DISCLAIMER

Our medical policies are designed for informational purposes only and are not an authorization, explanation of benefits or a contract. Receipt of benefits is subject to satisfaction of all terms and conditions of the coverage. Medical technology is constantly changing, and we reserve the right to review and update our policies periodically.

POLICY

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 not responsive to conservative therapy, such as an appropriate support bra, exercises, heat/cold treatment, and appropriate nonsteroidal anti-inflammatory agents or 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, because these symptoms and others may be subjective, Plans have implemented various patient selection criteria designed to be more objective. They include:

- 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 grams 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. Some Plans may use the Schnur Sliding Scale only for weight of resected tissue that falls below 500 to 600 grams.
- 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.

**BENEFIT APPLICATION**

**BLUECARD/NATIONAL ACCOUNT ISSUES**
Medical policies regarding reduction mammaplasty have focused on the distinction between a cosmetic procedure, performed primarily to improve the appearance of the breast, and a medically necessary procedure, performed primarily to relieve documented clinical symptoms. It should be noted that the emotional and psychosocial distress associated with body appearance does not constitute a medical rationale for reduction mammaplasty, and thus these indications would be considered cosmetic.

Determinations of whether a proposed therapy would be considered reconstructive or cosmetic should always be interpreted in the context of the specific benefits language. State or federal mandates may also dictate coverage decisions.

The requirement for the presence of functional impairment as a coverage criterion for a specific etiology may vary from Plan to Plan. It should be noted that, in general, the presence of functional impairment would render its treatment medically necessary and thus not subject to contractual definitions of reconstructive or cosmetic.

**BACKGROUND**

**MACROMASTIA**
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. Also, macromastia may be associated with psychosocial or emotional disturbances related to the large breast size.

**Treatment**
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.

While literature searches have identified many articles that discuss the surgical technique of reduction mammaplasty and have documented that reduction mammaplasty is associated with relief of physical and psychosocial symptoms, an important issue is whether reduction mammaplasty is a functional need or cosmetic. For some patients, the presence of medical indications is clear-cut: 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. Schnur et al (1991) at the request of third-party payers, developed a sliding scale. 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 performed for mixed reasons.

Schnur (1999) reviewed the 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 is 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**
Reduction mammaplasty is a surgical procedure and, as such, is not subject to regulation by the U.S. Food and Drug Administration.

**RATIONALE**
This evidence review was created in December 1995 and has been updated regularly with searches of the MEDLINE database. The most recent literature review was performed through December 11, 2017.

Evidence reviews assess the clinical evidence to determine whether the use of a technology improves the net health outcome. Broadly defined, health outcomes are length of life, quality of life, and ability to function—including benefits and harms. Every clinical condition has specific outcomes that are important to patients and to 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 a technology, 2 domains are examined: the relevance and the 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 is preferred to assess efficacy; however, in some circumstances, nonrandomized studies may be adequate. Randomized controlled trials 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.

**REDUCTION MAMMAPLASTY FOR MACROMASTIA - EFFICACY IN REDUCING SYMPTOMS**

**Randomized Controlled Trials**
Sabino Neto et al (2008) assessed functional capacity for 100 patients, ages 18 to 55 years, who were randomized to reduction mammaplasty or to waiting list control.\textsuperscript{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. 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) vs 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 visual analog scale from an average of 5.7 preoperatively to 1.3 postoperatively (p<0.001 for pre-post comparison within the mammoplasty group) vs visual analog scale average scores in the control group of 6.0 and 5.3 on the first and second evaluations, respectively (p=NS).

Saariniemi et al (2008) reported on quality of life (QOL) and pain in 82 patients randomized to reduction mammoplasty or a nonoperative group and evaluated at baseline and 6 months later.9 The authors reported that the mammoplasty 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 +0.06, 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 reduction mammoplasty within 6 weeks or after a 6-month waiting period to assess lung function.9 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 mammoplasty group compared with the control group.

**Observational Studies**

Singh and Losken (2012) reported on a systematic review of studies reporting outcomes after reduction mammoplasty.12 In 7 studies reporting on physical symptoms (n range, 11-92 patients), reviewers found reduction mammoplasty improved functional outcomes including pain, breathing, sleep, and headaches. Additional psychological outcomes noted included improvements in self-esteem, sexual function, and QOL.

Hernanz et al (2016) 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.13 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 were no significant differences in any SF-36 subscores except the body pain subscale between patients who had undergone reduction mammoplasty and age-matched controls.

Kerrigan et al (2002) published the results of the BRAVO (Breast Reduction: Assessment of Value and Outcomes) study, a registry of 179 women undergoing reduction mammoplasty.14 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. Also, 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, 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 (e.g., the weight of excised breast tissue).

**Adverse Events**

Thibaudeau et al (2010) conducted a systematic review to evaluate breastfeeding after reduction
mammaplasty.15 After a review of literature from 1950 through 2008, reviewers concluded that
reduction mammaplasty does not reduce the ability to breastfeed. In women who had reduction
mammaplasty, breastfeeding rates were comparable in the first month postpartum to rates in the
general population in North America.

Chen et al (2011) reported on a review of claims data to compare complication rates after breast surgery
in 2403 obese and 5597 nonobese patients.16 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 (14.6%) than nonobese patients
(1.7%; p<0.001). Complications included inflammation, infection, pain, and seroma/hematoma
development. Shermak et al (2011) also reported on a review of claims data comparing complication
rates by age after breast reduction surgery in 1192 patients.17 Infection occurred more frequently in
patients older than 50 years of age (odds ratio, 2.7; p=0.003). Additionally, women older than 50 years
experienced more wound healing problems (odds ratio, 1.6; p=0.09) and reoperative wound
débridement (odds ratio, 5.1; p=0.07). Other retrospective evaluations (2013, 2014) of large population
datasets have reported increased incidences of perioperative and postoperative complications with high
body mass index.18,19

**Section Summary: Reduction Mammaplasty for Macromastia-Efficacy in Reducing Symptoms**

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

**SUMMARY OF EVIDENCE**

For individuals who have symptomatic macromastia who receive reduction mammaplasty, the evidence
includes systematic reviews, randomized controlled trials, cohort studies, and case series. Relevant
outcomes are symptoms and functional outcomes. 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.

**SUPPLEMENTAL INFORMATION**

**PRACTICE GUIDELINES AND POSITION STATEMENTS**

The American Society of Plastic Surgeons has issued practice guidelines and a companion document on
criteria for third-party payers for reduction mammaplasty.20-22 The Society found that 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.” The Society also indicated the volume or weight of breast
tissue resection should not be criteria for reduction mammaplasty. If two or more symptoms are
present all or most of the time, reduction mammaplasty is appropriate.
U.S. PREVENTIVE SERVICES TASK FORCE RECOMMENDATIONS
Not applicable.

MEDICARE NATIONAL COVERAGE
There is no national coverage determination. In the absence of a national coverage determination, coverage decisions are left to the discretion of local Medicare carriers.

ONGOING AND UNPUBLISHED CLINICAL TRIALS
A search of ClinicalTrials.gov in January 2018 did not identify any ongoing or unpublished trials that would likely influence this review.

REFERENCES


**CODES**

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**Reduction Mammaplasty for Breast-Related Symptoms**

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