Title: Reduction Mammaplasty for Breast-Related Symptoms

Description/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. In addition, 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 relieve the associated clinical symptoms.

While the literature searches have identified many articles that discuss the surgical technique of reduction mammaplasty and have documented that reduction mammaplasty is associated with a relief of physical and psychosocial symptoms, 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. 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 mammoplasties 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.

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. 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 mammoplasty 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.

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**Regulatory Status:**

Reduction mammoplasty is a surgical procedure and, as such, is not subject to regulation by the U.S. Food and Drug Administration.

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**Medical Policy Statement**

The safety and effectiveness of reduction mammoplasty have been established. It may be considered a useful therapeutic option (and not considered cosmetic) when either:

- The patient meets specified patient selection guidelines.
- When done in conjunction with medically necessary breast reconstruction for the purposes of attaining breast symmetry.

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**Inclusionary and Exclusionary Guidelines (Clinically based guidelines that may support individual consideration and pre-authorization decisions)**

**Inclusions:**

A. Must meet both criteria (1-2):
   1. Patient must be old enough so that the breasts are fully grown
   2. Removal of more than one kilogram (1000 grams) of tissue per breast

OR

B. Must meet both B and C
   Two of the following criteria (1-3) must be met:
   1. Pain
      - Documented pain in the neck and/or shoulders or postural backache which must be of long-standing duration, AND
- Failure of conservative therapy, including an appropriate support bra, exercises, heat/cold treatments and appropriate non-steroidal anti-inflammatory agents or muscle relaxants

2. Shoulder grooving
3. Recurrent intertrigo between the breasts and the chest wall that has not responded to dermatologic treatment

C. Must meet both criteria:
   1. Patient must be old enough so that the breasts are fully grown
   2. The amount of tissue to be removed must be greater than or equal to the 22 percentile on the Schnur Scale.

The Schnur Sliding Scale (see below) is used by physicians to evaluate individuals being considered for breast reduction surgery.

Body surface area, along with average weight of breast tissue removed is incorporated into the chart. If the individual's body surface area and weight of breast tissue removed fall below the 22nd percentile, then the surgery is not medically necessary. If the individual's body surface area and weight of breast tissue removed is above the 22nd percentile, then the surgery is considered medically necessary if other applicable criteria are met.

*Calculation of Body Surface Area

Body surface area = the square root of height (cm) times weight (kg) divided by 3600.

To convert pounds to kilograms, multiply pounds by 0.45.
To convert inches to meters, multiply inches by .0254.

To calculate body surface area (BSA) see: <http://www-users.med.cornell.edu/~spon/picu/calc/bsacalc.htm>

**Schnur Sliding Scale (11)**

<table>
<thead>
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<th>Body Surface Area (in meters squared)*</th>
<th>Lower 22nd percentile (Grams to be removed per breast)</th>
</tr>
</thead>
<tbody>
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<td>1.35</td>
<td>199</td>
</tr>
<tr>
<td>1.40</td>
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</table>
### Exclusions:
Breast reduction is not covered for either of the following indications because it is considered cosmetic in nature and not medically necessary:
- Surgery is being performed to treat psychological symptomatology or psychosocial complaints, in the absence of significant physical, objective signs.
- Surgery is being performed for the sole purpose of improving appearance.

### CPT/HCPCS Level II Codes
(Note: The inclusion of a code in this list is not a guarantee of coverage. Please refer to the medical policy statement to determine the status of a given procedure)

**Established codes:**
- 19318

**Other codes (investigational, not medically necessary, etc.):**
- N/A
Rationale

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 (RCT) is preferred to assess efficacy; however, in some circumstances, nonrandomized studies may be adequate. RCTs 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

In 2008, Sabino Neto et al assessed functional capacity for 100 patients, ages 18 to 55 years, who 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) 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 VAS from an average of 5.7 preoperatively to 1.3 postoperatively (p<0.001 for pre-post comparison within the mammaplasty group) vs 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 +0.06, 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 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 the control group.

**Observational Studies**

Singh and Losken (2012) reported on a systematic review of studies reporting outcomes after reduction mammaplasty. 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 mammaplasty 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 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 mammaplasty 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 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 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).

**Adverse Events**

Thibaudeau et al (2010), conducted a systematic review to evaluate breastfeeding after reduction mammaplasty. After a review of literature from 1950 through 2008, reviewers concluded that reduction mammaplasty does not reduce the ability to breastfeed. In women
who have had reduction mammaplasty, 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. 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 increased incidences of perioperative and postoperative complications with high BMI.

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 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 (ASPS) has issued practice guidelines and a companion document on criteria for third-party payers for reduction mammaplasty. ASPS 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.” 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
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.

Government Regulations
National:
There is no national coverage determination (NCD). In the absence of an NCD, coverage decisions are left to the discretion of the local Medicare carriers.

Local:
WPS L34698 – Cosmetic and Reconstructive Surgery, original effective date 10/1/15, revision effective date 1/1/18.

Reduction Mammoplasty is the surgical reshaping of the breasts to reduce or lift enlarged or sagging breasts. Cosmetic surgery to reshape the breasts to improve appearance is not a Medicare benefit.

Macromastia (breast hypertrophy) is an increase in the volume and weight of breast tissue relative to the general body habitus. Breast hypertrophy may adversely affect other body systems: musculoskeletal, respiratory, and integumentary. Unilateral hypertrophy may result in symptoms following contralateral mastectomy.

Medical necessity for a reduction mammoplasty is limited to circumstances in which:
- There are signs and/or symptoms resulting from the enlarged breasts (macromastia) that have not responded adequately to non-surgical interventions, and
- To reduce the size of a normal breast to bring it into symmetry with a breast reconstructed after cancer surgery.

Non-surgical interventions preceding reduction mammoplasty should include as appropriate, but are not limited to, the following:
- Determining the macromastia is not due to an active endocrine or metabolic process
- Determining the symptoms are refractory to appropriately fitted supporting garments, or following unilateral mastectomy, persistent with an appropriately fitted prosthesis or reconstruction therapy at the site of the absent breast.
- Determining that dermatologic signs and/or symptoms are refractory to, or recurrent following, a completed

A medically reasonable and necessary reduction mammoplasty could be indicated in the presence of significantly enlarged breasts and the presence of at least one of the following signs and/or symptoms:

A. Back or neck or shoulder pain from macromastia and unrelieved by 6 months of:
   1. Conservative analgesia,
   2. Supportive measures (garment, etc.),
   3. Physical Therapy,
B. Significant arthritic changes in the cervical or upper thoracic spine, optimally managed with persistent symptoms and/or significant restriction of activity, or
C. Intertriginous maceration or infection of the inframammary skin refractory to dermatologic measures.  
D. Permanent shoulder grooving with skin irritation by supporting garment (bra strap).

The amount of breast tissue to be removed must be proportional to the body surface area (BSA) per the Schnur scale below. If only one breast meets the Schnur scale criteria; breast tissue may be removed from the other breast in order to achieve symmetry.

**Schnur Scale:**

<table>
<thead>
<tr>
<th>Body Surface Area (m²)</th>
<th>Average grams of tissue per breast to be removed</th>
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<tbody>
<tr>
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**Michigan Department of Health and Human Services:**  
CPT code 19318 has a facility fee assigned on the Practitioner and Medical Clinic Fee Schedule.  

(The above Medicare information is current as of the review date for this policy. However, the coverage issues and policies maintained by the Centers for Medicare & Medicare Services [CMS, formerly HCFA] are updated and/or revised periodically. Therefore, the most current CMS information may not be contained in this document. For the most current information, the reader should contact an official Medicare source.)

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**Related Policies**

- Reconstructive Breast Surgery/Management of Breast Implants  
- Prophylactic Mastectomy (Retired)

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**References**


23. Wisconsin Physicians Service Insurance Corporation, Local Coverage Determination (LCD): Cosmetic and Reconstructive Surgery (L34698), Original Effective Date 10/1/15, Revision Effective Date 1/1/17.

The articles reviewed in this research include those obtained in an Internet based literature search for relevant medical references through 2/8/18, the date the research was completed.
## Joint BCBSM/BCN Medical Policy History

<table>
<thead>
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<th>BCBSM Signature Date</th>
<th>BCN Signature Date</th>
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Next Review Date: 2nd Qtr, 2019
BLUE CARE NETWORK BENEFIT COVERAGE
POLICY: REDUCTION MAMMAPLASTY FOR BREAST-RELATED SYMPTOMS

Coverage Determination:

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<td>BCN65 (Medicare Complementary)</td>
<td>Coinsurance covered if primary Medicare covers the service.</td>
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Administrative Guidelines:

- The member's contract must be active at the time the service is rendered.
- Coverage is based on each member’s certificate and is not guaranteed. Please consult the individual member’s certificate for details. Additional information regarding coverage or benefits may also be obtained through customer or provider inquiry services at BCN.
- The service must be authorized by the member's PCP except for Self-Referral Option (SRO) members seeking Tier 2 coverage.
- Services must be performed by a BCN-contracted provider, if available, except for Self-Referral Option (SRO) members seeking Tier 2 coverage.
- Payment is based on BCN payment rules, individual certificate and certificate riders.
- Appropriate copayments will apply. Refer to certificate and applicable riders for detailed information.
- CPT - HCPCS codes are used for descriptive purposes only and are not a guarantee of coverage.