

# LCD - Cosmetic and Reconstructive Surgery (L35090)

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# LCD Information

## Document Information

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Cosmetic and Reconstructive Surgery

**Proposed LCD in Comment Period**

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## Issue

**Issue Description**

An inquiry was received to clarify, through formatting, the intent of the LCD. Formatting changes were created to section #4 Reduction Mammoplasty to aid the reader in the interpretation of the LCD. Additional formatting changes

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were made to bullets and indentations throughout the LCD to be consistent with formatting process. The URL address to the FDA page for "Risks and Complications of Breast Implants" in the Summary of Evidence section was checked for functionality. No change in coverage or content of the LCD was made.

## **CMS National Coverage Policy**

This LCD supplements but does not replace, modify or supersede existing Medicare applicable National Coverage Determinations (NCDs) or payment policy rules and regulations for cosmetic and reconstructive surgery. Federal statute and subsequent Medicare regulations regarding provision and payment for medical services are lengthy. They are not repeated in this LCD. Neither Medicare payment policy rules nor this LCD replace, modify or supersede applicable state statutes regarding medical practice or other health practice professions acts, definitions and/or scopes of practice. All providers who report services for Medicare payment must fully understand and follow all existing laws, regulations and rules for Medicare payment for cosmetic and reconstructive surgery and must properly submit only valid claims for them. Please review and understand them and apply the medical necessity provisions in the policy within the context of the manual rules. Relevant CMS manual instructions and policies may be found in the following Internet-Only Manuals (IOMs) published on the CMS Web site:

### **IOM Citations:**

- CMS IOM Publication 100-02, *Medicare Benefit Policy Manual*,
  - Chapter 1, Section 120 Services Related to and Required as a Result of Services Which Are Not Covered Under Medicare
  - Chapter 16, Section 10 General Exclusions from Coverage, Section 120 Cosmetic Surgery and Section 180 Services Related to and Required as a Result of Services Which Are Not Covered Under Medicare.
- CMS IOM Publication 100-03, *Medicare National Coverage Determinations (NCD) Manual*,
  - Chapter 1, Part 2, Section 140.2, Breast Reconstruction Following Mastectomy, Section 140.5 Laser Procedures and Section 250.4 Treatment of Actinic Keratosis.
- CMS IOM Publication 100-08, *Medicare Program Integrity Manual*,
  - Chapter 13, Section 13.5.4 Reasonable and Necessary Provision in an LCD

### **Social Security Act (Title XVIII) Standard References:**

- Title XVIII of the Social Security Act, Section 1862(a)(1)(A) states that no Medicare payment may be made for items or services which are not reasonable and necessary for the diagnosis or treatment of illness or injury.
- Title XVIII of the Social Security Act, Section 1862(a)(7). This section excludes routine physical examinations.
- Title XVIII of the Social Security Act, Section 1862 (a)(10). This section excludes Cosmetic Surgery.

## **Coverage Guidance**

### **Coverage Indications, Limitations, and/or Medical Necessity**

Compliance with the provisions in this LCD may be monitored and addressed through post payment data analysis and subsequent medical review audits.

### **History/Background and/or General Information**

According to the American Society of Plastic Surgeons (ASPS), the specialty of plastic surgery contains two main categories which are cosmetic surgery and reconstructive surgery.<sup>1</sup>

## **Cosmetic Surgery**

Cosmetic surgery is performed to reshape and adjust normal structures of the body to enhance the visual appearance. Please refer to CMS IOM Publication 100-02, *Medicare Benefit Policy Manual*, Chapter 16, Section 120 Cosmetic Surgery for detailed information.

## **Reconstructive Surgery**

Reconstructive surgery is performed to restore and improve function and correct any deformities or abnormal structures of the body that have been caused by congenital defects, developmental abnormalities, trauma, infection, tumors or disease.

## **Dermabrasion**

Dermabrasion is a form of skin resurfacing used to remove damaged skin and promote normal wound healing and skin rejuvenation. Standard dermabrasion uses a wire brush or a stainless steel wheel on which diamond chips have been bonded (diamond fraise) abrasers to plane the skin<sup>2</sup> whereas laser dermabrasion involves use of the argon laser, ultrapulse carbon dioxide (CO<sub>2</sub>) laser,<sup>3</sup> or flashlamp-pumped pulsed dye laser. The literature speaks to interventions to promote a more controlled wound healing process to avoid altered or dysregulated wound healing which is, characterized by prolonged or increased inflammation and is correlated with an overproduction of immature collagen III in contrast to mature collagen I which results in increased tissue fibrosis. The literature notes that there is a higher prevalence of hypertrophic scars occurring after burn injuries. Dysregulated healing leads to a hypertrophic scar which can be defined as a scar forming after injury that is larger or more raised than usual, or that results in contracture. Hypertrophic scar is more likely to occur after infection of the wound, closure of the wound with excessive tension, or with position of the wound in areas of skin with high natural tension; such as the shoulders, neck, and sternum.<sup>3</sup>

## **Abdominal Lipectomy/Panniculectomy**

Abdominal Lipectomy/Panniculectomy are surgical removal of hanging excessive fat and skin in a transverse or vertical wedge from the abdomen but does not include muscle plication or flap elevation. This surgery is considered reconstructive when it is performed to alleviate such complicating factors as inability to walk normally, chronic pain, ulceration created by the abdominal skin fold, or intertrigo dermatitis (dermatitis occurring on opposed surfaces of the skin, skin irritation, infection or chafing). This procedure may be done after weight loss surgery where there has been a great deal of weight loss with significant skin redundancy with complicating factors as above.

## **Reconstructive Breast Surgery - Removal of Breast Implants**

Reconstructive breast surgery is a surgical procedure that is designed to restore the normal appearance of a breast after a medically necessary mastectomy for breast cancer or other medical condition, injury or congenital abnormality, or unilateral hypertrophy resulting in symptoms following contralateral mastectomy. Surgery that is necessary to reduce the size of a normal contralateral breast to bring it into symmetry with a breast reconstructed after cancer surgery is considered reconstructive. In contrast, cosmetic breast surgery is defined as surgery designed to alter or enhance the appearance of a breast that has not undergone a medically reasonable and necessary surgery, an accidental injury/trauma, congenital defect, infection or other non-malignant disease.

Complications related to breast implants may potentially increase over time which could result in the need for removal.<sup>4</sup>

Some examples of complications associated with breast implants are:

- Capsular contracture which is the hardening of the breast tissue around the implant that could cause the tissue to tighten and cause pain.
- Rupture and deflation which is a hole or tear in the outer shell of the implant that can be caused by many different situations such as, but not limited to, capsule contracture, damage during procedures to the breast, physical stresses or trauma, etc.
- Infection which can occur within a few days, weeks, or any time after surgery. Some infections may not respond to antibiotics which could result in the implant needing to be removed.

## Reduction Mammoplasty

Macromastia (breast hypertrophy) is an increase in the volume and weight of breast tissue relative to the general body habitus. Breast hypertrophy may adversely affect other body systems (e.g., musculoskeletal, respiratory, integumentary). At times, unilateral hypertrophy may result in symptoms following contralateral mastectomy. Considerable attention has been given to the amount of breast tissue removed in differentiating between cosmetic and medically reasonable and necessary reduction mammoplasty. Arbitrary minimum weight breast tissue removed criteria do not consistently reflect the consequences of mammary hypertrophy in individuals with a unique body habitus.<sup>5</sup> There are wide variations in the range of height, weight and associated breast size that cause symptoms. The amount of tissue that must be removed to relieve symptoms will vary and depend upon these variations.

The Schnur sliding scale is an evaluation method for physicians to use on individuals considering breast reduction surgery. If the individual's body surface area and weight of breast tissue removed fall above the 22nd percentile, then the surgery is considered medically reasonable and necessary with the appropriate criteria.<sup>5</sup> The scale abbreviated below allows a rough estimate of the minimal amount of soft tissue to be removed to justify surgery to alleviate symptoms based on body surface area; breast tissue may be removed from the other breast in order to achieve symmetry.

### SCHNUR SCALE:

Body Surface Area (m <sup>2</sup> )	Average grams of tissue to be removed per breast
1.40-1.90	324-780g
1.91-2.00	795-935g
2.01-2.30	950-1000g
BSA>2.31	>1000g

Gestational or pregnancy-included gigantomastia occurs during pregnancy. This subtype is thought to be triggered by pregnancy hormones, usually during the first trimester. It occurs in just 1 out of every 100,000 pregnancies.<sup>6</sup> Gigantomastia may be defined as the excessive overgrowth of breast tissue per breast unilaterally or bilaterally, however, there is no universally accepted definition for the amount of growth. Gigantomastia has been associated with pregnancy, puberty, certain medications and certain autoimmune conditions. Extreme breast enlargement and excess weight of the breasts can result in physical complications including overstretching of the skin, skin rashes under the breasts, ulcers on the skin, neck, shoulder and back pain, headaches, mastalgia, breast asymmetry, temporary or permanent nerve damage, psychological, emotional and social problems. Hormonal treatment or a combination of treatments may be performed to reduce the size of the breasts and help ameliorate symptoms caused by hypertrophy of the breast(s). Literature review has shown that puberty and pregnancy-included gigantomastia

may reoccur after breast reduction surgery and that mastectomy is a more final treatment for gigantomastia.<sup>7</sup> A reduction mammoplasty or mastectomy with or without reconstruction is considered medically reasonable and necessary.

## **Gynecomastia**

Gynecomastia is defined as a unilateral or bilateral persistent benign mammary gland enlargement in men. Typically true gynecomastia presents with a solid tissue mass palpable below the nipple-areolar complex. Malignant changes such as male mammary carcinoma must always be ruled out.<sup>8</sup> There are numerous causes of gynecomastia. One cause is noted to be the imbalance of female to male hormones which triggers the onset of the disease. Endogenous causes may be hyperthyroidism, chronic liver disease, primary or secondary gonadal failure, androgen resistance syndromes, medication and drug abuse. A series of heart or hypertension medications can also trigger gynecomastia. The prevalence of asymptomatic gynecomastia is up to 65% and true gynecomastia must be distinguished from pseudo-gynecomastia.<sup>9</sup> This condition can cause significant clinical manifestations when the excessive breast weight adversely affects the supporting structures of the shoulders, neck, and trunk. Depending on the underlying cause, the therapy of gynecomastia may be conservative or surgical.<sup>9</sup> Medical treatment of pathological gynecomastia depends upon the cause. There are times when a gynecomastia procedure will require a more extensive mastectomy. Suction assisted lipectomy may be used as the primary method of removing excess tissue or as an adjunctive procedure to contour the anterior chest wall.<sup>10</sup> Mastectomy with nipple preservation or reduction mammoplasty is considered reconstructive and medically reasonable and necessary for males with gynecomastia Grade III and IV as defined on the ASPS gynecomastia scale or symptomatology or signs of deformity related to excess size.

American Society of Plastic Surgeons' gynecomastia scale (ASPS, 2015):

- 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

## **Rhinoplasty/Reconstructive Nasal Surgery**

Nasal surgery is any procedure performed on the external or internal structures of the nose, septum or turbinate. This surgery may be performed to improve abnormal function, reconstruct congenital or acquired deformities, or to enhance appearance. When nasal surgery is performed to improve nasal respiratory function, correct anatomic abnormalities caused by birth defects or disease, or revise structural deformities produced by trauma, the procedure is considered reconstructive.

Rhinoplasty is a procedure that changes the shape or appearance of the nose while improving or preserving the nasal airway. The primary purpose for rhinoplasty can be functional, aesthetic, or both and may include other procedures on the paranasal sinuses, septum, or turbinates.<sup>11</sup>

Septoplasty is a procedure used to correct deformities of the nasal septum which can often cause issues with airflow and difficulty breathing.

## **Covered Indications**

The following reconstructive procedures are considered medically reasonable and necessary:

### **1. Dermabrasion**

- Dermabrasion is considered medically reasonable and necessary for the treatment of rhinophyma. Rhinophyma is characterized by skin thickening, which can cause an enlargement of the nose due to excess tissue and overgrowth of sebaceous glands.<sup>12</sup> Rhinophyma may pose functional problems such as nasal airway obstruction, including sleep apnea.<sup>13,14</sup>

## 2. Abdominal Lipectomy/Panniculectomy

- Abdominal lipectomy/panniculectomy is considered medically reasonable and necessary when the pannus or panniculus hangs below the level of the symphysis pubis causing one or more of the following conditions:
  - Chronic intertrigo that consistently remains refractory to appropriate medical therapy (e.g., topical antifungals, corticosteroids, antibiotics) over a period of three months.<sup>15</sup>
  - Difficulty walking or functional impairment in activities of daily living.<sup>15,16</sup>
- If the procedure is being performed following significant weight loss, in addition to meeting the criteria noted above, there should be evidence that the patient has maintained a stable weight for at least six months. For patients whose weight loss is the result of bariatric surgery, abdominal lipectomy/panniculectomy should not be performed until at least 18 months after bariatric surgery and only when weight has been stable for at least the most recent six months.<sup>15</sup>

## 3. Reconstructive Breast Surgery: Removal of Breast Implants

The removal of implant(s), whether placed for reconstructive or cosmetic purposes, will be considered medically reasonable and necessary for the treatment of any one or more of the following conditions<sup>4</sup>:

- Broken or failed implant
- Infection or inflammatory reaction due to breast prosthesis; including infected breast implant, or rejection of breast implants.
- Implant extrusion
- Siliconoma or granuloma
- Interference with diagnosis of breast cancer
- Painful capsular contracture with disfigurement

## 4. Reduction Mammoplasty

Reduction mammoplasty will be considered medically reasonable and necessary when performed:

- To reduce the size of the breasts and help ameliorate symptoms caused by hypertrophy when:
  - The surgeon's estimate of breast size/weight/volume to be removed is proportional to the body surface area (BSA) per the Schnur scale<sup>5</sup> per breast to relieve symptoms.
  - There are signs or symptoms resulting from the enlarged breasts (macromastia) that have not responded adequately to non-surgical interventions.
    - Symptoms are refractory to appropriately fitted supporting garments, or following unilateral mastectomy, persistent with an appropriately fitted prosthesis or reconstruction therapy at the site of the absent breast.
    - Dermatologic signs or symptoms are refractory to or recurrent following a completed course of medical management.

- Intertriginous maceration, discoloration, chronic or recurrent infection of the inframammary skin refractory to dermatologic treatment measures.
- There is back pain from macromastia, unrelieved by:
  - Conservative analgesia.
  - Supportive measures (custom garment, etc.).
  - Physical therapy.
- There is shoulder grooving to a depth greater than 1 cm with skin irritation or darkening by supporting garment (bra strap).
- There are optimally managed significant arthritic changes in the cervical or upper thoracic spine, with persistent symptoms or significant restriction of activity.
- The macromastia is not due to an active endocrine, pharmaceutical or metabolic process.

OR

- To reduce the size of a normal breast to bring it into symmetry with a breast reconstructed after cancer surgery. Note: either the involved breast or contralateral breast may be treated to achieve symmetry.

## 5. Mastectomy for Gynecomastia

Medicare considers reduction mammoplasty reconstructive for gynecomastia. Mastectomy with nipple preservation or reduction mammoplasty is considered reconstructive and medically reasonable and necessary:

- For males with unilateral or bilateral gynecomastia Grade III and IV as defined on the ASPS gynecomastia scale or abnormal breast development with redundancy.
  - Persists more than 3 to 4 months after pathological causes are ruled out.
  - Persists after 3 to 4 months of unsuccessful medical treatment for pathological gynecomastia.<sup>10</sup>
- Pain or tenderness directly related to the breast tissue which has a clinically significant impact upon activities of daily living.
- Clinical symptoms refractory to a trial of analgesics or anti-inflammatory agents.
- For significant clinical manifestations when the excessive breast weight adversely affects the supporting structures of the shoulders, neck, and trunk.

## 6. Gigantomastia of Pregnancy

Medicare considers subtotal mastectomy or reduction mammoplasty for the unusual condition of Gigantomastia of Pregnancy accompanied by any of the following complications (and delivery is not imminent) medically reasonable and necessary for the following situations when signs or symptoms are refractory to medical treatment or physical interventions have not adequately alleviated symptoms such as:

- Massive infection;
- Significant hemorrhage;
- Tissue necrosis with slough;
- Ulceration of breast tissue;
- Intertriginous maceration or infection of the inframammary skin refractory related to dermatologic measures.



## 7. Rhinoplasty/Reconstructive Nasal Surgery

- Rhinoplasty is considered medically reasonable and necessary when the procedure is performed for correction or repair of **any** of the following indications:
  - Nasal deformity secondary to a cleft lip/palate or other congenital craniofacial deformity causing a functional impairment.<sup>17</sup>
  - Chronic, non-septal, nasal obstruction due to vestibular stenosis (i.e., collapsed internal valves).<sup>18, 19, 20, 21, 22</sup>
  - Secondary to trauma, disease, congenital defect with nasal airway obstruction that has not resolved after previous septoplasty/turbinectomy or would not be expected to resolve with septoplasty/turbinectomy alone.<sup>19</sup>
- Septoplasty is considered medically reasonable and necessary when performed for **any** of the following indications:
  - Septal deformity/deviation causing nasal airway obstruction that has proved unresponsive to a recent trial of conservative medical management (e.g., topical nasal corticosteroids, nasal decongestants, nasal dilators). This includes nasal airway obstructions that interfere with the effective use of medically necessary Continuous Positive Airway Pressure (CPAP) for the treatment of an obstructive sleep disorder.<sup>22, 27, 28</sup>
  - Recurrent sinusitis secondary to a deviated septum that does not resolve after appropriate medical and antibiotic therapy.<sup>23, 24, 25, 26</sup>
  - Recurrent epistaxis related to a septal deformity.<sup>24</sup>
  - Performed in association with cleft lip or cleft palate repair.<sup>17</sup>
  - For asymptomatic septal deviation/deformity that prevents access to other trans nasal areas when such access is required to perform a medically necessary procedure (e.g., ethmoidectomy).<sup>29</sup>

## Limitations

The following procedures will be considered cosmetic (which is not a covered Medicare benefit) or not medically reasonable and necessary when performed for the reasons listed below:

### 1. Dermabrasion

- Post-acne scarring
- Rosacea other than rhinophyma
- All other indications not identified as covered in the section above

### 2. Abdominal Lipectomy/Panniculectomy

- Repairing abdominal wall laxity, or diastasis recti to improve appearance.
- Redundancies resulting from weight loss or weight loss surgery when that tissue is without evidence of chronic infection or inflammation that is refractory to conservative treatment as outlined in the indications listed above.
- Improving appearance.
- Liposuction used for body contouring, weight reduction or the harvest of fat tissue for transfer to another body region for alteration of appearance or self-image or physical appearance.

- All other indications unless covered in the section above.

### 3. **Reconstructive Breast Surgery: Removal of Breast Implants**

- Surgery to reshape the breasts to improve appearance or self-image.
- Re-implantation of an implant inserted for cosmetic purposes only (that is, for reasons other than a history of mastectomy for treatment of breast cancer, lumpectomy, or treatment of contralateral breast to bring it into symmetry with a breast reconstructed after cancer surgery).

### 4. **Reduction Mammoplasty**

- Surgery performed primarily to reshape the breasts to improve appearance or self-image.
- Mammapexy unrelated to breast reconstruction following a medically necessary mastectomy.

### 5. **Mastectomy for Gynecomastia**

- Breast reduction or surgical mastectomy for gynecomastia, either unilateral or bilateral, as the first line treatment.
- When performed solely to improve appearance of the male breast or to alter contours of the chest wall.

**Note:** Liposuction or ultrasonically-assisted liposuction (suction lipectomy) used for the treatment of gynecomastia is considered integral to the primary procedure and would not be covered separately.

### 6. **Gigantomastia of Pregnancy**

- Surgery to reshape the breasts to improve appearance or self-image.
- All other indications not identified as covered in the section above.

### 7. **Rhinoplasty/Reconstructive Nasal Surgery**

- Solely to alter the patient's appearance or improve self-image in the absence of any signs or symptoms of functional abnormalities.
- As a primary treatment for an obstructive sleep disorder when the indications listed above have not been met.

**Notice:** Services performed for any given diagnosis must meet all of the indications and limitations stated in this LCD, the general requirements for medical necessity as stated in CMS payment policy manuals, any and all existing CMS national coverage determinations, and all Medicare payment rules.

### **Summary of Evidence**

The American Society of Plastic Surgeons explained plastic surgery may be reconstructive or cosmetic procedures.<sup>1</sup> Usually, reconstructive surgery is considered medically necessary to correct deformities created by congenital defects, trauma, or medical conditions. Cosmetic surgery is used to reshape or adjust parts of the anatomy to enhance the visual appearance and is usually considered not medically necessary. There are instances where these two subspecialties of plastic surgery overlap as there are certain conditions that can be deemed either reconstructive

or cosmetic in nature. Rhinoplasty surgery is a good example as this procedure is usually performed to improve the appearance of the nose but the procedure may also be medically necessary to improve nasal breathing or restore a normal appearance after a traumatic injury such as a nasal fracture.

### **Dermabrasion**

Chellappan and Castro<sup>13</sup> performed a case report to support the use of electrocautery and dermabrasion as the mainstay of treatment for severe rhinophyma. Rhinophyma is classified as stage IV rosacea which is the most advanced stage. It is characterized by phymatous changes which presents with hypertrophic thickening with edema of the nasal pyramid skin. Treatment for this condition should begin in the early stages to prevent progression into the more advanced stages with irreversible fibrotic changes. Extensive thickening of the tissue can obstruct external nasal valves making treatment of the rhinophyma medically necessary to alleviate respiratory issues. The patient in this case report had a history of acne rosacea which progressed into severe rhinophyma causing major deformity and nasal obstruction. Electrocautery and dermabrasion were performed to remove hypertrophic skin and create a smooth contour which resulted in a substantial improvement in respiratory function. The patient's skin returned to normal pigmentation and was scab-free four weeks after the procedure. This case report supports electrocautery dermabrasion as the mainstay of treatment which allows for smooth contouring, efficient hemostasis, and does not require multiple procedures.

Torresetti et al<sup>14</sup> performed a case report and review of literature regarding treatment of disfiguring rhinophyma. Medical treatments such as antibiotics and retinoids are useful in the early stages in hopes of suppressing sebum secretion and treating any associated infections. The general consensus for treatment of rhinophyma remains the surgical removal of the thickened tissue either by full thickness excision or partial thickness excision. Partial thickness excision has been largely performed by many different procedures including dermabrasion. In the cases of infiltrating rhinophyma, such as rhinophyma with underlying skin cancer, total eradication is considered and usually requires flap coverage or skin grafts.

Clarós et al<sup>30</sup> described their experience of rhinophyma based on a retrospective case study. Rhinophyma is considered the final stage of rosacea and a rare disease in the older population. There are many different surgical procedures that have been proposed for the management of this disease, but there has not been a consensus of which procedure "constitutes the gold standard." In this case study, twelve cases over a 12-year period were identified with patients of various ethnic origins, mean age of 71 years old and mostly male predominance. These patients reported a long history of rhinophyma with a mean duration of 10.75 years. The patients were treated with the classical dermabrasion technique with decortication and topical application of fibrin glue onto the skin surface to promote complete healing. "No recurrence was observed in this series and all the patients reported improved quality of life."

### **Abdominal Lipectomy/Panniculectomy**

Sachs et al<sup>15</sup> performed an overview of panniculectomy and some of the indications and clinical significance of performing the procedure. Panniculectomy is not a cosmetic procedure and must meet specific criteria to be medically necessary. This procedure is often performed on patients with large, overhanging abdominal skin known as a pannus which hangs down from the abdomen and sometimes covers the thighs, hips and knees. This excess skin and fat are often a result of weight gain. The pannus can become so large that it begins to interfere with activities of daily life and can cause skin infections and rashes such as intertrigo due to irritation and sweating. Typically, patients with skin conditions receive medical treatment such as topical antifungals, corticosteroids, and antibiotics.

There are different grades for the varying degrees of how far the pannus extends. Grade 1 is the pannus reaching the mons pubis, grade 5 is the pannus extending to or past the knees. Often for patients to qualify to have a panniculectomy they must fail three months of medical treatment for intertrigo, and the pannus must hang below the level of the pubis and be confirmed with photography. When a panniculectomy is performed, the excess fat and skin are removed to relieve the associated symptoms and restore normal function.

Patients who experienced dramatic weight loss can also develop excess lower abdominal skin which overhangs the

groin and pubic areas causing issues with walking, discomfort and/or skin irritation as well. Patients, who have lost weight without surgery, must maintain stable weight for at least 6 months prior to having a panniculectomy. For bariatric surgery patients, weight must remain stable for at least 18 months, including the most recent 6 months.

The American Society of Plastic Surgeons<sup>16</sup> outlined practice parameters that are focused on the surgical removal of excess skin and fat that occurs in obese patients or remains following massive weight loss. There are numerous procedures and techniques that have been developed to treat the defects associated with massive weight loss such as abdominoplasty, panniculectomy, circumferential lipectomy, torsoplasty, medial thigh lift, and breast reduction.

These practice parameters for patients who are preparing to undergo surgery for the removal of excess skin and fat include preoperative assessment and screening. This includes screening patients for depression, diabetes mellitus, gastroesophageal reflux disease (GERD), any nutritional deficiencies, abdominal wall hernias, and preoperative lab and diagnostic testing.

The excess skin that remains after significant weight loss is virtually impossible to correct or improve by exercise, diet, or further weight loss. Those patients who are not surgical candidates are left with very few alternative treatment options. Ideally, body contouring surgery is performed after weight loss has stabilized for two to six months. Post bariatric surgery patients usually reach a stable weight 12 to 18 months after surgery.

The operative treatment for the correction of the deformities associated with massive weight loss will vary depending on the patient's body type, fat deposition pattern, and the amount of weight loss. These deformities can cause patients not only a dissatisfaction of appearance, but functional disabilities as well, such as difficulty exercising, impaired ambulation, chronic pain, inability to perform activities of daily living, and difficulty with hygiene. Dermatological issues such as uncontrolled intertrigo, infections and skin necrosis can develop also. Semer et al<sup>31</sup> performed a prospective outcome study on patients who underwent an abdominal lipectomy during a 12-month period from September 2004 through September 2005. This is the first prospective outcome study of patients who have undergone reconstructive abdominal lipectomy as opposed to having a cosmetic abdominoplasty. Data was collected preoperatively, during surgery, and postoperatively at one-week, one-month, and six-month follow-up visits. There were 72 patients enrolled in the study with an age range from 21 to 68 with the majority of the patients being women. Fifty-eight of the patients had significant weight loss and maintained a stable weight for at least six months prior to surgery.

There were both major complications (requiring re-hospitalization or reoperation) and minor complications (requiring local outpatient care) post-operatively. The major complication rate was 5.6% and the minor complication rate was 27.8%. Four patients had major complications such as hematoma and wound breakdown/infection, both requiring reoperation. Twenty patients had minor complications such as seroma, infected seroma, and localized infection/minor wound breakdown.

There were two instruments selected for health-related quality-of-life measures, the Short Form-36 Health Survey (SF-36) and the Multidimensional Body-Self Relations Questionnaire (MBSRQ). These were administered at the preoperative visit to establish a baseline and again at the six-month postoperative visit to evaluate outcomes. At the end of the six-month follow-up period, data collected from 60 patients showed that 59 patients were happy to have had the surgery and one patient who was overall happy but would have preferred to have undergone a more extensive "cosmetic" procedure.

This study was initiated based on anecdotal evidence that there was a high major complication rate for this procedure, especially in patients who already had bariatric surgery; however, the data did not support this belief.

### **Reconstructive Breast Surgery: Removal of Breast Implants**

The Food and Drug Administration (FDA)<sup>4</sup> reviewed the risks of breast implants and the associated complications and adverse outcomes. The life of the implants and the chances of developing complications vary by person. The FDA lists some of the complications such as breast pain, the formation of scar tissue which can cause capsular

contracture, rupture and deflation of the breast implant, the development of different kinds of cancer such as non-Hodgkin's lymphoma or breast cancer, systemic symptoms, infections, or connective tissue diseases.

<https://www.fda.gov/medical-devices/breast-implants/risks-and-complications-breast-implants>

### **Breast reduction or surgical mastectomy for gynecomastia**

Lonie and colleagues<sup>32</sup> conducted a literature search of the PubMed and Cochrane Library, Medline and SCOPUS databases from 1966 to July 2018 according to Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines. Search terms included were breast reduction, reduction mammoplasty, treatment outcomes personal satisfaction, quality of life, questionnaire and instrument. Pre-determined inclusion criteria by two authors included articles which addressed bilateral reduction mammoplasty, excluding symmetrizing and post-cancer, and reported patient satisfaction or quality of life based on outcome questionnaires. The search results were further restricted to English language articles. The literature search yielded 2,361 studies, only 95 met the inclusion criteria, representing 9,716 patients.<sup>32</sup> (pg 433) Data was extracted from the included studies relating to demographics, surgical technique, questionnaires used and physical, psychological and aesthetic outcomes. Overall, the mean age was 37.8 years, body mass index (BMI) was 28.0, and combined tissue resection mass was 1,402.9 g. Fifty-eight studies listed overall satisfaction as primary endpoint, including 5,867 patients. Grouped data found overall satisfaction to be 90.3% (range, 67.6–100%). Of the studies investigated in the systematic review, a wide range of questionnaires for patient reported outcome measures, surgical technique and skin pattern excision and satisfaction were captured. The authors inferred that in almost all studies, patients reported improvements in the vast majority of pre-morbid symptoms both physical and mental health and stating a finding consistent with previous reviews of this subject.

Ngaage et al<sup>33</sup> conducted a retrospective study of patient satisfaction survey and chart review of demographics, operative data and postoperative course including complications for patients undergoing reduction mammoplasty over a 12 year period at a single institution at the University of Maryland Medical Center from 2006 to 2013. Potential participants were identified using the CPT code 19318-reduction mammoplasty. Included in the study were patients with 5 or more years of post-reduction follow-up. Exclusion criteria were reductions related to Oncologic conditions, patients that were deceased or patients that did not have functional telephone numbers. The participants preoperative Body Mass Index (BMI) was classified according to the World Health Organization Clinical Guidelines adopted by the National Institute of Health. Patients were put into 4 categories based on BMI (normal [ $<25$ ], overweight [ $25-29.9$ ], obese [ $30-39.9$ ], and morbidly obese [ $\geq 40$ ]). Seventy patients met the inclusion criteria. Patient satisfaction was assessed using a customized survey which was administered over the phone. Only patients with complete medical records who participated in the survey were included. Median time from surgery to survey was 6 years. Based on a 5-point Likert scale of 1 to 5 with 5 being highest satisfaction, study participants were asked questions on long-term outcomes following reduction mammoplasty. The questions were related to satisfaction with the decision to have breast reduction, satisfaction of the results post breast reduction, symptoms prior to breast reduction, symptom relief post breast reduction, satisfaction with aesthetic result and bra size before and after breast reduction. Study limitations included memory recall bias, use of a non validated questionnaire, study recruitment of participants lost to incomplete medical records and low sample size overall. Previous studies reporting patient outcomes following reduction mammoplasty at different time points with findings of satisfaction stable in the immediate and short-term postoperative period leads the authors to believe this to be supported by the study finding of high overall and aesthetic satisfaction also present at 12 years after breast reduction. Consequently, demonstrating that reduction mammoplasty has a clinically important and robust benefit.

### **Rhinoplasty/Reconstructive Nasal Surgery**

Ishii et al<sup>11</sup> created clinical guidelines to provide evidence-based recommendations for the treatment of patients who are candidates for rhinoplasty surgery. Rhinoplasty ranks among the most commonly performed cosmetic surgery in the United States. Rhinoplasty should be considered more than just a cosmetic procedure as it is often performed as a medically necessary surgery to improve nasal respiration and relieve any airway obstructions that are either congenital or acquired. While rhinoplasty may be performed to address a functional abnormality, it may inadvertently change or enhance the appearance of the nose. Often rhinoplasty is performed with adjunctive procedures which involve the nasal septum, nasal valve, nasal turbinates, or the paranasal sinuses. When adjunctive procedures are

performed without an impact on the nasal shape or appearance, they do not meet the definition of rhinoplasty.

These guidelines were created by a Guideline Development Group (GDG) that consisted of 16 members representing experts in plastic surgery, facial plastic and reconstructive surgery, otolaryngology, otology, rhinology, sleep medicine, psychiatry, advanced practice nursing, and consumer advocacy. There were three literature searches performed from May 2015 through December 2015 to identify clinical practice guidelines, systematic reviews, and randomized controlled trials. The information obtained during these searches was used to gather evidence, relevant treatments, and outcomes.

There were 10 evidence-based recommendations created based on Grade B and C quality of evidence with overall "preponderance of benefit over harm." (1) Clinicians should ask all patients about their motivation for surgery and expectations for outcomes. (2) Candidates should be assessed for comorbid conditions that could impact surgery. (3) The rhinoplasty candidate should be evaluated for nasal airway obstruction during preoperative assessment. (4) Candidates should be educated regarding what to expect after surgery and any potential complications. (5) Candidates should be counseled about the impact of surgery on nasal airway obstruction and how sleep apnea might affect perioperative management. (6) The patient should be educated about strategies to manage pain and discomfort after surgery. (7) Perioperative antibiotics for rhinoplasty should not be routinely prescribed for more than 24 hours after surgery. (8) Perioperative systemic steroids may be administered to the rhinoplasty patient. (9) Packing should not be routinely used in the nasal cavity of rhinoplasty patients at the conclusion of surgery. (10) Clinicians should document patient satisfaction with nasal appearance and function at a minimum of 12 months after surgery.

Included within this guideline were validated patient-outcome tools used to perform cosmetic and functional assessments for rhinoplasty. For cosmetic assessments, FACE-Q Rhinoplasty Instrument, Glasgow Benefit Inventory, and Rhinoplasty Outcome Evaluation were listed and for functional assessments, Nasal Obstruction Septoplasty Effectiveness (NOSE) scale and Sino-Nasal Outcome Test (SNOT-22) were also listed.

Kaufman et al<sup>17</sup> performed a literature review regarding various modalities for achieving a successful rhinoplasty for patients with cleft nasal deformity. The cleft nasal deformity presents as a difficult challenge in plastic surgery as it involves skin, mucosa, cartilage, and skeletal platform. Cleft lip nasal surgery can be divided into primary, intermediate, and secondary repairs. Early intervention can be beneficial for an earlier restoration of nasal shape with the increased chance for more symmetrical nasal growth. The primary rhinoplasty is performed with the intention to restore symmetry and reposition nasal structures so that deformities will not be exacerbated by further growth. Some patients may need to have an intermediate rhinoplasty before reaching school age in order to achieve greater symmetry and to help avoid future growth deformities. The best approach to performing a secondary rhinoplasty is to wait until nasal growth has concluded. This deformity is a complex condition that should be addressed during multiple stages of the patient's life to help achieve the best outcome.

Simon and Sidle<sup>19</sup> performed a literature review of surgical procedures used for augmenting the nasal airway. For patients presenting to otolaryngology clinics, the most common complaint is nasal obstruction. There are a number of different anatomical factors that can contribute to these obstructions and the sensation of decreased nasal airflow. The most common finding in patients with complaints of nasal obstructions is a deviated nasal septum secondary to congenital, traumatic, or iatrogenic etiologies. There are several procedures used to improve these obstructions that fall under the functional rhinoplasty technique such as but not limited to septoplasty, extracorporeal septoplasty, and correction of caudal septal deviation.

Septoplasty is usually performed on patients that present with anatomic changes of the septum which may hinder the function of the nasal airway. Extracorporeal septoplasty is usually performed for the more severe deviations or loss of significant portions of the septum which require reconstruction. Caudal septal deviation usually requires treatment beyond traditional septoplasty as these deviations are important on both appearance and functional levels. The caudal septum provides essential structure of the nose and when there is any deviation in these structures, significant deformities may develop. "Previous epidemiological studies have revealed that the finding of a straight

septum is present in only 42% of newborns and in adults, only 21%."<sup>19</sup>

De Sousa Michels et al<sup>27</sup> performed a summary of data and theories on the association between nasal obstruction and obstructive sleep apnea syndrome (OSAS). There are many nose and pharynx abnormalities that can cause snoring and sleep apnea such as rhinitis, turbinate hypertrophy, nasal polyps, and septal deviation. The treatment options for nasal obstructions include nasal dilators, surgical intervention, and medical treatment such as topical corticosteroids and sympathomimetic decongestants.

In the context of this article, surgical interventions such as septoplasty, rhinoseptoplasty, functional endoscopic sinus surgery, turbinectomy, and nasal valve surgery appear to be good therapeutic options for patients with nasal obstructions and OSAS. There are patients that may benefit from surgery as an adjuvant treatment to improve the effectiveness of continuous positive airway pressure (CPAP).

"Over 50% of CPAP users complain of significant nasal symptoms, such as nasal congestion, rhinorrhea, nasal dryness, and sneezing, which may become more significant if the patient presents any structural abnormality of the nose."<sup>27</sup> Functional or anatomical abnormalities in the nasal cavity may cause patients discomfort and hinder adjustment to the CPAP due to the device requiring higher pressure titration in order to eliminate respiratory events. Studies have shown that patients that had nasal surgery showed a decrease in the levels of CPAP titration. This article has concluded that nasal surgery may be helpful in patients with obstructive sleep apnea (OSA) who do not tolerate CPAP therapy when there is a nasal obstruction present.

Rhee et al<sup>34</sup> created a clinical consensus statement regarding the diagnosis and management of nasal valve compromise (NVC). "NVC is a distinct and primary cause of symptomatic nasal airway obstruction, yet there remain ambiguities and disparities in the diagnosis and management." The purpose of this clinical consensus statement was to help distinguish NVC from other disease processes that may cause nasal airway obstruction. An updated systematic review of literature was performed along with two rounds of surveys and conference calls with a panel of eight experts that was comprised based on their work in related fields and valued opinions. The survey covered the following categories: definition, history and physical examination, adjunctive tests, outcome measures, management, and coding. After reviewing the responses, targeted questions regarding NVC were formulated.

The categories of the survey that had the greatest percentage of consensus or near consensus were the definitions, history and physical examination, outcome measures and management. The categories with the larger percentage of no consensus were adjunctive tests and coding. The results of the surveys can be found in Tables 2-7.

After review, "the panel found that the literature consistently noted the benefit of surgical treatment of NVC, but the evidence relied mostly on uncontrolled studies."<sup>34</sup> There was a strong disagreement that there is a gold standard test to diagnosis NVC. There was a general consensus that NVC is best evaluated with history and physical findings and that endoscopy and photography can be useful but are not always necessary. Also, the panel found that the use of nasal steroid medications may not be helpful for treating NVC in the absence of rhinitis and mechanical treatments such as stents may be useful in selected patients. "Surgical treatment is the primary mode of treatment of NVC."<sup>34</sup>

### **Analysis of Evidence (Rationale for Determination)**

Available literature and the American Society of Plastic Surgeons support that certain plastic surgery procedures may be considered as reconstructive in nature and medically reasonable and necessary in those situations where functionality needs to be restored and any deformities need to be corrected.

Dermabrasion is used for the treatment of many different dermatological conditions such as acne scars, wrinkles, and different forms of rosacea. The treatments of these conditions are considered cosmetic as they are usually not associated with any functional impairment or deformities. Rhinophyma can cause thickening of the nasal skin which can develop into structural deformities that impede on the nasal airway openings and eventually leads to respiratory issues. The treatment of this condition is to remove the hypertrophic skin. There are several different procedures

used to treat rhinophyma but there is not a consensus of a gold standard treatment. The literature supports dermabrasion as a safe and successful procedure for rhinophyma with positive outcomes. This LCD will provide limited coverage for the use of dermabrasion as treatment for rhinophyma.

Panniculectomy is necessary when patients lose large amounts of weight and are left with excess skin and fat that is virtually impossible to lose regardless of the amount of exercise or any additional weight loss. Literature supports a panniculectomy as medically reasonable and necessary. This LCD will provide limited coverage for Panniculectomy in the treatment of excess skin and fat of the abdomen causing skin conditions that are refractory to medical treatment and that impede the patient's activities of daily living, ability to perform appropriate hygiene, and the ability to walk or exercise.

The FDA<sup>4</sup> has published information on the risks and complications of breast implants. This LCD is providing limited coverage for the removal of breast implants, whether placed for reconstructive or cosmetic purposes. The indications for removal are based on the complications and/or adverse outcomes published by the FDA.

In a study, based on questionnaire responses from women who had undergone reduction mammoplasty, Schnur and colleagues (1997)<sup>35</sup> reported that in properly selected individuals, reduction mammoplasty is a safe and effective procedure for relieving or improving symptoms related to symptomatic macromastia. The medical literature supports an approach based upon the measurement of body surface area such as the Schnur scale. Keeping with accepted medical opinion and medical evidence, the use of the Schnur scale is noted to ensure that an adequate amount of breast tissue be removed in order to maximize the probability of symptomatic relief. Additionally, specialty consensus opinion agrees that breasts are considered paired organs, and it is not possible to definitively relate symptoms to one breast or the other. Therefore, bilateral breast reduction mammoplasty may be considered appropriate if the amount of breast tissue anticipated for removal from at least one breast meets the minimum amount (weight) per the Schnur scale and all other criteria are met.

Many pieces of literature including guidelines and consensus statements recommend nasal surgery as the treatment for nasal airway obstructions, whether caused from deviated septum, collapsed internal/external valves, congenital defects, or trauma. The patient should be evaluated preoperatively to ascertain which anatomical part of the nasal airway is causing the obstruction and plan the appropriate surgical intervention. Most conditions require failure of conservative treatment such as steroids, decongestants, and dilators before moving to the final step of surgery.

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## General Information

### Associated Information

Please refer to the related Local Coverage Article: Billing and Coding: Cosmetic and Reconstructive Surgery A56587 for documentation requirements, utilization parameters and all coding information as applicable.

### Sources of Information

Novitas Solutions, Inc., L35090/ A56587 Cosmetic Reconstructive Surgery

American Society of Plastic and Reconstructive Surgery Reduction mammoplasty. Recommended criteria for third-party payer coverage.

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not responsible for the continuing viability of Website addresses listed below.

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# Revision History Information

REVISION HISTORY DATE	REVISION HISTORY NUMBER	REVISION HISTORY EXPLANATION	REASONS FOR CHANGE
07/11/2021	R9	LCD revised and published on 05/19/22 to reflect formatting changes related to an inquiry. These formatting changes were made to provide clarity to the LCD. There is no change in coverage.	<ul style="list-style-type: none"> <li>Other (Third party request)</li> </ul>
07/11/2021	R8	LCD revised and published on 02/17/2022 to adjust the URL address to the FDA page for "Risks and Complications of Breast Implants" in the Summary of Evidence section of the LCD.	<ul style="list-style-type: none"> <li>Typographical Error</li> </ul>
07/11/2021	R7	LCD posted for notice on 05/27/2021 to become effective 07/11/2021.  01/14/2021 Proposed LCD posted for comment.	<ul style="list-style-type: none"> <li>Creation of Uniform LCDs Within a MAC Jurisdiction</li> </ul>
11/07/2019	R6	LCD revised and published on 11/07/2019. Consistent with CMS Change Request 10901, the entire coding section has been removed from the LCD and placed into the related Billing and Coding Article, A56587. All CPT codes and coding information within the text of the LCD has been placed in the Billing and Coding Article.	<ul style="list-style-type: none"> <li>Other (CMS Change Request 10901)</li> </ul>
05/30/2019	R5	LCD revised and published on 05/30/2019. The IOM Citations section was revised to add the section title to the CMS IOM Publication 100-02, Medicare Benefit Policy Manual, Chapter 16: Section 10, 120 and 180, CMS IOM Publication 100-03, Medicare National Coverage Determinations Manual, Chapter 1, Part 2, Sections 140.2, 140.4 and 250.5, CMS IOM Publication 100-04, Medicare Claims Processing Manual, Chapter 32: Section 260 and to add the Reasonable and Necessary IOM reference since the language contained in that reference and the reference was removed from the body of the policy. All billing and coding related information has been moved to the Local Coverage Article: Billing and Coding: Cosmetic and Reconstructive Surgery (A56587). The following ICD-10 codes have been added to the ICD-10 Code Group 3 of the Billing and Coding Article in response to an inquiry: Z90.11, Z90.12, Z90.13, and Z15.01. There was no change to coverage indications in this policy with this revision.	<ul style="list-style-type: none"> <li>Other (Change in LCD process per CR 10901)</li> </ul>
04/14/2017	R4	LCD revised and published on 06/08/2017 effective for dates of	<ul style="list-style-type: none"> <li>Other ( <ul style="list-style-type: none"> <li>Clarification</li> </ul> </li> </ul>

REVISION HISTORY DATE	REVISION HISTORY NUMBER	REVISION HISTORY EXPLANATION	REASONS FOR CHANGE
		service on and after 04/14/2017 to remove the dual diagnosis code requirement in Group 4 for CPT code 19318 when ICD-10 diagnosis code Z48.3 is reported; ICD-10 diagnosis code N62 does not need reported when ICD-10 diagnosis code Z48.3 is reported.	<ul style="list-style-type: none"> <li>◻ Inquiry</li> </ul>
12/31/2015	R3	LCD revised to include reference to the original ICD-10 source.	<ul style="list-style-type: none"> <li>• Other (Clarification)</li> </ul>
12/31/2015	R2	LCD posted for notice on 11/05/2015. LCD becomes effective for dates of service on and after 12/31/2015  05/14/2015 DL35090 Draft LCD posted for comment.	<ul style="list-style-type: none"> <li>• Creation of Uniform LCDs With Other MAC Jurisdiction</li> <li>• Revisions Due To ICD-10-CM Code Changes</li> </ul>
10/01/2015	R1	LCD revised to remove dermal injection information including HCPCS codes C9800, G0429, Q2026, and Q2028 and associated ICD-10 codes, B20, E88.1, and F43.21 effective for dates of service on or after 10/01/2014. (LCD Updated 05/08/2014).	<ul style="list-style-type: none"> <li>• Other (Information is duplicative of NCD.)</li> </ul>

## Associated Documents

### Attachments

N/A

### Related Local Coverage Documents

### Articles

[A56587 - Billing and Coding: Cosmetic and Reconstructive Surgery](#)

[A58771 - Response to Comments: Cosmetic and Reconstructive Surgery](#)

### LCDs

[DL35090 - \(MCD Archive Site\)](#)

### Related National Coverage Documents

N/A

### Public Versions

UPDATED ON	EFFECTIVE DATES	STATUS
05/13/2022	07/11/2021 - N/A	Currently in Effect (This Version)
02/10/2022	07/11/2021 - N/A	Superseded
05/21/2021	07/11/2021 - N/A	Superseded

UPDATED ON	EFFECTIVE DATES	STATUS
11/01/2019	11/07/2019 - 07/10/2021	Superseded
Some older versions have been archived. Please visit the MCD Archive Site to retrieve them.		

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## Keywords

N/A