Gynecomastia Surgery

Policy Number: MP.012.16
Effective Date: October 1, 2023

➲ Instructions for Use

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Application

UnitedHealthcare Commercial

This Medical Policy applies to all UnitedHealthcare Commercial benefit plans.

UnitedHealthcare Individual Exchange

This Medical Policy applies to Individual Exchange benefit plans in all states except for Colorado.

Coverage Rationale

➲ See Benefit Considerations

A mastectomy for treatment of Benign Gynecomastia for a male member under age 18 is considered reconstructive and medically necessary when all the following criteria are met:

- Gynecomastia or breast enlargement with moderate to severe chest pain causing a Functional or Physical Impairment. The inability to participate in athletic events, sports, or social activities is not considered to be a functional or physical, or physiological impairment.
- Persistent gynecomastia after cessation of prescribed medications and appropriate screening(s) of non-prescription and/or recreational drugs or substances that have a known side effect of gynecomastia (examples include, but are not limited to the following: testosterone, marijuana, asthma drugs, phenothiazines, anabolic steroids, cimetidine, and calcium channel blockers).
- The breast enlargement must be present for at least two years, and appropriate evaluation of medical causes with supporting laboratory testing has been normal. If so, lab tests might include, but are not limited to the following must be performed:
  - Hormone testing (e.g., beta-human chorionic gonadotropin, estradiol, follicle-stimulating hormone, luteinizing hormone, prolactin, testosterone)

- Liver enzymes
- Serum creatinine
- Thyroid function studies

Mastectomy for treatment of Benign Gynecomastia for a male member aged 18 and over is considered reconstructive and medically necessary when all the following criteria are met:

- Discontinuation of medications, nutritional supplements, and non-prescription medications or substances (Examples include, but are not limited to the following: testosterone, marijuana, asthma drugs, phenothiazines, anabolic steroids, cimetidine, and calcium channel blockers) that have known side effect of gynecomastia or breast enlargement and the breast size did not regress after discontinuation of use as appropriate.
- Glandular breast tissue is the primary cause of gynecomastia as opposed to fatty deposits (pseudo gynecomastia) and is documented on physical exam and/or mammography.
- Gynecomastia or breast enlargement with moderate to severe chest pain causing a Functional or Physical Impairment. The inability to participate in athletic events, sports, or social activities is not considered to be a functional or physical, or physiological impairment.
- Appropriate evaluation of medical causes with supporting laboratory testing has been normal. If so, Lab tests might include, but are not limited to the following must be performed:
  - Hormone testing (e.g., beta-human chorionic gonadotropin, follicle-stimulating hormone, estradiol, luteinizing hormone, prolactin, testosterone)
  - Liver enzymes
  - Serum creatinine
  - Thyroid function studies

Note: Regardless of age, if a tumor or neoplasm is suspected, a breast ultrasound and/or mammogram may be performed. As indicated, a breast biopsy may also be performed.

Documentation Requirements

Benefit coverage for health services is determined by the member specific benefit plan document and applicable laws that may require coverage for a specific service. The documentation requirements outlined below are used to assess whether the member meets the clinical criteria for coverage but do not guarantee coverage of the service requested.

CPT Code*	Required Clinical Information
Gynecomastia Surgery	

19300	Medical notes documenting the following, when applicable:
	• History of the medical condition
	• Relevant history of prescribed medication
	• Screening for non-prescription and/or recreational drugs or substances (examples include but are not limited to testosterone, marijuana, asthma drugs, phenothiazines, anabolic steroids, cimetidine, and calcium channel blockers)
	• Severity of pain and details of functional or physiological impairment(s)
	• Frontal and lateral high quality, color photographs of the torso, including expected outcome
	  ○ **Note**: All images must be labeled with the:
	  ▪ Date taken
	  ▪ Applicable case number obtained at time of notification, or member's name and ID number
	  ○ Submission of photographs can be submitted via the external portal at http://www.uhcprovider.com/paan; faxes will not be accepted
	• Treatment plan for proposed surgery
	• Reports of all recent imaging studies and applicable diagnostic tests, including:
	  ○ Mammography
	  ○ Hormone testing (e.g., beta-human chorionic gonadotropin, estradiol, follicle-stimulating hormone, luteinizing hormone, prolactin, testosterone)
	  ○ Liver enzymes
	  ○ Serum creatinine

CPT Code*	Required Clinical Information
	○ Thyroid function studies

*For code description, refer to the Applicable Codes section.

Definitions

The following definitions may not apply to all plans. Refer to the member specific benefit plan document for applicable definitions.

Benign Gynecomastia: Gynecomastia is defined as a unilateral or bilateral persistent benign mammary gland enlargement in men. Typically, true gynecomastia presents with a solid tissue mass palpable below the nipple-areolar complex. Malignant changes such as male mammary carcinoma must always be ruled out. There are numerous causes of gynecomastia. One cause is noted to be the imbalance of female to male hormones which triggers the onset of the disease. Endogenous causes may be hyperthyroidism, chronic liver disease, primary or secondary gonadal failure, androgen resistance syndromes, medication and drug abuse. A series of heart or hypertension medications can also trigger gynecomastia. The prevalence of asymptomatic gynecomastia is up to 65% and true gynecomastia must be distinguished from pseudo-gynecomastia. This condition can cause significant clinical manifestations when the excessive breast weight adversely affects the supporting structures of the shoulders, neck, and trunk. Depending on the underlying cause, the therapy of gynecomastia may be conservative or surgical (LCD - cosmetic and reconstructive surgery, 2021).

American Society of Plastic Surgeons' gynecomastia scale (ASPS, 2015):
- 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 indistinct from the chest with skin redundancy present.
- Grade IV: Marked breast enlargement with skin redundancy and feminization of the breast

Congenital Anomaly: A physical developmental defect is present at the time of birth and is identified within the first twelve months of delivery (COC, 2018).

Cosmetic Procedures: Procedures or services that change or improve appearance without significantly improving physiological function (COC, 2018).

Functional or Physical Impairment: A functional or physical, or physiological impairment causes deviation from the normal function of a tissue or organ. This results in a significantly limited, impaired, or delayed capacity to move, coordinate actions, or perform physical activities and is exhibited by difficulties in one or more of the following areas: physical and motor tasks, independent movement, performing basic life functions.

Reconstructive Procedures: Reconstructive Procedures when the primary purpose of the procedure is either of the following:
- Treatment of a medical condition
- Improvement or restoration of physiologic function

Reconstructive Procedures include surgery or other procedures related to an injury, sickness, or Congenital Anomaly. The primary result of the procedure is not a changed or improved physical appearance.

Procedures that correct an anatomical Congenital Anomaly without improving or restoring physiologic function are considered Cosmetic Procedures. The fact that you may suffer psychological consequences or socially avoidant behavior due to an injury, sickness or Congenital Anomaly does not classify surgery (or other procedures done to relieve such consequences or behavior) as a reconstructive procedure (COC, 2018).

Applicable Codes

The following list(s) of procedure and/or diagnosis codes is provided for reference purposes only and may not be all inclusive. Listing of a code in this policy does not imply that the service described by the code is a covered or non-covered health service.

Benefit coverage for health services is determined by the member specific benefit plan document and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment. Other Policies and Guidelines may apply.

Note: Coding for suction lipectomy is addressed in the Medical Policy titled Panniculectomy and Body Contouring Procedures.

CPT Code	Description
19300	Mastectomy for gynecomastia

Description of Services

Gynecomastia is a benign proliferation of glandular breast tissue in men. Physiologic gynecomastia is common in newborns, adolescents, and older men. Treatment is directed at minimizing emotional distress and physical discomfort. Nonphysiologic gynecomastia may be caused by chronic conditions including but not limited to cirrhosis, hypogonadism, and renal insufficiency; use of medications, supplements, or illicit drugs; and, rarely, tumors. Discontinuing using contributing medications and treating underlying diseases is the standard of practice. Medications, such as estrogen receptor modulators and surgery, have a role in treating gynecomastia in select patients. Mastectomy is the surgical removal of glandular breast tissue through an open incision or, more recently, through minimally endoscopic techniques. Cases considered severe may require larger incisions (Dickson, 2012).

Benefit Considerations

Most benefit plans explicitly exclude coverage for treatment of Benign Gynecomastia. However, some states require coverage.

Refer to the member specific benefit plan document to determine availability of benefits for these procedures.

Clinical Evidence

Innocenti and associates (2022) performed a systematic review of the literature related to incidences of complications for different approaches in gynecomastia correction. In total, 94 articles were obtained consisting of 7294 individuals being analyzed. Three groups were created: aspiration techniques, consisting of 874 individuals (11.98%); surgical excision techniques, consisting of 2764 individuals (37.90%); and combined techniques, consisting of 3656 individuals (50.12%). The notable complications for each group totaled 1407. In the surgical excision techniques group, there were 847 (30.64%), 130 (14.87%) in the aspiration techniques group, and 430 (11.76%) in the combined techniques group. The authors concluded that the combined use of surgical excision and aspiration techniques reduces the rate of complications compared to that of the surgical excision alone; however, the lack of unique classification and presence of several surgical methods represents a bias in the literature review.

In 2021, Trinchieri et al. conducted a systematic review and meta-analysis of randomized clinical trials concerning treatment-related gynecomastia for individuals taking spironolactone, antiandrogens, 5 alpha-reductase inhibitors, lipid-lowering, and psychotropic drugs through a systematic review and meta-analysis of randomized clinical trials. For men receiving antiandrogens, there was an increased risk of gynecomastia (OR = 17.38, 95% CI: 11.26 to 26.82; 6 trials, 9599 participants) and 5 alpha-reductase inhibitors compared to controls (OR = 1.77, 95% CI: 1.53 to 2.06; 7 series out of 6 trials, 34860 participants). Compared to controls, using spironolactone in mixed-gender populations were considered to have substantially higher odds of having gynecomastia (OR = 8.39, 95% CI: 5.03 to 13.99; 14 trials, 3745 participants). There was a noteworthy variance in the odds of having gynecomastia in an evaluation between risperidone and quetiapine (OR = 4.32, 95% CI: 1.31 to 14.27; 3 trials, 343 participants), however; no placebo-controlled trials concentrating on the risk of gynecomastia for individuals taking antipsychotic drugs was obtainable. Antiandrogens, 5 alphareductase inhibitors, and spironolactone are associated with an increased risk of developing gynecomastia.

Holzmer and colleagues., (2020) conducted a comprehensive review of the literature regarding the surgical management of gynecomastia to analyze surgical practice patterns and trends pertaining to the grade and severity of gynecomastia. The

primary data points were the complication rate, including hematoma, seroma, infection, necrosis, drain use, gynecomastia grade, and surgical intervention. A total of 1112 individuals received surgical treatment for gynecomastia, with the most used technique being skin-sparing mastectomy with or without liposuction, followed by mastectomy with skin reduction. The most common complication noted was hematoma formation which comprised 5.8% of complications, followed by seroma, 2.4%. Those who routinely utilized drain placement demonstrated a higher rate of hematoma/seroma formation (9.78% vs. 8.36%; P = 0.0051). However, a limitation is a large discrepancy in the percentage of grade III individuals found in each group (50.23% vs. 4.36%; P = 0.0000). The authors concluded that there is a wide range of surgical techniques for treating gynecomastia. No definitive, universally accepted algorithm exists showing the ideal surgical approach for treating gynecomastia based on severity. An individualized approach based on gynecomastia grade and individual preference should assist the surgeon in providing the best outcomes.

A randomized controlled trial was conducted by Hasan in 2019 to compare operative techniques; modified Benelli technique vs. subcutaneous mastectomy using periareolar incision. Participants were divided into two groups regarding their surgical technique to carry out the trial. Group A consisted of 75 individuals undergoing surgical treatment with subcutaneous mastectomy using periareolar incision, and group B included 75 individuals being managed by the modified Benelli technique. The trial results uncovered that the modified Benelli technique; had a lower operating time and retained a cosmetically acceptable position of the areola; however, there was much pleating of the skin compared to the periareolar incision. The authors concluded that the modified Benelli technique offers a reasonably simple surgical approach with an aesthetically positive outcome to treat gynecomastia with a low rate of complications and recurrences.

In a 2018 systematic review, Sollie sought to identify the psychological domains affected by gynecomastia and the effect of surgical treatment on these. Primary outcomes consisted of quality of life and several psychological domains after surgical treatment for gynecomastia, specifically, vitality, emotional discomfort, limitations due to physical aspects, and limitations due to pain. The author concluded that the impact of surgical treatment for gynecomastia is beneficial for several of the psychological domains and restrictions due to pain; however, the current level of evidence on the subject is low, requiring future studies that examine the impact of the surgical intervention for gynecomastia on psychological domains are necessary.

In 2018, Nuzzi and colleagues studied the effect of surgical treatment for gynecomastia on the quality of life in adolescents through surveys. The surveys were distributed to adolescents ages 12-21 with gynecomastia and male controls. The surveys consisted of the short-form 36v2 (SF-36), Rosenberg Self-Esteem Scale (RSES), and Eating-Attitudes Test-26. Surveys were completed at baseline, postoperatively, six months, one year, three- and five-year follow-ups. Participants in the study were 64 unaffected male controls. For the five SF-36 domains: general health, vitality, social functioning, role-emotional, and mental health, the individuals with gynecomastia scored significantly worse than controls and on the RSES. Postoperative improvements were noted in the scores of the RSES and the four SF-36 domains physical functioning, role-physical, bodily pain, and social functioning. Gynecomastia subjects scored similarly to controls in all SF-36 domains and the RSES postoperatively. Limitations in the study consist of the need for follow-up BMI data and the lack of comparison between baseline physical activity and the SF-36 survey, which confirms that the subjects have the potential for physical activity. Additional limitations include the sample size, risk for bias, and recruitment from a single, large tertiary care facility. The authors concluded that surgical treatment of gynecomastia improves the quality of life for adolescents, especially those overweight individuals with severe gynecomastia, and measurable improvements in psychosocial and physical functioning are evident.

Zavlin D et al. (2017) performed a retrospective analysis from the American College of Surgeons National Surgical Quality Improvement Program databases for adults and pediatrics to produce two cohorts that underwent surgical repair of gynecomastia. The study's goal was to assess patient demographics, surgical outcomes, and complications. A total of 1787 individuals were identified, 204 pediatric and 1583 adult males. The mean ages were 15.8 and 39.6, respectively. The results demonstrated low surgical (3.9 and 1.9%) and medical (0.0 and 0.3%) complications within the standardized 30-day postoperative period. Children and adolescents, however, required double mean operative times compared to adults (111.3 vs. 56.7 min). The authors concluded that operative gynecomastia treatment remains a safe modality across all age groups.

Clinical Practice Guidelines

American Society of Andrology and European Academy of Andrology (ASA/EAA)

- The existence of an underlying pathology should be considered for gynecomastia in adulthood. The recommendation is to identify an apparent cause for gynecomastia in adulthood, including the use of medication recognized to be related to gynecomastia, which should not preclude a detailed investigation (moderate quality).

- Initial screening is suggested to rule out lipomastia, apparent breast cancer, or testicular cancer, which may be completed by a general practitioner or another clinical professional (very low-quality).
- In those cases where a comprehensive diagnostic workup is necessary, it should be accomplished by a specialist (very low-quality).
- The individual's medical history is recommended to incorporate information involving the onset and duration of gynecomastia, sexual development and function, and administration or abuse of substances associated with gynecomastia (moderate quality).
- The physical examination should identify signs of under-virilization or systemic disease (high quality).
- Breast examination should confirm the presence of palpable glandular tissue to differentiate from lipomastia (pseudo-gynecomastia) and rule out the suspicion of malignant breast tumor (high quality).
- The physical examination should involve the assessment of the genitalia to rule out the presence of a palpable testicular tumor and to identify testicular atrophy (high quality).
- Genitalia examination assisted by a testicular ultrasound, as the detection of a testicular tumor by palpation has low sensitivity (low quality).
- A set of evaluations may incorporate T, E2, SHBG, LH, FSH, TSH, prolactin, hCG, AFP, and liver adrenal function tests (low quality).
- Breast imaging may assist when the clinical examination is vague (low quality).
- If the clinical picture is suspect of a malignant lesion, a core needle biopsy should be completed (low quality).
- Watchful waiting should occur after treatment of underlying pathology or cessation of the administration/abuse of substances connected with gynecomastia (low quality).
- Treatment should be offered exclusively to men with established testosterone insufficiency (moderate quality).
- The use of selective estrogen receptor modulators (SERMs), aromatase inhibitors (Ais), or non-aromatizable androgens for treating gynecomastia, in general, is not recommended (low quality).
- Surgical treatment is only for individuals with persistent gynecomastia, which does not regress naturally or through subsequent medical therapy. The magnitude and type of surgery depend on the size of breast enlargement and the quantity of adipose tissue (low quality) (Kanakis et al., 2019).

American Society of Plastic Surgeons (ASPS)

The 2016 ASPS's recommendations for gynecomastia surgery for adolescents:

- Unilateral or bilateral grade II or grade III gynecomastia present (per modified McKinney and Simon, Hoffman, and Kohn scales)
  - Continues more than one year following pathological sources ruled out
  - Continues after six months of failed medical treatment for pathological gynecomastia
- Unilateral or bilateral grade IV gynecomastia present (per modified McKinney and Simon, Hoffman, and Kohn scales)
  - Continues more than six months following pathological reasons ruled out
  - Continues after six months of failed medical treatment for pathological gynecomastia
- Pain and discomfort due to the distention and stiffness from the hypertrophied breast Gynecomastia may cause considerable psychological anguish, particularly in adolescents struggling with matters associated with sexual identity and self-image

The ASPS's recommendations for gynecomastia surgery for adults:

- Breast biopsy is suggested when malignancy is presumed
- Unilateral or bilateral grade III or IV gynecomastia present (per modified McKinney and Simon, Hoffman, and Kohn scales)
  - Continues for more than 3 to 4 months following pathological reasons ruled out
  - Continues after 3 to 4 months of failed medical therapy for pathological gynecomastia
- Pain and discomfort due to the distention and stiffness from the hypertrophied breast (French, 2016)

U.S. Food and Drug Administration (FDA)

This section is to be used for informational purposes only. FDA approval alone is not a basis for coverage.

Surgeries for the treatment of gynecomastia are procedures and therefore not regulated by the FDA. Refer to the following website for additional information: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm. (Accessed February 8, 2023)

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Policy History/Revision Information

Date	Summary of Changes
10/01/2023	**Application** ***Individual Exchange Plans*** • Removed language indicating this Medical Policy does not apply to Individual Exchange benefit plans in the states of Massachusetts, Nevada, and New York **Supporting Information** • Archived previous policy version MP.012.15

Instructions for Use

This Medical Policy provides assistance in interpreting UnitedHealthcare standard benefit plans. When deciding coverage, the member specific benefit plan document must be referenced as the terms of the member specific benefit plan may differ from the standard plan. In the event of a conflict, the member specific benefit plan document governs. Before using this policy, please check the member specific benefit plan document and any applicable federal or state mandates. UnitedHealthcare reserves the right to modify its Policies and Guidelines as necessary. This Medical Policy is provided for informational purposes. It does not constitute medical advice.

This Medical Policy may also be applied to Medicare Advantage plans in certain instances. In the absence of a Medicare National Coverage Determination (NCD), Local Coverage Determination (LCD), or other Medicare coverage guidance, CMS allows a Medicare Advantage Organization (MAO) to create its own coverage determinations, using objective evidence-based rationale relying on authoritative evidence (Medicare IOM Pub. No. 100-16, Ch. 4, §90.5).

UnitedHealthcare may also use tools developed by third parties, such as the InterQual® criteria, to assist us in administering health benefits. UnitedHealthcare Medical Policies are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice.