I. POLICY

Reduction mammoplasty 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 nonsteroidal anti-inflammatory agents/muscle relaxants; OR
- Recurrent or chronic intertrigo between the pendulous breast and the chest wall

*Photographic documentation required for both indications

Reduction mammoplasty is considered investigational for all other indications not meeting the above criteria as there is insufficient evidence to support a conclusion concerning the health outcomes or benefits associated with this procedure.

Reduction mammoplasty is considered a reconstructive procedure and medically necessary when performed on the unaffected breast following previous radical surgery for disease when the purpose is to provide symmetry with the breast on which the mastectomy has been performed. (Act 51 of 1997).

Cross-reference:
MP-1.103 Reconstructive Breast Surgery/Management of Breast Implants
MP-1.129 Surgical Treatment of Gynecomastia
MP-1.036 Prophylactic Mastectomy and Prophylactic Bilateral Oophorectomy
MP-1.004 Cosmetic and Reconstructive Surgery
II. PRODUCT VARIATIONS

This policy is applicable to all programs and products administered by Capital BlueCross unless otherwise indicated below.

BlueJourney HMO*       BlueJourney PPO*       FEP PPO**

* Refer to Novitas Solutions Local Coverage Determination (LCD) L35090 Cosmetic and Reconstructive Surgery.
** Refer to FEP Medical Policy Manual MP-7.01.21 Reduction Mammoplasty for Breast Related Symptoms. The FEP Medical Policy manual can be found at: www.fepblue.org

III. DESCRIPTION/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 mammoplasty 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.

IV. RATIONALE

The most recent literature review was performed for the period of January 2016 through December 20, 2016. The following is a summary of the key findings to date.

EFFICACY IN REDUCING SYMPTOMS

Randomized Controlled Trials
In 2008, Sabino Neto et al assessed functional capacity in which 100 patients, ages 18 to 55 years, were randomized to reduction mammoplasty 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 mammoplasty 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 mammoplasty 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 decreased on the VAS from an average of 5.7 preoperatively to 1.3 postoperatively (p<0.001 for pre-post comparison within the mammoplasty group) versus 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 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 receive reduction mammoplasty 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 mammoplasty group compared with the control group.

Beraldo et al (2016) reported on a trial of 60 patients randomized to reduction mammoplasty or to no surgery.12 Trial outcomes were sexual function and depressive symptoms. At 6 months, Female Sexual Function Index scores were higher in the reduction mammoplasty group (27.5 vs 22.5, p<0.001). Level of depression, as measured by the Beck Depression Inventory, was lower in the reduction mammoplasty group (7.2 vs 13.7, p=0.01). Analyses using categories of sexual function or depression showed similar results.

**Observational Studies**

Singh and Losken (2012) reported on a systematic review of studies reporting outcomes after reduction mammoplasty.13 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.

In 2016, Hernanz et al 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.14 In the preoperative state, SF-
36 physical health component subscore was significantly lower for patients with symptomatic macromastia (40) than for agematched controls (53; p<0.001), with differences in 5 of the 8 subscales. At 18 months postprocedure, there was no significant difference in any SF-36 subscores except the body pain subscale between patients who had undergone reduction mammoplasty 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 mammoplasty. 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 (e.g., weight of excised breast tissue).

Section Summary: Efficacy in Reducing Symptoms
Systematic reviews, randomized trials, and observational studies have shown that several measures of function and QOL improve after reduction mammoplasty.

COMPLICATIONS
Thibaudeau et al (2010) conducted a systematic review to evaluate breastfeeding after reduction mammoplasty. After a review of literature from 1950 through December 2008, reviewers concluded that reduction mammoplasty does not reduce the ability to breastfeed. In women who had reduction mammoplasty, 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 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 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 experienced more wound healing problems (OR=1.6; p=0.09) and reoperative wound debridement (OR=5.1; p=0.07). Other retrospective evaluations (2013, 2014) of large population datasets have reported an increased incidence of perioperative and postoperative complications with high BMI. 19,20

**SUMMARY OF EVIDENCE**
For individuals who have symptomatic macromastia who receive reduction mammaplasty, the evidence includes systematic reviews, randomized controlled trials, and case series. Relevant outcomes are symptoms and functional outcomes. These 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.

**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. 21-23 ASPS found 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.

**MEDICARE NATIONAL COVERAGE**
There is no national coverage determination (NCD). In the absence of an NCD, coverage decisions are left to the discretion of local Medicare carriers.

**ONGOING AND UNPUBLISHED CLINICAL TRIALS**
A search of ClinicalTrials.gov in January 2017 did not identify any ongoing or unpublished trials that would likely influence this review.
V. DEFINITIONS

ACT 51 OF 1997 –THE MASTECTOMY ACT: PA mandate that prohibits health insurance companies from requiring mastectomies to be performed on an outpatient basis. Other requirements include coverage for: One home health visit within 48 hours after discharge when the discharge is within 48 hours of the admission for the mastectomy; Reconstructive surgery, including surgery to re-establish symmetry and mastectomy –related prosthetic devices.

COSMETIC SURGERY: An elective procedure performed primarily to change a person’s appearance by surgically altering a physical characteristic that does not prohibit normal function, but is considered unpleasant or unsightly.

INTERTRIGO: A superficial dermatitis occurring on apposed skin surfaces, such as the axillae, creases of the neck, intergluteal fold, groin, between the toes and beneath pendulous breasts, with obesity being a predisposing factor, caused by moisture, friction, warmth and sweat retention and characterized by erythema, maceration, burning, itching and sometimes erosions, fissures and exudations and secondary infections.

RECONSTRUCTIVE SURGERY: A procedure performed to improve or correct a functional impairment, restore a bodily function or correct a deformity resulting from birth defect or accidental injury. The fact that a member might suffer psychological consequences from a deformity does not, in the absence of bodily functional impairment, qualify surgery as being reconstructive surgery.

VI. BENEFIT VARIATIONS

The existence of this medical policy does not mean that this service is a covered benefit under the member’s contract. Benefit determinations should be based in all cases on the applicable contract language. Medical policies do not constitute a description of benefits. A member’s individual or group customer benefits govern which services are covered, which are excluded, and which are subject to benefit limits and which require preauthorization. Members and providers should consult the member’s benefit information or contact Capital for benefit information.

VII. DISCLAIMER

Capital’s medical policies are developed to assist in administering a member’s benefits, do not constitute medical advice and are subject to change. Treating providers are solely responsible for medical advice and treatment of members. Members should discuss any medical policy related to their coverage or condition with their provider and consult their benefit information to determine if the service is covered. If there is a discrepancy between this
MEDICAL POLICY

<table>
<thead>
<tr>
<th>POLICY TITLE</th>
<th>REDUCTION MAMMOPLASTY FOR BREAST-RELATED SYMPTOMS</th>
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<tbody>
<tr>
<td>POLICY NUMBER</td>
<td>MP-1.013</td>
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*Note:* This list of codes may not be all-inclusive, and codes are subject to change at any time. The identification of a code in this section does not denote coverage as coverage is determined by the terms of member benefit information. In addition, not all covered services are eligible for separate reimbursement.

Covered when medically necessary:

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<th>CPT Codes®</th>
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ICD-10-CM Diagnosis Codes

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<tr>
<td>L30.4</td>
<td>Erythema intertrigo</td>
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<tr>
<td>N65.1</td>
<td>Disproportion of reconstructed breast</td>
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*If applicable, please see Medicare LCD or NCD for additional covered diagnoses.

IX. REFERENCES


Other sources:


X. POLICY HISTORY

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<td></td>
<td>CAC 7/26/11 Adopted BCBSA criteria regarding documentation of shoulder, neck or back pain and intertrigo. Revised policy criteria regarding photographs and</td>
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**Policy Title** | **Reduction Mammaplasty for Breast-Related Symptoms**
--- | ---
**Policy Number** | MP-1.013

- Estimated amount of tissue to be removed according to selected BCBSA policy guidelines. Removed all information regarding gynecomastia and created a separate policy.

**CAC 8/28/12** Policy statement changed to indicate intertrigo must be recurrent or chronic. To remain as consensus review. References updated. Added FEP variation to reference MP-7.01.21 Reduction Mammaplasty Codes reviewed 8/21/12

**CAC 6/4/2013** Minor. Added statement indicating reduction mammaplasty in order to reduce the contralateral breast (for symmetry purposes) is considered medically necessary for congenital anomalies (e.g., Poland's syndrome, breast hypoplasia or absence) when specific criteria are met.

**CAC 3/25/14** Consensus. No change to policy statements. References reviewed. Rationale section added.

**CAC 6/2/15** Minor revision. BCBSA policy adopted. Background, references and rationale updated. Title changed to “Reduction Mammaplasty for Breast-Related Symptoms”. Coding reviewed.

**Admin posting 9/28/15.** Schnur scale revised in definition section.

**12/31/15** Administrative Change. Added Medicare variation to reference LCD L35090 Cosmetic and Reconstructive Surgery

**Admin posting 1/26/16** Policy revised for clarification to note that photographs are required for both medical necessity indications. Policy guidelines removed as they addressed a variety of selection criteria that could be utilized, not just photographs.

**CAC 5/31/16** Consensus review. No changes to the policy statements. References and rationale updated. Coding reviewed.

**Admin update 1/1/17:** Product variation section reformatted.

**CAC 5/23/17** Consensus review. No changes to the policy statements. References and rationale updated. Coding reviewed.

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