Policy Statement

The California Reconstructive Surgery Act (Health & Safety Code Section 1367.63 and the Insurance Code Section 10123.88) defines “reconstructive surgery” as surgery performed to correct or repair abnormal structures of the body caused by congenital defects, developmental abnormalities, trauma, infection, tumors, or disease to do either of the following:

- Create a normal appearance to the extent possible
- Improve function

In interpreting whether a proposed procedure meets the definition of reconstructive surgery, as defined by law, the procedure may be denied as not medically necessary under any of the following conditions:

- The procedure is likely to result in only minimal improvement in appearance, in accordance with the standard of care as practiced by physicians specializing in reconstructive surgery
- The treating surgeon cannot or will not provide sufficient documentation, including (when appropriate) medical quality color photographs, which accurately depicts the extent of the clinical problem
- There is alternative approved medical or surgical intervention with equal or superior clinical outcomes

According to the provisions of California law (SB 255, 2012), the workup and full treatment of gynecomastia associated with known or suspected breast cancer is considered medically necessary.

Coverage for gynecomastia surgery may require independent consideration of whether the surgery is considered medically necessary or reconstructive (see the Reconstructive Services Medical Policy).

Gynecomastia surgery (unilateral or bilateral) may be considered medically necessary when all of the following criteria are met:

- Patient is greater than 18 years of age, or 18 months postpuberty, whichever is younger
- Glandular breast tissue (true gynecomastia) is confirmed on physical exam and/or mammography or tissue biopsy
- Gynecomastia is not the result of adolescence (puberty), obesity, or reversible effects of prescription or non-prescription medications or substances which can be discontinued
- Documentation supports underlying etiologies or contributory conditions have been considered, or excluded and/or treated
- Medical photographic evidence (anterior and lateral views) of significant structural abnormality substantiates the request for surgery

Policy Guidelines

The technique of liposuction in combination with gynecomastia surgery is considered incidental and included in the primary procedure.

Physiologic gynecomastia includes the following:

- Neonatal gynecomastia
- Prepubertal gynecomastia
- Pubertal gynecomastia
- Increasing age
Pathologic gynecomastia is associated with both androgen deficiency and estrogen excess. These causes can be correlated to (not an inclusive list):

- Hypogonadism (testicular failure)
- Endocrine disorders (e.g., hyperprolactinemia, hyperthyroidism)
- Metabolic disorders (e.g., cirrhosis, or refeeding after starvation)
- Neoplasms (e.g., testicular, prostate and adrenal)
- Breast cancer

Pharmacological gynecomastia presents as a side effect of certain drugs or substances including, but not limited to:

- Alcohol
- Amphetamines
- Anabolic steroids and androgens (prescribed and over the counter)
- Anti-androgens (e.g., flutamide, finasteride [Proscar], and spironolactone [Aldactone])
- Anti-anxiety medications (e.g., Valium)
- Antibiotics
- Anti-retroviral agents (e.g., Efavirenz [Sustiva])
- Chemotherapeutic agents
- Heart medications (e.g., digoxin, calcium channel blockers)
- Herbal remedies
- Heroin
- Marijuana
- Methadone
- Tricyclic antidepressants
- Ulcer medications (e.g., cimetidine)

Diagnostic evaluation, if an underlying cause or condition is suspected, may include any of the following (not an all-inclusive list):

- Complete blood count
- Chemistry panel if medically indicated (e.g., diabetes, hypertension)
- Estrogen, testosterone, prolactin, growth hormone, human chorionic gonadotropin
- Thyroid stimulating hormone or thyroid studies
- Chest x-ray: history of smoking, suspicion for cancer
- Electrocardiogram for patients over 40 years
- Mammogram: large breast and suspicion of cancer

**Description**

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. Gynecomastia may be associated with various physiological, pathological, or pharmacological causes that alter normal hormonal balance. Treatment of gynecomastia involves consideration of the underlying cause. Surgical removal of the breast tissue, using either surgical excision or liposuction may be considered if conservative therapies are not effective or possible.

**Related Policies**

- N/A

**Benefit Application**

Benefit determinations should be based in all cases on the applicable contract language. To the extent there are any conflicts between these guidelines and the contract language, the contract language will control. Please refer to the member's contract benefits in effect at the
time of service to determine coverage or non-coverage of these services as it applies to an individual member.

Some state or federal mandates [e.g., Federal Employee Program (FEP)] prohibits plans from denying Food and Drug Administration (FDA)-approved technologies as investigational. In these instances, plans may have to consider the coverage eligibility of FDA-approved technologies on the basis of medical necessity alone.

**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.

**Rationale**

**Background**

**Gynecomastia**

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. 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)
- An adverse effect of certain drugs
- 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**

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.

**Literature Review**

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.

Gynecomastia
Clinical Context and Therapy Purpose
The purpose of surgical therapy for 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 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 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 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 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 gynecomastia, follow-up is 5 years.

Setting
Patients with 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.

The surgical procedure may involve surgical excision (i.e., mastectomy). More recently, liposuction has been used.\textsuperscript{1,2} 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 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.\textsuperscript{5} Outcomes assessed included treatment-related morbidity and adverse events and patient reported outcomes (PROs). The PROs included patient satisfaction using the Breast Evaluation Questionnaire (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 (e.g., nipple projection, p=0.005). 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 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<0.05, 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 1. Summary of Nonrandomized Studies Characteristics

<table>
<thead>
<tr>
<th>Study</th>
<th>Study Type</th>
<th>Country</th>
<th>Dates</th>
<th>Participants</th>
<th>Treatment 1</th>
<th>Treatment 2</th>
<th>Follow-Up</th>
</tr>
</thead>
<tbody>
<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>
<td>6-months</td>
<td></td>
</tr>
<tr>
<td>Nuzzi (2018)\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>
<td>5-years</td>
</tr>
</tbody>
</table>
Table 2. Summary of Observational Comparative Study Results (Abdelrahman 2018<sup>5</sup>)

<table>
<thead>
<tr>
<th>Study</th>
<th>Mean pre-operative BEQ</th>
<th>Mean post-operative BEQ</th>
<th>Patients' mean overall satisfaction score (SD)</th>
<th>Morbidities 1</th>
<th>Morbidities 2</th>
</tr>
</thead>
<tbody>
<tr>
<td>Abdelrahman (2018)&lt;sup&gt;5&lt;/sup&gt; Study group</td>
<td>2.1 (0.2)</td>
<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>
</tr>
<tr>
<td>p-value</td>
<td>.001</td>
<td>.001</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

BEQ: Breast evaluation questionnaire; SD: standard deviation

Table 3. Summary of Observational Comparative Study Results (Nuzzi 2018<sup>6</sup>)

<table>
<thead>
<tr>
<th>Study</th>
<th>SF-36 - Physical Functioning (SD)</th>
<th>SF-36 - Bodily Pain (SD)</th>
<th>SF-36 - General Health (SD)</th>
<th>SF-36 - Social Functioning (SD)</th>
<th>RSES (SD)</th>
<th>EAT-26 (SD)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nuzzi (2018)&lt;sup&gt;6&lt;/sup&gt; Treatment group</td>
<td>97.0 (7.2)</td>
<td>81.2 (11.0)</td>
<td>77.4 (17.8)</td>
<td>84.6 (22.0)</td>
<td>32.5 (6.4)</td>
<td>8.0 (6.5)</td>
</tr>
<tr>
<td>Control</td>
<td>97.1 (11.6)</td>
<td>78.7 (15.3)</td>
<td>83.6 (16.0)</td>
<td>88.3 (20.6)</td>
<td>34.8 (5.8)</td>
<td>3.8 (5.2)</td>
</tr>
<tr>
<td>p-value</td>
<td>.78</td>
<td>.59</td>
<td>.59</td>
<td>.42</td>
<td>.26</td>
<td>.001</td>
</tr>
</tbody>
</table>

SF-36: short-form 36v2; SD: standard deviation; RSES: Rosenberg self-esteem scale; EAT-26: eating-attitudes test-26

Section Summary: 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.<sup>3</sup> 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 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.

Surgical removal of the breast tissue, using either surgical excision or liposuction may be considered if conservative therapies are not effective or possible.

Surgical treatment of gynecomastia may require consideration of whether such surgery would be considered medically necessary, not medically necessary, or reconstructive based on the indications addressed in the policy statement.

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.<sup>4</sup> 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.”

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 February 2019 did not identify any ongoing or unpublished trials that would likely influence this review.

References


Documentation for Clinical Review

Please provide the following documentation (if/when requested):
• History and physical and/or consultation notes including:
  o Duration of condition, prior treatment and response(s)
• Lab and/or pathology reports (if applicable)
• Mammography or radiological reports (if applicable)
• Quality medical photographs (anterior and lateral views) substantiating the request for surgery
**Post Service**
- Operative report(s)

**Coding**

This Policy relates only to the services or supplies described herein. Benefits may vary according to product design; therefore, contract language should be reviewed before applying the terms of the Policy. Inclusion or exclusion of codes does not constitute or imply member coverage or provider reimbursement.

**MN/NMN**

The following services may be considered medically necessary when policy criteria are met. Services may be considered not medically necessary when policy criteria are not met.

<table>
<thead>
<tr>
<th>Type</th>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>CPT</td>
<td></td>
<td></td>
</tr>
<tr>
<td>19300</td>
<td></td>
<td>Mastectomy for gynecomastia <em>(Code effective 1/1/2020)</em></td>
</tr>
<tr>
<td>19301</td>
<td></td>
<td>Mastectomy, partial (e.g., lumpectomy, tylectomy, quadrantectomy, segmentectomy)</td>
</tr>
<tr>
<td>19303</td>
<td></td>
<td>Mastectomy, simple, complete</td>
</tr>
<tr>
<td>19304</td>
<td></td>
<td>Mastectomy, subcutaneous <em>(Deleted code effective 1/1/2020)</em></td>
</tr>
<tr>
<td>19304</td>
<td></td>
<td>Mastectomy, subcutaneous <em>(Deleted code effective 1/1/2020)</em></td>
</tr>
<tr>
<td>19303</td>
<td></td>
<td>Mastectomy, simple, complete</td>
</tr>
<tr>
<td>19318</td>
<td></td>
<td>Reduction mammoplasty <em>(Code effective 1/1/2020)</em></td>
</tr>
</tbody>
</table>

**Policy History**

This section provides a chronological history of the activities, updates, and changes that have occurred with this Medical Policy.

<table>
<thead>
<tr>
<th>Effective Date</th>
<th>Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>03/01/2007</td>
<td>Policy Revision Separated from Reduction Mammaplasty policy. BCBSA MPP adopted. Policy statement unchanged.</td>
</tr>
<tr>
<td>01/11/2008</td>
<td>Policy Revision Policy updated with literature review; medical necessity criteria developed.</td>
</tr>
<tr>
<td>10/28/2009</td>
<td>Coding update</td>
</tr>
<tr>
<td>07/01/2011</td>
<td>Policy title change from Gynecomastia with position change</td>
</tr>
<tr>
<td>03/30/2015</td>
<td>Policy clarification</td>
</tr>
<tr>
<td>06/30/2015</td>
<td>Coding update</td>
</tr>
<tr>
<td>12/04/2015</td>
<td>Policy title change from Gynecomastia Surgery Policy revision with position change</td>
</tr>
<tr>
<td>04/01/2016</td>
<td>Policy revision without position change</td>
</tr>
<tr>
<td>04/01/2017</td>
<td>Policy revision without position change</td>
</tr>
<tr>
<td>04/01/2018</td>
<td>Policy revision without position change</td>
</tr>
<tr>
<td>07/01/2018</td>
<td>Policy statement clarification</td>
</tr>
<tr>
<td>04/01/2019</td>
<td>Policy title change from Surgical Treatment of Bilateral Gynecomastia Policy revision without position change</td>
</tr>
<tr>
<td>03/01/2020</td>
<td>Coding update</td>
</tr>
</tbody>
</table>

**Definitions of Decision Determinations**

**Medically Necessary:** Services that are Medically Necessary include only those which have been established as safe and effective, are furnished under generally accepted professional standards to treat illness, injury or medical condition, and which, as determined by Blue Shield, are: (a) consistent with Blue Shield medical policy; (b) consistent with the symptoms or diagnosis;
(c) not furnished primarily for the convenience of the patient, the attending Physician or other provider; (d) furnished at the most appropriate level which can be provided safely and effectively to the patient; and (e) not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of the Member’s illness, injury, or disease.

**Investigational/Experimental:** A treatment, procedure, or drug is investigational when it has not been recognized as safe and effective for use in treating the particular condition in accordance with generally accepted professional medical standards. This includes services where approval by the federal or state governmental is required prior to use, but has not yet been granted.

**Split Evaluation:** Blue Shield of California/Blue Shield of California Life & Health Insurance Company (Blue Shield) policy review can result in a split evaluation, where a treatment, procedure, or drug will be considered to be investigational for certain indications or conditions, but will be deemed safe and effective for other indications or conditions, and therefore potentially medically necessary in those instances.

### Prior Authorization Requirements (as applicable to your plan)

Within five days before the actual date of service, the provider must confirm with Blue Shield that the member's health plan coverage is still in effect. Blue Shield reserves the right to revoke an authorization prior to services being rendered based on cancellation of the member’s eligibility. Final determination of benefits will be made after review of the claim for limitations or exclusions.

Questions regarding the applicability of this policy should be directed to the Prior Authorization Department at (800) 541-6652, or the Transplant Case Management Department at (800) 637-2066 ext. 3507708 or visit the provider portal at www.blueshieldca.com/provider.

Disclaimer: This medical policy is a guide in evaluating the medical necessity of a particular service or treatment. Blue Shield of California may consider published peer-reviewed scientific literature, national guidelines, and local standards of practice in developing its medical policy. Federal and state law, as well as contract language, including definitions and specific contract provisions/exclusions, take precedence over medical policy and must be considered first in determining covered services. Member contracts may differ in their benefits. Blue Shield reserves the right to review and update policies as appropriate.