underlying hormonal disorder (ie, conditions causing either estrogen excess or testosterone deficiency such as liver disease or an endocrine disorder)
- An adverse effect of certain drugs (ie, hormone therapy for prostate cancer, anabolic steroids, cimetidine, etc.)
- Obesity
- Related to specific age groups, for example:
  - Neonatal gynecomastia, related to the action of maternal or placental estrogens
Adolescent gynecomastia, which consists of transient, bilateral breast enlargement which may be tender

- Gynecomastia of aging, related to the decreasing levels of testosterone and relative estrogen excess

**Treatment**

Treatment of gynecomastia involves consideration of the underlying cause. For example, treatment of the underlying hormonal disorder, cessation of drug therapy, or weight loss may all be effective therapies. Gynecomastia may also resolve spontaneously, and adolescent gynecomastia may resolve with aging.

Prolonged gynecomastia causes periductal fibrosis and stromal hyalinization, which prevent regression of the breast tissue. Surgical removal of the breast tissue, using surgical excision or liposuction may be considered if the conservative therapies are not effective or possible and the gynecomastia does not resolve spontaneously or with aging.

**Summary of Evidence**

For individuals with gynecomastia who receive surgical treatment, the evidence includes case series. Relevant outcomes are symptoms, functional outcomes, health status measures, quality of life, and treatment-related morbidity. Because there are no randomized controlled trials on surgical treatment of bilateral gynecomastia, it is not possible to determine with a high level of confidence whether surgical treatment improves symptoms or functional impairment. Conservative therapy should adequately address any physical pain or discomfort, and gynecomastia does not typically cause functional impairment. The evidence is insufficient to determine the effect of the technology on net health outcomes.

Men who are receiving hormone therapy for prostate cancer may have gynecomastia as a side effect that will potentially reverse after treatment stops. Prophylactic radiotherapy has been shown to decrease the incidence of hormone induced gynecomastia by more than 50%. An alternative course of action, which may be more convenient for the patient, is the prophylactic use of tamoxifen. Tamoxifen may also mitigate or resolve gynecomastia during its early or proliferative phase. In severe long-standing gynecomastia, surgery is warranted since medical therapies are less likely to succeed.²
Henley noted that most cases of male prepubertal gynecomastia are classified as idiopathic. However, he investigated possible causes of gynecomastia in three prepubertal boys who were otherwise healthy and had normal serum concentrations of endogenous steroids. In all three boys, gynecomastia coincided with the topical application of products that contained lavender and tea tree oils. Gynecomastia resolved in each patient shortly after the use of products containing these oils was discontinued. Furthermore, studies in human cell lines indicated that the two oils had estrogenic and antiandrogenic activities. He concluded that repeated topical exposure to lavender and tea tree oils probably caused prepubertal gynecomastia in these boys.3

Rosen et al. looked at obesity as a root cause of gynecomastia and the role of obesity in persistent gynecomastia on psychological distress in adolescent males. This retrospective study reviewed demographics and surgical outcomes of adolescents with gynecomastia comparing obese/overweight to normal weighted patients. Between 1997-2008, 69 patients were identified with male “breasts” from database screening. By using BMI criteria, 51% were obese, 16% overweight and 33% normal-weighted. Major complications occurred in 4 patients (5.8%); minor complications in 19 (27.5%). Potential causes other than obesity were found in 27%. Obese patients required more extensive operations (P = 0.009). Obese adolescents suffer greater psychological impact preoperatively (P = 0.02) and have no difference in satisfaction (P = 0.47) or complication rates (P = 0.33) than normal-weighted patients. The authors concluded that obesity should not be used as an absolute contraindication to gynecomastia surgery.4

Koshy and colleagues questioned the routine pathologic examination of breast tissue that is excised for adolescent gynecomastia, given the benign nature of the condition. They conducted a retrospective chart review to examine the incidence of pathologic abnormalities in patients 21 years or younger who had undergone subcutaneous mastectomy for gynecomastia. A literature review was also performed to determine the historical prevalence of cases of atypia or malignancy in cases of adolescent gynecomastia. Finally, an informal survey was performed of major children’s hospitals regarding their practice of pathologic examination for adolescent gynecomastia. The chart review demonstrated that over the past 10 years, 81 patients with gynecomastia underwent subcutaneous mastectomy. All cases were negative for malignancy, with only one case of cellular atypia. They found that the literature has historically reported six cases of carcinoma and five cases of atypia. Of 22 survey respondents, all either routinely performed or required pathologic examination of breast tissue excised for gynecomastia. The out-of-pocket cost for self-pay patients to perform pathologic examinations has been quoted at $1268 for bilateral cases. They concluded that the incidence of malignancy or abnormal pathology associated with gynecomastia tissue in the adolescent male is extremely low, and given the associated costs, the pathologic examination of breast tissue excised for gynecomastia in individuals 21 years of age or younger should be neither routinely performed nor required.
but should be performed only when desired by either the patient, the patient’s family, or the managing physician.⁵

Several surgical approaches have been described in the literature for removing glandular breast tissue. Procedures to treat gynecomastia include direct excision (mastectomy), liposuction, ultrasound-assisted liposuction or a combination of these.

Lanitis and colleagues studied gynecomastia surgical outcomes at a single institution from 1998 through 2007. A total of 748 males were referred to the center for breast symptoms. From that total, 65 males (102 breasts) with a median age of 26 years old had surgery for gynecomastia. A total of 82 breasts were treated with mastectomies and 22 with skin reduction. The procedures carried out were subcutaneous mastectomy or breast disk excision, with or without skin reduction. Major post-surgical complications consisted of hematomas requiring evacuation, wound infection; partial nipple necrosis, dehiscence, and wound break down occurred in 12 breasts. The authors concluded that after excluding malignancy, most males with gynecomastia can be managed conservatively. Conservative treatments could include counseling for reassurance, weight reduction and medications.⁶

Li and colleagues analyzed the surgical approaches to the treatment of gynecomastia and outcomes over a 10-year period. Retrospective data was collected from patients undergoing surgical correction of gynecomastia at one hospital in Taiwan from 2000-2010. The data were analyzed for etiology, stage of gynecomastia, surgical technique, complications, risk factors, and revision rate. The surgical result was evaluated with self-assessment questionnaires. A total of 41 patients with 75 operations were included. Techniques included subcutaneous mastectomy alone or with additional ultrasound-assisted liposuction (UAL) and isolated UAL. The surgical revision rate for all patients was 4.8%. The skin-sparing procedure gave good surgical results in grade IIb and grade III gynecomastia with low revision and complication rates. The self-assessment report revealed a good level of overall satisfaction and improvement in self-confidence (average scores 9.4 and 9.2, respectively, on a 10-point scale). The authors conclude that the treatment of gynecomastia requires an individualized approach, with their proposal that subcutaneous mastectomy combined with UAL could be used as the first choice for surgical treatment of grade II and III gynecomastia.⁷

Rohrich et al. suggest that ultrasound-assisted suction lipectomy as a treatment for gynecomastia reduces scarring and improves removal of fibrous male breast tissue.⁸ There is a lack of evidence in peer-reviewed scientific literature that suction lipectomy (liposuction) whether ultrasound-assisted or not does more than remove adipose tissue. Surgical intervention by mastectomy is the more definitive treatment to remove the glandular breast tissue in males with symptomatic gynecomastia.
A systematic review published in 2015 included 14 studies on the treatment of gynecomastia.\textsuperscript{12} None of the studies were randomized, all were judged to be at high risk of bias, and the body of evidence was determined to be of very low quality by GRADE (Grading of Recommendations, Assessment, Development and Evaluations) evaluation.

**Ongoing Clinical Trials**

A search of ClinicalTrials.gov in December 2018 did not identify any ongoing or unpublished trials that would likely influence this review.

**Practice Guidelines and Position Statements**

**American Society of Plastic Surgeons**

The American Society of Plastic Surgeons (ASPS) issued practice criteria for third-party payers in 2002, which was affirmed in 2015.\textsuperscript{4} ASPS classified gynecomastia using the following scale, which was adapted from the McKinney and Simon, Hoffman and Kohn scales:

<table>
<thead>
<tr>
<th>Grade</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>I</td>
<td>Small breast enlargement with localized button of tissue that is concentrated around the areola.</td>
</tr>
<tr>
<td>II</td>
<td>Moderate breast enlargement exceeding areola boundaries with edges that are indistinct from the chest</td>
</tr>
<tr>
<td>III</td>
<td>Moderate breast enlargement exceeding areola boundaries with edges that are distinct from the chest with skin redundancy present</td>
</tr>
<tr>
<td>IV</td>
<td>Marked breast enlargement with skin redundancy and feminization of the breast</td>
</tr>
</tbody>
</table>

According to ASPS, in adolescents, surgical treatment for unilateral or bilateral grade II or grade III gynecomastia “may be appropriate if the gynecomastia persists for more than 1 year after pathological causation is ruled out (or 6 months if grade IV) and continues after 6 months of unsuccessful medical treatment for pathological gynecomastia”. In adults, surgical treatment for unilateral or bilateral grade III or grade IV gynecomastia “may be appropriate if the gynecomastia persists for more than 3-4 months after pathological causes ruled out and continues after 3 or 4 months of unsuccessful medical treatment for pathological gynecomastia”. ASPS also indicated that surgical treatment of gynecomastia may be appropriate when distention and tightness cause “pain and discomfort”.

This policy is more restrictive than the recommendations made by ASPS.
U.S. Preventive Services Task Force Recommendations

Surgery for gynecomastia is not a preventive service.

Medicare National Coverage

There is no national coverage determination.

Regulatory Status

Removal of the breast tissue is a surgical procedure and, as such, is not subject to regulation by the U.S. Food and Drug Administration.

References

10. BlueCross BlueShield Association Evidence Positioning System Surgical Treatment of Bilateral Gynecomastia. Evidence Positioning System, Policy No. 7.01.13, 2019


<table>
<thead>
<tr>
<th>Date</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>11/05/97</td>
<td>Add to Surgery Section - New Policy</td>
</tr>
<tr>
<td>11/12/02</td>
<td>Replace Policy - Policy reviewed without literature review; new review date only.</td>
</tr>
<tr>
<td>02/10/04</td>
<td>Replace Policy - Policy status changed from AR.7.01.13 to PR.7.01.121. Remains medically necessary.</td>
</tr>
<tr>
<td>09/01/04</td>
<td>Replace Policy - Policy renumbered from PR.7.01.121. No changes to dates.</td>
</tr>
<tr>
<td>06/14/05</td>
<td>Replace Policy - Policy reviewed without literature review; new review date only. Status changed to AR.</td>
</tr>
<tr>
<td>06/09/06</td>
<td>Disclaimer and Scope update - No other changes.</td>
</tr>
<tr>
<td>02/26/07</td>
<td>Update Codes - No other changes.</td>
</tr>
<tr>
<td>06/12/07</td>
<td>Replace Policy - Policy statement expanded to indicate removal of glandular tissue as cosmetic in the absence of a physical functional impairment; definitions of physical functional impairment, cosmetic and reconstructive surgery added to Benefit Application section. Policy status changed from AR to PR.</td>
</tr>
<tr>
<td>04/08/08</td>
<td>Replace Policy - Policy reviewed with literature search; no change to the policy statement. Requirement of histologic exam of tissue was deleted from Policy Guidelines. Reference added.</td>
</tr>
<tr>
<td>02/10/09</td>
<td>Replace Policy - Policy reviewed with literature search. Policy statement updated to remove the cosmetic statement and include “not medically necessary” for all</td>
</tr>
<tr>
<td>Date</td>
<td>Comments</td>
</tr>
<tr>
<td>------------</td>
<td>------------------------------------------------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>02/09/10</td>
<td>Replace Policy - Policy updated with literature search. No change to policy statement.</td>
</tr>
<tr>
<td>03/08/11</td>
<td>Replace Policy - Policy updated with literature search. No change to policy statement.</td>
</tr>
<tr>
<td>09/23/11</td>
<td>Related Policies updated; 10.01.514 added.</td>
</tr>
<tr>
<td>01/06/12</td>
<td>Replace Policy – Policy updated with literature search. No change in policy statement.</td>
</tr>
<tr>
<td>03/11/13</td>
<td>Replace Policy. Policy split into malignant and non-malignant sections. Policy section has ASPS grades III-IV added for criteria to be met for unilateral or bilateral gynecomastia, added duration of symptoms is 2 years and pain is unresponsive to medical management. Liposuction added as investigational. Definitions moved to Policy Guidelines section. Added the condition can be bilateral or unilateral to the Description section. Benefit application section revised. Description and Rationale sections updated based on a literature review through December 2012; and clinical vetting with 2 pediatricians. Policy statement changed as noted.</td>
</tr>
<tr>
<td>05/02/14</td>
<td>Annual review. Not Medically Necessary policy statement is changed to cosmetic to align with medical policy 10.01.514 Cosmetic and Reconstructive Services. A literature search through March 2014 did not prompt any changes to the rationale section. No new references added. Policy statement changed as noted. ICD-9 and ICD-10 procedure and diagnosis codes removed per MPI instruction; these are not utilized in adjudication of the policy.</td>
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<tr>
<td>05/27/15</td>
<td>Annual Review. Policy updated with literature search. No change to policy statement.</td>
</tr>
<tr>
<td>05/01/16</td>
<td>Annual Review, changes approved April 12, 2016. Policy updated with literature review through February 2016; reference 12 added. Policy statement unchanged.</td>
</tr>
<tr>
<td>03/01/17</td>
<td>Annual Review, changes approved February 14, 2017. Policy reviewed with literature search. No new references added. Cosmetic policy statement changed to not medically necessary. Policy moved into new format.</td>
</tr>
<tr>
<td>05/01/17</td>
<td>Interim review, changes approved April 11, 2017. Policy reviewed with literature search. No change to the policy statement.</td>
</tr>
<tr>
<td>05/01/19</td>
<td>Annual Review, approved April 9, 2019. Policy updated with literature review through December 2018; references 5-6 added. Added criteria statement for medically necessary non-malignant indications for mastectomy for gynecomastia.</td>
</tr>
</tbody>
</table>

**Disclaimer:** This medical policy is a guide in evaluating the medical necessity of a particular service or treatment. The Company adopts policies after careful review of published peer-reviewed scientific literature, national guidelines and local standards of practice. Since medical technology is constantly changing, the Company reserves the right to review and update policies as appropriate. Member contracts differ in their benefits. Always consult the member benefit booklet or contact a member service representative to determine coverage for a specific medical service or supply.
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U.S. Department of Health and Human Services
200 Independence Avenue SW, Room 509F, HHH Building
Washington, D.C. 20201
Email AppealsDepartmentInquiries@Premera.com

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