Cigna Medical Coverage Policy

Subject: Breast Reconstruction Following Mastectomy or Lumpectomy

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INSTRUCTIONS FOR USE

The following Coverage Policy applies to health benefit plans administered by Cigna companies. Coverage Policies are intended to provide guidance in interpreting certain standard Cigna benefit plans. Please note, the terms of a customer’s particular benefit plan document (Group Service Agreement, Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document) may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a customer’s benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a customer’s benefit plan document always supersedes the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. In certain markets, delegated vendor guidelines may be used to support medical necessity and other coverage determinations. Proprietary information of Cigna. Copyright ©2014 Cigna

Coverage Policy

Coverage for breast reconstruction* and breast prostheses following mastectomy or lumpectomy is governed by federal and/or state mandates.

Breast Reconstruction

*Please note: Coverage for breast reconstruction services following mastectomy and lumpectomy is available to both females and males. In addition, a diagnosis of breast cancer is not required for breast reconstruction services to be covered, and the timing of reconstructive services is not a factor in coverage.

Cigna covers breast reconstruction following mastectomy or lumpectomy for EITHER of the following:

- breast reconstruction procedures performed on the diseased/affected breast (i.e., breast on which the mastectomy/lumpectomy was performed), including:
  - areolar and nipple reconstruction
- areolar and nipple tattooing
- autologous fat transplant (i.e., lipoinjection, lipofilling, lipomodeling)
- breast implant removal and subsequent reimplantation
- capsulectomy
- capsulotomy
- implantation of tissue expander
- implantation of U.S. Food and Drug Administration (FDA)-approved internal breast prosthesis
- oncoplastic reconstruction
- reconstructive surgical revisions
- 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

- breast reconstruction procedures performed on the nondiseased/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

Cigna covers each of the following products* as medically necessary when used in association with a covered, medically necessary breast reconstruction procedure:

- AlloDerm®
- AlloMax™
- FlexHD® Acellular Hydrated Dermis
- NeoForm™ Dermis
- SurgiMend®

Cigna does not cover ANY of the following products* when used in association with a breast reconstruction procedure because they are considered experimental, investigational or unproven (this list may not be all-inclusive):

- Biodesign® Nipple Reconstruction Cylinder
- DermaCell™
- DermaMatrix Acellular Dermis
- hMatrix®
- Permacol®
- Radiesse®
- Repriza®
• **Strattice™** Reconstructive Tissue Matrix

*Note: Refer to the table in Appendix A for a list of products and the associated CPT and HCPCS codes.*

Cigna does not cover ANY of the following breast reconstruction procedures because such treatment is considered experimental, investigational or unproven for this indication:

- autologous fat transplant with the use of adipose-derived stem cells
- vascularized lymph node transfer (VLNTx)
- xenograft cartilage grafting

Cigna does not cover suction lipectomy or ultrasonically-assisted suction lipectomy (liposuction) for correction of surgically-induced donor site asymmetry (e.g., trunk or extremity) that results from one or more flap breast reconstruction procedures because such treatment is considered cosmetic in nature and not medically necessary.

Cigna covers removal of either a saline-filled OR silicone gel-filled breast implant when associated with breast reconstruction following mastectomy or lumpectomy for ANY indication, including for the purpose of producing a symmetrical appearance of the nondiseased breast. Refer to the Breast Implant Removal Coverage Policy for additional information on breast implant removal.

Following removal of a breast implant, Cigna covers the subsequent surgical implantation of a new U.S. Food and Drug Administration (FDA)-approved breast implant as 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/nondiseased breast following mastectomy or lumpectomy in the opposite breast

### External Breast Prostheses and Mastectomy Bras

Cigna covers external breast prostheses and mastectomy bras following mastectomy or lumpectomy under the core medical benefits of the plan.

Cigna does not cover an external breast prosthesis or mastectomy bra for any other indication because each is considered not medically necessary.

This Coverage Policy does not address treatments for lymphedema. For information on these treatments, refer to the separate Cigna Coverage Policies Lymphedema Pumps and Compression Garments, and Complex Lymphedema Therapy (Complete Decongestive Therapy).

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### General Background

Breast reconstruction was originally designed to reduce post-mastectomy complications and to establish symmetry between the surgical breast and the contralateral breast. Surgical procedures that are performed to establish symmetry can include: breast reduction; breast augmentation with an FDA-approved breast implant; and/or areola-with-nipple reconstruction and nipple-area tattooing. Breast reconstruction after mastectomy has evolved over the last century to become an integral component of therapy for patients with breast cancer. Reconstruction can occur immediately after a mastectomy, or be delayed for weeks or years until a patient undergoes radiation, chemotherapy, or determines whether they want breast reconstruction.

### Prosthetic Reconstruction

**Breast Implants:** Breast implants can be inserted at the same time as the mastectomy (e.g., direct-to-implant breast reconstruction or one-stage immediate breast reconstruction) or in two stages, using an implanted tissue expander in the first stage followed by removal of the expander and insertion of a permanent breast implant (e.g., two-stage reconstruction or two-stage delayed reconstruction). The FDA-approved implant is placed either
deep in the breast on the pectoral fascia (submammary) or beneath the pectoralis major. The advantages of tissue expander implant reconstruction are the reliability, simplicity, and avoidance of donor-site morbidity. Complications associated with the use of breast implants can occur in the immediate perioperative period or years later. Such complications include exposure, extrusion, or infection of the implants. Longer term problems also include asymmetry, capsular contracture, malposition of the implant, rupture, and pain. These conditions, when they become clinically significant, may require removal of the implant (Roehl, et al., 2012; American Cancer Society [ACS], 2014; Roostaeian, et al., 2012).

Indications for implant reconstruction include: bilateral reconstruction; individuals requiring augmentation in addition to reconstruction; individuals not suited for long surgery; a lack of abdominal tissue; individual unwilling to have additional scars on either their back or abdomen; and a small breast mound with minimal ptosis. Relative contraindications to implant reconstruction include: young age (i.e., may need implant replaced multiple times); individual unwilling to follow up; very large or ptotic breast. The contraindications to implant reconstruction include: silicone allergy; fear of implants; previously failed implants; or need for adjuvant radiation therapy (Roehl, et al., 2012).

**U.S. Food and Drug Administration (FDA):** In the FDA labeling for approved breast implants Mentor Corp., Santa Barbara, CA; Allergan Corp. (formerly Inamed), Irvine, CA and Sientra, Inc., Santa Barbara, CA are listed as manufacturers of silicone and saline breast implants.

FDA-approved saline-filled implants:
- Allergan Medical RTV Saline-Filled Breast Implant
- Mentor Saline-Filled and Spectrum™ Breast Implants

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 silicone gel-filled breast implants:
- Allergan Natrelle®
- Allergan Natrelle® 410 Highly Cohesive Anatomically Shaped Silicone-Filled Breast Implant
- Mentor MemoryGel®
- Sientra® Silicone Gel Breast Implant

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 precancer of a breast that has not been adequately treated, or who are pregnant or nursing (FDA, 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” (FDA, 2011).

**Tissue Expanders**
Following mastectomy, some individuals have inadequate elasticity in the remaining tissue to accommodate and support a breast implant. For these individuals, tissue expanders can be inserted under the chest muscle or skin. The expander is an empty balloon-like container that, over time, is injected with saline. This inflation causes the tissue to expand. The tissue expander is surgically removed once an adequate pocket has been established, and the permanent implant is then inserted. The most appropriate patients for this type of reconstruction are individuals who do not qualify for autogenous reconstruction, individuals who do not want additional scars from other donor sites, individuals who prefer a typically quicker postoperative recovery period, and individuals who have relatively small breasts. Contraindication for this type of reconstruction are mastectomy flaps that are too thin for adequate implant coverage and the completed or planned use of adjuvant
radiation therapy because of higher implant complication rates (American Cancer Society, 2009; Hu, et al., 2007).

**Tissue Flap Procedures**

Autologous breast reconstruction procedures are safe and effective and are a well-established standard of care include tissue/muscle reconstruction procedures (e.g., flaps). Methods of autologous tissue breast reconstruction include local flaps and distant flaps. Local flaps rely on transposition of muscle, subcutaneous tissue, and skin into the mastectomy defect based on the attached native blood supply of the muscle (e.g., latissimus dorsi myocutaneous (LD) flap and the pedicled transverse rectus abdominus myocutaneous (TRAM) flap). Distant flap breast reconstruction requires the use of microvascular free-tissue transfer (e.g., free TRAM flap, deep inferior epigastric perforator [DIEP] flap, superficial inferior epigastric artery perforator [SIEP] flap, inferior or superior gluteal flap, superior gluteal artery perforator flap, Reubens flap, and the transverse upper gracilis (TUG) flap). Breast reconstruction using these donor sites relies on harvesting the flap with its vascular pedicle, which is anastomosed using microsurgical technique to appropriate recipient vessels in the mastectomy site. The two most common types of tissue flap procedures are the TRAM flap and the LD flap. Other tissue flap surgeries are more specialized, and may not be available everywhere. The choice of procedure for a given individual is affected by her age, her health, her contralateral breast size and shape, her personal preference, and the expertise of the reconstructive surgeon (Roehl, et al., 2012; ACS, 2013; Spear et al., 2007; Mehrara et al., 2006; Alderman et al., 2006; Garvey et al., 2006; Bajaj et al., 2006; Wechselberger, et al., 2004; Behnam et al., 2003).

**Transverse Rectus Abdominus Myocutaneous (TRAM) Flap:** The TRAM flap is the most commonly performed autologous reconstructive procedure and is considered the gold standard in breast reconstruction because of the lower abdominal tissue’s similarities in consistency with breast tissue. There are three types of TRAM flaps: unipedicle, bipedicle, or free. Pedicle flaps involve leaving the flap attached to its original blood supply and tunneling it under the skin to the breast area. Free flap involves cutting the flap free of skin, fat, blood vessels, and muscle from its original location and attaching the flap to blood vessels in the chest area. The advantage of these procedures lies in the consistency of the reconstructed breast and its aesthetic appearance. These procedures are indicated for individuals with (Zenn, 2013, Roehl, et al., 2012):

- large tissue requirement after a radical mastectomy
- history of radiation to the chest wall
- small or large opposite breast that is difficult to match with an implant
- previous failure of implant reconstruction
- excess lower abdominal tissue

Abdominal complications resulting from this surgery include loss of abdominal strength, abdominal bulge and hernia formations. It is recommended that reconstruction be delayed when adjuvant chemotherapy is planned, as complications of the reconstruction can be detrimental in beginning the individual’s therapy.

Numerous factors place an individual at higher risk for complications and are therefore considered relative contraindications to TRAM flap surgery (e.g., cardiac and/or pulmonary disease, diabetes, history of pulmonary embolus or deep venous thrombosis) (Zenn, 2013, Roehl, et al., 2012):

**Latissimus Dorsi Myocutaneous (LD) Flap:** The LD flap moves muscle and skin from the back to reconstruct the breast. The LD flap is ideally suited for single-stage reconstruction for individuals with small breasts and a moderate degree of ptosis and for patients with no available abdominal donor site due to scars or lack of tissue. The LD flap can be used to correct lumpectomy defects which require a smaller implant or no implant. Some individuals may have weakness in their back, shoulder, or arm after this surgery. Relative contraindications to the LD flap include: planned postoperative radiation therapy, bilateral reconstruction, and significant breast ptosis. Contraindications to the LD flap include: previous lateral thoracotomy and individuals with large breast volume who do not desire reduction (Roehl, et al., 2012).

**Superior or Inferior Gluteal Free Flap:** The superior or inferior gluteal free flap requires skin, fat, blood vessels, and muscle is removed from the gluteus maximus to reconstruct the breast. This technique is an option for when the abdomen is no longer an alternative for flap transfer. This flap is technically complex and has
complications including: seroma, sciatica, unfavorable scar location, and asymmetrical buttock contour (Roehl, et al., 2012).

**Deep Inferior Epigastric Perforator (DIEP) Flap:** A modification of the free TRAM flap is the deep inferior epigastric perforator (DIEP) flap. This flap does not harvest any muscle or fascia from the abdomen, and reportedly has significantly less donor-site morbidity than the usual TRAM flap. Patients are thought to have reduced postoperative pain, a lower risk of abdominal bulge or hernia, and less postoperative abdominal donor-site weakness. In reducing the amount of disturbance to the abdominal wall donor site, however, use of the DIEP flap unavoidably reduces the number of perforators supplying blood to the flap. This could potentially lead to a reduced supply of blood to the flap, thereby causing an increase in partial flap loss and fat necrosis (Kroll, 2000).

**Rubens Flap:** The Rubens flap is based on the circumflex iliac vessels and is an option for individuals who have an excess of soft tissue over the hips. Because this reconstructive procedure is limited in bulk and skin envelope, and often requires a balancing procedure on the contralateral hip, it is not usually considered as a first option for breast reconstruction (Roehl, et al., 2012).

**Transverse Upper Gracilis (TUG) Flap**

The TUG flap is taken from the upper inner thigh area. Part or all of the gracilis muscle is included with the flap to ensure the most reliable blood supply. This is a breast reconstructive method for those individuals who have limited flap donor sites. Candidates for TUG flap breast reconstruction include individuals desiring autogenous breast reconstruction with sufficient upper inner thigh tissue but who have had a previous abdominoplasty or a flap previously taken from their abdomen. Very thin or athletic individuals who may have insufficient abdominal donor tissue may be candidates for the TUG flap. This flap may be referred to as the TUG Perforator Flap which, as a perforator flap, it is a flap made of skin and fat only (no muscle). The TUG Myocutaneous Flap includes skin, fat, a portion of the gracillis muscle and the blood vessels associated with it to keep it alive. It is not usually considered as a first option for breast reconstruction.

**Reconstruction of the Nipple-Areolar Complex**

This portion of the breast reconstruction is usually performed as a second or third stage after the breast mound has been constructed. 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. It has been reported that within 12 months, most reconstructed nipples undergo a 50% reduction in projection. Therefore, the nipple should be made larger than desired during the initial surgery. The rebuilding of the nipple-areolar area is conducted first, and the tattooing procedure is done when swelling has subsided, usually 3–6 weeks after nipple creation. Successful nipple-areola reconstruction is expected to maintain nipple projection and areola size; however, longevity of this reconstruction is highly variable and is influenced by factors such as tissue thickness, scar contracture, trauma and radiation. Tattooing is commonly repeated (Beckenstein, 2014; Chun, 2013; Roehl, et al., 2012; Heitland, et al., 2006; Guerra, et al., 2003).

Local tissue flaps are the most frequently performed methods of reconstruction. A common donor site is the medial thigh skin. Nipple reconstruction with local flaps is achieved with various techniques, each with its own proponents and benefits. These include the skate flap, bell flap, double opposing tab flap, star flap, top-hat flap, twin flap, propeller flap, S flap, rolled dermal-fat flap, and autologous cartilage. Acellular dermal matrices used alone or in conjunction with local flaps are being proposed as well as injectable materials for nipple reconstruction. Some have also advocated creating a more stable de-epithelialized skin base for the reconstructed nipple to minimize loss of projection (Beckenstein, 2014; Chun, 2013).

The use of cartilage is another method of nipple reconstruction, particularly in prosthetic reconstruction where there might be a soft-tissue deficiency. The procedure is applicable to both unilateral and bilateral nipple reconstruction, is reported to be an easy procedure to perform, does not involve a donor site, and maintains long-lasting projection. A reported disadvantage of donated cartilage is that the resulting nipple is firm and unnatural in feel. If the grafts are placed too superficially and do not have a smooth contour, they can extrude through the skin, warranting revision and/or removal. Caution is recommended with thin skin flaps or irradiated tissue which can also make extrusion more likely. The use of simple nipple–areola tattooing is recommended for these patients. During the informed consent, it is recommended that the patient be warned that the cartilage is from an organ donor and there is a minor risk of infectious diseases (Beckenstein, 2014). Autologous cartilage grafting in breast reconstruction procedures is the standard of care. There is a lack of 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.

Loss of nipple projection commonly occurs a few years after reconstruction. This problem may be reduced with the use of bell and double opposing tab flaps. Secondary nipple reconstruction has been proposed by various procedures such as re-elevating the flap; inserting autologous dermal tissue, autologous or banked cartilage; and using filler injection or AlloDerm. Discoloration and uneven pigment distribution may occur over time and can usually be corrected with tattooing (Chun, 2013).

Radiesse® (BioForm Medical, Inc., San Mateo, CA) has been proposed to reshape nipples after reconstruction of the breast following mastectomy. Radiesse injections consist of very small, smooth calcium hydroxylapatite (CaHA) microspheres that are suspended in a water-based gel carrier. Radiesse has received PMA approval by the FDA as a medical device for subdermal implantation for two indications: correction of moderate to severe facial wrinkles and folds such as nasolabial folds and the correction of facial fat loss in people with human immunodeficiency virus (FDA, 2006c). There remains a lack of evidence in the peer reviewed published literature on the long term outcomes, safety and efficacy of Radiesse in breast reconstructive procedures.

The Cook Biodesign® Nipple Reconstruction Cylinder (Cook Biotech Incorporated, West Lafayette, IN) is a porcine non-cross-linked, non-dermis-based biologic graft material that is marketed for breast procedures including breast reconstruction, breast revision and mastopexy. It may be used in combination with Biodesign® Tissue Generation Matrix. On June 20, 2011, the Cook Biodesign Nipple Reconstruction Cylinder received FDA 510(k) approval. The FDA indications for use for the Biodesign Nipple Reconstruction Cylinder states it is intended for implantation to reinforce soft tissue where weakness exists, in plastic and reconstructive surgery of the nipple. The cylinder is supplied sterile and is intended for one-time use. The Biodesign Nipple Reconstruction Cylinder is a rolled Small Intestinal Submucosa (SIS) mesh and available in sizes from 0.7 cm to 1.0 cm in diameter and 1.0 cm to 2.5 cm in length. The cylinder is a scaffold which becomes infiltrated by the host cells during the body’s natural repair process. The device is implanted using a skin flap procedure that prevents migration of the device. The clinical performance of the Biodesign Nipple Reconstruction Cylinder was assessed in two case studies and anecdotal evidence of 186 device implants. Of the 188 implants, complications included device extrusion (number of extrusions not given). Follow-up periods ranged from 2 to 12 months. The clinical studies showed the Biodesign Nipple Reconstruction Cylinder as substantially equivalent to its predicates in its application (FDA, 2011). There is a lack of evidence in the peer reviewed published literature regarding the long term outcomes and efficacy of the Cook Biodesign Nipple Reconstruction Cylinder for use in breast reconstruction or for any other indication.

Contralateral Breast
Although the goal of breast reconstruction is to restore symmetry, the process may leave the opposite or contralateral breast larger or smaller than the surgical breast. To correct this asymmetry, a mastopexy or reduction mammoplasty may be performed on the contralateral breast. If the reconstructed breast is larger, then an augmentation mammoplasty with implant may be performed on the nondiseased breast (Roehl, et al., 2012).

Oncoplastic Reconstruction
Oncoplastic procedures are performed immediately or one to two weeks after lumpectomy, once final pathology is available. They include rearrangement of the remaining breast tissue through a variety of techniques, often adhering to breast reduction principles. In addition, more tissue can be brought into the breast to correct the volume deficit, often in the form of a latissimus dorsi flap. Indications for these procedures depend on the patient’s preoperative breast size, available remaining breast tissue, and overall goals for ultimate breast size and shape. All these procedures are done prior to radiation to prevent the contracture of the lumpectomy defect and distortion of the nipple-areolar complex (Roehl, et al., 2012).

Radiation Tattoo Markers: Ink markers are tattooed as landmarks before radiotherapy of breast cancer with the purpose of obtaining a precise radiation field. These tattoos are permanent, but are the size of a freckle. Individuals may have these tattoo markers removed via laser or punch biopsy excision as a part of the overall breast reconstruction procedure (Bregnhoj, et al., 2010).

Nonsurgical Options
Some women may choose not to have breast reconstruction or are poor candidates for reconstruction. For these women, an external breast prosthesis and mastectomy bras are additional options (Hu, et al., 2007).
Skin Substitutes
During breast reconstruction, acellular dermal skin substitutes (i.e., AlloDerm®, AlloMax™, FlexHD®, and SurgiMend®) are primarily used in the setting of tissue expander and breast implant reconstruction. Patients should be in overall good health and have no underlying condition that would restrict blood flow or interfere with the normal healing process (e.g., uncontrolled diabetes, hypertension, previous surgery). These matrixes may be indicated when there is insufficient tissue expander or implant coverage by the pectoralis major muscle and additional coverage is required, as may be the case in a very thin patient; if there is viable but compromised or thin post-mastectomy skin flaps that are at risk of dehiscence or necrosis; or if there is a need to re-establish the inframammary fold and lateral mammary fold landmarks. When used in appropriate candidates, these skin substitutes are proposed to improve control over placement of the inframammary fold and final breast contour, enhance use of available mastectomy skin, reduce the number of expander fills necessary, reduce time to complete expansion and eventual implant exchange, potential improved management of a threatened implant, reduce the need for explantation and the potential for reduction in the incidence of capsular contracture. However, there are ongoing concerns regarding the increased risk of seroma and infection, a higher risk of an implant having to be removed, and tissue flap death (American Cancer Society, 2012; Nguyen, et al., 2011; Sbitany and Serletti, 2011).

There is a paucity of data comparing the skin substitute products directly. The products vary in many aspects, including the source of tissue, processing, storage, surgical preparation and available sizes. The most familiar product to most plastic surgeons, AlloDerm, was the first human dermis product available in 1994 (Cheng, et al., 2012).

U.S. Food and Drug Administration (FDA)
Depending on the purpose of the product and how it functions, skin substitutes are regulated by the FDA premarket approval (PMA) process, 510(k) premarket notification process, or the FDA regulations for banked human tissue.

Products that are classified by the FDA under the PMA process as a class III, high-risk device require clinical data to support their claims for use. These devices may be used as a long-term skin substitute or a temporary synthetic skin substitute. They actively promote healing by interacting directly or indirectly with the body tissues.

Other wound care devices are approved by the 510(k) process, and their primary purpose is to protect the wound and provide a scaffold for healing. They may or may not be integrated into the body tissue. Some devices are rejected by the body after approximately ten days to several weeks and removed prior to definitive wound therapy or skin grafting.

The following is a list of skin substitutes, not derived from human tissue, that are FDA approved (this list may not be all-inclusive):

- Permacol
- Strattice
- SurgiMend

Donated skin that requires minimal processing and is not significantly changed in structure from its natural form is classified by the FDA as banked human tissue, is not considered a medical device, and does not require PMA or 510(k) approval. Donated skin is regulated by the American Association of Tissue Banks (AATB) and the FDA guidelines for banked human tissue. AATB oversees a voluntary accreditation program and the FDA focuses on preventing the transmission of communicable diseases by requiring donor screening and testing. Tissue establishments must register with the FDA and list each cell or tissue produced. An example of a banked human tissue product is AlloDerm, an acellular dermal matrix (FDA, 2004; Department of Health and Human Services, 2001).

The following skin substitutes are derived from human tissue and therefore subject to the rules and regulations for banked human tissue developed by the American Association of Tissue Banks (AATB) (this list may not be all-inclusive):
• Alloderm
• Allomax
• DermaCell
• DermaMatrix
• FlexHD
• hMatrix
• Repriza

The safety and efficacy of the skin substitutes listed below are supported by the evidence in the published peer-reviewed scientific literature and/or are established treatment options for post-mastectomy breast reconstruction.

**AlloDerm**: AlloDerm (LifeCell Corporation, Branchburg, NJ) is an acellular dermal matrix allograft classified as banked human tissue by the FDA because it is minimally processed and not significantly changed in structure from the natural material. AlloDerm is an established treatment option and is supported by the evidence in the published peer-reviewed scientific literature for tissue repair during postmastectomy breast reconstruction (McCarthy, et al., 2012; Cheng, et al., 2012; Vardanian, et al., 2012; Jansen and Macadam, 2011; Salzberg, et al., 2011; Joanna, et al., 2011; Antony, et al., 2010; Haddock, et al., 2007; Breuing and Colwell, 2007; Zienowicz, et al., 2007; Gamboa-Bobadilla, 2006; Glasberg, et al., 2006; Salzberg, 2006; Breuing, et al., 2005; Nahabedian, 2005). AlloDerm is available in two forms. One product is a Tissue Regeneration Matrix and the other is a Ready to Use matrix. The Ready to Use with a contour shape was specifically designed for breast reconstruction.

**AlloMax**: AlloMax Surgical Graft (Bard Davol, Inc. Warwick, RI) is an acellular non-cross-linked human dermis allograft. Because AlloMax is a natural human product it is classified as banked human tissue and does not require FDA approval. It is regulated by the American Association of Tissue Banks and the FDA guidelines for banked human tissue. AlloMax Surgical Graft is available in multiple sizes. The AlloMax Surgical Graft for Breast Reconstruction (previously marketed as NeoForm™) is proposed for post-mastectomy breast reconstruction and is an established skin substitute for this indication (Venturi, et al., 2013; Bard, 2013).

**FlexHD Acellular Hydrated Dermis**: FlexHD Acellular Hydrated Dermis (Musculoskeletal Transplant Foundation, Edison, NJ and Ethicon Inc., Somerville, NJ) is a matrix derived from donated human allograft skin. The product is regulated by the American Association of Tissue Banks and the FDA guidelines for banked human tissue. FlexHD is indicated for the replacement of damaged or inadequate integumental tissue or for the repair, reinforcement or supplemental support of soft tissue defects. Flex HD is available in multiple sizes. Results of case series and retrospective reviews in the peer-reviewed literature support the safety and efficacy of FlexHD for use during postmastectomy breast reconstruction. FlexHD is an established skin substitute for this indication (Liu, et al., 2014; Seth, et al., 2013; Seth, et al., 2012; Brooke, et al., 2012; Rawlani, et al., 2011; Cahan, et al., 2011; Topol, et al., 2008).

**NeoForm Dermis**: Neoform Dermis (Mentor Corp., Santa Barbara, CA) is a solvent-dehydrated, gamma-irradiated preserved human allograft dermis indicated for use as a soft tissue graft for horizontal and vertical soft tissue augmentation of thickness and length, such as breast reconstruction. Neoform is classified as banked human tissue by the FDA. Although evidence in the published, peer-reviewed scientific literature supporting the use of this product in breast reconstruction is limited, Neoform Dermis is an established skin substitute used for tissue expansion in breast reconstruction following a mastectomy. Neoform is no longer available for distribution.

**SurgiMend Collagen Matrix**: SurgiMend or SurgiMend Collagen Matrix (TEI Biosciences Inc., Boston, MA) is an acellular dermal tissue matrix derived from fetal or neonatal bovine dermis. The matrix acts as a scaffold that is progressively integrated, remodeled, and replaced by the functional host tissue. Approved as a Class II, FDA 510(k) device, SurgiMend is “intended for implantation to reinforce soft tissue where weakness exists and for the surgical repair of damage or ruptured soft tissue membranes” specifically for plastic and reconstructive surgery, muscle flap reinforcement, and hernia repair (e.g., abdominal, inguinal, femoral, diaphragmatic, scrotal, umbilical, incisional) (FDA, 2009). SurgiMend products include SurgiMend Collagen Matrix and SurgiMend PRS for breast reconstruction. SurgiMend is available in multiple sizes and thicknesses. Results of case series and retrospective reviews in the peer-reviewed literature support the safety and efficacy of SurgiMend for use during...
postmastectomy breast reconstruction. SurgiMend is an established skin substitute for this indication (Butterfield, et al., 2013, Gaster, et al., 2013, Ohkuma, et al., 2013; Endress, et al., 2012; Craft, et al., 2011; Cromwell, et al., 2009; TEI Biosciences, 2013).

**Other Skin Substitutes**

Additional skin substitutes have been proposed as treatment options in breast reconstruction as discussed below, but the evidence in the published peer-reviewed scientific literature does not support the safety and efficacy of the use of these substitutes. The number of available studies is limited and involves small, heterogeneous patient populations, short-term follow-ups, minimal comparisons to the established treatment method for the condition, and/or lack of a control group. In some cases, reported outcomes are inconsistent, and a consensus on patient selection criteria and the appropriate surgical approach and techniques that should be used have not been established.

**Dermacell™:** Dermacell is provided by the Skin and Wound Allograft Institute, which is a wholly owned subsidiary of LifeNet Health®, Virginia Beach, VA. Dermacell is an acellular human dermis allograft collagen scaffold proposed for the treatment of breast reconstruction. LifeNet Health is registered with the FDA as an establishment producing tissue- and cellular-based products (LifeNet Health, 2012). Dermacell is available in multiple sizes. There is insufficient evidence in the peer-reviewed literature to support the safety and efficacy of Dermacell (Vashi, 2014).

**DermaMatrix Acellular Dermis:** DermaMatrix (Synthes Inc., West Chester, PA) is an allograft derived from human skin and is classified by the FDA as banked human tissue. DermaMatrix is proposed for use for breast reconstruction postmastectomy. Evidence in the published, peer-reviewed scientific literature supporting the use of this product in breast reconstruction is lacking and its role is unclear. Studies are primarily in the form of retrospective reviews with small patient populations (Becker, et al., 2009; Brooke, et al., 2012; Michelotti, et al., 2013).

**hMatrix®**
hMatrix Acellular Dermis (Bacterin International Holdings Inc., Belgrade, MT) is an acellular dermal scaffold processed from donated human skin. The dermis is processed using a proprietary method and the matrix is packaged and sterilized using low-dose gamma irradiation. hMatrix is regulated by the American Association of Tissue Banks and the FDA guidelines for banked human tissue. The product is stored and supplied frozen. Bacterin hMatrix PR for breast augmentation (Bacterin, 2013). hMatrix is available in four sizes. There is insufficient evidence to support the safety and efficacy of hMatrix as a skin substitute.

**Permacol®:** The Permacol Crosslinked Porcine Dermal Collagen Surgical Mesh (Tissue Sciences Laboratories PLC, Hants, United Kingdom), a xenograft, is a fibrous flat sheet comprised of acellular porcine dermal collagen and elastin. According to the U.S. Food and Drug Administration (FDA) 510(k) approval, Permacol® is intended for use as a soft tissue patch to reinforce soft tissue where weakness exists and for the surgical repair of damaged or ruptured soft tissue membranes (FDA, 2000). Breast reconstruction is not specifically mentioned as an approved FDA indication. However, muscle flap reinforcement is an FDA-approved indication for use. Permacol is available in multiple sizes. Evidence in the published, peer-reviewed scientific literature supporting the use of this product in breast reconstruction is lacking and its role is unclear (Ramsden, et al., 2009).

**Repriza® Acellular Dermal Matrix:** Repriza (Promethean Lifesciences Inc., Pittsburgh, PA) is a human skin, acellular dermal matrix. The product is regulated by the American Association of Tissue Banks and the FDA guidelines for banked human tissue. Repriza is membrane free and proposed for implantation for reconstructive surgery including breast reconstruction, abdominal wall reconstruct and augmentation of soft tissue irregularities. The matrix is provided in 4X12 cm and 6X16 cm sheets. It can also be custom made. The product is marketed by Specialty Surgical Products, Inc. (SSP) (SSP, 2014). There is insufficient evidence to support the safety and efficacy of Repriza for breast reconstructive surgery.

**Strattice ™**
Reconstructive Tissue Matrix or LTM Surgical Mesh: Strattice Reconstructive Tissue Matrix or LTM Surgical Mesh (LifeCell Corporation, Branchburg, NJ) is an acellular, xenographic tissue matrix derived from porcine dermics. (LifeCell, 2010, FDA, 2007). It is FDA 510(k) approved as LTM-RC surgical mesh “for use as a soft tissue patch to reinforce soft tissue where weakness exists and for the surgical repair of damaged or ruptured soft tissue membranes. The implant is intended for the reinforcement of soft tissues repaired by
sutures or suture anchors, during rotator cuff surgery. Indications for use also include the repair of hernias and/or body wall defects which require the use of reinforcing or bridging material to obtain the desired surgical outcome” (FDA, 2007). Strattice is proposed for use during postmastectomy breast reconstruction to support medial repair for breast pocket size and position. Strattice is available in seven sizes with various shapes. There is insufficient evidence in the published peer-reviewed scientific literature supporting the efficacy of Strattice (Glasberg and Light, 2012).

**Systematic Review and Meta-Analysis:** Ho et al. (2012) conducted a systematic review and meta-analysis to determine an aggregate estimate of risks associated with acellular dermal matrix (ADM)-assisted breast reconstruction. AlloDerm was used in the majority of studies. ADMs other than AlloDerm were used in one study (i.e., FlexHD, Strattice). Seven complications were studied including seroma, cellulitis, infection, hematoma, skin flap necrosis, capsular contracture, and reconstructive failure. Sixteen studies met the inclusion criteria. The pooled complication rates were seroma 6.9%, cellulitis 2.0%, infection 5.7%, skin flap necrosis 10.9%, hematoma 1.3%, capsular contracture 0.6% and reconstructive failure 5.1%. Five studies reported findings for both the ADM and non-ADM patients and were used in the meta-analysis to calculate pooled OR. ADM-assisted breast reconstructions had a higher likelihood of seroma, infection, and reconstructive failure than breast reconstructions without the use of ADM. The relation of ADM use to hematoma, cellulitis, was inconclusive. In the studies evaluated, ADM-assisted breast reconstructions exhibited a higher likelihood of seroma, infection, and reconstructive failure than prosthetic-based breast reconstructions using traditional musculofascial flaps. ADM is associated with a lower rate of capsular contracture. The authors reported that given the relatively low quality evidence that currently exists in the literature, additional randomized-controlled studies are needed to further evaluate the safety and efficacy of ADM in implant-based breast reconstruction.

Kim et al. (2012) conducted a systematic review and meta-analysis to evaluate complication outcomes from human acellular dermal matrix (ADM) used as an adjunct to traditional submuscular tissue expander/implant breast reconstruction. Forty eight uncontrolled cohort studies met inclusion criteria. Thirteen studies had information only on human ADM matrix-based reconstruction, 29 had information only on submuscular-based reconstructions, and six reported complications on human ADM and submuscular techniques. A total of 2037 human ADM reconstructions and 12,847 submuscular reconstructions were included in the meta-analysis. A total of 877 human ADM and 3464 muscular reconstructions from six studies were used to calculate relative risks. Average follow-up time was 13.8 months in the human ADM group and 28.3 months in the submuscular cohort. There was an increased rate of total complications, 15.4% vs. 14.0%; seroma, 4.8% vs. 3.5%; infection, 5.3% vs. 4.7%; and flap necrosis, 6.9% vs. 4.9% in the human ADM cohort compared to the submuscular reconstruction cohort. The rate of hematomas was greater in the submuscular cohort 1.5% vs. 1% in the human ADM. Meta-analysis revealed an increase in the risk of total complications (relative risk, 2.05; 95 percent confidence interval, 1.55 to 2.70), seroma (relative risk, 2.73; 95 percent confidence interval, 1.67 to 4.46), infection (relative risk, 2.47; 95 percent confidence interval, 1.71 to 3.57), and reconstructive failure (relative risk, 2.80; 95 percent confidence interval, 1.76 to 4.45) in the human ADM cohort. There was a trend toward increased risk of hematoma (relative risk, 2.06; 95 percent confidence interval, 0.86 to 4.95) and flap necrosis (relative risk, 1.56; 95 percent confidence interval, 0.85 to 2.85) in the human acellular dermal matrix cohort, but the results were not statistically significant. The majority of pooled complication analyses showed significant heterogeneity. The meta-analysis suggested that the use of human ADM increases complication rates compared to submuscular approach.

Nguyen et al (2011) conducted a systematic review of the literature to assess the quality and quantity of evidence regarding the use of acellular dermal matrices (ADM) (e.g., AlloDerm) in prosthetic breast reconstruction. Eighteen articles in the form of case reports, prospective cohort studies and retrospective reviews met inclusion criteria. The authors analyzed the evidence for the following proposed advantages of ADM: decrease or eliminate the need for expanders to create a tissue pocket for an implant; reduction in postoperative pain; decrease in operative time; increased initial fill volumes; fewer expansions; precise control of over the lateral and inframammary fold; ability to use more of the mastectomy skin flaps; faster time to completion of reconstruction; improved lower pole expansion; decreased incidence of capsular contractures; decreased rate of revisions; improved aesthetic outcome of the breast. The authors concluded that there was insufficient data to support any of the above proposed benefits of ADM for breast reconstruction due to the paucity of actual data and conflicting data. Some studies did not formally quantify or report applicable data; evidence was inconsistent due to the variations in size of the matrix, type of mastectomy, size and viability of the mastectomy flaps and surgeon judgment; and data was conflicting due to variations in surgical technique, patients’ physical characteristics, and number of expansions used.
Professional Societies/Organizations:
The 2013 American Society of Plastic Surgeons (ASPS) Evidence-Based Clinical Practice Guideline: Breast Reconstruction with Expanders and Implants discusses recommendations for acellular dermal matrix (ADM) stating that "evidence on acellular dermal matrix (ADM) in post-mastectomy expander/implant breast reconstruction is varied and conflicting. Surgeons should evaluate each clinical case individually and objectively determine the use of ADM" Level III Evidence Recommendation Grade: C. Grading C is described as an option with qualifying evidence Levels II, III, or IV evidence, but findings inconsistent. Implications for practice: Clinicians should be flexible in their decision-making regarding appropriate practice, although they may set bounds on alternatives; patient preference should have a substantial influencing role.

Autologous Fat Transplant (Lipoinjection, Lipofilling, Lipomodeling)
Despite various techniques of reconstruction with autologous tissues or prostheses, autologous fat transplant (i.e., lipoinjection, lipofilling, lipomodeling) has been proposed to replace volume after breast reconstruction or to fill defects in the breast following breast conservation surgery. It has been proposed as a stand alone procedure or as an adjunct to other breast reconstruction techniques. The use of autologous fat transplant for primary breast augmentation is controversial due to a lack of clarity regarding its safety and efficacy. It has been proposed that injection of fat into a previous tumor site may create a new environment for cancer and adjacent cells. Additionally, fat transplant to the breast has been discouraged since it has been reported that calcifications secondary to fat necrosis may mimic breast cancer or that radiological changes post fat grafting would obscure and delay the diagnosis of subsequent breast cancer. In breast reconstruction, unlike elsewhere in the body, fat is implanted in a poorly vascularized and loose space which may attribute to the poor results.

Autologous fat transplant generally involves the transfer of fat from the abdomen or thighs into the breast under local anesthesia. The harvested fat is injected into the breast, usually in small parcels and thin strips, at different levels in the subcutis. It has been reported that a certain amount of fat resorption is expected in all cases of fat grafting. Clinically, volume loss has been reported between 40%-60% and usually within the first 4-6 months. Patients usually have 2-4 sessions of lipomodelling depending on their condition. The proposed benefit of the procedure is that it can restore volume to the breast without the morbidity associated with other reconstruction techniques. Although refinement in technique has aided reproducibility of favorable results, a standardized method of fat harvest, preparation, and injection is needed. Results are dependent on technique and surgeon expertise. It is recommended that breast reconstruction using autologous fat transfer be carried out by surgeons with specialist expertise and training in the procedure.

Literature Review: The available literature consists mostly of case reports, case series and expert opinion and describes autologous fat transplant for various breast indications, both cosmetic and reconstructive. Although the published evidence supporting the role of autologous fat transplant as a breast reconstruction procedure is not robust, limited data from several small studies indicate that autologous fat transplant raises no major safety concerns and may improve outcomes in a carefully selected subset of patients. Additionally, autologous fat transplant is widely used and accepted in clinical practice as a breast reconstruction procedure (Claro, et al., 2012; Parikh, et al., 2012; Saint-Cyr, et al., 2012; Rosing, et al., 2011; de Blacam, et al., 2011; Losken, et al., 2011; Petit, et al., 2011a; Petit, et al., 2011b; Illouz, et al., 2009; Hyakusoku, et al., 2009; Kanchwala, et al., 2009; American Society of Plastic Surgeons (ASPS), 2009; Chan, et al., 2008; American Society for Dermatologic Surgery (ASDS); 2008; Coleman, et al., 2007; Spear, et al., 2005). Research is ongoing to distinguish benign from malignant lesions after fat grafting (Parikh, et al., 2012).

Systematic Review and Meta-Analysis: In a systematic review of the literature Saint-Cyr et al. (2012) reported that autologous fat transplantation to the breast is a safe option for patients seeking reconstructive surgery, but further studies are needed to clearly demonstrate the specific risks to patients. Due to the heterogeneity of the studies, a formal meta-analysis could not be done, and thus the results are primarily descriptive. Out of 19 chosen studies, 11 had patients receiving autologous fat transplantation as an adjunct to breast reconstruction, while five studies enrolled patients receiving the procedure for strictly cosmetic purposes. In patients receiving fat grafting to the breast, infection, liponecrotic cysts, fat necrosis and calcifications, and even pneumothoraces have been reported. Presently, these complications are not thought to interfere with future breast cancer detection. The authors reported that although there are many recent case studies and retrospective reports on autologous fat grafting, large subject prospective cohort studies performing both reconstructive and cosmetic surgeries with well-defined outcome and follow-up measures would be a beneficial addition to the current literature. With the advent of innovative imaging technology, more data may be obtained that contain volumetric...
analyses of patients before and after fat transfer, as the question of the amount of adipose resorption and long-term stability of the grafts remain to be elucidated. The authors reported that further studies confirming the findings discussed in this systematic literature review and expanding the current role of autologous fat transfer to the breast are needed to determine whether or not this adjunct to breast augmentation is an effective and safe procedure with reproducible results.

Claro et al., 2012 reported on the indications and safety of autologous fat transfer, by means of a systematic review of clinical complications, radiographic changes and incidence of breast cancer (primary or recurrent) in women treated with fat grafting to the breast. The review included 60 articles with 4601 patients. No randomized controlled trials were collected in the review. Thirty studies used fat grafting for augmentation and 41 for reconstructive procedures. The incidence of clinical complications, identified in 21 studies, was 3.9% (117 of 3015); the majority were induration and/or palpable nodularity. Radiographic abnormalities occurred in 332 (13.0%) of 2560 women (17 studies); more than half were consistent with cysts. Local recurrence of breast cancer (14 of 616, 2.3%) was evaluated in three studies, of which only one was prospective. The authors reported that “in this review the rate of breast cancer recurrence in women who had fat grafting to the breast was similar to published rates for patients undergoing mastectomy who did not receive fat grafting. At present there is no evidence that fat grafting increases the risk of breast cancer but confirmation of oncological safety awaits the results of controlled trials”.

Rosing et al. (2011) conducted a systematic review of the literature, comparing technique, clinical outcome, radiologic impact, and complications in all available data. Seven articles (four case series, two retrospective reviews, and one case report) focused on technique and outcome. Five articles (two case series and three case reports) focused on the radiologic impact. Five articles (two case series, two case reports, and one retrospective review) reported on specific complications. No randomized controlled trials were collected in the review. The lower abdomen or thigh was used as the donor site by all 11 reporting authors. It is unclear whether manual or liposuction harvesting is superior. Graft processing and its impact on graft take and subsequent clinical outcome are inconsistent. All the case series in the review reported varying levels of patient satisfaction with the procedure correlated with the lack of complications and some degree of lasting improvement in breast size and shape. A review of case reports showed isolated complications of liponecrotic cyst formation, infection, or sepsis or an unsatisfactory result. The authors reported that is reasonable to assume that if autologous fat grafting and implant-based breast augmentation were equal on all fronts, including safety, reproducibility of result, risk, time of surgery, patients would choose fat grafting. However, the two methods currently are not equal. Fat grafting for breast augmentation requires more than one procedure to achieve adequate size and contour. Lack of procedural standardization yields less predictable results and different complications than traditional implant-based augmentation. The authors reported that further strong evidence-based studies are necessary to confirm the findings discussed in this review and to expand the role of autologous fat grafting for primary breast augmentation without concerns for its safety and effectiveness.

**Professional Societies/Organizations:** The 2012 Post-Mastectomy Fat Graft/Fat Transfer American Society of Plastic Surgeons (ASPS) Guiding Principles updates and supplements the 2009 Fat Transfer/Fat Graft and Fat Injection ASPS Guiding Principles. The authors state that, "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. A grade B recommendation encourages clinicians to employ the available information while remaining cognizant of newer, evidence-based findings. The existing evidence suggests autologous fat grafting as an effective option in breast reconstruction following mastectomy while demonstrating moderate to significant aesthetic improvement. In addition, the available evidence also cites autologous fat grafting as a useful modality for alleviating post mastectomy pain syndrome. Furthermore, the evidence suggests autologous fat grafting as a viable option for improving the quality of irradiated skin present in the setting of breast reconstruction" (ASPS, 2012).

The 2008 American Society for Dermatologic Surgery (ASDS) guidelines of care on injectable fillers states that, “One significant concern is the safety of fat transfer into the female breast. Calcifications and nodularity may develop and require the patient to undergo numerous tests and repeated evaluations to rule out an underlying malignancy” (Alam, et al., 2008).

**Use Outside the US:** In 2012 The National Institute of Excellence (NICE) (United Kingdom) published an interventional procedure guidance and overview of breast reconstruction using lipomodelling after breast cancer.
treatment. The guidance states that the “current evidence on the efficacy of breast reconstruction using lipomodelling after breast cancer treatment is adequate and the evidence raises no major safety concerns. Therefore this procedure may be used provided that normal arrangements are in place for clinical governance, consent and audit. There is a theoretical concern about any possible influence of the procedure on recurrence of breast cancer in the long term, although there is no evidence of this in published reports. NICE therefore encourages long-term data collection on this procedure. Patient selection should be carried out by a breast cancer multidisciplinary team. Breast reconstruction using lipomodelling after breast cancer treatment should only be carried out by surgeons with specialist expertise and training in the procedure” (NICE, 2012).

The Australian Safety and Efficacy Register of New Interventions Procedures –Surgical (ASERNIP-S) published a systematic review on autologous fat transfer for cosmetic and reconstructive breast augmentation. The authors concluded that "the evidence base in this review is rated as poor, limited by the quality of the available evidence. Specific limitations of the evidence include absence of studies comparing autologous fat transfer to the nominated comparator procedures, as well as a lack of standardized reporting of outcomes. Autologous fat transfer for cosmetic and reconstructive breast augmentation is considered to be at least as safe as the nominated comparator procedures. It is important to note that this rating is based on indirect comparisons that have been made using overall complication rates. Important safety data examining the effect of microcalcifications following autologous fat transfer on subsequent breast cancer detection were not reported in the studies included in this review; therefore, safety in regards to this outcome cannot be determined. The efficacy of autologous fat transfer cannot be determined from the literature included in this review. Efficacy outcomes reported in the included autologous fat transfer studies varied from those reported for the nominated comparator procedures; therefore, it was not possible to compare efficacy. However, the inability of autologous fat transfer to achieve a volume increase comparable to that of prostheses or autologous tissue augmentation suggests that it is less efficacious than these comparator procedures. There is a need for controlled trials (ideally randomized), assessing the effects of microcalcifications following autologous fat transfer on immediate and long-term breast cancer detection, to be conducted. Studies to determine the maximal breast volume increase reliably achieved by autologous fat transfer would also be useful in order to define the patient population who would benefit most from the procedure, as well as which breast indications should be treated using autologous fat transfer” (Leopardi, et al., 2010).

**Autologous Fat Transplant with the use of Adipose-Derived Stem Cells**

Research has indicated that subcutaneous fat contains many stem and regenerative cells including cells important in tissue survival and vascularization. It is proposed that autologous adipose-derived regenerative cells (ADRCs) may increase graft survival. With the growing use of autologous fat grafting, published preclinical and clinical data describing cell enriched adipose tissue transplants in breast defect repairs and breast augmentation are increasing. After adipose harvesting using syringe liposuction, the tissue is processed with a system such as the Celution 800 System®, (Cytori Therapeutics, Inc., San Diego, CA) which washes the graft and isolates ADRCs (Kamakura, et al., 2011).

**Literature Review:** The available literature is limited and consists mostly of case reports and case series, both cosmetic and reconstructive. Optimal patient selection criteria have not been established through well-designed comparative clinical trials with long-term outcomes data (Kamakura, et al., 2011; Yoshimura, et al., 2008).

Pérez-Cano et al. (2012) conducted a single-arm, prospective, multicenter clinical trial of 71 women who underwent breast conserving surgery for breast cancer and autologous adipose-derived regenerative cell (ADRC)-enriched fat grafting for reconstruction of defects = 150 mL (the RESTORE-2 trial). Endpoints included patient and investigator satisfaction with functional and cosmetic results and improvement in overall breast deformity at 12 months post-procedure. Females presenting with partial mastectomy defects and without breast prosthesis were eligible. The RESTORE-2 protocol allowed for up to two treatment sessions and 24 patients elected to undergo a second procedure following the six-month follow-up visit. Of the 67 patients treated, 50 reported satisfaction with treatment results through 12 months. Sixty-one patients underwent radiation therapy as part of their treatment; two patients did not receive radiation and the status of radiation treatment was not known for the other four patients. Using the same metric, investigators reported satisfaction with 57 out of 67 patients. There were no serious adverse events associated with the ADRC-enriched fat graft injection procedure. There were no reported local cancer recurrences. The investigators reported improvement from baseline through 12 months in the degree of retraction or atrophy in 29 out of 67 patients, while 34 patients had no change and four patients reported worse symptoms. Post-radiation fibrosis at 12 months was reported as improved in 29 patients, while 35 patients had no change and three patients had worse symptoms. Management
of atrophy was reported as improved in 17 patients, with 48 patients having no change and two patients reporting worse symptoms. The authors reported that future comparative studies are needed to determine the benefit of ADRC-enriched fat grafting as compared to traditional fat grafting in various clinical circumstances.

In a case series study, Kamakura et al. (2011), reported on the use of autologous adipose-derived stem cell (ADSC) enriched fat grafting for breast augmentation (n=20). After the adipose tissue was harvested by liposuction, it was processed in the Celution 800 System® to wash and isolate the adipose-derived regenerative cells and produce a fat graft enriched with the regenerative cells. The average number of cells per gram of harvested adipose tissue was $3.4 \times 10^5$, and the mean cell viability as measured with an automated cell counting system before graft delivery was 85%. Clinical outcomes measured included improvement in circumferential breast measurement from baseline state. There was improvement in circumferential breast measurement in all patients, and breast measurements were stable by three months after grafting. At nine months, the mean breast measurement had increased 3.3cm from preoperative measurements. Through nine months, overall patient satisfaction was 75%, and physician satisfaction 69%. The procedure was well-tolerated without any serious adverse events. Postoperative cyst formation was seen in two patients. This study was limited by small sample size, no control group and lack of long-term outcomes. The authors reported that to date, a randomized, controlled study has not been performed to compare the outcomes of cell-enriched fat transfer with those of traditional fat transfer.

**Professional Societies/Organizations:** In 2011, the American Society for Aesthetic Plastic Surgery and the American Society of Plastic Surgeons Task Force published a joint statement addressing stem cells and fat grafting. The Task Force recommendations state that, "Terms such as "stem cell therapy" or "stem cell procedure" should be reserved to describe those treatments or techniques where the collection, concentration, manipulation, and therapeutic action of the stem cells is the primary goal, rather than a passive result, of the treatment. For example, standard fat grafting procedures which do transfer some stem cells naturally present within the tissue should be described as a fat grafting procedure, not a stem cell procedure. The marketing and promotion of stem cell procedures in aesthetic surgery is not adequately supported by clinical evidence at this time" (ASPS, 2011).

**Suction-Assisted Liposuction**
Suction-assisted liposuction of the trunk or extremity area is a procedure in which excess fat deposits are removed using a liposuction cannula with the goal of recontouring the body, thereby improving appearance. This procedure may be performed alone or as one component of the flap breast reconstruction procedure. Suction-assisted liposuction, when performed alone and not as part of a medically necessary flap breast reconstruction procedure is considered cosmetic in nature. When the procedure is performed as part of a medically necessary flap breast reconstruction procedure, suction-assisted liposuction of the trunk or extremity area is considered incidental to the primary procedure.

**Vascularized Lymph Node Transfers (VLNTx) for Lymphedema**
Lymphedema is the accumulation of protein-rich interstitial fluid within the skin and subcutaneous tissue. Lymphedema is most commonly seen in breast cancer patients following axillary dissection (including sentinel lymph node dissection), radiation, or tumor recurrence. There is no cure for lymphedema. Manual therapies are the standard of care for lymphedema. Operative intervention has traditionally been recommended if medical therapy is ineffective in controlling lymphedema or preventing complications. Surgery is recommended for impaired extremity function secondary to gross extremity size and weight, severe skin changes, and recurrent lymphangitis (more than three episodes per year). Physiologic procedures attempt to re-establish lymphatic drainage, whereas excisional procedures debulk the limb, removing both fibrosclerotic and normal, lymph-producing tissue and fat. Physiologic procedures include lymphangioplasty, pedicle flap procedures (omentum transposition, enteromesenteric bridge), and microsurgical anastomosis (lymph nodal-venous, lymphaticovenous (Charles procedure), buried dermal flap (Thompson procedure), staged subcutaneous excision beneath flaps (modified Homans’ procedure) and suction-assisted lipectomy. Surgeries are not commonly performed because of limited success rates and/or high rates of recurrence or complications (Saanisto, et al., 2012; Stubblefield, 2011).

An emerging treatment that has been proposed for the treatment of symptomatic lymphedema in postmastectomy patients is vascularized lymph node transfer (VLNTx). This is a microsurgical procedure in which normal lymph nodes and their associated adipose tissues are transferred to a region of the body with
symptomatic lymphedema. The goal is to decrease limb size, alleviate subjective symptoms and potentially reduce daily compression requirements and slow progression of the disease.

Raju et al. (2014) completed a review of the literature for VLNTx with updates and comparisons on current application, techniques, results, studies and possible future implications. The authors concluded that “Although the results with the use of VLNT for treatment of lymphedema have been largely positive, further exploration into standardized protocols for diagnosis, treatment optimization, and patient outcomes assessment is needed”.

**Literature Review:** No randomized controlled trials or systematic reviews are available in the peer-reviewed scientific literature for VLNTx in breast reconstruction. The available literature is comprised of small retrospective case series. Optimal patient selection criteria have not been established through well-designed comparative clinical trials with long-term outcomes data.

In a case series study, Saaristo et al. (2012) describe a modified breast reconstruction flap containing lymph nodes from the groin area to reconstruct both the missing breast and the lymphatic network anatomy in the operated axilla. Breast reconstruction was completed in 87 patients. For all patients with lymphedema symptoms (n=9), a modified lower abdominal reconstruction flap containing lymph nodes and lymphatic vessels surrounding the superficial circumflex vessel pedicle was performed. Operation time, donor site morbidity, and postoperative recovery between the two groups (lymphedema breast reconstruction and breast reconstruction) were compared. The effect on the postoperative lymphatic vessel function was examined. The average operation time was 426 minutes in the lymphedema breast reconstruction group and 391 minutes in the breast reconstruction group. The postoperative abdominal seroma formation was increased in patients with lymphedema. Postoperative lymphoscintigraphy demonstrated at least some improvement in lymphatic vessel function in five of six patients with lymphedema. The upper limb perimeter decreased in seven of nine patients. Physiotherapy and compression was no longer needed in three of nine patients. No edema problems were detected in the lymph node donor area. None of the operated patients with lymphedema reported pain, hernias, or edema symptoms in the donor area (low abdominal wall or lower limb). A total of three of nine patients with lymphedema have discontinued the use of compression and physiotherapy eight months to two years after the breast reconstruction and lymph node transfer. The authors reported that the lymph node transfer is still considered an experimental surgery and this study is the third report on the efficacy of the lymph node transfer in the treatment of lymphedema.

In a case series study, Gharb et al. (2011) reported the outcome of vascularized lymph node transfer with hilar perforators compared with the conventional technique. A total of 21 patients affected by early stage II upper limb lymphedema were included in the study. A total of 11 patients received a free groin flap containing lymph nodes, and 10 patients received vascularized inguinal lymph nodes with hilar perforators. Mean follow-up was 46 and 40 months, respectively. Complications, secondary procedures, circumference of the limb, and subjective symptomatology were registered. There was no statistical difference in the limb circumference measurements between the two groups preoperatively. Differences between preoperative and postoperative measurements were statistically significant only in the perforator-based group at the levels below elbow, wrist, and midpalm (p=0.004, 0.002, 0.007, respectively). All the other differences were not statistically significant. The number of secondary procedures was significantly higher in the standard group (p=0.03). There were two cases of partial flap loss and donor site lymphorrhea in the standard group. In both the groups, visual analog scale scores improved after the operation.

In a case series study, Lin et al. (2009) evaluated the outcome of vascularized groin lymph node transfer using the wrist as a recipient site in patients with post-mastectomy upper extremity lymphedema. A total of 13 consecutive patients underwent vascularized groin lymph node transfer for post-mastectomy upper extremity lymphedema. A vascularized groin lymph node nourished by the superficial circumflex iliac vessels was harvested and transferred to the dorsal wrist of the lymphedematous limb. The superficial radial artery and the cephalic vein were used as the recipient vessels. Outcome was assessed by upper limb girth, incidence of cellulitis, and lymphoscintigraphy. All flaps survived, and one flap required re-exploration, with successful salvage. No donor-site morbidity was encountered. At a mean follow-up of 56.31 ± 27.12 months, the mean reduction rate (50.55±19.26%) of the lymphedematous limb was statistically significant between the preoperative and postoperative groups (p<0.01). The incidence of cellulitis was decreased in 11 patients. Postoperative lymphoscintigraphy indicated improved lymph drainage of the affected arm, revealing decreased lymph stasis and rapid lymphatic clearance.
In an initial report of this surgery which was performed in France, Becker et al. (2006) reported on retrospective data collected on 24 patients treated with inguinal lymph node transfers to the axillary region. Patients with lymphedema for more than five years underwent lymph node transplantation. In this case series, upper limb perimeter returned to normal in 10 cases, decreased in 12 cases, and remained unchanged in two cases. The 10 cases in which upper limb perimeter returned to normal were described as being “cured.” The authors reported that “no current gold standard for evaluation of lymphedema exists; hence, evaluating results of treatments remains difficult and appears controversial”. Long-term results were evaluated according to skin elasticity and existence of infectious disease, decrease or disappearance of the lymphedema assessed by measurements, effects observed on isotopic lymphangiography, and ability to stop or to discontinue physiotherapy after six months. Long-term results were also evaluated according to the duration of the lymphedema before surgery and occurrence of downstaging after surgery. Physiotherapy was discontinued after six months in 14 patients and after 12 months in one patient. In the nine other patients, physiotherapy remained necessary and was performed once weekly in seven patients. Physiotherapy was thus discontinued in 15 patients (62.5%). No results were reported after 12 months.

External Breast Prostheses and Mastectomy Bras Following Mastectomy or Lumpectomy

Breast reconstruction has become an integral component of the treatment of patients with breast cancer who have undergone a mastectomy or lumpectomy. External breast prostheses are available for women who have uneven- or unequal-sized breasts and who decide not to, or are waiting to, undergo surgical breast reconstruction. They may choose to wear a breast prosthesis and mastectomy bra, or elect to wear a mastectomy garment that has the prosthesis already inserted in it.

Prostheses can attach to the skin with a fabric backing and adhesive or may be worn unattached with a mastectomy bra. Prefabricated prostheses come in various shapes, sizes and skin tones. Custom-fabricated prostheses are custom-designed and special ordered for the individual. These are usually patterned after a mold that is taken of the breast and chest wall prior to surgery. In general, prefabricated prostheses can adequately meet the external prosthetic needs of most individuals. Therefore, custom-fabricated prosthetic garments would not generally be considered medically necessary. Reusable external nipple prostheses are available to cover flat or missing nipples.

U.S. Food and Drug Administration (FDA)

The FDA classifies external aesthetic restoration prostheses as Class I devices that are exempt from premarket notification (FDA, 2013).

Federal Mandate

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

Under this mandate, benefits for breast reconstruction services following mastectomy or lumpectomy must be provided to both men and women; a diagnosis of breast cancer cannot be required; and timing of breast reconstruction services is not a factor in coverage. In addition, the mandate prohibits any limitations to the number of prostheses or the length of time from the date of the mastectomy.

Summary

Restoration of a normal breast form through breast reconstruction is performed for individuals undergoing mastectomy or lumpectomy. Selection of the reconstructive technique is based on anatomic patient factors and is an individualized decision between the individual and their physician. Current breast reconstruction procedures that are safe and effective and are well-established standards of care include: tissue/muscle reconstruction procedures (e.g., flaps), implantation of tissue expander, implantation of U.S. Food and Drug Administration (FDA)-approved internal breast prosthesis, areolar and nipple reconstruction, and areolar and nipple tattooing. Suction-assisted lipectomy of the trunk or extremity, when performed purely for cosmesis, is considered not medically necessary.
Although the published evidence supporting the role of AlloDerm, AlloMax, FlexHD, Neoform Dermis and SurgiMend in breast reconstruction procedures is not robust, limited data from several small studies, as well as acceptance and limited use of these products by certain specialists in the practicing community indicate that these products may improve outcomes in a carefully selected subset of breast reconstruction patients. Based on the current peer-reviewed literature, the role of these products for any other indication has not been established.

Due to the limited number of studies with small heterogeneous patient populations, variable outcomes and study designs, and a lack of comparison to established treatment options, evidence in the published peer-reviewed scientific literature does not support the safety and efficacy of other skin substitutes for breast reconstruction procedures.

Although the published evidence supporting the role of autologous fat transplant (i.e., lipoinjection, lipofilling, lipomodeling) as a breast reconstruction procedure is not robust, limited data from several small studies indicate that autologous fat transplant raises no major safety concerns and may improve outcomes in a carefully selected subset of patients. Additionally, autologous fat transplant is widely used and accepted in clinical practice as a breast reconstruction procedure.

The role of autologous fat transplant with the use of adipose-derived stem cells, vascularized lymph node transfer (VLNTx) and xenograft cartilage grafting in breast reconstruction has not been established. Optimal patient selection criteria have not been established through well-designed comparative clinical trials with long-term outcomes data.

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

### Appendix A

**Product/CPT/HCPCS Code Crosswalk**

<table>
<thead>
<tr>
<th>Product</th>
<th>CPT® Code</th>
<th>HCPCS Code</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Covered When Medically Necessary</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>AlloDerm®</td>
<td>15271-15274, 15777</td>
<td>Q4116</td>
</tr>
<tr>
<td>AlloMax™</td>
<td>15271-15274, 15777</td>
<td>C1781, C5271-C5274, Q4100</td>
</tr>
<tr>
<td>FlexHD®</td>
<td>15271-15274, 15777</td>
<td>C5271-C5274, Q4128</td>
</tr>
<tr>
<td>NeoForm Dermis</td>
<td>15271-15274, 15777</td>
<td>C1781, C5271-C5274, Q4100</td>
</tr>
<tr>
<td>SurgiMend® Collagen Matrix</td>
<td>15271-15274, 15777</td>
<td>C5271-C5274, C9358;C9360</td>
</tr>
<tr>
<td><strong>Experimental, Investigational or Unproven and Not Covered</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Biodesign® Nipple Reconstruction Cylinder</td>
<td>19350</td>
<td></td>
</tr>
<tr>
<td>Permacol®</td>
<td>15271-15278, 15777</td>
<td>C5271-C5278, Q4122</td>
</tr>
<tr>
<td>PermaMatrix Acellular Dermis</td>
<td>15271-15278, 15777</td>
<td>C1781, Q4100</td>
</tr>
<tr>
<td>Repriza®</td>
<td>15271-15278</td>
<td>Q4134</td>
</tr>
<tr>
<td>Repriza®</td>
<td>15271-15278</td>
<td>Q4110;C9364</td>
</tr>
<tr>
<td>Strattice®</td>
<td>15271-15278, 15777</td>
<td>C5271-C5274, Q4143</td>
</tr>
</tbody>
</table>

**Coding/Billing Information**

**Note:**
1) This list of codes may not be all-inclusive.
2) Deleted codes and codes which are not effective at the time the service is rendered may not be eligible
for reimbursement.

**Breast Reconstruction**

Covered when medically necessary:

<table>
<thead>
<tr>
<th>CPT®* Codes</th>
<th>Description</th>
</tr>
</thead>
<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>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>15273</td>
<td>Application of skin substitute graft to trunk, arms, legs, total wound surface area greater than or equal to 100 sq cm; first 100 sq cm wound surface area, or 1% of body area of infants and children</td>
</tr>
<tr>
<td>15274</td>
<td>Application of skin substitute graft to trunk, arms, legs, total wound surface area greater than or equal to 100 sq cm; each additional 100 sq cm wound surface area, or part thereof, or each additional 1% of body area of infants and children, or part thereof (List separately in addition to code for primary procedure)</td>
</tr>
<tr>
<td>15777</td>
<td>Implantation of biologic implant (eg, acellular dermal matrix) for soft tissue reinforcement (eg, 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>19316</td>
<td>Mastopexy</td>
</tr>
<tr>
<td>19318</td>
<td>Reduction mammoplasty</td>
</tr>
<tr>
<td>19324</td>
<td>Mammoplasty, augmentation; without prosthetic implant</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>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>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</td>
</tr>
</tbody>
</table>
(TRAM), double pedicle, including closure of donor site

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<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>
</tbody>
</table>

*Note: Not covered when used to report Cook Biodesign® Nipple Reconstruction Cylinder.*

<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 square centimeters</td>
</tr>
<tr>
<td>C9360</td>
<td>Dermal substitute, native, non-denatured collagen, neonatal bovine origin (Surgimend collagen matrix), per 0.5 square centimeters</td>
</tr>
<tr>
<td>L8600</td>
<td>Implantable breast prosthesis, silicone or equal</td>
</tr>
<tr>
<td>Q4116</td>
<td>Alloderm, per square centimeter</td>
</tr>
<tr>
<td>Q4128</td>
<td>Flex hd, allopatch hd, or matrix hd, per square centimeter</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>
</tbody>
</table>

Covered as medically necessary when used to report the application of AlloMax™, FlexHD® Acellular Hydrated Dermis, Neoform™ Dermis, or SurgiMend® used in association with a covered medically necessary breast reconstruction procedure:

<table>
<thead>
<tr>
<th>HCPCS Codes</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>C5271</td>
<td>Application of low cost 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>C5272</td>
<td>Application of low cost 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>C5273</td>
<td>Application of low cost skin substitute graft to trunk, arms, legs, total wound surface area greater than or equal to 100 sq cm; first 100 sq cm wound surface area, or 1% of body area of infants and children</td>
</tr>
<tr>
<td>C5274</td>
<td>Application of low cost skin substitute graft to trunk, arms, legs, total wound surface area greater than or equal to 100 sq cm; each additional 100 sq cm wound surface area, or part thereof, or each additional 1% of body area of infants and children, or part thereof (list separately in addition to code for primary procedure)</td>
</tr>
</tbody>
</table>

Covered as medically necessary when used to report AlloMax™ or NeoForm™ Dermis used in association with a covered medically necessary breast reconstruction procedure:

<table>
<thead>
<tr>
<th>CPT® Codes</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Q4100</td>
<td>Skin substitute, not otherwise specified</td>
</tr>
<tr>
<td>C1781</td>
<td>Mesh (implantable)</td>
</tr>
</tbody>
</table>
Covered when used to report autologous fat transplant (i.e., 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>19499</td>
<td>Unlisted procedure, breast</td>
</tr>
</tbody>
</table>

Experimental/Investigational/Unproven/Not Covered when used to report a product as not covered as listed in the policy statement above:

<table>
<thead>
<tr>
<th>CPT® Codes</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>11950</td>
<td>Subcutaneous injection of filling material (eg, collagen); 1 cc or less</td>
</tr>
<tr>
<td>11951</td>
<td>Subcutaneous injection of filling material (eg, collagen); 1.1 to 5.0 cc</td>
</tr>
<tr>
<td>11952</td>
<td>Subcutaneous injection of filling material (eg, collagen); 5.1 to 10.0 cc</td>
</tr>
<tr>
<td>11954</td>
<td>Subcutaneous injection of filling material (eg, collagen); over 10.0 cc</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>15273</td>
<td>Application of skin substitute graft to trunk, arms, legs, total wound surface area greater than or equal to 100 sq cm; first 100 sq cm wound surface area, or 1% of body area of infants and children</td>
</tr>
<tr>
<td>15274</td>
<td>Application of skin substitute graft to trunk, arms, legs, total wound surface area greater than or equal to 100 sq cm; each additional 100 sq cm wound surface area, or part thereof, or each additional 1% of body area of infants and children, or part thereof (List separately in addition to code for primary procedure)</td>
</tr>
<tr>
<td>15777</td>
<td>Implantation of biologic implant (eg, acellular dermal matrix) for soft tissue reinforcement (ie, breast, trunk) (List separately in addition to code for primary procedure)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>HCPCS Codes</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>C9364</td>
<td>Porcine implant (Permacol), per square cm</td>
</tr>
<tr>
<td>Q2026</td>
<td>Injection, radiess®, 0.1 ml</td>
</tr>
<tr>
<td>Q4122</td>
<td>Dermicel, per square centimeter</td>
</tr>
<tr>
<td>Q4134</td>
<td>Hmatrix, per square centimeter</td>
</tr>
<tr>
<td>Q4130</td>
<td>Strattice™ tm, per square centimeter</td>
</tr>
<tr>
<td>Q4143</td>
<td>Repriza, per square centimeter</td>
</tr>
</tbody>
</table>

Experimental/Investigational/Unproven/Not Covered when used to report DermaMatrix:

<table>
<thead>
<tr>
<th>HCPCS Codes</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Q4100</td>
<td>Skin substitute, not otherwise specified</td>
</tr>
</tbody>
</table>

Experimental/Investigational/Unproven/Not Covered when used to report DermaMatrix or Strattice™:

<table>
<thead>
<tr>
<th>HCPCS Codes</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>C1781</td>
<td>Mesh (implantable)</td>
</tr>
</tbody>
</table>

Experimental/Investigational/Unproven/Not Covered when used to report the application of
DermaMatrix or Repriza®:

<table>
<thead>
<tr>
<th>HCPCS Codes</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>C5271</td>
<td>Application of low cost 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>C5272</td>
<td>Application of low cost 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>C5273</td>
<td>Application of low cost skin substitute graft to trunk, arms, legs, total wound surface area greater than or equal to 100 sq cm; first 100 sq cm wound surface area, or 1% of body area of infants and children</td>
</tr>
<tr>
<td>C5274</td>
<td>Application of low cost skin substitute graft to trunk, arms, legs, total wound surface area greater than or equal to 100 sq cm; each additional 100 sq cm wound surface area, or part thereof, or each additional 1% of body area of infants and children, or part thereof (list separately in addition to code for primary procedure)</td>
</tr>
</tbody>
</table>

Experimental/Investigational/Unproven/Not Covered when used to report autologous fat transplant with 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>19499</td>
<td>Unlisted procedure, breast</td>
</tr>
</tbody>
</table>

Experimental/Investigational/Unproven/ Not Covered when used to report vascularized lymph node transfer (VLNTx):

<table>
<thead>
<tr>
<th>CPT® Codes</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>38999</td>
<td>Unlisted procedure, hemic or lymphatic system</td>
</tr>
</tbody>
</table>

Cosmetic in nature/Not Medically Necessary/Not Covered when used to report correction of surgically-induced donor site asymmetry that results from flap breast reconstruction procedures:

<table>
<thead>
<tr>
<th>CPT® Codes</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>15877</td>
<td>Suction assisted lipectomy; trunk</td>
</tr>
<tr>
<td>15879</td>
<td>Suction assisted lipectomy; lower extremity</td>
</tr>
</tbody>
</table>

External Breast Prostheses and Mastectomy Bras Following Mastectomy or Lumpectomy

Covered when medically necessary:

<table>
<thead>
<tr>
<th>HCPCS Codes</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>L8000</td>
<td>Breast prosthesis; mastectomy bra</td>
</tr>
<tr>
<td>L8001</td>
<td>Breast prosthesis, mastectomy bra, with integrated breast prosthesis form, unilateral</td>
</tr>
<tr>
<td>L8002</td>
<td>Breast prosthesis, mastectomy bra, with integrated breast prosthesis form, bilateral</td>
</tr>
<tr>
<td>L8015</td>
<td>External breast prosthesis garment, with mastectomy form, post mastectomy</td>
</tr>
<tr>
<td>L8020</td>
<td>Breast prosthesis; mastectomy form</td>
</tr>
<tr>
<td>L8030</td>
<td>Breast prosthesis; silicone or equal, without integral adhesive</td>
</tr>
<tr>
<td>L8031</td>
<td>Breast prosthesis; silicone or equal, with integral adhesive</td>
</tr>
<tr>
<td>L8032</td>
<td>Nipple prosthesis, reusable, any type, each</td>
</tr>
</tbody>
</table>
L8035  Custom breast prosthesis, post mastectomy, molded to patient model
L8039  Breast prosthesis, not otherwise specified

References


126. U.S. Food and Drug Administration (FDA). Center for Devices and Radiological Health. Sientra
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