Title: Surgical Treatment of Gynecomastia

State and Federal mandates and health plan member contract language, including specific provisions/exclusions, take precedence over Medical Policy and must be considered first in determining eligibility for coverage. To verify a member's benefits, contact Blue Cross and Blue Shield of Kansas Customer Service.

The BCBSKS Medical Policies contained herein are for informational purposes and apply only to members who have health insurance through BCBSKS or who are covered by a self-insured group plan administered by BCBSKS. Medical Policy for FEP members is subject to FEP medical policy which may differ from BCBSKS Medical Policy.

The medical policies do not constitute medical advice or medical care. Treating health care providers are independent contractors and are neither employees nor agents of Blue Cross and Blue Shield of Kansas and are solely responsible for diagnosis, treatment and medical advice.

If your patient is covered under a different Blue Cross and Blue Shield plan, please refer to the Medical Policies of that plan.

### Populations
- Individuals: With bilateral gynecomastia

### Interventions
- Interventions of interest are:
  - Surgical treatment

### Comparators
- Comparators of interest are:
  - Conservative treatment

### Outcomes
- Relevant outcomes include:
  - Symptoms
  - Functional outcomes
  - Health status measures
  - Quality of life
  - Treatment-related morbidity

**DESCRIPTION**

Bilateral 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.
**OBJECTIVE**
The objective of this policy is to evaluate whether surgical treatment of bilateral gynecomastia improves functional outcomes.

**BACKGROUND**

**Bilateral Gynecomastia**
Bilateral 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. Bilateral gynecomastia may be associated with any of the following:

- 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
- Obesity
- Related to specific age groups, ie,
  - 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 prevent regression of the breast tissue. Surgical removal of the breast tissue, using surgical excision or liposuction, may be considered if the conservative therapies above are not effective or possible and the gynecomastia does not resolve spontaneously or with aging.

**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.
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.

**POLICY**
A. Surgical removal of breast tissue such as mastectomy or liposuction as a treatment of gynecomastia is considered contractually **noncovered**.

B. Surgical treatment of gynecomastia for pain is considered **not medically necessary**.

C. An incisional biopsy is considered **medically necessary** for male breast masses that have features atypical for gynecomastia when malignancy is a valid concern.

**Policy Guidelines**
1. Reconstructive surgery for gynecomastia with no functional impairment is contractually noncovered.
2. Pain associated with gynecomastia is typically mild, transient and medically treatable.

**RATIONALE**
This evidence review was originally created in 1995 and has been regularly updated with literature reviews. The most recent literature review was conducted for the period through December 11, 2017.

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
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.

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 was 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.

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 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.

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.”

According to ASPS, in adolescents, surgical treatment for unilateral or bilateral grade II or III gynecomastia may be appropriate if the gynecomastia persists for more than 1 year after pathologic causation is ruled out (or 6 months if grade IV) and continues after 6 months if medical treatment is unsuccessful. In adults, surgical treatment for unilateral or bilateral grade III or IV gynecomastia may be appropriate if the gynecomastia persists for more than 3 or 4 months after pathologic causation is ruled out and continues after 3 or 4 months of medical treatment that is unsuccessful. ASPS also indicates 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.

ONGOING AND UNPUBLISHED CLINICAL TRIALS

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

CODING

The following codes for treatment and procedures applicable to this policy are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement. 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.

CPT/HCPCS

19101 Biopsy of breast; open, incisional
19300 Mastectomy for gynecomastia

ICD-10 Diagnoses

C50.021 Malignant neoplasm of nipple and areola, right male breast
C50.022 Malignant neoplasm of nipple and areola, left male breast
C50.121 Malignant neoplasm of central portion of right male breast
C50.122 Malignant neoplasm of central portion of left male breast
C50.221 Malignant neoplasm of upper-inner quadrant of right male breast
C50.222 Malignant neoplasm of upper-inner quadrant of left male breast
C50.321 Malignant neoplasm of lower-inner quadrant of right male breast
C50.322 Malignant neoplasm of lower-inner quadrant of left male breast
C50.421 Malignant neoplasm of upper-outer quadrant of right male breast
C50.422 Malignant neoplasm of upper-outer quadrant of left male breast
C50.521 Malignant neoplasm of lower-outer quadrant of right male breast
C50.522 Malignant neoplasm of lower-outer quadrant of left male breast
C50.621 Malignant neoplasm of axillary tail of right male breast
C50.622 Malignant neoplasm of axillary tail of left male breast
C50.821 Malignant neoplasm of overlapping sites of right male breast
C50.822 Malignant neoplasm of overlapping sites of left male breast
C50.921 Malignant neoplasm of unspecified site of right male breast
C50.922 Malignant neoplasm of unspecified site of left male breast
N62 Hypertrophy of breast
N64.4 Mastodynia
N63.11 Unspecified lump in the right breast, upper outer quadrant
N63.12 Unspecified lump in the right breast, upper inner quadrant
N63.13 Unspecified lump in the right breast, lower outer quadrant
N63.14 Unspecified lump in the right breast, lower inner quadrant
N63.21 Unspecified lump in the left breast, upper outer quadrant
N63.22 Unspecified lump in the left breast, upper inner quadrant
N63.23 Unspecified lump in the left breast, lower outer quadrant
N63.24 Unspecified lump in the left breast, lower inner quadrant
N63.31 Unspecified lump in axillary tail of the right breast
N63.32 Unspecified lump in axillary tail of the left breast
N63.41 Unspecified lump in right breast, subareolar
N63.42 Unspecified lump in left breast, subareolar

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<tr>
<td>02-26-2013</td>
<td>Description section updated.</td>
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REFERENCES


Other References

1. Blue Cross and Blue Shield of Kansas Surgery Liaison Committee, August 2010.