Medical Policy

BlueCross BlueShield Kansas
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Title: Surgical Treatment of Gynecomastia

Professional / Institutional
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If your patient is covered under a different Blue Cross and Blue Shield plan, please refer to the Medical Policies of that plan.

Populations	Interventions	Comparators	Outcomes
Individuals: • With bilateral gynecomastia	Interventions of interest are: • Surgical treatment	Comparators of interest are: • Conservative treatment	Relevant outcomes include: • 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 3. 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 evidence review is to evaluate whether the 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 3. Bilateral gynecomastia may be associated with any of the following:

- An underlying hormonal disorder (ie, 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, ie,
    - 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 prevents the 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.

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

A. Reconstructive surgery for gynecomastia with no functional impairment is contractually noncovered.

B. Pain associated with gynecomastia is typically mild, transient and medically treatable.

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.

RATIONALE

This evidence review was created with searches of the PubMed database. The most recent literature update was performed through December 17, 2024

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 function¾including 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.

Promotion of greater diversity and inclusion in clinical research of historically marginalized groups (e.g., People of Color [African-American, Asian, Black, Latino and Native American]; LGBTQIA (Lesbian, Gay, Bisexual, Transgender, Queer, Intersex, Asexual); Women; and People with Disabilities [Physical and Invisible]) allows policy populations to be more reflective of and findings more applicable to our diverse members. While we also strive to use inclusive language related to these groups in our policies, use of gender-specific nouns (e.g., women, men, sisters, etc.) will continue when reflective of language used in publications describing study populations.

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 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 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 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.

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.

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.

Review of Evidence
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 (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 that were not included in the below systematic reviews were identified to assess various surgical interventions to treat male gynecomastia.

Systematic Reviews
Two systematic reviews on gynecomastia treatment that have been conducted are described in Tables 1 and 2. A systematic review by Fagerlund et al (2015) included 17 studies on pharmacologic and/or surgical treatment of gynecomastia.[3,] The body of evidence was determined to be of very low quality by Grading of Recommendations, Assessment, Development, and Evaluations (GRADE) criteria; the method of patient satisfaction rating also varied between studies which resulted in difficulties interpreting the results. None of the included studies were randomized, and all were judged to be at high-risk of bias.

A systematic review by Prasetyono et al (2022) included 18 studies (N=244) on liposuction-assisted gynecomastia surgery in patients with specified Simon's classification of gynecomastia grade I and II.[4,] The method of patient satisfaction rating also varied between studies which resulted in difficulties interpreting the results. Only 2 studies were considered good quality in terms of level of evidence, and the authors noted that there was a high risk of bias in all included studies which precludes them from drawing any non-biased conclusion.

Table 1. Systematic Review Characteristics

Study	Dates	Trials	Participants[1]	N (Range)	Design	Duration
Fagerlund et al (2015) [3,]	2000-2014	17	Male patients with gynecomastia that underwent medical and/ or surgical treatment	826 (NR)	Cohort and case-series	Minimum follow-up of 6 months
Prasetyono et al (2022) [4,]	2011-2020	18	Male patients with gynecomastia that underwent liposuction-assisted surgery with or without	244 (NR)	Cohort, case-series, RCT	Minimum follow-up of 6 months

Study	Dates	Trials	Participants[1]	N (Range)	Design	Duration
			pharmacological intervention			

[1] Key eligibility criteria.
NR: not reported; RCT: randomized controlled trial

Table 2. Systematic Review Results

Study	Complication/ Side Effect Rates (%)	Reoperation Rate (%)
Fagerlund et al (2015)[3,]		
Total N	NR	NR
Range (%)	0% to 20%	NR
Prasetyono et al (2022) [4,]		
Total N	NR	NR
Range (%)	0.06% to 26.67%	0.6% to 25%

Nonrandomized Studies

Exposure of new techniques, quality of life assessments, and other nonsurgical outcomes have been reported in the literature; studies that were not included in the systematic reviews above are described below.

Nuzzi et al (2018) published a longitudinal cohort study aimed at measuring changes in health-related quality of life following surgical management of gynecomastia using 3 surveys administered over a 5-year period to both the intervention group and age- and sex-matched controls.[5,] 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 participated in the study. Race or ethnicity of patients were not described. 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.

Liu et al (2022) reported on a cohort of 34 patients (N=50 breasts; 16 bilateral and 18 unilateral) diagnosed with glandular gynecomastia who were treated with endoscope-assisted minimally invasive surgery.[6,] According to Simon's classification of gynecomastia, grade I (n=10), grade IIA (n=25), and grade IIB (n=15) patients were included. Race or ethnicity of patients were not described. Median follow-up duration was 21 months (range, 12 to 34). Short-term complications included pain, postoperative bleeding, and subcutaneous seroma. Long-term complications included dysesthesia of the nipple-areolar complex and redundant skin. Cosmetic outcomes were assessed by 2 surgeons at 6 months post-procedure. Cosmetic outcomes based on predetermined criteria were as follows: very good (15/34; 44.1%), good (17/34; 50%), and

average (2/34; 5.9%). Satisfaction of patients was scored using a 5-point Likert scale, and the average was 4.4 points (+/- standard deviation of 0.5).

Table 3. Summary of Nonrandomized Studies Characteristics

Study	Study Type	Country	Dates	Participants	Treatment	Treatment	Follow-Up
Nuzzi et al (2018)[5,]	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 yrs
Liu et al (2022) [6,]	Prospective, longitudinal cohort study	China	2018-2020	Adolescents and adults diagnosed with glandular gynecomastia (N= 50 breasts; 16 bilateral and 18 unilateral)	Surgical intervention		21 mos

Table 4. Summary of Observational Comparative Study Results

Study						
	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)[5,]						
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
			Patients' mean overall satisfaction score (SD)	Short-term complications (n)	Long-term Complications (n)	
Liu et al (2022) [6,]						
Treatment group			4.4 (0.5)	Pain (n=21) Postoperative bleeding (n=1) Subcutaneous seroma (n=3)	Dysesthesia of the NAC (n=2) Redundant skin (n=2)	

EAT-26: eating-attitudes test-26; NAC: nipple–areolar complex ; 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. Two systematic reviews included studies on the surgical treatment of gynecomastia; however, the majority of evidence was determined to be of low quality with a high risk of bias.

SUPPLEMENTAL INFORMATION

The purpose of the following information is to provide reference material. Inclusion does not imply endorsement or alignment with the evidence review conclusions.

Practice Guidelines and Position Statements

Guidelines or position statements will be considered for inclusion in 'Supplemental Information' if they were issued by, or jointly by, a US professional society, an international society with US representation, or National Institute for Health and Care Excellence (NICE). Priority will be given to guidelines that are informed by a systematic review, include strength of evidence ratings, and include a description of management of conflict of interest.

American Society of Plastic Surgeons

In 2002, affirmed 2015, the American Society of Plastic Surgeons (ASPS) issued practice criteria for third-party payers.[7,] 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 "unilateral 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 "unilateral 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."

American Society of Andrology

In 2019, the American Society of Andrology, in collaboration with the European Academy of Andrology, released clinical practice guidelines on gynecomastia evaluation and management.[8,] Their recommendation related to surgical intervention is as follows:

- "We suggest surgical treatment only for patients with long-lasting GM [gynecomastia], which does not regress spontaneously or following medical therapy. The extent and type of surgery depend on the size of breast enlargement, and the amount of adipose tissue [weak recommendation, low quality of evidence]."

U.S. Preventive Services Task Force Recommendations
Not applicable.

Ongoing and Unpublished Clinical Trials
A search of ClinicalTrials.gov in December 2024 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. This may not be a comprehensive list of procedure codes applicable to this policy.

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.

The code(s) listed below are medically necessary ONLY if the procedure is performed according to the "Policy" section of this document.

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

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: ▪ Added ICD-10 Diagnosis *(Effective October 1, 2014)*
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: ▪ 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: ▪ 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: ▪ Added ICD-10 codes: N63.15, N63.25
04-16-2021	Updated Description section.
	Updated Rationale section.
	Updated References section.
04-08-2022	Updated Description Section

REVISIONS	
	Updated Rationale Section
	Updated Coding Section • Removed ICD-10 Codes: C50.021, C50.022, C50.121, C50.122, C50.221, C50.222, C50.321, C50.322, C50.421, C50.422, C50.521, C50.522, C50.621, C50.622, C50.821, C50.822, C50.921, C50.922
	Updated References Section
03-28-2023	Updated Description Section
	Updated Rationale Section
	Updated Coding Section ▪ Removed ICD-10 Codes
	Updated References Section.
03-26-2024	Updated Description Section
	Updated Rationale Section
	Updated References Section
03-27-2025	Updated Description Section
	Updated Rationale Section
	Updated References Section

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6. Liu C, Tong Y, Sun F, et al. Endoscope-Assisted Minimally Invasive Surgery for the Treatment of Glandular Gynecomastia. Aesthetic Plast Surg. Dec 2022; 46(6): 2655-2664. PMID 35237883
7. 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 December 17, 2024.
8. Kanakis GA, Nordkap L, Bang AK, et al. EAA clinical practice guidelines-gynecomastia evaluation and management. Andrology. Nov 2019; 7(6): 778-793. PMID 31099174

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.