Clinical Policy Title: Reduction mammoplasty for male gynecomastia

Clinical Policy Number: CCP.1160

Effective Date: July 1, 2015
Initial Review Date: February 18, 2015
Most Recent Review Date: April 2, 2019
Next Review Date: April 1, 2020

Related policies:

CCP.1048 Breast reduction surgery

ABOUT THIS POLICY: AmeriHealth Caritas has developed clinical policies to assist with making coverage determinations. AmeriHealth Caritas’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 AmeriHealth Caritas 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. AmeriHealth Caritas’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. AmeriHealth Caritas’s clinical policies are reflective of evidence-based medicine at the time of review. As medical science evolves, AmeriHealth Caritas will update its clinical policies as necessary. AmeriHealth Caritas’s clinical policies are not guarantees of payment.

Coverage policy

AmeriHealth Caritas 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:

For Adolescents
- Unilateral or bilateral grade II or grade III gynecomastia present (per modified McKinney and Simon, Hoffman and Kohn scales)
  - Persists more than one year after pathological causes ruled out.
  - Persists after six months of unsuccessful medical treatment for pathological gynecomastia.
- Unilateral or bilateral grade IV gynecomastia present (per modified McKinney and Simon, Hoffman and Kohn scales)
  - Persists more than six months after pathological causes ruled out.
  - Persists after six months of unsuccessful medical treatment for pathological gynecomastia.
• Pain and discomfort due to the distention and tightness from the hypertrophied breast. Gynecomastia may cause considerable psychological distress, especially in adolescents who are struggling with issues related to sexual identity and self-image.

For Adults
• Breast biopsy is indicated when malignancy is suspected.
• Unilateral or bilateral grade III or IV gynecomastia present (per modified McKinney and Simon, Hoffman and Kohn scales).
  o Persists more than 3 to 4 months after pathological causes ruled out.
  o Persists after 3 to 4 months of unsuccessful medical treatment for pathological gynecomastia.
• Pain and discomfort due to the distention and tightness from the hypertrophied breast.

Prolonged presence of breast enlargement in the male patient leads to the development of periductal fibrosis and stromal hyalinization, preventing regression of breast tissue and causing pain and discomfort due to the distention and tightness from the hypertrophied breast (American Society of Plastic Surgeons, 2015).

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 (American Society of Plastic Surgeons, 2015).

AmeriHealth Caritas 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 grades, by severity levels, known as McKinney and Simon, Hoffman and John scales. Each is based on size of breast enlargement, plus characteristics of enlargement, with Grade IV being most severe:

Grade I - Small breast enlargement with localized button of tissue 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 (American Society of Plastic Surgeons, 2015).

Most cases of gynecomastia are benign and of cosmetic, not clinical, importance. Cases in which local pain and tenderness are present could sometimes represent underlying illness, medication, or congenital condition. In some cases, such as pubertal gynecomastia, breast enlargement resolves spontaneously. Surgery to remove enlarged breast tissue might be necessary when gynecomastia does not resolve spontaneously or with medical therapy (Narula, 2014).

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 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 considered (Leung, 2017). In 2016, 27,760 American men underwent the procedure, up 36 percent from 20,351 in 2000 (American Society of Plastic Surgeons, 2017).

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 (Johnson, 2009).
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 (Johnson, 2009).

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**

AmeriHealth Caritas searched PubMed and the databases of:
- UK National Health Services Centre for Reviews and Dissemination.
- Agency for Healthcare Research and Quality.
- The Centers for Medicare & Medicaid Services.
- Cochrane reviews.

Searches were conducted on February 19, 2019. Search terms were: “reduction mammoplasty,” and “gynecomastia.”

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.

In 2011, the American Society of Plastic Surgeons issued a guideline on mammoplasty for male gynecomastia, addressing six aspects of the surgery. The following year, the Society published a review that found inconclusive evidence on whether increased body mass index is associated with increased risk of complications. Perioperative antibiotics may reduce the risk of infection associated with reduction mammaplasty, and in standard reduction mammaplasty procedures without liposuction, the use of drains is not beneficial. Reduction mammaplasty has been shown to improve quality of life (Kallainen, 2012).

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 systematic review of six studies (n = 313) revealed reduction mammaplasty had a generally positive effect on patient psychological concerns caused by male gynecomastia, i.e., quality of life, vitality, emotional discomfort, limitations due to physical aspects, and limitations due to pain. However, data quality issues prompted researchers to caution against making conclusive judgements (Sollie, 2018).

A systematic review of 11 articles identified 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).

A systematic review consisted of 10 studies of male adolescents and young adults with gynecomastia, each of which was limited to case studies and small sample sizes. However, researchers found no intervention other than surgery to address psychosocial distress causes by gynecomastia (Rew, 2015).

A study of 2,497 males undergoing aesthetic breast surgery documented that correction of gynecomastia was the most common procedure (n = 1,613, or 64.6 percent of all procedures). The complication rate was a relatively low 1.80 percent and smoking was identified as a significant ($P = .03$) risk factor (Gupta, 2017).
An analysis of 1574 male body-builders age 18 - 51 with surgically-treated gynecomastia (removal of at least 95 percent of glandular tissue) treated over a 30-year period were followed from 1 - 5 years. In 98 percent of cases, patients were aesthetically pleased with results. Hematoma rates dropped from nine to three percent in the first and second 15 years of the study. There were no infections, contour deformities, or recurrences (Blau, 2015).

A review of 312 males age 18 – 52 were treated surgically (subcutaneous mastectomy) for gynecomastia. After a follow-up of 12 – 60 post-operative months, no breast cancers were found; no skin or areola necrosis were referred, and no recurrence of gynecomastia were reported. Six cases of seroma and three cases of hematomas were found (Innocenti, 2017).

A study of 5113 breasts in males who underwent surgery for gynecomastia found 0.11 percent had in invasive carcinomas, and another 0.18 percent had in situ carcinomas. Prevalence of atypical ductal hyperplasia was 0.23 percent in patients under age 20, much less than the overall prevalence of 0.40 percent (Lapid, 2015).

**Policy updates:**

A total of one guideline/other and five peer-reviewed articles were added to, and two guidelines/other and 10 peer-reviewed articles removed from the policy in February, 2019.

The policy number was changed from CP#16.03.07 to CCP.1160 in February, 2019.

**References**

**Professional society guidelines/other:**


Peer-reviewed references:


**Centers for Medicare & Medicaid Services National Coverage Determinations:**

No National Coverage Determinations identified as of the writing of this policy.
Local Coverage Determinations:

L 33939 Reduction Mammaplasty.

L 35001 Reduction Mammaplasty.

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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