**Breast Reduction Surgery and Gynecomastia Surgery**

**Policy**

*Please see amendment for Pennsylvania Medicaid at the end of this CPB.*

**Reduction Mammoplasty**

Aetna considers breast reduction surgery cosmetic unless breast hypertrophy is causing significant pain, paresthesias, or ulceration (see selection criteria below). Reduction mammoplasty for asymptomatic members is considered cosmetic.

Aetna considers breast reduction surgery medically necessary for non-cosmetic indications for women aged 18 or older or for whom growth is complete (i.e., breast size stable over one year) when any of the following criteria (I, II, or III) is met:

I. Macromastia: all of the following criteria must be met:

   A. Member has persistent symptoms in at least 2 of the anatomical body areas below, directly attributed to macromastia and affecting daily activities for at least 1 year:

     - Headaches
- Pain in neck
- Pain in shoulders
- Pain in upper back
- Painful kyphosis documented by X-rays
- Pain/discomfort/ulceration from bra straps cutting into shoulders
- Skin breakdown (severe soft tissue infection, tissue necrosis, ulceration, hemorrhage) from overlying breast tissue
- Upper extremity paraesthesias;

and

B. All of the following criteria are met:

1. Photographic documentation confirms severe breast hypertrophy;
   and

   a. There is a reasonable likelihood that the member’s symptoms are primarily due to macromastia; and
   b. Reduction mammoplasty is likely to result in improvement of the chronic pain; and
   c. Pain symptoms persist as documented by the physician despite at least a 3-month trial of therapeutic measures such as:

      - Analgesic/non-steroidal anti-inflammatory drugs (NSAIDs) interventions and/or muscle relaxants
      - Dermatologic therapy of ulcers, necrosis and refractory infection
      - Physical therapy/exercises/posturing maneuvers
      - Supportive devices (e.g., proper bra support, wide bra straps)
      - Chiropractic care or osteopathic manipulative treatment
      - Medically supervised weight loss program
      - Orthopedic or spine surgeon evaluation of spinal pain;

   and
2. Women 50 years of age or older are required to have a mammogram that was negative for cancer performed within the two years prior to the date of the planned reduction mammoplasty;

and

C. The surgeon estimates that at least the following amounts (in grams) of breast tissue, not fatty tissue, will be removed from each breast, based on the member's body surface area (BSA) calculated using the Mosteller formula:

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To calculate body surface area (BSA) see:

BMI and BSA (Mosteller)

OR

BSA (m²) = (height (in) x weight (lb))/3131 ($^{\frac{1}{2}}$ denotes square root)

BSA (m²) = (height (cm) x weight (kg))/3600 ($^{\frac{1}{2}}$ denotes square root)

Note: Breast reduction surgery will be considered medically necessary for women meeting the symptomatic criteria specified above, regardless of BSA, with more than 1 kg of breast tissue to be removed per breast.

Note: Chronic intertrigo, eczema, dermatitis, and/or ulceration in the inframammary fold in and of themselves are not considered medically necessary indications for reduction mammoplasty. The condition not only must be unresponsive to dermatological treatments (e.g., antibiotics or antifungal therapy) and conservative measures (e.g., good skin hygiene, adequate nutrition) for a period of 6 months or longer, but also must satisfy criteria stated in section I above.

Aetna considers liposuction-only reduction mammoplasty experimental and investigational because of insufficient evidence of its effectiveness.

II. Gigantomastia of Pregnancy:

The member has gigantomastia of pregnancy accompanied by any of the
following complications, and delivery is not imminent:

- Massive infection;
- Significant hemorrhage;
- Tissue necrosis with slough;
- Ulceration of breast tissue.

III. Asymmetry:

For medical necessity criteria for surgery to correct breast asymmetry, see CPB 0185 - Breast Reconstructive Surgery (../100_199/0185.html).

Gynecomastia Surgery

Aetna considers breast reduction, surgical mastectomy or liposuction for gynecomastia, either unilateral or bilateral, a cosmetic surgical procedure. Medical therapy should be aimed at correcting any reversible causes (e.g., drug discontinuance). Furthermore, there is insufficient evidence that surgical removal is more effective than conservative management for pain due to gynecomastia.

See also CPB 0031 - Cosmetic Surgery (0031.html), and CPB 0185 - Breast Reconstructive Surgery (../100_199/0185.html).

Background

Reduction Mammoplasty

Reduction mammoplasty or breast reduction surgery reduces the volume and weight of the female breasts by removing excess fat, glandular tissue and skin. The goals of the surgery are to relieve symptoms caused by heavy breasts, to create a natural, balanced appearance with normal location of the nipple and areola, to maintain the capacity for lactation and allow for future breast exams/mammograms with minimal scarring or decreased sensation.
The traditional method of breast reduction requires an open incision around the areola extending downward to the crease beneath the breast. The surgeon removes excess tissue, fat and skin before adjusting the placement of the nipple and areola appropriately.

In a liposuction-only reduction mammoplasty, a small access incision is made in one of the following locations: axillary (under the arm), periareolar (around the nipple) or in the inframammary fold (under the breast). Anesthesia may be injected along with saline solution until the tissue is firm, and a suction cannula is used to extract fat from the breast.

Reduction mammoplasty is among the most commonly performed cosmetic procedures in the United States. Reduction mammoplasty performed solely for cosmetic indications is considered by insurers to be not medically necessary treatment of disease and subject to the standard cosmetic surgery plan exclusion.

Reduction mammoplasty has also been used for relief of pain in the back, neck and shoulders. Because reduction mammoplasty may be used for both medically necessary and cosmetic indications, Aetna has set forth above objective criteria to distinguish medically necessary reduction mammoplasty from cosmetic reduction mammoplasty.

Reduction mammoplasty has been performed to relieve back and shoulder pain on the theory that reducing breast weight will relieve this pain. For pain interventions, evidence of effectiveness is necessary from well controlled, randomized prospective clinical trials assessing effects on pain, disability, and function. Well-designed trials are especially important in assessing pain management interventions to isolate the contribution of the intervention from placebo effects, the effects of other concurrently administered pain management interventions, and the natural history of the medical condition. Because of their inherently subjective nature, pain symptoms are especially prone to placebo effects.

In the case of reduction mammoplasty for relief of back, neck and shoulder pain, Aetna has considered this procedure medically necessary in women with excessively large breasts because it seems logical, even in the absence of firm clinical trial evidence, that this excessive weight would contribute to back and shoulder pain, and that removal of this excessive breast tissue would provide substantial pain relief, reductions in disability, and improvements in function.
The goal of medically necessary breast reduction surgery is to relieve symptoms of pain and disability. If an insufficient amount of breast tissue is removed, the surgery is less likely to be successful in relieving pain and any related symptoms from excessive breast weight (e.g., excoriations, rash).

Insurers have commonly used the amount of breast tissue to be removed as a criterion for evaluating the medical necessity of breast reduction surgery. In a survey of managed care policies regarding breast reduction surgery, Krieger and colleagues reported (2001) found that most of the respondents stated that they use weight of excised tissue as the main criterion for allowing the procedure, with an average cut-off value of 472 grams for a typical woman. Seitchik (1995) reviewed the amount of breast tissue removed from a series of 100 patients that underwent breast reduction surgery. The author average amount of breast tissue removed for women in 5 kg weight bands, ranging from 45-49 kg to 90+ kg. The average amount of breast tissue removed ranged from 430 g per breast to 1.6 kg per breast, with increased body weight associated with an increased amount of breast tissue to be removed. The average amount of tissue removed from an average weight woman (within the 70 to 74.9 kg weight band) in this study was 60 g per breast, with a range of 502 g to 700 g of tissue removed per breast.

Schnur et al (1991) reported on a sliding scale assigns a weight of breast tissue to be removed based on body weight and surface area. The study by Schnur et al was based on a survey of 92 plastic surgeons who reported on their care for 591 patients. Each surgeon who participated in the study reported on the height, weight, and volume of reduction of their last 15 to 20 patients, and each surgeon provided their “intuitive sense” regarding the motivation of each patient for breast reduction surgery. Schnur subsequently refuted the validity of the Schnur sliding scale and stated that the scale should no longer be used as a criterion for the determination of insurance coverage for breast reduction surgery (Nguyen et al, 1999).

Some individuals, however, have argued that reduction mammoplasty may be indicated in any woman who suffers from back and shoulder pain, regardless of how small her breasts are or how little tissue is to be removed (ASPS, 2002). They have argued that removal of even a few hundred grams of breast tissue can result in substantial pain relief. These individuals cite evidence from observational studies to support this position (e.g., Chadbourne et al, 2001; Kerrigan et al, 2001).
These studies did not find a relationship between breast weight or amount of breast tissue removed and the likelihood of response or magnitude of relief of pain after reduction mammoplasty.

It is not intuitively obvious, however, that breast weight would substantially contribute to back, neck and shoulder pain in women with normal or small breasts. Nor is it intuitively obvious that removal of smaller amounts of breast tissue would offer significant relief of back, shoulder or neck pain.

Criteria for reduction mammoplasty surgery from the American Society of Plastic Surgeons (ASPS, 2002; ASPS, 2011) states, among other things, that breast weight or breast volume is not a legitimate criterion upon which to distinguish cosmetic from functional indications. This conclusion is based primarily upon the Breast Reduction Assessment of Value and Outcomes (BRAVO) study, which is described in several articles (Kerrigan et al, 2001; Kerrigan et al, 2002; Collins et al, 2002). There are also several earlier, smaller studies that found reductions in symptoms and improvements in quality of life after reduction mammoplasty (Glatt et al, 1999; Bruhlmann and Tschopp, 1998; Blomqvist et al, 2000; and Behmand et al, 2000).

As explained below, the studies used to support the arguments for the medical necessity of breast reduction surgery are poorly controlled and therefore subject to a substantial risk of bias in the interpretation of results. Furthermore, the lack of an expected "dose-response" relationship between the amount of breast tissue removed and the magnitude of symptomatic relief in these studies raises questions about the validity of these studies and the effectiveness of breast reduction as a method of relieving shoulder and back pain.

A study reporting on a survey of health insurer policies on breast reduction surgery (Nguyen et al, 2004) found that no insurer medical policies could be supported by the medical literature. The authors (Nguyen et al, 2004) argue, based primarily on the results of the ASPS-funded BRAVO study (described below), that (with a single exception) no objective criteria for breast reduction surgery are supportable, including criteria based upon the presence of particular signs or symptoms, requirements based upon breast size or the amount of breast tissue removed, any minimum age limitations, any limitation based upon maximum body weight, requirements for a trial of conservative therapy, or the exclusion of certain procedures (liposuction). The only criterion that the authors found supportable
was a requirement for a pre-operative mammogram for women aged 40 years and older. The authors leave the reader with the conclusion that decisions about the medical necessity of breast reduction surgery in symptomatic women should be left entirely to the surgeon's discretion.

Several important points should be considered in evaluating these challenges to insurers' criteria for breast reduction surgery. First, the opinions and guidelines of medical professional organizations and consensus groups are considered according to the quality of the scientific evidence and supporting rationale. Second, it is the burden of the proponent of an intervention to provide reliable evidence of its effectiveness, not the burden of ones who question the effectiveness an intervention to provide definitive proof of ineffectiveness. Third, reliable evidence is especially important for pain interventions, because of the waxing and waning nature of pain and the susceptibility of this symptom to placebo effects and other biases that may confound interpretation of study results. Fourth, insurers have provided coverage for reduction mammaplasty in women with excessively large breasts; thus, the debate is about the effectiveness of removal of smaller amounts of breast tissue from women whose breast size most persons would consider within the normal range.

The authors of the BRAVO study reached several conclusions about reduction mammaplasty, most notably that breast size or the amount of breast tissue removed does not have any relationship to the outcome of breast reduction surgery (Kerrigan et al, 2002; Collins et al, 2002). The authors reach the remarkable conclusion that a woman with normal sized breasts who has only a few ounces of breast tissue removed is as likely to receive as much benefit from breast reduction surgery as a women with large breasts who has substantially more breast tissue removed. However, the BRAVO study is not of sufficient quality to reach reliable conclusions about the effectiveness of breast reduction surgery as a pain intervention. Although the BRAVO study is described as a controlled study, the "control" group is obtained, not from the same cohort, but from a separate cohort of individuals recruited from newspaper advertisements and solicitations at meetings for inclusion in a study of the population burden of breast hypertrophy; 75 % of this control group were obtained from 2 centers, but the characteristics of those 2 centers were not described. The control group was not followed longitudinally or treated according to any protocol to ensure that they received optimal conservative management; conclusions about the lack of effectiveness of conservative management were based on their responses to a questionnaire about whether
subjects tried any of 15 conservative interventions, and whether or not they thought these interventions provided relief of symptoms. Based largely upon these results, Nguyen et al (2004) reached the conclusion that a trial of conservative management is not an appropriate criterion for insurance coverage, even though responses to the BRAVO questionnaire indicated that operative candidates and hypertrophy controls received at least some pain relief from all of the conservative interventions, and for some conservative interventions, virtually all subjects reported at least some pain relief. In addition, Nguyen et al (2004) ignored a wealth of published evidence of the effectiveness of physical therapy, analgesics and other conservative measures on back and neck pain generally.

The operative group in the BRAVO study was drawn from a number of surgical practices that volunteered to participate in the study; no details are provided about how each center selected candidates for reduction mammaplasty, or how they chose patients who underwent mammaplasty for inclusion in the study. Of 291 subjects who were selected for inclusion in the study, only 179 completed follow-up. Thus, more than 1/3 of operative subjects selected for inclusion in the study did not complete it; most of the operative subjects who did not complete the study were lost to follow-up. Although the BRAVO study nominally included a "control group", there was no comparison group of subjects selected from the same cohort, who were randomized or otherwise appropriately assigned to reduce bias, and treated with conservative management according to a protocol to ensure optimal conservative care. Clinical outcomes were measured by operative subjects' responses to a questionnaire about symptoms and quality of life. The authors stated that operative subjects were told that their responses to the questionnaire were not to be used for insurance and thus the subjects had no motivation to exaggerate symptoms prior to surgery in questionnaire responses; however, it is not clear whether operative subjects would be willing to submit responses to a questionnaire from the doctor that differed substantially from the history that they provided to the doctor during their preoperative evaluation. Although operative subjects were examined before and after surgery, there was no attempt to employ any blinded or objective measures of disability and function to verify these self-reports. Operative subjects who completed the study reported reductions in pain and improvements in quality of life; however, these improvements may be attributable to placebo effects, the natural history of back pain, other concurrent interventions, regression to the mean, improvements in cosmesis (for quality of life measures), or other confounding variables that may bias in interpretation of results. Thus, this study would not be considered of sufficient quality to provide reliable
evidence of the effectiveness of a pain intervention.

Other references to smaller studies published prior to the BRAVO study have been cited, examining symptoms before and after reduction mammoplasty; each of these studies suffer from limitations similar to those identified with the BRAVO study. A study by Glatt et al (1999) was a retrospective analysis of responses to questionnaires sent to patients who underwent reduction mammoplasty regarding physical symptoms and body image. Of 110 subjects who were mailed questionnaires, approximately 50 % (61 subjects) provided responses. The investigators found little difference between obese and non-obese women concerning patient's reports of resolution of symptoms and improvement in body image. A study by Bruhlmann and Tschopp (1998) was a retrospective study of 246 patients from a surgical practice, approximately 50 % (132) of whom returned a questionnaire about their symptoms and satisfaction with aesthetic results, and their recollection of symptoms prior to surgery. It should be noted that this study reported a strong correlation between the amount of tissue removed and pain amelioration. It was also found that only 3 % of subjects reported that they had no aesthetic motivation for surgery. Behmand et al (2000) reported on the results of a questionnaire pre- and post-surgery in 69 subjects from a single practice who underwent reduction mammoplasty. Subjects were compared to age-matched norms from another study cohort. No data were provided on loss to follow-up. The article by Blomqvist et al (2000) is to another questionnaire study about health status and quality of life before and after surgery. Approximately 25 % of the 49 subjects included in this study did not return the post-operative questionnaire. Subjects responses were compared to an age-matched comparison group of women, although no further details about how this comparison group were provided. The investigators reported that subjects who were of normal weight were as likely to report benefit from reduction mammoplasty as subjects who were overweight.

The studies used to support the arguments for the medical necessity of breast reduction surgery are poorly controlled and therefore subject to a substantial risk of bias in the interpretation of results. Well-designed, prospective, controlled clinical studies have not been performed to assess the effectiveness of surgical removal of modest amounts of breast tissue in reducing neck, shoulder, and back pain and related disability in women. In addition, reduction mammoplasty needs to be compared with other established methods of relieving back, neck and shoulder
pain. Well-designed clinical trials provide reliable information about the effectiveness of an intervention, and provide valid information about the characteristics of patients who would benefit from that intervention.

For these reasons, there is insufficient evidence to support the use of reduction mammaplasty, without regard to the size of the breasts or amount of breast tissue to be removed, as a method of relieving chronic back, neck, or shoulder pain.

The American Society of Plastic Surgeons’ evidence-based clinical practice guideline on reduction mammaplasty (ASPS, 2011) states that in standard reduction mammaplasty procedures, evidence indicates that the use of drains is not beneficial. However, if liposuction is used as an adjunctive technique, the decision to use drains should be left to the surgeon’s discretion.

The American Society for Plastic Surgery (2011) advises to delay surgery until breast growth ceases: “Although waiting may prolong the psychological awkwardness, it is advisable to delay surgery until breast growth ceases in order to achieve the best result.” This is similar to the American College of Obstetricians and Gynaecologists’ 2011 Guidelines for Adolescent Health Care chapter on breast concerns in adolescents, which states regarding breast hypertrophy: “Preferably, treatment should be deferred until breast growth has been completed. If breast growth has been completed, breast reduction surgery is an option.” Marshall and Tanner (1969) shows that the final stage of breast maturity occurs about age 15 on average, but there is wide variation. Sabiston’s Textbook of Surgery (Burns & Blackwell, 2008) states that breast size should be stable for one year: “There is no set lower age limit but, for the adolescent with breast hypertrophy, reduction is deferred until the breasts have stopped growing and are stable in size for at least 12 months before surgery.”

Fischer et al (2014a) evaluated predictors of postoperative complications following reduction mammaplasty using the NSQIP) data sets. The NSQIP recorded two complication types: major complications (deep infection and return to operating room) and any complication (all surgical complications). Preoperative patient factors and comorbidities, as well as intraoperative variables, were assessed. Study subjects included 3538 patients with an average age of 43 years and body mass index of 31.6 kg/m(2) and most patients underwent outpatient surgery (80.5%) with an average operative time of 180 minutes. The incidence of overall surgical complications was 5.1% and the incidence of major surgical complications was
2.1%. The following factors were independently associated with any surgical complications: morbid obesity (odds ratio [OR], 2.1; P < .001), active smoking (OR, 1.7; P < .001), history of dyspnea (OR, 2.0; P < .001), and resident participation (OR, 1.8; P = .01) while factors associated with major complications included active smoking (OR, 2.7; P < .001), dyspnea (OR, 2.6; P < .001), resident participation (OR, 2.1; P < .001), and inpatient surgery (OR, 1.8; P = .01). The authors specified the value of these study results was in the identification of morbid obesity as a significant predictor of overall morbidity and active smoking as a strong predictor of major surgical morbidity.

Karamanos et al (2015) noted that although breast reduction mammoplasty accounts for more than 60,000 procedures annually, the literature remains sparse on outcomes. In this study the National Surgical Quality Improvement Program data set was queried for the Current Procedural Terminology code 19318 from the years 2005 to 2010, with principal outcome measurements of wound complications, surgical site infections, and reoperations. A total of 2779 patients were identified with a mean age of 42.7 (14.1) years and BMI of 31.6 (7.0) kg/m. Tobacco use was shown to have a higher rate of reoperation (p= 0.02) and BMI was identified as an independent risk factor for wound complications (odds ratio, 1.85, P = 0.005). The authors also noted that patients with BMI greater than 40 kg/m were significantly more likely to develop postoperative wound complications (p = 0.02). Karamanos et al (2015) identified their study as the largest sample on breast reduction in the literature, in which age and surgeon specialty did not correlate with negative results. In contrast, tobacco use and BMI were associated with worse breast reduction outcomes.

Nelson et al (2014a) analyzed population data from the 2005-2010 American College of Surgeons National Surgical Quality Improvement Program (NSQIP) database. They investigated effects of age on 30-day surgical outcomes for reduction mammoplasty with a goal of improving patient care, counseling, and risk stratification on 3537 patients. The study subjects were stratified into groups based on ages of <60 years and ≥60 years. Subgroup analysis further stratified the younger cohort into those <50 years and 50-60 years of age. Results illustrated that 3050 patients were <60 years of age (39.7 ± 11.8 years) and 487 were ≥60 years of age (65.1 ± 4.7 years). A total of 182 thirty-day postoperative surgical complications were documented, but stratifying patients into 2 age groups did not reveal an
association between age and any surgical complication (P = .26). The authors concluded that with proper patient selection, reduction mammoplasty can be performed safely on older patients.

Nelson et al (2014b) separately conducted a population level analysis of the 2005-2011 NSQIP datasets, identifying patients who underwent reduction mammoplasty, to determine the impact of obesity on early complications after reduction mammoplasty. Data was then analyzed for surgical complications, wound complications, and medical complications within 30 days of surgery on 4545 patients. Within this study population, 54.4% of patients were obese (BMI > 30 kg/m²), of which 1308 (28.8%) were Class I (BMI = 30-34.9 kg/m²), 686 (15.1%) were Class II (BMI = 35-39.9 kg/m²), and 439 (9.7%) were Class III (BMI > 40 kg/m²). The investigators found that comorbid conditions increased across obesity classifications (p < 0.001), with significant differences noted in all cohort comparisons except when comparing class I to class II (p = 0.12). Early complications were rare (6.1%), with superficial skin and soft tissue infections accounting for 45.8% of complications. Examining any complication, a significant increase was noted with increasing obesity class (p < 0.001). This was further isolated when comparing morbidly obese patients to non-obese (p < 0.001), class I (p < 0.001), and class II (p = 0.01) patients. This population-wide analysis - the largest and most heterogeneous study to date - has demonstrated that increasing obesity class is associated with increased early postoperative complications. Morbidly obese patients are at the highest risk, with complications occurring in nearly 12% of this cohort.

Srinivasah et al (2014) stated that although reduction mammoplasty has been shown to benefit physical, physiological, and psycho-social health there are recognized complications. The authors recruited 67 consecutive female patients who underwent inferior pedicle reduction mammoplasty in order to determine the effects of resection weight, BMI, age, and smoking on complication rates following reduction mammoplasty. Data were prospectively gathered on complications as a part of randomized control trial (RCT) examining psycho-social and quality of life (QOL) benefits of reduction mammoplasty. Sixteen (23%) patients had complications and higher resection weight, increased BMI, and older age were found to have statistically significant complication rates with p-values of p < 0.001, p = 0.034, and p = 0.004, respectively. The investigators also found that the incidence of complications was highest among current smokers and lowest among those who had never smoked with a 37% difference in the occurrence of
complication (p < 0.01). They concluded that higher resection weight, increased BMI, older age, and smoking are risk factors for complication and that patients should therefore be adequately counseled about losing weight and stopping smoking.

Merkkola-von Schantz and colleagues (2017) stated that contralateral reduction mammoplasty is regularly included in the treatment of breast cancer patients. These investigators analyzed the incidence of occult breast cancer and high-risk lesions in reduction mammoplasty specimens of women with previous breast cancer. They also analyzed if timing of reduction mammoplasty in relation to oncological treatment influenced the incidence of abnormal findings, and compared if patients with abnormal contralateral histopathology differed from the study population in terms of demographics. The study consisted of 329 breast cancer patients, who underwent symmetrizing reduction mammoplasty between 1/2007 and 12/2011. The data were retrospectively analyzed for demographics, operative and histopathology reports, oncological treatment, and post-operative follow-up. Reduction mammoplasty specimens revealed abnormal findings in 68 (21.5 %) patients. High-risk lesions (atypical ductal hyperplasia [ADH], atypical lobular hyperplasia [ALH], and lobular carcinoma in situ [LCIS]) were revealed in 37 (11.7 %), and cancer in 6 (1.9 %) patients. Abnormal histopathology correlated with higher age (p = 0.0053), heavier specimen (p = 0.0491), and with no previous breast surgery (p < 0.001). Abnormal histopathological findings were more frequent in patients with reduction mammoplasty performed prior to oncological treatment (p < 0.001), and in patients with immediate reconstruction (p = 0.0064). The authors concluded that the incidences of malignant and high-risk lesions were doubled compared to patients without prior breast cancer. Patients with abnormal histopathology could not be pre-operatively identified based on demographics. If reduction mammoplasty was performed before oncological treatment, the incidence of abnormal findings was higher. They stated that in the light of these findings, contralateral reduction mammoplasty with histopathological evaluation in breast cancer patients offered a sophisticated tool to catch those patients whose contralateral breast needs increased attention.

Mistry and associates (2017) examined outcomes following breast re-reduction surgery using a random pattern blood supply to the nipple and vertical scar reduction. A retrospective review was conducted of patients who underwent bilateral breast re-reduction surgery performed by a single surgeon over a 12-year period. Patient demographics, surgical technique, and outcomes were analyzed. A
total of 90 patients underwent breast re-reduction surgery. The average interval between primary and secondary surgery was 14 years (range of 0 to 42 years). The majority of patients had previously undergone primary breast reduction using an inferior pedicle [n = 37 (41%)]. Breast re-reduction surgery was most commonly performed using a random pattern blood supply, rather than recreating the primary pedicle [n = 77 (86%)]. The nipple-areola complex was re-positioned in 60% of patients (n = 54). The mean volume of tissue resected was 250 g (range of 22 to 758 g) from the right breast and 244 g (range of 15 to 705 g) from the left breast. Liposuction was also used adjunctively in all cases (average of 455 cc; range, 50 to 1,750 cc). Two patients experienced unilateral minor partial necrosis of the areolar edge but not of the nipple itself (2%). The authors concluded that breast re-reduction can be performed safely and predictably, even when the previous technique is not known; and 4 key principles were developed: (i) the nipple-areola complex can be elevated by de-epithelialization rather than recreating or developing a new pedicle; (ii) breast tissue is removed where it is in excess, usually inferiorly and laterally; (iii) the resection is complemented with liposuction to elevate the bottomed-out inframammary fold; and (iv) skin should not be excised horizontally below the inframammary fold. Level of Evidence = IV.

Post-Operative Wound Drains in Reduction Mammoplasty

In a Cochrane review, Khan and colleagues (2015) stated that wound drains are often used after plastic and reconstructive surgery of the breast in order to reduce potential complications. However, it is unclear if there is any evidence to support this practice. These researchers compared the safety and effectiveness of the use of wound drains following elective plastic and reconstructive surgery procedures of the breast. For the first update of this review, these investigators searched the Cochrane Wounds Group Specialised Register (searched March 4, 2015); the Cochrane Central Register of Controlled Trials (CENTRAL) (The Cochrane Library 2015, Issue 2); Ovid Medline (2012 to March 3, 2015); Ovid Medline (In-Process & Other Non-Indexed Citations March 3, 2015); Ovid Embase(2012 to March 3, 2015); and EBSCO CINAHL (2012 to March 4, 2015). There were no restrictions on the basis of date or language of publication. Three review authors undertook independent screening of the search results. All RCTs that compared the use of a wound drain with no wound drain following plastic and reconstructive surgery of the breast (breast augmentation, breast reduction and breast reconstruction) in women were eligible. Two review authors undertook independent data extraction of study
characteristics, methodological quality and outcomes (e.g., infection, other wound complications, pain, and length of hospital stay [LOS]). Risk of bias was assessed independently by 2 review authors. These researchers calculated the risk ratio (RR) for dichotomous outcomes and mean differences (MD) for continuous outcomes, with 95% confidence intervals (CI). Analysis was on an intention-to-treat basis. A total of 3 RCTs were identified and included in the review out of 190 studies that were initially screened; all evaluated wound drainage after breast reduction surgery. No new trials were identified for this first update. In total there were 306 women in the 3 trials, and 505 breasts were studied (254 drained, and 251 who were not drained). Apart from a significantly shorter LOS for those participants who did not have drains (MD 0.77; 95% CI: 0.40 to 1.14), there was no statistically significant impact of the use of drains on outcomes. The authors concluded that the limited evidence available showed no significant benefit of using post-operative wound drains in reduction mammoplasty, although LOS may be shorter when drains are not used. They stated that no data are available for breast augmentation or breast reconstruction, and this requires investigation.

Sugrue and associates (2015) evaluated the current practice patterns of drains usage by plastic and reconstructive and breast surgeons in United Kingdom (UK) and Ireland performing bilateral breast reduction (BBR). An 18-question survey was created evaluating various aspects of BBR practice; UK and Irish plastic and reconstructive and breast surgeons were invited to participate by an e-mail containing a link to a web-based survey. Statistical analysis was performed with student t-test and chi-square test. A total of 211 responding surgeons were analyzed, including 80.1% (171/211) plastic surgeons and 18.9% (40/211) breast surgeons. Of the responding surgeons, 71.6% (151/211) routinely inserted post-operative drains, for a mean of 1.32 days. Drains were used significantly less by surgeons performing greater than or equal to 20 BBRs (p = 0.02). With the majority of BBRs performed as an inpatient procedure, there was a trend towards less drain usage in surgeons performing this procedure as an out-patient; however, this was not statistically significant (p = 0.07). The authors concluded that even with the high level of evidence demonstrating the safety of BBR without drains, they are still routinely utilized. These investigators stated that in an era of evidence-based medicine, surgeons performing breast reductions must adopt the results from scientific research into their clinical practice.

Gynecomastia Surgery
Gynecomastia is a very common concern of male adolescence. Sixty to 70% of males develop a transient subareolar breast tissue during their adolescence (Tanner Stages II and III). Causes may include testosterone-estrogen imbalance, increased prolactin levels, or abnormal serum binding protein levels.

Gynecomastia has been classified into 2 types. In Type I (idiopathic) gynecomastia, the adolescent presents with a tender, firm mass beneath the areola. Most cases of type I gynecomastia are unilateral, and 20% of cases are bilateral. Type II gynecomastia is more generalized breast enlargement. Pseudogynecomastia refers to excessive fat tissue or prominent pectoralis muscles.

Gynecomastia may be drug-induced. Drugs commonly associated with the development of gynecomastia include amphetamines, marijuana, mebrobamate, opiates, amitriptyline, chlordiazepoxide, chlorpromazine, cimetidine, diazepam, digoxin, fluphenazine, haloperidol, imipramine, isoniazid, mesoridazine, methylodopa, perphenazine, phenothiazines, reserpine, spironolactone, thiethylperazine, tricyclic antidepressants, tirfluoperazine, trimeperazine, busulfan, vincristine, tamoxifen, methyltestosterone, human chorionic gonadotropins, and estrogens. Klinefelter's syndrome, testicular, adrenal, or pituitary tumors, and thyroid or hepatic dysfunction are also associated with gynecomastia.

Henley et al (2007) reported that repeated topical exposure to lavender and tea tree oils may be linked to prepubertal gynecomastia (idiopathic gynecomastia).

Management of gynecomastia should include evaluation, including laboratory testing, to identify underlying etiologies. Work-up of gynecomastia may include the following (GP Notebook, 2003):

- A detailed drug history, including list of medications, an assessment of indirect or environmental exposure to estrogenic compounds, and recreational drug use.
- A detailed physical examination, including testicular examination.
- Liver and thyroid function tests.
- Measurement of plasma gonadotrophins, human chorionic gonadotropin (hCG), testosterone, estradiol, and dehydroepiandosterone sulphate (DHEAS)
- An ultrasound scan of testicular masses
- Computed tomography scan of adrenal glands to identify adrenal lesions.
Treatment should be directed at correcting any underlying reversible causes. If gynecomastia is idiopathic, reassurance of the common, transient and benign nature of the condition should be given. Resolution of idiopathic gynecomastia may take several months to years. In a majority of boys with pubertal gynecomastia, the condition resolves within 18 months. Medical reduction has been achieved with agents such as dihydrotestosterone, danazol, and clomiphene. However, these medications should be reserved for those with no decrease in breast size after 2 years. Surgical removal is rarely indicated and the vast majority of the time is for cosmetic reasons, as there is no functional impairment associated with this disorder.

Many men with breast enlargement are found to have pseudo-gynecomastia. Removing the adipose tissue in pseudogynecomastia usually has no long term effect as adipose tissue reaccumulates unless the individual loses weight. A physician-supervised diet and exercise plan may be indicated in obese patients.

Transient pain that may occur as the breast enlarges and the capsule is stretched; these symptoms may be managed with analgesics. Mental health care professionals may be consulted to address psychological distress from gynecomastia.

In a review on “Surgical treatment of primary gynecomastia in children and adolescents”, Fischer et al (2014b) concluded that surgical correction of gynecomastia remains a purely elective intervention.

Autologous Platelet Gel During Breast Surgery

In a within-patient, randomized, patient- and assessor-blinded, controlled study, Anzarut et al (2007) evaluated the use of completely autologous platelet gel in 111 patients undergoing bilateral reduction mammoplasty to reduce post-operative wound drainage. Patients were randomized to receive the gel applied to the left or right breast after hemostasis was achieved; the other breast received no treatment. The primary outcome was the difference in wound drainage over 24 hours. Secondary outcomes included subjective as well as objective assessments of pain and wound healing. No statistically significant differences in the drainage, level of pain, size of open areas, clinical appearance, degree of scar pliability, or scar
erythema were noted. These investigators concluded that their findings do not support the use of completely autologous platelet gel to improve outcomes after reduction mammoplasty.

**Changes in Psychological Aspects after Gynecomastia Surgery**

Sollie (2018) noted that gynecomastia affects up to 2/3 of the male population. For many patients the psychological impact of the disease is substantial. Surgical treatment is indicated when medical treatments fail. Until now, most published research on the subject has focused on how effective surgical treatment is on correcting the cosmetic appearance of the breast. Little is known about the effect of surgical treatment on the psychological aspects of the disease. The author identified the psychological domains affected by the disease and the effect of surgical treatment on these. A systematic search of the published literature was performed. All studies on the subject were evaluated for inclusion and 6 studies were included in the review. Several of the included studies reported improvement in QOL and several psychological domains after surgical treatment for gynecomastia. Among these domains were: vitality, emotional discomfort, limitations due to physical aspects and limitations due to pain. Impact of surgical treatment for gynecomastia appeared to be beneficial for several psychological domains. The author concluded that the current level of evidence on this subject was very low and future studies, examining the impact of the surgical intervention for gynecomastia on psychological domains, are greatly needed. This investigators stated that these studies should include data from older individuals affected by gynecomastia and utilize valid tools of psychological measurement in order to better quantify the effect; elderly patients affected by the disease have been overlooked in the current research; more data on this subject could improve the pre-operative evaluation of these patients and help identify the patients who will benefit from treatment.

**Tamoxifen in the Treatment of Idiopathic Gynecomastia**

Kasielska-Trojan and associates (2018) analyzed digit ratio in relation to estrogen receptor (ER) and progesterone receptor (PR) expression and verified digit ratio (2D: 4D) as a marker of ER and PR over-expression in the male breast. This study included 35 patients who underwent breast reduction due to the idiopathic form of gynecomastia. The average age of the studied individuals was 25.7 years (SD = 7.8); ER and PR expression was detected in breasts, and digit ratios were
calculated in patients with idiopathic gynecomastia. ER expression did not correlate with the right (p = 0.51) and left 2D: 4D (p = 0.97). Also, there was no correlation between PR expression and 2D: 4D. A lack of correlation between these variables may result from the fact that the analyzed group of men with idiopathic gynecomastia was small in number, but at the same time, it appeared to be homogenous in these aspects (positive ER and/or PR expression and high digit ratio). The authors concluded that high digit ratio in men with gynecomastia may tend to be a marker of over-expression of ER and PR. This may justify an early use of tamoxifen in men with gynecomastia and a high digit ratio.

Mannu and colleagues (2018) stated that idiopathic gynecomastia is a benign breast disorder characterized by over-development of male breast tissue. It can cause discomfort and concern, resulting in patients seeking diagnosis and treatment. In a prospective, cohort study, these investigators evaluated the efficacy of tamoxifen therapy in resolving this condition. This trial included all male patients who presented to the authors’ breast clinic who were diagnosed with primary gynecomastia, and were treated with a trial of tamoxifen 10 mg daily therapy, over a 10-year period from October 2004 to October 2015. All patients underwent routine investigations to exclude secondary causes of gynecomastia. The endpoint was the complete resolution of gynecomastia. A total of 81 patients were included in this study. The mean age was 42.8 years (SD 19.5 years). Of these, 28.4 % were bilateral gynecomastia and 71.6 % were unilateral. The majority (87.7 %) of cases presented with accompanying mastalgia. Following treatment, 90.1 % (n = 73) had a complete response of their gynecomastia with tamoxifen therapy. Only 8 (9.9 %) patients did not have a complete resolution following tamoxifen therapy, of which 2 underwent subsequent surgical resection of their symptomatic gynecomastia. The authors concluded that this study was the largest to-date examining the role of tamoxifen in idiopathic gynecomastia, and these findings showed approximately 9 in every 10 men treated with tamoxifen therapy had successful resolution of their symptoms. These investigators support its use for idiopathic gynecomastia in eligible men following the careful discussion of its risks and benefits.

Appendix

Drugs associated with gynecomastia
- Estrogens and estrogen like drugs, including:
  - Diethylstibestrol;
  - Exposure to partners using estrogen containing vaginal creams;
  - Cosmetics containing estrogens
  - Digitoxin

- Drugs that enhance estrogen formation, including:
  - Gonadotrophins such as hCG
  - Following withdrawal of clomiphene

- Drugs which inhibit testosterone synthesis, including
  - Ketoconazole,
  - Metronidazole,
  - Spironolactone,
  - Cancer chemotherapy (alkylating agents, methotrexate, vinca alkaloids, imatinib, combination chemotherapy)

- Drugs that inhibit testosterone action, including
  - Androgen receptor blockers - bicalutamide
  - 5 α reductase inhibitors - finasteride, dutasteride
  - H2 blockers and proton pump inhibitors
  - Marijuana

- Drugs whose mechanism of action is unknown:
  - Tricyclic antidepressants
  - Angiotensin converting enzyme inhibitors (captopril, enalapril)
  - Heroin
  - Amiodarone
  - Busulfan
  - Methylldopa
  - Captopril
  - Growth hormone
• Reserpine
• Highly active antiretroviral therapy
• Calcium channel blockers (diltiazem, nifedipine, verapamil)
• Isoniazid

Others situations which can cause or lead to gynecomastia:

- Anabolic steroids (e.g., in bodybuilders)
- Healing balms, scented soaps, skin lotions, shampoos and styling gels containing lavender oil or tea tree oil

Adapted from General Practice Notebook.

American Society of Plastic Surgeons' gynecomastia scale:

- Grade II: Moderate breast enlargement exceeding areola boundaries with edges that are indistinct from the chest.
- Grade III: Moderate breast enlargement exceeding areola boundaries with edges that are indistinct from the chest with skin redundancy present.
- Grade IV: Marked breast enlargement with skin redundancy and feminization of the breast.

CPT Codes / HCPCS Codes / ICD-10 Codes

Information in the [brackets] below has been added for clarification purposes. Codes requiring a 7th character are represented by "+":

<table>
<thead>
<tr>
<th>Code</th>
<th>Code Description</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>CPT codes covered if selection criteria are met:</td>
</tr>
<tr>
<td>19318</td>
<td>Reduction mammoplasty</td>
</tr>
<tr>
<td></td>
<td>CPT codes not covered for indications listed in the CPB:</td>
</tr>
<tr>
<td>15877</td>
<td>Suction assisted lipectomy; trunk</td>
</tr>
<tr>
<td>19300</td>
<td>Mastectomy for gynecomastia</td>
</tr>
<tr>
<td></td>
<td>Other CPT codes related to the CPB:</td>
</tr>
<tr>
<td>17360</td>
<td>Chemical exfoliation for acne (eg, acne paste, acid)</td>
</tr>
<tr>
<td>Code</td>
<td>Code Description</td>
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<tr>
<td>-------</td>
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<tr>
<td>19301</td>
<td>Mastectomy, partial (e.g., lumpectomy, tylectomy, quadrantectomy, segmentectomy)</td>
</tr>
<tr>
<td>19316</td>
<td>Mastopexy</td>
</tr>
<tr>
<td>77065 - 77067</td>
<td>Diagnostic mammography, including computer-aided detection (CAD) when performed</td>
</tr>
<tr>
<td>96567</td>
<td>Photodynamic therapy by external application of light to destroy premalignant and/or malignant lesions of the skin and adjacent mucosa (eg, lip) by activation of photosensitive drug(s), each phototherapy exposure session</td>
</tr>
<tr>
<td>96573</td>
<td>Photodynamic therapy by external application of light to destroy premalignant lesions of the skin and adjacent mucosa with application and illumination/activation of photosensitizing drug(s) provided by a physician or other qualified health care professional, per day</td>
</tr>
<tr>
<td>98925 - 98929</td>
<td>Osteopathic manipulative treatment</td>
</tr>
<tr>
<td>98940 - 98943</td>
<td>Chiropractic manipulative treatment</td>
</tr>
<tr>
<td>99450</td>
<td>Basic life and/or disability examination that includes: Measurement of height, weight, and blood pressure; Completion of a medical history following a life insurance pro forma; Collection of blood sample and/or urinalysis complying with &quot;chain of custody&quot; protocols; and Completion of necessary documentation/certificates</td>
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Other HCPCS codes related to the CPB:

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<tr>
<td>S9449</td>
<td>Weight management classes, non-physician provider, per session</td>
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ICD-10 codes covered if selection criteria are met:

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<th>Code Description</th>
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<tr>
<td>G56.00 - G56.93</td>
<td>Mononeuropathies of upper limb [upper extremity paresthesia]</td>
</tr>
<tr>
<td>I96</td>
<td>Gangrene, not elsewhere classified [tissue necrosis]</td>
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<tr>
<td>L98.491 - L98.494</td>
<td>Non-pressure chronic ulcer of skin of other sites</td>
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<tr>
<td>N62</td>
<td>Hypertrophy of breast [symptomatic-causing significant pain, paresthesias, or ulceration]</td>
</tr>
<tr>
<td>N64.89</td>
<td>Other specified disorders of breast [soft tissue infection]</td>
</tr>
</tbody>
</table>
The above policy is based on the following references:


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60. Burdette TE, Kerrigan CL, Homa KA. Harmonic scalpel versus
electrocautery in breast reduction surgery: A randomized controlled trial.

(5):431-434.


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complications following breast reduction: Results from a randomized

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(6):641-647.

retrospective analysis of complications after oncoplastic breast reduction


AETNA BETTER HEALTH® OF PENNSYLVANIA

Amendment to
Aetna Clinical Policy Bulletin Number: 0017 Breast Reduction Surgery and Gynecomastia Surgery

For the Pennsylvania Medical Assistance Plan, mastectomy for gynecomastia (CPT code 19300) will be covered if medical necessity criteria are met.

www.aetnabetterhealth.com/pennsylvania  revised 09/13/2019