

Clinical Policy Title: Breast reduction surgery

Clinical Policy Number: 16.03.05

Effective Date: December 1, 2013
Initial Review Date: August 21, 2013
Most Recent Review Date: June , 2018
Next Review Date: June 2019

Related policies:

Policy contains:

- Reduction mammoplasty or mammaplasty.
- Breast reduction surgery.
- Breast hypertrophy.
- Gynecomastia.
- Body mass index.

CP#16.03.07 Reduction mammoplasty for male gynecomastia

ABOUT THIS POLICY: AmeriHealth Caritas has developed clinical policies to assist with making coverage determinations. AmeriHealth Caritas' 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' 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' 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' clinical policies are not guarantees of payment.

Coverage policy

AmeriHealth Caritas considers the use of breast reduction surgery to be clinically proven and, therefore, medically necessary when the following criteria are met: adult or adolescent females who have reached full adult height and legal age of consent to surgery with documented (by any health care provider) symptomatic breast hypertrophy meeting any of the following symptom criteria lasting at least one year that interfere with daily activities:

- Neck, upper back, and shoulder pain not associated with other diagnoses.
- Painful shoulder grooving from brassiere straps.
- Chronic intertriginous rash of the inframammary fold.
- Frequent episodes of headache, backache and upper extremity neuropathies.
- Symptoms attributable to an increase in the volume and weight of breast tissue beyond normal proportions.

In addition, all of the following criteria must be met:

- Failure of patient to respond to at least three months of optimal medical management with physical therapy.
- Patients 40 years or older must have a mammogram negative for cancer within one year of the planned procedure date.
- The pre-operative evaluation concludes that surgery will provide a likely prognosis of symptomatic relief.
- The estimated weight of breast tissue to be removed, per breast, will be at least that conforming to the Schnur sliding scale table, given in the Appendix (ASPS, 2011).

Limitations:

The procedure performed for relief of psychosocial distress (including cases of gynecomastia in males) and performed for cosmetic purposes are not clinically proven, and therefore not medically necessary.

Alternative covered services:

Medical management and physical therapy.

Background

Breast reduction surgery or reduction mammoplasty (alternate spelling, *mammaplasty*) is a surgical procedure to reduce the volume and weight of the female breasts. Mammoplasty is performed on women with excessively large breasts (macromastia), and aims to decrease the dimensions to obtain normal breast size. The procedure removes excess breast fat, glandular tissue, and skin to alleviate discomfort from overly large breasts.

During the operation, which is performed in a hospital or surgical center, the surgeon first makes several cuts in the breast, removes tissues and skin, and then stitches the skin back together. The procedure takes about 3-5 hours, and has been performed since the 1970s.

In 2016, a total of 61,821 breast reduction procedures were performed in the U.S. by members of the American Society of Plastic Surgeons (ASPS, 2017). Plastic surgeons perform most breast reductions, with a small proportion performed by general surgeons (Kordahi, 2015). The number of breast reduction procedures has increased rapidly in the last several decades (Alshanawani, 2013).

The procedure is performed for several reasons:

- To relieve back and neck pain, skin irritation, and posture problems caused by excessively large breasts, as mass of the breast tissue can cause a change in the body's center of gravity, resulting in pain and compression of the intervertebral disks.
- To reduce limitations on participating in athletic and other activities.

• For psychosocial reasons, especially to alter a woman's appearance, often to reduce her self-consciousness; this is considered a cosmetic procedure.

After the procedure, stitches are removed within 1-2 weeks. Most women undergoing the surgery experience pain for several days (some longer), in addition to swelling and bruising. Risks of the procedures during surgery include excessive bleeding, infection, reaction to anesthesia, and blood clots (which are rare). Risks after the surgery include scars, unevenly positioned nipples, breasts that are a different size or shape than the other, loss of feeling in the nipples or breasts, and the inability to breast feed.

Some women undergoing breast reduction have been diagnosed with cancer. Oncoplastic reduction mammoplasty removes cancer in the breast while incorporating aesthetically maximized approaches used in breast reduction (Chang, 2012).

Searches

AmeriHealth Caritas searched PubMed and the following databases:

- UK National Health Services Centre for Reviews and Dissemination.
- Agency for Healthcare Research and Quality's National Guideline Clearinghouse and other evidence-based practice centers.
- The Centers for Medicare & Medicaid Services (CMS).

We conducted searches on April 10, 2018. Search terms were "reduction mammoplasty," "breast reduction" and "breast hypertrophy." 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

The American College of Plastic Surgeons (ASPS) issued a guideline that identifies symptoms justifying breast reduction surgery (ASPS, 2011). The ASPS guideline addresses 1) procedural efficacy/symptom relief; 2) resection weight; 3) impact of Body Mass Index on surgical complications; 4) use of prophylactic antibiotics; 5) use of drains; and 6) effect on quality of life (Kalliainen, 2012). The National Comprehensive Cancer Network guideline recommends that non-invasive and conservative approaches

be attempted prior to any consideration of surgery for any symptoms linked with large breasts (Bevers, 2007).

Systematic reviews and meta-analyses have been published in the medical literature, and address various aspects of breast reduction surgery, including:

- <u>Infection Reduction</u>. A Cochrane study of three randomized controlled studies documented that prophylactic antibiotics reduced infection rates after breast reduction surgery by 75 percent (Shortt, 2014). This finding was similar to another significant reduction from a year prior in a review of 2971 patients undergoing breast reduction (Hardwicke, 2013), and a smaller meta-analysis of five articles (n=584) comparing patients given prophylactic antibiotics versus placebo (Zapata-Copete, 2017).
- <u>Benefits of wound drainage</u>. Another Cochrane study of three randomized controlled trials (n=306) showed that apart from a lower average hospital stay, wound drainage after breast reduction had no significant benefit (Khan, 2015).
- <u>Benefits of epinephrine</u>. A systematic review discovered that dilute epinephrine infiltration significantly reduced operative blood loss and need for blood transfusion (Hardwicke, 2012).
- Quality of life improvements. A systematic review of 16 studies indicated that all aesthetic
 procedures reviewed improved quality of life, and that reduction mammoplasty had the largest
 improvement of any procedure included (Dreher, 2016). A review of the literature revealed a
 consistent pattern of improved musculoskeletal pain, headache, sleep, breathing, self-esteem,
 sexual function, and (reduced) anxiety and depression (Singh, 2012).
 - <u>Obesity as risk factor</u>. A meta-analysis of 26 studies documented a 38 percent greater risk of complications in obese (versus non-obese) women undergoing reduction mammoplasty, particularly skin and fat necrosis (Myung, 2016). A study of 2779 patients revealed high body mass index to be an independent risk factor for wound complications (p=.005), while tobacco use was linked with a higher rate of re-operation (p=.02) (Karamanos, 2015). A study of 4545 breast reduction surgery patients found a statistically greater risk (nearly 12 percent) of complications in the morbidly obese (Nelson, 2014).
- Other risk factors. A meta-analysis of 16 studies (n=10,593) found higher complication rates for women with a body mass index >30 kg/m2 and smokers who underwent breast reduction. Higher rates were found for infections in overweight women and women with irradiated breasts, and higher wound dehiscence in smokers was documented (Zhang, 2016).

- Impact on breastfeeding. Reduction mammoplasty resulted in no reduced breastfeeding capacity one month after surgery, and should be encouraged to breast feed (Thibaudeau, 2010). A systematic review of 51 studies found that median breastfeeding success was four percent when there was no preservation of the column of parenchyma from the nipple areola complex to the chest wall, compared to 75 percent for partial preservation and 100 percent for full preservation (Kraut, 2017).
- Low complications after oncoplastic reduction mammoplasty. A systematic review of 17 studies (n=1324) of women with oncoplastic breast reduction reported low percentages of local-regional recurrence (3.1), re-excision (3.5), completion mastectomy (3.7), wound dehiscence (4.6), fat necrosis (4.3), infection (2.8), partial/total nipple necrosis (0.9), and seromas (0.6) (Piper, 2016).
- Reduced recurrence of virginal mammary hypertrophy. Women with virginal mammary
 hypertrophy, or rapid enlargement of one or both breasts in adolescence, had a significantly
 lower reduction of recurrence after breast reduction surgery, compared to mastectomy (Hoppe,
 2011).

Patient satisfaction surveys of 178 women (30 percent response of 600 surveys issued) found an average of 2.8 on a scale of 1 - 3 (i.e., nearly all "definitely agree" that they were satisfied with the procedure). An insignificant difference (p=0.57) exists between total breast tissue removed and patient response (Gonzalez, 2012).

Some studies reviewed outcomes of reduction mammoplasty by physician training and experience. One found that from 2005 to 2012 in the National Surgical Quality Improvement Project data base, 5,900 U.S. procedures were performed by plastic surgeons versus only 339 by general surgeons. Procedures by general surgeons had more failures of skin flaps and longer time in the operating room; no differences between the two groups were observed in infection and complication rates (Kordahi, 2015). A study of 1052 procedures from 1996 to 2010 found that after 15 years, average operating time fell by 38.3 percent (69.8 minutes), prompting authors to conclude that experience serves as a driver of improvement (Maruthappu, 2015).

Policy updates:

A total of three peer reviewed references were added to, and nine peer reviewed references removed from this policy in April 2018.

Summary of clinical evidence:

Citation	Content, Methods, Recommendations	
Piper (2016)	Key points:	

Citation	Content, Methods, Recommendations	
Outcomes following oncoplastic reduction mammoplasty	 Systematic review of 17 studies (n=1324) of reduction mammoplasty using oncoplastic technique Cases followed from 20 to 73 months after surgery Pooled local-regional recurrence rate was 3.1% Other percentages of adverse events were re-excision (3.5) completion mastectomy (3.7), wound dehiscence (4.6), fat necrosis (4.3), infection (2.8), partial/total nipple necrosis (0.9), seromas (0.6) Oncoplastic technique regarded as safe and effective 	
Kordahi (2015)	Key Points	
Comparing plastic and general surgeons performing reduction mammoplasty	 Evaluated procedures in National Surgical Quality Improvement Project database. From 2005-2012, 5900 procedures done by plastic surgeons, 339 by general surgeons. Patients operated on by general surgeons had more failures of skin flaps, longer operative time, but there was no difference in infection and complication rates between the two types of surgeons. Focused training in reduction mammography appears beneficial to the patient. 	
Maruthappu (2015)	Key Points	
Learning curves for surgeons performing reduction mammoplasty	 1052 reduction mammoplasties performed 1996-2010, 17 surgeons, median 61 procedures. After 15 years of experience, average operating time fell 38.3% (69.8 minutes). Experience serves as a driver of performance improvement. 	
Shortt (2014)	Key Points	
Change in infection rates in reduction mammoplasty patients given antibiotics as a prophylaxis	 3 Randomized Controlled Trials, 77 subjects. A 75% reduction in wound infections in patients given antibiotics. Recommended that pre-operative antibiotics should routinely be used in reduction mammoplasty 	
Singh (2012)	Key points:	
Benefits of reduction mammoplasty	 Systematic review of the medical literature on physical and psychological symptomatic improvements after reduction mammoplasty Physical improvements include musculoskeletal pain, headaches, sleep, and breathing Psychological benefits include self-esteem, sexual function, quality of life, reduced depression and anxiety After reduction mammoplasty, women exercise more and have fewer eating disorders 	

References

Professional society guidelines/other:

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Peer-reviewed references:

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Kordahi AM, Hoppe IC, Lee ES. Reduction mammoplasty: a comparison between operations performed by plastic surgery and general surgery. *Eplasty*. 2015;15:e41.

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Zhang MX, Chen CY, Fang QQ, et al. Risk factors for complications after reduction mammoplasty: a meta-analysis. *PLoS One*. 2016;11(12):e0167746. Doi: 10.137/journal.pone.0167746.

CMS National Coverage Determinations (NCDs):

No NCDs identified as of the writing of this policy.

Local Coverage Determinations (LCDs):

L33939 Reduction mammoplasty. Effective date October 1, 2015. https://www.cms.gov/medicare-coverage-database/details/lcd-

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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.

CPT Code	Description	Comment
19318	Reduction mammoplasty	

ICD-10 Code	Description	Comment
N62	Hypertrophy of breast	

HCPCS Level II Code	Description	Comment
N/A		

Appendix

The Schnur nomogram (below) has been promoted for use in calculating the amount of breast tissue to be removed in reduction mammoplasty. Tissue removal (gm) per breast was developed in 1991 using survey data from plastic surgeons. Its value for distinguishing medically necessary from cosmetic procedures has not been established (American Society of Plastic Surgeons, 2011).

Body surface area = (weight in $kg^{0.425}$ X height in $cm^{0.725}$) X 0.007184

Body Surface (m ²)	Estimated tissue removal/breast (gm)
1.35	199
1.40	218
1.50	260
1.55	284
1.60	310
1.65	338
1.70	370
1.75	404
1.80	441
1.85	482
1.90	527
2.00	628
2.05	687
2.10	750
2.15	819
2.20	895
2.25	978
2.30	1068
2.35	1167
2.40	1275
2.45	1393
2.50	1522
2.55	1662