

<b>CLINICAL MEDICAL POLICY</b>	
<b>Policy Name:</b>	Breast Reconstructive Surgery
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<b>Products:</b>	Highmark Health Options Medicaid
<b>Application:</b>	All participating hospitals and providers
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**DISCLAIMER**

**Highmark Health Options 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 Health Options may provide coverage under the medical surgical benefits of the Company's Medicaid products for medically necessary breast reconstructive surgery.

The qualifications of the policy will meet the standards of the National Committee for Quality Assurance (NCQA) and the Delaware Department of Health and Social Services (DHSS) and all applicable state and federal regulations.

**DEFINITIONS**

**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 development 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.

## **PROCEDURES**

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

In accordance with federal and state mandates, the following breast reconstruction services are covered:

- Reconstruction of the breast where the mastectomy was performed;

- Surgery and reconstruction of the other breast to produce a symmetrical appearance, including nipple tattooing;
- Prosthesis (implanted and/or external)
- Treatment of physical complications of mastectomy (including lymphedema);
- 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 men and women;
- Requires coverage for all stages of breast reconstruction

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

### Medical Necessity Guidelines

1. Immediate or delayed breast reconstruction performed on the diseased/affected breast, including:
  - A. Areolar and nipple reconstruction;
  - B. Areolar and nipple tattooing;
  - C. Autologous fat transplant (e.g., lipoinjection, lipofilling, lipomodeling);
  - D. Breast implant removal and subsequent reimplantation for implants done post-mastectomy or other covered reconstructive procedures;
  - E. Capsulectomy;
  - F. Capsulotomy;
  - G. Implantation of tissue expander;
  - H. Implantation of U.S. FDA-approved internal breast prosthesis;
  - I. Reconstructive surgical revisions;
  - J. Oncoplastic reconstruction;
  - K. 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) Ruben's 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
  - L. 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.

2. Breast reconstruction procedures performed on the non-diseased/unaffected breast after having a mastectomy/lumpectomy in order to produce a symmetrical appearance are considered medically necessary, including:
  - A. Areolar and nipple reconstruction;
  - B. Areolar and nipple tattooing;
  - C. Augmentation mammoplasty with implantation of FDA-approved internal breast prosthesis;
  - D. Autologous fat transplant (e.g., lipoinjection, lipofilling, lipomodeling);

- E. Breast implant removal and subsequent reimplantation when performed to produce a symmetrical appearance;
  - F. Breast reduction by mammoplasty or mastopexy;
  - G. Capsulectomy;
  - H. Capsulotomy;
  - I. Reconstructive surgery revisions to produce a symmetrical appearance
3. Breast reconstruction may require the use of skin substitutes. Skin substitutes are 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 viable but compromised or thin post-mastectomy flaps that are at risk of dehiscence or necrosis; OR
  - C. 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 considered medically necessary:

- A. AlloDerm® (acellular dermal matrix)
- B. Cortiva (formerly known as AlloMax™) (acellular dermal matrix)
- C. FlexHD® (acellular dermal matrix)

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

4. Removal, Revision, or Replacement of Breast Implants
- Removal, revision, or replacement of FDA-approved breast implants will be considered medically necessary when:
- A. The breast implant was originally implanted for reconstruction following a mastectomy for breast cancer and covered surgical reconstruction for breast abnormalities listed above; AND
  - B. There is implant rupture, failure, Baker Class III or IV contracture, implant exposure or extrusion; OR
  - C. There is infection or inflammatory reaction to a breast prosthesis including siliconoma, granuloma, or painful capsular contracture with disfigurement; OR
  - D. There is interference with the diagnosis or treatment of breast cancer
  - E. Removal, revision, or replacement of breast implants is not considered medically necessary for complications, immediate or delayed, from a prior cosmetic breast implant.
5. Capsulectomy/Capsulotomy
- A. Capsulectomy and/or capsulotomy is considered medically necessary when the original implant was placed during a covered breast reconstruction procedure.
  - B. Capsulectomy and/or capsulotomy is required due to a related complication of a covered medical condition or procedure.
  - C. Capsulectomy and/or capsulotomy is not considered medically necessary for complications, immediate or delayed, from a prior cosmetic breast implant.

## 6. Nonsurgical Option

An external breast prosthesis and mastectomy bra are covered benefits for women who choose not to have breast reconstruction or are poor candidates for reconstruction.

## 7. Treatment of Post-Mastectomy Complications

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

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

## 8. Poland Syndrome

Coverage is provided for surgical correction of chest wall deformity as a result of Poland syndrome when criteria are met:

- There is musculoskeletal chest wall deformities associated with Poland's syndrome. There must be a congenital absence or hypoplasia of pectoralis major and minor muscles; congenital partial absence of the upper costal cartilage;
- Functional impairment must be documented as decreased cardiac output; OR
- Abnormal function during exercise; OR
- Future cardiovascular compromise is anticipated; OR
- In the medical record there is documentation of signs and symptoms which impair the individual's ability to participate in activities of daily living;
- The procedure is expected to correct the functional impairment

**Note:** If there are no chest wall involvement in the case, the breast reconstruction related to Poland's syndrome is considered cosmetic and will be denied.

Please see MP-033-MD-DE for information regarding surgical procedures of the breast for individuals with gender dysphoria or incongruence or gender identity disorder.

## 9. Precautions

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

- A. Active smoking
- B. A body mass index (BMI) of 25 or greater
- C. Poorly managed diabetes

## 10. Non-covered Services

- Aspirations
- Biopsy (open or core);
- Excision of cysts, fibroadenomas or other benign or malignant tumors, aberrant breast tissue, duct lesions, nipple or areolar lesions;
- Treatment of gynecomastia

- 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

11. Contraindications

There are no known contraindications for breast reconstructive surgery.

12. When breast reconstructive surgery services are not covered

Breast reconstructive surgery is not covered for conditions other than those listed above; scientific evidence has not been established.

13. Post-payment Audit Statement

The medical record must include documentation that reflects the medical necessity criteria and is subject to audit by Highmark Health Options at any time pursuant to the terms of your provider agreement.

14. Place of Service

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

All procedure codes are considered to be outpatient procedures except for the following procedures:

<b>Inpatient CPT Procedure Codes</b>	
19361	Breast reconstruction with latissimus dorsi flap, without prosthetic implant
19364	Breast reconstruction with free flap
19367	Breast reconstruction with transverse rectus abdominis myocutaneous flap (TRAM), single pedicle, including closure of donor site
19368	Breast reconstruction with transverse rectus abdominis myocutaneous flap (TRAM), single pedicle, including closure of donor site; with microvascular anastomosis (supercharging)
19369	Breast reconstruction with transverse rectus abdominis myocutaneous flap (TRAM), double pedicle, including closure of donor site
21740	Reconstructive repair of pectus excavatum or carinatum; open

**GOVERNING BODIES APPROVAL**

The FDA published the regulatory history of breast implants in the United States.

<https://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/ImplantsandProsthetics/BreastImplants/ucm064461.htm>

Federal  
Informational

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.

Delaware

**Informational**

§3571 through §3577 Required Coverage for Reconstructive surgery following Mastectomy; Effective July 15, 2001. The Delaware Act requires coverage under the medical and surgical benefits with respect to mastectomy 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 physical complications of mastectomy, including lymphedemas

**CODING REQUIREMENTS**

Procedure Codes

\*Codes are Inpatient Procedure Codes

CPT Codes	Description
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 prosthesis
11971	Removal of tissue expander(s) without insertion of prosthesis
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)
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	Reduction mammoplasty
19324	Mammoplasty, augmentation; without prosthetic implant
19325	Mammoplasty, augmentation; with prosthetic implant
19328	Removal of intact mammary implant
19330	Removal of mammary implant material
19340	Immediate insertion of breast prosthesis following mastopexy, mastectomy or in reconstruction
19342	Delayed insertion of breast prosthesis following mastopexy, mastectomy or in reconstruction
19350	Nipple/areola reconstruction
19355	Correction of inverted nipples
19357	Breast reconstruction, immediate or delayed, with tissue expander, including subsequent expansion
*19361	Breast reconstruction with latissimus dorsi flap, without prosthetic implant
*19364	Breast reconstruction with free flap
19366	Breast reconstruction with other technique (e.g., autologous fat transplant without adipose derived stem cells or xenograft cartilage grafting)
*19367	Breast reconstruction with transverse rectus abdominis myocutaneous flap (TRAM), single pedicle, including closure of donor site
*19368	Breast reconstruction with transverse rectus abdominis myocutaneous flap (TRAM), single pedicle, including closure of donor site; with microvascular anastomosis (supercharging)
*19369	Breast reconstruction with transverse rectus abdominis myocutaneous flap (TRAM), double pedicle, including closure of donor site
19370	Open periprosthetic capsulotomy, breast
19371	Periprosthetic capsulectomy, breast
19380	Revision of reconstructed breast
19396	Preparation of mouldage 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
20926	Tissue grafts, other (e.g., paratenon, fat dermis)
*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)
L8000	Breast prosthesis; mastectomy bra
L8001	Breast prosthesis; mastectomy bra, with integrated breast prosthesis form, unilateral
L8002	Breast prosthesis; mastectomy bra, with integrated breast prosthesis form, bilateral
L8015	External breast prosthesis garment, with mastectomy form, post mastectomy
L8020	Breast prosthesis; mastectomy form
L8030	Breast prosthesis; silicone or equal, without integral adhesive
L8031	Breast prosthesis; silicone or equal, with integral adhesive
L8032	Nipple prosthesis, reusable, any type, each



L8035	Custom breast prosthesis, post mastectomy, molded to patient model
L8039	Breast prosthesis, not otherwise classified
L8600	Implantable breast prosthesis, silicone or equal
Q4100	Skin substitute, not otherwise specified
Q4116	AlloDerm, per square centimeter
Q4128	FlexHD or AllopathHD, 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) flaps(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

#### Diagnosis Codes

ICD-10 Codes	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
D	C
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
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
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
Z44.30	Encounter for fitting and adjustment of external breast prosthesis, unspecified breast
Z44.31	Encounter for fitting and adjustment of external right breast prosthesis
Z44.32	Encounter for fitting and adjustment of external left breast prosthesis
Z45.811	Encounter for adjustment or removal of right breast implant
Z45.812	Encounter for adjustment or removal of left breast implant
Z45.819	Encounter for adjustment or removal of unspecified breast implant
Z48.3	Aftercare following surgery for neoplasm
Z85.3	Personal history of malignant neoplasm of breast
Z90.10	Acquire absence of unspecified breast and nipple
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

## **REIMBURSEMENT**

Participating facilities will be reimbursed per their Highmark Health Options contract.

## **SUMMARY OF LITERATURE**

The American Cancer Society (2016) stated that breast cancer ranks second as a cause of death in women. The Society projected that in 2016, invasive breast cancer will be diagnosed in approximately 246,660

women and 2,600 men, and 61,000 new cases of in situ breast cancer will be diagnosed in women. 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 received 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.

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 in autologous fat grafting (ADSC) 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.

Poland syndrome is a congenital disorder associated with 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 (Genetic Home Reference) and the cause is unknown. 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 occurs. For a complete evaluation of the individual, typically a CT scan or MRI are performed. Other diagnostic tests can include echocardiography and pulmonary function testing.

### **POLICY SOURCE(S)**

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### Policy History

Date	Activity
04/14/2017	Initial policy developed
06/27/2017	QI/UM Committee approval
09/01/2017	Provider effective date
08/09/2017	EHS Revisions: Added Issue Date to opening policy box; updated Operational Guidelines; Added ‘Covered’ and ‘Non-covered’ to procedure code table in Attachment B; Added ‘Covered’ to diagnosis code table in Attachment C; added ‘informational’ to <i>Governing Bodies Approval</i> section under <i>Procedures</i> ; added ‘Informational’ to <i>Table in Attachment D</i> ; ‘Non-covered statement’ under <i>procedures section</i> has been updated as not medically necessary. Added information regarding the eligibility of procedure code 15877 to the Operational Guidelines.
09/11/2018	Annual Review: Added ‘Immediate or delayed’ to Bullet 1 under Procedures and added procedure TDAP to list of covered procedures. Removed the word ‘Covered’ from the procedure and diagnosis code tables in Attachments B & C. Under procedure codes in Attachment B; added: 11950, 11951, 11952, 11954 and 20926 as eligible; formatting changes
09/11/2018	QI/UM Committee Review Approval
11/15/2018	New provider effective date
07/16/2019	Annual review: Added MP-033-MD-DE as related policy; updated title of medical director; formatting changes; under Procedures, added #8 outlining medical necessity guidelines for Poland’s syndrome treatment; under Operational Guidelines, revised code Q4100 from prepayment to postpayment; in Attachment B added procedure codes 11960, 20900, & 20802; updated Summary of Literature with information on Poland’s syndrome; updated Literature section.
07/16/2019	QI/UM Committee Review Approval
09/16/2019	Provider effective date