

Medical Policy



Title: Surgical Treatment of Gynecomastia

Professional

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Populations	Interventions	Comparators	Outcomes
Individuals: <ul style="list-style-type: none"> • With bilateral gynecomastia 	Interventions of interest are: <ul style="list-style-type: none"> • Surgical treatment 	Comparators of interest are: <ul style="list-style-type: none"> • Conservative treatment 	Relevant outcomes include: <ul style="list-style-type: none"> • 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 three. 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 net health outcomes.

Background**Bilateral Gynecomastia**

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 three. Bilateral gynecomastia may be associated with any of the following:

- An underlying hormonal disorder (i.e., 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, i.e.,
 - 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

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.

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.

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 has been updated regularly with searches of the PubMed database. The most recent literature update was performed through November 17, 2020.

Evidence reviews assess the clinical evidence to determine whether the use of technology improves the net health outcome. Broadly defined, health outcomes are the length of life, quality of life, and ability to function^{3/4}including benefits and harms. Every clinical condition has specific outcomes that are important to patients and 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 technology, 2 domains are examined: the relevance, and 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 (RCT) is preferred to assess efficacy; however, in some circumstances, nonrandomized studies may be adequate. RCTs 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 PICO was used to select literature to inform this review.

Populations

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 3. 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.

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.

Comparators

The main comparators of interest are conservative treatment, which varies based on the underlying cause of the condition and can include treatment of an 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.

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

Study Selection Criteria

Methodologically credible studies were selected using the following principles:

- To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs;
- In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.
- To assess longer-term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.
- Studies with duplicative or overlapping populations were excluded.

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 (i.e., 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.

Nonrandomized Studies

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

Abdelrahman et al. (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 2016.³ Outcomes assessed included treatment-related morbidity and adverse events and patient-reported outcomes. The patient-reported outcome included patient satisfaction using the Breast Evaluation Questionnaire. Other notable information gained include treatment-related morbidity and adverse events. The postoperative aesthetic appearance was evaluated by 5 independent plastic surgeons ("observers") who were blinded to the surgery performed making their assessments based on preoperative and 6month postoperative photographs. The observers concluded that an acceptable postoperative 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 (e.g., 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.⁴ The surveys administered were the Short-Form 36 Health Survey Version2 (SF-36v2), 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 Eating-Attitudes Test-26 ($p<.05$, both), even after controlling for body mass index differences. Gynecomastia patients scored lower on 5 SF-36v2 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 4 SF-36v2 domains. Post-operatively, gynecomastia patients scored similarly to the control group on the SF-36v2 and RSES, indicating an improvement in quality of life.

Table 1. Summary of Nonrandomized Studies Characteristics

Study	Study Type	Country	Dates	Participants	Treatment	Treatment	Follow-Up
Abdelrahman et al. (2018) ³ ,	Retrospective analysis	Egypt	2014-2016	Individuals with grade I or II gynecomastia (n=18)	Traditional liposuction and glandular liposculpturing		6-mos
Nuzzi et al. (2018) ⁴ ,	Prospective, longitudinal cohort study	U.S.	2008-2017	Adolescents diagnosed with unilateral or bilateral gynecomastia (n=44) and male controls (n=64)	Surgical intervention	Control	5-ys

Table 2. Summary of Observational Comparative Study Results

Study	Mean pre-operative BEQ	Mean post-operative BEQ	Patients' mean overall satisfaction score(SD)	Morbidities	Morbidities	
Abdelrahman et al. (2018) ³ ,						
Study group	2.1 (0.2)	4.1 (0.2)	4.7 (0.7)	Wound infection (1/18, 5.56%)	Complaints of breast tissue remnant and requests for subsequent operation (2/18; 11.1%)	
p-value	.001	.001				
	SF-36v2 – Physical Functioning (SD)	SF-36v2 – Bodily Pain (SD)	SF-36v2 – General Health (SD)	SF-36v2 – Social Functioning (SD)	RSES (SD)	EAT-26 (SD)
Nuzzi et al (2018) ⁴ ,						
Treatment group	97.0 (7.2)	81.2 (11.0)	77.4 (17.8)	84.6 (22.0)	32.5 (6.4)	8.0 (6.5)
Control	97.1 (11.6)	78.7 (15.3)	83.6 (16.0)	88.3 (20.6)	34.8 (5.8)	3.8 (5.2)
p-value	.78	.59	.59	.42	.26	.001

BEQ: Breast evaluation questionnaire; EAT-26: eating-attitudes test-26; RSES: Rosenberg self-esteem scale; SF-36v2: short-form 36 health survey version 2; SD: standard deviation.

Section Summary: Bilateral Gynecomastia

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 a literature search. A systematic review published in 2015 included 14 studies

on the treatment of gynecomastia.⁵ None 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 criteria. The literature addresses itself to quality of life patient-reported outcomes with a focus on adolescents.

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 (RCTs) on surgical treatment of bilateral gynecomastia, it is not possible to determine with a high level of confidence 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 that the technology results in an improvement in the net health outcome.

SUPPLEMENTAL INFORMATION

Practice Guidelines and Position Statements

In 2002, affirmed 2015, the American Society of Plastic Surgeons (ASPS) issued practice criteria for third-party payers.⁶ The 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 “[u]nilateral or bilateral grade II or III gynecomastia” may be appropriate if the gynecomastia “persists for more than 1 year after pathological causation is ruled out” (or 6 months if grade IV) and continues “after 6 months of unsuccessful medical treatment for pathological gynecomastia.” In adults, surgical treatment for “[u]nilateral or bilateral grade III or IV gynecomastia” may be appropriate if the gynecomastia “persists for more than 3 or 4 months after pathological causes ruled out [and continues] after 3 or 4 months of unsuccessful medical treatment for pathological gynecomastia.” The ASPS also indicated 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 November 2020 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.

CPT/HCPCS

19101 Biopsy of breast; open, incisional
 19300 Mastectomy for gynecomastia

ICD-10 Diagnoses

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
 N63.15 Unspecified lump in the right breast, overlapping quadrants
 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
 N63.25 Unspecified lump in the left breast, overlapping quadrants
 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

03-15-2012	Policy added to the bcbsks.com web site.
02-26-2013	Description section updated.
	Reference section updated.
12-31-2013	Policy reviewed.
	In Coding section: <ul style="list-style-type: none"> ▪ Added ICD-10 Diagnosis (<i>Effective October 1, 2014</i>)
04-13-2016	Updated Description section.
	Updated Rationale section.
	Updated References section.
03-29-2017	Updated Description section.
	Updated Rationale section.
	Updated References section.
10-01-2017	In Coding section: <ul style="list-style-type: none"> ▪ Added ICD-10 codes: N63.11, N63.12, N63.13, N63.14, N63.21, N63.22, N63.23, N63.24, N63.31, N63.32, N63.41, N63.42. ▪ Removed ICD-10 code: N63.
03-28-2018	Updated Rationale section.
	In Coding section: <ul style="list-style-type: none"> ▪ Removed ICD-9 codes.
	Updated References section.
03-27-2019	Updated Description section.
	Updated Rationale section.
	Updated References section.
10-01-2019	In Coding section: <ul style="list-style-type: none"> ▪ Added ICD-10 codes: N63.15, N63.25
04-16-2021	Updated Description section.
	Updated Rationale section.
	Updated References section.

REFERENCES

1. Rohrich RJ, Ha RY, Kenkel JM, et al. Classification and management of gynecomastia: defining the role of ultrasound-assisted liposuction. *Plast Reconstr Surg.* Feb 2003; 111(2): 909-23; discussion 924-5. PMID 12560721
2. Goes JC, Landecker A. Ultrasound-assisted lipoplasty (UAL) in breast surgery. *Aesthetic Plast Surg.* Jan-Feb 2002; 26(1): 1-9. PMID 11891589
3. Abdelrahman I, Steinvall I, Mossaad B, et al. Evaluation of Glandular Liposculpture as a Single Treatment for Grades I and II Gynaecomastia. *Aesthetic Plast Surg.* Oct 2018; 42(5): 1222-1230. PMID 29549405
4. Nuzzi LC, Firriolo JM, Pike CM, et al. The Effect of Surgical Treatment for Gynecomastia on Quality of Life in Adolescents. *J Adolesc Health.* Dec 2018; 63(6): 759-765. PMID 30279103
5. Fagerlund A, Lewin R, Rufolo G, et al. Gynecomastia: A systematic review. *J Plast Surg Hand Surg.* 2015; 49(6): 311-8. PMID 26051284
6. American Society of Plastic Surgeons. ASPS Recommended Insurance Coverage Criteria for Third-Party Payers: Gynecomastia. 2002 (affirmed 2015); https://www.plasticsurgery.org/Documents/Health-Policy/Positions/Gynecomastia_ICC.pdf. Accessed November 17, 2020.

Other References

1. Blue Cross and Blue Shield of Kansas Surgery Liaison Committee, August 2004, August 2005, August 2010.
2. Blue Cross and Blue Shield of Kansas Family Medicine Liaison Committee, July 2004.
3. Blue Cross and Blue Shield of Kansas Pediatric Liaison Committee, July 2004.