

Medical Benefit		Effective Date: 04/01/16	Next Review Date: 01/21
Preauthorization	Yes	Review Dates: 03/07, 03/08, 01/09, 01/10, 01/11, 01/12, 01/13, 01/14, 01/15, 01/16, 01/17, 01/18, 01/19, 01/20	

Preauthorization is required.

The following protocol contains medical necessity criteria that apply for this service. The criteria are also applicable to services provided in the local Medicare Advantage operating area for those members, unless separate Medicare Advantage criteria are indicated. If the criteria are not met, reimbursement will be denied and the patient cannot be billed. Please note that payment for covered services is subject to eligibility and the limitations noted in the patient's contract at the time the services are rendered.

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 to relieve the associated clinical symptoms.

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.

POLICY

Reduction mammoplasty may be considered **medically necessary** for the following:

- To attain symmetry of the non-diseased breast as part of the reconstructive surgery following a mastectomy.

Reduction mammoplasty may be considered **medically necessary** when ALL five of the following nonmastectomy related criteria have been met:

1. Macromastia is causing at least **two** of the following conditions/symptoms with documented failure of at least one continuous three-month trial of appropriate medical management:
 - Back, neck and/or shoulder pain
 - Intertrigo
 - Paresthesias of hands and/or arms
 - Permanent shoulder grooving

AND

2. Macromastia/gigantomastia defined as wearing a bra with a cup size greater or equal to “DD”

AND

3. Preoperative photos confirm the presence of BOTH of the following:
 - Significant breast hypertrophy
 - Permanent shoulder grooving from bra straps and/or intertrigo if stated to be present

AND

4. Patient has a body mass index (BMI) of 35 or less to eliminate the possibility that obesity is contributing to the symptoms of back, neck and/or shoulder pain and/or paresthesias of hands and/or arms

AND

5. An estimated tissue reduction of 500 grams per breast or 1000 grams bilaterally is planned. However, removal of less tissue may be considered for an individual of short stature and weight upon review by Medical Director. Information regarding an individual’s height and weight must be supplied. In no situations will removal of less than 350 grams per breast be considered medically necessary.

Reduction mammoplasty performed solely to improve one’s appearance or self-esteem without signs and symptoms of functional abnormality **is considered cosmetic and not medically necessary**.

The use of liposuction to perform breast reduction is considered **investigational**.

Reduction mammoplasty is restricted to age 18 and over as full breast development must occur prior to the surgery.

MEDICARE ADVANTAGE

Reduction mammoplasty is considered **medically necessary** when the patient has significant symptoms that have interfered with normal daily activities, despite conservative management, for at least six months, including **at least one** of the following criteria:

1. History of back and/or shoulder pain which adversely affects activities of daily living (ADLs) unrelieved by, e.g.,:
 - conservative analgesia (e.g., such as NSAID, compresses, massage, etc.)
 - supportive measures (e.g., such as garments, back brace, etc.)
 - physical therapy

- correction of obesity.
2. History of significant arthritic changes in the cervical or upper thoracic spine, optimally managed with persistent symptoms and/or significant restriction of activity, e.g.,:
 - signs and symptoms of ulnar paresthesias
 - cervicalgia
 - torticollis
 - acquired kyphosis.
 3. Signs and symptoms of:
 - intertriginous maceration or infection of the inframammary skin (e.g., hyperpigmentation, bleeding, chronic moisture, and evidence of skin breakdown), refractory to dermatologic measures, or
 - shoulder grooving with skin irritation (e.g., areas of excoriation and breakdown) by appropriate supporting garment.

AND

To be considered a non-cosmetic procedure it is expected that at least a minimal amount of breast tissue will be removed. The following are guidelines (not rules) that address the patient's body surface area (BSA) and the amount of breast tissue removed:

BSA 1.35-1.45 199-238g

BSA 1.46-1.55 239-284g

BSA 1.56-1.69 285-349g

Equal to or greater than 350g

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 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 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.

REGULATORY STATUS

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

Services that are the subject of a clinical trial do not meet our Technology Assessment and Medically Necessary Services Protocol criteria and are considered investigational. *For explanation of experimental and investigational, please refer to the Technology Assessment and Medically Necessary Services Protocol.*

It is expected that only appropriate and medically necessary services will be rendered. We reserve the right to conduct prepayment and postpayment reviews to assess the medical appropriateness of the above-referenced procedures. **Some of this protocol may not pertain to the patients you provide care to, as it may relate to products that are not available in your geographic area.**

REFERENCES

We are not responsible for the continuing viability of web site addresses that may be listed in any references below.

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