

Medical Policy



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Blue Cross Blue Shield Association

Title: Reduction Mammoplasty for Breast-Related Symptoms

PRE-DETERMINATION of services is not required, but is highly recommended.

http://www.bcbsks.com/CustomService/Forms/pdf/15-17_predeterm_request_fm.pdf

Professional

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Populations	Interventions	Comparators	Outcomes
Individuals: • With symptomatic macromastia	Interventions of interest are: • Reduction mammoplasty	Comparators of interest are: • Nonsurgical treatment	Relevant outcomes include: • Symptoms • Functional outcomes

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 relieve the associated clinical symptoms.

OBJECTIVE

The objective of this policy is to evaluate the clinical situations where the evidence demonstrates that reduction mammoplasty improved the net health outcome.

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,¹⁻⁹ 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.¹⁰ 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.

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.¹¹ 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. See Appendix Table 1 for the Schnur Sliding Scale.

REGULATORY STATUS

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

POLICY

- A. Reduction mammoplasty may be considered **medically necessary** for the treatment of macromastia in patients at least 18 years of age or for whom growth is complete (ie, height, weight, and breast size stable for over 12 months) when the amount of breast tissue (not fatty tissue) resected is at least 1000 g per breast and photographs are provided for visual documentation of breast hypertrophy.
- B. Reduction mammoplasty may be considered **medically necessary** for the treatment of macromastia in patients at least 18 years of age or for whom growth is complete (ie, height, weight, and breast size stable for over 12 months) when well-documented clinical symptoms are present, including, but not limited to:
 1. 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**
 2. Recurrent or chronic intertrigo between the pendulous breast and the chest wall with skin breakdown that is refractory to standard treatment options; **AND**
 3. ALL of the following objective criteria:
 - a. 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), or documenting the presence of intertrigo with skin breakdown; **AND**

- b. The amount of breast tissue (not fatty tissue) resected per breast would be at or above 22% using the Schnur Sliding Scale (see Appendix), which suggests a minimum amount of breast tissue (not fatty tissue) to be removed for the procedure to be considered medically necessary, based on the patient's body surface area.
- C. Reduction mammoplasty is considered **non-covered** for all other indications not meeting the above criteria.
- D. Liposuction-only reduction mammoplasty is considered **experimental / investigational** because of insufficient evidence of its effectiveness.

Policy Guidelines

1. Lipoaspirate will not be counted toward volume of breast tissue removed.
2. Medical records from the primary care physician who has diagnosed or treated the symptoms prompting this request may also be required.
3. If amount of breast tissue (not fatty tissue) actually resected is less than 22% based on the Schnur Sliding Scale, medical necessity will be reviewed on a case by case basis.

RATIONALE

The most recent literature review was performed for the period of through December 6, 2018. The following is a summary of the key findings to date.

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 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.

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 patients with symptomatic macromastia.

The question addressed in this evidence review is: does reduction mammoplasty improve the net health outcome for women with symptomatic macromastia?

The following PICOTS were used to select literature to inform this review.

Patients

The relevant population of interest is women 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 issue 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, recurrent intertrigo in the mammary fold. The condition may also be associated with psychosocial or emotional disturbances.

Timing

The existing literature evaluating reduction mammoplasty as a treatment for symptomatic macromastia has varying lengths of follow-up, ranging from 6 to 18 months. While studies described below all reported at least one outcome of interest, longer follow-up was necessary to fully observe outcomes. Therefore, at least one year of follow-up is considered necessary to demonstrate efficacy.

Setting

Patients with symptomatic macromastia are managed by general or plastic surgeons in an inpatient clinical setting.

Study Selection Criteria

Methodologically credible studies were selected using the following principles:

- a. To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs;

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

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.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. 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) 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 visual analog scale from an average of 5.7 preoperatively to 1.3 postoperatively ($p<0.001$ for pre-post comparison within the mammoplasty group) vs visual analog scale average scores in the control group of 6.0 and 5.3 on the first and second evaluations, respectively ($p=NS$).

Saariniemi et al (2008) 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 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.

Key trials are reported in Tables 1 and 2 below.

Table 1. Summary of Key RCT Characteristics

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

RCT: randomized controlled trial; NR: not reported.

Table 2. Summary of Key RCT 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
Sabino Neto (2008)						
Mammoplasty	8.9 to 4.9 (p<0.001)	5.9 to 1.2 (p<0.001)	5.7 to 1.3 (p<0.001)			
Control	9.1 to 9.0 (p>0.999)	6.2 to 6.2 (NR)	6.0 to 5.3 (p<0.001)			
Saariniemi (2008)						
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
P-value				<0.001	<0.002	<0.001

RSES: Rosenberg Self-Esteem Scale; RMDQ: Roland-Morris Disability Questionnaire; VAS: visual analog scale; NR: not reported; RCT: randomized controlled trial.

The purpose of the gaps table (Table 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 Design and Conduct Gaps

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

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

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

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

^c Selective Reporting key: 1. Not registered; 2. Evidence of selective reporting; 3. Evidence of selective publication.

^d 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).

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

^f 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.¹² 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.

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.¹³ 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; $p < 0.001$), 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 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.¹⁴ 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. 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 (eg, the weight of excised breast tissue).

Adverse Events

Thibaudeau et al (2010) conducted a systematic review to evaluate breastfeeding after reduction mammoplasty.¹⁵ 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 2403 obese and 5597 nonobese patients.¹⁶ 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%; $p < 0.001$). 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.¹⁷ Infection occurred more frequently in patients older than 50 years of age (odds ratio, 2.7; $p = 0.003$). Additionally, women older than 50 years experienced more wound healing problems (odds ratio, 1.6; $p = 0.09$) and reoperative wound débridement (odds ratio, 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 body mass index.^{18,19}

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 QOL improve after reduction mammoplasty.

SUMMARY OF EVIDENCE

For individuals who have symptomatic macromastia who receive reduction mammoplasty, the evidence includes systematic reviews, randomized controlled trials, cohort studies, and case series. Relevant outcomes are symptoms and functional outcomes. Studies have indicated that reduction mammoplasty 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 mammoplasty. 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

American Society of Plastic Surgeons

In 2011, The American Society of Plastic Surgeons issued practice guidelines and a companion document on criteria for third-party payers for reduction mammoplasty.^{20,21} The Society found that level I evidence has shown reduction mammoplasty 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." The Society also indicated the volume or weight of breast tissue resection should not be criteria for reduction mammoplasty. If two or more symptoms are present all or most of the time, reduction mammoplasty is appropriate. This practice guideline has been officially archived and an update is scheduled for 2019.

U.S. PREVENTIVE SERVICES TASK FORCE RECOMMENDATIONS

Not applicable.

ONGOING AND UNPUBLISHED CLINICAL TRIALS

A search of ClinicalTrials.gov in December 2018 did not identify any ongoing or unpublished trials that would likely influence this review.

CODING

The following codes for treatment and procedures applicable to this policy are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement. 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.

CPT/HCPCS

19318 Reduction mammoplasty

ICD-10 Diagnoses

N62 Hypertrophy of breast

L98.491	Non-pressure chronic ulcer of skin of other sites limited to breakdown of skin
M25.511	Pain in right shoulder
M25.512	Pain in left shoulder
M54.89	Other dorsalgia
M54.9	Dorsalgia, unspecified

REVISIONS

01-20-2017	Policy added to the bcbsks.com web site on 12-21-2016 with an effective date of 01-20-2017.
03-29-2017	Updated Description section.
	Updated Rationale section.
	Updated References section.
03-28-2018	Updated Description section.
	Updated Rationale section.
	Updated References section.
03-27-2019	Updated Description section.
	Updated Rationale section.
	Updated References section.

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APPENDIX**Appendix Table 1. Schnur Sliding Scale**

Body Surface Area, m ²	22% (g)	Body Surface Area, m ²	22% (g)	Body Surface Area, m ²	22% (g)	Body Surface Area, m ²	22% (g)
1.35	199	1.72	384	2.09	737	2.46	1419
1.36	203	1.73	390	2.10	750	2.47	1445
1.37	207	1.74	397	2.11	764	2.48	1470
1.38	210	1.75	404	2.12	778	2.49	1496
1.39	214	1.76	411	2.13	791	2.50	1522
1.40	218	1.77	419	2.14	805	2.51	1550
1.41	222	1.78	426	2.15	819	2.52	1578
1.42	226	1.79	434	2.16	834	2.53	1606
1.43	230	1.80	441	2.17	849	2.54	1634
1.44	234	1.81	449	2.18	865	2.55	1662
1.45	238	1.82	457	2.19	880	2.56	1690
1.46	242	1.83	466	2.20	895	2.57	1718
1.47	247	1.84	474	2.21	912	2.58	1746
1.48	251	1.85	482	2.22	928	2.59	1774
1.49	256	1.86	491	2.23	945	2.60	1802
1.50	260	1.87	500	2.24	961	2.61	1830
1.51	265	1.88	509	2.25	978	2.62	1858
1.52	270	1.89	518	2.26	996	2.63	1886
1.53	274	1.90	527	2.27	1014	2.64	1914
1.54	279	1.91	537	2.28	1032	2.65	1942
1.55	284	1.92	546	2.29	1050	2.66	1970
1.56	289	1.93	556	2.30	1068	2.67	1998
1.57	294	1.94	565	2.31	1088	2.68	2026
1.58	300	1.95	575	2.32	1108	2.69	2054
1.59	305	1.96	586	2.33	1127	2.70	2082
1.60	310	1.97	596	2.34	1147	Calculation of body surface area: Body surface area = the square root of height (cm) × weight (kg) / 3600 To convert pounds to kilograms, multiply pounds by 0.45. To convert inches to centimeters, multiply inches by 2.54.	
1.61	316	1.98	607	2.35	1167		
1.62	321	1.99	617	2.36	1189		
1.63	327	2.00	628	2.37	1210		
1.64	332	2.01	640	2.38	1232		
1.65	338	2.02	652	2.39	1253		
1.66	344	2.03	663	2.40	1275		
1.67	351	2.04	675	2.41	1299		
1.68	357	2.05	687	2.42	1322		
1.69	364	2.06	700	2.43	1346		
1.70	370	2.07	712	2.44	1369		
1.71	377	2.08	725	2.45	1,393		