Surgical Treatment of Bilateral Gynecomastia

**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

If a procedure is determined to be reconstructive surgery, as defined above, the procedure may be denied as **not medically necessary** under any of the following conditions:

- The procedure, if not primarily intended to improve function, is likely to result in only minimal improvement in appearance
- 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 male 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):
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**

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. 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

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)
- 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 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

Physiologic gynecomastia can occur at times of male hormonal change such as in infancy, adolescence, or old age. Gynecomastia seen in newborns is normally the result of excess maternal or placental estrogens, usually resolving a few weeks after delivery. Breast tissue enlargement in pubertal (adolescent) males usually occurs at a median age of 14 years. For the majority of males whose pubertal gynecomastia is not due to obesity, the breast development shrinks or disappears within a couple of years. Pubertal gynecomastia often regresses spontaneously in six months; 75% of cases resolve within two years of onset; and approximately 90% of cases resolve within three years. The adult condition is less likely to resolve spontaneously. Finally, gynecomastia can occur as part of the normal aging process due to increased body fat, primary testicular failure and/or increase in the estrogen-androgen ratio. Most cases are considered normal findings and no treatment is necessary.

Pathologic gynecomastia can be caused by diseases, conditions, medications or illicit drugs or alcohol that decrease the production or activity of testosterone, or increase the production or activity of estrogen. In some cases the cause is unknown. Specific diseases associated with gynecomastia include, but are not limited to, hypogonadism (testicular failure), liver cirrhosis (e.g., Laennec's cirrhosis), renal failure, malnutrition, endocrine disorders (e.g., hyperprolactinemia, hyperthyroidism), neoplasms (e.g., testicular tumors, pituitary tumors,
malignancies increasing human chorionic gonadotropin, germ cell tumors, adrenal tumors, feminizing adrenal tumors and bronchogenic carcinoma), familial disorders, chromosomal abnormalities (e.g., Klinefelter’s syndrome), and patients receiving antiretroviral therapy for human immunodeficiency virus (HIV). Only one percent of male breast enlargement is due to malignancy.¹

Gynecomastia can be induced by various prescription and non-prescription medications or substances that can increase estrogen effects by possessing intrinsic estrogen-like properties, stimulating estrogen synthesis, or supplying an estrogen precursor (See Policy Guidelines). There are also drugs that can reduce testosterone levels by causing testicular damage, blocking the synthesis of testosterone, or blocking androgen action. Examples include, but are not limited to, estrogens, chemotherapeutic agents, gonadotropins, ketoconazole, metronidazole, spironolactone, antidepressants, antiulcer drugs, as well as herbal remedies. The consumption of illegal drugs or substances including marijuana, methadone, heroin, amphetamines, alcohol and anabolic steroids can contribute to gynecomastia as well.¹⁵⁻⁷

Generally, no treatment is required for physiologic gynecomastia. Over time, fibrotic tissue replaces symptomatic proliferation of glandular tissue and tenderness resolves.⁴⁻⁶ Reassurance of the patient and/or parent may sufficiently address this. Pharmacological gynecomastia often responds to modification or discontinuation of the offending medication or substance. Patients whose conditions are due to an endocrine or metabolic disorder (e.g., malnutrition) should receive appropriate medical treatment first.¹ Medical therapies have been proven to be most effective when gynecomastia onset is recent and caused by testosterone deficiency. In many cases once inactive fibrotic tissue develops, medical treatment becomes less effective.

Decisions regarding surgery are dependent on the outcome of treatment of the underlying disorder. The surgical procedure may involve surgical excision (i.e., mastectomy) or more recently, liposuction has been used.⁸⁻⁹ In some instances, adolescent gynecomastia may be reported as tender or painful, and the presence of these symptoms may be presented as a rationale for the medical necessity of surgical treatment. However, the pain associated with adolescent gynecomastia is typically self-limiting or responds to analgesic therapy.

Summary of Evidence
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.

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

American Society of Plastic Surgeons
The American Society of Plastic Surgeons (ASPS) issued practice criteria for third-party payers.¹⁰ In this document, the ASPS classified gynecomastia with 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 (NCD). In the absence of an NCD, coverage decisions are left to the discretion of local Medicare carriers.

**Ongoing and Unpublished Clinical Trials**
An online search of ClinicalTrials.gov in February 2018, identified no clinical trials that addressed surgery for gynecomastia.

**References**

Documentation for Clinical Review

Please provide the following documentation (if/when requested):

- History and physical and/or consultation notes including:
  - 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.

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<tr>
<th>Type</th>
<th>Code</th>
<th>Description</th>
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<tr>
<td>CPT®</td>
<td>19300</td>
<td>Mastectomy for gynecomastia</td>
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<tr>
<td></td>
<td>19301</td>
<td>Mastectomy, partial (e.g., lumpectomy, tylectomy, quadrantectomy, segmentectomy)</td>
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<tr>
<td></td>
<td>19303</td>
<td>Mastectomy, simple, complete</td>
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<td>19304</td>
<td>Mastectomy, subcutaneous</td>
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<td>HCPCS</td>
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Policy History

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

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<tr>
<th>Effective Date</th>
<th>Action</th>
<th>Reason</th>
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<tbody>
<tr>
<td>03/01/2007</td>
<td>Policy Revision Separated from Reduction Mammaplasty policy. BCBSA MPP adopted. Policy statement unchanged.</td>
<td>Medical Policy Committee</td>
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<tr>
<td>01/11/2008</td>
<td>Policy Revision Policy updated with literature review; medical necessity criteria developed.</td>
<td>Medical Policy Committee</td>
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<tr>
<td>10/28/2009</td>
<td>Coding update</td>
<td>Administrative Review</td>
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<tr>
<td>07/01/2011</td>
<td>Policy title change from Gynecomastia with position change</td>
<td>Medical Policy Committee</td>
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<tr>
<td>03/30/2015</td>
<td>Policy clarification</td>
<td>Medical Policy Committee</td>
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Definitions of Decision Determinations

**Medically Necessary:** A treatment, procedure, or drug is medically necessary only when it has been established as safe and effective for the particular symptoms or diagnosis, is not investigational or experimental, is not being provided primarily for the convenience of the patient or the provider, and is provided at the most appropriate level to treat the condition.

**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 government 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. Please call (800) 541-6652 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.