BlueCross BlueShield of Alabama

Name of Policy:
Reduction Mammaplasty

Policy #: 056
Category: Surgery

Latest Review Date: February 2016
Policy Grade: D

Background/Definitions:

As a general rule, benefits are payable under Blue Cross and Blue Shield of Alabama health plans only in cases of medical necessity and only if services or supplies are not investigational, provided the customer group contracts have such coverage.

The following Association Technology Evaluation Criteria must be met for a service/supply to be considered for coverage:

1. *The technology must have final approval from the appropriate government regulatory bodies;*
2. *The scientific evidence must permit conclusions concerning the effect of the technology on health outcomes;*
3. *The technology must improve the net health outcome;*
4. *The technology must be as beneficial as any established alternatives;*
5. *The improvement must be attainable outside the investigational setting.*

Medical Necessity means that health care services (e.g., procedures, treatments, supplies, devices, equipment, facilities or drugs) that a physician, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury or disease or its symptoms, and that are:

1. *In accordance with generally accepted standards of medical practice; and*
2. *Clinically appropriate in terms of type, frequency, extent, site and duration and considered effective for the patient's illness, injury or disease; and*
3. *Not primarily for the convenience of the patient, physician or other health care provider; and*
4. *Not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient's illness, injury or disease.*

Description of Procedure or Service:

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 (breast reduction) is a surgical excision of a substantial portion of breast tissue that includes the skin and underlying glandular tissue. Reduction mammaplasty may reduce the size, change the shape, and/or lift the breast tissue.

Policy:

Reduction mammaplasty meets Blue Cross and Blue Shield of Alabama's medical criteria for coverage for women aged 18 or older or for female adolescents whose breasts are fully developed; i.e., patient has maintained current height, weight, and breast size for 12 months, when:

- a **minimum of 500 grams** of breast tissue is to be removed from **each** breast; **OR**
- a **combined minimum total of 1000 grams** of breast tissue is to be removed from both breasts **(effective 10/01/2012); OR**
- a women is of small stature (5 feet 3 inches and under), consideration will be given for removal of less than 500 grams of breast tissue from each breast using the Schnur Sliding Scale chart. Body surface area is calculated and then the Schnur Sliding Scale chart is used to determine the number of grams to be removed from each breast. (See www-users.med.cornell.edu/~spon/picu/calc/bsacalc.htm)

And two or more of the following medical indications are met:

- Pain in the upper back and shoulders resulting in documented treatment and interference with activities of daily living. This pain should be evaluated to determine that it is not associated with another diagnosis such as arthritis. The pain is not relieved by conservative therapy including an appropriate support bra, exercises, heat/cold treatments and appropriate non-steroidal anti-inflammatory agents/muscle relaxants.
- Dermatitis of skin of shoulder or shoulder grooving not responding to conservative treatment, including support bra.
- Intertrigo between the pendulous breast and the chest wall
- Sternal notch to nipple measurements of 26 cm or greater

To ensure the above criteria are met, the patient's medical records must contain frontal and lateral view photographs, patient's height and weight, amount of breast tissue removed documented by pathology report, documentation of the size and shape of the breast causing symptomology, and documentation of patient's symptomology for 6 months prior to procedure.

Liposuction as a sole procedure for reduction mammaplasty does not meet Blue Cross and Blue Shield of Alabama's medical criteria for coverage and is **non-covered**. Liposuction may be used as an adjunct procedure to the surgical procedure of reduction mammaplasty.

Reduction mammoplasty does not meet Blue Cross and Blue Shield of Alabama's medical criteria for coverage and is considered **investigational for all other indications not meeting the above criteria.**

Reduction Mammaplasty performed post-mastectomy for cancer, on the contralateral breast to match the prosthesis size, is not required to meet the criteria for reduction mammaplasty.

Blue Cross and Blue Shield of Alabama does not approve or deny procedures, services, testing, or equipment for our members. Our decisions concern coverage only. The decision of whether or not to have a certain test, treatment or procedure is one made between the physician and his/her patient. Blue Cross and Blue Shield of Alabama administer benefits based on the member's contract and corporate medical policies. Physicians should always exercise their best medical judgment in providing the care they feel is most appropriate for their patients. Needed care should not be delayed or refused because of a coverage determination.

Key Points:

Female breast hypertrophy, or macromastia, is the development of abnormally large breasts in the female. This condition can cause significant clinical manifestations when the excessive breast weight adversely affects the supporting structures of the shoulders, neck and trunk. Macromastia is distinguished from large, normal breasts by the presence of persistent, painful symptoms and physical signs. The American Society of Plastic Surgeons states that macromastia causes significant clinical symptoms when the excessive breast weight adversely affects the supporting structures of the shoulders, neck and trunk. The condition can be improved and alleviated by reduction mammaplasty. The procedure is considered reconstructive in nature for this condition. This condition can be improved and the associated signs and symptoms can be alleviated by reduction mammaplasty surgery. Prior to undergoing surgery, it is recommended that the patient be within 20% of their ideal body weight. Antoniuk states this will facilitate the surgery, but also avoid medical complications associated with obesity. Hidalgo, et al states that liposuction is used mostly as an adjunct instead of a primary reduction modality. Liposuction is most commonly used to reduce prominence lateral to the anterior axillary line and to soften fullness over the pectoralis muscle near the axilla if this area is particularly prominent. Liposuction will continue to be considered investigational as a single procedure for reduction mammaplasty due to the limited scientific data that is published at this time.

Efficacy in Reducing Symptoms

Observational Studies

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

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 mammaplasty. 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 propose 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 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.

Randomized Controlled Trials

In 2008, Sabino Neto et al reported on a study to assess functional capacity in which 100 patients, ages 18 to 55 years, were randomized to reduction mammaplasty or waiting list control. 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 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 to 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 region decreased on 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 (no significant change).

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 six months later. 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. 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 control.

Beraldo et al reported trial of 60 patients randomized to receive either reduction mammaplasty or no operation. The outcomes of this study 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.

Studies Reporting Complications

Thibaudeau and colleagues, in 2010, conducted a systematic review to evaluate breastfeeding after reduction mammaplasty. 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 and colleagues reported on a review of claims data to compare complication rates after breast surgery in 2,403 obese and 5,597 non-obese patients. Of these patients, breast reduction was performed in 1,939 (80.7%) in the study group and 3,569 (63.8%) in the control group. Obese patients had significantly more claims for complications within 30 days after breast reduction surgery than non-obese 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 1,192 patients. 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.

Section Summary: Efficacy in Reducing Symptoms

Observational studies and several randomized show improvements in several measures of function and QOL.

Autologous Platelet Gel during Breast Surgery

Anzarut et al (2007) reported on their assessment of the effectiveness of topical application of completely autologous platelet gel during breast surgery to reduce postoperative wound drainage. Tissue sealants are being used to reduce postoperative wound drainage and improve surgical outcomes. There are few randomized, double-blind, controlled trials assessing the efficacy of these agents. One-hundred eleven (111) patients were included in this within-patient, randomized, patient and assessor-blinded, controlled trial to assess the use of completely autologous platelet gel in bilateral reduction mammaplasty. Patients were randomized by applying the gel to either the left or right breast after hemostasis was achieved; the other breast received no treatment. The primary outcome was the difference in wound drainage over 24 hours. Secondary outcomes included subjective and objective assessments of pain and wound healing. Results revealed that there were no statistically significant differences in the drainage, level of pain, size of open areas, clinical appearance, degree of scar pliability, or scar erythema. The authors concluded that these results do not support the use of completely autologous platelet gel to improve outcomes after reduction mammaplasty.

Summary

The evidence for reduction mammaplasty in individuals who have symptomatic macromastia includes randomized controlled trials and case series. Relevant outcomes are symptoms and functional outcomes. These studies indicate 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. These outcomes are achieved with acceptable complication rates. Overall, reduction mammaplasty in appropriately selected patients is associated with improvements in several important health outcomes.

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. 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 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.

Key Words:
Reduction mammoplasty, breast reduction, liposuction, reduction mammaplasty, macromastia, gigantomastia

Approved by Governing Bodies:
Surgical procedures are not regulated by the U.S. Food and Drug Administration

Benefit Application:
Coverage is subject to member's specific benefits. Group specific policy will supersede this policy when applicable.
ITS: Home Policy provisions apply
FEP contracts: Special benefit consideration may apply. Refer to member's benefit plan. FEP does not consider investigational if FDA approved and will be reviewed for medical necessity.

Clay County Hospital - **Effective for services rendered on or after 7/1/05 in addition to the criteria listed in the policy above**, the patient must be within 10% of their ideal body weight as defined by the Metropolitan Life Height & Weight Tables in order for the mammaplasty to be considered medically necessary by this plan. www.halls.md/ideal-weight/met.htm

Current Coding:
CPT code:

19318 Reduction mammaplasty

References:

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Policy History:

Medical Policy Group, July 2002
Medical Policy Administration Committee, July 2002
Available for comment July 19-September 3, 2002
Medical Policy Administration Committee, October 2002
Available for comment October 29-December 12, 2002
Medical Policy Group, January 2004
Medical Policy Group, June 2005 **(3)**
Medical Policy Group, January 2006 **(1)**
Medical Policy Group, July 2007 **(1)**
Medical Policy Group, February 2009 **(1)**
Medical Policy Group, May 2010 **(1)**
Medical Policy Group, November 2011 **(1)** Update to Key Points; no change in policy statement
Medical Policy Group; October 2012 **(1)** Update to Policy, and Key Points related to addition of coverage criteria of combined minimum total of 1000 grams of breast tissue removed from both breasts
Medical Policy Administration Committee, October 2012
Available for comment October 24 through December 10, 2012
Medical Policy Group, July 2013 **(1)** Update to Key Points and References; no change in policy statement
Medical Policy Group, November 2013 **(1)** Policy reviewed with literature search, policy statement unchanged, no references added
Medical Policy Panel, November 2014
Medical Policy Group, February 2015 **(3):** Updates to Description, Key Points, Key Words, Approved Governing Bodies, and References. Added Policy statement to include "all other indications not meeting the above criteria" is investigational. Policy intent unchanged.

Medical Policy Group, November 2015 **(1)** added the word “female” before word ”adolescents” in the criteria section for clarification; policy intent unchanged.
Medical Policy Panel, February 2016
Medical Policy Group, February 2016 (**2**): 2016 Updates to Key Points and References; no change in policy statement.

The Schnur Sliding Scale Chart

Body Surface Area (m^2)	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

$$BSA\ (m^2) = ([height\ (in) \times weight\ (lb)]/3131)^{½}$$

$$BSA\ (m^2) = ([height\ (cm) \times weight\ (kg)]/3600)^{½}$$