



CLINICAL MEDICAL POLICY	
<b>Policy Name:</b>	Breast Reconstructive & Gynecomastia Surgery
<b>Policy Number:</b>	MP-052-MD-PA
<b>Responsible Department(s):</b>	Medical Management
<b>Provider Notice/Issue Date:</b>	02/01/2023; 06/01/2022; 06/18/2021; 05/25/2020; 06/17/2019; 09/01/2018
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<b>Next Annual Review:</b>	03/2023
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<b>Products:</b>	Highmark Wholecare <sup>SM</sup> Medicaid
<b>Application:</b>	All participating hospitals and providers
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**Policy History**

Date	Activity
03/01/2023	Provider Effective date
01/19/2023	PARP Approval
11/16/2022	QI/UM Committee review
11/16/2022	Urgent Revision: Per PARP request, gynecomastia surgery is no longer considered only cosmetic in nature and should be considered medically necessary under specific circumstances. Added gynecomastia surgery medical necessity guidelines. Added CPT code 19300 & ICD-10 code N62. Added CMS guidance. Added Gynecomastia Scale to 'Informational' section. Updated 'Summary of Literature' and 'Reference Sources' sections.
07/01/2022	Provider Effective date
05/09/2022	PARP Approval
03/16/2022	QI/UM Committee review
03/16/2022	Annual Review: Reformatted Procedure section numbering. Updated Summary of Literature and Reference Sources sections. Added the following statement to the 'Non-covered Services' section, per PARP request: <i>Any requests for services that do not meet criteria set in the policy may be evaluated by a Medical Director as a program exception on a case-by-case basis.</i> Updated the following CPT code descriptions per AMA guidelines: 15772, 19318, 19325, 19328, 19330, 19340, 19342, 19357, 19361, 19364, 19367, 19368, 19369, 19370, 19371, 19380, & Q4128. The

	following CPT codes have been deleted: 19324, 19366, & 20926. The following ICD-10 codes have been removed: Z45.819 & Z90.10.
07/19/2021	Provider Effective Date
05/13/2021	PARP Approval
03/17/2021	QI/UM Committee Review
03/17/2021	Annual Review: Reformatted policy criteria with minor syntax changes to criteria, revised medical necessity statement throughout policy. Added CPT codes 14000 and 14001 to list of covered codes. Updated Summary of Literature and references.
06/22/2020	Provider effective date
05/04/2020	PARP approval
03/18/2020	QI/UM Committee Review
03/18/2020	Annual Review: Formatting changes; no criteria changes but added necessary diagnostic criteria which provides documentation of impairment with Poland syndrome; removed hyperlinks; added ICD-10 codes C84.60 to C84.79, D48.61 & D48.62 N64.82; Removed 1.6 under the Procedure section and removed the following diagnosis & HCPCS codes as they related to external prosthesis and the policy scope is surgical reconstruction-Z44.30, Z44.31, & Z44.32, L8000 – L8039. Removed procedure code 19355 as unrelated to breast reconstruction. Added information and coding related to Breast Implant Associated Lymphoma. Added 3 new 2020 CPT codes as eligible services 15769, 15771, 15772.
06/17/2019	Provider effective date
04/14/2017	Initial policy developed

### **Disclaimer**

Highmark Wholecare<sup>SM</sup> medical policy is intended to serve only as a general reference resource regarding coverage for the services described. This policy does not constitute medical advice and is not intended to govern or otherwise influence medical decisions.

### **Policy Statement**

Highmark Wholecare<sup>SM</sup> may provide coverage under the medical surgical benefits of the Company's Medicaid products for medically necessary breast reconstructive surgery.

This policy is designed to address medical necessity guidelines that are appropriate for the majority of individuals with a particular disease, illness or condition. Each person's unique clinical circumstances warrant individual consideration, based upon review of applicable medical records.

(Current applicable Pennsylvania HealthChoices Agreement Section V. Program Requirements, B. Prior Authorization of Services, 1. General Prior Authorization Requirements.)

## **Definitions**

**Prior Authorization Review Panel (PARP)** – A panel of representatives from within the Pennsylvania Department of Human Services who have been assigned organizational responsibility for the review, approval and denial of all PH-MCO Prior Authorization policies and procedures.

**Acellular Skin Substitutes** – Products that contain a matrix or scaffold composed of materials such as collagen, hyaluronic acid, and fibronectin. These materials are obtained from either human (dermis, amniotic membrane or placenta) or nonhuman (bovine, porcine, and ovine) sources.

**Reconstructive Breast Surgery** – Surgical procedures performed to correct or repair abnormal structures of the breast that are designed to restore the normal appearance of one breast or both breasts.

**Reconstructive Surgery** – Surgical procedures performed on abnormal structures of the body caused by congenital deformity, trauma, infection, tumors, or disease. These procedures are performed to improve function but may also be done to approximate a normal appearance.

**Reduction Mammoplasty** – A surgical procedure to decrease breast size.

**Cosmetic Surgery** – Procedures are considered cosmetic when intended to change a physical appearance that would be considered within normal human anatomic variation. Cosmetic services are often described as those that are primarily intended to preserve or improve appearance and self-esteem.

**Congenital Anomaly** – A physical developmental defect that is present at the time of birth and that is identified within the first 12 months of birth.

**Functional/Physical Impairment** – A functional/physical or physiological impairment causes deviation from normal function of a tissue or organ. This results in a significantly limited, impaired, or delayed capacity to move, coordinate actions, or perform physical activities, and is exhibited by difficulties in one or more of the following areas: physical and motor tasks; independent movement; performance of basic life functions.

**Prophylactic Mastectomy** – A surgical procedure to remove a breast or both breasts with the purpose of reducing the risk of breast cancer in women determined to be at intermediate or high risk for developing breast cancer.

**Poland Syndrome** – A rare developmental disorder that is present at birth. It is characterized by absence or underdevelopment of certain muscles in the chest and abnormally short, webbed fingers. Other findings associated with this syndrome can include underdevelopment or absence of one nipple (including the darkened area around the nipple [areola]) and/or patchy axilla hair growth. Typically, the physical abnormalities are unilateral and affect the right side primarily.

**Deep Inferior Epigastric Perforator (DIEP) Flap** – A type of breast reconstruction in which blood vessels called deep inferior epigastric perforators, as well as the skin and fat connected to them, are removed from the lower abdomen and transferred to the chest to reconstruct a breast after mastectomy, without the sacrifice of any of the abdominal muscles.

**Thoracodorsal Artery Perforator (TDAP)** – A reconstructive breast procedure that uses the skin and fat tissue from the upper back to reconstruct the breast after cancerous breast tissue is removed.

**Gynecomastia** - an increase in the amount of breast gland tissue in boys or men, caused by an imbalance of the hormones estrogen and testosterone and can affect one or both breasts, sometimes unevenly.

## **Procedures**

### 1. Reconstructive Breast Surgery

Reconstructive breast surgery may be considered medically necessary for patients who have had a mastectomy, with or without a diagnosis of cancer. A mastectomy includes partial (lumpectomy, tylectomy, quadrantectomy, and segmentectomy), simple, and radical.

2. Breast surgery is considered reconstructive, and therefore medically necessary, when there are abnormalities related to trauma, congenital defects, infection, or other non-malignant diseases such as Poland syndrome.

3. In accordance with federal and state mandates, breast reconstruction services are covered when ANY of the following medical necessity guidelines are met:

- A. Reconstruction of the breast where the mastectomy was performed; OR
- B. Surgery and reconstruction of the other breast to produce a symmetrical appearance, including nipple tattooing; OR
- C. Prosthesis (implanted and/or external); OR
- D. Treatment of physical complications of mastectomy (including lymphedema); OR

Federal and state mandates also list the following:

- Timing of the reconstructive services is not a factor in coverage
- Cancer does not have to be the reason for the mastectomy
- The mandate applies to all genders
- Coverage is required for all stages of breast reconstruction

**Note:** There is no mandated coverage for revision of a completed breast reconstruction to improve appearance.

4. Immediate or delayed breast reconstruction may be considered medically necessary when performed on the diseased/affected breast for ANY of the following:

- A. Areolar and nipple reconstruction; OR
- B. Autologous fat transplant (e.g., lipoinjection, lipofilling, lipomodeling); OR
- C. Capsulectomy; OR
- D. Breast implant removal and subsequent reimplantation for implants done post-mastectomy or other covered reconstructive procedures; OR
- E. Capsulotomy; OR
- F. Implantation of tissue expander; OR
- G. Implantation of US FDA-approved internal breast prosthesis; OR
- H. Reconstructive surgical revisions; OR
- I. Oncoplastic reconstruction; OR
- J. Tissue/muscle reconstruction procedures (e.g., flaps), including but not limited to the following:
  - 1) Deep inferior epigastric perforator (DIEP) flap;
  - 2) Latissimus dorsi (LD) myocutaneous flap;
  - 3) Rubens flap;
  - 4) Superficial inferior epigastric perforator/artery (SEIP/SIEA) flap;

- 5) Superior or inferior gluteal free flap;
  - 6) Transverse rectus abdominus myocutaneous (TRAM) flap;
  - 7) Transverse upper gracilis (TUG) flap;
  - 8) Thoracodorsal artery perforator (TDAP) flap; OR
- K. FDA-approved tissue expanders post-mastectomy with/without skin substitutes that have also been approved by the FDA.

**Note:** There must be clear documentation in the operative report on the size of the resection, the size of the defect, incisions made, the nature of the flap(s), the size of the flap(s), and how they are rotated or transposed.

5. Breast reconstruction procedures performed on the non-diseased/unaffected breast after having a mastectomy/lumpectomy in order to produce a symmetrical appearance may be considered medically necessary for ANY of the following conditions:
  - A. Areolar and nipple construction; OR
  - B. Areolar and nipple tattooing; OR
  - C. Augmentation mammoplasty with implantation of FDA-approved internal breast prosthesis; OR
  - D. Autologous fat transplant (e.g., lipoinjection, lipofilling, lipomodeling); OR
  - E. Breast implant removal and subsequent reimplantation when performed to produce a symmetrical appearance; OR
  - F. Breast reduction by mammoplasty or mastopexy; OR
  - G. Capsulectomy; OR
  - H. Capsulotomy; OR
  - I. Reconstructive surgery revisions to produce a symmetrical appearance
  
6. Breast reconstruction may require the use of skin substitutes. Skin substitutes may be considered medically necessary when ANY ONE of the following medically necessary criteria are met:
  - A. When there is insufficient tissue expander or implant coverage by the pectoralis major muscle, and additional coverage is required; OR
  - B. When there is insufficient tissue expander or implant coverage by the pectoralis major muscle, and additional coverage is required; OR
  - C. When there is viable but compromised or thin post-mastectomy flaps that are at risk of dehiscence or necrosis; OR
  - D. The infra-mammary fold and lateral mammary folds have been undermined during mastectomy, and re-establishment of these landmarks is needed.

The following FDA-approved skin substitutes used in breast reconstruction following a mastectomy for breast cancer are covered:

- AlloDerm® (acellular dermal matrix) (Q4116)
- Cortiva (formerly known as AlloMax™) (acellular dermal matrix) (Q4100)
- FlexHD® (acellular dermal matrix) (Q4128)

All other skin substitutes used in breast reconstruction following a mastectomy are considered not medically necessary.

7. Removal, Revision, or Replacement of Breast Implants

Removal, revision, or replacement of FDA-approved breast implants will be considered medically necessary when the breast implant was originally implanted for reconstruction following a mastectomy for breast cancer and covered surgical reconstruction for breast abnormalities listed above, and ANY ONE of the following conditions are met:

- A. There is implant rupture, failure, Baker Class III or IV contracture, implant exposure or extrusion; OR
- B. There is infection or inflammatory reaction to a breast prosthesis including siliconoma, granuloma, or painful capsular contracture with disfigurement; OR
- C. There is interference with the diagnosis or treatment of breast cancer.

**Note:** Removal, revision, or replacement of breast implants is not considered medically necessary for complications, immediate or delayed, from a prior cosmetic breast implant, and those complications are related to the cosmetic implant itself.

8. Capsulectomy/capsulotomy may be considered medically necessary when ANY of the following conditions are met:

- A. When the original implant was placed during a covered breast reconstruction procedure; OR
- B. When the capsulectomy/capsulotomy is required due to a related complication of a covered medical condition or procedure.

**Note:** Capsulectomy and/or capsulotomy is not considered medically necessary for complications, immediate or delayed, from a prior cosmetic breast implant.

9. Mastectomy for Gynecomastia

Mastectomy for gynecomastia may be considered medically necessary when ALL of the following criteria are met:

- A. The patient meets the criteria for Grade II, III, or IV (see *Informational* section below); AND
- B. The patient is 18 years of age or older and has a current BMI of less than or equal to 25; AND
- C. Excess breast tissue is glandular breast tissue and not fatty breast tissue, with confirmation by mammogram or histology; AND
- D. Condition has been present for no less than 2 years and any contributing factor has been treated for at least one year; AND
- E. Underlying causes have been excluded and addressed, including but not limited to, underlying hormonal disorders, obesity, or medication therapy. Examples include:
  - Hypogonadism, endocrine disorders, metabolic disorders, neoplasms, or male breast cancer
  - Pharmacologic gynecomastia (i.e., gynecomastia induced by pharmacological agents, including but not limited to, cimetidine, digitalis, methadone, marijuana, clomiphene, chemotherapeutic agents, anti-retroviral agents, herbal remedies, chlorpromazine, and anabolic steroids)

**Note:** Mastectomy for gynecomastia when performed for a clinical concern that a breast mass may represent breast carcinoma may be considered medically necessary.

For any other indication other than those listed above, mastectomy for gynecomastia is considered cosmetic and, therefore, not medically necessary.

Mastectomy for gynecomastia is not considered medically necessary when performed solely for to improve appearance.

Mastectomy for gynecomastia is not considered medically necessary when performed solely to treat psychological symptoms.

#### 10. Poland Syndrome

Surgical correction of chest wall deformity as a result of Poland syndrome may be considered medically necessary when ALL of the following criteria are met:

- A. There is musculoskeletal chest wall deformities associated with Poland syndrome. There must be a congenital absence or hypoplasia of pectoralis major and minor muscles with congenital partial absence of the upper costal cartilage, the functional impairment is documented, and there is a decreased cardiac output is demonstrated by echocardiography;  
OR
- B. Abnormal/reduced lung function during exercise pulmonary function tests with:
  - 1) A CT scan of the chest demonstrates a pectus index greater than 3.25 ratio (normal is 2.5); AND
  - 2) In the medical record, there is documentation of signs and symptoms which impair the individual's ability to participate in activities of daily living.

**Note:** If there is no chest wall involvement in the case, the breast reconstruction related to Poland syndrome is considered cosmetic and is considered not medically necessary.

**Note:** Please see policy MP-033-MD-PA "Gender Affirmation Services" for information regarding surgical procedures of the breast for individuals with gender dysphoria, incongruence, or gender identity disorder.

#### 11. Treatment of Post-Mastectomy Complications

Coverage will be provided for the treatment of ANY of the following complications of a mastectomy:

- A. Lymphedema:
  - 1) Lymphedema pumps,
  - 2) Compression lymphedema sleeves,
  - 3) Complex decongestive physiotherapy (CDP); OR
- B. Infection; OR
- C. Removal of breast implant due to rupture; OR
- D. Replacement of new breast implant.

#### 12. Precautions

The following conditions have been identified as possible risk factors for breast reconstructive surgery and should be adequately addressed by the performing provider prior to surgery:

- A. The patient is an active smoker
- B. The patient has a body mass index (BMI) of 25 or greater
- C. The patient has poorly managed diabetes

13. Breast reconstructive surgery is not medically necessary for conditions other than those listed above; scientific evidence has not been established. The following conditions/procedures are not medically necessary:

- Aspirations not related to breast reconstruction
- Biopsy (open or core) not related to breast reconstruction

- Excision of cysts, fibroadenomas or other benign or malignant tumors, aberrant breast tissue, duct lesions, nipple or areolar lesions not related to breast reconstruction
- Treatment of gynecomastia not related to breast reconstruction
- Lipectomy (suction or ultrasonically-assisted suction) for correction of surgically-induced donor site asymmetry that results from one or more flap breast reconstruction procedure(s) is not covered as not medically necessary
- Removal and/or replacement of an existing breast implant if the earlier breast implant was performed for cosmetic reasons when there are no local breast complications
- Implantation or reimplantation of breast implant(s) for cosmetic reasons
- Breast reconstruction using adipose-derived stem cells (ADSC) in autologous fat grafting;
- Vascularized lymph node transfer (VLNTx)
- Xenograft cartilage grafting
- Breast surgery for cosmetic reasons not related to breast reconstruction
- Any requests for services that do not meet criteria set in the policy may be evaluated by a Medical Director as a program exception on a case-by-case basis.

#### 14. Contraindications

There are no known contraindications for breast reconstructive surgery.

#### 15. Post-payment Audit Statement

The medical record must include documentation that reflects the medical necessity criteria and is subject to audit by Highmark Wholecare<sup>SM</sup> at any time pursuant to the terms of your provider agreement.

#### 16. Place of Service

The proper place of service for breast reconstructive surgery can be inpatient, outpatient, or the provider office.

#### 17. Related Policies

- MP-033-MD-PA Gender Affirmation Services
- MP-032-MD-PA Skin Replacement Therapy for Chronic Non-healing Wounds in the Outpatient Setting
- MP-082-MD-PA Cosmetic Procedures

### **Governing Bodies Approval**

#### CMS

The Centers for Medicare and Medicaid Services (CMS) has published the following guidance:

- National Coverage Determination (NCD) Breast Reconstruction Following Mastectomy (140.2)
- Local Coverage Determination (LCD) Cosmetic and Reconstructive Surgery (L35090)
- Local Coverage Article (LCA) Billing and Coding: Cosmetic and Reconstructive Surgery (A56587)

The Women's Health and Cancer Rights Act of 1998 (WHCRA) is a federal law that provides protections to patients who choose to have breast reconstruction in connection with a mastectomy. Patients can elect to have breast reconstruction, and coverage must be provided for:

- All stages of reconstruction of the breast on which the mastectomy has been performed;
- Surgery and reconstruction of the other breast to produce a symmetrical appearance; and



- Prostheses and treatment of physical complications of all stages of the mastectomy, including lymphedema.

#### Pennsylvania

1997 Pa.ALS51; 1977 Pa.SB 176

Scope: Reimbursement for Length of Stay/Inpatient Care Following Mastectomy  
Reimbursement for Breast Reconstruction and Prosthesis

#### Breast Cancer Reconstructive Surgery Coverage Act

Bill signed into law October 21, 1998 and effective October 1, 1998

Provides mandatory insurance coverage for a 48-hour hospital stay and related breast reconstruction following a mastectomy. Provides for opposite breast reconstruction for symmetry, and requires home health care visits for mastectomy patients discharged before 48 hours. Provides protection to women who need time to recover from the trauma of major surgery.

Note the following:

- Cancer does not have to be the reason for the mastectomy
- The mandate applies to all genders
- Mandates coverage for all stages of breast reconstruction
- Does not mandate coverage for revision of a completed breast reconstruction to improve appearance

#### Extension of Medicaid for Breast Cancer Treatment

Effective January 1, 2002

Executive Order by Governor Ridge (Pennsylvania) in June 2001

- Extends the state's Medicaid coverage to uninsured women diagnosed with breast or cervical cancer through the Centers for Disease Control's National Breast and Cervical Cancer Early Detection Program
- Covers any other medical needs through the period of treatment
- Entitles qualified women to immediate free treatment paid for through Medicaid
- Guarantees coverage to women in Pennsylvania of their full treatment costs through Pennsylvania's Medicaid program
- Covers the expenses of patients with breast and cervical cancer whose incomes are too high to meet the traditional guidelines for Medicaid, a federal-state health coverage program
- No time limit on reconstructive surgery

Act 81 of 2002: Effective June 28, 2002, removed the 6-year time limit on mandatory insurance coverage for reconstructive surgery following mastectomy. It directs that all health care policies also cover physical complications from breast cancer, including lymphedema, and provides for prosthetics.

### **Summary of Literature**

The American Cancer Society (2022) states that breast cancer is the second most common cancer in women in the U.S., and makes up approximately 30% of all new female cancers each year. The current estimates for 2022 are about 287,850 new cases of invasive breast cancer will be diagnosed in women. Currently there are more than 3.8 million breast cancer survivors in the United States. With the increased incidence of breast cancer, there are many individuals receiving mastectomies to eliminate any and all possible existence of malignancy. There are multiple state mandates outlining mandatory reconstructive breast surgery for patients that have had a mastectomy.

When mastectomy is the treatment of choice, breast reconstruction is required to rebuild/restore the normal appearance of the affected breast. Reconstructive breast surgery can also be performed due to accidental injury or trauma. Procedures are also performed on the contralateral (normal) breast in order to achieve symmetry. The most common type of breast reconstruction is the insertion of breast implants. Artificial implants can be silicone gel-filled or saline-filled prostheses. Other breast reconstruction treatment types include autologous tissue from the abdomen, back, or buttocks. The actual reconstruction process on the affected breast can require multiple or staged surgeries, surgical revision(s), and surgery on the unaffected breast to correct asymmetry. The decision of the surgical technique to be utilized is made by the surgeon and the patient.

During breast reconstruction, it may be necessary to insert breast implants, tissue expanders, or to perform capsulotomy, capsulectomy, or the removal of breast implants. Breast reconstruction using autologous tissue is common. Flaps can be created using transverse rectus abdominis muscles (TRAM), deep inferior epigastric perforator (DIEP), latissimus dorsi (LD), superficial inferior epigastric artery (SIEA), transverse upper gracilis (TUG), and the superior gluteal artery perforator (SGAP).

Use of autologous fat grafting is a procedure where the patient's fat cells are collected and placed to restore volume after breast reconstruction or to repair defects in the breast following breast conservation surgery (NICE, 2012).

Acellular dermal skin substitutes are used during breast reconstruction when there is insufficient tissue expander or implant coverage by the pectoralis major muscle, and additional coverage is required, when there is compromised or thin post-mastectomy skin flaps that are at risk of dehiscence or necrosis, or it is necessary to improve the inframammary fold.

In an analysis of the short-term complication between human acellular dermis and submuscular tissue expander in breast reconstruction, Davila et al. (2013), reported similar post-operative complications and risks between these two reconstructive approaches.

Although the published evidence supporting the role of AlloDerm, AlloMax, FlexHD, and Neoform Dermis in breast reconstruction procedures is not robust, limited data from several small studies, as well as acceptance and limited use of these products by certain specialists in the practicing community, indicate that these products may improve outcomes in a carefully selected subset of breast reconstruction patients. Based on the current peer-reviewed literature, the role of these products for any other indication has not been established. Few authors have argued against the overall safety of acellular dermis-based reconstruction. Most studies have reported improved aesthetic outcomes and acceptable complication rates (Kim, Davila, Fine, Long, 2021).

The published evidence supporting the role of autologous fat transplant (i.e., lipoinjection, lipofilling, lipomodelling) as a breast reconstruction procedure has limited data from several small studies, indicating that autologous fat transplant raises no major safety concerns and may improve outcomes in a carefully selected subset of patients. Additionally, autologous fat transplant is widely used and accepted in clinical practice as a breast-reconstruction procedure.

There are multiple studies on the use of adipose-derived stem cells (ADSC) in autologous fat grafting in patients who have breast cancer and are undergoing autologous fat grafting. However, the studies are small, single-arm, and several are prospective. Studies that report on outcomes of overall survival, disease-specific survival, changes in disease severity, functional outcomes, quality of life, and treatment-related morbidity are limited. At this time, the evidence to support coverage is insufficient.

The role of autologous fat transplant with the use of adipose-derived stem cells, vascularized lymph node

transfer (VLNTx), and xenograft cartilage grafting in breast reconstruction has not been established. Optimal patient selection criteria have not been established through well-designed comparative clinical trials with long-term outcomes data.

External breast prostheses are available for women who have uneven- or unequal-sized breasts and who decide not to, or are waiting to, undergo surgical breast reconstruction. Health care professionals need to provide women with information and resources to participate in the breast restoration decision-making process.

In a question and answer publication from the FDA (2019), it was reported that Breast Implant Associated Anaplastic Large Cell Lymphoma (BIA-ALCL) can develop following breast implants. Based on current data, the risk of BIA-ALCL is higher for textured surface implants versus smooth surface implants. Certain other textured breast products, specifically certain textured tissue expanders, should not be used. The type of implant fill does not appear to be a risk factor because there are insufficient large, well-designed epidemiologic studies to date. The FDA has issued new recommendations for patients who have or have had these products. While the risk for developing this type of cancer can be low, individuals need to be advised regarding this issue when breast implants are being considered.

The American Society of Plastic Surgeons (ASPS) recognized 688 cases worldwide of breast implant associated lymphoma and 270 cases in the United States. As of January 24, 2020, there are now 307 suspected/confirmed BIA-ALCL cases in the United States. All cases have been reported to the Patient Registry and Outcomes For breast Implants and anaplastic large cell Lymphoma etiology and Epidemiology (PROFILE) Registry, a joint collaboration between ASPS, the Plastic Surgery Foundation (PSF), and the FDA. The FDA Safety Communication published a voluntary recall of the Allergan Biocell implants and tissue expanders as of July 24, 2019.

This FDA Safety Communication alerted health care professionals that the listed breast implants and tissue expanders that should be stopped. However, the FDA did not recommend the routine removal of these or other types of breast implants in patients who have no symptoms. Patients who have had these types of implants should be educated, and discussions held with a health care professional.

The most recent practice guidelines published by the ASPS state that based on the evidence in their report, the Work Group recommends that surgeons contemplating breast reconstruction on their next patient consider the following: the patient's preferences and risk factors, the setting in which the surgeon works (academic versus community practice), resources available, the evidence shown in the guideline, and, equally important, the surgeon's technical expertise. Although theoretical superiority of one technique may exist, this remains to be reported in the literature, and future methodologically robust studies are needed. The ASPS advises that breast reconstruction occurs in stages regardless of the type of reconstruction; it is not a one-time procedure. To achieve symmetry, as described in the Women's Health and Cancer Rights Act, additional surgeries, including revisions on either breast, to improve scarring, adjust volume and contour, and nipple reconstruction and tattooing will usually be necessary (ASPS, 2020).

#### Poland Syndrome

Poland syndrome is a congenital disorder associated with a range of malformations of ribs typically on one side, most often the right side, but can occur bilaterally. The syndrome has been estimated to occur in 1 in 20,000 newborns, affecting twice as many males than females and the cause is unknown (Genetic Home Reference). Several researchers have suggested that the syndrome is the result of a disruption of blood flow at the sixth week of embryonic development and affected blood vessels that will become the subclavian and vertebral arteries. This syndrome's hallmark findings include the absence of or hypoplasia of the pectoralis major and minor muscles, absence of costal cartilages, hypoplasia of the breast and

subcutaneous tissue, along with a variety of hand (syndactyl) and upper extremity anomalies. In severe cases, cardiac and/or pulmonary compression and cardiac displacement occur. For a complete evaluation of the individual, typically a CT scan or MRI is performed. Other diagnostic tests can include echocardiography and pulmonary function testing.

Reconstructive surgery for Poland syndrome depends on the severity of the malformation. A hypoplastic breast may be reconstructed with an implant (possibly expansion first). In case of maldeveloped muscles (e.g. the pectoralis muscle), an LD flap seems indicated. In case of additional thoracic malformations, more extensive, individual surgery is needed. Additionally, the position of the nipple-areola complex may need correction. For symmetry reasons, surgery to the contralateral breast can be considered. Reconstructive surgery in patients with Poland's syndrome is feasible and recommended for psychosocial reasons in these patients (Lantzsch, Lampe, Kantelhardt, 2013).

#### Gynecomastia Surgery

Gynecomastia is a condition of overdeveloped or enlarged breasts in men that can occur at any age. The condition can be the result of hormonal changes, heredity, obesity or the use of certain drugs. Gynecomastia is characterized by excess localized fat, excess glandular tissue development, excess breast skin, and/or the presence of a unilateral or bilateral breasts. Patients who have completed puberty and have had persistent gynecomastia for more than a year are unlikely to have a full reversal of gynecomastia with medical treatment alone due to permanent fibrosis, and therefore are good candidates for surgery (ASPS, 2021). Gynecomastia surgery is considered cosmetic in nature and is not covered unless there are specific circumstances, which can be reviewed by a medical director.

The ASPS recommends the following for adults with gynecomastia:

- Breast biopsy when malignancy is suspected
- Breast reduction due to pain and discomfort due to the distention and tightness from the hypertrophied breast
- Breast reduction for unilateral or bilateral grade III or IV gynecomastia present (per modified McKinney and Simon, Hoffman and Kohn scales) as prolonged presence of breast enlargement in the male patient leads to the development of periductal fibrosis and stromal hyalinization, preventing regression of breast tissue and causing pain and discomfort due to the distention and tightness from the hypertrophied breast.

American Society of Andrology and European Academy of Andrology (ASA/EAA) have published guidelines on gynecomastia evaluation and management. The purpose of gynecomastia assessment should be the detection of underlying pathological conditions, reversible causes and the discrimination from other breast lumps, particularly breast cancer. The assessments should comprise a thorough medical history and physical examination of the breast and genitalia (including testicular ultrasound). Surgical treatment is recommended only for patients with long-lasting gynecomastia, which does not regress spontaneously or following medical therapy. The extent and type of surgery should depend on the size of breast enlargement, and the amount of adipose tissue (ASA/EAA, 2017).

## **Coding Requirements**

### Breast Reconstructive Surgery Procedure Codes

<b>CPT Code</b>	<b>Description</b>
11920	Tattooing, intradermal introduction of insoluble opaque pigments to correct color defects of skin, including micropigmentation; 6.0 sq. cm or less
11921	Tattooing, intradermal introduction of insoluble opaque pigments to correct color defects of skin, including micropigmentation; 6.1 to 20.0 sq. cm
11922	Tattooing, intradermal introduction of insoluble opaque pigments to correct color defects of skin, including micropigmentation; each additional 20 sq. cm, or thereof (List separately in addition to code for primary procedure)
11950	Subcutaneous injection of filling material (e.g., collagen); 1 cc or less
11951	Subcutaneous injection of filling material (e.g., collagen); 1.1 to 5.0 cc
11952	Subcutaneous injection of filling material (e.g., collagen); 5.1 to 10.0 cc
11954	Subcutaneous injection of filling material (e.g., collagen); over 10.0 cc
11960	Insertion of tissue expander(s) for other than breast, including subsequent expansion
11970	Replacement of tissue expander with permanent implant
11971	Removal of tissue expander(s) without insertion of implant
14000	Adjacent tissue transfer or rearrangement, trunk; defect 10 sq cm or less
14001	Adjacent tissue transfer or rearrangement, trunk; defect 10.1 sq cm to 30.0 sq cm
15271	Application of skin substitute graft to trunk, arms, legs, total wound surface area up to 100 sq. cm; first 25 sq.cm or less wound surface area
15272	Application of skin substitute graft to trunk, arms, legs, total wound surface area up to 100 sq. cm; each additional 25 sq. cm wound surface area, or part thereof (List separately in addition to code for primary procedure)
15769	Grafting of autologous soft tissue, other, harvested by direct excision (e.g., fat, dermis, fascia)
15771	Grafting of autologous fat harvested by liposuction technique to trunk, breasts, scalp, arms, and/or legs; 50 cc or less injectate
15772	Grafting of autologous fat harvested by liposuction technique to trunk, breasts, scalp, arms, and/or legs; each additional 50 cc injectate, or part thereof; (List separately in addition to code for primary procedure)
15777	Implantation of biologic implant (e.g., acellular dermal matrix) for soft tissue reinforcement (i.e., breast, trunk) (List separately in addition to code for primary procedure)
15877	Suction assisted lipectomy; trunk [when specified as a breast reconstruction procedure following breast surgery]
19316	Mastopexy
19318	Breast reduction
19325	Breast augmentation with implant
19328	Removal of intact breast implant
19330	Removal of ruptured breast implant, including implant contents (eg, saline, silicone gel)
19340	Insertion of breast implant on same day of mastectomy (ie, immediate)
19342	Insertion or replacement of breast implant on separate day from mastectomy
19350	Nipple/areola reconstruction
19357	Tissue expander placement in breast reconstruction, including subsequent expansion(s)
*19361	Breast reconstruction; with latissimus dorsi flap
*19364	Breast reconstruction; with free flap (eg, fTRAM, DIEP, SIEA, GAP flap)

*19367	Breast reconstruction; with single-pedicled transverse rectus abdominis myocutaneous (TRAM) flap
*19368	Breast reconstruction; with single-pedicled transverse rectus abdominis myocutaneous (TRAM) flap, requiring separate microvascular anastomosis (supercharging)
*19369	Breast reconstruction; with bipedicled transverse rectus abdominis myocutaneous (TRAM) flap
19370	Revision of peri-implant capsule, breast, including capsulotomy, capsulorrhaphy, and/or partial capsulectomy
19371	Peri-implant capsulectomy, breast, complete, including removal of all intracapsular contents
19380	Revision of reconstructed breast (eg, significant removal of tissue, re-advancement and/or re-inset of flaps in autologous reconstruction or significant capsular revision combined with soft tissue excision in implant-based reconstruction)
19396	Preparation of moulage for custom breast implant
20900	Bone graft, any donor area, minor or small (e.g., dowel or button)
20902	Bone graft, any donor area, major or large
*21740	Reconstructive repair of pectus excavatum or carinatum; open
21742	Reconstructive repair of pectus excavatum or carinatum; minimally invasive approach (Nuss procedure), without thoracoscopy
21743	Reconstructive repair of pectus excavatum or carinatum; minimally invasive approach (Nuss procedure), with thoracoscopy
<b>HCPCS Codes</b>	
C1789	Prosthesis, breast (implantable)
L8600	Implantable breast prosthesis, silicone or equal
Q4100	Skin substitute, not otherwise specified [Cortiva (formerly known as AlloMax™) (acellular dermal matrix)]
Q4116	AlloDerm, per sq cm
Q4128	FlexHD or AllopathHD, or Matrix HD, per sq cm
S2066	Breast reconstruction with gluteal artery perforator (GAP) flap, including harvesting of the flap, microvascular transfer, closure of donor site and shaping the flap into a breast, unilateral
S2067	Breast reconstruction of a single breast with 'stacked' deep inferior epigastric perforator (IEP) flap(s) and/or gluteal artery perforator (GAP) flap(s), including harvesting of the flap(s), microvascular transfer, closure of donor site(s) and shaping the flap into a breast, unilateral
S2068	Breast reconstruction with deep inferior epigastric perforator (DIEP) flap or superficial inferior epigastric artery (SIEA) flap, including harvesting of the flap, microvascular transfer, closure of donor site and shaping of the flap into a breast, unilateral

\*These codes are considered as Inpatient Procedure Codes

#### Breast Reconstructive Surgery Diagnosis Codes

ICD-10 Code	Description
C44.501	Unspecified malignant neoplasm of skin of breast
C44.511	Basal Cell carcinoma of skin of breast
C44.521	Squamous cell carcinoma of skin of breast
C44.591	Other specified malignant neoplasm of skin of breast
C50.011	Malignant neoplasm of nipple and areola right female breast

C50.012	Malignant neoplasm of nipple and areola left female breast
C50.021	Malignant neoplasm of nipple and areola right male breast
C50.022	Malignant neoplasm of nipple and areola left male breast
C50.111	Malignant neoplasm of central portion of right female breast
C50.112	Malignant neoplasm of central portion of left female breast
C50.121	Malignant neoplasm of central portion of right male breast
C50.122	Malignant neoplasm of central portion of left male breast
C50.211	Malignant neoplasm of upper-inner quadrant of right female breast
C50.212	Malignant neoplasm of upper-inner quadrant of left female breast
C50.221	Malignant neoplasm of upper-inner quadrant of right male breast
C50.222	Malignant neoplasm of upper-inner quadrant of left male breast
C50.311	Malignant neoplasm of lower-inner quadrant of right female breast
C50.312	Malignant neoplasm of lower-inner quadrant of left female breast
C50.321	Malignant neoplasm of lower-inner quadrant of right male breast
C50.322	Malignant neoplasm of lower-inner quadrant of left male breast
C50.411	Malignant neoplasm of upper-outer quadrant of right female breast
C50.412	Malignant neoplasm of upper-outer quadrant of left female breast
C50.421	Malignant neoplasm of upper-outer quadrant of right male breast
C50.422	Malignant neoplasm of upper-outer quadrant of left male breast
C50.511	Malignant neoplasm of lower-outer quadrant of right female breast
C50.512	Malignant neoplasm of lower-outer quadrant of left female breast
C50.521	Malignant neoplasm of lower-outer quadrant of right male breast
C50.522	Malignant neoplasm of lower-outer quadrant of left male breast
C50.611	Malignant neoplasm of axillary tail of right female breast
C50.612	Malignant neoplasm of axillary tail of left female breast
C50.621	Malignant neoplasm of axillary tail of right male breast
C50.622	Malignant neoplasm of axillary tail of left male breast
C50.811	Malignant neoplasm of overlapping sites of right female breast
C50.812	Malignant neoplasm of overlapping sites of left female breast
C50.821	Malignant neoplasm of overlapping sites of right male breast
C50.822	Malignant neoplasm of overlapping sites of left male breast
C50.911	Malignant neoplasm of unspecified site of right female breast
C50.912	Malignant neoplasm of unspecified site of left female breast
C50.921	Malignant neoplasm of unspecified site of right male breast
C50.922	Malignant neoplasm of unspecified site of left male breast
C79.2	Secondary malignant neoplasm of skin
C79.81	Secondary malignant neoplasm of breast
C84.60	Anaplastic large cell lymphoma, ALK-positive, unspecified site
C84.61	Anaplastic large cell lymphoma, ALK-positive, lymph nodes of head, face and neck
C84.62	Anaplastic large cell lymphoma, ALK-positive, intrathoracic lymph nodes
C84.63	Anaplastic large cell lymphoma, ALK-positive, intra-abdominal lymph nodes
C84.64	Anaplastic large cell lymphoma, ALK-positive, lymph nodes of axilla and upper arm
C84.65	Anaplastic large cell lymphoma, ALK-positive, lymph nodes of inguinal region and lower limb
C84.66	Anaplastic large cell lymphoma, ALK-positive, intrapelvic lymph nodes
C84.67	Anaplastic large cell lymphoma, ALK-positive, lymph nodes of multiple sites

C84.68	Anaplastic large cell lymphoma, ALK-positive, spleen
C84.69	Anaplastic large cell lymphoma, ALK-positive, extranodal and solid organ sites
C84.70	Anaplastic large cell lymphoma, ALK-negative , unspecified site
C84.71	Anaplastic large cell lymphoma, ALK-negative, lymph nodes of head, face and neck
C84.72	Anaplastic large cell lymphoma, ALK-negative, intrathoracic lymph nodes
C84.73	Anaplastic large cell lymphoma, ALK-negative, intra-abdominal lymph nodes
C84.74	Anaplastic large cell lymphoma, ALK-negative, lymph nodes of axilla and upper arm
C84.75	Anaplastic large cell lymphoma, ALK-negative, lymph nodes of inguinal region and lower limb
C84.76	Anaplastic large cell lymphoma, ALK-negative, intrapelvic lymph nodes
C84.77	Anaplastic large cell lymphoma, ALK-negative, lymph nodes of multiple sites
C84.78	Anaplastic large cell lymphoma, ALK-negative, spleen
C84.79	Anaplastic large cell lymphoma, ALK-negative, extranodal and solid organ sites
D05.01	Lobular carcinoma in situ of right breast
D05.02	Lobular carcinoma in situ of left breast
D05.11	Intraductal carcinoma in site of right breast
D05.12	Intraductal carcinoma in site of left breast
D48.61	Neoplasm of uncertain behavior of right breast
D48.62	Neoplasm of uncertain behavior of left breast
D05.81	Other specified type of carcinoma in situ of right breast
D05.82	Other specified type of carcinoma in situ of left breast
D05.91	Unspecified type of carcinoma in situ of right breast
D05.92	Unspecified type of carcinoma in situ of left breast
D48.61	Neoplasm of uncertain behavior of right breast
D48.62	Neoplasm of uncertain behavior of left breast
N60.11	Diffuse cystic mastopathy of right breast
N60.12	Diffuse cystic mastopathy of left breast
N60.21	Fibroadenosis of right breast
N60.22	Fibroadenosis of left breast
N60.31	Fibrosclerosis of right breast
N60.32	Fibrosclerosis of left breast
N64.82	Hypoplasia of breast
N65.0	Deformity of reconstructed breast
N65.1	Disproportion of reconstructed breast
Q67.6	Pectus excavatum
Q67.7	Pectus carinatum
Q79.8	Other congenital malformations of musculoskeletal system (Poland Syndrome)
Q83.0	Congenital absence of breast with absent nipple
Q83.2	Absent nipple
T85.41XA	Breakdown (mechanical) of breast prosthesis and implant, initial encounter
T85.41XD	Breakdown (mechanical) of breast prosthesis and implant, subsequent encounter
T85.41XS	Breakdown (mechanical) of breast prosthesis and implant, sequela
T85.42XA	Displacement of breast prosthesis and implant, initial encounter
T85.42XD	Displacement of breast prosthesis and implant, subsequent encounter
T85.42XS	Displacement of breast prosthesis and implant, sequela



T85.43XA	Leakage of breast prosthesis and implant, initial encounter
T85.43XD	Leakage of breast prosthesis and implant, subsequent encounter
T85.43XS	Leakage of breast prosthesis and implant, sequela
T85.44XA	Capsular contracture of breast implant, initial encounter
T85.44XD	Capsular contracture of breast implant, subsequent encounter
T85.44XS	Capsular contracture of breast implant, sequela
T85.49XA	Other mechanical complication of breast prosthesis and implant, initial encounter
T85.49XD	Other mechanical complication of breast prosthesis and implant, subsequent encounter
T85.49XS	Other mechanical complication of breast prosthesis and implant, sequela
T85.79XA	Infection and inflammatory reaction due to other internal prosthetic devices, implants and grafts, initial encounter
T85.79XD	Infection and inflammatory reaction due to other internal prosthetic devices, implants and grafts, subsequent encounter
T85.79XS	Infection and inflammatory reaction due to other internal prosthetic devices, implants and grafts, sequela
Z40.01	Encounter for prophylactic removal of breast
Z42.1	Encounter for breast reconstruction following mastectomy
Z42.8	Encounter for other plastic and reconstructive surgery following medical procedure or healed injury
Z45.811	Encounter for adjustment or removal of right breast implant
Z45.812	Encounter for adjustment or removal of left breast implant
Z48.3	Aftercare following surgery for neoplasm
Z85.3	Personal history of malignant neoplasm of breast
Z90.11	Acquired absence of right breast and nipple
Z90.12	Acquired absence of left breast and nipple
Z90.13	Acquired absence of bilateral breasts and nipples
Z98.82	Breast implant status

#### Gynecomastia Surgery Procedure Code

<b>CPT Code</b>	<b>Description</b>
19300	Mastectomy for gynecomastia

#### Gynecomastia Surgery Diagnosis Code

<b>ICD-10 Code</b>	<b>Description</b>
N62	Hypertrophy of breast

## **Informational**

### **Baker Classification Breast Implant Contractures**

- Grade I: Augmented breast feels as soft as normal breast
- Grade II: Breast is less soft, and the implant can be palpated, but it is not visible
- Grade III: Breast is firm, palpable, and the implant (or its distortion) is visible
- Grade IV: Breast is hard, painful, cold, tender, and distorted

### **American Society of Plastic Surgeons Gynecomastia Scale** (adapted from the McKinney and Simon, Hoffman and Kohn scales)

- **Grade I:** Small breast enlargement with localized button of tissue that is concentrated around the areola.
- **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 distinct from the chest with skin redundancy present.
- **Grade IV:** Marked breast enlargement with skin redundancy and feminization of the breast.

## **Reimbursement**

Participating facilities will be reimbursed per their Highmark Wholecare<sup>SM</sup> contract.

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