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Reduction Mammoplasty

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Disclaimer

Carefully check state regulations and/or the member contract.

Each benefit plan, summary plan description or contract defines which services are covered, which services are excluded, and which services are subject to dollar caps or other limitations, conditions or exclusions. Members and their providers have the responsibility for consulting the member's benefit plan, summary plan description or contract to determine if there are any exclusions or other benefit limitations applicable to this service or supply. **If there is a discrepancy between a Medical Policy and a member's benefit plan, summary plan description or contract, the benefit plan, summary plan description or contract will govern.**

Coverage

This medical policy does NOT address Gender Reassignment Services (Transgender Services). This medical policy IS NOT TO BE USED for Gender Reassignment Services. Refer to SUR717.001, Gender Assignment Surgery and Gender Reassignment Surgery and Related Services.

Special Comment Regarding Cosmetic Services: Many contracts have exclusions for services or supplies provided for cosmetic procedures. For example, the following services would not be covered for a cosmetic breast reduction (unilateral or bilateral) which is **unrelated** to post mastectomy reconstruction with contralateral breast surgery, post accidental injury or trauma:

1. Diagnostic evaluation of, or
2. Preparation for, or
3. Conjunction with, or
4. Treatment of breast hypertrophy or hypermastia.

NOTE 1: See Medical Policy SUR716.001 Cosmetic and Reconstructive Procedures for treatment of congenital breast asymmetry.

Medical Necessity Documentation Requirements: ALL requests seeking coverage of reduction mammoplasty must include all required documentation before a medical necessity determination can be made.

Photo Documentation Requirements: Photo documentation that is consistent with the physical exam findings of breast hypertrophy and shoulder grooving.

Reduction mammoplasty for symptomatic breast hypertrophy or hypermastia in individuals who are 18 years of age or older **may be considered medically necessary** when ALL the following criteria are met:

1. The patient has significant symptoms, documented in their medical records, that interfere with activities of daily living, including but not limited to, the following:
 - a) Pain in the upper back, neck, and shoulders which is long-standing in duration and increasing in intensity and is not related to other musculoskeletal causes (e.g., poor posture, acute strains, post traumatic conditions, poor lifting techniques, or other evidence of overuse), OR
 - b) Persistent, clinical, and nonseasonal submammary intertrigo which is refractory and unresponsive to comprehensive local hygiene and topical anti-infective therapy, OR
 - c) Ulnar nerve paresthesia or compression, which results in pain and/or numbness in the arms and/or hands; **AND**
2. The patient's history and physical exam documents the following:
 - a) Significant shoulder grooving or ulceration of the skin of the shoulder; AND
 - b) Obvious breast hypertrophy; AND
 - c) Physical exam consistent with symptoms precipitating request for reduction mammoplasty; AND
 - d) Failure of at least 6-weeks of conservative measures including:
 - Physical therapy for back, neck or shoulder pain including a maintenance home exercise program, or
 - Appropriate support bra with weight distributing straps, or
 - Appropriate local hygiene and topical pharmacologic treatments for intertrigo; AND
 - e) Documentation of patient's body surface area (BSA), based on the Schnur Sliding Scale (SSS), in which the patient's breast weight (per breast) is estimated at greater than the 22nd percentile line (Refer to SSS and calculation of BSA in the Description Section) consisting of breast tissue (not fatty tissue) to be removed. **(See NOTE 3)**

NOTE 2: Claims are subject to review for the actual amount of breast tissue removed. The final coverage determination may be based on a post-operative pathology report confirming the amount and type of breast tissue resected and that this amount is greater than the 22nd percentile of the SSS nomogram based upon the patient's pre-operative BSA and that the tissue removed consisted of breast and not adipose or fatty tissue.

NOTE 3: Tissue removed that plots between the 5th and 22nd percentile of the Schnur Sliding Scale may be either cosmetic or reconstructive. Determination will be based on the review of the information provided.

A staged reduction mammoplasty preceding a nipple sparing mastectomy or lumpectomy for breast cancer **may be considered medically necessary** in order to preserve the viability of the nipple.

Reduction mammoplasty **is considered not medically necessary** when the above criteria are not met, including but not limited to treating psychosocial symptomatology, psychosocial complaints related to appearance, or as a method to restore normal emotional functioning.

Use of liposuction, with or without ultrasound assistance, to perform a reduction mammoplasty **is considered experimental, investigational and/or unproven.**

Policy Guidelines

None.

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. 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 (Schnur Sliding Scale; SSS). (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 breast. These responses were 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 (BSA), 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 cut points 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 an individual is within 20% of their ideal body weight. While weight loss might relieve symptoms, durable weight loss is notoriously difficult and might be unrealistic in many cases.

Schnur Sliding Scale (SSS)

| Schnur Sliding Scale | |
|--|--|
| Body Surface Area in Meters squared (m²) | Breast Weight in Grams (gm) at the 22nd percentile |
| 1.35 | 199 |
| 1.40 | 218 |
| 1.45 | 238 |
| 1.50 | 260 |
| 1.55 | 284 |
| 1.60 | 310 |
| 1.65 | 338 |
| 1.70 | 370 |
| 1.75 | 404 |
| 1.80 | 441 |
| 1.85 | 482 |
| 1.90 | 527 |
| 1.95 | 575 |
| 2.00 | 628 |
| 2.05 | 687 |
| 2.10 | 750 |
| 2.15 | 819 |

| | |
|------|------|
| 2.20 | 895 |
| 2.25 | 978 |
| 2.30 | 1068 |
| 2.35 | 1167 |
| 2.40 | 1275 |
| 2.45 | 1393 |
| 2.50 | 1522 |
| 2.55 | 1662 |

Calculation of Body Surface Area (BSA), as shown in the following (using centimeters for height and kilograms for weight):

1. $BSA = \text{the square root of } ([\text{height} \times \text{weight}] \div 3600)$.
2. To convert pounds to kilograms, multiply pounds by 0.4536.
3. To convert inches to centimeters, multiply inches by 2.54.

Regulatory Status

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

Rationale

Medical policies 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 (QOL), 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 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 policy.

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.

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 (VAS). The reduction mammoplasty group showed improvement in functional status, with an average score of 5.7 preoperatively and 1.3 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 ($p = NS$ [not significant]).

Saariniemi et al. (2008) reported on the 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 versus +0.7, $p < 0.001$), the Utility Index score (SF-6D; change, +17.5 versus +0.6), the index score of QOL (SF-15D; change, +8.6 versus +0.06, $p < 0.001$), and SF-36 Mental Component Summary score (change, +7.8 versus -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 versus -3.5, $p < 0.001$), and Finnish Pain Questionnaire scores (-21.5 versus -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 | |
|-------------------------------|-----------|-------|-----------|---|------------------------------|------------------------------|
| | | | | | Active | Comparator |
| Sabino Neto et al. (2008) (7) | Brazil | 1 | 2002-2004 | Female patients (age 18-55 years) with breast hypertrophy (N=100) | Reduction mammoplasty (N=50) | Waiting list control (N=50) |
| Saariniemi et al. (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 | Change (Pre- to | Change (Pre- to | Change (Pre- to Post- | Change (Pre- to Post- | Change (Pre- to Post- |
|-------|----------------|-----------------|-----------------|-----------------------|-----------------------|-----------------------|
| | | | | | | |

| | Post-operative) in RSES | Post-operative) in RMDQ | Post-operative) in VAS | operative) in SF-36 Utility Index Score | operative) in Mental Summary Score | operative) in Pain Score |
|--------------------------------------|-------------------------|-------------------------|------------------------|---|------------------------------------|--------------------------|
| Sabino Neto et al. (2008) (7) | | | | | | |
| Mamma-plasty | 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 et al. (2008) (9) | | | | | | |
| Mamma-plasty | | | | 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; SF36: Short Form-36 quality of life questionnaire.

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 ^a | Intervention ^b | Comparator ^c | Outcomes ^d | Duration of Follow-up ^e |
|-------------------------------|-------------------------|---------------------------|---|---|------------------------------------|
| Sabino Neto et al. (2008) (7) | | | 3. Comparator group on waiting list without additional intervention described | 5. Clinical significant difference not prespecified | |
| Saariniemi et al. (2008) (9) | | | 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.

^a 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.

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

^c Comparator key: 1. Not clearly defined; 2. Not standard or optimal; 3. Delivery not similar intensity as intervention; 4. Not delivered effectively.

^d 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.

^e Follow-Up key: 1. Not sufficient duration for benefit; 2. Not sufficient duration for harms.

Table 4. Study Design and Conduct Limitations

| Study | Allocation ^a | Blinding ^b | Selective Reporting ^c | Follow-Up ^d | Power ^e | Statistical ^f |
|-------------------------------|-------------------------|-----------------------|----------------------------------|--------------------------------------|--------------------|-------------------------------|
| Sabino Neto et al. (2008) (7) | | 1, 2, 3. No blinding | | | | 3. Some p-values not reported |
| Saariniemi et al. (2008) (9) | | 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 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 QOL. 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. (13) 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. (14) In the preoperative state, SF-36 physical health component subscore was significantly lower for patients with symptomatic macromastia (n=40) than for age-matched controls (n=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. (15) 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 (e.g., the weight of excised breast tissue).

Adverse Events

Thibaudeau et al. (2010) conducted a systematic review to evaluate breastfeeding after reduction mammoplasty. (16) 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. (17) 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. (18) 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 debridement (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 (BMI). (19, 20)

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.

Staged Reduction Mammoplasty

Hammond and Little (2022) examined the role of premastectomy mastopexy and breast reduction in the reconstruction of the enlarged or ptotic breast. (21) Patients undergoing nipple-sparing mastectomy who have enlarged or ptotic breasts are at risk for skin flap and/or nipple-areola complex necrosis. Premastectomy mastopexy or breast reduction may reduce the risk for these complications. A retrospective review of 20 patients (39 implant-based reconstructions) who underwent premastectomy reduction mammoplasty or mastopexy followed by nipple-sparing mastectomy and immediate staged tissue expander/implant-based breast reconstruction. Final reconstruction involved tissue expander exchange for a permanent implant with associated fat grafting. No cases of mastectomy flap necrosis or partial necrosis of the nipple-areola complex with delayed wound healing was seen. All patients completed the reconstructive process successfully. The review showed premastectomy mastopexy or breast reduction may afford a protective effect against mastectomy flap or nipple-areola complex necrosis in patients with large or ptotic breasts who subsequently undergo nipple-sparing mastectomy with immediate breast reconstruction.

In 2024, Awaida et al. conducted a retrospective analysis looking at staged mastopexy before nipple-sparing mastectomy. (22) Breast reconstruction following nipple-sparing mastectomy (NSM) in patients with large or ptotic breasts remains a challenge because of the risk of ischemic complications and the difficulty in managing the redundant skin envelope. Patients with a genetic predisposition to breast cancer underwent staged breast reduction/mastopexy before NSM and reconstruction. In patients with in-situ disease or invasive cancer, the first stage consisted of lumpectomy and oncoplastic reduction/mastopexy. Breast reconstruction at the second stage was performed with free abdominal flaps or breast implants and acellular dermal matrix. In total, 47 patients (84 breasts) underwent this staged approach. All patients had a genetic predisposition to breast cancer. The time interval between the two stages was

11.5 months (range, 1.3 to 23.6 months). Twelve breasts (14.3%) were reconstructed with free abdominal flaps, six (7.1%) with tissue expanders, and 66 (78.6%) with permanent subpectoral implants and acellular dermal matrix. There was one case of postoperative superficial nipple-areola complex epidermolysis (1.2%), and two cases of partial mastectomy skin flap necrosis (2.4%). The mean follow-up time after completion of reconstruction was 8.3 months. Mastopexy or breast reduction before NSM and reconstruction is a safe procedure with a low risk of ischemic complications. (Level of evidence: Therapeutic, IV.)

Shih et al. (2024) conducted a retrospective analysis of staged breast reconstruction utilizing primary nipple repositioning surgery prior to nipple-sparing mastectomy. (23) Staged nipple-sparing mastectomy (NSM) following mastopexy or breast reduction has become increasingly utilized in patients with large or ptotic breasts. The safety and efficacy of this approach has been demonstrated in recent years. However, the optimal timing between stages has not been established. Data of all patients at a single institution who underwent staged NSM following mastopexy or reduction mammoplasty for therapeutic or prophylactic oncologic surgical management from 2016 to 2020 were reviewed. Nineteen patients (38 breasts) underwent staged NSM following planned mastopexy/breast reduction. The mean time interval between stages was 25 weeks. No patients developed nipple areolar complex necrosis. Infection and hematoma were seen in one breast (2.6%) and seroma in two (5.3%) after NSM. Delayed wound healing was seen in eight breasts (21.1%) after first stage mastopexy/reduction and in 12 breasts (31.6%) after NSM. Skin flap necrosis was noted in two breasts (5.3%) after NSM. No patients developed oncological recurrence. Mean patient-reported post-operative satisfaction and well-being scores were 63 and 67 out of 100, respectively. Results suggest that this procedure can be performed safely with cosmetically favorable results if surgeons wait an average of 25 weeks between first and second stage procedures. While surgical and oncological results have largely been favorable, an optimal time period between stages has not yet been established. The staged approach was appropriate to perform in patients with moderately large or ptotic breasts. Overall, this treatment algorithm produces favorable results.

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 an improvement in the net health outcome.

For individuals who have a staged reduction mammoplasty preceding a nipple sparing mastectomy or lumpectomy for breast cancer, the evidence includes retrospective reviews. Relevant outcomes are symptoms and functional outcomes. Studies have shown that a staged reconstruction is a safe procedure with a low risk of ischemic complications for individuals with

large or ptotic breasts. While the optimal time frame has not been established, favorable results have been shown if surgeons wait an average of 25 weeks between first and second stage procedures. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

Practice Guidelines and Position Statements

American Society of Plastic Surgeons (ASPS)

In 2011, the ASPS issued practice guidelines and a companion document on criteria for third-party payers for reduction mammoplasty. (24, 25) 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."

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 policy.

Coding

Procedure codes on Medical Policy documents are included **only** as a general reference tool for each policy. **They may not be all-inclusive.**

The presence or absence of procedure, service, supply, or device codes in a Medical Policy document has no relevance for determination of benefit coverage for members or reimbursement for providers. **Only the written coverage position in a Medical Policy should be used for such determinations.**

Benefit coverage determinations based on written Medical Policy coverage positions must include review of the member's benefit contract or Summary Plan Description (SPD) for defined coverage vs. non-coverage, benefit exclusions, and benefit limitations such as dollar or duration caps.

| | |
|--------------------|-------|
| CPT Codes | 19318 |
| HCPCS Codes | None |

*Current Procedural Terminology (CPT®) ©2023 American Medical Association: Chicago, IL.

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Centers for Medicare and Medicaid Services (CMS)

The information contained in this section is for informational purposes only. HCSC makes no representation as to the accuracy of this information. It is not to be used for claims adjudication for HCSC Plans.

The Centers for Medicare and Medicaid Services (CMS) does not have a national Medicare coverage position. Coverage may be subject to local carrier discretion.

A national coverage position for Medicare may have been developed since this medical policy document was written. See Medicare's National Coverage at <<https://www.cms.hhs.gov>>.

| Policy History/Revision | |
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| Date | Description of Change |
| 12/01/2024 | Document updated with literature review. The following change to coverage was made: Added "A staged reduction mammoplasty preceding a nipple sparing mastectomy or lumpectomy for breast cancer may be considered medically necessary in order to preserve the viability of the nipple." References 13, 21-23 and 25 added; others updated. |
| 07/15/2023 | Reviewed. No changes. |
| 05/15/2022 | Document updated with literature review. Coverage unchanged. Reference 20 updated. |
| 01/01/2022 | Added Note 3 to Coverage: Tissue removed that plots between the 5 th and 22 nd percentile of the Schnur Sliding Scale may be either cosmetic or reconstructive. Determination will be based on the review of the information provided. |
| 07/01/2021 | Reviewed. No changes. |
| 08/15/2020 | Document updated with literature review. Coverage unchanged. No new references added. |
| 10/15/2019 | Reviewed. No changes. |
| 01/15/2019 | Document updated with literature review. Coverage unchanged. No references added; one removed. |
| 03/15/2018 | Document updated with the following modification to Coverage: Changed from "Reduction mammoplasty is considered cosmetic and not medically necessary for the treatment of psychosocial indications or as a method to restore normal emotional functioning" to "Reduction mammoplasty is considered not medically necessary when the above criteria are not met, including but not limited to treating psychosocial symptomatology, psychosocial complaints related to appearance, or as a method to restore normal emotional functioning." |
| 01/15/2018 | Document updated with literature review. The following was added to the Coverage section: Photo Documentation Requirements: Photo documentation that is consistent with the physical exam findings of breast hypertrophy and shoulder grooving. The following was changed for failure of conservative measures, which states, "Failure of at least 6-weeks of conservative measures including." The following was removed from failure of conservative measures, "Anti-inflammatory agents unless medically contraindicated." |
| 08/01/2016 | Document updated with literature review. Coverage unchanged. |
| 02/01/2015 | Reviewed. No changes. |
| 11/01/2013 | Document updated with literature review. Coverage unchanged. |
| 07/15/2009 | Coverage revised by adding age limitation of age 18 for consideration if procedure is medically necessary. The word "comprehensive" was removed from coverage criteria. |

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| 02/01/2009 | The following change(s) were made to Coverage criteria: Application of heat and cold compression as a symptomatic conservative therapy measure removed as a requirement to determine medical necessity. |
| 04/01/2008 | Policy reviewed without literature review; new review date only. |
| 01/15/2008 | Coverage changed |
| 09/15/2006 | Coverage changed |
| 02/15/2006 | Revised/updated entire document |
| 09/01/2005 | Revised/updated entire document |
| 08/01/1999 | Revised/updated entire document |
| 05/01/1996 | Medical policy number changed |
| 01/01/1996 | Revised/updated entire document |
| 10/01/1994 | Revised/updated entire document |
| 06/01/1991 | New medical document |