Title: Surgical Treatment of Gynecomastia

**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 3. 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 is a benign enlargement of the male breast, either due to increased adipose tissue, glandular tissue, fibrous tissue, or a combination of all 3. 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 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.
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 22, 2016.

As previously noted, 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) or, more recently, liposuction has been used.\(^1\)\(^2\) In some instances, adolescent gynecomastia may be reported as tender or painful, and the presence of these symptoms may be presented as a rationale for the medical necessity of 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 literature search. A systematic review published in 2015 included 14 studies on the treatment of gynecomastia.\(^3\) 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 evaluation.

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. 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 2017 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.

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<th>Description</th>
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<td>19101</td>
<td>Biopsy of breast; open, incisional</td>
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<td>19300</td>
<td>Mastectomy for gynecomastia</td>
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<th>ICD-9 Diagnoses</th>
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175.0  Malignant neoplasm of male breast
175.9  Malignant neoplasm of male breast; other and unspecified sites of male breast

ICD-10 Diagnoses (Effective October 1, 2015)

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

REVISIONS

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REFERENCES

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