BlueCross BlueShield of Alabama

Name of Blue Advantage Policy:
Gynecomastia Surgery

Policy #: 114
Category: Surgery

Latest Review Date: March 2019
Policy Grade: D

Background:

Blue Advantage *medical policy does not conflict with Local Coverage Determinations (LCDs), Local Medical Review Policies (LMRPs) or National Coverage Determinations (NCDs) or with coverage provisions in Medicare manuals, instructions or operational policy letters. In order to be covered by Blue Advantage the service shall be reasonable and necessary under Title XVIII of the Social Security Act, Section 1862(a)(1)(A). The service is considered reasonable and necessary if it is determined that the service is:*

1. *Safe and effective;*
2. *Not experimental or investigational*;*
3. *Appropriate, including duration and frequency that is considered appropriate for the service, in terms of whether it is:*
   - *Furnished in accordance with accepted standards of medical practice for the diagnosis or treatment of the patient's condition or to improve the function of a malformed body member;*
   - *Furnished in a setting appropriate to the patient's medical needs and condition;*
   - *Ordered and furnished by qualified personnel;*
   - *One that meets, but does not exceed, the patient's medical need; and*
   - *At least as beneficial as an existing and available medically appropriate alternative.*

In accordance with Title XVIII of the Social Security Act, Section 1862 (a)(10) cosmetic surgery or expenses incurred in connection with such surgery is not covered except as required for the prompt repair of accidental injury or for improvement of the functioning of a malformed body member.

Routine costs of qualifying clinical trial services with dates of service on or after September 19, 2000 which meet the requirements of the Clinical Trials NCD are considered reasonable and necessary by Medicare. Providers should bill* ***Original Medicare* *for covered services that are related to* ***clinical trials*** *that meet Medicare requirements (Refer to Medicare National Coverage Determinations Manual, Chapter 1, Section 310 and Medicare Claims Processing Manual Chapter 32, Sections 69.0-69.11).*

Description of Procedure or Service:

Gynecomastia is the benign enlargement of the male breast, either due to increased adipose tissue, glandular tissue, fibrous tissue, or a combination of all three. The most common cause of gynecomastia in the male is puberty. It accounts for more than 65 percent of male breast disorders. In true gynecomastia, the breast enlargement is due to glandular breast tissue; in pseudogynecomastia, the breast enlargement is secondary to fat accumulation. The condition may occur in one or both breasts and begins as a small lump beneath the nipple, which may be tender. Gynecomastia during puberty is not uncommon, is self-limiting and usually resolves spontaneously within two years. The etiology appears to be related to an increase in estrogens, a decrease in androgens or some alteration in the estrogen-androgen level. Surgical removal of the breast tissue may be considered if conservative therapies are not effective.

Gynecomastia can be attributed to physiologic, pathologic, or pharmacologic causes. Physiologically in newborns breast development may be associated with galactorrhea. It is also seen with aging and teenage boys. Causes of pathologic gynecomastia may include testicular and pituitary tumors, chronic liver disease, genetic disorders/congenital endocrine conditions (Klinefelter's disease) and kidney failure. The surgical procedure may involve surgical excision (i.e. mastectomy) or more recently, liposuction has been used.

Pharmacological causes are related to side effects of many drugs. Examples of these drugs include anabolic steroids, cannabinoids, psychotropics, antihypertensives and estrogens for prostatic/testicular carcinoma.

Some men and boys have fat on their chest that makes it look as though they have breasts. This condition is called pseudogynecomastia, and is not the same as gynecomastia. Pectoral hypertrophy can also be confused with gynecomastia.

Policy:

Effective for dates of service on or after July 1, 2016:

Blue Advantage will treat **Mastectomy for gynecomastia as a covered benefit** for:

- Adult and mid to late pubertal (age 14 to 20) male patients with non-tender, palpable breast tissue;
- Adult male patients with recent onset of progressive breast enlargement with or without tenderness;
- Patients with Klinefelter's Syndrome.

The following information will be used to determine if true gynecomastia is present (except in those patients with Klinefelter's Syndrome). **True gynecomastia is defined as the presence of glandular tissue and not fatty tissue**:

- Full history that includes conditions present for at least 12 months on an adolescent, medication history to include drugs, alcohol, and specific questions regarding hepatic dysfunction, testicular insufficiency (decreased libido or impotence), pulmonary symptoms suggestive of lung cancer, and hyperthyroidism;

- Physical exam that includes description of palpation of breast, evidence of any alteration of expected secondary sexual characteristics, and testicular, liver, and thyroid examination;
- Work-up of any abnormal findings;
- Medical evaluation to exclude endocrinopathy;
- Pre-op photos;
- Post-operatively, a pathology report may be requested to confirm the presence of glandular tissue as **removal of fatty tissue is considered cosmetic**.

For an adult male with recent onset of progressive breast enlargement, with or without tenderness and mid to late pubertal patients, the following **additional information** will be used to determine true gynecomastia versus other etiologies. **True gynecomastia is defined as the presence of glandular tissue and not fatty tissue**:

- Emphasis on drug-induced gynecomastia (with discontinuance of the drug, if possible, for one month with re-evaluation);
- Measurement of serum chorionic gonadotropin, testosterone, estradiol, and luteinizing hormone is required when no underlying cause is apparent;
- If reports result in diagnosis of idiopathic gynecomastia, the condition may be monitored for six months.

Mastectomy for gynecomastia does not meet Blue Advantage coverage criteria for:

- **Pubertal gynecomastia with tender palpable breast tissue or fatty tissue**;
- **Drug related gynecomastia** (these may include but not limited to: androgens and anabolic steroids, oral and topical estrogens, spironolactone, methyldopa, phenytoin, cimetidine, digitalis, psychoactive agents, alcohol, marijuana);
- **Removal of fatty tissue**.

Blue Advantage will **not cover** mastectomy for gynecomastia **performed by liposuction ONLY.**

Effective for dates of service prior to July 1, 2016:
Blue Advantage will treat **Gynecomastia** surgery as a **non-covered** benefit and as **cosmetic**.

Blue Advantage does not approve or deny procedures, services, testing, or equipment for our members. Our decisions concern coverage only. The decision of whether or not to have a certain test, treatment or procedure is one made between the physician and his/her patient. Blue Advantage administers benefits based on the members' contract and medical policies. Physicians should always exercise their best medical judgment in providing the care they feel is most appropriate for their patients. Needed care should not be delayed or refused because of a coverage determination.

Key Points:

This has been updated regularly with searches of the MEDLINE database. The most recent literature update was performed through December 6, 2018.

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

Clinical Context and Therapy Purpose

The purpose of surgical therapy for bilateral gynecomastia is to provide a treatment option that is an alternative to or an improvement on existing therapies, such as conservative treatment.

The question addressed in this evidence review is: is the net health outcome of individuals with bilateral gynecomastia improved by surgical treatment?

The following PICOTS were used to select literature to inform this review.

Patients

The relevant population of interest is individuals with bilateral gynecomastia, a benign enlargement of the male breast due either to increased adipose, glandular, or fibrous tissue or a combination of the three. An underlying hormonal disorder, obesity, and an adverse effect of certain drugs may be associated with the condition. Additionally, the bilateral gynecomastia may be related to specific age groups, including neonates, adolescents, and in aging men with decreasing levels of testosterone and relative estrogen excess.

Interventions

The therapy being considered is surgical treatment: removal of the breast tissue by surgical excision or liposuction.

Comparators
The main comparators of interest is conservative treatment, which varies based on the underlying cause of the condition and can include treatment of underlying hormonal disorder, cessation of drug therapy, and weight loss.

Outcomes
The general outcomes of interest are symptoms, functional outcomes, health status measures, quality of life, and treatment-related morbidity. Symptoms of bilateral gynecomastia may include enlargement, tenderness, and lumps in the breast tissue.

Timing
Evaluation of the general outcomes of interest requires a long follow-up period beyond the immediate postoperative period if surgery is performed. In the existing literature evaluating surgery as a treatment for bilateral gynecomastia, follow-up is 5 years.

Setting
Patients with bilateral gynecomastia are managed by plastic surgeons in an outpatient setting.

Study Selection Criteria
Methodologically credible studies were selected using the following principles:

a. To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs;

b. In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.

c. To assess longer term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.

d. Studies with duplicative or overlapping populations were excluded.

The surgical procedure may involve surgical excision (ie, mastectomy). 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 basis for surgical treatment. However, the pain associated with adolescent gynecomastia is typically self-limiting or responds to analgesic therapy.

No randomized clinical trials were identified to assess various surgical interventions to treat male gynecomastia.

<u>Nonrandomized Studies</u>
Pubertal gynecomastia is a common condition with an overall incidence of 38 percent in males 10 to 16 years of age, increasing to 65 percent at age 14, and dropping to 14 percent in 16-year-old boys. During adolescence, 75 percent of the gynecomastia cases are bilateral by the breasts are often affected to different degrees. Pubertal gynecomastia often regresses spontaneously in

six months, 75 percent within two years of onset, and 90 percent resolve within three years of onset.

For diagnosis of the condition, which is obvious, the etiology must be determined. This is achieved by the history, physical examination, and appropriate laboratory evaluation. There must be a review of systems, monitoring for organ changes in the liver, testes, prostate, adrenal, pituitary, lungs and thyroid. A complete drug history must be taken. A physical examination includes checking the listed organs and breasts. Laboratory studies may need to include liver function studies or urine studies for 17-ketosteroids, androgens, and gonadotropic hormones. Consultation with an endocrinologist may be valuable for evaluation of these patients. The presence of an underlying tumor (breast or testicular) needs to be excluded. If puberty is the cause, it is best to wait as long as two years to allow spontaneous regression to occur. This information is per Grabb and Smith's *Plastic Surgery*.

Exposure of new techniques, quality of life assessments and other nonsurgical outcomes have been reported in the literature.

Abdelrahman (2018) published a retrospective analysis of 18 patients with grade I-II gynecomastia treated with a combination of traditional liposuction and glandular liposculpturing between 2014 and 2016. Outcomes assessed included treatment-related morbidity and adverse events and patient reported outcomes (PROs). The PROs included patient satisfaction using the Breast Evaluation Questionaire (BEQ). Other notable information gained include treatment-related morbidity and adverse events. The post-operative aesthetic appearance was evaluated by 5 independent plastic surgeons ("observers") who were blinded to the surgery performed making their assessments based on preoperative and 6 month postoperative photographs. The observers concluded that an acceptable post-operative result was achieved (92% of the ratings); 8% of the ratings suggested subsequent liposuction needed to be performed. The level of agreement was assessed and statistically significant for varying aesthetic variables (eg, nipple projection, p=.005). Treatment-related morbidities or adverse events were minimal and include wound infection (1/18, 5.56%) and complaints of breast-tissue remnants and requests for subsequent operation (2/18, 11.1%).

Nuzzi et al (2018) published a longitudinal cohort study aimed at measuring changes in health-related quality of life following surgical management of gynecomastia in adolescents using 3 surveys administered over a 5-year period to both the intervention group and age- and sex-matched controls. The surveys administered were the Short-form 36v2 (SF-36), Rosenberg Self-Esteem Scale (RSES), and Eating-Attitudes Test-26. From 2008 to 2017, 44 patients who underwent treatment of gynecomastia and 64 unaffected controls who participated in the study. Patients in the intervention group scored significantly poorer at baseline compared with controls on both the RSES and EAT-26 ($p<.05$, both), even after controlling for BMI differences. Gynecomastia patients scored lower on five SF-36 domains than the controls: general health, vitality, social functioning, role-emotional, and mental health ($p<.05$, all). Scores significantly improved post-operatively on the RSES and in four SF-36 domains. Post-operatively, gynecomastia patients scored similarly to the control group on the SF-36 and RSES, indicating an improvement in quality of life.

Laiturt et al discussed the treatment of adolescent gynecomastia and partly due to a lack of information in the literature for severe cases of gynecomastia. The review was based on the author's use of inferior pedicle reduction mammaplasty and subcutaneous mastectomy in adolescents with gynecomastia. Data was collected for a 10-year period and this included 20 patients. Eight patients had bilateral inferior pedicle reduction mammaplasty, and 12 patients underwent either unilateral or bilateral subcutaneous mastectomy. Mean amount of tissue removed after bilateral reduction mammaplasty was 275.1g. Mean follow-up was 18.8 months. The authors concluded that many adolescents with true gynecomastia have mild or self-limited disease; operative treatment may provide significant benefit to the remainder. Milder grades of gynecomastia can be managed with subcutaneous mastectomy. Selected severe cases can be safely and effectively treated with reduction mammaplasty.

Fan et al and Qutob et al reported on endoscopic subcutaneous mastectomy or minimally invasive excision. According to Fan et al, the use of endoscopic subcutaneous mastectomy without skin excision was introduced as a new standard surgical technique for Grade IIB and III gynecomastia. At the writing of the article, 125 breasts had undergone the procedure. The authors found that endoscopic subcutaneous mastectomy is a new choice for the treatment of gynecomastia. Qutob et al studied the use of a vacuum-assisted biopsy device (VABD) and liposuction to provide minimally invasive approach. Thirty-six male patients with Grade I and II gynecomastia were recruited (22 bilateral and 14 unilateral). All underwent mammotome excision and liposuction, with no conversions to open procedure. Minimum follow-up time was two months. Thirty-four had excellent results and two required a redo procedure. The authors concluded that this new, minimally invasive, surgical approach for gynecomastia gave excellent results with minimal morbidity.

In 2010, Petty et al analyzed outcomes of ultrasound-assisted liposuction using an arthroscopic shaver to remove breast tissue. This method was then compared with other techniques for the management of gynecomastia. A retrospective study of a total of 227 males divided into four groups: open incision (n=45), open incision plus liposuction (n=56), liposuction only (n=50), and liposuction plus arthroscopic shaver (n=76). Photographs and medical records were used to compare the results of these different procedures. Liposuction plus the arthroscopic shaver had the overall highest mean score based on appearance, symmetry, residual tissue and prominent scarring. The liposuction alone is unable to remove the glandular/fibrous breast tissue seen in many of these cases. In conclusion, it was noted that higher quality studies are needed to determine the safety and effectiveness of ultrasound-assisted lipectomy with an arthroscopic shaver.

Autologous Platelet Gel during Breast Surgery

Anzarut et al reported on their assessment of the effectiveness of topical application of completely autologous platelet gel during breast surgery to reduce postoperative wound drainage. Tissue sealants are being used to reduce postoperative wound drainage and improve surgical outcomes. There are few randomized, double-blind, controlled trials assessing the efficacy of these agents. One hundred eleven (111) patients were included in this within-patient, randomized, patient and assessor-blinded, controlled trial to assess the use of completely autologous platelet gel in bilateral reduction mammaplasty. Patients were randomized by applying the gel to either the left or right breast after hemostasis was achieved; the other breast

received no treatment. The primary outcome was the difference in wound drainage over 24 hours. Secondary outcomes included subjective and objective assessments of pain and wound healing. Results revealed that there were no statistically significant differences in the drainage, level of pain, size of open areas, clinical appearance, degree of scar pliability, or scar erythema. The authors concluded that these results do not support the use of completely autologous platelet gel to improve outcomes after reduction mammaplasty.

Summary of Evidence

The medical literature indicates that gynecomastia is due to the stimulated growth of glandular breast tissue and does not significantly affect the disposition of fatty tissue. Therefore, mastectomy for gynecomastia should focus on the removal of glandular tissue underlying the condition. The use of liposuction as a method of mastectomy for gynecomastia has not been sufficiently proven to remove glandular tissue and is not considered an acceptable alternative to standard surgical approaches.

Practice Guidelines and Position Statements

The American Society of Plastic Surgeons

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 the ASPS, in adolescents, surgical treatment for unilateral or bilateral grade II or III gynecomastia may be appropriate if the gynecomastia persists for more than one year after pathological causation is ruled out (or six months if grade IV) and continues after six months if medical treatment is unsuccessful. In adults, surgical treatment for unilateral or bilateral grade III or grade IV gynecomastia is ruled out and continues after three to four months after pathological causation is ruled out and continues after three to four months of medical treatment that is unsuccessful. The ASPS also indicates surgical treatment of gynecomastia may be appropriate when distention and tightness cause pain and discomfort.

U.S. Preventive Services Task Force Recommendations

Surgery for gynecomastia is not a preventive service.

Key Words:

Gynecomastia, mastectomy

Approved by Governing Bodies:

Removal of breast tissue is a surgical procedure and, as such, is not subject to regulation by the U.S. Food and Drug Administration.

Benefit Application:

Coverage is subject to member's specific benefits. Group specific policy will supersede this policy when applicable.

Current Coding:

CPT codes:

19300 Mastectomy for gynecomastia

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Policy History:

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Medical Policy Group, May 2006
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This policy is intended to be used for adjudication of claims (including pre-admission certification, pre-determinations, and pre-procedure review) in Blue Cross and Blue Shield's administration of plan contracts.