Corporate Medical Policy

Breast Reconstruction

Description of Procedure or Service

Breast reconstruction often involves multiple procedures performed in stages and can either begin at the time of mastectomy/lumpectomy or be delayed until a later date. Breast reconstruction may involve insertion of tissue expanders or breast implants, capsulotomy, capsulectomy or removal of breast implants.

Benefit Application

Breast reconstruction, except reconstruction for diagnosis of breast cancer, requires a medical necessity review.

GEHA will not provide coverage for skin grafts or implants considered experimental or investigational regardless of breast cancer diagnosis.

This medical policy relates only to the services or supplies described herein. Please refer to the Member’s Benefit Booklet for availability of benefits.

Policy Statement

GEHA will provide coverage for all states of breast reconstruction surgery following a mastectomy/lumpectomy, such as: surgery to produce a symmetrical appearance of breasts; treatment of any physical complications, such as lymphedemas; breast prosthesis; and surgical bras and replacements.

When Breast Reconstruction is covered

The breast reconstruction surgery is intended to correct, restore, or improve anatomical and/or functional impairments that have resulted from mastectomy or lumpectomy, therapeutic interventions (for example, radiation), or disease of the breast. Intact breast implant removal is intended to correct, restore, or improve anatomical and/or functional impairments that result from extrusion of the implant through skin, implant infections, or breast cancer recurrence.

Coverage is available without regard to gender or cancer diagnosis.

A. Breast reconstruction procedures performed on the diseased/affected breast (i.e., breast on which the mastectomy/lumpectomy was performed), including:

1. Areolar and nipple reconstruction
2. Areolar and nipple tattooing
3. Autologous fat transplant (i.e., liposuction, lipoinjection, lipofilling, lipomodeling)
4. Breast implant removal and subsequent re-implantation
5. Capsulectomy
6. Capsulotomy
7. Implantation of tissue expander
8. Implantation of U.S. Food and Drug Administration (FDA)-approved internal breast prosthesis
9. Oncoplastic reconstruction
10. Reconstructive surgical revisions
11. Tissue/muscle reconstruction procedures (e.g., flaps), including, but not limited to, the following:
   a. Deep inferior epigastric perforator (DIEP) flap
   b. Latissimus dorsi (LD) myocutaneous flap
   c. Ruben’s flap
   d. Superficial inferior epigastric perforator/artery (SIEP/SIEA) flap
   e. Superior or inferior gluteal free flap
   f. Thoracodorsal artery perforator (TDAP) flap
   g. Transverse rectus abdominus myocutaneous (TRAM) flap
   h. Transverse upper gracilis (TUG) flap
12. Ruptured, leaking or diseased implant removal from a non-medically necessary implantation

B. Breast reconstruction procedures performed on the non-diseased/unaffected/contralateral breast, to produce a symmetrical appearance, including:
   1. Areolar and nipple reconstruction
   2. Areolar and nipple tattooing
   3. Augmentation mammoplasty
   4. Augmentation with implantation of FDA-approved internal breast prosthesis when the unaffected breast is smaller than the smallest available internal prosthesis
   5. Autologous fat transplant (i.e., liposuction, lipoinjection, lipofilling, lipomodeling)
   6. Breast implant removal and subsequent re-implantation when performed to produce a symmetrical appearance:
      a. Following removal of a breast implant, the subsequent surgical implantation of a new U.S. Food and Drug Administration (FDA)-approved breast implant is considered medically necessary for EITHER of the following:
• Breast reconstruction of a diseased or affected breast following mastectomy or lumpectomy

• Creation of a symmetrical appearance in the contralateral/non-diseased breast following mastectomy or lumpectomy in the opposite breast

7. Breast reduction by mammoplasty or mastopexy

8. Capsulectomy

9. Capsulotomy

10. Reconstructive surgery revisions to produce a symmetrical appearance

C. The following products are considered medically necessary for a medically necessary breast reconstruction:

1. Alloderm
2. DermACELL
3. DermaMatrix
4. FlexHD
5. Strattice
6. Cortiva

GEHA considers all other skin substitute graft products experimental and investigational for the purposes of this coverage policy.

Breast reconstruction coverage does not include the following:

A. Aberrant breast tissue (non-cancerous) removal is considered cosmetic and not medically necessary

B. Aspiration of fluid, tissue biopsy, ductal lesion removal, as well as other diagnostic therapies are not covered in this policy

C. Treatment of gynecomastia is addressed in the Gynecomastia policy located at http://www.geha.com/

D. Breast reconstruction has been successfully completed post Mastectomy/lumpectomy and the member chooses to enlarge their breasts for cosmetic reasons is not medically necessary

E. Breast reconstruction revision after symmetry has been achieved due to body changes relating to normal aging, weight gain or loss, etc. is considered cosmetic and not medically necessary.

F. Xenograft cartilage grafting is not a standard of care. There is a lack of evidence in peer reviewed literature on the long term outcomes, safety and efficacy.

G. Autologous transplant of adipose-derived stem cells is not a standard of care. There is a lack of clinical trials and long term outcome data to prove safety and efficacy.
H. Removal of asymptomatic, intact breast implants is not covered.

I. Breast Re-implantation after removal of a diseased implant from a prior non-medically necessary implantation.

**Policy Guidelines**

The Women’s Health and Cancer Rights Act of 1998 (WHCRA) was enacted as a federal mandate in October 1998. The federal mandate defines coverage for breast reconstruction following mastectomy as:

- Reconstruction of the breast on which the mastectomy was performed
- Surgery and reconstruction on the other breast to produce symmetrical appearance
- Prostheses and treatment of physical complications in all stages of mastectomy, including lymphedemas (Centers for Medicare and Medicaid Services, 2019).

**Physician Documentation**

A. The following are required to determine medical necessity for breast reconstruction surgery (must be submitted by treating surgeon):

1. The primary diagnosis name and ICD-10 codes for the condition requiring reconstruction
2. The most recent medical evaluation, including summary of the medical history and last physical examination
3. Results from diagnostic imaging and laboratory tests pertinent to the diagnosis
4. Surgical treatment plan including:
   a. Method of reconstruction
   b. Grafting or tissues to be used
   c. Implants to be used (if applicable)

**Background**

According to CDC statistics (2018), not counting some kinds of skin cancer, breast cancer in the United States is the most common cancer in women, no matter the race or ethnicity. Breast cancer is the most common cause of death among Hispanic women and the second most common cause of death from cancer among white, black, Asian/Pacific Islander and American Indian/Alaska Native women.

Clinical indications may include a lumpectomy, partial mastectomy or a complete mastectomy. These procedures may cause disfigurement leading to altered body image.

In 1998, breast reconstruction following mastectomy was legislated as a right in the United States following passage of the Women’s Health and Cancer Rights Act of 1997 (Lee & Sheckter, 2018). Since that time, breast cancer treatment and subsequent surgical reconstruction have greatly improved: Nearly 40% of women undergo reconstruction following mastectomy and recent reporting from the
American Society of Plastic Surgeons (2019) estimates that more than 106,000 reconstructive breast procedures occurred in 2017.

The National Comprehensive Cancer Network established principles of breast reconstruction following surgical mastectomy (2019). For mastectomy, the possibility of reconstruction should be discussed and a preoperative evaluation of reconstructive options should be considered. Surgical options include procedures such as breast implants, tissue expanders, autologous tissue transplantation, nipple and areola reconstruction and tattooing as well as surgery contra laterally to improve symmetry. Breast reconstruction can be immediate or delayed.

Breast reconstruction generally falls into two categories: implant-based reconstruction or flap reconstruction. Implant reconstruction relies on breast implants to help form a new breast mound. Flap (or autologous) reconstruction uses the patient's own tissue from another part of the body to form a new breast.

There are a number of factors that should be taken into consideration when choosing which option is best: type of mastectomy, cancer treatments, and patient's body type.

Post-mastectomy immediate breast reconstruction in the US continues to experience an upward trend owing to heightened awareness, innovations in reconstructive technique, growing evidence of improved patient reported outcomes and shifts in mastectomy patterns. Women with unilateral breast cancer are increasingly electing to undergo contralateral prophylactic mastectomy, instead of unilateral mastectomy or opting for breast conservation. The ascent in prophylactic surgeries correlates temporally to a shift towards prosthetic methods of reconstruction as the most common technique. Factors associated with the choice for implants include younger age, quicker recovery time, along with documented safety and enhanced aesthetic outcomes with newer generations of devices. Despite advances in autologous transfer, its growth is constrained by the greater technical expertise required to complete microsurgical transfer and potential barriers such as poor relative reimbursement. The increased use of radiation as an adjuvant treatment for management of breast cancer has created additional challenges for plastic surgeons who need to consider the optimal timing and method of breast reconstruction to perform in these patients (Panchal & Matros, 2017).

The American Society of Plastic Surgeons (2013) defines some of the breast reconstruction procedures below:

**Breast reconstruction with implants**

Implant-based breast reconstruction may be possible if the mastectomy or radiation therapy have left sufficient tissue on the chest wall to cover and support a breast implant. For patients with insufficient tissue on the chest wall, or for those who don't desire implants, breast reconstruction will require a flap technique (also known as autologous reconstruction).

In 2019, The US FDA conducted a multicentered, cohort study to analyze the long-term safety and efficacy of patient with breast implants. Large post-approval studies (LPAS) prospectively monitor long-term implant-related outcomes and systemic harms for silicone/saline implants from 2 manufacturers (Allergan and Mentor) placed for primary/revision augmentation/reconstruction. Systemic harms, self-
harm, and reproductive outcomes are compared with normative data. Implant-related complications are analyzed by implant composition and operative indication in the short and long terms.

LPAS data includes 99,993 patients, 56% of implants were silicone for primary augmentation. Long-term magnetic resonance imaging surveillance is under 5%. Compared with normative data, silicone implants are associated with higher rates of Sjogren syndrome (Standardized incidence ratio [SIR] 8.14), scleroderma (SIR 7.00), rheumatoid arthritis (SIR 5.96), stillbirth (SIR 4.50), and melanoma (SIR 3.71). One case of BI-ALCL is reported. There is no association with suicide. In the short term, rupture is higher for saline (2.5% vs. 0.5%, P < 0.001), and capsular contracture higher for silicone (5.0% vs. 2.8%, P < 0.001). At 7 years, reoperation rate is 11.7% for primary augmentation, and 25% for primary/revision reconstruction. Capsular contracture (III/IV) occurs in 7.2% of primary augmentations, 12.7% primary reconstructions, and is the most common reason for reoperation among augmentations.

This is the largest study of breast implant outcomes. Silicone implants are associated with an increased risk of certain rare harms; associations need to be further analyzed with patient-level data to provide conclusive evidence. Long-term safety and implant-related outcomes should inform patient and surgeon decision-making when selecting implants (Coroneos, et. al., 2019).

Despite the fact that several million women have had their breasts reconstructed over the last 20 years, the small number of studies and the low numbers of women included in these studies does not allow us to draw any definitive conclusions about the which is the best type of breast implant. Currently, the decisions are made based on the surgeon experience and opinion alone (Rocco et al., 2016).

**Immediate breast reconstruction above the pectoral muscle**

This procedure is performed in combination with the mastectomy and results in an immediate breast mound. After the mastectomy has been performed by the breast surgeon, the plastic surgeon will place the breast implant by a variety of different methods to help the implant maintain correct anatomic position, above the pectoralis muscle.

Immediate implant-based breast reconstruction has similar complication rates, need for revision, and aesthetic outcomes but fewer office visits and less reconstructive time when compared with tissue expander immediate breast reconstruction. In the appropriately selected patient, it is a safe option that provides similar outcomes in less time compared with staged expander-based reconstruction (Roostaeian et al., 2012).

**Immediate breast reconstruction under the pectoral muscle**

This procedure is also performed as a combination with the mastectomy and results in an immediate breast mound. The incision generally is performed through the mastectomy site. Once the mastectomy is completed, the plastic surgeon will elevate the pectoralis major muscle. This will allow the muscle to retract upward and allow a pocket to be developed underneath the muscle and at the bottom of the normal breast position.

A biodegradable acellular dermal matrix (ADM) will be placed at the bottom of the breast or inframammary crease and attached to the muscle. The breast implant will be placed under the ADM and your own muscle. This allows the breast implant to settle in a normal position, and the ADM stretches into a pleasing, rounded lower breast shape.
Delayed breast reconstruction utilizing tissue expander

The initial portion of this procedure entails the breast surgeon performing a standard mastectomy and possible axillary dissection. In many instances, a drain will be placed between the muscle and the skin of the mastectomy.

Once these procedures have been performed, the plastic surgeon will divide the lower pole of the chest wall muscle, elevate the chest wall muscle and the lateral chest muscle together upwards towards the collarbone. After that is done, the muscle and tissue below is elevated together to form the pocket for the breast expander at the base of the breast or the inframammary crease. The pocket is made large enough for the expander to be placed and the muscle closed. Occasionally, there is a need for placement of a small amount of acellular dermal matrix (ADM) to assist in the closure of the muscle.

There are two types of breast tissue expander ports. One, similar to a chemotherapy port, is placed separate from the tissue expander, usually along the rib cage. This will require a separate small incision for the port. The second type is a port that is contained within the expander itself. In both instances, the ports will be used to inflate the tissue expander over several visits with saline solution. The port is accessed with a small needle and saline is injected into the expander through the port site.

Tissue expansion usually occurs weekly according to patient tolerance. The volume of the tissue expanders commonly exceeds the weight of the mastectomy tissue. Once the final tissue expansion, or stretching, is completed there will be a time of passive expansion where little to no volume is added to the tissue expanders. Once this is completed, a second outpatient procedure will be necessary to remove the tissue expander and place the permanent breast prosthesis.

Immediate breast tissue expander placement

The surgical process for saline breast tissue expanders and breast expanders following mastectomy are the same. Expanders with saline have been used for decades but recently, a new type of expander using air, which allows for more patient control, have been introduced.

The expander is placed into a submuscular or subcutaneous space with no external filling ability. The expander will fill with compressed air contained within the expander itself. The patient will do self-controlled expander fills utilizing an external automatic activation device at home and will achieve similar results to the standard saline filled tissue expansion devices.

Immediate breast reconstruction utilizing latissimus dorsi muscle

This procedure is performed as a secondary operation immediately during the mastectomy or delayed after radiation.

The latissimus flap is frequently used when the amount of soft tissue is limited secondary to surgery, the pectoralis muscle is absent, partially removed or damaged secondary to radiation. It entails undermining the skin on the back and releasing some of the skin allowing it to remain attached to the muscle. The main muscle and artery is called pedicle flap. This flap is released from the back, passed through a tunnel that is made underneath the axilla and into the anterior chest to fill the mastectomy defect site. The muscle is placed and sutured to the chest wall. An implant is then placed behind this flap and in front of the chest. One can also use a tissue expander and gradually increase to breast size.
The advantage to this expander is it can completely replace the amount of breast tissue that has been removed and protect the latissimus flap. A completely inflated implant or a postoperative adjustable expander/implant can be immediately placed. It is not uncommon to require a secondary revision procedure to gain more accurate symmetry of both breasts. The latissimus flap is recommended for patients who have already had mastectomy and radiation. The use of radiation frequently limits the amount of implant surgery that can be performed. The secondary advantage of this flap is that it brings new blood flow and healthy skin to the radiated field. It is also recommended for patients who are very thin and have limited options for flap reconstruction.

**Breast reconstruction with abdominal-based flaps**

Sometimes a mastectomy or radiation therapy will leave insufficient tissue on the chest wall to cover and support a breast implant. In these cases, breast reconstruction usually requires a flap technique (also known as autologous reconstruction). This is the most common method of tissue reconstruction, using lower abdominal skin and fat to create a breast shape. Some women may not be candidates for abdominal-based flaps for various reasons:

- Not enough donor tissue in the lower abdomen
- Prior scars that may have damaged important blood vessels
- Previous flaps that have failed and seeking an alternative

The main advantage of the procedure lies in the consistency of the reconstructed breast; it is similar to the natural breast in softness and in the way the tissue drapes on the chest. Because the tissue is part of the patient’s body, it does not incite foreign-body reaction or capsular contractures, which have plagued implant reconstructions. Furthermore, since scars fade and tissues soften, the reconstruction only improves over time, which is not true of implant reconstructions (Deutsch, et al., 2018).

Gabbay et al. (2005) researched a method of midabdominal TRAM flap in the morbidly obese. They concluded that although there were complications in this population, the use of the midabdominal TRAM flap technique represents an alternative method for postmastectomy breast reconstruction in morbidly obese patients.

**Pedicled TRAM flap**

A transverse rectus abdominis (TRAM) flap uses the muscle, fat and skin from your lower abdomen to reconstruct a breast. In order to survive on your chest in its new location, this tissue requires a blood supply. The blood supply to this tissue comes from the underlying rectus muscle. The flap remains attached to your rectus abdominis muscle and is tunneled up through the abdomen and chest to create the breast mound.

Spear et al. (2007) conducted a retrospective study of 224 peicled TRAM flap patients over a 10 year period and concluded that obese patients, in contrast to normal weight and overweight patients, have a statistically significantly higher risk for developing overall (one or more) and multiple flap complications, overall donor-site complications, TRAM flap delayed wound healing, and minor flap necrosis.

**Free TRAM flap**

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Like the TRAM flap, the free TRAM flap is also based on the blood vessels coming through the rectus abdominis muscle. However, in this flap the muscle above and below the blood vessels is divided, so that only a portion of muscle is removed. The entire flap is then transplanted to the chest. The blood vessels from the muscle are connected to blood vessels in the chest using a microscope.

The blood supply is furnished by microscopic reconnection of the inferior epigastric artery and vein(s) at the mastectomy site. While this procedure is more technically exacting and formidable compared with other TRAM techniques, experienced microsurgeons routinely perform free-tissue transfers with success rates of more than 98% at most centers. When performed properly in the properly selected patient, the free TRAM flap procedure may produce a breast reconstruction superior to that of any other technique (Deutsch et al., 2018).

**DIEP flap**

The DIEP flap utilizes the same lower abdominal skin and fat as the TRAM and free TRAM flap; however, it spares the rectus abdominis muscle and fascia. Rather than taking the entire muscle or a small portion of the muscle, the small blood vessels – an artery and a vein – that come through the muscle to the skin and fat are identified; these vessels are then dissected through the muscle prior to being divided. Once they are divided, the tissue is again transplanted to the chest and the vessels are connected to blood vessels in the chest.

**SIEA flap**

The superficial inferior epigastric artery SIEA flap also uses the lower abdominal skin and tissue, but the blood vessels that supply this flap do not go through the abdominal muscle. Rather, they only go through the fat. Advantages of this flap include preservation of the abdominal muscles, resulting in less postoperative pain and a speedier recovery. However, these blood vessels may not be present in all women; and even when present, may be too small to provide a reliable blood supply for a flap. For these reasons, the SIEA flap is not performed as frequently as the DIEP or free TRAM flaps.

With some types of flaps, use of abdominal donor tissue for reconstruction after mastectomy is associated with motor weakness, pain, functional changes, delayed wound healing, and bulges or hernias. However, unlike the commonly performed TRAM and DIEP flaps, the SIEA flap technique does not involve incision of the rectus abdominis muscle or fascia, removal of the deep inferior epigastric vessels, or violation of any motor nerves, and may therefore lead to less pain, less donor-site morbidity, and shorter hospitalization (Hayes, 2014).

**Breast reconstruction with thigh-based flaps**

Sometimes a mastectomy or radiation therapy will leave insufficient tissue on the chest wall to cover and support a breast implant. In these cases, breast reconstruction usually requires a flap technique (also known as autologous reconstruction).

Thigh-based flaps may be a good option for women with small to medium volume breasts. To achieve a larger size, these flaps may be combined with an implant or another. These techniques require training in microsurgery.

Some women may not be candidates for thigh-based flaps for various reasons:

- Not enough donor tissue in the upper thighs
- Prior scars that may have damaged important blood vessels
- Previous flaps have failed and they are seeking an alternative

**Gracilis-based flaps**

Gracilis-based flaps are based on the gracilis muscle, located in the upper inner thigh. The gracilis muscle helps bring the leg toward the body, and its function will be lost after this type of surgery. During these procedures, a flap of skin, fat, muscle and blood vessels from the upper thigh is moved to the chest to rebuild the breast. Blood vessels are carefully reattached using microsurgery.

Different names are used to describe the orientation of the resulting donor site incision on the upper inner thigh: a reoperation may be necessary to assess the blood flow.

Different names are used to describe the orientation of the resulting donor site incision on the upper inner thigh:

- TUG flap: Transverse Upper Gracilis flap
- VUG flap: Vertical Upper Gracilis flap
- DUG flap: Diagonal Upper Gracilis flap

**Profunda Artery Perforator flap**

PAP flap uses skin and fat from the back of the upper thigh to reconstruct the breast using microsurgery. PAP stands for Profunda Artery Perforator, which is a blood vessel that supplies this area of the thigh. No muscle is used, so a PAP flap is considered muscle-sparing. For patients with a desire for autogenous breast reconstruction and insufficient abdominal fat for conventional abdominal flaps, secondary options such as gluteal perforator flaps or latissimus flaps are usually considered (DellaCroce, 2018.)

**Breast reconstruction with gluteal-based flaps**

Gluteal-based flaps use skin and fat from the buttocks. SGAP flap stands for Superior Gluteal Artery Perforator, which is located in the upper buttock. During this procedure, a flap of skin, fat and blood vessels is moved to the chest to rebuild the breast. Blood vessels are carefully reattached using microsurgery. Because no muscle is used, an SGAP flap is considered a muscle-sparing flap.

Similarly, the IGAP flap, or Inferior Gluteal Artery Perforator flap, uses tissue near the bottom of the buttocks near the crease. The IGAP is less favorable because the incision ends up near the weight-bearing region during sitting.

**Reconstruction of the Nipple/Areolar Complex**

Following mastectomy, breast reconstruction can provide significant psychosocial benefits for women. Because the reconstructed nipple is not easily moved, nipple reconstruction is usually reserved as the final step in breast reconstruction and is critical for providing an aesthetically pleasing breast. Patients with loss of the nipple and areola from cancer excision, trauma, or congenital absence continue to experience psychological distress even long after breast mound reconstruction has taken place. Studies have shown that recreation of the nipple-areola complex has a high correlation with overall patient satisfaction and acceptance of body image. Thus, completion of the breast reconstruction by creating a
nipple-areola complex that matches the contralateral nipple in terms of size, shape, projection, and position adds significantly to the reconstructive result (Chun, 2019).

Reconstruction of the nipple/areolar region is usually performed as a second or third stage after the breast mound has been created. The recreation of the nipple-areolar complex involves various proposed techniques such as skin grafts, autologous and xenograft cartilage grafts, local tissue flaps, tissue-engineered structures, and tattooing and/or transplantation of nipple-areolar tissue from the opposite breast.

**Fat Grafting**

Autologous fat grafting (AFG) uses the patient’s own body fat to fill and correct volume loss or contour deformities of the breast caused by surgical tumor removal and/or breast reconstruction procedures. The procedure involves harvesting fat from the abdomen, thighs, buttocks, or flank; processing the harvested fat to remove blood, oil, and debris; and injecting the processed fat into the target breast area(s). Kamakura & Ito (2011) studied 20 Japanese women who received autologous fat grafting in breast augmentation. No serious or unexpected adverse events were reported. Despite a growing uptake in the use of AFG among patients having undergone surgery for breast cancer, questions remain regarding the safety of the procedure (Claro et al., 2012), (De Blacam et al., 2011). Some in vitro studies have indicated that adipocytes and their associated milieu may directly stimulate tumor growth and progression, and adipose-derived stem cells within the graft may increase the risk of malignant transformation (Hayes, 2015) (Petit et al., 2011).

The National Institute for Health and Clinical Excellence (NICE) established guidelines for lipomodelling after breast cancer treatment (2012). The guidelines recommend clinical governance, support and audit along with long-term data collection. The patient selection should be carried out by a multidisciplinary team. The procedure should only be carried out by surgeons with specialist expertise and training in the procedure.

In 2016, De Decker et al. performed a systematic review of over 2400 patients. Results showed AFG or lipofilling appears to be an oncological safe technique with a low morbidity in women with a history of breast cancer. In order to have a better understanding and evidence of the oncological safety a randomized controlled trial is urgently needed. We further recommend that all AFG be registered in the cancer register.

American Society of Plastic Surgeons (ASPS) guidelines on fat grafting (2013) state, "An evaluation of available literature on autologous fat grafting following mastectomy with no remaining native breast tissue indicates that the body of evidence is comprised mostly of case series, and when combined, the studies provide consistent evidence, thus resulting in grade B recommendations." Further, ASPS policy goes on to support fat grafting, "Autologous fat grafting should no longer be considered experimental but should be regarded as part of reconstructive surgery when it is performed to approximate a normal appearance of the breasts following mastectomy or lumpectomy or in patients with asymmetry or hypoplasia of other origins."

**Acellular Dermal Matrix**

Acellular dermal matrix has enhanced implant-based reconstruction and remains useful in immediate prosthetic breast reconstruction. It is associated, however, with higher rates of postoperative seroma
and infection. Careful patient selection, choice of tissue expander/implant volume, and postoperative management are warranted to optimize overall reconstructive outcome (Chun et al., 2010).

Optimizing the inframammary fold with acellular dermal matrix creates a superior aesthetic result. Its use appears safe and is associated with less capsular contracture and mechanical shift and improvement in the inframammary fold appearance, without increasing postoperative complications (Vardanian, A. et al., 2011).

Human Acellular Dermal Matrix (HADMs) are extracellular collagen matrices derived from human (allograft) tissues. In immediate postmastectomy breast reconstruction, HADM is used to cover a temporary tissue expander or permanent implant. Placement of HADM provides a substitute for native tissues, and a graft to join released pectoralis major muscles, thus enabling completion of breast reconstruction without autologous grafting or further muscle dissection. HADM may also improve cosmesis of reconstructed breasts.

There is an insufficient quantity of evidence to inform whether patient-oriented efficacy outcomes are improved by the use of HADM. Conflicting evidence suggests HADM may be associated with more infections compared with no use of matrix. There is an insufficient quantity of acceptable quality evidence to inform selection of HADM type or selection of HADM over animal-derived acellular dermal matrix, as only 1 included study addresses each specific comparison made (Hayes, 2017).

Acellular matrixes are composed of bovine, porcine or human composition. Studies have shown similar results with the use of all three matrixes (Butterfield, 2013), (Chang & Lui, 2017), (Dikmans et al., 2016), (Gaster et al., 2013), (Glasberg & Light, 2012), (Hayes, 2017), (Ho et al., 2012), (Ibrahim et al., 2013).

In 2013, the Association of Breast Surgery and the British Association of Plastic, Reconstructive and Aesthetic Surgeons established joint guidelines for the use of acellular dermal matrix in breast reconstructive procedures.

In 2019, Haddock and Levine studied 72 reconstructive breast surgery patients noting that there is a mathematical relationship between fill volume and surface area as well as height of the acellular dermal matrix used. This analysis provides a guideline for immediate implant expansion to surgeons using acellular dermal matrix in reconstructive breast surgery.

**Adipose Derived Stem Cells**

Adipose-derived stem cells (ADSCs) have become the gold standard as a cell source for tissue engineering. They are particularly attractive for breast reconstruction as they exhibit potential for proliferation, preferential differentiation to adipocytes, and maintenance of mature adipose graft volume. However, the oncological safety of their use for adipose tissue regeneration, particularly in patients who have had a malignancy has been questioned (O’Halloran et al., 2017).

Autologous fat grafting and adipose-derived stem cells are two distinct entities with two different risk profiles, and should be regulated as such. Autologous fat grafting prepared with the additional step of stromal vascular fraction isolation is considered a form of "stem cell therapy" given the high concentration of stem cells found in stromal vascular fraction. Much ambiguity existed in the distinction between autologous fat grafting and stromal vascular fraction initially, in terms of both their biological properties and how they should be regulated. The market has capitalized on this in the past decade to sell unproven "stem cell" therapies to unknowing consumers while exploiting the regulatory liberties of
traditional fat grafting. This led to a Draft Guidance from the U.S. Food and Drug Administration in 2014 proposing stricter regulations on fat grafting in general, which in turn elicited a response from plastic surgeons, who have safely used autologous fat grafting in the clinical setting for over a century. After a series of discussions, the U.S. Food and Drug Administration released its Final Guidance in November of 2017, which established clear distinctions between autologous fat grafting and stromal vascular fraction and their separate regulations.

Xenograft Cartilage Grafting

Xenograft cartilage grafting involves the use of non-autologous cartilage. The tissue can result in overly firm and unnatural nipple consistency. If the grafts are placed superficially and do not have a smooth contour, they can extrude through the skin requiring revision. Autologous cartilage grafting in breast reconstruction procedures is the standard of care. There is a lack of evidence in the peer reviewed published literature on the long-term outcomes, safety and efficacy of Xenograft cartilage use in breast reconstructive procedures.

Lymphedema is a common, progressive, and often debilitating condition that can occur after breast cancer treatment. Preliminary reports on vascularized lymph node transfer (VLNT) have been promising. Nguyen et al., (2015) propose an algorithmic approach to simultaneous VLNT with microvascular breast reconstruction (MBR) and provide early results. The algorithm provided a reliable approach to optimizing simultaneous abdominal free flap breast reconstruction and VLNT and demonstrated promising results. Long-term studies are warranted to further delineate and improve the safety and efficacy of lymph node transfers.

Regulatory Status

Breast reconstruction is a procedure; the US Food and Drug Administration does not regulate the procedure but does regulate the devices used for the procedure. The FDA approved saline-filled breast implants for breast augmentation in women age 18 or older and for breast reconstruction in women of any age. They are also used in revision surgeries, which correct or improve the result of an original surgery.

FDA-approved saline-filled implants:

- Allergan Medical RTV Saline-Filled Breast Implant
- Ideal Implant Saline-Filled Breast Implant
- Mentor Saline-Filled and Spectrum™ Breast Implants

The FDA labeling for silicone and saline breast implantation states breast implant surgery should not be performed in women with: an active infection, existing cancer or pre-cancer of a breast that has not been adequately treated, or who are pregnant or nursing.

FDA-approved silicone gel-filled breast implants:

- Allergan Natrelle®
- Mentor MemoryGel®
• Mentor MemoryShape™ Silicone Gel-Filled Breast Implant
• Sientra® Silicone Gel Breast Implant (U.S. Food and Drug Administration, 2012).

In June 2011 the FDA released a report updating the clinical and scientific information for silicone gel-filled breast implants, including preliminary safety data from studies conducted by the manufacturers as a condition of their November 2006 approval. The conclusion in the report states that, “Based on the totality of the evidence, the FDA believes that silicone gel-filled breast implants have a reasonable assurance of safety and effectiveness when used as labeled. Despite frequent local complications and adverse outcomes, the benefits and risks of breast implants are sufficiently well understood for women to make informed decisions about their use. Manufacturers and physicians should continue to provide balanced and up-to-date information to women considering breast implants to help inform their decisions” (U.S. Food and Drug Administration, 2012).

The following codes are for reference purposes only and do not imply that the service is covered or non-covered under the member’s benefit policy. Applicable codes may include but are not limited to:

<table>
<thead>
<tr>
<th>CPT Codes</th>
<th>Description</th>
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<tbody>
<tr>
<td>11920</td>
<td>Tattooing, intradermal introduction of insoluble opaque pigments to correct color defects of skin, including micropigmentation; 6.0 sq. cm or less</td>
</tr>
<tr>
<td>11921</td>
<td>Tattooing, intradermal introduction of insoluble opaque pigments to correct color defects of skin, including micropigmentation; 6.1 to 20.0 sq. cm</td>
</tr>
<tr>
<td>11922</td>
<td>Tattooing, intradermal introduction of insoluble opaque pigments to correct color defects of skin, including micropigmentation; each additional 20.0 sq. cm (List separately in addition to code for primary procedure)</td>
</tr>
<tr>
<td>11970</td>
<td>Replacement of tissue expander with permanent prosthesis</td>
</tr>
<tr>
<td>11971</td>
<td>Removal of tissue expander(s) without insertion of prosthesis</td>
</tr>
<tr>
<td>13100</td>
<td>Repair, complex, trunk; 1.1 cm to 2.5 cm</td>
</tr>
<tr>
<td>13101</td>
<td>Repair, complex, trunk; 2.6 cm to 7.5 cm</td>
</tr>
<tr>
<td>13102</td>
<td>Repair, complex, trunk; each additional 5 cm or less (List separately in addition to code for primary procedure)</td>
</tr>
<tr>
<td>15271</td>
<td>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</td>
</tr>
<tr>
<td>15272</td>
<td>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)</td>
</tr>
<tr>
<td>15769</td>
<td>Grafting of autologous soft tissue, other, harvested by direct excision (eg, fat, dermis, fascia)</td>
</tr>
<tr>
<td>15771</td>
<td>Grafting of autologous fat harvested by liposuction technique to trunk, breasts, scalp, arms, and/or legs; 50 cc or less injectate</td>
</tr>
<tr>
<td>15772</td>
<td>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)</td>
</tr>
<tr>
<td>Code</td>
<td>Description</td>
</tr>
<tr>
<td>--------</td>
<td>-----------------------------------------------------------------------------</td>
</tr>
<tr>
<td>15777</td>
<td>Implantation of biologic implant (e.g., acellular dermal matrix) for soft tissue reinforcement (e.g., breast, trunk) (List separately in addition to code for primary procedure)</td>
</tr>
<tr>
<td>15839</td>
<td>Excision, excessive skin and subcutaneous tissue (includes lipectomy); other area</td>
</tr>
<tr>
<td>15877†</td>
<td>Suction assisted lipectomy; trunk</td>
</tr>
<tr>
<td>19316</td>
<td>Mastopexy</td>
</tr>
<tr>
<td>19318</td>
<td>Reduction mammoplasty</td>
</tr>
<tr>
<td>19325</td>
<td>Mammoplasty, augmentation; with prosthetic implant</td>
</tr>
<tr>
<td>19328</td>
<td>Removal of intact mammary implant</td>
</tr>
<tr>
<td>19330</td>
<td>Removal of mammary implant material</td>
</tr>
<tr>
<td>19340</td>
<td>Immediate insertion of breast prosthesis following mastopexy, mastectomy or in reconstruction</td>
</tr>
<tr>
<td>19342</td>
<td>Delayed insertion of breast prosthesis following mastopexy, mastectomy or in reconstruction</td>
</tr>
<tr>
<td>19350‡‡</td>
<td>Nipple/areola reconstruction</td>
</tr>
<tr>
<td>19355</td>
<td>Correction of inverted nipples</td>
</tr>
<tr>
<td>19357</td>
<td>Breast reconstruction, immediate or delayed, with tissue expander, including subsequent expansion</td>
</tr>
<tr>
<td>19361</td>
<td>Breast reconstruction with latissimus dorsi flap, without prosthetic implant</td>
</tr>
<tr>
<td>19364</td>
<td>Breast reconstruction with free flap</td>
</tr>
<tr>
<td>19366</td>
<td>Breast reconstruction with other technique</td>
</tr>
<tr>
<td>19367</td>
<td>Breast reconstruction with transverse rectus abdominis myocutaneous flap (TRAM), single pedicle, including closure of donor site</td>
</tr>
<tr>
<td>19368</td>
<td>Breast reconstruction with transverse rectus abdominis myocutaneous flap (TRAM), single pedicle, including closure of donor site; with microvascular anastomosis (supercharging)</td>
</tr>
<tr>
<td>19369</td>
<td>Breast reconstruction with transverse rectus abdominis myocutaneous flap (TRAM), double pedicle, including closure of donor site</td>
</tr>
<tr>
<td>19370</td>
<td>Open periprosthetic capsulotomy, breast</td>
</tr>
<tr>
<td>19371</td>
<td>Periprosthetic capsulectomy, breast</td>
</tr>
<tr>
<td>19380</td>
<td>Revision of reconstructed breast</td>
</tr>
<tr>
<td>19396</td>
<td>Preparation of moulage for custom breast implant</td>
</tr>
<tr>
<td>19499+++</td>
<td>Unlisted procedure, breast</td>
</tr>
</tbody>
</table>

†Note: Considered incidental to the primary procedure when used to report suction-assisted lipectomy of the trunk as part of a medically necessary flap breast reconstruction procedure. It is inappropriate to code for liposuction in addition to the fat grafting code.

‡‡Note: Considered not medically necessary when used to report Cook Biodesign® Nipple Reconstruction Cylinder or Juvederm®.

+++Note: Considered medically necessary when used to report thoracodorsal artery perforator (TDAP) flap with a breast reconstruction procedure performed on the diseased/affected breast (i.e., breast on which the mastectomy/lumpectomy was performed).
<table>
<thead>
<tr>
<th>HCPCS Codes</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>C1789</td>
<td>Prosthesis, breast (implantable)</td>
</tr>
<tr>
<td>C9358</td>
<td>Dermal substitute, native, non-denatured collagen, fetal bovine origin (SurgiMend Collagen Matrix), per 0.5 sq cm</td>
</tr>
<tr>
<td>L8600</td>
<td>Implantable breast prosthesis, silicone or equal</td>
</tr>
<tr>
<td>Q4100</td>
<td>Skin substitute, not otherwise specified</td>
</tr>
<tr>
<td>Q4116</td>
<td>Alloderm, per square centimeter</td>
</tr>
<tr>
<td>Q4122</td>
<td>Dermacell, per square centimeter</td>
</tr>
<tr>
<td>Q4128</td>
<td>Flex HD or Allopatch HD, or Matrix HD per square centimeter</td>
</tr>
<tr>
<td>Q4130</td>
<td>Strattice TM, per sq. cm</td>
</tr>
<tr>
<td>S2066</td>
<td>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</td>
</tr>
<tr>
<td>S2067</td>
<td>Breast reconstruction of a single breast with &quot;stacked&quot; 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</td>
</tr>
<tr>
<td>S2068</td>
<td>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</td>
</tr>
<tr>
<td>S8950</td>
<td>Complex lymphedema therapy, each 15 minutes</td>
</tr>
</tbody>
</table>

Considered medically necessary when used to report autologous fat transplant (i.e., liposuction, lipoinjection, lipofilling, lipomodeling) without the use of adipose-derived stem cells or xenograft cartilage grafting:

<table>
<thead>
<tr>
<th>CPT Codes</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>19366</td>
<td>Breast reconstruction with other technique</td>
</tr>
<tr>
<td>19380</td>
<td>Revision of reconstructed breast</td>
</tr>
<tr>
<td>20926</td>
<td>Tissue grafts, other (e.g., paratenon, fat, dermis)</td>
</tr>
</tbody>
</table>

**Scientific References**


DellaCroce FJ. Perforator Flap Reconstruction Treatment and Management. Updated Nov 9, 2018.. Available at URL address: http://emedicine.medscape.com/article/1276406-treatment


Origination Date: Sept. 2019 Peer Reviewed: June 2021 Next Review Date: June 2022


**Policy implementation and updates**

September 2019 Origination

September 2020 policy statement clarification; physician documentation clarification; references reviewed and updated.

June 2021 no changes to benefit coverage or criteria. Reference updates with added background information relating to breast implants.