Reduction Mammaplasty for Breast-Related Symptoms

Description

Reduction mammaplasty is a surgical procedure designed to remove a variable proportion of breast tissue.

Background

Macromastia, or gigantomastia, is an ill-defined term 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 relieve the associated clinical symptoms.

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

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, (1-9) the medical policy focuses on the distinction of whether the proposed reduction mammaplasty is medically necessary or cosmetic in nature. For some patients the presence of medical indications is clear-cut, ie, a clear documentation of recurrent intertrigo, or ulceration secondary to shoulder grooving. However, most patients, the documentation between a cosmetic and medically necessary procedure will be unclear and subjective in nature. Criteria for medically necessary reduction mammaplasty are not well addressed in the published medical literature, and thus the optimal patient selection criteria cannot rely on an evidence-based approach. Therefore, the policy guidelines do not endorse a particular set of patient selection criteria, ie, the use of photographs, amount of breast tissue removed, or a combination of approaches.

Breast Weight

The following discussion focuses on the published literature addressing the use of weight of excised breast as coverage criteria. In 2001, Krieger and Lesavoy reported on a survey of managed care policies regarding reduction mammaplasty. (10) Most of the respondents to the survey stated that they use weight of excised tissue as the main criterion for allowing the procedure. The average cut-off value for this determination was 472 g. While 500 g appears to be a commonly cited cut-off weight of excised tissue, there appears to be no documentation in the literature as to the sensitivity and specificity of this value in distinguishing cosmetic from medically necessary procedures. (11) Also, the use of a single weight cut-off does not address the issue of the relationship between body surface area and weight of excised tissue. In 1991, Schnur et al, at the request of third-party payers, developed a sliding scale. (11) This sliding scale was based on survey responses of 92 of 200 solicited plastic surgeons, who reported the height, weight, and amount of breast tissue removed from
each breast from the last 15 to 20 reduction mammoplasties that had been performed. The 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 cut-off weight of breast tissue removed according to the 5th percentile and 22nd percentile lines. Based on their estimates, those with breast weight above the 22nd percentile line likely had the procedure performed for medical reasons, while those below the 5th percentile line likely had the procedure performed for cosmetic reasons, and those falling between the lines had the procedure formed for mixed reasons.

In 1999, Schnur reviewed the experience of the sliding scale as a coverage criterion and reported that while many payers had adopted this scale, many had also misused it. (12) The author pointed out that if a payer uses weight of resected tissue as a coverage criterion, then if the weight falls below the 5th percentile line, the reduction mammoplasty would be considered cosmetic, above the 22nd percentile line would be considered medically necessary, and those that fell between these lines would be considered on a case-by-case basis. The author also questions the frequent requirement that a woman be within 20% of her ideal body weight. While weight loss might indeed relieve symptoms, durable weight loss is notoriously difficult and may be unrealistic in many cases.

In 2012, Gonzalez et al reported on 178 patients who had breast reduction surgery primarily for symptomatic macromastia. Patients completed the Breast-Q questionnaire once after surgery, and retrospective chart reviews were completed to assess patient outcomes and determine whether any correlation exists between outcomes and patient size or amount of breast tissue removed. (13) Most patients responded to the surgery with satisfaction with a mean response on the Breast Q questionnaire of 2.8 (2, somewhat agree; 3, definitely agree). The mean BMI of patients was 28.3 kg/m and correlated significantly with the amount of breast tissue removed (p<0.001). The mean amount of breast tissue removed was 1220.9 g but did not correlate significantly with patient quality-of-life responses (p=0.57).

**Functional Impairment**

Singh and Losken, in 2012, reported on a systematic review of studies reporting outcomes after reduction mammoplasty. (14) The reviewers found reduction mammoplasty improves functional outcomes including pain, breathing, sleep, and headaches. Additional psychological outcomes noted in the review include improvements in self-esteem, sexual function, and quality of life.

In 2002, Kerrigan and Collins published the results of the BRAVO (Breast Reduction: Assessment of Value and Outcomes) study, a registry of 179 women undergoing reduction mammoplasty. (15) Women were asked to complete quality-of-life 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 propose that the presence of 2 physical symptoms might be an appropriate cut-off for determining medical necessity for breast reduction. For example, while 71.6% of the hypertrophic controls reported none or one symptom, only 12.4% of those considered surgical candidates reported none or one symptom. This observation is difficult to evaluate because the study
does 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, BMI,
bra cup size, or weight of resected breast tissue) had a statistically significant relationship with
outcome improvement. The authors conclude that the determination of medical necessity should be
based on patients’ self-reported symptoms rather than more objectively measured criteria, such as
weight of excised breast tissue.

In 2008, Sabino Neto et al, reported on a study to assess functional capacity in which 100 patients,
ages 18-55 years, were randomized to receive reduction mammaplasty or be placed on a waiting list
to serve as a control group. (7) Patient exclusion criteria included BMI greater than 30 kg/m²,
asymmetry in mammary hypertrophy, chronic disease, smoking, or daily medication use. Forty-six
patients from each group completed the study. At the onset of the study and 6 months later, patients
were assessed for functional capacity using the Roland-Morris instrument (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 to 1.2
within 6 months postoperatively (p<0.001 for pre-/post-comparison within 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 region decreased on VAS from an average of 5.7 preoperatively to
1.3 postoperatively (p<0.001 for pre- post-comparison within mammaplasty group) versus VAS
average scores in the control group of 6.0 and 5.3 on the first and second evaluations, respectively
(no significant change). Three patients did not report any improvement in low back pain after surgery.
The authors noted a need for exercise programs after surgery to improve posture malpositions
developed after years of mammary hypertrophy.

Also in 2008, Saariniemi et al reported on a study to assess quality of life and pain in which 82
patients were randomized to reduction mammaplasty or a nonoperative group in which patients were
evaluated at the onset of the study and 6 months later. (9) The authors reported the mammaplasty
group had significant improvements in quality of life, as measured by the Physical Component
Summary score of the 36-Item Short-Form Health Survey (change of +9.7 vs. +0.7, p<0.001), the
utility index score (Short Form [SF]-6D) (+17.5 vs +0.6), the index score of quality of life (SF-15D;
+8.6 vs +0.06, p<0.001), and the SF-36 Mental Component Summary score (+7.8 vs -1.0, p<0.002).
There were also improvements in breast-related symptoms, as measured by the Finnish Breast-
Associated Symptoms questionnaire score (-47.9 vs. -3.5, p<0.001), and the Finnish Pain
Questionnaire score (-21.5 vs. -1.0, p<0.001).

Iwuagwu et al 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 to control. This is in contrast to previous studies, such as Cunha et al who reported
improvements in lung function after reduction mammaplasty in 12 patients followed prospectively in a
cohort study. (16) Arterial blood gases did not differ significantly pre- or postoperatively.
Complications

Thibaudeau et al, in 2010, conducted a systematic review to evaluate breastfeeding after reduction mammaplasty. (17) After a review of literature from 1950 through December 2008, the authors concluded reduction mammaplasty does not reduce the ability to breastfeed. In women who have had reduction mammaplasty, breastfeeding was found to be comparable for the first month postpartum 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. (18) Of these patients, breast reduction was performed in 1939 (80.7%) in the study group and 3569 (63.8%) in the control group. Obese patients had significantly more claims for complications within 30 days after breast reduction surgery than nonobese patients (14.6% vs. 1.7%, respectively, 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 to compare complication rates in relation to age after breast reduction surgery in 1192 patients. (19) 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 also experienced more wound healing problems (OR = 1.6; p=0.09) and reoperative wound debridement (OR= 5.1; p=0.07). Other retrospective evaluations of large population datasets have also reported an increased incidence of perioperative and postoperative complications with high BMI. (20, 21)

Ongoing and Unpublished Clinical Trials

A previously reported ongoing trial (online site ClinicalTrials.gov, NCT01297621) randomized 60 patients to evaluate patient satisfaction, sexuality, and physical activity outcomes after reduction mammaplasty was completed in June 2013. As of October 16, 2014, there were no reported results for this study, which was carried out in Brazil, and there were no additional active clinical trials that addressed functional outcomes for reduction mammaplasty.

Practice Guidelines and Position Statements

The American Society of Plastic Surgeons (ASPS) issued practice guidelines and a companion document on criteria for third-party payers for reduction mammaplasty. (22-24) The ASPS indicates 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 indicates 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

Reduction mammaplasty is not a preventive service.
Summary

Reduction mammaplasty is a surgical procedure designed to remove a variable proportion of breast tissue. The available evidence from randomized controlled and prospective studies indicates 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 following reduction mammaplasty. Therefore, the available evidence for reduction mammaplasty is sufficient to demonstrate improvements in net health outcomes. Reduction mammaplasty may be considered medically necessary in patients with macromastia, who have a minimum 6-week history of shoulder, neck, or back pain that is not responsive to conservative therapy, and not caused by any other identifiable condition. Reduction mammaplasty may also be considered medically necessary in patients with recurrent or chronic intertrigo between the pendulous breast and the chest wall.

Medicare National Coverage

There is no national coverage determination (NCD).

References


Policy History

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Keywords

- Breast reduction
- Reduction mammaplasty

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on March 20, 2015 and is effective April 15, 2015.

Signature on file

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