

<b>7.01.21</b>		<b>Reduction Mammoplasty for Breast-Related Symptoms</b>	
<b>Original Policy Date:</b>	December 4, 2015	<b>Effective Date:</b>	April 1, 2024
<b>Section:</b>	7.0 Surgery	<b>Page:</b>	Page 1 of 14

**Policy Statement**

In interpreting whether a proposed procedure meets the definition of reconstructive surgery, as defined by law, the procedure may be denied as **not medically necessary** under **any** of the following conditions:

- 1) The procedure is likely to result in only minimal improvement in appearance, in accordance with the standard of care as practiced by providers specializing in reconstructive surgery
  - 2) The treating surgeon cannot or will not provide sufficient documentation, including (when appropriate) medical quality color photographs, which accurately depicts the extent of the clinical problem (see [Policy Guidelines](#) and [Documentation for Clinical Review](#) sections)
  - 3) There is alternative approved medical or surgical intervention with equal or superior clinical outcomes
  - 4) The procedure is for [cosmetic](#) purposes only
- I. Reduction mammoplasty may be considered **medically necessary** for the treatment of macromastia when well-documented clinical symptoms are present, including but not limited to **either** of the following:
    - A. 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
    - B. Recurrent or chronic intertrigo between the pendulous breast and the chest wall
  - II. Reduction mammoplasty is considered **investigational** for all other indications not meeting the above criteria.

**NOTE:** Refer to [Appendix A](#) to see the policy statement changes (if any) from the previous version.

**Policy Guidelines**

The presence of shoulder, neck, or back pain is the most common stated *medical* rationale for reduction mammoplasty. However, because these symptoms and others may be subjective, Plans have implemented various selection criteria designed to be more objective. These criteria 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 individual'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 individual must be within 20% of ideal body weight to eliminate the possibility that obesity is contributing to the symptoms of neck or back pain.

**Note:** Quality color photographs or imaging reports showing the extent of the problem should be included with the medical records sent to support medical necessity.

For the purpose of this policy, the qualified reviewer will differentiate a normal structure from an abnormal one based on **any** of the following elements:

- The availability of published normative data for specific anatomic measurements (e.g., cephalometric data for orthognathic surgery)
- The normal structures wide range of accepted variations in diverse populations (e.g., nasal size and shape)
- The presence of a cosmetic implant, in the absence of adjacent native tissue structural pathology, does not constitute an abnormal structure (e.g., cosmetic unilateral, bilateral or asymmetrical saline breast implants)

In determining whether or not a procedure is likely to result in more than minimal improvement in appearance, the qualified reviewer will consider both the size and location of the structural abnormality.

“Cosmetic surgery” means surgery that is performed to alter or reshape normal structures of the body in order to improve appearance. Under existing California statutes, medically necessary services to treat complications from a non-covered service (e.g., cosmetic surgery) are a covered benefit as addressed below.

### Coding

The following CPT code is specific for this procedure:

- **19318**: Breast reduction

### Description

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 mammoplasty 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.

### Related Policies

- N/A

### Benefit Application

Benefit determinations should be based in all cases on the applicable contract language. To the extent there are any conflicts between these guidelines and the contract language, the contract language will control. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

Some state or federal mandates (e.g., Federal Employee Program [FEP]) prohibits plans from denying Food and Drug Administration (FDA)-approved technologies as investigational. In these instances, plans may have to consider the coverage eligibility of FDA-approved technologies on the basis of medical necessity alone.

### Regulatory Status

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

**State:**

The California Reconstructive Surgery Act (Health & Safety Code Section 1367.63 and the Insurance Code Section 10123.88) defines "reconstructive surgery" as surgery performed to correct or repair abnormal structures of the body caused by congenital defects, developmental abnormalities, trauma, infection, tumors, or disease to do **either** of the following (see also Blue Shield of California Medical Policy: Reconstructive Services):

- 1) Create a normal appearance to the extent possible
- 2) Improve function

**Rationale****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 mammoplasty 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 mammoplasty and have documented that reduction mammoplasty is associated with relief of physical and psychosocial symptoms,<sup>1-9</sup> an important issue is whether reduction mammoplasty 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 mammoplasty are not well-addressed in the published medical literature.

Some protocols on the medical necessity of reduction mammoplasty 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.<sup>10</sup> 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 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.

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.<sup>11</sup> 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 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.

### **Literature Review**

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 1 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. 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.

Promotion of greater diversity and inclusion in clinical research of historically marginalized groups (e.g., People of Color [African-American, Asian, Black, Latino and Native American]; LGBTQIA (Lesbian, Gay, Bisexual, Transgender, Queer, Intersex, Asexual); Women; and People with Disabilities [Physical and Invisible]) allows policy populations to be more reflective of and findings more applicable to our diverse members. While we also strive to use inclusive language related to these groups in our policies, use of gender-specific nouns (e.g., women, men, sisters, etc.) will continue when reflective of language used in publications describing study populations.

### **Reduction Mammoplasty for Macromastia-Efficacy in Reducing Symptoms**

#### **Clinical Context and Therapy Purpose**

The purpose of reduction mammoplasty is to provide a treatment option that is an alternative to or an improvement on existing therapies, such as nonsurgical treatment, in individuals with symptomatic macromastia.

The following PICO was used to select literature to inform this review.

#### ***Populations***

The relevant population of interest is individuals with symptomatic macromastia, or gigantomastia, a condition that describes breast hyperplasia or hypertrophy.

#### ***Interventions***

The therapy being considered is reduction mammoplasty, a surgical procedure that removes a variable proportion of breast tissue to relieve the associated clinical symptoms and address emotional and psychosocial issues related to large breast size.

#### ***Comparators***

Comparators of interest include nonsurgical treatment which primarily involves analgesia, clothing modifications, physical therapy and other measures to address symptoms.

### **Outcomes**

The general outcomes of interest are symptoms and functional outcomes. Symptoms of symptomatic macromastia can include mastalgia, pain in the shoulders, back, and neck, or recurrent intertrigo in the mammary fold. The condition may also be associated with psychosocial or emotional disturbances.

### **Study Selection Criteria**

Methodologically credible studies were selected using the following principles:

- To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs;
- In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.
- To assess longer term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.
- Studies with duplicative or overlapping populations were excluded.

### **Review of Evidence**

#### **Randomized Controlled Trials**

Sabino Neto et al (2008) assessed functional capacity for 100 patients, ages 18 to 55 years, who were randomized to reduction mammoplasty or to waiting list control.<sup>7</sup> 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 mammoplasty group showed improvement in functional status, with an average score of 5.9 preoperatively and 1.2 within 6 months postoperatively ( $p<.001$  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 visual analog scale from an average of 5.7 preoperatively to 1.3 postoperatively ( $p<.001$  for pre-post comparison within the mammoplasty group) versus visual analog scale average scores in the control group of 6.0 and 5.3 on the first and second evaluations, respectively ( $p$ =not significant).

Saariniemi et al (2008) reported on the quality of life and pain in 82 patients randomized to reduction mammoplasty or a nonoperative group and evaluated at baseline and 6 months later.<sup>9</sup> The authors reported that the mammoplasty group had significant improvements in quality of life 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,  $p<.001$ ), the Utility Index score (SF-6D; change, +17.5 vs +0.6), the index score of quality of life (SF-15D; change, +8.6 vs +0.06,  $p<.001$ ), and SF-36 Mental Component Summary score (change, +7.8 vs -1.0,  $p<.002$ ). 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,  $p<.001$ ), and Finnish Pain Questionnaire scores (-21.5 vs -1.0,  $p<.001$ ).

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.<sup>8</sup> 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.

Key trials are reported in Tables 1 and 2 below.

**Table 1. Summary of Key Randomized Controlled Trial Characteristics**

Study; Trial	Countries	Sites	Dates	Participants	Interventions	
					Active	Comparator
Sabino Neto (2008) <sup>7</sup>	Brazil	1	2002-2004	Female patients (age 18 to 55 yrs) with breast hypertrophy (n=100)	Reduction mammoplasty (n=50)	Waiting list control (n=50)
Saariniemi (2008) <sup>9</sup>	Finland	1	NR	Female patients with symptomatic breast hypertrophy (n=82)	Reduction mammoplasty (n=40)	Non-operative control (n=42)

NR: not reported.

**Table 2. Summary of Key Randomized Controlled Trial Results**

Study	Change (Pre- to Postoperative) in RSES	Change (Pre- to Postoperative) in RMDQ	Change (Pre- to Postoperative) in VAS	Change (Pre- to Postoperative) in SF-36 Utility Index Score	Change (Pre- to Postoperative) in Mental Summary Score	Change (Pre- to Postoperative) in Pain Score
<b>Sabino Neto (2008)<sup>7</sup></b>						
Mammoplasty	8.9 to 4.9 (p<.001)	5.9 to 1.2 (p<.001)	5.7 to 1.3 (p<.001)			
Control	9.1 to 9.0 (p>.999)	6.2 to 6.2 (NR)	6.0 to 5.3 (p<.001)			
<b>Saariniemi (2008)<sup>9</sup></b>						
Mammoplasty				0.645 to 0.820	46.0 to 53.8	28.5 to 7.0
Control				0.657 to 0.663	47.2 to 46.2	27.5 to 26.5
<b>P-value</b>				<.001	<.002	<.001

NR: not reported; RSES: Rosenberg Self-Esteem Scale; RMDQ: Roland-Morris Disability Questionnaire; SF-36: 36-Item Short-Form Health Survey; VAS: visual analog scale.

The purpose of the gaps tables (Table 3 and 4) is to display notable gaps identified in each study. This information is synthesized as a summary of the body of evidence following each table and provides the conclusions on the sufficiency of evidence supporting the position statement.

**Table 3. Study Relevance Limitations**

Study	Population <sup>a</sup>	Intervention <sup>b</sup>	Comparator <sup>c</sup>	Outcomes <sup>d</sup>	Duration of Follow-up <sup>e</sup>
Sabino Neto (2008) <sup>7</sup>			3. Comparator group on waiting list without additional intervention described	5. Clinical significant difference not prespecified	
Saariniemi (2008) <sup>9</sup>			3. Comparator group did not receive surgery and had no other intervention described	5. Clinical significant difference not prespecified	

The study limitations stated in this table are those notable in the current review; this is not a comprehensive gaps assessment.

<sup>a</sup> Population key: 1. Intended use population unclear; 2. Clinical context is unclear; 3. Study population is unclear; 4. Study population not representative of intended use.

<sup>b</sup> Intervention key: 1. Not clearly defined; 2. Version used unclear; 3. Delivery not similar intensity as comparator; 4. Not the intervention of interest.

<sup>c</sup> Comparator key: 1. Not clearly defined; 2. Not standard or optimal; 3. Delivery not similar intensity as

intervention; 4. Not delivered effectively.

<sup>d</sup> Outcomes key: 1. Key health outcomes not addressed; 2. Physiologic measures, not validated surrogates; 3. No CONSORT reporting of harms; 4. Not established and validated measurements; 5. Clinical significant difference not prespecified; 6. Clinical significant difference not supported.

<sup>e</sup> Follow-Up key: 1. Not sufficient duration for benefit; 2. Not sufficient duration for harms.

**Table 4. Study Design and Conduct Limitations**

Study	Allocation <sup>a</sup>	Blinding <sup>b</sup>	Selective Reporting <sup>c</sup>	Follow-Up <sup>d</sup>	Power <sup>e</sup>	Statistical <sup>f</sup>
Sabino Neto (2008) <sup>7</sup>		1,2,3. No blinding				3. Some p-values not reported
Saariniemi (2008) <sup>9</sup>		1,2,3. No blinding		1. 22% of patients lost to follow-up		

The study limitations stated in this table are those notable in the current review; this is not a comprehensive gaps assessment.

<sup>a</sup> Allocation key: 1. Participants not randomly allocated; 2. Allocation not concealed; 3. Allocation concealment unclear; 4. Inadequate control for selection bias.

<sup>b</sup> Blinding key: 1. Not blinded to treatment assignment; 2. Not blinded outcome assessment; 3. Outcome assessed by treating physician.

<sup>c</sup> Selective Reporting key: 1. Not registered; 2. Evidence of selective reporting; 3. Evidence of selective publication.

<sup>d</sup> Follow-Up key: 1. High loss to follow-up or missing data; 2. Inadequate handling of missing data; 3. High number of crossovers; 4. Inadequate handling of crossovers; 5. Inappropriate exclusions; 6. Not intent to treat analysis (per protocol for noninferiority trials).

<sup>e</sup> Power key: 1. Power calculations not reported; 2. Power not calculated for primary outcome; 3. Power not based on clinically important difference.

<sup>f</sup> Statistical key: 1. Intervention is not appropriate for outcome type: (a) continuous; (b) binary; (c) time to event; 2. Intervention is not appropriate for multiple observations per patient; 3. Confidence intervals and/or p values not reported; 4. Comparative treatment effects not calculated.

### Observational Studies

Singh and Losken (2012) reported on a systematic review of studies reporting outcomes after reduction mammoplasty.<sup>12</sup> In 7 studies reporting on physical symptoms (n range, 11 to 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 quality of life. Torresetti et al (2022) conducted another systematic review to examine the potential association between bilateral breast reduction and improvement in lung function in women with macromastia.<sup>13</sup> The review included 15 studies published from 1974 to 2018 (n range, 1 to 50 patients). The findings showed that reduction mammoplasty can lead to changes in objective respiratory parameters, such as spirometric tests or arterial blood gas measurements, but the clinical significance of these changes was unclear.

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.<sup>14</sup> 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;  $p < .001$ ), 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.<sup>15</sup> Women were asked to complete quality of life 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 mammoplasty.<sup>16</sup> After a review of literature from 1950 through 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.

Chen et al. (2011) reported on a review of claims data to compare complication rates after breast surgery in 2,403 obese and 5,597 nonobese patients.<sup>17</sup> 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%;  $p < .001$ ). 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.<sup>18</sup> Infection occurred more frequently in patients older than 50 years of age (odds ratio, 2.7;  $p = .003$ ). Additionally, women older than 50 years experienced more wound healing problems (odds ratio, 1.6;  $p = .09$ ) and reoperative wound debridement (odds ratio, 5.1;  $p = .07$ ). Other retrospective evaluations (2013, 2014) of large population datasets have reported increased incidences of perioperative and postoperative complications with high body mass index.<sup>19,20</sup>

### Section Summary: Reduction Mammoplasty for Macromastia-Efficacy in Reducing Symptoms

Systematic reviews, randomized trials, and observational studies have shown that several measures of function and quality of life improve after reduction mammoplasty.

### Supplemental Information

The purpose of the following information is to provide reference material. Inclusion does not imply endorsement or alignment with the evidence review conclusions.

### Practice Guidelines and Position Statements

Guidelines or position statements will be considered for inclusion in 'Supplemental Information if they were issued by, or jointly by, a US professional society, an international society with US representation, or National Institute for Health and Care Excellence (NICE). Priority will be given to guidelines that are informed by a systematic review, include strength of evidence ratings, and include a description of management of conflict of interest.

### American Society of Plastic Surgeons

In 2011, the American Society of Plastic Surgeons (ASPS) issued practice guidelines and a companion document on criteria for third-party payers for reduction mammoplasty.<sup>21,22</sup> This guideline was updated and reaffirmed in March 2021. Based on high quality evidence, the ASPS strongly recommends that "postmenarche female patients presenting with breast hypertrophy should be offered reduction mammoplasty surgery as first-line therapy over nonoperative therapy based solely on the presence of multiple symptoms rather than resection weight." The guideline goes on to state



that "reduction mammoplasty surgery is considered standard of care for symptomatic breast hypertrophy." The companion document notes that medical records should document the symptoms associated with the hypertrophy the patient has experienced, and lists the following:

- "Documentation may include pain that patient experiences in the neck, back, or breasts related to movement
- Difficulties in daily activities such as grocery shopping, banking, using transportation, preparing meals, feeding, showering, etc.
- Documentation of any secondary complications or infections that may have occurred as a result of hypertrophy or macromastia including intertrigo, chronic rash, cervicalgia, dorsalgia, or kyphosis
- Documentation of prior procedures or therapies may be included but not required for approval
- Photographs demonstrating the patient's breast appearance, possible shoulder grooves and kyphosis can be included in the medical documentation
- Significant scientific evidence supports non-operative therapies should not be required prior to approval of the procedure."

### 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 December 2023 did not identify any ongoing or unpublished trials that would likely influence this review.

## References

1. Dabbah A, Lehman JA, Parker MG, et al. Reduction mammoplasty: an outcome analysis. *Ann Plast Surg.* Oct 1995; 35(4): 337-41. PMID 8585673
2. Schnur PL, Schnur DP, Petty PM, et al. Reduction mammoplasty: an outcome study. *Plast Reconstr Surg.* Sep 1997; 100(4): 875-83. PMID 9290655
3. Hidalgo DA, Elliot LF, Palumbo S, et al. Current trends in breast reduction. *Plast Reconstr Surg.* Sep 1999; 104(3): 806-15; quiz 816; discussion 817-8. PMID 10456536
4. Glatt BS, Sarwer DB, O'Hara DE, et al. A retrospective study of changes in physical symptoms and body image after reduction mammoplasty. *Plast Reconstr Surg.* Jan 1999; 103(1): 76-82; discussion 83-5. PMID 9915166
5. Collins ED, Kerrigan CL, Kim M, et al. The effectiveness of surgical and nonsurgical interventions in relieving the symptoms of macromastia. *Plast Reconstr Surg.* Apr 15 2002; 109(5): 1556-66. PMID 11932597
6. Iwuagwu OC, Walker LG, Stanley PW, et al. Randomized clinical trial examining psychosocial and quality of life benefits of bilateral breast reduction surgery. *Br J Surg.* Mar 2006; 93(3): 291-4. PMID 16363021
7. Sabino Neto M, Demattê MF, Freire M, et al. Self-esteem and functional capacity outcomes following reduction mammoplasty. *Aesthet Surg J.* 2008; 28(4): 417-20. PMID 19083555
8. Iwuagwu OC, Platt AJ, Stanley PW, et al. Does reduction mammoplasty improve lung function test in women with macromastia? Results of a randomized controlled trial. *Plast Reconstr Surg.* Jul 2006; 118(1): 1-6; discussion 7. PMID 16816661
9. Saariniemi KM, Keranen UH, Salminen-Peltola PK, et al. Reduction mammoplasty is effective treatment according to two quality of life instruments. A prospective randomised clinical trial. *J Plast Reconstr Aesthet Surg.* Dec 2008; 61(12): 1472-8. PMID 17983882

10. Schnur PL, Hoehn JG, Ilstrup DM, et al. Reduction mammoplasty: cosmetic or reconstructive procedure?. *Ann Plast Surg.* Sep 1991; 27(3): 232-7. PMID 1952749
11. Schnur PL. Reduction mammoplasty-the schnur sliding scale revisited. *Ann Plast Surg.* Jan 1999; 42(1): 107-8. PMID 9972729
12. Singh KA, Losken A. Additional benefits of reduction mammoplasty: a systematic review of the literature. *Plast Reconstr Surg.* Mar 2012; 129(3): 562-570. PMID 22090252
13. Torresetti M, Zuccatosta L, Di Benedetto G. The effects of breast reduction on pulmonary functions: A systematic review. *J Plast Reconstr Aesthet Surg.* Dec 2022; 75(12): 4335-4346. PMID 36229312
14. Hernanz F, Fidalgo M, Muñoz P, et al. Impact of reduction mammoplasty on the quality of life of obese patients suffering from symptomatic macromastia: A descriptive cohort study. *J Plast Reconstr Aesthet Surg.* Aug 2016; 69(8): e168-73. PMID 27344408
15. Kerrigan CL, Collins ED, Kim HM, et al. Reduction mammoplasty: defining medical necessity. *Med Decis Making.* 2002; 22(3): 208-17. PMID 12058778
16. Thibaudeau S, Sinno H, Williams B. The effects of breast reduction on successful breastfeeding: a systematic review. *J Plast Reconstr Aesthet Surg.* Oct 2010; 63(10): 1688-93. PMID 19692299
17. Chen CL, Shore AD, Johns R, et al. The impact of obesity on breast surgery complications. *Plast Reconstr Surg.* Nov 2011; 128(5): 395e-402e. PMID 21666541
18. Shermak MA, Chang D, Buretta K, et al. Increasing age impairs outcomes in breast reduction surgery. *Plast Reconstr Surg.* Dec 2011; 128(6): 1182-1187. PMID 22094737
19. Gust MJ, Smetona JT, Persing JS, et al. The impact of body mass index on reduction mammoplasty: a multicenter analysis of 2492 patients. *Aesthet Surg J.* Nov 01 2013; 33(8): 1140-7. PMID 24214951
20. Nelson JA, Fischer JP, Chung CU, et al. Obesity and early complications following reduction mammoplasty: an analysis of 4545 patients from the 2005-2011 NSQIP datasets. *J Plast Surg Hand Surg.* Oct 2014; 48(5): 334-9. PMID 24506446
21. American Society of Plastic Surgeons. Reduction Mammoplasty: ASPS Recommended Insurance Coverage Criteria for Third-Party Payers. 2021; <https://www.plasticsurgery.org/documents/Health-Policy/Reimbursement/insurance-2021-reduction-mammoplasty.pdf>. Accessed December 20, 2023.
22. Perdakis G, Dillingham C, Boukovalas S, et al. American Society of Plastic Surgeons Evidence-Based Clinical Practice Guideline Revision: Reduction Mammoplasty. *Plast Reconstr Surg.* Mar 01 2022; 149(3): 392e-409e. PMID 35006204

## Documentation for Clinical Review

### Please provide the following documentation:

- **History and physical and/or consultation notes including:**
  - Pain or other symptoms and duration if applicable
  - Documented intertrigo and duration, if applicable
  - Conservative treatment(s) duration and response
  - BMI
- Quality photographs showing the extent of the issue to be addressed if applicable
- Amount of breast tissue planned for removal if applicable

### Post Service

- Procedure report

## Coding

*This Policy relates only to the services or supplies described herein. Benefits may vary according to product design; therefore, contract language should be reviewed before applying the terms of the Policy.*

*The following codes are included below for informational purposes. Inclusion or exclusion of a code(s) does not constitute or imply member coverage or provider reimbursement policy. Policy Statements are intended to provide member coverage information and may include the use of some codes for clarity. The Policy Guidelines section may also provide additional information for how to interpret the Policy Statements and to provide coding guidance in some cases.*

Type	Code	Description
CPT®	19318	Breast reduction
HCPCS	None	

## Policy History

This section provides a chronological history of the activities, updates and changes that have occurred with this Medical Policy.

Effective Date	Action
12/04/2015	BCBSA Medical Policy adoption
04/01/2016	Policy revision without position change
04/01/2017	Policy revision without position change
04/01/2018	Policy revision without position change
04/01/2019	Policy revision without position change
05/01/2020	Annual review. No change to policy statement. Literature review updated. Policy title changed from Reduction Mammoplasty for Breast-Related Symptoms to current one.
01/01/2021	Coding update
04/01/2021	Annual review. No change to policy statement. Literature review updated.
10/01/2021	Policy statement clarification.
04/01/2022	Annual review. No change to policy statement. Policy guidelines and literature review updated.
03/01/2023	Administrative update.
04/01/2023	Annual review. No change to policy statement. Literature review updated. Policy title changed from Reduction Mammoplasty to current one.
04/01/2024	Annual review. Policy statement, guidelines and literature review updated.

## Definitions of Decision Determinations

**Medically Necessary:** Services that are Medically Necessary include only those which have been established as safe and effective, are furnished under generally accepted professional standards to treat illness, injury or medical condition, and which, as determined by Blue Shield, are: (a) consistent with Blue Shield medical policy; (b) consistent with the symptoms or diagnosis; (c) not furnished primarily for the convenience of the patient, the attending Physician or other provider; (d) furnished at the most appropriate level which can be provided safely and effectively to the patient; and (e) 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 the Member's illness, injury, or disease.

**Investigational/Experimental:** A treatment, procedure, or drug is investigational when it has not been recognized as safe and effective for use in treating the particular condition in accordance with generally accepted professional medical standards. This includes services where approval by the federal or state governmental is required prior to use, but has not yet been granted.

**Split Evaluation:** Blue Shield of California/Blue Shield of California Life & Health Insurance Company (Blue Shield) policy review can result in a split evaluation, where a treatment, procedure, or drug will be considered to be investigational for certain indications or conditions, but will be deemed safe and effective for other indications or conditions, and therefore potentially medically necessary in those instances.

### Prior Authorization Requirements and Feedback (as applicable to your plan)

Within five days before the actual date of service, the provider must confirm with Blue Shield that the member's health plan coverage is still in effect. Blue Shield reserves the right to revoke an authorization prior to services being rendered based on cancellation of the member's eligibility. Final determination of benefits will be made after review of the claim for limitations or exclusions.

Questions regarding the applicability of this policy should be directed to the Prior Authorization Department at (800) 541-6652, or the Transplant Case Management Department at (800) 637-2066 ext. 3507708 or visit the provider portal at [www.blueshieldca.com/provider](http://www.blueshieldca.com/provider).

We are interested in receiving feedback relative to developing, adopting, and reviewing criteria for medical policy. Any licensed practitioner who is contracted with Blue Shield of California or Blue Shield of California Promise Health Plan is welcome to provide comments, suggestions, or concerns. Our internal policy committees will receive and take your comments into consideration.

For utilization and medical policy feedback, please send comments to: [MedPolicy@blueshieldca.com](mailto:MedPolicy@blueshieldca.com)

*Disclaimer: This medical policy is a guide in evaluating the medical necessity of a particular service or treatment. Blue Shield of California may consider published peer-reviewed scientific literature, national guidelines, and local standards of practice in developing its medical policy. Federal and state law, as well as contract language, including definitions and specific contract provisions/exclusions, take precedence over medical policy and must be considered first in determining covered services. Member contracts may differ in their benefits. Blue Shield reserves the right to review and update policies as appropriate.*

**Appendix A**

POLICY STATEMENT	
BEFORE <u>Red font: Verbiage removed</u>	AFTER <u>Blue font: Verbiage Changes/Additions</u>
<p>Reduction Mammoplasty for Breast-Related Symptoms 7.01.21</p> <p><b>Policy Statement:</b>                      The California Reconstructive Surgery Act (Health &amp; Safety Code Section 1367.63 and the Insurance Code Section 10123.88) defines "reconstructive surgery" as surgery performed to correct or repair abnormal structures of the body caused by congenital defects, developmental abnormalities, trauma, infection, tumors, or disease to do <b>either</b> of the following (see also Blue Shield of California Medical Policy: Reconstructive Services):</p> <ol style="list-style-type: none"> <li>1) Create a normal appearance to the extent possible</li> <li>2) Improve function</li> </ol> <p>In interpreting whether a proposed procedure meets the definition of reconstructive surgery, as defined by law, the procedure may be denied as <b>not medically necessary</b> under <b>any</b> of the following conditions:</p> <ol style="list-style-type: none"> <li>1) The procedure is likely to result in only minimal improvement in appearance, in accordance with the standard of care as practiced by <b>physicians</b> specializing in reconstructive surgery</li> <li>2) The treating surgeon cannot or will not provide sufficient documentation, including (when appropriate) medical quality color photographs, which accurately depicts the extent of the clinical problem (see <a href="#">Policy Guidelines</a> and <a href="#">Documentation for Clinical Review</a> sections)</li> <li>3) There is alternative approved medical or surgical intervention with equal or superior clinical outcomes</li> <li>4) The procedure is for <u>cosmetic</u> purposes only</li> </ol> <p>I. Reduction mammoplasty may be considered <b>medically necessary</b> for the treatment of macromastia when well-documented clinical symptoms are present, including but not limited to <b>either</b> of the following:</p> <ol style="list-style-type: none"> <li>A. Documentation of a minimum 6-week history of <u>shoulder, neck, or back pain</u> related to macromastia not responsive to conservative therapy, such as an appropriate support bra,</li> </ol>	<p>Reduction Mammoplasty for Breast-Related Symptoms 7.01.21</p> <p><b>Policy Statement:</b></p> <p>In interpreting whether a proposed procedure meets the definition of reconstructive surgery, as defined by law, the procedure may be denied as <b>not medically necessary</b> under <b>any</b> of the following conditions:</p> <ol style="list-style-type: none"> <li>1) The procedure is likely to result in only minimal improvement in appearance, in accordance with the standard of care as practiced by <b>providers</b> specializing in reconstructive surgery</li> <li>2) The treating surgeon cannot or will not provide sufficient documentation, including (when appropriate) medical quality color photographs, which accurately depicts the extent of the clinical problem (see <a href="#">Policy Guidelines</a> and <a href="#">Documentation for Clinical Review</a> sections)</li> <li>3) There is alternative approved medical or surgical intervention with equal or superior clinical outcomes</li> <li>4) The procedure is for <u>cosmetic</u> purposes only</li> </ol> <p>I. Reduction mammoplasty may be considered <b>medically necessary</b> for the treatment of macromastia when well-documented clinical symptoms are present, including but not limited to <b>either</b> of the following:</p> <ol style="list-style-type: none"> <li>A. Documentation of a minimum 6-week history of <u>shoulder, neck, or back pain</u> related to macromastia not responsive to conservative therapy, such as an appropriate support bra,</li> </ol>

POLICY STATEMENT

BEFORE <b>Red font: Verbiage removed</b>	AFTER <b>Blue font: Verbiage Changes/Additions</b>
<p>exercises, heat/cold treatment, and appropriate nonsteroidal anti-inflammatory agents or muscle relaxants</p> <p>B. Recurrent or chronic intertrigo between the pendulous breast and the chest wall</p> <p>II. Reduction mammoplasty is considered <b>investigational</b> for all other indications not meeting the above criteria.</p>	<p>exercises, heat/cold treatment, and appropriate nonsteroidal anti-inflammatory agents or muscle relaxants</p> <p>B. Recurrent or chronic intertrigo between the pendulous breast and the chest wall</p> <p>II. Reduction mammoplasty is considered <b>investigational</b> for all other indications not meeting the above criteria.</p>