Medical Coverage Policy

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Breast Reconstruction Following Mastectomy or Lumpectomy

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Overview

This Coverage Policy addresses reconstructive breast surgery following mastectomy or lumpectomy.

- For treatments related to lymphedema, see Cigna Medical Coverage Policies:
  - 0354 Compression Devices
  - 0531 Surgical Treatments for Lymphedema and Lipedema
  - Cobranded Cigna/American Specialty Health Coverage Policy Guideline 157 Complex Lymphedema Therapy (Complete Decongestive Therapy).
- For breast reconstruction related to gender dysphoria treatment, see Cigna Medical Coverage Policy 0266 Gender Dysphoria Treatment.
- For the surgical treatment of gynecomastia, see Cigna Medical Coverage Policy 0195 Gynecomastia Surgery.
- For breast reduction surgery on the non-diseased/contralateral breast following a mastectomy or lumpectomy, see Cigna Medical Coverage Policy 0152 Breast Reduction.
- For surgical procedures for the excision of redundant or excessive skin, see Cigna Medical Coverage Policy 0470 Redundant Skin Surgery.

Coverage Policy

Coverage for breast reconstruction* and breast prostheses 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.**

Breast reconstruction following mastectomy or lumpectomy is considered medically necessary 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 (including correction of inverted nipple)
  - autologous fat transplant (i.e., lipoinjection, lipofilling, lipomodeling)

  - breast implant removal and subsequent reimplantation
  - capsulectomy
  - capsulotomy
  - flat closure chest wall reconstruction
  - implantation of tissue expander
  - implantation of U.S. Food and Drug Administration (FDA)-approved internal breast prosthesis
  - liposuction of the breast
  - oncoplastic reconstruction (e.g., breast reduction, mastopexy)
  - reconstructive surgical revisions
  - tissue/muscle reconstruction (i.e., flap procedures)

- **breast reconstruction procedures performed on the nondiseased/unaffected/contralateral breast, in order to produce a symmetrical appearance, including:**

  - areolar and nipple reconstruction
  - augmentation mammoplasty
  - 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
  - liposuction of the breast
  - reconstructive surgery revisions to produce a symmetrical appearance

The following skin and soft tissue substitutes* are considered medically necessary when used in association with a medically necessary breast reconstruction procedure:

- AlloMax™
- Cortiva®
- DermACELL®
- FlexHD® Acellular Hydrated Dermis
- GalaFLEX™ Scaffold
- GalaFLEX 3D™ Scaffold
- GalaFLEX 3DR™ Scaffold
- GalaFLEX LITE™ Scaffold

Avance® Nerve Graft® is considered medically necessary when used in association with mastectomy or breast reconstruction procedures when nerves cannot be preserved.

The following skin and soft tissue substitutes* when used in association with a breast reconstruction procedure are considered experimental, investigational, or unproven (this list may not be all-inclusive):

- ARTIA™ Reconstructive Tissue Matrix
- BellaDerm® Acellular Hydrated Dermis
- Biodesign® Nipple Reconstruction Cylinder
- DuraSorb® Monofilament Mesh
- Essence Acellular Dermal Matrix
- JUVÉDERM®
- OviTex® PRS

- Permacol™
- Phasix™ Mesh
- Radiesse®
- Renuva®
- SimpliDerm®
- Strattice™ Reconstructive Tissue Matrix
- SurgiMend® PRS

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

Suction lipectomy, ultrasonically-assisted suction lipectomy (liposuction) or excision of redundant skin for correction of surgically-induced donor site asymmetry (e.g., trunk or extremity) or tissue protruding at the end of a scar (e.g., dog ear, standing cone) that results from one or more flap breast reconstruction procedures is considered cosmetic in nature and not medically necessary

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 is considered medically necessary. Refer to the Breast Implant Removal Medical Coverage Policy for additional information on breast implant removal.

Coding Information

Notes:

1. This list of codes may not be all-inclusive since the American Medical Association (AMA) and Centers for Medicare and Medicaid Services (CMS) code updates may occur more frequently than policy updates.
2. Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement.

Breast Reconstruction

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

CPT®* Codes	**Description**
15771	Grafting of autologous fat harvested by liposuction technique to trunk, breasts, scalp, arms, and/or legs; 50 cc or less injectate
15772	Grafting of autologous fat harvested by liposuction technique to trunk, breasts, scalp, arms, and/or legs; each additional 50 cc injectate, or part thereof (List separately in addition to code for primary procedure)
15777	Implantation of biologic implant (eg, acellular dermal matrix) for soft tissue reinforcement (eg, breast, trunk) (List separately in addition to code for primary procedure)
15877†	Suction assisted lipectomy; trunk
19316	Mastopexy
19318	Breast reduction
19325	Breast augmentation with implant
19328	Removal of intact breast implant

CPT®* Codes	Description
19330	Removal of ruptured breast implant, including implant contents (eg, saline, silicone gel)
19340	Insertion of breast implant on same day of mastectomy (ie, immediate)
19342	Insertion or replacement of breast implant on separate day from mastectomy
19350	Nipple/areola reconstruction
19355	Correction of inverted nipples
19357	Tissue expander placement in breast reconstruction, including subsequent expansion(s)
19370	Revision of peri-implant capsule, breast, including capsulotomy, capsulorrhaphy, and/or partial capsulectomy
19371	Peri-implant capsulectomy, breast, complete, including removal of all intracapsular contents
19380	Revision of reconstructed breast (eg, significant removal of tissue, re-advancement and/or re-inset of flaps in autologous reconstruction or significant capsular revision combined with soft tissue excision in implant-based reconstruction)
19499††	Unlisted procedure, breast

†Note: Considered Cosmetic and Not Medically Necessary when used to report correction of surgically-induced donor site asymmetry (e.g., trunk or extremity) or tissue protruding at the end of a scar (e.g., dog ear, standing cone) that results from one or more flap breast reconstruction procedures

††Note: Considered Medically Necessary when used to report thoracodorsal artery perforator (TDAP) flap with a breast reconstruction procedure performed on the diseased/affected breast.

Considered Not Medically Necessary/Cosmetic in nature when used to report correction of surgically-induced donor site asymmetry or excess tissue that results from flap breast reconstruction procedures. Considered incidental to the primary procedure when used to report suction-assisted lipectomy of the trunk as part of a medically necessary flap breast reconstruction procedure:

CPT®* Codes	Description
15839	Excision, excessive skin and subcutaneous tissue (includes lipectomy); other area
15877†	Suction assisted lipectomy; trunk

†Note: Considered Medically Necessary when used to report liposuction of diseased/affected breast or nondiseased/unaffected/contralateral breast in order to produce a symmetrical appearance

Skin/Tissue Substitutes/Fillers (see Appendix)

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

HCPCS Codes	Description
Q4122	Dermacell, per square centimeter
Q4128	Flex hd or allopatch hd, or matrix hd per square centimeter

Considered Medically Necessary when used to report AlloMax™:

HCPCS Codes	Description
C1781	Mesh (implantable)
Q4100	Skin substitute, not otherwise specified

Considered Medically Necessary when used to report Cortiva®:

HCPCS Codes	Description
C9399	Unclassified drugs or biologicals
Q4100	Skin substitute, not otherwise specified

Considered Medically Necessary when used to report GalaFLEX™, GalaFLEX 3DR™, GalaFLEX 3D™, and GalaFLEX Lite™ Scaffolds:

HCPCS Codes	Description
C1781	Mesh (implantable)
C9399	Unclassified drugs or biologicals
Q4100	Skin substitute, not otherwise specified

Considered Medically Necessary when used to report Avance® Nerve Graft®:

CPT®* Codes	Description
64912	Nerve repair; with nerve allograft, each nerve, first strand (cable)
64913	Nerve repair; with nerve allograft, each additional strand (List separately in addition to code for primary procedure)

HCPCS Codes	Description
C9399	Unclassified drugs or biologicals
Q4100	Skin substitute, not otherwise specified

Considered Experimental/Investigational/Unproven:

HCPCS Codes	Description
C9358	Dermal substitute, native, nondenatured collagen, fetal bovine origin (SurgiMend Collagen Matrix), per 0.5 sq cm
C9360	Dermal substitute, native, nondenatured collagen, neonatal bovine origin (SurgiMend Collagen Matrix), per 0.5 sq cm
C9364	Porcine implant, Permacol, per sq cm
Q2026	Injection, Radiesse, 0.1 ml

HCPCS Codes	Description
Q4130	Strattice TM, per sq cm

Considered Experimental/Investigational/Unproven when used to report ARTIA™ Reconstructive Tissue Matrix and Biodesign® Nipple Reconstruction Cylinder:

HCPCS Codes	Description
C1763	Connective tissue, nonhuman (includes synthetic)

Considered Experimental/Investigational/Unproven when used to report when used to report DuraSorb® Monofilament Mesh, OviTex® PRS, and Phasix™ Mesh:

HCPCS Codes	Description
C1781	Mesh (implantable)

Considered Experimental/Investigational/Unproven when used to report BellaDerm® Acellular Hydrated Dermis:

HCPCS Codes	Description
C1781	Mesh (implantable)
C9399	Unclassified drugs or biologicals
Q4100	Skin substitute, not otherwise specified

Considered Experimental/Investigation/Unproven when used to report Essence Acellular Dermal Matrix:

HCPCS Codes	Description
C1762	Connective tissue, human (includes fascia lata)

Considered Experimental/Investigational/Unproven when used to report JUVÉDERM®:

HCPCS Codes	Description
C9399	Unclassified drugs or biologicals

Considered Experimental/Investigational/Unproven when used to report SimpliDerm®:

HCPCS Codes	Description
C9399	Unclassified drugs or biologicals
Q4100	Skin substitute, not otherwise specified

Considered Experimental/Investigational/Unproven when used to report Renuva®:

HCPCS Codes	Description

J3590	Unclassified biologics

Considered Experimental/Investigational/Unproven when used to report the injection of a non-covered product listed in the policy statement above:

CPT®* Codes	Description
11950	Subcutaneous injection of filling material (eg, collagen); 1 cc or less
11951	Subcutaneous injection of filling material (eg, collagen); 1.1 to 5.0 cc
11952	Subcutaneous injection of filling material (eg, collagen); 5.1 to 10.0 cc
11954	Subcutaneous injection of filling material (eg, collagen); over 10.0 cc

General Background

Breast reconstruction following mastectomy or lumpectomy is a standard surgical option to restore shape, appearance, symmetry, and size to the affected breast and/or unaffected (contralateral) breast. The two primary types of breast reconstruction are implantation of an internal breast prosthesis (breast implant) and tissue/muscle reconstruction (flap procedures). Breast implants and flaps may also be used together. Other procedures may be required for optimal results including areolar and nipple reconstruction, areolar and nipple tattooing, autologous fat transplant, and liposuction. Breast reconstruction may be performed immediately following mastectomy and lumpectomy or in a delayed fashion, depending on clinical factors, individual preference, and planned adjuvant treatments. Individuals who elect not to undergo reconstruction may choose to use an external breast prosthesis and mastectomy bra (American Society of Plastic Surgeons, 2025; American Cancer Society, 2025a, 2025b, and 2025c).

Areolar And Nipple Reconstruction (including correction of inverted nipple)

Areolar and nipple reconstruction (including correction of inverted nipple) is considered the final stage of breast reconstruction. This procedure is intended to successfully restore the shape, color, and overall appearance of both the nipple and areola. Established techniques for nipple-areolar reconstruction include the use of autogenous flaps, local bilobed or trilobed flaps, skin grafts, and nipple sharing methods. Pigmentation may be achieved through tattooing to match the natural color of the nipple and areola. Nipple reconstruction may be performed immediately during breast reconstruction or delayed until the breast has achieved a more definitive shape. The decision to pursue nipple-areolar reconstruction should be patient-driven (Kumbla, et al., 2024).

U.S. Food and Drug Administration (FDA)

Breast reconstruction following mastectomy or lumpectomy, including areolar and nipple reconstruction, is considered a surgical procedure and does not require FDA review or approval.

JUVÉDERM®

A variety of tissue engineering strategies for reconstruction of the nipple-areolar complex have been proposed, including hyaluronic acid (Berkane, et al., 2024). JUVÉDERM® (AbbVie) is an injectable gel hyaluronic acid-based dermal filler (implant). According to the manufacturer, "The JUVÉDERM® Collection of Fillers has products that are FDA approved to temporarily add volume to different areas of the face: the cheeks, chin, temples, smile lines, lips, undereyes, and jawline"

(AbbVie, 2025a). JUVÉDERM includes JUVÉDERM Ultra XC, JUVÉDERM Ultra Plus XC, JUVÉDERM VOLBELLA® XC, JUVÉDERM VOLUMA® XC, JUVÉDERM VOLLURE® XC, and JUVÉDERM VOLUX XC (AbbVie, 2025a).

U.S. Food and Drug Administration (FDA)

Breast reconstruction following mastectomy or lumpectomy, including areolar and nipple reconstruction is considered a surgical procedure and does not require FDA review or approval. However, JUVÉDERM is considered a Class III medical device and was approved via the FDA Premarket Approval (PMA) pathway: (P050047) (P110033) (Product Code: LMH). The approved indications for JUVÉDERM and its variants are strictly for aesthetic facial applications (FDA, 2025a).

Literature Review

Currently, there is insufficient high-quality evidence in the published, peer-reviewed scientific literature to support the safety, efficacy, or clinical utility of hyaluronic acid-based dermal fillers, including JUVÉDERM, for breast, areolar, or nipple reconstruction.

Radiesse®

A variety of tissue engineering strategies for reconstruction of the nipple-areolar complex have been proposed, including calcium hydroxylapatite, sometimes referred to as calcium hydroxyapatite (Berkane, et al., 2024.) Radiesse is an injectable dermal filler (implant) composed of smooth calcium hydroxylapatite microspheres suspended in a sodium carboxymethylcellulose gel carrier. According to the manufacturer, "RADIESSE® and RADIESSE® (+) Injectable Implants are FDA-approved for subdermal implantation for the correction of moderate to severe facial wrinkles and folds, such as nasolabial folds. RADIESSE® is also indicated for hand augmentation to correct volume loss in the dorsum of the hands. Radiesse (+) injectable implant is also indicated for deep injection (subdermal and/or supraperiosteal) for soft tissue augmentation to improve moderate to severe loss of jawline contour in adults over the age of 21" (Merz North America, Inc., 2025).

U.S. Food and Drug Administration (FDA)

Breast reconstruction following mastectomy or lumpectomy, including areolar and nipple reconstruction, is considered a surgical procedure and does not require FDA review or approval. However, Radiesse is considered a Class III medical device and was approved via the FDA PMA pathway: (P050037) (P050052) (Product Code: LMH). Neither breast reconstruction nor areolar and nipple reconstruction are specifically mentioned as approved indications for Radiesse or its variants (FDA, 2025a).

Literature Review

Currently, there is insufficient high-quality evidence in the published, peer-reviewed scientific literature to support the safety, efficacy, or clinical utility of calcium hydroxylapatite, including Radiesse, for breast, areolar, or nipple reconstruction.

Biodesign® Nipple Reconstruction Cylinder

The Biodesign Nipple Reconstruction Cylinder (NRC) (Cook Biotech, Inc.) is a tightly rolled cylinder of extracellular matrix collagen derived from porcine small intestinal submucosa (SIS). The NRC is intended for implantation to reinforce soft tissue where weakness exists during plastic and

reconstructive surgery of the nipple. SIS consists of fibrillar collagens, glycosaminoglycans, and adhesive glycoproteins that serve as a scaffold for cellular migration and proliferation. Once implanted, the NRC is intended to facilitate the formation of an organized extracellular matrix through collagen deposition, while serving as a biomaterial stent over which skin flaps can be created to achieve nipple projection (FDA, 2025e; Collins, et al., 2016).

U.S. Food and Drug Administration (FDA)

Breast reconstruction following mastectomy or lumpectomy, including areolar and nipple reconstruction, is considered a surgical procedure and does not require FDA review or approval. However, the NRC is considered a Class II medical device and regulated by the FDA via the 510(k) pathway. According to the FDA, "The Biodesign Nipple Reconstruction Cylinder is intended for implantation to reinforce soft tissue where weakness exists, in plastic and reconstructive surgery of the nipple" (FDA, 2025e).

Device or Product	Identifier	Manufacturer
Biodesign Nipple Reconstruction Cylinder	K110402	Cook Biotech, Inc.

*FDA product code: FTM

Note: Coverage decisions are not based solely on FDA approval. Device or product names are provided for example purposes only. Their inclusion does not indicate endorsement or preference for any specific brand or model. This list is not intended to reflect all available products or technologies.

Literature Review

Currently, there is insufficient high-quality evidence in the published, peer-reviewed scientific literature to support the safety, efficacy, or clinical utility of the NRC for areolar and nipple reconstruction.

In the first multi-center prospective study, Collins et al. (2016) reported on the use of the) NRC during reconstruction of the nipple after mastectomy in patients with a history of breast cancer and mastectomy. Unilateral or bilateral nipple reconstruction was performed. Skin flaps were raised, the NRC was placed beneath the flaps as a stent, and the site was protected for up to four weeks with a nipple shield. Nipple projection was measured for 12 months after surgery. Patient satisfaction was measured, and adverse events were recorded. Follow-up examinations were performed at one week, and then at one, three, six, and 12 months after surgery. A total of 82 nipple reconstructions were performed in 50 patients. Related postoperative adverse events were minor, but reported in eight reconstructions (9.8%), representing seven patients (14.0%). Average projection at six and 12 months was 4.1 ± 1.6 mm and 3.8 ± 1.5 mm, respectively, compared with 10.5 ± 2.2 mm, one week after surgery. Of patients completing the satisfaction questionnaire at 12 months, 70/75 (93.3%) of reconstructions were rated "pleased" or "very pleased" with the overall outcome. Overall, 45/46 (97.8%) patients would recommend nipple reconstruction to other women. This study is limited by the small homogenous sample size, lack of a control group, and short-term follow-up.

Autologous Fat Transplant (i.e., Lipoinjection, Lipofilling, Lipomodeling)

Autologous fat transplant, also referred to as autologous fat grafting, is considered an oncologically safe and widely accepted surgical technique to optimize volume, contour, symmetry, and aesthetic outcomes in breast reconstruction following mastectomy or lumpectomy. During the procedure, fat is harvested from suitable donor sites (e.g., flanks, abdomen, thighs, buttocks,

lower back), processed (washed/decanted), and then reinjected into the breast as a physical filler. Autologous fat transplant may be performed on the affected breast and/or unaffected (contralateral) breast, as standalone procedure for localized deficits, or in conjunction with other procedures (i.e., breast implants and flaps). Autologous fat transplant typically requires more than one treatment to achieve optimal results due to expected volume loss and reabsorption (de Vita and Michelina, 2024; Farhadi and Grufman, 2024; Schaverien and Raine, 2024).

U.S. Food and Drug Administration (FDA)

Breast reconstruction following mastectomy or lumpectomy, including autologous fat transplant, is considered a surgical procedure and does not require FDA review or approval.

Professional Societies/Organizations

American Society of Plastic Surgeons (ASPS): ASPS (2015) published evidence-based guiding principles for post-mastectomy fat graft/fat transfer that state:

- "Aesthetic Outcome: Studies indicate that breast cancer patients undergoing fat grafting as an adjunct to post-mastectomy breast reconstruction experience moderate to significant aesthetic improvement, particularly for volume, contour and superomedial fullness. The evidence also suggests that cosmetic outcome is significantly enhanced after serial fat grafting and that, overall, patients are satisfied with aesthetic results.
- Breast Cancer Recurrence: Evidence suggests that in post-mastectomy breast reconstruction patients, fat grafting does not increase the risk of breast cancer recurrence. As surveillance is integral for the management of any breast cancer patient, fat grafting to post-mastectomy reconstructed breasts does not delay diagnosis of breast cancer recurrence. When reviewed by experienced radiologists, the presence of oil cysts and fat necrosis on mammography, ultrasound and MRI imaging is distinguishable from suspicious lesions. Surveillance should continue to be rigorous and it is encouraged that radiologists who are experienced in breast imaging work with plastic surgeons to facilitate imaging accuracy.
- Complications: Although there is variability in physician technique for fat grafting, the evidence suggests that post-mastectomy breast reconstruction with fat grafting is effective and is associated with a low risk of complications. Furthermore, there is increasing evidence that fat grafting is an effective surgical technique for treating post-mastectomy pain syndrome.
- Radiation Therapy: There is a growing body of evidence that suggests no increased risk of complications when fat grafting is employed in the presence of previously irradiated tissue.
- Technique: The number of fat grafting sessions required varies per patient. Studies suggest that a majority of patients require more than one fat grafting session to achieve adequate aesthetic results, and that each additional session will contribute to gradual improvement of the overall outcome."

<u>Flat Closure Chest Wall Reconstruction</u>

Some individuals may elect to forgo breast reconstruction for a variety of personal reasons. Others may not be candidates for breast reconstruction due to health issues (e.g., obesity, blood circulation issues). In these situations, flat closure chest wall reconstruction is an option. The National Cancer Institute defines an "aesthetic flat closure" as "A type of surgery that is done to rebuild the shape of the chest wall after one or both breasts are removed. An aesthetic flat closure may also be done after removal of a breast implant that was used to restore breast shape. During an aesthetic flat closure, extra skin, fat, and other tissue in the breast area are removed. The

remaining tissue is then tightened and smoothed out so that the chest wall appears flat." (American Cancer Society, 2025b; National Cancer Institute, 2025)

U.S. Food and Drug Administration (FDA)

Breast reconstruction following mastectomy or lumpectomy, including flat closure chest wall reconstruction, is considered a surgical procedure and does not require FDA review or approval.

Implantation of Tissue Expander

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 to cause 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 (Hu, et al., 2007).

U.S. Food and Drug Administration (FDA)

Breast reconstruction following mastectomy or lumpectomy, including implantation of a tissue expander, is considered a surgical procedure and does not require FDA review or approval. However, tissue expanders are considered Class II medical devices and regulated by the FDA via the 510(k) pathway. Numerous tissue expanders and accessories are cleared for various surgical applications including breast reconstruction (FDA, 2025e; FDA, 2019a).

Device or Product	Identifier	Manufacturer
Mentor™ PliaForm™ Breast Tissue Expander w/ Suture Tabs	K242963	Mentor Worldwide, LLC
Mentor™ CPX™ 4 PLUS Enhance Breast Tissue Expander	K243836	Mentor Worldwide, LLC
AlloX2 Pro Tissue Expanders	K214124	Sientra, Inc.
Motiva Flora SmoothSilk Tissue Expander	K211676	Motiva, Usa, LLC
Artoura Breast Tissue Expanders with Smooth Surface	K161176	Mentor Worldwide, LLC
Natrelle 133 Plus Tissue Expander	K143354	Mentor Worldwide, LLC

*FDA product codes: LCJ

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On February, 25 2025b, the FDA published an update regarding the labeling for approved breast implants. The update also notes the July 2019 voluntary recall of the Natrelle BIOCELL textured breast implants and tissue expanders.

On October 23, 2019a, the FDA published an update regarding types of breast implants. The update notes: "There are some risks in using tissue expanders. The use of tissue expanders may result in breast tissue injury and skin thinning, pain, especially during saline filling, and infection. The expander may rupture, and the site or port for saline injection may become infected."

Implantation of U.S. Food and Drug Administration (FDA)-approved Internal Breast Prosthesis

Internal breast prostheses, also referred to as a breast implants, for breast reconstruction are medical devices composed of an outer silicone shell filled with either silicone gel or saline. These implants are available in various sizes and shapes to accommodate individual patient anatomy and reconstructive needs. Breast implants are an established surgical technique used for both reconstructive and cosmetic purposes, including restoration of breast appearance following mastectomy, correction of congenital or traumatic defects, management of significant asymmetries, and revision surgeries to correct or improve the result of an original surgery. Contraindications to breast implants include active infection, untreated breast cancer, and current breastfeeding. Complications associated with breast implants include seroma, bleeding and hematoma, skin necrosis, and infection, implant capsular contracture, implant exposure or malposition, suboptimal aesthetic appearance, and breast implant-associated malignancy (e.g., anaplastic large cell lymphoma, squamous cell carcinoma, other lymphomas). Reoperation or removal of breast implants may be required for the management of some complications. Implants are not lifetime devices and may require replacement or revision over time (American Cancer Society, 2025a; Nahabedian, 2025; Schaverien and Raine, 2024; FDA, 2019a).

U.S. Food and Drug Administration (FDA)

Breast reconstruction following mastectomy or lumpectomy, including implantation of a breast implant, is considered a surgical procedure and does not require FDA review or approval. However, breast implants are considered Class III medical devices and regulated by the FDA via the PMA pathway. Silicone gel-filled breast prosthesis are approved for breast augmentation in women at least 22 years old and for breast reconstruction. Silicone inflatable breast prosthesis are approved for breast augmentation in women at least 18 years old and for breast reconstruction. Breast implants are also used in revision surgeries to correct or improve the result of an original surgery (FDA, 2025a; FDA, 2019a).

Silicone Gel-Filled Breast Prosthesis:

Device or Product	Identifier	Manufacturer
Natrelle Silicone-Filled Breast Implants	P020056	Allergan
MemoryGel Silicone Gel -Filled Breast Implants	P030053	Mentor Corp.
Natrelle Highly Cohesive Silicone-Filled Breast Implants	P040046	Allergan
Mentor MemoryShape Breast Implants	P060028	Mentor Worldwide, LLC
Sientra Silicone Gel Breast Implants	P070004	Tiger Aesthetics Medical, LLC
Motiva SmoothSilk Round Ergonomix Silicone Gel-Filled Breast Implants, Motiva SmoothSilk Round Silicone Gel-Filled Breast Implants	P230005	Motiva USA, LLC

*FDA product codes: FTR

Silicone Inflatable Breast Prosthesis:

Device or Product	Identifier	Manufacturer
Puregraft Serene Breast Implant	P120011	Bimini Health Tech
Natrelle Saline Breast Implants	P990074	Allergan
Mentor Corporation Saline-Filled And Spectrum® Mammary Prostheses	P990075	Mentor Worldwide, LLC

*FDA product codes: FWM

Note: Coverage decisions are not based solely on FDA approval. Device or product names are provided for example purposes only. Their inclusion does not indicate endorsement or preference for any specific brand or model. This list is not intended to reflect all available products or technologies.

On February, 25 2025b, the FDA published an update regarding the labeling for approved breast implants: "Breast implant labeling is provided to ensure a patient receives and understands the benefits and risks of these devices. Labeling may include patient brochures, instructions intended for physicians, and other written or printed materials accompanying the breast implant. There is both the original labeling at the time the FDA approved the breast implant and the current labeling, that is updated with post approval study information and to adequately communicate the risks." The update includes the approved labeling and a summary of safety and effectiveness data for all FDA-approved saline-filled and silicone gel-filled breast implant. The update also notes the July 2019 voluntary recall of the Natrelle BIOCELL textured breast implants and tissue expanders.

On February 6, 2025c, the FDA published an update regarding medical device reports (post-market surveillance) for systemic symptoms in women with breast implants. Between January 1, 2008 and June 30, 2024, the FDA's review identified a total of 10,318 medical device reports meeting the established search criteria for systemic symptoms. The top 10 most frequently reported systemic-related search terms were fatigue (41.1%), joint issues (30.9%), anxiety (22.9%), autoimmune diseases (22.6%), fog (22.5%), hair loss (19.6%), illness (18.7%), depression (16.9%), rash (16.7%), and weight (loss, gain, other) (16.5%). Of the total, 40.8% of reports indicated the patient underwent breast implant removal at some time following the beginning of symptoms. The average time to breast implant removal was 9.1 years, with a range of 0 to 47 years. Only 785 reports provided information related to symptoms following breast implant removal, with 687 reporting improvement and 98 reporting either no improvement or worsening of symptoms.

On February 6, 2025d the FDA published an update regarding medical device reports (post-market surveillance) of breast implant-associated anaplastic large cell lymphoma. Since 2011, the FDA has received a total of 1,380 medical device reports from the U.S. and outside of the U.S. of breast implant-associated anaplastic large cell lymphoma (BIA-ALCL).

On December 14, 2023a, the FDA published an update regarding the risks and complications of breast implants. The update discusses actions the FDA has taken since 2021 to strengthen breast implant risk communication and help individuals who are considering breast implants make informed decisions. The update notes: "Some of the complications and adverse outcomes of breast implants include:

- Implant complications, such as breast pain and changes in nipple and breast sensation
- Additional surgeries, with or without removal of the device (also see Implant Removal)
- Capsular contracture, scar tissue (capsule) that forms around the implant and squeezes the implant
- Rupture and deflation

- Breast implant associated-anaplastic large cell lymphoma (BIA-ALCL), a type of non-Hodgkin's lymphoma (cancer of the immune system)
- Reports of Squamous Cell Carcinoma (SCC), various lymphomas other than BIA-ALCL, and mesenchymal tumors, including sarcoma
- Connective tissue disease, breast cancer, and reproductive problems
- Systemic symptoms
- Impact on breastfeeding
- Effects on children”

On March 8, 2023b, the FDA published an update regarding considerations for patients prior to undergoing breast augmentation, reconstruction or revision surgery including:

- “Breast implants are not lifetime devices. The longer you have your implants, the more likely it will be for you to have them removed or replaced.
- You should assume that you will need to have additional surgeries (reoperations) because breast implants are not lifetime devices and complications can occur.
- Even if you have complications, the cost of implant removal or implant replacement may not be covered by insurance.
- The longer you have breast implants, the more likely you are to experience complications and adverse outcomes, which may be cosmetically undesirable and irreversible.
- The most common local complications and adverse outcomes are capsular contracture, reoperation and implant removal. Other local complications include rupture or deflation, wrinkling, asymmetry, scarring, pain, and infection at the incision site. For a more complete list of complications and adverse outcomes that may occur for a specific breast implant, you should ask your surgeon for the manufacturer's patient labeling and educational materials or review the relevant labeling.
- Read the manufacturer's patient labeling and other educational materials carefully and discuss any questions you have with your surgeon before deciding.
- There are different shapes, styles and textures of breast implants. Discuss your goals and expectations and the benefits and risks of breast implants with your surgeon.
- If you have your implants removed but not replaced, you may experience changes to your natural breasts such as dimpling, chest wall concavity, puckering, wrinkling, breast tissue loss, or other undesirable cosmetic changes.
- Breast implants need to be monitored for as long as you have them. If you have silicone gel filled breast implants, your health care provider may recommend that you have regular exams using magnetic resonance imaging (MRI) or ultrasound that may not be covered by your insurance, to screen for breast implant rupture and other complications.
- If you notice any abnormal changes in your breasts or implants, you will need to see your surgeon or health care provider promptly.
- There is a risk of developing a type of cancer called breast implant-associated anaplastic large cell lymphoma (BIA-ALCL) in the breast or scar tissue (capsule) surrounding the implant. BIA-ALCL is not breast cancer. Treatment of BIA-ALCL involves removal of the implant and the capsule surrounding the implant. Some patients have also required chemotherapy and/or radiation therapy
- Although treatable, there is a risk of death for patients diagnosed with BIA-ALCL.
- Some breast implant patients report a variety of systemic symptoms, such as chronic fatigue, brain fog, joint and muscle pain, which may not meet the diagnostic criteria to be categorized as a disease. Patients refer to these symptoms collectively as "breast implant illness (BII)." In some cases, patients report that removal of their breast implants without replacement appears to reverse their symptoms.
- Breast reconstruction often involves the implantation of not only a breast implant device but also a surgical mesh device. Implanting surgical mesh as part of breast implant surgeries has not been approved by the FDA.”

On October 23, 2019b, the FDA published an update regarding questions and answers about BIA-ALCL. The update provides information and recommendations for patients and health care professionals regarding BIA-ALCL.

Professional Societies/Organizations

American Association of Plastic Surgeons (AAPS): AAPS (Clemens, et al., 2024) published a consensus statement regarding the management and prevention of BIA-ALCL that recommend:

- "Use of macrotextured breast implants should be discontinued, and surveillance of patients who received breast implants, whether smooth or textured surface, should be implemented.
- Implant manufacturers should disclose publicly, or for independent academic analysis, their internal surveillance data, detailing both the number of BIA-ALCL cases reported to them and their country-specific and global sales and implantation figures for their respective breast implants.
- No change in the use of smooth-surface breast implants is warranted at this time, based on BIA-ALCL data.
- Currently available evidence is sufficient to determine that the association of textured breast implants and BIA-ALCL does meet the definition of causation based on the Bradford Hill criteria.
- An en bloc capsulectomy with explantation, resection of associated masses, and excision of involved lymph nodes is recommended for patients with BIA-ALCL, when deemed appropriate as part of a multidisciplinary evaluation.
- The addition of chemotherapy/immunotherapy to surgical explantation of textured breast implants may be considered in patients with stage IIA disease if disease is unresectable (invasive to critical structures), and it is recommended for patients with stage IIB or higher-stage BIA-ALCL, when deemed appropriate as part of a multidisciplinary evaluation. Neoadjuvant immunotherapy may be considered for borderline resectable or locally advanced unresectable disease at diagnosis if it achieves enough downstaging to permit a curative-intent surgery.
- The addition of radiation therapy (25 to 30 Gy) to surgical excision and explantation is recommended for patients with unresectable BIA-ALCL, when deemed appropriate as part of a multidisciplinary evaluation.
- Based on the potential for risk reduction, prophylactic explantation of macrotextured surface implants can be deemed reasonable. Furthermore, after implementing a risk stratification and surveillance plan, coupled with an informed discussion about the benefits of surgery, it may also be considered reasonable for explantation of any type of textured implant. It is important to differentiate between a procedure being reasonable—referring to the potential to mitigate risk—and it being advisable. While we acknowledge the reasonableness of these procedures, the determination of their advisability rests solely with the discretion of the surgeon in consultation with the patient. Before the release of this consensus statement, government authorities and national surgical societies had not acknowledged the potential for risk reduction through prophylactic explantation. Consequently, they either have not recommended such procedures or simply have no existing recommendation on the matter.
- Prophylactic explantation of the contralateral textured breast implant is recommended in patients with a confirmed BIA-ALCL diagnosis due to the risk of unrecognized or occult bilateral disease.
- Preemptive notification of the risk of developing BIA-ALCL is recommended for all patients with textured breast implants. Occult fluid collections or masses may be recognized earlier in patients with textured silicone implants undergoing routine surveillance for gel leak.

- Genetic markers may have prognostic value and may implicate future therapeutic targets. Broad genetic testing of patients with BIA-ALCL beyond clinical trials is not recommended at this time; however, the further identification of markers may provide future indications for genetic testing.
- Evidence of pathways involving chronic inflammation and the acquisition of driving oncogenic events may be considered as increasing the risk for developing BIA-ALCL in patients with textured breast implants."

Oncoplastic Reconstruction (e.g., breast reduction, mastopexy)

Oncoplastic reconstruction (e.g., breast reduction, mastopexy) involves the excision of breast tumors with a wide margin of resection, followed by immediate or staged surgery to restore the natural shape of the breast. Reconstruction often includes contralateral procedures to ensure breast symmetry. Selection of reconstruction method is based on tumor characteristics, breast size and shape, and patient preference, utilizing both volume displacement (e.g., local tissue rearrangement, reduction mammaplasty, and mastopexy) and volume replacement strategies (e.g., local and remote flaps). The published clinical evidence demonstrates that oncoplastic breast surgery is safe, effective, and results in high patient satisfaction. Breast conservation with oncoplastic techniques achieves survival and local recurrence outcomes comparable to those observed with modified radical mastectomy. Wider resection margins reduce positive margin rates, decrease the need for re-excision, and may lower subsequent mastectomy rates. Long-term follow-up data indicate low local recurrence rates, high overall survival, and satisfactory cosmetic outcomes, with multiple studies confirming the oncologic safety and dual benefits of cancer control and aesthetic restoration (Kumbla, et al., 2024; Nahabedian, 2020).

U.S. Food and Drug Administration (FDA)

Breast reconstruction following mastectomy or lumpectomy, including oncoplastic reconstruction, is considered a surgical procedure and does not require FDA review or approval.

Liposuction Of the Breast

Liposuction of the breast is a common surgical technique widely accepted as a safe and effective standard practice for secondary contour correction in both ipsilateral and contralateral breast reconstruction. This method involves suction-assisted removal of adipose tissue to address contour irregularities, volume excess, or localized fat necrosis that may arise after primary autologous or implant-based breast reconstruction. Liposuction is typically performed after the initial reconstructive surgery, often three to six months postoperatively or after completion of adjuvant therapy, to allow tissues to stabilize and swelling to subside. Liposuction may be used alone or in combination with other techniques such as autologous fat grafting, direct tissue excision, or implant augmentation to achieve optimal aesthetic outcomes (Roubaud, et al., 2026; Schaverien and Raine, 2024; Farhadi and Grufman, 2024; Rose and Wu, 2020).

U.S. Food and Drug Administration (FDA)

Breast reconstruction following mastectomy or lumpectomy, including liposuction of the breast, is considered a surgical procedure and does not require FDA review or approval.

Tissue/Muscle Reconstruction (i.e., flap procedures)

Tissue/muscle reconstruction (i.e., flap procedures), also referred to as autologous breast reconstruction, is an established surgical technique that utilizes the patient's own tissue (skin, fat, and sometimes muscle) from donor sites including the abdomen, back, thigh, or buttocks to

reconstruct a breast defect. Flap-based reconstruction creates a breast with texture and appearance that closely resemble natural tissue following mastectomy or lumpectomy. Aesthetic outcomes may also improve over time with flaps. Autologous reconstruction is indicated for both immediate and delayed breast reconstruction. Flaps may be pedicled, remaining attached to their original blood supply and rotated into position, or free, requiring complete detachment and microsurgical revascularization (Schaverien and Raine, 2024).

Examples of flaps used in autologous breast reconstruction include:

- Deep circumflex iliac artery (DCIA) flap (Rubens flap)
- Deep inferior epigastric artery perforator (DIEP) flap
- Extended latissimus dorsi (LD) flap
- Free transverse rectus abdominis musculocutaneous (TRAM) flap
- Inferior gluteal artery perforator (IGAP) flap
- Laparoscopically harvested omentum free flap (LHOFF)
- Lateral thigh perforator (LTP) flap
- LD flap
- Lumbar artery perforator (LAP) flap
- Muscle-sparing TRAM (MS-TRAM) flap
- Omental fat-augmented free flap (O-FAFF)
- Pedicled TRAM flap
- Profunda artery perforator (PAP) flap
- Superficial inferior epigastric artery (SIEA) flap
- Superior gluteal artery perforator (SGAP) flap
- Thoracodorsal artery perforator (TDAP) flap
- Transverse upper gracilis (TUG) flap

U.S. Food and Drug Administration (FDA)

Breast reconstruction following mastectomy or lumpectomy, including tissue/muscle reconstruction, is considered a surgical procedure and does not require FDA review or approval.

Contralateral Breast

Breast symmetry is a core objective of breast reconstruction. Contralateral breast symmetrization encompasses adjunct procedures performed to achieve bilateral aesthetic balance. More than one procedure may be required to achieve symmetry. Standard approaches include contralateral augmentation mammoplasty, augmentation with implantation of FDA-approved internal breast prosthesis, contralateral reduction mammoplasty, mastopexy, and autologous fat transplant (de Vita and Michelina, 2024; Sbitany and Lentz, 2020).

Skin and Soft Tissue Substitutes

A variety of tissue engineering strategies for breast reconstruction have been proposed, including acellular dermal matrix (ADM) and synthetic meshes and scaffolds. ADM is harvested from humans or animals and consists of collagen, elastic fibers, and other components of the extracellular matrix, such as fibronectin, laminin, and hyaluronic acid. ADM may enhance skin coverage and reduce the risk of capsule contracture, particularly after the placement of a silicone implant or tissue expander. Synthetic meshes and scaffolds include resorbable polymers that are intended to provide structural support, guide tissue ingrowth, and maintain breast shape and volume. (Berkane, et al., 2024). Allograft adipose matrix, derived from donated human fat tissue, has also been proposed as an off-the-shelf alternative to autologous fat transplant to improve volume, contour, symmetry, and overall aesthetic outcomes. Neurotization using allografts has

been proposed as a means to bridge large nerve gaps when nerve autografts are not feasible. These nerve allografts are intended to recover sensation earlier and with increased quality and quantity (Hamilton, et al., 2021).

U.S. Food and Drug Administration (FDA)

Breast reconstruction following mastectomy or lumpectomy is considered a surgical procedure and does not require FDA review or approval. However, the FDA does regulate human cells or tissue intended for implantation, transplantation, infusion, or transfer into human recipients, including skin and soft tissue substitutes. These products are referred to as human cells, tissue, and cellular and tissue-based products (HCT/Ps).

- HCT/Ps that meet certain requirements, including minimally manipulated and intended for homologous use, as outlined in Title 21, Code of Federal Regulations, Part 1271 (21CFR1271) and Section 361 of the Public Service Act (PSA), are not required to be FDA approved or cleared to be legally marketed.
- HCT/Ps that don't meet the criteria outlined in 21CFR1271, but that are regulated under Section 351 of the PSA are considered drugs, devices, and/or biological products that require FDA clearance or approval to be legally marketed.
- All HCT/Ps require registration with the FDA prior to marketing.

Skin and soft tissue substitutes harvested from animals are regulated by the FDA as a medical devices and require FDA clearance or approval to be legally marketed.

Synthetic meshes and scaffolds are regulated by the FDA as medical devices and require FDA clearance or approval to be legally marketed (FDA, 2025e; FDA, 2024; FDA, 2020; FDA, 2019c; FDA, 2019d; FDA, 2016).

Skin and Soft Tissue Substitutes Considered Medically Necessary When Used in Association with a Medically Necessary Breast Reconstruction Procedure

Literature Review

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

AlloMax™: AlloMax Surgical Graft (Becton, Dickinson and Company) is a human-derived ADM and HCT/P that doesn't require FDA clearance or approval to be legally marketed (Establishment Name: C. R. Bard, Inc.) (FDA, 2024; Venturi, et al., 2013). AlloMax is an established treatment option and is supported by the evidence in the published peer-reviewed scientific literature for breast reconstruction following mastectomy or lumpectomy (Venturi, et al., 2013).

Cortiva®: Cortiva (Evergen) is a human-derived ADM and HCT/P that doesn't require FDA clearance or approval to be legally marketed (Establishment Name: RTI Surgical, Inc.) (Evergen, 2025; FDA, 2024). According to the manufacturer, "Cortiva® allograft dermis is a non-crosslinked acellular dermal matrix (ADM). It is a safe and natural biologic option for the repair, replacement, reconstruction, or augmentation of soft tissues including plastic and reconstructive surgery procedures." Cortiva includes Cortiva Silhouette®, Cortiva 1mm Perforated Tailored, Cortiva 1mm Tailored, Cortiva 1mm Perforated, and Cortiva 1mm (Evergen, 2025). Two randomized controlled trials have demonstrated that Cortiva is noninferior to AlloDerm in short-term prepectoral, partial submuscular, and submuscular implant-based breast reconstruction outcomes. Cortiva is an established treatment option and is supported by the evidence in the published peer-reviewed

scientific literature for breast reconstruction following mastectomy or lumpectomy (ECRI, 2025a; Keane, et al., 2024; Parikh, et al, 2018).

ECRI (2025a) performed an evidence analysis regarding Cortiva and Cortiva 1mm allograft dermis for breast reconstruction. The analysis of available evidence included one randomized controlled trial and three nonrandomized studies. ECRI concluded that the evidence suggests Cortiva appears effective for postmastectomy breast reconstruction. Seroma and hematoma rates were similar to AlloDerm. However, the evidence is insufficient to compare Cortiva with AlloDerm on quality of life, expander or implant explantations, tissue flap necrosis, and capsular contracture. The available studies are statistically imprecise, do not exclude the possibility of differences between the two ADMs, and the long-term effects are unknown. Additional randomized controlled trials comparing Cortiva with other ADMs and non-ADM techniques are needed to guide clinical decisions.

DermACELL®: DermACELL (LifeNet Health) is a human-derived ADM and HCT/P that doesn't require FDA clearance or approval to be legally marketed (Establishment Name: LifeNet Health) (LifeNet Health, 2025; FDA, 2024). According to the manufacturer, DermACELL has clinical application in soft tissue reconstruction (LifeNet Health, 2025). DermACELL has evolved into an accepted skin substitute for breast reconstruction following mastectomy or lumpectomy, with the clinical evidence primarily in the form of case series and retrospective reviews (Tanas, et al., 2025; Glynou, et al., 2024; Davison, et al., 2024; Swisher, et al., 2022; Ortiz, 2017; Chang and Liu, 2017; Pittman, et al., 2016; Zenn, et al. 2016; Bullocks, et al., 2014; Vashi, 2014).

FlexHD® Acellular Hydrated Dermis: FlexHD Acellular Hydrated Dermis (Musculoskeletal Transplant Foundation) is a human-derived ADM and HCT/P that doesn't require FDA clearance or approval to be legally marketed (Establishment Name: Musculoskeletal Transplant Foundation) (Musculoskeletal Transplant Foundation , 2025a; FDA, 2024). According to the manufacturer, "FlexHD PLIABLE is used for the replacement of damaged or inadequate integumental tissue for the repair, reinforcement or supplemental support of soft tissue defects" (Musculoskeletal Transplant Foundation , 2025a). FlexHD products include FlexHD Pliable, FlexHD Pliable Perforated, FlexHD Pliable Shaped, FlexHD Pliable Shaped Perforated, FlexHD Pliable MAX, FlexHD Pliable PRE, FlexHD Structural, and FlexHD Diamond (Musculoskeletal Transplant Foundation, 2025b). Results of case series and retrospective reviews in the peer-reviewed literature support the safety and efficacy of FlexHD for breast reconstruction following mastectomy or lumpectomy. FlexHD is an established skin substitute for this indication (Glynou, et al., 2024; Lee and Mun, 2017; Liu, et al., 2014; Seth, et al., 2013; Ho, et al., 2012; Seth, et al., 2012; Brooke, et al., 2012; Rawlani, et al., 2011; Cahan, et al., 2011; Topol, et al., 2008).

GalaFLEX™ Scaffold, GalaFLEX 3D™ Scaffold, GalaFLEX 3DR™ Scaffold, and GalaFLEX LITE™ Scaffold: According to the manufacturer, "The GalaFLEX™ Scaffold collection is bioabsorbable, monofilament and constructed of poly-4-hydroxybutyate (P4HB) – an advanced, biologically derived polymer. The GalaFLEX™ Scaffold collection supports, repairs, and reinforces soft tissue in plastic and reconstructive surgery procedures" (Becton, Dickinson and Company, 2025a). The collection includes GalaFLEX Scaffold, GalaFLEX 3D Scaffold, GalaFLEX 3DR Scaffold, and GalaFLEX LITE Scaffold. GalaFLEX Scaffold is considered a Class II medical device and was cleared via the FDA 510(k) pathway: (K140533) (K161092) (K162922) (K233999) (Product Code: OOD) (FDA, 2025e). Although the published literature investigating GalaFLEX Scaffold is primarily in the form of retrospective reviews and case series with small patient populations and short-term follow-ups. GalaFLEX Scaffold, GalaFLEX 3D Scaffold, GalaFLEX 3DR Scaffold, and GalaFLEX LITE Scaffold have evolved into a standard of care for breast reconstruction following mastectomy or lumpectomy (Arnautovic, et al., 2025; ECRI, 2025b; Movassaghi, et al., 2024; Sigalove, et al., 2022; Frey and Choi, 2020; Adams, et al., 2018; Nair et al., 2018; Adams, et al., 2016).

ECRI (2025b) performed an evidence analysis regarding GalaFLEX Surgical Scaffold for soft-tissue reinforcement in breast reconstruction surgery. The analysis of available evidence included one nonrandomized comparison study. ECRI concluded that the evidence suggests GalaFlex, in addition to AlloDerm, appears to work for breast reconstruction. GalaFLEX does not differ from AlloDerm alone in safety and effectiveness. However, the study was at a high risk of bias. The study also used GalaFlex in conjunction with AlloDerm, confounding the interpretation of results.

Avance Nerve Graft®: Mastectomy can result in diminished or absent sensation which can lead to a decreased sense of femininity and sexuality and potential thermal or mechanical injury. Neurotization is a technique used to repair the loss of sensation and can be achieved through autografts, allografts, or nerve conduit tubes, depending on the length of the gap. Neurotization using allografts has been proposed as a means to bridge large nerve gaps when nerve autografts are not feasible. These nerve allografts are intended to recover sensation earlier and with increased quality and quantity (Hamilton, et al., 2021). Avance Nerve Graft (AxoGen Corporation) is a human-derived HCT/P that doesn't require FDA clearance or approval to be legally marketed (Establishment Name: Axogen Corporation) (AxoGen Corporation, 2025; FDA, 2024). According to the manufacturer, "Avance Nerve Graft is a processed nerve allograft (human) intended for the surgical repair of peripheral nerve discontinuities to support regeneration across the defect" (AxoGen Corporation, 2025). However, on December 3, 2025, the manufacturer received FDA approval of a Biologics License Application (BLA 125816) for AVANCE® (acellular nerve allograft-arwx) with the following indications: "AVANCE is a regenerative peripheral nerve scaffold indicated for the treatment of peripheral nerve functional deficits" (FDA, 2025f).

The evidence to support the safety and efficacy of neurotization with processed nerve allografts (e.g., Avance Nerve Graft) following mastectomy or lumpectomy. Studies are in the form of a systematic review, cohort studies and case reports. (Peled, et al., 2023; Momeni, et al., 2021; Djohan, et al., 2020; Peled and Peled, 2019).

Sorenson, et al. (2025) conducted a systematic review to synthesize available evidence on nipple-areolar complex neurotization in implant-based breast reconstruction following nipple-sparing mastectomy, focusing on sensory recovery, patient satisfaction, and surgical techniques. The review included six studies reporting on 212 patients and 257 neurotized breasts; two studies also included non-neurotized breasts for comparison. Inclusion criteria included studies that reported nipple neurotization patient outcomes in implant-based breast reconstruction after nipple-sparing mastectomy and used a technique involving nerve coaptation, nerve grafting, or alternative neurotization methods. Primary outcomes included sensory recovery, and secondary outcomes included patient-reported satisfaction, complications, and aesthetic outcomes; sensory recovery assessment methods varied across studies and included multiple objective testing approaches and patient-reported instruments (including BREAST-Q in some studies). Follow-up timing varied across included studies, with sensory assessment generally commencing at approximately three months postoperatively and recurring about every three months up to 12 months. The review reported improvements in nipple-areolar complex sensory outcomes and high patient satisfaction after neurotization; however, variability in neurotization methods, measured sensory outcomes, and follow-up duration limited direct comparisons, and comparative findings did not consistently reach statistical significance. No neurotization-related complications such as neuroma formation, chronic nerve pain, or allodynia were reported. The authors concluded that nipple neurotization in implant-based breast reconstruction is associated with improved sensory recovery and patient satisfaction following nipple-sparing mastectomy.

Guido et al. (2025) conducted a study to determine the degree and timing of sensory return following nipple-areolar complex neurotization during nipple sparing mastectomy. The study included 47 participants (representing 94 breasts); 23 underwent therapeutic mastectomies with contralateral prophylactic mastectomy and 24 underwent bilateral risk-reducing mastectomies due

to genetic predisposition and/or strong family history. Inclusion criteria included individuals who underwent bilateral nipple-sparing mastectomy with direct-to-implant, prepectoral reconstruction between May 2019 and December 2021. Exclusion criteria were not reported. The intervention involved identifying and dissecting lateral intercostal nerve branches (T4 and T5) during mastectomy, then reconstructing transected intercostal nerves to a subareolar target using either an autograft or a processed nerve allograft. Outcomes measured included quantitative nipple/breast sensation (1-point moving discrimination using a pressure-specified sensory device), patient-reported nipple sensation and responsiveness to touch (modified BREAST-Q), and reports of persistent painful nipple-areolar complex sensation or discomfort at testing time points. Follow-up assessments occurred at six weeks, three months, six months, and 12 months after mastectomy. Nipple sensation progressively returned to baseline by one year, with 74% achieving excellent quantitative sensory scores at 12 months. Patient-reported sensation increased from 53% at six months to 70% at 12 months, and 92% reported nipples as very or somewhat responsive to touch at one year. None of the patients reported painful or uncomfortable nipple-areolar complex sensations beyond the 6-week time point; other adverse events were not reported. Study limitations including lack of a control group, reliance on historical comparisons, and limitations of the patient-reported outcome assessments. The authors concluded that neurotization facilitates restoration of baseline nipple sensation on quantitative assessment by one year for most patients.

Momeni et al., (2021) conducted a cohort study of individuals from a single institution to evaluate sensation outcomes of the reconstructed breast following neurotization using a processed nerve allograft. Patients (n=59; breasts=96) ranged in age from 24–69 years old. A total of 33 patients were white, 14 were Asian, and 12 were Hispanic. Patients who underwent microsurgical breast reconstruction following mastectomy with free abdominal flaps by a single surgeon with follow-up of ≥ 12 months were included in the study. Patients who underwent autologous reconstruction using donor-sites other than the abdomen, reconstruction with stacked flaps, and implant-based reconstruction were excluded. There were two cohort groups: patients who underwent flap neurotization utilizing a 1-2 mm x 50 mm processed human nerve allograft (i.e., Avance, AxoGen Corporation) (n=39; breasts=59) and those who did not undergo neurotization (n=20; breasts=37). The primary outcome measured was cutaneous pressure threshold using the Semmes-Weinstein monofilaments test at nine pre-defined locations on the breast. Follow-up took place at 3, 6, 12, and 18 months. The majority of patients in both groups underwent bilateral immediate reconstruction following nipple-sparing mastectomy for malignancy. However, procedures also included areola-sparing, skin sparing, and simple mastectomy and reconstruction also included delayed-immediate and delayed. A total of 22 patients (group 1=22 breasts; group 2=14 breasts) had a complete data set at ≥ 12 months and were included in the final analysis. Compared to those who did not undergo neurotization, group one was associated with a greater likelihood for return of protective sensation in the majority of breast locations ($p<0.01$). Author noted limitations of the study included: non-randomized study design, small sample size, and a lack of secondary outcomes (e.g., impact of medical conditions, chemotherapy, radiotherapy on sensory outcomes). Additional limitations of the study include short term follow-up, heterogeneity of mastectomy procedures, and the lack of safety outcome measures.

Skin and Soft Tissue Substitutes Considered Experimental, Investigational, or Unproven When Used in Association with a Breast Reconstruction Procedure (This List May Not Be All-Inclusive)

Literature Review

Additional skin and soft tissue substitutes have been proposed as treatment options for breast reconstruction following mastectomy or lumpectomy. However, 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, the 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.

ARTIA™ Reconstructive Tissue Matrix: ARTIA Reconstructive Tissue Matrix (ARTIA RTM) (AbbVie; Allergan Aesthetics) is a porcine derived ADM (AbbVie, 2025b). ARTIA Reconstructive Tissue Matrix is considered a Class II medical device and was cleared via the FDA 510(k) pathway (K162752) (Product Code: FTM): "ARTIA Tissue Matrix 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 which require the use of reinforcing or bridging material to obtain the desired surgical outcome. The implant is intended for reinforcement in plastic and reconstructive surgery." (FDA, 2025e). There is insufficient evidence to support the safety and efficacy of ARTIA Reconstructive Tissue Matrix as a skin substitute for breast reconstructive surgery (Glynou, et al., 2024).

BellaDerm® Acellular Hydrated Dermis: BellaDerm Acellular Hydrated Dermis (Musculoskeletal Transplant Foundation) is a human-derived ADM and HCT/P that doesn't require FDA clearance or approval to be legally marketed (Establishment Name: Musculoskeletal Transplant Foundation) (FDA, 2024). According to the manufacturer, "BellaDerm® Pliable developed by MTF Biologics, is a natural allograft option specifically consented for cosmetic procedures" (Musculoskeletal Transplant Foundation, 2025c). There is insufficient evidence to support the safety and efficacy of BellaDerm Acellular Hydrated Dermis as a skin substitute for breast reconstructive surgery.

DuraSorb® Monofilament Mesh: DuraSorb® Monofilament Mesh (Integra LifeSciences Corporation) is described by the manufacturer as a "100% bioresorbable scaffold engineered from trusted polydioxanone (PDO) material to address limitations in current soft tissue reinforcement options, support natural healing, and minimize risk of infection" (Integra LifeSciences Corporation, 2025). DuraSorb Monofilament Mesh is considered a Class II medical device and was cleared via the FDA 510(k) pathway (K181094) (Product Code: FTL): "Polydioxanone Surgical Scaffold is indicated for use in reinforcement of soft tissue where weakness exists." (FDA, 2025e). Higher-level evidence is lacking in the published peer-reviewed literature to support the clinical effectiveness of DuraSorb Monofilament Mesh for breast reconstruction following mastectomy or lumpectomy (Arnautovic, et al., 2025; ECRI, 2024).

ECRI (2024) performed an evidence analysis regarding DuraSorb Monofilament Mesh for breast reconstruction. The analysis of available evidence included one nonrandomized comparison study and four small case series. ECRI concluded that very-low-quality data suggests DuraSorb Monofilament Mesh can be used successfully for breast reconstruction. However, there is no evidence available to determine how DuraSorb Monofilament Mesh compares to other materials used in breast reconstruction.

Essence Acellular Dermal Matrix
Essence Acellular Dermal Matrix (ADM) (Bimini Health Tech, Plano, TX) is a terminally sterilized acellular dermal matrix derived from human cadaveric dermis. It is proposed for plastic and reconstructive surgery procedures. Essence Acellular Dermal Matrix (ADM) implants are regulated as 361 Human Cell and Tissue Products (HCT/Ps) as defined in US FDA 21 CFR 1271, and are restricted to homologous use for the repair, replacement, reconstruction or augmentation of soft tissue by a qualified healthcare professional (e.g., physician) (Bimini Health Tech, 2026). Essence is available in two thicknesses and multiple shapes and sizes. There is insufficient evidence to support the safety and efficacy of Essence Acellular Dermal Matrix for any indication.

OviTex® PRS: According to the manufacturer, "OviTex PRS is the only biologic reinforced with interwoven polymer suture designed specifically for plastic and reconstructive surgery. Our next generation reinforced biologic is purposefully designed for consistency in stretch, permeability and handling while facilitating functional remodeling" (TELA Bio, Inc., 2025). OviTex PRS includes Short-Term Resorbable, Permanent, and Long-Term Resorbable variants, as well as a OviTex IHR, marketed for use in laparoscopic and robotic-assisted inguinal hernia repair (TELA Bio, Inc., 2025a; TELA Bio, Inc., 2025b). OviTex PRS is considered a Class II medical device and was cleared via the FDA 510(k) pathway (K141053) (K214070) (K241126) (K243595) (Product Code: FTM). These devices are indicated for implantation as surgical meshes to reinforce or repair weakened soft tissue in plastic, reconstructive, and/or hernia/body wall defect repair (FDA, 2025e). Higher-level evidence in the published, peer-reviewed scientific literature supporting the use of OviTex PRS in breast reconstruction is lacking and its role is unclear (ECRI, 2025c).

ECRI (2025c) performed an evidence analysis regarding OviTex PRS for breast reconstruction. The analysis of available evidence included two retrospective comparison studies. ECRI concluded that the evidence suggests OviTex PRS is safe and works as intended for breast reconstruction. However, the two studies are of very low quality. The studies include too few patients to support conclusions regarding the comparative effectiveness of OviTex PRS. The studies are at high risk of bias due to a lack of randomization and lack generalizability due to single-center design. Randomized controlled trials that compare OviTex with other tissue repair products are required to assess comparative safety and effectiveness.

Permacol™: According to the manufacturer, "Permacol™ surgical implant is intended for use as a soft tissue implant to reinforce soft tissue where weakness exists." "The implant is made of a sterile, off-white, moist, tough, and flexible, fibrous flat sheet of crosslinked acellular porcine dermal collagen-based matrix" (Medtronic, 2025). Permacol is considered a Class II medical device and was cleared via the FDA 510(k) pathway (K992556) (K013625) (K021056) (K043366) (K050355) (K120605) (Product Code: FTL; FTM). These devices are indicated for reinforcement and repair of weakened or damaged soft tissue in a variety of applications, including abdominal wall and parastomal hernias, inguinal, diaphragmatic, femoral, scrotal, umbilical, and incisional hernias; pelvic organ prolapse and pelvic floor reconstruction; muscle flap reinforcement; sacrocolposuspension; urethral sling placement; plastic and reconstructive surgery of the face and head; and rotator cuff repair. (FDA, 2025e). Evidence in the published, peer-reviewed scientific literature supporting the use of Permacol in breast reconstruction is lacking and its role is unclear (Knabben, et al., 2017; Ramsden, et al., 2009).

Phasix™ Mesh: Phasix Mesh (Becton, Dickinson and Company) is a fully resorbable poly-4-hydroxybutyrate (P4HB) monofilament mesh scaffold intended for ventral hernia repair and soft tissue reconstruction (Becton, Dickinson and Company, 2025). Phasix Mesh is considered a Class II medical device and was cleared via the FDA 510(k) pathway (K120728) (K142818) (K143380) (K161424) (K173143) (K182008) (K190185) (K243241) (Product Code: FTL; OOD; OWT). These devices are indicated for reinforcement of soft tissue where weakness exists, primarily in hernia repair procedures, including umbilical, groin, and hiatal hernias, and may include positioning systems or patch configurations to facilitate placement during surgical repair of fascial defects (FDA, 2025e). Evidence in the published, peer-reviewed scientific literature supporting the use of Phasix Mesh in breast reconstruction is lacking and its role is unclear.

Renuva®: Renuva (Musculoskeletal Transplant Foundation) is an allograft adipose matrix and HCT/P that doesn't require FDA clearance or approval to be legally marketed (Establishment Name: Musculoskeletal Transplant Foundation) (FDA, 2024) (MTF Biologics, 2025). According to the manufacturer, "Renuva® is an off-the-shelf alternative to autologous fat transfer. It is used to restore volume in the face, hands and body in a short, in-office procedure. The adipose allograft is processed to preserve the extracellular matrix containing collagens, proteins, and growth factors

found in adipose tissue. The resulting matrix serves as a framework to support the cellular repopulation and vascularization at the site of injection. Renuva is to be used where fat naturally exists" (Musculoskeletal Transplant Foundation, 2025d). Evidence in the published, peer-reviewed scientific literature supporting the use of Renuva in breast reconstruction is lacking and its role is unclear.

SimpliDerm®: SimpliDerm (Elutia) is a human-derived ADM and HCT/P that doesn't require FDA clearance or approval to be legally marketed (Establishment Name: Berkeley Biologics LLC) (FDA, 2024). According to the manufacturer, "SimpliDerm is to be used for the repair or replacement of damaged or insufficient integumental tissue. It may also be used for the repair, reinforcement, or supplemental support of soft tissue defects or any other homologous use of human integument." The SimpliDerm variants include perforated and non-perforated and ellipse and square shapes (Elutia, 2025). There is insufficient evidence in the published peer-reviewed scientific literature to support the safety and efficacy of SimpliDerm for breast reconstruction following mastectomy or lumpectomy.

Strattice™ Reconstructive Tissue Matrix: Strattice Reconstructive Tissue Matrix (AbbVie) is a porcine derived ADM. According to the manufacturer, "STRATTICE™ Reconstructive Tissue Matrix (RTM), STRATTICE™ RTM Perforated, STRATTICE™ RTM Extra Thick, and STRATTICE™ RTM Laparoscopic are intended for use as soft tissue patches to reinforce soft tissue where weakness exists and for the surgical repair of damaged or ruptured soft tissue membranes. Indications for use of these products 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. STRATTICE™ RTM Laparoscopic is indicated for such uses in open or laparoscopic procedures" (AbbVie, 2025c). Strattice, previously branded LTM Surgical Mesh and LTM-Perforated Surgical Mesh, is considered a Class II medical device and was cleared via the FDA 510(k) pathway (K070560) (K150712) (Product Code: FTM). These devices are indicated for use as a surgical mesh to reinforce soft tissue where weakness exists and to repair damaged or ruptured soft tissue membranes, specifically for hernias and/or body wall defects requiring reinforcing or bridging material (FDA, 2025e). There is insufficient evidence in the published peer-reviewed scientific literature to support the safety and efficacy of Strattice. Studies are primarily in the form of retrospective reviews (Glynou, et al., 2024; Dikmans, et al., 2016; Barber, et al., 2015; Lardi, et al., 2014; Kilchenmann, et al., 2014; Maxwell, et al., 2014; Glasberg and Light, 2012; Ho, et al., 2012).

SurgiMend® PRS: is a fetal/neonatal bovine derived ADM. According to the manufacturer, "SurgiMend is intended for implantation to reinforce soft tissue where weakness exists and for the surgical repair of damaged or ruptured soft tissue membranes. SurgiMend is specifically indicated for: • Plastic and reconstructive surgery. • Muscle flap reinforcement. • Hernia repair including abdominal, inguinal, femoral, diaphragmatic, scrotal, umbilical, and incisional hernias." SurgiMend variants include SurgiMend 1.0-4.0, SurgiMend MP, SurgiMend PRS, and SurgiMend PRS Meshed (Integra LifeSciences Corporation, 2023). SurgiMend is considered a Class II medical device and was cleared via the FDA 510(k) pathway (K083898) (K162965) (K171357) (Product Code: FTM; OXH). These devices are indicated for implantation to reinforce soft tissue where weakness exists and to surgically repair damaged or ruptured soft tissue membranes, including applications in plastic and reconstructive surgery, muscle flap reinforcement, and hernia repair (abdominal, inguinal, femoral, diaphragmatic, scrotal, umbilical, and incisional) (FDA, 2025e). There is insufficient evidence to support the safety and efficacy of SurgiMend for breast reconstruction following mastectomy or lumpectomy (Glynou, et al., 2024; Butterfield, et al., 2013, Gaster, et al., 2013, Ohkuma, et al., 2013; Endress, et al., 2012; Craft, et al., 2011).

Systematic Review and Meta-Analysis

Arnautovic et al. (2025) conducted a systematic review and meta-analysis to evaluate complication rates and outcomes associated with biosynthetic mesh used in implant-based breast reconstruction. The systematic review included 24 studies encompassing 2167 reconstructed breasts and six mesh types. The types of mesh included TIGR Matrix (Novus Scientific) (8 studies), Vicryl (Ethicon, Inc.) (8 studies), DuraSorb (Integra LifeSciences) (1 study), GalaFLEX (Becton, Dickinson and Company) (1 study), polydioxanone (PDO) mesh (Poly-Med) (3 studies), and Type-1a polypropylene (TiLOOP Bra) (PFM Medical) (3 studies). Studies meeting the following criteria were included in the systematic review: implant-based reconstruction (single-stage immediate or two-stage) utilizing the specified meshes and at least 6 months of follow-up. Studies of abdominal mesh and non-English articles were excluded. Outcomes of interest included hematoma, seroma, infection, skin necrosis, and implant loss. The pooled study results revealed the following complication rates: hematoma formation 2.5% (Q=0.25%, I2=58.27%), seroma formation 5.26% (Q=23.81%, I2=37.01%), infection 4.8% (Q=6.02%, I2=149.34%), skin necrosis 5.5% (Q=0.86%, I2=423.78%), and implant loss 3.85% (Q=6.55%, I2=129.07%). The authors concluded that despite differences in mesh characteristics, the overall reported rate of complications was low. Biosynthetic mesh should be considered for breast reconstruction, given its demonstrated safety and potential to decrease short-term complications when compared to ADM. Limitations of the systematic review include heterogeneity between studies, predominance of non-randomized evidence, insufficient power to detect differences between mesh types, incomplete reporting of implant plane, surgical technique, and sterility protocol, and limited data on long-term outcomes.

Glynou et al. (2024) conducted a systematic review and network meta-analysis to compare outcomes among commonly used ADMs in women undergoing implant-based breast reconstruction. The systematic review included 7667 women and 11,988 breasts across 51 studies. Of these, 27 studies contributed to the quantitative network meta-analysis. ADMs included AlloDerm (7133 breasts) (AlloDerm FD, AlloDerm RTU, and unspecified AlloDerm), ARTIA (porcine) (83 breasts), Braxon (porcine) (100 breasts), DermACELL (521 breasts), FlexHD (878 breasts), Strattice (2156 breasts) (porcine), and SurgiMend (1117 breasts) (bovine). Inclusion criteria encompassed women receiving implant-based reconstruction using the specified ADM types in immediate or delayed, unilateral or bilateral procedures. Studies focused on secondary reconstructive procedures such as reconstruction revision, aesthetic or cosmetic procedures, non-implant-based reconstruction, and revision surgeries were excluded. The primary outcome was the incidence of the most commonly reported complications associated with each ADM type, including seroma, hematoma, and wound dehiscence (short term complications) and capsular contracture, rotation, failure (implant removal), and infection (long-term complications). The mean follow-up was 27.8 months. The study results revealed that the complication rates varied. Porcine ADMs had the highest rates of seroma and hematoma formation (10.3% and 2.7%, respectively). AlloDerm FD had the highest rates of wound dehiscence and implant failure (3.1% and 11.8%, respectively), followed by the porcine ADMs (11.2%). AlloDerm FD and the porcine ADMs had the highest rates of infections (11.0% and 11.2%, respectively). Capsular contracture was a rare complication across all ADM types, with no statistically significant differences observed. Compared to AlloDerm RTU, AlloDerm FD showed significantly higher risks of infection, explantation, and wound dehiscence. The authors concluded that overall ADM complication profiles in implant-based breast reconstruction were similar, except for higher risks associated with AlloDerm FD relative to AlloDerm RTU. This suggested ADM choice may not significantly impact overall outcomes, except in specific cases like AlloDerm FD. However, additional high-quality, long-term, two-arm studies are required to confirm the comparative profiles of specific ADM types and to account for potential confounding variables through multivariable regression analysis. The authors noted several limitations in the existing literature, including small sample sizes, potential sources of bias such as conflicts of interest, lack of uniformity in outcome and complication reporting, absence of precise definitions, and variability in clinical practice. Additionally, several studies lacked comprehensive reporting of patient demographic data and details regarding therapeutic interventions.

Ho et al. (2012) conducted a systematic review and meta-analysis to determine an aggregate estimate of risks associated with 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 odds ratio. 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, and skin flap necrosis 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 was 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 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 12847 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% versus 14.0%; seroma, 4.8% versus 3.5%; infection, 5.3% versus 4.7%; and flap necrosis, 6.9% versus 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% versus 1% in the human ADM cohort. 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 ADM cohort, but the results were not statistically significant. Most pooled complication analyses showed significant heterogeneity. The meta-analysis suggested that the use of human ADM increases complication rates compared to submuscular approach.

Suction-Assisted Lipectomy and Excision of Redundant Skin

Suction-assisted lipectomy of the trunk or extremity area is a procedure in which excess fat deposits are removed using a liposuction cannula. Excision of redundant skin is a procedure in which excess skin and/or subcutaneous tissue (e.g., dog ear, standing cone) is removed. Both procedures have the goal of recontouring the body, thereby improving appearance. These procedures may be performed alone or as one component of the flap breast reconstruction procedure. Suction-assisted lipectomy and excision of redundant skin, when performed alone and not as part of a medically necessary flap breast reconstruction procedure are considered cosmetic in nature. When these procedures are performed as part of a medically necessary flap breast reconstruction procedure, they are considered incidental to the primary procedure.

U.S. Food and Drug Administration (FDA)

Breast reconstruction following mastectomy or lumpectomy, including suction-assisted lipectomy and excision of redundant skin, is considered a surgical procedure and does not require FDA review or approval.

Professional Societies/Organizations

National Comprehensive Cancer Network (NCCN): NCCN (2025) published guidelines on breast cancer, including general principles of breast reconstruction, that state:

- "Breast reconstruction may be an option for any patient receiving surgical treatment for breast cancer. All patients undergoing breast cancer treatment should be educated about breast reconstructive options as adapted to their individual clinical situation. However, breast reconstruction should not interfere with the appropriate surgical, medical, and radiation management of the cancer or the scope of appropriate surgical treatment for this disease. Coordinating consultation and surgical treatment with a reconstructive surgeon should be executed within a reasonable time frame. The process of breast reconstruction should not govern the timing or the scope of appropriate surgical treatment for this disease. The availability of or the practicality of breast reconstruction should not result in the delay or refusal of appropriate surgical, medical, and radiation intervention.
- Some patients may choose not to have reconstruction after mastectomy. The option to undergo mastectomy alone with a surgically optimized closure should be offered to all patients as part of a comprehensive discussion of reconstructive options. Achieving the optimal result in this scenario may require additional procedures beyond the initial mastectomy. See BINV-H (6) for patient factors influencing choice of reconstruction.
- Selection of reconstructive option and timing of reconstruction option is based on an assessment of cancer treatment, body habits of patients, obesity, smoking history, comorbidities, and patient concerns. Smoking and obesity (WHO Class 2 and 3) increase the risk of perioperative complications for all types of breast reconstruction. Patients with these high-risk factors should be counseled about their increased risk for complications following breast reconstruction, including donor site complications/hernias and bulges of the abdominal wall, delayed healing, mastectomy skin flap necrosis, total flap failure (obesity), and implant failure (smoking).
- Nipple areolar reconstruction should be offered to patients if the nipple-areolar complex (NAC) has been removed as part of their cancer treatment. Various techniques are available for nipple reconstruction. Three-dimensional (3-D) tattooing can be offered to patients as an option for NAC reconstruction.
- Additionally, patients who are not satisfied with the cosmetic outcome following completion of breast cancer treatment should be offered reconstructive surgery consultation.
- Patients known to harbor genetic mutations that increase the risk of breast cancer may opt to undergo bilateral prophylactic mastectomies with reconstruction. Reconstruction can be performed with prosthetic, autologous tissue, or a combination of implant with autologous tissue.
- Skin-sparing mastectomy should be performed by an experienced breast surgery team that works in a coordinated, multidisciplinary fashion to guide proper patient selection for skin-sparing mastectomy, determine optimal sequencing of the reconstructive procedure(s) in relation to adjuvant therapies, and perform a resection that achieves appropriate surgical margins.
- Revisional surgery may be necessary after breast reconstruction. This may include procedures such as fat grafting, mastopexy, direct excision/suction-assisted lipectomy, contralateral procedures (in cases of unilateral reconstruction), and others. Patients should

be informed before reconstruction that revision surgery may be necessary."

Federal Mandate

"The Women's Health and Cancer Rights Act of 1998 (WHCRA) provides protections for individuals who elect breast reconstruction after a mastectomy. Under WHCRA, group health plans offering mastectomy coverage must provide coverage for certain services relating to the mastectomy, in a manner determined in consultation with the attending physician and the patient.

The required coverage includes:

- All stages of reconstruction of the breast on which the mastectomy was performed;
- Surgery and reconstruction of the other breast to produce a symmetrical appearance;
- Prostheses; and
- Treatment of physical complications of the mastectomy, including lymphedema" U.S. Department of Labor, 2025)

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.

However, WHCRA does not include coverage for:

- breast asymmetry unrelated to mastectomy or lumpectomy;
- deformity related to trauma (e.g., burns); or
- poor cosmetic result after breast reduction or cosmetic surgery.

Health Equity Considerations

Health equity is the highest level of health for all people; health inequity is the avoidable difference in health status or distribution of health resources due to the social conditions in which people are born, grow, live, work, and age.

Social determinants of health are the conditions in the environment that affect a wide range of health, functioning, and quality of life outcomes and risks. Examples include safe housing, transportation, and neighborhoods; racism, discrimination and violence; education, job opportunities and income; access to nutritious foods and physical activity opportunities; access to clean air and water; and language and literacy skills.

Morrow, et al. (2014) conducted a retrospective analysis of women in Los Angeles and Detroit diagnosed with breast cancer who underwent mastectomy and remained disease free at four years to evaluate for breast reconstruction correlates and possible unmet needs of reconstruction. Women (n=485) aged 20–79 years were included in the study if they: were diagnosed with ductal carcinoma in situ (DCIS) or invasive breast cancer between June 2005-February 2007, reported to the National Cancer Institute's Surveillance, Epidemiology, and End Results (SEER) program registries, could complete a questionnaire in English or Spanish, underwent mastectomy and remained disease free at four years. Participants were excluded if they: had stage IV breast cancer, died prior to the initial survey, or were Asian because of enrollment in other studies. In order to ensure sufficient representation of racial/ethnic minorities, Latina and Black women were oversampled. The primary outcome was whether or not a women underwent breast reconstruction

at any time post mastectomy. Patient satisfaction with various aspects of the reconstruction decision making process (i.e., satisfaction with their decision to have reconstruction, whether they regret their reconstruction choice, satisfaction about being informed about reconstructive issues) and reasons why a participant did not have reconstruction or delayed reconstruction were secondary outcomes. Patient demographics (i.e., age, education, race/ethnicity, partner status, income, insurance, smoking status), clinical/treatment factors (i.e., staging, comorbidities, breast size, chemotherapy, radiation, timing of reconstruction), and geographic location were independent variables that were considered. Follow-up via patient surveys took place at a mean of nine- and 50-months post cancer diagnosis. Overall, 41.6% of the 485 patients treated with mastectomy who remained disease-free had breast reconstruction; 24.8% (n=146) of the procedures were done at the time of mastectomy, and 16.8% (n=76) were delayed. Surgery with implants or tissue expanders was the most common type of reconstruction (61.9%). Compared with respondents, non-respondents to the follow-up survey were more likely to be Black (35.2% versus 26.7%; p<0.001) or Latina (17.2% versus 13.3%; p=0.002), more likely to have stage II or III disease (54.9% versus 37.8%; p<0.001), and more likely to have received mastectomy (37.5% versus 30.8%; p<0.001). Black patients, those with a high school or lower education level, those without private insurance, women with any major co-morbid condition, older women, those residing in Los Angeles County, and those patients who received chemotherapy were significantly less likely to undergo reconstruction than their counterparts. A total of 13.3% of women reported being dissatisfied with the decision-making process and was associated with being Black or Latina (p=0.032) but not with lower income or education levels. The most common reasons among all women for not undergoing reconstruction was a desire to avoid additional surgery (48.5%), the opinion that reconstruction was unimportant (33.8%), and fear of implants (36.3%). However, ethnic minority groups were less likely to report the desire to avoid additional surgery (70.0% for non-Black, non-Latina patients versus 39.7% and 34.1% for Blacks and Latinas, respectively; p<0.001) or that reconstruction was not important (42.4% for non-Black, non-Latina patients versus 21.6% and 31.3% for Blacks and Latinas, respectively; p=0.043). More Latinas reported concerns about cancer detection interference, procedure complications, or not being able to take time off from work or family. More Blacks and Latinas reported not having insurance coverage as a barrier to reconstruction. The study is limited by the small geographic sampling, retrospective study design, and possible errors in patient recall. This study highlights the need for additional patient level education on factors that negatively impact the breast reconstruction decision making process especially among minority women.

Appendix

Product	CPT® Code	HCPCS Code
Considered Medically Necessary		
AlloMax™	15777	C1781, Q4100
Avance Nerve Graft®	64912, 64913	C9399, Q4100
Cortiva®	15777	C9399, Q4100
DermACELL®	15777	Q4122
FlexHD® Acellular Hydrated Dermis	15777	Q4128
GalaFLEX™ Scaffold	15777	C1781, C9399, Q4100
GalaFLEX 3DR™ Scaffold	15777	C1781, C9399, Q4100
GalaFLEX 3D™ Scaffold	15777	C1781, C9399,Q4100
GalaFLEX Lite™ Scaffold	15777	C1781, C9399, Q4100
Considered Experimental, Investigational, Or Unproven		

ARTIA™ Reconstructive Tissue Matrix	15777	C1763
BellaDerm® Acellular Hydrated Dermis	15777	C1781, C9399, Q4100
Biodesign® Nipple Reconstruction Cylinder	19350	C1763
DuraSorb® Monofilament Mesh	15777	C1781
Essence Acellular Dermal Matrix	15777	C1762
JUVÉDERM®	11950-11954, 19530	C9399
OviTex® PRS	15777	C1781
Permacol™	15777	C9364
Phasix™ Mesh	15777	C1781
Radiesse®	11950-11954, 19350	Q2026
Renuva®	No specific code	J3590
SimpliDerm®	15777	C9399, Q4100
Strattice™ Reconstructive Tissue Matrix	15777	Q4130
SurgiMend® PRS	15777	C9358, C9360

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Revision Details

Type of Revision	Summary of Changes	Date
Annual Review	• Revised policy statement for breast reconstruction following mastectomy or lumpectomy. • Removed policy statement for intraoperative assessment of tissue perfusion.	4/15/2026

	• Revised policy statement for skin and soft tissue substitutes considered medically necessary. • Revised policy statement for skin and soft tissue substitutes considered experimental, investigational, or unproven. • Removed policy statement for the use of adipose-derived stem cells in autologous fat transplantation and xenograft cartilage grafting. • Removed policy statement for subsequent surgical implantation of a new U.S. Food and Drug Administration (FDA)-approved breast implant. • Removed policy statement for external breast prostheses and mastectomy bras. • Added Essence Acellular Dermal Matrix to list of EIU products.	
Annual Review	• Added GalaFLEX® products as medically necessary for breast reconstruction	4/15/2025
Focused Review	• Revised policy statement for the list of non-covered products.	9/15/2024
Annual Review	• Revised policy statement for areolar and nipple reconstruction. • Added policy statement for "flat closure chest wall reconstruction". • Revised policy statement for oncoplastic reconstruction. • Added policy statement for "DuraSorb® Monofilament Mesh/ Polydioxanone Surgical Scaffold™" to the list of EIU products. • Removed policy statement for hMatrix and Repriza. • Revised policy statement for lipectomy or excision of redundant skin statement.	3/15/2024