Reduction Mammaplasty for Breast-Related Symptoms

Description

Macromastia, or gigantomastia, is a condition that describes breast hyperplasia or hypertrophy. Macromastia may result in clinical symptoms such as shoulder, neck, or back pain, or recurrent intertrigo in the mammary folds. In addition, macromastia may be associated with psychosocial or emotional disturbances related to the large breast size. Reduction mammaplasty is a surgical procedure designed to remove a variable proportion of breast tissue to address emotional and psychosocial issues and/or to relieve the associated clinical symptoms.

Background

While the literature search identified many articles that discuss the surgical technique of reduction mammaplasty and document that reduction mammaplasty is associated with a relief of physical and psychosocial symptoms,\textsuperscript{1-9} an important issue is whether reduction mammaplasty is a functional need or cosmetic in nature. For some patients, the presence of medical indications is clear-cut: a clear documentation of recurrent intertrigo or ulceration secondary to shoulder grooving. For some patients, the documentation differentiating between a cosmetic and a medically necessary procedure will be unclear. Criteria for medically necessary reduction mammaplasty are not well-addressed in the published medical literature.

Some protocols on the medical necessity of reduction mammaplasty are based on the weight of removed breast tissue. The basis of weight criteria is not related to the outcomes of surgery, but to surgeons retrospectively classifying cases as cosmetic or medically necessary. In 1991, Schnur et al, at the request of third-party payers, developed a sliding scale.\textsuperscript{10} This scale was based on survey responses from 92 of 200 solicited plastic surgeons, who reported the height, weight, and amount of breast tissue removed from each a breast from the last 15 to 20 reduction mammaplasties they had performed. Surgeons were also asked if the procedures were performed for cosmetic or medically necessary reasons. The data were then used to create a chart relating the body surface area and the cutoff weight of breast tissue removed that differentiated cosmetic and medically necessary procedures. Based on their estimates, those with a breast tissue removed weight above the 22nd percentile likely had the procedure for medical reasons, while those below the 5th percentile likely had the procedure performed for cosmetic reasons; those falling between the cutpoints had the procedure formed for mixed reasons.

In 1999, Schnur reviewed use of the sliding scale as a coverage criterion and reported that, while many payers had adopted it, many had also misused it.\textsuperscript{11} Schnur pointed out that if a payer used weight of resected tissue as a coverage criterion, then if the weight fell below the 5th percentile, the
reduction mammaplasty would be considered cosmetic; if above the 22nd percentile, it would be considered medically necessary; and if between these cutpoints, it would be considered on a case-by-case basis. Schnur also questioned the frequent requirement that a woman be within 20% of her ideal body weight. While weight loss might relieve symptoms, durable weight loss is notoriously difficult and might be unrealistic in many cases.

**Regulatory Status**

Surgical procedures are not regulated by the U.S. Food and Drug Administration.

**Policy**

*This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.*

Reduction mammaplasty may be considered **medically necessary** for the treatment of macromastia when well-documented clinical symptoms are present, including but not limited to:

- Documentation of a minimum 6-week history of shoulder, neck, or back pain related to macromastia that is not responsive to conservative therapy, such as an appropriate support bra, exercises, heat/cold treatment, and appropriate non-steroidal anti-inflammatory agents/muscle relaxants.

- Recurrent or chronic intertrigo between the pendulous breast and the chest wall.

Reduction mammaplasty is considered **investigational** for all other indications not meeting the above criteria.

**Policy Guidelines**

The presence of shoulder, neck, or back pain is the most common stated medical rationale for reduction mammaplasty. However, since this symptom is entirely subjective, certain patient documentation may assist in making the criteria more objective in nature. These have included:

- Use of photographs, providing a visual documentation of breast size, or documenting the presence of shoulder grooving, an indication that the breast weight results in grooving of the bra straps on the shoulder.

- Requirement of a specified amount of breast tissue to be resected, commonly 500 to 600 g per breast.

- Use of the Schnur sliding scale, which suggests a minimum amount of breast tissue to be removed for the procedure to be considered medically necessary, based on the patient's body surface area. (See Rationale section for further discussion) (The Schnur sliding scale may be used only for weight of resected tissue that falls below 500 to 600 g.)

- Requirement that the patient must be within 20% of ideal body weight to eliminate the possibility that obesity is contributing to the symptoms of neck or back pain.
Rationale

EFFICACY IN REDUCING SYMPTOMS

Randomized Controlled Trials

In 2008, Sabino Neto et al assessed functional capacity in which 100 patients, ages 18 to 55 years, were randomized to reduction mammaplasty or to waiting list control.⁷ Forty-six patients from each group completed the study. At baseline and 6 months later, patients were assessed for functional capacity using the Roland-Morris Disability Questionnaire (0=best performance, 24=worst performance) and for pain using a visual analog scale (VAS). The reduction mammaplasty group showed improvement in functional status, with an average score of 5.9 preoperatively and 1.2 within 6 months postoperatively (p<0.001 for pre-post comparison within the mammaplasty group) versus an unchanged average score of 6.2 in the control group on the first and second evaluations. Additionally, pain in the lower back decreased on the VAS from an average of 5.7 preoperatively to 1.3 postoperatively (p<0.001 for pre-post comparison within the mammaplasty group) versus VAS average scores in the control group of 6.0 and 5.3 on the first and second evaluations, respectively (p=NS).

Also in 2008, Saariniemi et al reported on quality of life (QOL) and pain in 82 patients randomized to reduction mammaplasty or a nonoperative group and evaluated at baseline and 6 months later.⁹ The authors reported that the mammaplasty group had significant improvements in QOL from baseline to 6 months, as measured by the Physical Component Summary score of the 36-Item Short-Form Health Survey (SF-36; change, +9.7 vs +0.7, p<0.001), the Utility Index score (SF-6D; change, +17.5 vs +0.6), the index score of QOL (SF-15D; change, +8.6 vs +0.6, p<0.001), and SF-36 Mental Component Summary score (change, +7.8 vs -1.0, p<0.002). There were also improvements in breast-related symptoms from baseline to 6 months, as measured by Finnish Breast-Associated Symptoms questionnaire scores (-47.9 vs -3.5, p<0.001), and Finnish Pain Questionnaire scores (-21.5 vs -1.0, p<0.001).

Iwuagwu et al (2006) reported on 73 patients randomized to receive reduction mammaplasty within 6 weeks or after a 6-month waiting period to assess lung function.⁸ All patients had symptoms related to macromastia. Postoperative lung function correlated with the weight of breast tissue removed, but there were no significant improvements in any lung function parameters for the mammaplasty group compared with the control group.

Beraldo et al (2016) reported on a trial of 60 patients randomized to reduction mammaplasty or to no surgery.¹² Trial outcomes were sexual function and depressive symptoms. At 6 months, Female Sexual Function Index scores were higher in the reduction mammaplasty group (27.5 vs 22.5, p<0.001). Level of depression, as measured by the Beck Depression Inventory, was lower in the reduction mammaplasty group (7.2 vs 13.7, p=0.01). Analyses using categories of sexual function or depression showed similar results.

Observational Studies

Singh and Losken (2012) reported on a systematic review of studies reporting outcomes after reduction mammaplasty.¹³ In 7 studies reporting on physical symptoms (n range, 11-92 patients), reviewers found reduction mammaplasty improved functional outcomes including pain, breathing,
sleep, and headaches. Additional psychological outcomes noted included improvements in self-esteem, sexual function, and QOL.

In 2016, Hernanz et al reported on a descriptive cohort study of 37 consecutive obese patients who underwent reduction mammoplasty for symptomatic macromastia, along with 37 age-matched women hospitalized for short-stay surgical procedures. In the preoperative state, SF-36 physical health component subscore was significantly lower for patients with symptomatic macromastia (40) than for age-matched controls (53; p<0.001), with differences in 5 of the 8 subscales. At 18 months postprocedure, there was no significant difference in any SF-36 subscores except the body pain subscale between patients who had undergone reduction mammoplasty and age-matched controls.

In 2002, Kerrigan et al published the results of the BRAVO (Breast Reduction: Assessment of Value and Outcomes) study, a registry of 179 women undergoing reduction mammoplasty. Women were asked to complete QOL questionnaires and a physical symptom count both before and after surgery. The physical symptom count focused on the number of symptoms present that were specific to breast hypertrophy and included upper back pain, rashes, bra strap grooves, neck pain, shoulder pain, numbness, and arm pain. In addition, the weight and volume of resected tissue were recorded. Results were compared with a control group of patients with breast hypertrophy, defined as size DD bra cup, and normal-sized breasts, who were recruited from the general population. The authors proposed that the presence of 2 physical symptoms might be an appropriate cutoff for determining medical necessity for breast reduction. For example, while 71.6% of the hypertrophic controls reported none or 1 symptom, only 12.4% of those considered surgical candidates reported none or 1 symptom. This observation is difficult to evaluate because the study did not report how surgical candidacy was determined. The authors also reported that none of the traditional criteria for determining medical necessity for breast reduction surgery (height, weight, body mass index [BMI], bra cup size, or weight of resected breast tissue) had a statistically significant relation with outcome improvement. The authors concluded that the determination of medical necessity should be based on patients' self-reported symptoms rather than more objectively measured criteria (eg, weight of excised breast tissue).

Section Summary: Efficacy in Reducing Symptoms

Systematic reviews, randomized trials, and observational studies have shown that several measures of function and QOL improve after reduction mammoplasty.

COMPLICATIONS

Thibaudeau et al (2010) conducted a systematic review to evaluate breastfeeding after reduction mammoplasty. After a review of literature from 1950 through December 2008, reviewers concluded that reduction mammoplasty does not reduce the ability to breastfeed. In women who had reduction mammoplasty, breastfeeding rates were comparable in the first month postpartum to rates in the general population in North America.

In 2011, Chen et al reported on a review of claims data to compare complication rates after breast surgery in 2403 obese and 5597 nonobese patients. Of these patients, breast reduction was performed in 1939 (80.7%) in the study group and in 3569 (63.8%) in the control group. Obese patients had significantly more claims for complications within 30 days after breast reduction surgery (14.6%) than nonobese patients (1.7%; p<0.001). Complications included inflammation, infection, pain, and seroma/hematoma development. Also in 2011, Shermak et al reported on a review of claims
data comparing complication rates by age after breast reduction surgery in 1192 patients.\textsuperscript{18} Infection occurred more frequently in patients older than 50 years of age (odds ratio [OR], 2.7; p=0.003). Additionally, women older than 50 years experienced more wound healing problems (OR=1.6; p=0.09) and reoperative wound débridement (OR=5.1; p=0.07). Other retrospective evaluations (2013, 2014) of large population datasets have reported an increased incidence of perioperative and postoperative complications with high BMI.\textsuperscript{19,20}

**Practice Guidelines and Position Statements**

**American Society of Plastic Surgeons**

The American Society of Plastic Surgeons (ASPS) has issued practice guidelines and a companion document on criteria for third-party payers for reduction mammaplasty.\textsuperscript{21-23} ASPS found level I evidence has shown reduction mammaplasty is effective in treating symptomatic breast hypertrophy, which “is defined as a syndrome of persistent neck and shoulder pain, painful shoulder grooving from brassiere straps, chronic intertriginous rash of the inframammary fold, and frequent episodes of headache, backache, and neuropathies caused by heavy breasts caused by an increase in the volume and weight of breast tissue beyond normal proportions.” ASPS also indicated the volume or weight of breast tissue resection should not be criteria for reduction mammaplasty. If 2 or more symptoms are present all or most of the time, reduction mammaplasty is appropriate.

**U.S. Preventive Services Task Force Recommendations**

Not applicable

**Summary of Evidence**

For individuals who have symptomatic macromastia who receive reduction mammaplasty, the evidence includes systematic reviews, randomized controlled trials, and case series. Relevant outcomes are symptoms and functional outcomes. These studies have indicated that reduction mammaplasty is effective at decreasing breast-related symptoms such as pain and discomfort. There is also evidence that functional limitations related to breast hypertrophy are improved after reduction mammaplasty. These outcomes are achieved with acceptable complication rates. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

**Medicare National Coverage**

There is no national coverage determination (NCD).

**References**


Policy History

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<td>New Policy</td>
<td>Policy reviewed with literature search; policy statements unchanged;</td>
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Keywords

Breast reduction
Reduction mammaplasty

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on March 17, 2017 and is effective April 15, 2017.

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