Clinical Policy Title: Reduction mammoplasty for male gynecomastia

Clinical Policy Number: 16.03.07

Effective Date: July 1, 2015
Initial Review Date: February 18, 2015
Most Recent Review Date: April 19, 2017
Next Review Date: April 2017

Related policies:

**CP# 16.03.05  Breast reduction surgery**

ABOUT THIS POLICY: Keystone First has developed clinical policies to assist with making coverage determinations. Keystone First’s clinical policies are based on guidelines from established industry sources, such as the Centers for Medicare & Medicaid Services (CMS), state regulatory agencies, the American Medical Association (AMA), medical specialty professional societies, and peer-reviewed professional literature. These clinical policies along with other sources, such as plan benefits and state and federal laws and regulatory requirements, including any state- or plan-specific definition of “medically necessary,” and the specific facts of the particular situation are considered by Keystone First when making coverage determinations. In the event of conflict between this clinical policy and plan benefits and/or state or federal laws and/or regulatory requirements, the plan benefits and/or state and federal laws and/or regulatory requirements shall control. Keystone First's clinical policies are for informational purposes only and not intended as medical advice or to direct treatment. Physicians and other health care providers are solely responsible for the treatment decisions for their patients. Keystone First’s clinical policies are reflective of evidence-based medicine at the time of review. As medical science evolves, Keystone First will update its clinical policies as necessary. Keystone First’s clinical policies are not guarantees of payment.

Coverage policy

Keystone First considers the use of reduction mammoplasty for male gynecomastia to be clinically proven and, therefore, medically necessary when any of the following criteria are met:

- Up to age 18 and all of the following:
  - Gynecomastia has been present for at least two years since pubertal onset.
  - Gynecomastia persists after six months of unsuccessful medical treatment for pathological gynecomastia.
  - There is clinically significant functional impairment (e.g., chronic skin irritation with pain, related psychological disorder requiring therapy).
  - The patient has a significant psychological disorder due to gynecomastia
- Older than age 18 and all of the following:
  - Gynecomastia does not regress after cessation of medications known to cause the condition (e.g., calcium channel blockers, cimetidine, phenothiazines, spironolactone, theophylline; is not due to the use of anabolic steroids, alcohol abuse, or illegal drugs).
  - No evidence of other medical causes for gynecomastia as indicated by normal results for all of the following:
- Serum creatinine.
- Liver enzymes.
- Thyroid function tests.
- Hormone evaluation (e.g., testosterone, LH, FSH, estradiol, prolactin, beta HCG).
- THC/cannabis
- Mammography, ultrasound, or needle biopsy has ruled out breast cancer.
- The gynecomastia is classified as Grade II, III, or IV (per American Society of Plastic Surgeons [ASPS] classification) by physical examination.
- Gynecomastia is not the result of obesity.
- Photographic documentation confirms severe breast hypertrophy.

Limitations:

Use of surgical treatment for gynecomastia is not medically necessary for the following indications, because each is considered cosmetic in nature:
- When the only purpose is to improve appearance of the male breast or to alter contours of the chest wall.
- When the only purpose is to treat psychological or psychosocial complaints.

Keystone First considers lipectomy or ultrasonically assisted suction lipectomy (liposuction) the only method of treatment for gynecomastia to be unproven in the treatment of gynecomastia.

Alternative covered services:

Continued evaluation by the treating physician.

Background

Gynecomastia is a benign enlargement of the male breast (sometimes bilateral, sometimes unilateral) caused by an imbalance in the ratio of circulating male hormone (testosterone) to female hormone (estrogen). Gynecomastia occurs with normal hormonal changes during puberty or aging but is also associated with other conditions or drugs that alter the hormonal ratio. Gynecomastia is characterized by the growth of glandular tissue within the breast, the growth of glandular tissue and fatty tissue deposits, or an accumulation of fatty tissue alone (Ansstas, 2016).

Gynecomastia is classified into four categories, by severity levels. The condition is often associated with pain or tenderness warranting medical intervention, and patients also seek treatment due to social concerns and embarrassment. Most cases are physiological, and no treatment other than reassurance is needed. Adolescent gynecomastia almost always resolves within two years; the 30 percent to 40 percent of older males with the condition rarely require treatment (Johnson, 2009). For those cases that are treated, tamoxifen is the preferred treatment. If this drug fails, reduction mammoplasty may be

Gynecomastia is also associated with several other conditions. Men who use anabolic steroids to enhance athletic performance often demonstrate gynecomastia. Gynecomastia has been reported as a common side effect of certain therapies for prostate cancer, including nonsteroidal antiandrogen monotherapy. The use of illegal drugs, such as marijuana and heroin, and other substances, including methadone and alcohol, has also been linked to gynecomastia. Additionally, gynecomastia is associated with androgen deficiency and/or estrogen excess and may result from the use of medications (e.g., estrogens, androgens, calcium channel blockers, antihypertensives, digitalis preparations, aldactone), endocrine abnormalities (e.g., hyperthyroidism), tumors (e.g., testicular), chronic disease (e.g., cirrhosis of the liver), chromosomal abnormalities (e.g., Klinefelter syndrome), and other familial disorders.

In male patients, reduction mammoplasty is performed for symptomatic gynecomastia as an open procedure or a combination of surgical excision and liposuction. The specific surgical technique will vary depending on the degree of breast hypertrophy present and the amount of fat tissue versus breast tissue removed. Surgical excision of breast tissue is used for true gynecomastia, as this glandular tissue cannot be suctioned. Reduction mammoplasty is indicated for gynecomastia not related to malignancy or caused by other treatable factors (NIH, 2017).

A systematic review of 11 articles found 11 classification systems for gynecomastia surgery. There were 10 unique features, including breast size, skin redundancy, breast ptosis, tissue predominance, upper abdominal laxity, breast tuberosity, nipple malposition, chest shape, absence of sternal notch, and breast skin elasticity. On average, classification systems included two to three of these (Waltho, 2017).

An integral component in the evaluation of gynecomastia is recognizing and discontinuing any drugs that can cause the disorder. Contributory medications should be discontinued or changed to an alternative medication, if available. A strong relationship has been established between gynecomastia and a variety of medications.

**Searches**

Keystone First searched PubMed and the databases of:

- UK National Health Services Centre for Reviews and Dissemination.
- Agency for Healthcare Research and Quality’s National Guideline Clearinghouse and other evidence-based practice centers.
- The Centers for Medicare & Medicaid Services (CMS).

Searches were conducted on March 16, 2017. Search terms were: “mastectomy, reduction mammoplasty, gynecomastia, and liposuction” (MeSH).
We included:

- **Systematic reviews**, which pool results from multiple studies to achieve larger sample sizes and greater precision of effect estimation than in smaller primary studies. Systematic reviews use predetermined transparent methods to minimize bias, effectively treating the review as a scientific endeavor, and are thus rated highest in evidence-grading hierarchies.
- **Guidelines based on systematic reviews.**
- **Economic analyses**, such as cost-effectiveness, and benefit or utility studies (but not simple cost studies), reporting both costs and outcomes — sometimes referred to as efficiency studies — which also rank near the top of evidence hierarchies.

**Findings**

Most of the literature on mammoplasty addresses females, not males with gynecomastia. The evidence base for surgery for gynecomastia is somewhat weak and limited to observational case series. Clinical outcomes other than complications were not routinely addressed. The existing studies reflect a variety of approaches and describe multiple individual techniques. Further, most of the studies have small patient numbers and employ varying classification systems for gynecomastia, and the etiology of the condition varies among patients. The majority of the studies have a retrospective design and lack controls, and the extent and length of follow-up is often unclear. All of these factors limit the ability to evaluate and compare outcomes between the studies. Although the evidence base is poor, the best inference is a substantial proportion of patients may achieve a satisfactory outcome, although some may require additional treatment or procedures for complications. Surgery for gynecomastia is an appropriate option for carefully selected patients with symptomatic persistent disease who have not responded to medical therapy when surgery is performed by a surgeon with experience in the selected technique and when tissue is submitted for histopathological examination.

A systematic review of 14 articles found that among procedures for male gynecomastia, traditional surgical excision of glandular tissue with liposuction provides the most consistent results with a low complication rate, although there are other surgeries that have shown good results (Fagerlund, 2015). A study of 102 breasts from 65 male adolescents with gynecomastia found that just 22 underwent mammoplasty, while the others underwent mastectomy, indicating that mammoplasty is selected for surgery in only a minority of gynecomastia cases.

A review of 126 cases of male gynecomastia (111 of which were bilateral) undergoing surgery documented 17.72 percent with a complication. Patients reported an improvement in quality of life, with an average score of 8.2 out of 10 (Brafa, 2011).

A review of 20 adolescent gynecomastia patients who underwent surgery included eight with bilateral mammoplasty and 12 with subcutaneous mastectomy. All but one (87 percent) of the mammoplasty patients had an excellent outcome, leading authors to conclude that while milder cases of gynecomastia can be managed with subcutaneous mastectomy, selected severe cases can be effectively treated with mammoplasty (Laituri, 2010).
Mammoplasty is becoming less invasive. One study reviewed 36 male patients (58 breasts) who underwent surgery using a vacuum-assisted biopsy device and liposuction. Only one intra-operative complication was recorded, two patients required a second procedure, and 34 of 36 patients reported excellent satisfaction (Qutob, 2010).

Mastectomies for gynecomastia are also becoming minimally invasive, and are not drastically different from mammoplasty. Surgery in 53 males with grade I and II gynecomastia was reviewed, after use of liposuction through an inframammary fold incision and excision of the glandular tissue by minimal periareolar approach. Of the 104 breasts involved, there were only two post-operative hemorrhages and two re-operations due to cosmetic reasons. Surgery lasted a median of 72 minutes (Schroder, 2015).

While gynecomastia is considered a benign disease, a recent review found 6.76 percent (5 of 74) males age 17 – 29 undergoing surgery for the condition had a ductal carcinoma in situ, suggesting histopathological examination of the resected gynecomastia tissue should be performed in males with the disease (Shirah, 2016). Another study of 5113 male breasts found 0.11 percent had invasive carcinomas, and another 0.18 percent had in situ carcinomas (Lapid, 2015).

**Policy updates:**

A total of three guidelines/other and 11 peer reviewed articles were added to the policy.

**Summary of clinical evidence:**

<table>
<thead>
<tr>
<th>Citation</th>
<th>Content, Methods, Recommendations</th>
</tr>
</thead>
</table>
                         | Key points:
                         |   - 17 studies, all not randomized, high risk of bias, low quality of evidence.
                         |   - Several types of surgery, including mammoplasty, described with good results, minimal scars, and various complication levels.
                         |   - Traditional surgery provides most consistent results and low complication rate. |
| Brafa (2011)           | Complications and satisfaction after surgery for gynecomastia
                         | Key points:
                         |   - 126 male gynecomastia cases (111 bilateral, 15 unilateral) underwent surgery.
                         |   - Average age: 28 years, most given adenomectomy, others given circumareolar or vertical scar incision and liposuction.
                         |   - Complication rate was 17.72%; all patients reported improvement in quality of life (average 8.2 of 10). |
| Laituri (2010)         | Surgical treatment of adolescents with gynecomastia
                         | Key points:
                         |   - 20 patients underwent surgery for gynecomastia (eight with bilateral mammoplasty, 12 with unilateral or bilateral subcutaneous mastectomy); average follow-up: 18.8 mos.
                         |   - One patient developed seoma after mastectomy; one patient had mild subcutaneous asymmetry after mammoplasty requiring no further intervention.
                         |   - Seven of eight mammoplasty patients had excellent cosmetic outcome after mammoplasty.
                         |   - Authors conclude most milder surgical gynecomastia cases can be treated with mastectomy; selected severe cases can be effectively treated with mammoplasty. |
Quotob (2010)  
Efficacy of minimally invasive excision of gynecomastia

**Key points:**
- Review of 36 patients with gynecomastia requesting surgical intervention (22 bilateral, 14 unilateral); average age 33.3 years
- All underwent vacuum-assisted biopsy device and liposuction, followed > 2 months
- 34 of 36 patients reported excellent satisfaction
- 1 intra-operative complication recorded, 2 needed repeat procedures, 3 developed small hematomas that resolved spontaneously

**Adopted classification system for gynecomastia by ASPS to characterize the severity of gynecomastia:**

<table>
<thead>
<tr>
<th>Grade I</th>
<th>Small breast enlargement with localized button of tissue around the areola.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Grade II</td>
<td>Moderate breast enlargement exceeding areola boundaries with edges that are indistinct from the chest.</td>
</tr>
<tr>
<td>Grade III</td>
<td>Moderate breast enlargement exceeding areola boundaries with edges that are distinct from the chest with skin redundancy present.</td>
</tr>
<tr>
<td>Grade IV</td>
<td>Marked breast enlargement with skin redundancy and feminization of the breast.</td>
</tr>
</tbody>
</table>

**References**

**Professional society guidelines/other:**


**Peer-reviewed references:**


**CMS National Coverage Determinations (NCDs):**

No NCDs identified as of the writing of this policy.

**Local Coverage Determinations LCDs:**

Revision to the Part B LCD (L55226). Effective July 25, 2016. [https://www.cms.gov/medicare-coverage-database/details/article-details.aspx?articleId=55226&ver=2&CoverageSelection=Both&ArticleType=All&PolicyType=Final&s=All&KeyWord=mammoplasty&KeyWordLookUp=Title&KeyWordSearchType=And&bc=gAAAAACAAAAAAA%3d%3d&. Accessed March 16, 2017.](https://www.cms.gov/medicare-coverage-database/details/article-details.aspx?articleId=55226&ver=2&CoverageSelection=Both&ArticleType=All&PolicyType=Final&s=All&KeyWord=mammoplasty&KeyWordLookUp=Title&KeyWordSearchType=And&bc=gAAAAACAAAAAAA%3d%3d&)

**Commonly submitted codes**

Below are the most commonly submitted codes for the service(s)/item(s) subject to this policy. This is not an exhaustive list of codes. Providers are expected to consult the appropriate coding manuals and bill accordingly.

<table>
<thead>
<tr>
<th>CPT Code</th>
<th>Description</th>
<th>Comment</th>
</tr>
</thead>
<tbody>
<tr>
<td>19300</td>
<td>Mastectomy for gynecomastia</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>ICD-10 Code</th>
<th>Description</th>
<th>Comment</th>
</tr>
</thead>
<tbody>
<tr>
<td>N62</td>
<td>Hypertrophy of breast</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>HCPCS Level</th>
<th>Description</th>
<th>Comment</th>
</tr>
</thead>
<tbody>
<tr>
<td>N/A</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>