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WellCare Prescription Insurance

WellCare Texan Plus (Medicare – Dallas & Houston markets)

Breast Reconstructive Surgery

Policy Number: HS-276

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Revised Date(s): 2/4/2016; 6/2/2016; 5/4/2017;
12/7/2017; 10/4/2018

APPLICATION STATEMENT

The application of the Clinical Coverage Guideline is subject to the benefit determinations set forth by the Centers for Medicare and Medicaid Services (CMS) National and Local Coverage Determinations and state-specific Medicaid mandates, if any.

DISCLAIMER

The Clinical Coverage Guideline (CCG) is intended to supplement certain standard WellCare benefit plans and aid in administering benefits. Federal and state law, contract language, etc. take precedence over the CCG (e.g., Centers for Medicare and Medicaid Services [CMS] National Coverage Determinations [NCDs], Local Coverage Determinations [LCDs] or other published documents). The terms of a member's particular Benefit Plan, Evidence of Coverage, Certificate of Coverage, etc., may differ significantly from this Coverage Position. For example, a member's benefit plan may contain specific exclusions related to the topic addressed in this CCG. Additionally, CCGs relate exclusively to the administration of health benefit plans and are NOT recommendations for treatment, nor should they be used as treatment guidelines. Providers are responsible for the treatment and recommendations provided to the member. The application of the CCG is subject to the benefit determinations set forth by the Centers for Medicare and Medicaid Services (CMS) National and Local Coverage Determinations, and any state-specific Medicaid mandates. Links are current at time of approval by the Medical Policy Committee (MPC) and are subject to change. Lines of business are also subject to change without notice and are noted on www.wellcare.com. Guidelines are also available on the site by selecting the Provider tab, then "Tools" and "Clinical Guidelines".

BACKGROUND

The most common reason for breast reconstruction is to repair defects caused by breast cancer. Breast cancer is the second most frequently occurring cancer in the United States. A woman has a 12.5% lifetime risk of developing breast cancer and a 3.5% lifetime risk of dying from the disease. This risk generally increases with age. If she develops an invasive or in situ breast cancer, her risk of developing a second cancer in either breast increases by 0.5 to 1.0% per year. Approximately 5% to 10% of breast cancers are believed to be inherited, and as many as half of these are related to two breast cancer susceptibility genes, BRCA1 and BRCA2. Although uncommon, breast cancer also occurs in men, accounting for less than 1% of all breast cancers. Many women find that surgical reconstruction of the missing breast is an essential component in their recovery from cancer. Similarly, reconstruction of the opposite breast to provide symmetry and balance is an integral part of this process.¹

Patients usually presents to the plastic surgeon's office with a history of prior diagnosis and/or treatment for breast cancer. Patients who have had breast cancer may have had only a biopsy of the mass, a lumpectomy, or a simple mastectomy (alone or with axillary lymph node sampling or removal). Any of these surgical treatments may have been supplemented with radiation treatment to the breast and/or regional lymph nodes. Other cancer related treatments may include a modified radical mastectomy, chemotherapy and/or radiation, which may have an effect on the reconstructive site. Expander / implant reconstruction is the most commonly performed technique in the United States for post-mastectomy breast reconstruction.^{1,2}

Non-cancerous breast deformities may occur in men or women and result from a variety of conditions including congenital errors, trauma, disease or aging. Some of the more common deformities that require breast reconstruction surgery include Poland's Syndrome and tuberous breast(s).³

Reconstructive Surgery Options^{1,4}

According to the American Society of Plastic Surgeons (ASPS), the type of breast reconstruction surgery is dependent on the nature of the defect and the overall health of the patient. Various surgical techniques can be used for the treatment of malignant conditions.

- Mastectomies can be total or partial. Reconstruction of a surgical defect caused by the removal of a breast cancer can be done at the time that the cancer is removed (immediate reconstruction) or any time thereafter (delayed reconstruction). The timing may be dependent on the need for additional treatment for malignancy, including chemotherapy and/or radiation. Furthermore, mastectomies can be skin-sparing or not skin-sparing. Skin-sparing mastectomies are generally performed for smaller and less invasive breast cancers, and offer a better cosmetic result for immediate breast reconstruction.
- A lumpectomy is a surgical alternative to mastectomy and is almost always combined with subsequent radiation treatment. It is generally used for lesions that are less than 4 cm in size. However, some patients who undergo a lumpectomy still need reconstructive surgery because of the defect created during surgical removal. The defect can vary significantly due to the size of the original tumor, the shape of the incision and the side effects of radiation used after lumpectomy. Reconstruction of the breast mound itself will require the use of a breast implant, autologous tissue, or both. The choice of surgical technique will depend on many factors, including the nature of the defect, the amount of tissue available for reconstruction, the underlying musculature, and the radiation history. Other factors in the patient's history will impact these choices such as age, other diseases such as diabetes, and the use of nicotine.
- If a breast implant is used, there must be sufficient skin left on the chest wall after surgery to cover the implant and sufficient underlying muscle to support it. When this skin is tight or insufficient it can be expanded or stretched by use of a tissue expander prior to placing a permanent implant. The tissue expander is itself a temporary prosthesis and in its position beneath the skin and/or chest muscle will, over time, stretch the overlying tissue as saline is injected incrementally over weeks to months. Once expansion is complete, the expander is removed and a permanent implant can be put in its place at a second surgery.¹
- The transverse rectus abdominus muscle (TRAM) flap is performed if a patient is not a candidate for tissue expansion and breast implant, or if the patient wishes to have only autologous tissue used. The TRAM flap can be either pedicled (using its inherent blood supply from a single artery and vein) or a free tissue transfer. The choice of performing a TRAM flap is dependent on the patient's overall health, the quality and quantity of the lower abdominal tissues, prior abdominal surgery, and smoking history. When a patient is at risk for flap complications from having a pedicled TRAM, delaying the TRAM flap or choosing free tissue transfer of the TRAM are options. In the delay procedure, the more dominant blood supply to the flap, the deep inferior epigastric artery, is ligated to increase blood from the deep superior epigastric artery. This procedure opens up small vessels in regions of the flap and makes the flap more hearty. The final surgery which is usually done one to three weeks later is less risky due to the artificially created more robust blood supply. The free TRAM tissue transfer involves completely disconnecting both blood supplies and reconnecting the more dominant deep inferior epigastric artery using microvascular techniques. Another local muscle flap is the latissimus dorsi muscle. This muscle, taken from the back and side of the patient with some overlying back

skin, can be used to restore the breast or to cover an implant. Often the latissimus muscle alone is not adequate to create a breast mound and an implant must be used to achieve volume. This flap is a good choice for patients who are not TRAM candidates or those who wish to have an implant with a history of prior radiation. It can also be used as a secondary treatment when local complications on the chest wall require additional tissue. Other flap techniques that may be used for breast reconstruction are free tissue transfers including the superior gluteal flap, the lateral thigh flap, the deep inferior epigastric perforator (DIEP) flap, and the Rubens flap. These flaps are generally utilized only when the first line choices cannot be used.

- Skin sparing mastectomy (removal of breast tissue only) and immediate breast reconstruction may be appropriate for certain early stage cancers. Research has shown this to be effective and without increased risk of recurrence. Usually the opposite breast will require treatment to achieve balance and symmetry with the reconstructed side. This is undertaken at the time when the final mound configuration is mature and can include a lifting of the breast through skin removal (mastopexy) or complete reduction of both skin and breast tissue (reduction mammaplasty). When the opposite breast remains smaller than the reconstructed breast placement of a small implant on this side can achieve symmetry as well. Follow-up care for breast reconstruction includes serial office visits for drain removal, suture removal, and assessment of wound healing during the first 4-6 weeks. If a tissue expander is being used, infusions of saline through an implanted port may take place as often as twice a week. Beyond that period, less frequent serial office visits are required to assess continued healing, appearance, scar maturation and patient satisfaction. Additional surgery for nipple reconstruction is usually delayed until the breast mound surgery has been finalized and the shape has matured. This surgery is usually undertaken as an outpatient surgery and can include local tissue rearrangement of grafts. Final pigmentation of the nipple can be achieved through tattoo techniques that adjust the color to the patient's opposite nipple or skin type. It is not uncommon for secondary surgery to be done to adjust the mound, the opposite breast or the final nipple reconstruction. These procedures are generally performed as an outpatient and result in high patient satisfaction from the overall result.

National Comprehensive Cancer Network⁵

The following are part of NCCN's 2014 "Principles of Breast Reconstruction Following Surgery":

- Breast reconstruction may be an option for any woman receiving surgical treatment for breast cancer. All women undergoing breast cancer treatment should be education about breast reconstructive options as adapted to their individual clinical situation. However, breast reconstruction should not interfere with the appropriate surgical management of the cancer. The process of breast reconstruction should not govern timing or the scope of appropriate surgical treatment for this disease. The availability of or the practicality of breast reconstruction should not result in the delay or refusal of appropriate surgical intervention.
- An evaluation of the likely cosmetic outcome of lumpectomy should be performed prior to surgery. Oncoplastic techniques for breast conservation can extend breast-conserving surgical options in situations where the resection itself would likely yield an unacceptable cosmetic outcome. Application of these procedures may reduce the need for mastectomy and reduce the chances of secondary surgery for re-excision while minimizing breast deformity. Patients should be informed of the possibility of positive margins and potential need for secondary surgery, which could include re-excision segmental resection, or could require mastectomy with or without loss of the nipple. Oncoplastic procedures can be combined with surgery on the contralateral unaffected breast to minimize long-term asymmetry.
- For mastectomy, the possibility of reconstruction should be discussed and a preoperative evaluation of reconstructive options should be considered. Surgical options for breast reconstruction following mastectomy include:
 - Procedures that incorporate breast implants (e.g., tissue expander placement followed by implant placement, immediate implant placement);
 - Procedures that incorporate autologous tissue transplantation (e.g., pedicled TRAM flap, fat grafting, various microsurgical flaps from the abdomen, back, buttocks, and thigh)

- Procedures that incorporate both breast implants and autologous tissue transplantation (e.g., latissimus dorsi flaps)
- Breast reconstruction following mastectomy can commence at the same time as mastectomy (“immediate”) or at some time following the completion of cancer treatment (“delayed”). In many cases, breast reconstruction involves a staged approach requiring more than one procedure such as:
 - Surgery on the contralateral breast to improve symmetry
 - Revision surgery involving the breast and/or donor site
 - Nipple and areola reconstruction and tattoo pigmentation

Centers for Medicare and Medicaid Services⁶

During recent years, there has been a considerable change in the treatment of diseases of the breast such as fibrocystic disease and cancer. While extirpation of the disease remains of primary importance, the quality of life following initial treatment is increasingly recognized as of great concern. The increased use of breast reconstruction procedures is due to several factors:

- A change in epidemiology of breast cancer, including an apparent increase in incidence;
- Improved surgical skills and techniques;
- The continuing development of better prostheses; and
- Increasing awareness by physicians of the importance of postsurgical psychological adjustment.

Reconstruction of the affected and the contralateral unaffected breast following a medically necessary mastectomy is considered a relatively safe and effective non-cosmetic procedure. Accordingly, program payment may be made for breast reconstruction surgery following removal of a breast for any medical reason. Program payment may not be made for breast reconstruction for cosmetic reasons.

Women’s Health and Cancer Rights Act⁷

The Women’s Health and Cancer Rights Act (WHCRA) was signed into law on October 21, 1998 and contains protections for patients who elect breast reconstruction in connection with a mastectomy for breast malignancy. For plan participants and beneficiaries receiving benefits in connection with a mastectomy, plans offering coverage for a mastectomy must also cover reconstructive surgery and other benefits related to a mastectomy. Under WHCRA, mastectomy benefits must include coverage for:

- Reconstruction of the breast on which the mastectomy was performed (any type of reconstruction on either or both breast, affected and unaffected, including but not limited to the procedures listed above as medically necessary. The timing of reconstructive services is not a factor in coverage);
- Surgery and reconstruction of the other breast to produce a symmetrical appearance;
- Prostheses and physical complications at all stages of mastectomy, including lymphedemas.

Under WHCRA, mastectomy benefits may be subject to annual deductibles and coinsurance consistent with those established for other benefits under the plan or coverage.

Breast reconstruction surgery (for breast cancer surgeries) includes, but may not be limited to:

- Insertion of breast implants
- Insertion of tissue expanders
- Mastopexy
- Nipple repigmentation (tattoo)
- Transverse rectus abdominis myocutaneous (TRAM) flap, deep inferior epigastric perforator (DIEP) flap, latissimus dorsi (LD) myocutaneous flap, superficial inferior epigastric artery (SIEA) flap, transverse upper gracilis (TUG) flapprofunda artery perforator flap, superior gluteal artery perforator (SGAP) flap or other free or pedicle flap procedures.

POSITION STATEMENT

Applicable To:

- Medicaid
- Medicare

Exclusions

Breast Reconstruction **is not considered medically necessary and not a covered benefit** when any of the following apply:

1. Surgery is performed to correct breast asymmetry when performed for non-medically necessary cosmetic reasons.
2. Breast reconstruction surgery is performed to correct complications from breast reduction surgeries (e.g., asymmetry) when performed for non-medically necessary cosmetic reasons.
3. For replacement implants following medically necessary removal of breast implants originally placed for cosmetic purposes.

Coverage

Breast Reconstruction Surgery for Cancerous Breasts

The following indications **are considered medically necessary and a covered benefit** for breast reconstruction surgery:

1. Following a medically necessary prophylactic mastectomy; **OR**,
2. Complications with or removal of breast implant(s) following a medically necessary mastectomy; **OR**,
3. Trauma (within 12 months post injury); **OR**,
4. Following a medically necessary mastectomy or lumpectomy resulting in a significant deformity*[^] (e.g., for treatment of, or prophylaxis for, breast cancer; for chronic, severe fibrocystic breast disease [cystic mastitis]; or member is unresponsive to medical therapy); **OR**,
5. Breast reconstruction procedures performed on the **diseased/affected breast** (i.e., breast on which the mastectomy / lumpectomy was performed), including:
 - o areolar and nipple reconstruction
 - o areolar and nipple tattooing
 - o autologous fat transplant (i.e., lipoinjection, lipofilling, lipomodeling)
 - o breast implant removal and subsequent reimplantation
 - o capsulectomy
 - o capsulotomy
 - o implantation of tissue expander
 - o implantation of U.S. Food and Drug Administration (FDA)-approved internal breast prosthesis
 - o oncoplastic reconstruction
 - o reconstructive surgical revisions
 - o tissue/muscle reconstruction procedures (e.g., flaps), including, but not limited to, the following :
 - deep inferior epigastric perforator (DIEP) flap
 - latissimus dorsi (LD) myocutaneous flap
 - Ruben's flap
 - superficial inferior epigastric perforator (SIEP) flap
 - superior or inferior gluteal free flap
 - transverse rectus abdominus myocutaneous (TRAM) flap
 - transverse upper gracilis (TUG) flap

OR,

6. Breast reconstruction procedures (for breast cancer surgeries) performed on the **non-diseased / unaffected / contralateral breast**, in order to produce a symmetrical appearance, including:
- areolar and nipple reconstruction
 - areolar and nipple tattooing
 - augmentation mammoplasty
 - augmentation with implantation of FDA-approved internal breast prosthesis when the unaffected breast is smaller than the smallest available internal prosthesis
 - autologous fat transplant (i.e., lipoinjection, lipofilling, lipomodeling)
 - breast implant removal and subsequent reimplantation when performed to produce a symmetrical appearance
 - breast reduction by mammoplasty or mastopexy
 - capsulectomy
 - capsulotomy
 - reconstructive surgery revisions to produce a symmetrical appearance

* Breast reconstruction surgery is applicable to males and females.

^ A diagnosis of breast cancer is not required at all times and the timing of reconstructive services is not a factor in coverage.

Breast Reconstruction Surgery for Non-Cancerous Breasts

Breast reconstruction surgery for non-cancerous breasts **is considered medically necessary** for the following:

1. Member has one of the following:
 - A. Congenital deformities of the breasts affecting the physical and psychological life of the member; **OR,**
 - B. Deformities of the breast resulting from unintended injuries (i.e. accidents); **OR,**
 - C. Severe fibrocystic breast disease causing functional limitation on the life of the member; **OR,**
 - D. Unintended complications of breast surgeries for non-malignant conditions causing pain, discomfort, irritation, bleeding, drainage, or complication affecting lactation;

AND,
2. All reviews for breast reconstruction of non-cancerous breasts must go to Medical Director for secondary review.

CODING

CPT®* Codes

- 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 20.0 sq cm, or part thereof (list separately in addition to code for primary procedure)
- 11970** Replacement of tissue expander with permanent prosthesis
- 11971** Removal of tissue expander(s) without insertion of prosthesis
- 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
- 19367** Breast reconstruction with transverse rectus abdominis myocutaneous flap (TRAM), single pedicle, including 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 moulage for custom breast implant

Covered HCPCS Codes

- C1789** Prosthesis, breast (implantable)
- L8600** Implantable breast prosthesis, silicone or equal
- 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 (DIEP) 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 the flap into a breast, unilateral

ICD-10 CM Diagnosis Codes – not all inclusive

- C50.011 - C50.929** Malignant neoplasm of breast
- C79.81** Secondary malignant neoplasm of breast
- D05.00 – D05.92** Carcinoma in situ of breast
- D24.1 – D24.9** Benign neoplasm of breast
- D48.60 – D48.62** Neoplasm of uncertain behavior of breast
- D49.3** Neoplasm of unspecified behavior of breast
- N64.89** Other specified disorders of breast (acquired deformity)
- N65.0 – N65.1** Deformity and disproportion of reconstructed breast
- Q83.0 - Q83.9** Congenital malformations of breast
- T85.41XA – T85.49XS** Mechanical complication of breast prosthesis and implant
- Z42.1** Encounter for breast reconstruction following mastectomy
- Z85.3** Personal history of malignant neoplasm of breast
- Z90.10 - Z90.13** Acquired absence of breast and nipple

ICD-10 PCS Procedure Codes

ICD-10-PCS Codes

Refer to the following ICD-10-PCS table(s) for specific PCS code assignment based on physician documentation.

NOTE: Per ICD-10-PCS Coding Guidelines, “ICD-10-PCS codes are composed of seven characters. Each character is an axis of classification that specifies information about the procedure performed. Within a defined code range, a character specifies the same type of information in that axis of classification. One of 34 possible values can be assigned to each axis of classification in the seven-character code”.

- 0H0__Z** Alteration of Breast
- 0HB__ZZ** Excision of Breast
- 0HH__NZ** Insertion of Tissue Expander into Breast
- 0HM__XZZ** Reattachment of Breast/ Nipple, External Approach

0HN__ZZ	Release of Breast/Nipple
0HP__Z	Removal of Tissue Expander/Synthetic Substitute, Breast
0HQ__ZZ	Repair of Breast/Nipple
0HR__Z	Replacement of Breast/Nipple
0HS__ZZ	Reposition of Breast/Nipple
0HU__Z	Supplement of Breast/Nipple
0HW__JZ	Revision of Synthetic Substitute in Breast
0HX5XZZ	Transfer Chest Skin, External Approach
0JD__ZZ	Extraction of Subcutaneous Tissue and Fascia, Percutaneous Approach
0KX__ZZ	Transfer Thorax Muscle
0KX__Z6	Transfer Abdomen Muscle, Transverse Rectus Abdominis Myocutaneous Flap
3E00XMZ	Introduction of Pigment into Skin and Mucous Membranes, External Approach

Coding information is provided for informational purposes only. The inclusion or omission of a CPT, HCPCS, or ICD-10 code does not imply member coverage or provider reimbursement. Consult the member's benefits that are in place at time of service to determine coverage (or non-coverage) as well as applicable federal / state laws.

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MEDICAL POLICY COMMITTEE HISTORY AND REVISIONS

Date	Action
10/4/2018	<ul style="list-style-type: none"> • Approved by MPC. No changes.
12/7/2017	<ul style="list-style-type: none"> • Approved by MPC. Added requirement for all requests for surgery to non-cancerous breasts go for mandatory secondary review.
5/4/2017	<ul style="list-style-type: none"> • Approved by MPC. No changes.
6/2/2016	<ul style="list-style-type: none"> • Approved by MPC. Updated exclusions.
2/4/2016	<ul style="list-style-type: none"> • Approved by MPC. Coding updates only.