Surgical Treatment of Bilateral Gynecomastia

Policy Number: 7.01.13  
Origination: 4/2006  
Last Review: 4/2019  
Next Review: 4/2020

Policy
Blue Cross and Blue Shield of Kansas City (Blue KC) will provide coverage for surgical treatment of bilateral gynecomastia when it is determined to be medically necessary because the criteria shown below are met.

When Policy Topic is covered
See Considerations below, for discussion of potential coverage eligibility based on reconstructive services.

When Policy Topic is not covered
Surgical removal of breast tissue, such as mastectomy or liposuction, as a treatment of gynecomastia is considered cosmetic due to the lack of a functional impairment. See Considerations below, for discussion of potential coverage eligibility based on reconstructive services.

Considerations
Concepts of medical necessity are based on the presence of a functional impairment.

Gynecomastia occurs in up to 75 per cent of boys to some degree, usually during the first stages of puberty. Gynecomastia may be unilateral or bilateral and occurs most frequently in mid to later stages of puberty. Gynecomastia lasts generally at least 2 years. In few instances the breast tissue is compatible to that in Tanner stage 3 or 4 female breast development. It is in such instances that spontaneous regression is less likely and surgical intervention may be appropriate, particularly when the breast is pendulous and hypertrophy is a significant somatic problem.

A work up of gynecomastia secondary to pathologic conditions should be done first to exclude testicular tumors, inadvertent chronic estrogen ingestion, fibromas or lipomas, drugs affecting androgen or estrogen production, anorchia or acquired testicular failure, Klinefelter syndrome, etc.
In routine transient pubertal gynecomastia, reassurance and psychosocial support, weight loss, and physical activity are appropriate measures. In severe or prolonged cases with no apparent regression for more than 2 years and when pubertal development is nearly completed, surgical intervention may be considered.

Therefore, surgical treatment of gynecomastia in adolescent males (21 years of age and under) may be considered when all of the following are met:
- Symptoms must be present for two or more years after obtaining Tanner Stage 3 sex maturity rating; and
- A work up to rule out gynecomastia secondary to pathologic conditions must be completed; and
- Breast tissue is compatible to that in Tanner stage 3 or 4 female breast development.

**Description of Procedure or Service**

<table>
<thead>
<tr>
<th>Populations</th>
<th>Interventions</th>
<th>Comparators</th>
<th>Outcomes</th>
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<tbody>
<tr>
<td>Individuals:</td>
<td>Interventions of interest are:</td>
<td>Comparators of interest are:</td>
<td>Relevant outcomes include:</td>
</tr>
<tr>
<td>With bilateral gynecomastia</td>
<td>Surgical treatment</td>
<td>Conservative treatment</td>
<td>Symptoms</td>
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<td>Functional outcomes</td>
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<td>Health status measures</td>
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<td>Quality of life</td>
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<td>Treatment-related morbidity</td>
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Bilateral gynecomastia refers to the 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.

For individuals with bilateral 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 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 health outcomes.

**Background**

Bilateral gynecomastia refers to the benign enlargement of the male breast, either due to increased adipose tissue, glandular tissue, fibrous tissue, or a combination of all three. Bilateral gynecomastia may be associated with any of the following:

- An underlying hormonal disorder (i.e., conditions causing either estrogen excess or testosterone deficiency such as liver disease or an endocrine disorder)
- A side effect of certain drugs
- Associated with obesity
- Related to specific age groups, i.e.,
  - Neonatal gynecomastia, related to 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 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 prevents regression of the breast tissue. Surgical removal of the breast tissue, using either surgical excision or liposuction may be considered if the above conservative therapies are not effective or possible and the gynecomastia does not resolve spontaneously or with aging.

**Rationale**

This evidence review was created in December 1995 and has been updated regularly with searches of the MEDLINE database. The most recent literature update was performed through December 6, 2018.

Evidence reviews assess the clinical evidence to determine whether the use of a technology improves the net health outcome. Broadly defined, health outcomes are length of life, quality of life, and ability to function—including benefits and harms. Every clinical condition has specific outcomes that are important to patients and to managing the course of that condition. Validated outcome measures are necessary to ascertain whether a condition improves or worsens; and whether the magnitude of that change is clinically significant. The net health outcome is a balance of benefits and harms.

To assess whether the evidence is sufficient to draw conclusions about the net health outcome of a technology, 2 domains are examined: the relevance and the quality and credibility. To be relevant, studies must represent one or more intended clinical use of the technology in the intended population and compare an effective and appropriate alternative at a comparable intensity. For some conditions, the alternative will be supportive care or surveillance. The quality and credibility of the evidence depend on study design and conduct, minimizing bias and confounding that can generate incorrect findings. The randomized controlled trial is preferred to assess efficacy; however, in some circumstances, nonrandomized studies may be adequate. Randomized controlled trials are rarely large enough or long enough to capture less common adverse events and long-
term effects. Other types of studies can be used for these purposes and to assess generalizability to broader clinical populations and settings of clinical practice.

**Bilateral Gynecomastia**

**Clinical Context and Therapy Purpose**
The purpose of surgical therapy for bilateral gynecomastia is to provide a treatment option that is an alternative to or an improvement on existing therapies, such as conservative treatment.

The question addressed in this evidence review is: is the net health outcome of individuals with bilateral gynecomastia improved by surgical treatment?

The following PICOTS were used to select literature to inform this review.

**Patients**
The relevant population of interest is individuals with bilateral gynecomastia, a benign enlargement of the male breast due either to increased adipose, glandular, or fibrous tissue or a combination of the three. An underlying hormonal disorder, obesity, and an adverse effect of certain drugs may be associated with the condition. Additionally, the bilateral gynecomastia may be related to specific age groups, including neonates, adolescents, and in aging men with decreasing levels of testosterone and relative estrogen excess.

**Interventions**
The therapy being considered is surgical treatment: removal of the breast tissue by surgical excision or liposuction.

**Comparators**
The main comparators of interest is conservative treatment, which varies based on the underlying cause of the condition and can include treatment of underlying hormonal disorder, cessation of drug therapy, and weight loss.

**Outcomes**
The general outcomes of interest are symptoms, functional outcomes, health status measures, quality of life, and treatment-related morbidity. Symptoms of bilateral gynecomastia may include enlargement, tenderness, and lumps in the breast tissue.

**Timing**
Evaluation of the general outcomes of interest requires a long follow-up period beyond the immediate postoperative period if surgery is performed. In the existing literature evaluating surgery as a treatment for bilateral gynecomastia, follow-up is 5 years.

**Setting**
Patients with bilateral gynecomastia are managed by plastic surgeons in an outpatient setting.
Study Selection Criteria
Methodologically credible studies were selected using the following principles:

a. To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs;
b. In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.
c. To assess longer term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.
d. Studies with duplicative or overlapping populations were excluded.

Coverage eligibility for treatment of bilateral gynecomastia is largely a contract/benefits issue related to the distinction between cosmetic and reconstructive services. The surgical procedure may involve surgical excision (ie, mastectomy). More recently, liposuction has been used. In some instances, adolescent gynecomastia may be reported as tender or painful, and the presence of these symptoms may be presented as a basis for surgical treatment. However, the pain associated with adolescent gynecomastia is typically self-limiting or responds to analgesic therapy.

No randomized clinical trials were identified to assess various surgical interventions to treat male gynecomastia.

Nonrandomized Studies
Exposure of new techniques, quality of life assessments and other nonsurgical outcomes have been reported in the literature.

Abdelrahman (2018) published a retrospective analysis of 18 patients with grade I-II gynecomastia treated with a combination of traditional liposuction and glandular liposculpturing between 2014 and 2016. Outcomes assessed included treatment-related morbidity and adverse events and patient reported outcomes (PROs) The PROs included patient satisfaction using the Breast Evaluation Questionaire (BEQ). Other notable information gained include treatment-related morbidity and adverse events. The post-operative aesthetic appearance was evaluated by 5 independent plastic surgeons (“observers”) who were blinded to the surgery performed making their assessments based on preoperative and 6 month postoperative photographs. The observers concluded that an acceptable post-operative result was achieved (92% of the ratings); 8% of the ratings suggested subsequent liposuction needed to be performed. The level of agreement was assessed and statistically significant for varying aesthetic variables (eg, nipple projection, p=.005). Treatment-related morbidities or adverse events were minimal and include wound infection (1/18, 5.56%) and complaints of breast-tissue remnants and requests for subsequent operation (2/18, 11.1%).

Nuzzi et al (2018) published a longitudinal cohort study aimed at measuring changes in health-related quality of life following surgical management of gynecomastia in adolescents using 3 surveys administered over a 5-year period to
both the intervention group and age- and sex-matched controls.\textsuperscript{6} The surveys administered were the Short-form 36v2 (SF-36), Rosenberg Self-Esteem Scale (RSES), and Eating-Attitudes Test-26. From 2008 to 2017, 44 patients who underwent treatment of gynecomastia and 64 unaffected controls who participated in the study. Patients in the intervention group scored significantly poorer at baseline compared with controls on both the RSES and EAT-26 (p<.05, both), even after controlling for BMI differences. Gynecomastia patients scored lower on five SF-36 domains than the controls: general health, vitality, social functioning, role-emotional, and mental health (p<.05, all). Scores significantly improved post-operatively on the RSES and in four SF-36 domains. Post-operatively, gynecomastia patients scored similarly to the control group on the SF-36 and RSES, indicating an improvement in quality of life.

<table>
<thead>
<tr>
<th>Study</th>
<th>Study Type</th>
<th>Country</th>
<th>Dates</th>
<th>Participants</th>
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<th>Treatment\textsuperscript{2}</th>
<th>Follow-Up</th>
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<tr>
<td>Abdelrahman (2018)\textsuperscript{5}</td>
<td>Retrospective analysis</td>
<td>Egypt</td>
<td>2014-2016</td>
<td>Individuals with grade I or II gynecomastia (n=18)</td>
<td>Traditional liposuction and glandular liposculpturing</td>
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<td>Nuzzi (2010)\textsuperscript{6}</td>
<td>Prospective, longitudinal cohort study</td>
<td>US</td>
<td>2008-2017</td>
<td>Adolescents diagnosed with unilateral or bilateral gynecomastia (n=44) and male controls (n=64)</td>
<td>Surgical intervention</td>
<td>Control</td>
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<table>
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<tr>
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<th>Mean pre-operative BEQ</th>
<th>Mean post-operative BEQ</th>
<th>Patients’ mean overall satisfaction score (SD)</th>
<th>Morbidities\textsuperscript{1}</th>
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<tr>
<td>Study group</td>
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<td>4.1 (0.2)</td>
<td>4.7 (0.7)</td>
<td>Wound infection (1/18, 5.56%)</td>
<td>Complaints of breast tissue remnant and requests for subsequent operation (2/18; 11.1%)</td>
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<td>p-value</td>
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<td>.001</td>
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| SF-36 – Physical Functioning (SD) | SF-36 – Bodily Pain (SD) | SF-36 – General Health (SD) | SF-36 – Social Functioning (SD) | RSES (SD) | EAT-26 (SD) |
Section Summary: Bilateral Gynecomastia

To demonstrate improvement in health outcomes, controlled trials are needed that report clinically important outcomes such as improvement in functional status. No such trials were identified through a literature search. A systematic review published in 2015 included 14 studies on the treatment of gynecomastia. None 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 criteria. The literature addresses itself to quality of life patient reported outcomes with a focus on adolescents.

Summary of Evidence

For individuals with bilateral 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.

Supplemental Information

Practice Guidelines and Position Statements

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

- “Grade I: Small breast enlargement with localized button of tissue that is concentrated around the areola.
- “Grade II: Moderate breast enlargement exceeding areola boundaries with edges that are indistinct from the chest.
- “Grade III: Moderate breast enlargement exceeding areola boundaries with edges that are distinct from the chest with skin redundancy present.
- “Grade IV: Marked breast enlargement with skin redundancy and feminization of the breast.”

BEQ= Breast evaluation questionnaire; EAT-26 = eating-attitudes test-26; RSES = Rosenberg self-esteem scale; SF-36 = short-form 36v2; CI = confidence interval
According to ASPS, in adolescents, surgical treatment for “[u]nilateral or bilateral grade II or 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 “[u]nilateral or bilateral grade III or IV gynecomastia” may be appropriate if the gynecomastia “persists for more than 3 or 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.”

**U.S. Preventive Services Task Force Recommendations**

Not applicable.

**Medicare National Coverage**

There is no national coverage determination. In the absence of a national coverage determination, coverage decisions are left to the discretion of local Medicare carriers.

**Ongoing and Unpublished Clinical Trials**

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

**REFERENCES**


**Billing Coding/Physician Documentation Information**

**19300** Mastectomy for gynecomastia

**ICD-10 Codes:**

**N62** Hypertrophy of breast (includes gynecomastia)

**Additional Policy Key Words**
### Policy Implementation/Update Information

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<th>Description</th>
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<td>4/1/08</td>
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<td>4/1/12</td>
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State and Federal mandates and health plan contract language, including specific provisions/exclusions, take precedence over Medical Policy and must be considered first in determining eligibility for coverage. The medical policies contained herein are for informational purposes. The medical policies do not constitute medical advice or medical care. Treating health care providers are independent contractors and are neither employees nor agents Blue KC and are solely responsible for diagnosis, treatment and medical advice. No part of this publication may be reproduced, stored in a retrieval system or transmitted, in any form or by any means, electronic, photocopying, or otherwise, without permission from Blue KC.