Clinical Policy Title: Breast reconstruction following breast cancer surgery

Clinical Policy Number: 13.03.04

Effective Date: April 1, 2017
Initial Review Date: November 16, 2016
Most Recent Review Date: November 16, 2016
Next Review Date: November 2017

Policy contains:
- Breast reconstruction
- Lumpectomy
- Mastectomy

Related policies:
- CP# 05.03.03 Prophylactic mastectomy
- CP# 16.03.05 Breast reduction surgery
- CP# 16.03.08 Cosmetic, plastic, and scar revision surgery

ABOUT THIS POLICY: Prestige Health Choice has developed clinical policies to assist with making coverage determinations. Prestige Health Choice’s clinical policies are based on guidelines from established industry sources, such as the Centers for Medicare & Medicaid Services (CMS), state regulatory agencies, the American Medical Association (AMA), medical specialty professional societies, and peer-reviewed professional literature. These clinical policies along with other sources, such as plan benefits and state and federal laws and regulatory requirements, including any state- or plan-specific definition of “medically necessary,” and the specific facts of the particular situation are considered by Prestige Health Choice when making coverage determinations. In the event of conflict between this clinical policy and plan benefits and/or state or federal laws and/or regulatory requirements, the plan benefits and/or state and federal laws and/or regulatory requirements shall control. Prestige Health Choice’s clinical policies are for informational purposes only and not intended as medical advice or to direct treatment. Physicians and other health care providers are solely responsible for the treatment decisions for their patients. Prestige Health Choice’s clinical policies are reflective of evidence-based medicine at the time of review. As medical science evolves, Prestige Health Choice will update its clinical policies as necessary. Prestige Health Choice’s clinical policies are not guarantees of payment.

Coverage policy

Prestige Health Choice considers the use of breast reconstruction following breast cancer surgery to be clinically proven and, therefore medically necessary. These surgeries include mastectomy or lumpectomy following a diagnosis of cancer and prophylactic mastectomy for persons documented as high risk for cancer. Procedures included in this policy are breast implants, tissue flap procedures, and nipple/areolar reconstruction. Autologous fat grafts are also considered medically necessary if the physician and patient agree on this approach.

Breast reconstruction must be performed by a credentialed plastic surgeon.

This policy complies with the Women’s Health and Cancer Rights Act of 1998, which requires plans that provide coverage for mastectomy also cover reconstruction of the breast with mastectomy, to include
surgery on the non-mastectomy breast to create a symmetrical appearance, breast prostheses, and treatment of any mastectomy complications (CMS, 2016).

**Limitations:**

Coverage determinations are subject to benefit limitations and exclusions as delineated by the state Medicaid authority. The Florida Medicaid website can be accessed at http://ahca.myflorida.com/Medicaid/.

All other uses of breast reconstruction following breast cancer surgery, including scar revision and surgery for cosmetic purposes, are considered investigational and experimental.

**Alternative covered services:**

Breast prosthesis

**Background**

Breast cancer is the most commonly-diagnosed cancer in the U.S. A total of 249,260 new cases will be diagnosed in Americans in 2016, all but 2,600 of them women (Howlader, 2016), up from 175,900 new cases in 1991 (Ries, 1991). About 20 percent of breast cancer cases are classified as *in situ*, as opposed to invasive cancers.

From 1998-2007, the proportion of U.S. women undergoing mastectomy who also had breast reconstruction rose from 46 to 63 percent. Part of this increase is the rising number of women who elect to have contralateral prophylactic mastectomy (Jagsi, 2014). Factors increasing the likelihood of women electing reconstruction include younger age, white race, metropolitan locale, and lower stage disease; rates also vary considerably by geographic areas (Agarwal, 2011).

A breast can be surgically reconstructed after a mastectomy or lumpectomy (simultaneously or at a later date) by using artificial implants or autologous tissue from other body parts. Reconstruction may be completed in a single procedure, but multiple procedures may be needed. Reconstruction can be performed on the diseased breast, or on the other breast to address asymmetry.

One means of surgical reconstruction of the breast uses implants of a silicone exterior that contain saline or silicone gel. In a single-procedure implant, breast tissue is removed and the implant is placed beneath the chest muscle; the implant is held in place by a graft made of skin. Some procedures must first implant tissue expanders during mastectomy. The tissue slowly expands the sac over several months to stretch the skin until the full size implant can be supported; a subsequent procedure removes the expander and inserts the transplant.

While the durability of implants has improved over time, up to half of all implants must be replaced.
within 10 years, due to ruptures, infections, or pain experienced by the patient.

The second type of surgical reconstruction is a tissue flap procedure. This procedure can either use tissue removed from the abdomen or the upper back, and transplanted to the breast.

Autologous fat grafts, using the transverse rectus abdominis myocutaneous (TRAM) flap, are commonly used in breast reconstruction. The procedure uses fat, skin, and muscle from the abdomen to restore breast volume and contour in women after they undergo mastectomy or lumpectomy. Several surgeries may be necessary to complete the procedure. The procedure is well tolerated and is considered safe (NICE, 2012 and Gutkowski, 2009). Another means of using abdominal fat and skin to reconstruct the breast is deep inferior epigastric perforation (DIEP). It contains no muscle or fascia, as does the TRAM flap.

The latissimus dorsi flap procedure is a relatively common method of breast reconstruction that uses muscle, fat, skin, and blood vessels from the upper back. Rather than removing this tissue from the body, the surgeon moves it to the front of the chest, into the breast area.

Nipple and areolar reconstruction, whose purpose is to match the new nipple and areola to the original one, can be another procedure in breast restoration, if the patient elects. Tissue is taken from the new breast or from other skin, and transplanted. Some patients may only have a two-dimensional tattoo.

If the patient is undergoing radiation therapy or chemotherapy, a postponement of any breast reconstruction is advised until after the therapy is completed.

**Searches**

Prestige Health Choice searched PubMed and the databases of:
- UK National Health Services Centre for Reviews and Dissemination.
- Agency for Healthcare Research and Quality’s National Guideline Clearinghouse and other evidence-based practice centers.
- The Centers for Medicare & Medicaid Services (CMS).

We conducted searches on October 20, 2016. Search term was: “breast reconstruction.”

We included:
- **Systematic reviews**, which pool results from multiple studies to achieve larger sample sizes and greater precision of effect estimation than in smaller primary studies. Systematic reviews use predetermined transparent methods to minimize bias, effectively treating the review as a scientific endeavor, and are thus rated highest in evidence-grading hierarchies.
- **Guidelines based on systematic reviews.**
- **Economic analyses**, such as cost-effectiveness, and benefit or utility studies (but not simple
cost studies), reporting both costs and outcomes — sometimes referred to as efficiency studies — which also rank near the top of evidence hierarchies.

**Findings**

In November 2012, the United Kingdom’s Association of Breast Surgery and British Association of Plastic Reconstructive and Aesthetic Surgeons issued a practice guideline on oncoplastic breast reconstruction. The guideline featured 25 quality indicators that include patient education, process of care, and measuring patient outcomes (Rainsbury, 2014).

Soon after the UK guideline, the American Society of Plastic Surgeons (ASPS) approved an evidence-based guideline on breast reconstruction with expanders and implants (Alderman, 2014). The ASPS guideline provided evidence to support:

1. Patients undergoing mastectomy should be offered preoperative referral to a plastic surgeon
2. Irradiating the expander or implant is associated with elevated risk of postoperative complications
3. Use of pre-operative antibiotics is appropriate, as is halting antibiotic use 24 hours after surgery, except when a surgical drain is present
4. Post-operative expander/implant reconstruction does not adversely affect oncologic outcomes

In addition, the ASPS found that evidence is limited, varies, or is of substandard quality for association between postoperative complications and timing, association between acellular dermal matrix and surgical complications, and optimal timing of post mastectomy expander/implant breast reconstruction.

Infections are common in breast reconstruction, often exceeding 20 percent (Phillips, 2013). The general consensus is that 24 hours of prophylactic antibiotics prior to breast reconstruction is warranted. However, there are conflicting data and opinions on the need for and duration of perioperative antibiotic administration and thus further studies on the topic are needed (Phillips, 2013 and Phillips, 2016).

A meta-analysis of 31 studies (n=139,894) found that women who had immediate breast reconstruction (IBR) after mastectomy were 51 percent more likely to experience surgical site infection than those with no reconstruction after mastectomy. There were no significant differences in overall survival, disease-free survival, and local recurrence between the two groups (Zhang, 2016). Another meta-analysis of 10 articles found that rates of breast cancer recurrence in women with and without IBR were similar (Gieni, 2012).

A study of 5012 women compared outcomes for women who underwent autologous vs. implant-tissue-expander reconstruction immediately after mastectomy. The two groups experienced similar readmission rates. However, women in the autologous group experienced higher overall complications,
i.e. 19.96 vs 5.86 percent), and higher rates of reoperation, i.e. 9.7 vs. 6.5 percent (Mlodinow, 2013).

Several types of implants, such as saline/silicone, anatomically shaped/round, and fixed/variable volume, are available to patients. A limited number of studies to link these approaches with relative risk for adverse outcomes have been performed, and no conclusive evidence has been developed (Rocco, 2016).

A review of 17 studies compared one-stage and two-stage prosthesis-based reconstruction. Women in the one-stage group had higher construction failure and overall complication rates, but costs were lower despite added expenses for complications (Lee, 2016). Another review found greater risk of flap necrosis and implant failure with direct-to-implant reconstruction (Basta, 2015). Another study determined that nipple-sparing mastectomy with immediate autologous breast reconstruction is safe when performed in a single stage, but stopped short of declaring that this should be the standard of care (Levine, 2013).

Some studies have focused on the risks of nipple-sparing mastectomy, which affects subsequent reconstruction procedures. One systematic review of 48 studies found a 22 percent complication rate, a 7 percent nipple necrosis rate, a locoregional recurrence rate of 1.8 percent, and a distant metastasis rate of 2.2 percent. The authors conclude that the procedure was safe due to the low rates of locoregional and distant metastasis rates. However, variations in complication and nipple necrosis rates by incision location and reconstruction method suggest further trials to determine the best methods needed (Endara, 2013).

Studies of complications from autologous fat grafting found that necrosis was the most common complication (4.4%), biopsy was required in 2.7% of cases, and interval mammogram required in 11.5%. There were no observed differences in oncological event rates between mastectomy patients with and without autologous fat grafts (Agha, 2015). Breast cancer recurrences for mastectomy patients who did and did not undergo autologous fat grafts have been similar, even though not all studies were of good quality (Hayes, 2015).

Concerns have been raised about adverse outcomes after breast reconstruction for women who have had mastectomy and who require radiation therapy. A review of 11 studies found a high morbidity odds ratio for women with mastectomy who had breast reconstruction and radiation compared to those who had no reconstruction. Delaying reconstruction until after radiation therapy had no effect on this finding (Barry, 2011).

A study of 45,465 women with breast cancer under age 65 who underwent mastectomy from 2002-2006 found considerable variation of breast reconstruction rates after mastectomy among racial groups and payers. Compared to white women, lower rates of reconstruction were documented for African Americans (-43%), Hispanics (-30%), and Asians (-55%). Compared to women with private insurance, lower rates were found for those with public insurance (-65%) and those who are uninsured (-67%) (Shippee, 2014).
The cost of breast reconstruction has been addressed in the peer-reviewed literature. One study of 14,764 women who underwent mastectomy in 2008 showed average hospital charges varied among those with autologous reconstruction ($48,680), breast implant/tissue expander ($42,850), and no reconstruction ($22,300) (Wexelman, 2014). An analysis concluded that, compared to no reconstruction, autologous reconstruction was cost-effective and implant-based technology was not, reflecting the trend at academic medical centers to use autologous reconstruction more often (Grover, 2013). Researchers at the Hospital of the University of Pennsylvania agreed; the two types of surgery had similar average costs for the initial surgery, but implants had a higher cost for secondary procedures ($10,158 vs. $3,201), and a higher cost of unplanned revisions over time (Fischer, 2014).

Policy updates:

No updates.

Summary of clinical evidence:

<table>
<thead>
<tr>
<th>Citation</th>
<th>Content, Methods, Recommendations</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lee (2016)</td>
<td>Outcomes of one-stage vs. two-stage prosthesis-based breast reconstruction</td>
</tr>
<tr>
<td>Phillips (2016)</td>
<td>Need for antibiotic prophylaxis after implant-based breast reconstruction</td>
</tr>
<tr>
<td>Zhang (2016)</td>
<td>Comparison of outcomes for mastectomy with vs. without reconstruction</td>
</tr>
<tr>
<td>Shippee (2014)</td>
<td>Variations in reconstruction rates by payer group and racial/ethnic group</td>
</tr>
<tr>
<td>Endara (2013)</td>
<td>Literature review on nipple-sparing mastectomies</td>
</tr>
</tbody>
</table>
1.8%.
- Complication rate with autologous reconstruction = 23.7%, nipple necrosis rate = 17.3%.

Mlodinow (2013)
Comparison of outcomes between types of breast reconstruction

Key points:
- Study of 5012 patients who had implant/expander or autologous reconstruction.
- Groups had similar readmission rates (4.34% implant and 5.32% autologous).
- Autologous group had higher rate of complications (19.96% vs. 5.86%).
- Autologous group had higher rate of reoperation (9.7% vs. 6.5%).
- Common predictors of readmission include operative time, American Society of Anesthesiologist class 3 and 4, superficial surgical site infection.

Barry (2011)
Breast reconstruction and radiotherapy

Key points:
- Meta-analysis of 11 studies (n=1105) of patients undergoing breast reconstruction with or without post-mastectomy radiotherapy.
- Radiation therapy more likely to suffer morbidity (OR = 4.2); thus autologous flap reconstruction is linked with less morbidity, compared to implant-based reconstruction.
- Delaying breast reconstruction until after radiation therapy had no effect on outcome.

Glossary

**Autologous fat grafts** — a procedure that uses fat, skin, and muscle from the abdomen to restore breast volume and contour in women after undergoing mastectomy or lumpectomy.

**Areola** — small circular area surrounding the nipple.

**Breast reconstruction** — procedure performed following a mastectomy or other breast cancer surgery that rebuilds the breast mound to match the size and shape of the other breast.

**Fat grafting** — (for breasts) method of enhancing the breast by using excess fat cells instead of implants.

**Implants** — (for breasts after cancer surgery) addition of a silicone exterior that contain saline or silicone gel, in which breast tissue is removed and the implant is placed beneath the chest muscle.

**Lipomodelling** — injection of fat into the breast to fill out any dents or irregularities in the new breast’s contour.

**Lumpectomy** — removal of cancer and other abnormal tissue in only a portion of the breast (also known as breast-conserving surgery).

**Mastectomy** — removal of all breast tissue from a breast that is cancerous, or a breast from women who are at high risk for breast cancer.

References
Professional society guidelines/other:


Peer-reviewed references:


Phillips BT, Bishawi M, Dagum AB, Khan SU, Bui DT. A systematic review of antibiotic use and infection in


**CMS National Coverage Determinations (NCDs):**

140.2 Breast Reconstruction Following Mastectomy. CMS Medicare Coverage Database Web site. [https://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=64&ncdver=1&CoverageSelection=Both&ArticleType=All&PolicyType=Final&s=All&KeyWord=breast+reconstruction%22&KeyWordLookUp=Title&KeyWordSearchType=And&bc=gAAAA CAAAAAAA%3d%3d&]. Medicare payment may be made for breast reconstruction following mastectomy for any medical, non-cosmetic reason. Effective January 1, 1997. Accessed October 24, 2016.

**Local Coverage Determinations (LCDs):**

No LCDs identified as of the writing of this policy.
**Commonly submitted codes**

Below are the most commonly submitted codes for the service(s)/item(s) subject to this policy. This is not an exhaustive list of codes. Providers are expected to consult the appropriate coding manuals and bill accordingly.

<table>
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<th>CPT Code</th>
<th>Description</th>
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<td>19357</td>
<td>Breast reconstruction, immediate or delayed, with tissue expander, including subsequent expansion</td>
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<tr>
<td>19361</td>
<td>Breast reconstruction with latissimus dorsi flap, without prosthetic implant</td>
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<tr>
<td>19364</td>
<td>Breast reconstruction with free flap</td>
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<tr>
<td>19366</td>
<td>Breast reconstruction with other technique</td>
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<tr>
<td>19367</td>
<td>Breast reconstruction with transverse rectus abdominis myocutaneous flap (TRAM), singe pedicle, including closure of donor site</td>
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<tr>
<td>19368</td>
<td>Breast reconstruction with transverse rectus abdominis myocutaneous flap (TRAM), singe pedicle, including closure of donor site; with microvascular anastomosis</td>
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<tr>
<td>19369</td>
<td>Breast reconstruction with transverse rectus abdominis myocutaneous flap (TRAM), double pedicles, including closure of donor site</td>
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