Clinical Policy Title: Breast Reduction Surgery

Clinical Policy Number: 16.03.05

Effective Date: December 1, 2013
Initial Review Date: August 21, 2013
Most Recent Review Date: July 20, 2016
Next Review Date: July, 2017

Related policies:
None.

ABOUT THIS POLICY: Keystone First has developed clinical policies to assist with making coverage determinations. Keystone First’s clinical policies are based on guidelines from established industry sources, such as the Centers for Medicare & Medicaid Services (CMS), state regulatory agencies, the American Medical Association (AMA), medical specialty professional societies, and peer-reviewed professional literature. These clinical policies, along with other sources, such as plan benefits and state and federal laws and regulatory requirements, including any state- or plan-specific definition of “medically necessary,” and the specific facts of the particular situation are considered by Keystone First when making coverage determinations. In the event of conflict between this clinical policy and plan benefits and/or state or federal laws and/or regulatory requirements, the plan benefits and/or state and federal laws and/or regulatory requirements shall control. Keystone First’s clinical policies are for informational purposes only and not intended as medical advice or to direct treatment. Physicians and other health care providers are solely responsible for the treatment decisions for their patients. Keystone First’s clinical policies are reflective of evidence-based medicine at the time of review. As medical science evolves, Keystone First will update its clinical policies as necessary. Keystone First’s clinical policies are not guarantees of payment.

Coverage policy

Keystone First considers the use of breast reduction surgery to be clinically proven and, therefore, medically necessary when the following criteria are met: adult or adolescent females who have reached full adult height and legal age of consent to surgery with documented (by any health care provider) symptomatic breast hypertrophy meeting any of the following symptom criteria lasting at least one year that interfere with daily activities:

- Neck, upper back, and shoulder pain not associated with other diagnoses.
- Painful shoulder grooving from brassiere straps.
- Chronic intertriginous rash of the inframammary fold.
- Frequent episodes of headache, backache and upper extremity neuropathies.
- Symptoms attributable to an increase in the volume and weight of breast tissue beyond normal proportions.
In addition, all of the following criteria must be met:

- Failure of patient to respond to at least three months of optimal medical management with physical therapy.
- Patients 40 years or older must have a mammogram negative for cancer within one year of the planned procedure date.
- The pre-operative evaluation concludes that surgery will provide a likely prognosis of symptomatic relief.
- The estimated weight of breast tissue to be removed, per breast, will be at least that conforming to the Schnur sliding scale table, given in the Appendix (American Society of Plastic Surgeons, 2011).

Limitations:

The procedure performed for relief of psychosocial distress (including cases of gynecomastia in males) is not covered. The procedure performed for cosmetic purposes is not covered.

Alternative covered services:

Medical management and physical therapy.

Background

Breast reduction surgery or reduction mammoplasty (alternate spelling, *mammaplasty*) is a surgical procedure to reduce the volume and weight of the female breasts. Mammoplasty is performed on women with excessively large breasts (macromastia), and aims to decrease the dimensions to obtain normal breast size. The procedure removes excess breast fat, glandular tissue, and skin to alleviate discomfort from overly large breasts.

During the operation, which is performed in a hospital or surgical center, the surgeon first makes several cuts in the breast, removes tissues and skin, and then stitches the skin back together. The procedure takes about 3 to 5 hours, and has been performed since the 1970s.

In 2013, a total of 62,611 such procedures were performed in the U.S. (American Society of Plastic Surgeons, 2015). Most breast reductions are performed by plastic surgeons, with a small proportion performed by general surgeons (Kordahi, 2015).

The procedure is performed for several reasons:
• To relieve back and neck pain, skin irritation, and posture problems caused by excessively large breasts, as mass of the breast tissue can cause a change in the body’s center of gravity, resulting in pain and compression of the intervertebral disks.
• To reduce limitations on participating in athletic and other activities.
• For psychosocial reasons, especially to alter a woman’s appearance, often to reduce her self-consciousness; this is considered a cosmetic procedure.

After the procedure, stitches are removed within 1-2 weeks. Most women undergoing the surgery experience pain for several days (some longer), in addition to swelling and bruising. Risks of the procedures during surgery include excessive bleeding, infection, reaction to anesthesia, and blood clots (which are rare). Risks after the surgery include scars, unevenly positioned nipples, breasts that are a different size or shape than the other, loss of feeling in the nipples or breasts, and the inability to breast feed.

Some women undergoing breast reduction have been diagnosed with cancer. Oncoplastic reduction mammoplasty removes cancer in the breast while incorporating aesthetically maximized approaches used in breast reduction (Chang, 2012).

Searches

Keystone First searched PubMed and the following databases:
• UK National Health Services Centre for Reviews and Dissemination.
• Agency for Healthcare Research and Quality’s National Guideline Clearinghouse and other evidence-based practice centers.
• The Centers for Medicare & Medicaid Services (CMS).

We conducted searches on June 20, 2016. Search terms were “reduction mammoplasty,” “breast reduction” and “breast hypertrophy.”

We included:

• Systematic reviews, which pool results from multiple studies to achieve larger sample sizes and greater precision of effect estimation than in smaller primary studies. Systematic reviews use predetermined transparent methods to minimize bias, effectively treating the review as a scientific endeavor, and are thus rated highest in evidence-grading hierarchies.
• Guidelines based on systematic reviews.
• Economic analyses, such as cost-effectiveness, and benefit or utility studies (but not simple cost studies), reporting both costs and outcomes — sometimes referred to as efficiency studies — which also rank near the top of evidence hierarchies.

Findings
The number of breast reduction procedures has increased rapidly in the last several decades (Alshanawani, 2013). Extensive experience with reduction mammoplasty has produced solid evidence in the peer-reviewed medical literature that the surgery is relatively safe and improves the quality of life among symptomatic women judged to have a medical need for the surgery.

One recent report found a significant improvement in symptoms and quality of life one month/one year post-operative, and that 96.6% of women expressed satisfaction and would recommend the surgery to others (Perez-Panzano, 2016). Another found that patient satisfaction and health-related quality of life were “vastly improved” (Cohen, 2016). A study that used the Breast Related Symptoms Questionnaire showed 55 of 59 women reported no symptoms/less frequent symptoms; the greatest improvements were observed in those who were obese and who had pendulous breasts (Valtonen, 2014). A report from Finland documented improvements in health-related quality of life six months after breast reduction, similar to those undergoing total joint replacement of the hip and knee (Saariniemi, 2008).

One study found older women (age >60 vs. age <35) had a higher satisfaction with the procedure, despite the fact the older group had more comorbidities and more complications (Braig, 2016). However, another report found higher rates (among women > 50) of infections, wound healing problems, and reoperative wound debridement, which the authors attributed partially due to hormone deficiency (Shermak, 2011).

Complication rates have also been documented. One report found that 23.9% of women undergoing the procedure experienced complications (Srinivasaiah, 2014). Another found the early complication rate to be 6.1%, almost half of these to be superficial skin and soft tissue infection. (Nelson, 2014). Both concluded the procedure was relatively well-tolerated.

Those women at greatest risk for complications after surgery and/or need for reoperation were obese and those who currently smoke (Srinivasaiah, 2014; Nelson, 2014; Karamanos, 2015). Obesity was defined as those with a Body Mass Index (BMI) of at least 40. Counseling on smoking and weight loss was discussed in several reports. Other reports found no difference in outcomes between obese and non-obese patients, including length of stay, complications, sequels, reoperations, and symptom improvement (Guemes, 2016) and patient satisfaction (Gonzalez, 2012).

Only one study was found comparing reduction mammoplasty with another procedure. The article compared reduction mammoplasty and inframammary incisions in the management of giant fibroadenomas. Among patients with severe preoperative asymmetry, all eight (8) inframammary patients had persistent post-operative skin redundancy, compared to none of the seven (7) reduction mammoplasty patients (Ugboro, 2012).
Some studies reviewed outcomes of reduction mammoplasty by physician training and experience. One found that from 2005 to 2012 in the National Surgical Quality Improvement Project data base, 5,900 procedures were performed by plastic surgeons vs. only 339 by general surgeons. Procedures by general surgeons had more failures of skin flaps and longer time in the operating room; no differences between the two groups were observed in infection and complication rates (Kordahi, 2015). A study of 1052 procedures from 1996 to 2010 found that after 15 years, average operating time fell by 38.3% (69.8 minutes), prompting authors to conclude that experience serves as a driver of improvement (Maruthappu, 2015).

Methods used in reduction mammoplasty were explored to improve outcomes. Moistening one breast with tranexamic acid and the other with saline before closure found 39% less drain fluid production in medicine group, with no difference in pain or complications post-surgery (Ausen, 2015). Using prophylactic antibiotics resulted in a 75% reduction in wound infections (Shortt, 2014). Other methods resulted in no improvements. Using wound drainage had no significant impact on outcomes except shorter length of stay (Khan, 2015). Scar segments treated with topical calcipotriol found no difference in prevalence of hypertrophic scars (vanderMeer, 2009).

Oncoplastic reduction mammography is also covered in the literature, with positive results. One systematic review of 17 studies followed 1324 women undergoing the procedure for 20 to 73 months, and found low rates of local/regional recurrence (3.1%), re-excision (3.5%), wound dehiscence (4.6%), fat necrosis (4.3%), infection (2.8%), partial/total nipple necrosis (0.9%), and seromas (0.6%), along with high rates of breast conservation and low rates of re-excisions (Piper, 2016).

Policy updates:

Information was added to the Background section on the description and number of breast reduction surgery procedures. Some limitations were moved into the Coverage section. Four (4) of the nine (9) terms in the glossary were removed. New references were added, some of which are in the Summary of Clinical Evidence section. Four (4) citations were added to the Clinical Trials section. The table on Schnur tissue has been moved from the Glossary section to an Appendix.

Summary of clinical evidence:

<table>
<thead>
<tr>
<th>Citation</th>
<th>Content</th>
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</thead>
<tbody>
<tr>
<td>Cohen (2016)</td>
<td>Key Points:</td>
</tr>
<tr>
<td>Changes in health-related</td>
<td>• 20 women operated on by a single surgeon.</td>
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<tr>
<td>quality of life after</td>
<td>• Completed BREAST-Q reduction mammoplasty module before surgery, and 0-3/3-12 months after.</td>
</tr>
<tr>
<td>reduction mammoplasty</td>
<td>• Patient satisfaction and health related quality of life vastly improved after surgery.</td>
</tr>
<tr>
<td>Perez-Panzano (2016)</td>
<td>Key Points:</td>
</tr>
<tr>
<td>Changes in quality of life</td>
<td>• 121 women, 44.6% obese, 34.7% smokers, evaluated 1 and 12 months after surgery.</td>
</tr>
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<td>Content</td>
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| After reduction mammoplasty | • Significant improvement of symptoms and quality of life.  
• 96.6% patient satisfaction/would recommend to others 12 months after surgery. |
| Berberoglu (2015) | **Key Points:**  
• Reduction mammoplasty can improve cervical lordosis and thoracic kyphosis, alleviating patient back/neck/lumbar pain.  
• Positive correlation identified between amount of breast tissue removed and decreased neck/back/lumbar pain.  
• Mammoplasty resulted in psychosocial improvements including decreased depression severity and improved Quality of Life (QoL). |
| Kordahi (2015) | **Key Points:**  
• Evaluated procedures in National Surgical Quality Improvement Project database.  
• From 2005-2012, 5900 procedures done by plastic surgeons, 339 by general surgeons.  
• Patients operated on by general surgeons had more failures of skin flaps, longer operative time, but there was no difference in infection and complication rates between the two types of surgeons.  
• Focused training in reduction mammography appears beneficial to the patient. |
| Maruthappu (2015) | **Key Points:**  
• 1052 reduction mammoplasties performed 1996-2010, 17 surgeons, median 61 procedures.  
• After 15 years of experience, average operating time fell 38.3% (69.8 minutes).  
• Experience serves as a driver of performance improvement. |
| Shortt (2014) | **Key Points:**  
• 3 Randomized Controlled Trials, 77 subjects.  
• A 75% reduction in wound infections in patients given antibiotics.  
• Recommended that pre-operative antibiotics should routinely be used in reduction mammoplasty. |
| American Society of Plastic Surgeons (2011) | **Key Points:**  
• English-language human studies: systematic reviews; randomized controlled trials (RCTs); descriptive reports (treatment or complications).  
• Databases but not dates reported.  
• Resection volume does not correlate with degree of post-op symptom relief; eligibility for surgery should be defined by symptoms rather than breast volume.  
• Increased resection weight may increase complications; patients should be informed of risk.  
• Inconclusive evidence for association of increased BMI with increased complications: discretion of surgeon to operate on patients with increased BMI. |

**Glossary**

**Body mass index (BMI)** — A measure for human body shape based on height and weight. Overweight and obese are defined as over 25 and 30 mg/kg^2^, respectively.

**Breast hypertrophy** — Usually defined as breast weight exceeding three (3) percent of total body weight (also macromastia).
Breast reduction surgery — A procedure that involves removal of breast tissue and skin (also known as reduction mammoplasty).

Gynecomastia — The benign enlargement of breast tissue in males. It may be associated with changes in testosterone levels, use of medications or presence of metabolic disorders.

Reduction Mammoplasty — See breast reduction surgery.

Symptomatic breast hypertrophy — A syndrome of persistent neck and shoulder pain, painful shoulder grooving from brassiere straps, chronic intertriginous rash of the inframammary fold, and/or frequent episodes of headache, backache and upper extremity neuropathies caused by an increase in the volume and weight of breast tissue beyond normal proportions (American Society of Plastic Surgeons, 2011).

References

Professional society guidelines/other:


Peer-reviewed references:


**Clinical trials:**

Searched clinicaltrials.gov on June 21, 2016 using terms term “reduction mammoplasty.” | Open Studies. 48 studies found, four (4) relevant.


**CMS National Coverage Determinations (NCDs):**

No NCDs identified as of the writing of this policy.

**Local Coverage Determinations (LCDs):**

No LCDs identified as of the writing of this policy.

**Commonly submitted codes**

Below are the most commonly submitted codes for the service(s)/item(s) subject to this policy. This is not an exhaustive list of codes. Providers are expected to consult the appropriate coding manuals and bill accordingly.

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Appendix A:

The Schnur nomogram (below) has been promoted for use in calculating the amount of breast tissue to be removed in reduction mammoplasty. Tissue removal (gm) per breast was developed in 1991 using survey data from plastic surgeons. Its value for distinguishing medically necessary from cosmetic procedures has not been established (American Society of Plastic Surgeons, 2011).

\[
\text{Body surface area} = \text{weight in kg}^{0.425} \times \text{height in cm}^{0.725} \times 0.007184
\]

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<th>Body Surface (m²)</th>
<th>Estimated tissue removal/breast (gm)</th>
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