



CIGNA MEDICAL COVERAGE POLICY

The following Coverage Policy applies to all plans administered by CIGNA Companies including plans administered by Great-West Healthcare, which is now a part of CIGNA.

**Subject Breast Reconstruction
Following Mastectomy or
Lumpectomy**

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Coverage Policy Number0178**

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INSTRUCTIONS FOR USE

Coverage Policies are intended to provide guidance in interpreting certain **standard** CIGNA HealthCare benefit plans as well as benefit plans formerly administered by Great-West Healthcare. Please note, the terms of a participant's particular benefit plan document [Group Service Agreement (GSA), 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 participant'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 participant's benefit plan document **always supercedes** 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 group 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. Proprietary information of CIGNA. Copyright ©2010 CIGNA

Coverage Policy

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

***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:**
 - 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
 - capsulotomy
 - capsulectomy
 - implantation of tissue expander
 - implantation of U.S. Food and Drug Administration (FDA)-approved internal breast prosthesis
 - areolar and nipple reconstruction
 - areolar and nipple tattooing
 - reconstructive surgical revisions
 - breast implant removal and subsequent reimplantation
- **breast reconstruction procedures performed on the nondiseased/unaffected/contralateral breast, in order to produce a symmetrical appearance, including:**
 - breast reduction by mammoplasty or mastopexy
 - augmentation mammoplasty
 - augmentation with implantation of FDA-approved internal breast prosthesis when the unaffected breast is smaller than the smallest available internal prosthesis
 - areolar and nipple reconstruction
 - areolar and nipple tattooing
 - reconstructive surgery revisions to produce a symmetrical appearance
 - breast implant removal and subsequent reimplantation when performed to produce a symmetrical appearance
 - capsulotomy
 - capsulectomy

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

- AlloDerm®
- NeoForm™ Dermis

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):

- DermaMatrix Acellular Dermis
- FlexHD® Acellular Dermis
- Permacol®
- Radiesse®
- Stratattice™ Reconstructive Tissue Matrix

CIGNA does not cover autologous fat transplant (i.e., lipoinjection) used in association with breast reconstruction because such treatment is considered experimental, investigational or unproven for this indication.

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

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).

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.

The breast can be reconstructed in conjunction with mastectomy using breast implants, autologous tissue (i.e., flaps) or a combination of the two (e.g., latissimus/implant composite reconstructions). Reconstruction selection is based on an assessment of cancer treatment, patient body habitus, smoking history, co-morbidities and patient concerns (National Comprehensive Cancer Network [NCCN], 2010).

Prosthetic Reconstruction

Breast Implants: Breast implants can be inserted at the same time as the mastectomy 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. 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 (Wilhelmi and Phillips, 2008).

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 (Wilhelmi and Phillips, 2008).

U.S. Food and Drug Administration (FDA)

There are currently four breast implants approved by the FDA for marketing in the U.S. In May 2000, Mentor Corp., Santa Barbara, CA and Allergan Corp. (formerly Inamed) Irvine, CA, received premarket approval for saline-filled breast implants. These implants were approved for breast augmentation in women age 18 or older and for breast reconstruction in women of any age (FDA, 2009a).

In November 2006, Allergan and Mentor received premarket approval for their silicone gel-filled breast implants (i.e., Inamed[®] Silicone-Filled Breast Implants and Mentor MemoryGel[™] Silicone Gel-Filled Breast Implants). These implants were approved for breast augmentation in women age 22 or older and for breast reconstruction in women of any age. All breast implants other than these four approved devices are considered investigational devices, including the more cohesive (“gummy bear”) implants which are made of a firmer silicone gel filler to help maintain the shape of the implant. The implant is referred to as gummy bear due to the consistency of the implant. For a patient to receive an investigational breast implant in the U.S., they must enroll in a clinical study (FDA, 2009a).

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, 2009b).

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).

Allogeneic Tissue

Post-mastectomy breast reconstruction with the insertion of an implant is technically the simplest form of breast reconstruction. Unfortunately, numerous complications have been reported after reconstruction including, but not limited to, rippling, symmastia, implant malposition, bottoming out and implant exposure. Many of these problems are more apparent in thin individuals. An option for treatment of these conditions is acellular dermal allografts (i.e., AlloDerm[®], NeoForm[™] Dermis) (Zienowicz, et al., 2007; Baxter, 2003).

AlloDerm (HCPCS Q4100, Q4116 Current Procedural Terminology [CPT] 15330–15331): 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 supported by the studies in the peer-reviewed literature for use during postmastectomy breast reconstruction (Spear, et al., 2008; Bindingavele, 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).

Neoform Dermis (HCPCS Q4100, CPT 15330–15331): Neoform Dermis (Mentor Corp., Santa Barbara, CA) is a solvent-dehydrated, gamma-irradiated preserved human allograft dermis. According to the manufacturer's website, Neoform Dermis is used for tissue expansion in breast reconstructive procedures. Although evidence in the published, peer-reviewed scientific literature supporting the use of this product in breast reconstruction is limited, use of this product in a carefully selected subset of individuals has the potential to improve patient outcomes.

DermaMatrix Acellular Dermis (HCPCS Q4100, CPT 15330–15331): 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.

Becker et al. (2009) conducted a retrospective review to compare the outcomes of the use of DermaMatrix (n=25) to AlloDerm (n=25) in patients who underwent immediate expander-based breast reconstruction following unilateral (n=20) or bilateral mastectomy (n=10). The median follow-up for the AlloDerm group was 15 months and 13.5 months for the DermaMatrix group. The only significant difference in the operative and reconstructive course between the two groups was that the AlloDerm patients had drains in place 11 mean number of days compared to 13 mean number of days in the DermaMatrix group (p=0.02). The DermaMatrix group had one incidence of seroma and one infection/cellulites. There were no complications in the AlloDerm group.

FlexHD[®] Acellular Hydrated Dermis (HCPCS Q4100, CPT 15170, 15330–15331): FlexHD Acellular Hydrated Dermis is derived from donated human allograft skin. The tissue is prehydrated and has been proposed for post-mastectomy breast reconstruction. In alliance with Ethicon[™], Inc. the Musculoskeletal Transplant Foundation (Edison, NJ) processes the skin to remove the epidermal and dermal cells and preserve the remaining components and extracellular matrix of the dermis. The resulting allograft has been proposed as a framework to support cellular repopulation and vascularization at the surgical site. Evidence in the published, peer-reviewed scientific literature supporting the use of this product in breast reconstruction is lacking and its role is unclear.

Permacol[®] (HCPCS C9364):

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. 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).

Strattice[™] Reconstructive Tissue Matrix or LTM Surgical Mesh (HCPCS Q4100, CPT 15430–15431):

Strattice Reconstructive Tissue Matrix or LTM Surgical Mesh (LifeCell Corporation, Branchburg, NJ) is a xenographic tissue matrix derived from porcine dermis (LifeCell, 2010, FDA, 2007). According to the FDA 510(k) approval, LTM Surgical Mesh 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. Indications for use 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. The FDA 510K Summary lists Permacol as one of the predicate devices on which this approval was based (FDA, 2007). There is a lack of evidence in the peer-reviewed literature supporting the efficacy of Strattice in breast reconstructive procedures.

Radiesse[®]

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.

Autologous Tissue

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 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 (Wilhelmi and Phillips, 2008; 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).

Tissue Flap Procedures

Transverse Rectus Abdominus Myocutaneous (TRAM) Flap: The TRAM flap is the most commonly performed autologous reconstructive procedure. 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, 2009):

- 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) (Wilhelmi and Phillips, 2008; Zenn, 2009):

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 (Wilhelmi and Phillips, 2008).

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 (Wilhelmi and Phillips, 2008).

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 (Wilhelmi and Phillips, 2008).

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 gracilis 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 skin grafts, small flaps, and tattooing and/or transplantation of nipple-areolar tissue from the opposite breast. 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 (Diana, et al., 2009; Wilhelmi and Phillips, 2008).

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 (Wilhelmi and Phillips, 2008).

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).

Autologous Fat Transplant (Lipoinjection)

Autologous fat transplant (i.e., lipoinjection) has been proposed for use in for breast reconstruction procedures. Fat grafting 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. Optimal patient selection criteria have not been established through well-designed comparative clinical trials with long-term outcomes data (Hyakusoku, et al, 2009; Chan, et al., 2008).

In 2007, the American Society of Plastic Surgeons (ASPS) formed a task force to conduct an assessment regarding the safety and efficacy of autologous fat grafting, specifically to the breast. The Task Force clinical application conclusion states that “based on a review of the current literature and a lack of strong data, the task force cannot make specific recommendations for the clinical use of fat grafts. Although fat grafts may be considered for use in the breast and other sites, the specific techniques of graft harvesting, preparation, and injection are not standardized. The results, therefore, may vary depending on the surgeon’s technique and experience with the procedure. Although there are few data to provide evidence for long-term safety and efficacy of fat grafting, the reported complications suggest that there are associated risks. Regarding fat grafting to the breast, there are no reports suggesting an increased risk of malignancy associated with fat grafting. There is a potential risk of fat grafts interfering with breast physical examination or breast cancer detection; however, the limited data available suggest that fat grafts may not interfere with radiologic imaging in detecting breast cancer” (Gutowski, 2009; ASPS, 2009).

Suction-Assisted Lipectomy

Suction-assisted lipectomy 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 lipectomy, 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 lipectomy of the trunk or extremity area is considered incidental to the primary procedure.

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 acellular dermal allografts (i.e., AlloDerm[®], Neoform[™] Dermis) in breast reconstruction procedures are 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 indicates that these products may improve outcomes in a carefully selected subset of patients.

The role of autologous fat transplant (i.e., lipoinjection) 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. The use of lipoinjection and its effectiveness in breast reconstruction procedures requires further investigation. There is also insufficient evidence in the peer-reviewed literature to support the use of other products (e.g., Permacol[®], Radiesse[®], DermaMatrix Acellular Dermis, Stratattice[™] Reconstructive Tissue Matrix, FlexHD[®] Acellular Hydrated Dermis) in breast reconstruction.

Coding/Billing Information

Note: This list of codes may not be all-inclusive.

Covered when medically necessary:

CPT [®] * Codes	Description
11920	Tattooing, intradermal introduction of insoluble opaque pigments to correct color defects of skin, including micropigmentation; 6.0 sq cm or less
11921	Tattooing, intradermal introduction of insoluble opaque pigments to correct color

	defects of skin, including micropigmentation; 6.1 to 20.0 sq cm
11970	Replacement of tissue expander with permanent prosthesis
11971	Removal of tissue expander(s) without insertion of prosthesis
13100	Repair, complex, trunk; 1.1 cm to 2.5 cm
13101	Repair, complex, trunk; 2.6 cm to 7.5 cm
13102	Repair, complex, trunk; each additional 5 cm or less (List separately in addition to code for primary procedure)
15330 [†]	Acellular dermal allograft, trunk, arms, legs; first 100 sq cm or less, or 1% of body area of infants and children
15331 [†]	Acellular dermal allograft, trunk, arms, legs; each additional 100 sq cm, or each additional 1% of body area of infants and children, or part thereof (List separately in addition to code for primary procedure)
15430	Acellular xenograft implant; first 100 sq cm or less, or 1% of body area of infants and children
15431	Acellular xenograft implant; each additional 100 sq cm, or each additional 1% of body area of infants and children, or part thereof (List separately in addition to code for primary procedure)
19316	Mastopexy
19318	Reduction mammoplasty
19324	Mammoplasty, augmentation; without prosthetic implant
19325	Mammoplasty, augmentation; with prosthetic implant
19328	Removal of intact mammary implant
19330	Removal of mammary implant material
19340	Immediate insertion of breast prosthesis following mastopexy, mastectomy or in reconstruction
19342	Delayed insertion of breast prosthesis following mastopexy, mastectomy or in reconstruction
19350	Nipple/areola reconstruction
19357	Breast reconstruction, immediate or delayed, with tissue expander, including subsequent expansion
19361	Breast reconstruction with latissimus dorsi flap, without prosthetic implant
19364	Breast reconstruction with free flap
19366	Breast reconstruction with other technique
19367	Breast reconstruction with transverse rectus abdominis myocutaneous flap (TRAM), single pedicle, including closure of donor site
19368	Breast reconstruction with transverse rectus abdominis myocutaneous flap (TRAM), single pedicle, including closure of donor site; with microvascular anastomosis (supercharging)
19369	Breast reconstruction with transverse rectus abdominis myocutaneous flap (TRAM), double pedicle, including closure of donor site
19370	Open periprosthetic capsulotomy, breast
19371	Periprosthetic capsulectomy, breast
19380	Revision of reconstructed breast

[†]**Note:** Covered as medically necessary when used to report acellular dermal allografts used in association with a covered medically necessary breast reconstruction procedure when a specific category I or category III CPT code or a specific HCPCS code is not available.

HCPCS Codes	Description
C1789	Prosthesis, breast (implantable)
L8600	Implantable breast prosthesis, silicone or equal
Q4100 [†]	Skin substitute, not otherwise specified
Q4116	Skin substitute, alloderm, per square centimeter (Effective 07/01/2009)
S2066	Breast reconstruction with gluteal artery perforator (GAP) flap, including

	harvesting of the flap, microvascular transfer, closure of donor site and shaping the flap into a breast, unilateral
S2067	Breast reconstruction of a single breast with "stacked" deep inferior epigastric perforator (DIEP) flap(s) and/or gluteal artery perforator (GAP) flap(s), including harvesting of the flap(s), microvascular transfer, closure of donor site(s) and shaping the flap into a breast, unilateral
S2068	Breast reconstruction with deep inferior epigastric perforator (DIEP) flap or superficial inferior epigastric artery (SIEA) flap, including harvesting of the flap, microvascular transfer, closure of donor site and shaping the flap into a breast, unilateral

†**Note:** Covered as medically necessary when used to report acellular dermal allografts used in association with a covered medically necessary breast reconstruction procedure when a specific category I or category III CPT code or a specific HCPCS code is not available.

ICD-9-CM Diagnosis Codes	Description
174.0–174.9	Malignant neoplasm of female breast
175.0–175.9	Malignant neoplasm of male breast
198.81	Secondary malignant neoplasm of other specified sites; breast
232.5	Carcinoma in situ of skin of trunk, except scrotum
233.0	Carcinoma in situ of breast
996.52	Mechanical complication of other specified prosthetic device, implant, and graft; due to graft of other tissue, not elsewhere classified
996.54	Mechanical complication of other specified prosthetic device, implant, and graft; due to breast prosthesis
996.69	Infection and inflammatory reaction due to internal prosthetic device, implant, and graft; due to other internal prosthetic device, implant, and graft
996.79	Other complications of internal (biological) (synthetic) prosthetic device, implant, and graft; due to other internal prosthetic device, implant, and graft
V10.3	Personal history of malignant neoplasm; breast
V45.71	Acquired absence of breast
V50.41	Prophylactic organ removal: breast
V51	Aftercare involving plastic surgery
V52.4	Fitting and adjustment of breast prosthesis and implant
	Multiple/Varied

Experimental/Investigational/Unproven/Not Covered:

HCPCS Codes	Description
15877 [†]	Suction assisted lipectomy; trunk
15879 [†]	Suction assisted lipectomy; trunk; lower extremity
C9364	Porcine implant (Permacol), per square cm

†**Note:** Not covered when performed for correction of surgically-induced donor site asymmetry that results from flap breast reconstruction procedures.

*Current Procedural Terminology (CPT®) © 2010 American Medical Association: Chicago, IL.

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Policy History

Pre-Merger Organizations	Last Review Date	Policy Number	Title
CIGNA HealthCare	8/15/2008	0178	Breast Reconstruction Following Mastectomy or Lumpectomy
Great-West Healthcare	7/05/2005	95.233.07	Breast Surgery, Reconstruction after Mastectomy

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Connecticut General Life Insurance Company has acquired the business of Great-West Healthcare from Great-West Life & Annuity Insurance Company (GWLA). Certain products continue to be provided by GWLA (Life, Accident and Disability, and Excess Loss). GWLA is not licensed to do business in New York. In New York, these products are sold by GWLA's subsidiary, First Great-West Life & Annuity Insurance Company, White Plains, N.Y.