

Corporate Medical Policy

Reduction Mammoplasty

Description of Procedure or Service

Reduction mammoplasty or breast reduction surgery reduces the volume and weight of the female breasts by removing excess fat, glandular tissue and skin. Macromastia 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. The goals of the surgery are to relieve symptoms caused by heavy breasts, to create a natural, balanced appearance with normal location of the nipple and areola, to maintain the capacity for lactation and allow for future breast exams/mammograms with minimal scarring or decreased sensation.

Background

Current literature discusses the surgical techniques of reduction mammoplasty and documents that reduction mammoplasty is associated with relief of physical and psychosocial symptoms. An important issue is whether reduction mammoplasty is medically necessary or cosmetic in nature. For some patients, the presence of medical indications is clear-cut, i.e., a clear documentation of recurrent intertrigo or ulceration secondary to shoulder grooving. For others, the distinction between a cosmetic and medically necessary procedure will be unclear. Criteria for medically necessary reduction mammoplasty are not well-addressed in the published medical literature. Reduction mammoplasty has been performed to relieve back and shoulder pain on the theory that reducing breast weight will relieve this pain. In the case of reduction mammoplasty for relief of back, neck and shoulder pain, this procedure is generally believed to be medically necessary in women with excessively large breasts. Despite the lack of firm clinical trial evidence, it appears rational that this excessive weight could contribute to back and shoulder pain, and that removal of excessive breast tissue would provide substantial pain relief. If an insufficient amount of breast tissue is removed, the surgery is less likely to be successful in relieving pain and any related symptoms.

The amount of breast tissue to be removed has been a standard criterion for evaluating the medical necessity of breast reduction surgery. In a survey of managed care policies regarding breast reduction surgery, Krieger found that most of the respondents stated that they use weight of excised tissue as the main criterion for allowing the procedure, with an average cut-off value of 472 grams for a typical woman. The studies used to support the arguments for the medical necessity of breast reduction surgery are poorly controlled and therefore subject to a substantial risk of bias in the interpretation of results. Furthermore, the lack of an expected "dose-response" relationship between the amount of breast tissue removed and the magnitude of symptomatic relief in these studies raises questions about the validity of these studies and the effectiveness of breast reduction as a method of relieving shoulder and back pain.

There have been a number of studies challenging current payer criteria for reduction mammoplasty. The positions of medical professional organizations and consensus groups must be considered according to

the quality of the scientific evidence and supporting rationale. It is the burden of the proponent of an intervention to provide reliable evidence of its effectiveness, not the burden of ones who question the effectiveness an intervention to provide definitive proof of ineffectiveness. The cyclic nature of pain and the susceptibility of this symptom to placebo effects may confound interpretation of study results. Coverage for reduction mammoplasty in women with excessively large breasts has been provided for many years; therefore, the debate is about the effectiveness of removing smaller amounts of breast tissue from women whose breast size falls within the normal range.

Schnur et al (1991) reported on a sliding scale that assigns a weight of breast tissue to be removed based on body weight and surface area. The study by Schnur et al was based on a survey of 92 plastic surgeons who reported on their care for 591 patients. Each surgeon who participated in the study reported on the height, weight, and volume of reduction of their last 15 to 20 patients, and each surgeon provided their “intuitive sense” regarding the motivation of each patient for breast reduction surgery. Schnur subsequently refuted the validity of the Schnur sliding scale and stated that the scale should no longer be used as a criterion for the determination of insurance coverage for breast reduction surgery.

Some individuals, however, have argued that reduction mammoplasty may be indicated in any woman who suffers from back and shoulder pain, regardless of how small her breasts are or how little tissue is to be removed (ASPS, 2002). They have argued that removal of even a few hundred grams of breast tissue can result in substantial pain relief. These individuals cite evidence from observational studies to support this position (Chadbourne, 2001; Kerrigan, 2001). These studies did not find a relationship between breast weight or amount of breast tissue removed and the likelihood of response or magnitude of relief of pain after reduction mammoplasty.

It is not intuitively obvious, however, that breast weight would substantially contribute to back, neck and shoulder pain in women with normal or small breasts. Nor is it intuitively obvious that removal of smaller amounts of breast tissue would offer significant relief of back, shoulder or neck pain. Criteria for reduction mammoplasty surgery from the American Society of Plastic Surgeons (ASPS, 2002; ASPS, 2011) states, among other things, that breast weight or breast volume is not a legitimate criterion upon which to distinguish cosmetic from functional indications. This conclusion is based primarily upon the Breast Reduction Assessment of Value and Outcomes (BRAVO) study, which is described in several articles. There are also several earlier, smaller studies that found reductions in symptoms and improvements in quality of life after reduction mammoplasty (Glatt, Bruhlmann, Blomqvist and Behmand)

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. 13 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 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 relationship 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, such as weight of excised breast tissue. Operative subjects who

completed the study reported reductions in pain and improvements in quality of life; however, these improvements may be attributable to placebo effects, the natural history of back pain, other concurrent interventions, regression to the mean, improvements in cosmesis, or other confounding variables that may bias in interpretation of results. Thus, this study would not be considered of sufficient quality to provide reliable evidence of the effectiveness of a pain intervention.

The authors of the BRAVO study reached several conclusions about reduction mammoplasty, most notably that breast size or the amount of breast tissue removed does not have any relationship to the outcome of breast reduction surgery (Kerrigan (2002); Collins 2006). The authors reached the conclusion that a woman with normal sized breasts who has only a few ounces of breast tissue removed is as likely to receive as much benefit from breast reduction surgery as women with large breasts that has substantially more breast tissue removed. However, the BRAVO study is not of sufficient quality to reach reliable conclusions about the effectiveness of breast reduction surgery as a pain intervention. Although the BRAVO study is described as a controlled study, the "control" group is obtained, not from the same cohort, but from a separate cohort of individuals recruited from newspaper advertisements and solicitations at meetings for inclusion in a study of the population burden of breast hypertrophy; 75 % of this control group were obtained from 2 centers, but the characteristics of those 2 centers were not described. The control group was not followed longitudinally or treated according to any protocol to ensure that they received optimal conservative management; conclusions about the lack of effectiveness of conservative management were based on their responses to a questionnaire about whether subjects tried any of 15 conservative interventions, and whether or not they thought these interventions provided relief of symptoms. Based largely upon these results, Nguyen (2008) reached the conclusion that a trial of conservative management is not an appropriate criterion for insurance coverage, even though responses to the BRAVO questionnaire indicated that operative candidates and hypertrophy controls received at least some pain relief from all of the conservative interventions, and for some conservative interventions, virtually all subjects reported at least some pain relief. In addition, Nguyen ignored a wealth of published evidence of the effectiveness of physical therapy, analgesics and other conservative measures on back and neck pain generally.

Other references to smaller studies published prior to the BRAVO study have been cited, examining symptoms before and after reduction mammoplasty; each of these studies suffer from limitations similar to those identified with the BRAVO study. A study by Glatt (1999) was a retrospective analysis of responses to questionnaires sent to patients who underwent reduction mammoplasty regarding physical symptoms and body image. Of 110 subjects who were mailed questionnaires, approximately 50 % (61 subjects) provided responses. The investigators found little difference between obese and non-obese women concerning patient's reports of resolution of symptoms and improvement in body image. A study by Bruhlmann and Tschopp (1998) was a retrospective study of 246 patients from a surgical practice, approximately 50 % (132) of whom returned a questionnaire about their symptoms and satisfaction with aesthetic results, and their recollection of symptoms prior to surgery. It should be noted that this study reported a strong correlation between the amounts of tissue removed and pain amelioration. It was also found that only 3 % of subjects reported that they had no aesthetic motivation for surgery. Behmand (2000) reported on the results of a questionnaire pre- and post-surgery in 69 subjects from a single practice who underwent reduction mammoplasty. Subjects were compared to age-matched norms from another study cohort. No data were provided on loss to follow-up. The article by Blomqvist (2000) is to another questionnaire study about health status and quality of life before and after surgery. Approximately 25 % of the 49 subjects included in this study did not return the post-operative questionnaire. Subject's responses were compared to an age-matched comparison group of women, although no further details about how this comparison group was provided. The investigators

reported that subjects who were of normal weight were as likely to report benefit from reduction mammoplasty as subjects who were over-weight. A study reporting on a survey of health insurer policies on breast reduction surgery Nguyen (2008) found that no insurer medical policies could be supported by the medical literature. The authors argue, based primarily on the results of the ASPS-funded BRAVO study (described below), that (with a single exception) no objective criteria for breast reduction surgery are supportable, including criteria based upon the presence of particular signs or symptoms, requirements based upon breast size or the amount of breast tissue removed, any minimum age limitations, any limitation based upon maximum body weight, requirements for a trial of conservative therapy, or the exclusion of certain procedures (liposuction). The only criterion that the authors found supportable was a requirement for a pre-operative mammogram for women aged 40 years and older. The authors concluded that decisions about the medical necessity of breast reduction surgery in symptomatic women should be left entirely to the surgeon's discretion. Based on the above, it is clear studies used to support the arguments for the medical necessity of breast reduction surgery are poorly controlled and therefore subject to a substantial risk of bias in the interpretation of results. Well-designed, prospective, controlled clinical studies have not been performed to assess the effectiveness of surgical removal of modest amounts of breast tissue in reducing neck, shoulder, and back pain and related disability in women. In addition, reduction mammoplasty needs to be compared with other established methods of relieving back, neck and shoulder pain. Well-designed clinical trials provide reliable information about the effectiveness of an intervention, and provide valid information about the characteristics of patients who would benefit from that intervention. Therefore, there is insufficient evidence to support the use of reduction mammoplasty, without regard to the size of the breasts or amount of breast tissue to be removed, as a method of relieving chronic back, neck, or shoulder pain.

The American Society for Plastic Surgery (2015) advises to delay surgery until breast growth ceases: "Although waiting may prolong the psychological awkwardness, it is advisable to delay surgery until breast growth ceases in order to achieve the best result." This is similar to the American College of Obstetricians and Gynecologists' 2016 Guidelines for Adolescent Health Care chapter on breast concerns in adolescents, which states regarding breast hypertrophy: "Preferably, treatment should be deferred until breast growth has been completed. If breast growth has been completed, breast reduction surgery is an option." Marshall and Tanner (1969) shows that the final stage of breast maturity occurs about age 15 on average, but there is wide variation. Sabiston's Textbook of Surgery (Burns & Blackwell, 2008) states that breast size should be stable for one year: "There is no set lower age limit but, for the adolescent with breast hypertrophy, reduction is deferred until the breasts have stopped growing and are stable in size for at least 12 months before surgery."

Karamanos (2015) noted that although breast reduction mammoplasty accounts for more than 60,000 procedures annually, the literature remains sparse on outcomes. In this study the National Surgical Quality Improvement Program data set was queried for the Current Procedural Terminology code 19318 from the years 2005 to 2010, with principal outcome measurements of wound complications, surgical site infections, and reoperations. A total of 2779 patients were identified with a mean age of 42.7 (14.1) years and BMI of 31.6 (7.0) kg/m. Tobacco use was shown to have a higher rate of reoperation ($p=0.02$) and BMI was identified as an independent risk factor for wound complications (odds ratio, 1.85, $P=0.005$). The authors also noted that patients with BMI greater than 40 kg/m were significantly more likely to develop postoperative wound complications ($p=0.02$). They identified their study as the largest sample on breast reduction in the literature, in which age and surgeon specialty did not correlate with negative results. In contrast, tobacco use and BMI were associated with worse breast reduction outcomes.

Nelson (2014) separately conducted a population level analysis of the 2005-2011 NSQIP datasets, identifying patient who underwent reduction mammoplasty, to determine the impact of obesity on early complications after reduction mammoplasty. The results demonstrated that increasing obesity class is associated with increased early postoperative complications.

Srinivasaiah (2014) stated that although reduction mammoplasty has been shown to benefit physical, physiological, and psycho-social health there are recognized complications. They concluded that higher resection weight, increased BMI, older age, and smoking are risk factors for complication and that patients should therefore be adequately counseled about losing weight and stopping smoking. In 2016 a large meta-analysis was published by Zhang et al (2016) to identify risk factors for complications after reduction mammoplasty (RM). An extensive search of the literature describing complications after RM was performed using the PubMed Central, Embase, and Cochrane databases. The following risk factors were extracted: age, body mass index (BMI), tissue resection weight per breast (TRW), smoking and radiation therapy. Odds ratios (OR) were pooled with 95% confidence intervals (CI) to evaluate the relationship between these risk factors and complications after RM. The authors corroborated earlier evidence regarding obesity by Nelson (2014) and Srinivasaiah (2014). They also further corroborated risks involving smoking and RM from earlier studies. They concluded that BMI 30 kg/m² and smoking increase the risk of complications. Persons who are obese or irradiated are more likely to develop infections, and smokers experienced a higher incidence of wound dehiscence than did nonsmokers. However, patients aged 50 years and total reduction weight of 1000 g are not associated with complications from RM. Based on this meta-analysis and many previous studies, it furthers the recommendation that weight loss and smoking cessation should be done prior to any RM to lessen the risk of early complications.

Regulatory Status

Reduction mammoplasty is a procedure and, therefore, not subject to FDA regulation. However, any medical devices, drugs, biologics, or tests used as a part of this procedure may be subject to FDA regulation.

Benefit Application

Cosmetic surgery is defined as any surgical procedure (or any portion of a procedure) performed primarily to improve physical appearance through change in bodily form, except repair of accidental injury if repair is initiated promptly or as soon as the member's condition permits is considered a non-covered benefit under the GEHA Service Benefit Plan.

This medical policy relates only to the services or supplies described herein. Please refer to the Member's Benefit Booklet for availability of benefits.

Policy Statement

GEHA will provide coverage for reduction mammoplasty when it is determined to be medically necessary because the medical criteria and guidelines as documented below have been demonstrated.

When Reduction Mammoplasty is covered

GEHA considers breast reduction surgery medically necessary for symptomatic macromastia for women aged 18 or older or for whom growth is complete (defined as breasts that have reached developmental maturity with size stable for at least one year) when all of the following criteria are met:

- A. Member has persistent symptoms in at least 2 of the anatomical body areas below that are well documented, directly attributed to macromastia and affecting daily activities for at least 1 year:
- Headaches
 - Pain in neck
 - Pain in shoulders
 - Pain in upper back
 - Painful kyphosis documented by X-rays
 - Pain/discomfort/ulceration from bra straps cutting into shoulders
 - Skin breakdown defined as severe soft tissue infection, tissue necrosis, ulceration, or hemorrhage from overlying breast tissue
 - Upper extremity paresthesias;
- AND
- B. Photographic documentation confirms severe breast hypertrophy;
- AND
- C. Symptoms persist as documented by the physician despite at least a 6-month trial of therapeutic measures that may include the following, where clinically appropriate:
- Analgesic/non-steroidal anti-inflammatory drugs (NSAIDs) interventions and/or muscle relaxants
 - Dermatologic therapy of ulcers, necrosis and refractory infection. The condition must be unresponsive to dermatological treatments (e.g., antibiotics or antifungal therapy) and conservative measures (e.g., good skin hygiene, adequate nutrition.
 - Physical therapy/exercises/posturing maneuvers
 - Supportive devices (e.g., proper bra support, wide bra straps)
 - Chiropractic care or osteopathic manipulative treatment
 - Medically supervised weight loss program
 - Orthopedic or spine surgeon evaluation of spinal pain
- AND
- D. Women 40 years of age or older are required to have a mammogram that was negative for cancer performed within the year prior to the date of the planned reduction mammoplasty
- AND
- E. The surgeon estimates that at least the following amounts (in grams) of breast tissue, not fatty tissue, will be removed from each breast, based on the member's body surface area (BSA) (as defined by the Schnur Scale within Appendix A of this policy).

When Reduction Mammoplasty is not covered

GEHA considers breast reduction surgery cosmetic unless breast hypertrophy is causing physical symptomatology that fails conservative management as designated above. Reduction mammoplasty for asymptomatic members is considered cosmetic. Reduction mammoplasty performed solely for cosmetic indications is considered to be not medically necessary treatment of disease and subject to the standard cosmetic surgery plan exclusion.

Liposuction only reduction mammoplasty is considered experimental and investigational because of insufficient evidence of its effectiveness.

Autologous Platelet Gel during Breast Surgery is considered unproven and experimental.

Policy Guidelines

The Schnur scale remains the source used by GEHA to determine that the weight of breast tissue to be removed based upon body weight and surface area is sufficient to represent a therapeutic reduction. (See appendix A).

Breast reduction includes nipple-areolar complex management, whether it's preserved on a pedicle or repositioned as a free graft. Grafting of the nipple-areolar complexes should not typically be separately coded from the breast reduction.

Physician documentation

Requests for coverage of reduction mammoplasty require the submitting provider to present:

- Clinical documentation that demonstrates the clinical findings noted above
- Serial medical records that demonstrate the extent of evaluation and management
- Pictures that correlate with the clinical findings of macromastia
- Documentation of the surgical plan, including the amount of breast tissue proposed for removal

Applicable codes

19318 Reduction Mammoplasty.

Scientific references

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Policy implementation and updates

4/2018 Revision of format and streamlined content. No material changes in coverage.

3/2019 Reviewed. No material changes in coverage. Updated referenced statements with newer articles that supported the same content.

Appendix A:

Table: Weight of breast tissue removed, per breast, as a function of body surface area

Body Surface Area (m2)	Average grams of tissue per breast to be removed
1.35	199
1.40	218
1.45	238
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
1.95	575

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
2.60	1806
2.65	1972
2.70	2154
2.75	2352
2.80	2568
2.85	2804
2.90	3061
2.95	3343
3.00	3650
3.05	3985
3.10	4351
3.15	4750

3.20	5186
3.25	5663
3.30	6182
3.35	6750
3.40	7369
3.45	8045
3.50	8783
3.55	9589
3.60	10468
3.65	11428
3.70	12476
3.75	13619
3.80	14867
3.85	16230
3.90	17717
3.95	19340
4.00	21112
4.05	23045
4.10	25156
4.15	27459
4.20	29972
4.25	32716
4.30	35710
4.35	38977

4.40	42543
4.45	46435
4.50	50682
4.55	55316
4.60	60374
4.65	65893
4.70	71915
4.75	78487
4.80	85658

$BSA (m^2) = ([height (in) \times weight (lb.)] / 3131)^{1/2}$ (1/2 denotes square root)