Clinical Policy Title: Reduction mammoplasty for male gynecomastia

Coverage policy

AmeriHealth Caritas Pennsylvania 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).

- 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).
- 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 (see glossary).
- 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.

AmeriHealth Caritas Pennsylvania 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 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. The condition is often associated with pain or tenderness warranting medical intervention, and patients also seek treatment due to social concerns and embarrassment. Certain drugs may alleviate gynecomastia, but when these are not effective, surgery might be needed.

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. Approximately one-third of adolescents with Klinefelter syndrome develop enlarged breasts; however, only about 10 percent of those cases have breast enlargement that requires surgery (National Institutes of Health, 2004). Although less than 1 percent of all breast carcinomas occur in men (NCI, 2013), patients with Klinefelter syndrome have a higher risk of developing breast cancer than either the general population or even other patients with idiopathic gynecomastia. Idiopathic gynecomastia carries no increased risk of breast cancer.

For gynecomastia, mastectomy refers to the surgical removal of glandular breast tissue, through an open incision or, recently, through minimally invasive endoscopic techniques. Severe gynecomastia might require larger incisions involving resection of skin and nipple transposition. Liposuction is often used in conjunction with excision to remove fatty tissue and to contour the chest following breast-tissue removal for a more natural appearance. The patient usually wears compressive garments to aid in postoperative healing. The surgery is performed on an inpatient or outpatient basis by a plastic surgeon or general surgeon.

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 (Di Lorenzo et al., 2005; Wise et al., 2005; Iverson and Lynch, 2004). Reduction mammoplasty is indicated for gynecomastia not related to malignancy or caused by other treatable causes (American Society of Plastic and Reconstructive Surgeons, 1995).

According to Williams et al. (2002), an integral component in the evaluation of gynecomastia is recognizing and discontinuing any drugs that can cause the disorder (Williams and Larsen, 2002; Noble, 2001). Contributory medications should be discontinued or changed to an alternative medication, if available.

A strong relationship has been established between gynecomastia and the following medications (Perdona et al., 2005; Wise et al., 2005):

- Flutamide.
- Ketoconazole.
- Cimetidine.
- Chemotherapeutic alkylating agents (e.g., cisplatin, 5-fluorouracil, ifosfamide).
Colombo-Benkmann (1999) conducted a study on indications for and results of surgical therapy for male gynecomastia to analyze factors determining diagnostic versus cosmetic indication and postoperative results in the treatment of gynecomastia. Data from 100 patients and 141 breasts were analyzed retrospectively and re-evaluated by questionnaire (n = 81) and clinical examination (n = 33). Except for two patients, all underwent subcutaneous mastectomy through various incisions. The results showed diagnostic surgery was exclusively performed in unilateral, nodular gynecomastia, preferentially of Grade I. Higher-grade, bilateral gynecomastia led mainly to cosmetic surgery. Minor complications (skin retraction, hypertrophic scars, hypesthesia and skin redundancy) occurred in 53 percent of patients and significantly more often in Grades II or III gynecomastia. Each incision was preferentially associated with specific sequelae. However, 86 percent of patients were satisfied with surgical results. His conclusion was that laterality, consistency, grade and age at onset of symptoms determine surgical indication. Despite the high number of sequelae due to preoperative grade and selected incision, most patients were satisfied with postoperative results.

**Searches**

AmeriHealth Caritas Pennsylvania 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 February 16, 2015. 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**

True breast tissue can be distinguished from adipose tissue by mammography or ultrasound. These
modalities are valuable in differentiating benign from malignant masses and used as an adjunct to physical examination. Bilateral mammography is helpful in the evaluation of asymmetric, bilateral gynecomastia. If a mass is detected, it is usually located in the larger breast (Morakkabati-Spitz et al., 2006; Wise et al., 2005; Mehta, 2003).

According to a July 2012 Hayes Health Technology brief, eight case series were included in a report; the duration of follow-up was not always clear; and usually only complications were reported with little data on other outcomes. The evidence on the efficacy and safety of surgery for gynecomastia suggests overall the surgeries are safe, and the majority of patients are satisfied with the cosmetic outcome. In general, there are fewer complications associated with recently emerging minimally invasive procedures, and patients requiring large or extensive resections have higher complication rates and less satisfactory cosmetic results due to scarring. The need for removal of large amounts of tissue and being overweight predicted a higher rate of complications and less satisfactory outcomes. Complications occurred in 3 percent to 47 percent of patients, with 0 percent to 37 percent requiring additional treatment and/or revision surgery.

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.

Policy updates:

Added new Local Coverage Determination (LCD), March 16, 2016.
Changed the name of policy from “Mastectomy” to “Reduction mammoplasty for male gynecomastia.”

Summary of clinical evidence:

<table>
<thead>
<tr>
<th>Citation</th>
<th>Content, Methods, Recommendations</th>
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<tbody>
<tr>
<td>Ferraro GA (2014)</td>
<td>Key points:</td>
</tr>
<tr>
<td>Clinical and surgical management of unilateral pre-pubertal</td>
<td>• Introduction: Gynecomastia is the benign proliferation of glandular tissue in the male breast. This condition is thought to be caused by the imbalance between estrogen action relative to androgen action at the breast tissue level. Bilateral</td>
</tr>
</tbody>
</table>
gynecomastia is frequently found in the neonatal period, early in puberty and with increasing age. Prepubertal unilateral gynecomastia in the absence of endocrine abnormalities is extremely rare, with only a few cases in literature.

- **Presentation of case:** We present an otherwise healthy boy of 12 years old with unilateral breast masses. No abnormalities were found on ultrasonography and on all endocrine parameters. Treatment consisted of a new "modified" Webster technique.

- **Discussion:** The results confirmed validity of this technique in terms of esthetic and functional results and patient satisfaction. Atypical presentations of gynecomastia are often not recognized. The main pathophysiology of gynecomastia is alteration in the balance between the stimulatory effect of estrogen and the inhibitory effects of androgens on the development of the breast. If there is no causal treatment, surgical resection is the therapy of first choice.

- **Conclusion:** The exact mechanism of unilateral gynecomastia formation in our case is unclear. The evaluation of unilateral gynecomastia can therefore be complex. In conclusion, the surgical treatment of unilateral gynecomastia requires an individual approach based on an appropriate diagnostic algorithm.

### Dobs A et al. (2005)

**Purpose:** Gynecomastia is a potentially treatment-limiting adverse event in men receiving hormone therapy for prostate cancer.

**Key points:**

- **Materials and methods:** In large, randomized, placebo-controlled studies, approximately 50 percent or more of patients with prostate cancer experienced gynecomastia due to multiple mechanisms. Although its severity was mostly reported as mild to moderate, gynecomastia was cited as the reason for most premature withdrawals from therapy. In patients with advanced forms of prostate cancer, bilateral orchiectomy was associated with the lowest incidence of gynecomastia, followed by nonsteroidal antiandrogen therapy, diethylstilbestrol and estrogen in rank order.

- **Results:** It is important that gynecomastia be well-managed in patients with prostate cancer who want to proceed with hormone therapy. Patients should be assessed for the likely etiology of gynecomastia, and preventive therapy or treatment for established gynecomastia should be instituted. Prophylactic radiotherapy has been shown to decrease the incidence of hormone-induced gynecomastia by more than 50 percent. An alternative course of action which may be more convenient for the patient is the prophylactic use of tamoxifen. Tamoxifen may also mitigate or resolve gynecomastia during its early or proliferative phase. In severe long-standing gynecomastia, surgery is warranted since medical therapies are less likely to succeed. Aromatase inhibitors and 4-hydroxytamoxifen are investigational.

- **Conclusions:** Gynecomastia is a significant problem in men undergoing hormonal therapy for prostate cancer. It requires prompt recognition, evaluation and management.

### Quotob et al. (2010)

In a small prospective case series, evaluated the efficacy and safety of the use of VABD and liposuction to treat

**Key points:**

- The patients were followed at six to eight weeks after surgery. Patient satisfaction (poor, average, good or excellent) was ascertained, and the surgeon-assessed result was evaluated in a visual analog scale (VAS) (scale 0 – 10 where 0 was worst outcome and 10 was the best). The VAS considered symmetry, scarring and natural appearance. There were no (0%) conversions to open surgery.
gynecomastia in 36 patients with grade I or II disease (mean age 33.3 years, range 16 to 88; bilateral, 22; unilateral, 14).

- The average operative time was 50.3 minutes (range 30 to 80). There was one (3%) intraoperative complication in which a small area of the areola was sucked into the Mammothe® and required excision. At follow up, 34 (94%) patients reported excellent satisfaction while two (6%) had residual gynecomastia requiring revision surgery.
- Three (8%) patients had small transient hematomas at follow up. The mean VAS score was 7.9 (range 4 to 9). While these results are promising, confirmation of the efficacy and safety of this technique is needed in prospective randomized controlled trials.

Glossary

Gynecomastia (true) — A benign proliferation of the glandular component of male breast tissue caused by an excess of circulating estrogen, a deficiency of androgens or an altered androgen-to-estrogen ratio.

Klinefelter syndrome (47, XXY) — A genetic condition caused when someone has two X chromosomes and one Y chromosome. Males normally have an X chromosome and a Y chromosome (46, XY), and females normally have two X chromosomes (46, XX).

Mastectomy — Open, surgical excision of the breast to remove breast tissue.

Medically necessary — A service or benefit is medically necessary if it is compensable under the Medical Assistance program and if it meets any one of the following standards:

- The service or benefit will, or is reasonably expected to, prevent the onset of an illness, condition or disability.
- The service or benefit will, or is reasonably expected to, reduce or ameliorate the physical, mental or developmental effects of an illness, condition, injury or disability.
- The service or benefit will assist the member in achieving or maintaining maximum functional capacity in performing daily activities, taking into account both the functional capacity of the member and those functional capacities appropriate for members of the same age.

Mixed gynecomastia — Breast enlargement secondary to both glandular and fat tissue.

Pseudogynecomastia — Breast enlargement due to fat or adipose accumulation.

Reduction Mammoplasty — Breast reduction surgery performed to decrease breast size by removing breast tissue; includes open procedure (mastectomy) or liposuction.

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>
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<tbody>
<tr>
<td>Grade II</td>
<td>Moderate breast enlargement exceeding areola boundaries with edges that are indistinct from the chest.</td>
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<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>
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<tr>
<td>Grade IV</td>
<td>Marked breast enlargement with skin redundancy and feminization of the breast.</td>
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**References**

**Professional society guidelines/other:**


**Peer-reviewed references:**


Clinical trials:

Searched clinicaltrials.gov on February 16, 2016 using terms male breast cancer, gynecomastia and mastectomy. | Open Studies. Eight studies found, zero relevant.

CMS National Coverage Determinations (NCDs):

No NCDs identified as of the writing of this policy.

Local Coverage Determinations LCDs:

Reduction Mammoplasty (L33939). Effective October 1, 2015.

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.
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<table>
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<table>
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