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Medicaid Medical Coverage Policy

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Table of Contents

Description Coverage Limitations References Appendix Coverage Determination Coding Information Change Summary

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Description

Breast reconstruction surgery rebuilds a breast's shape following a mastectomy or trauma and may be performed immediately, be delayed or be completed in stages. The surgeon forms a breast mound by using autologous tissue taken from other areas of an individual's body (abdomen, back, buttocks, thighs), placing an artificial implant, or using a tissue expander if necessary, depending on the final desired breast size.

Breast implants are silicone sacs filled with saline (salt water) or silicone gel. The development of scar tissue around a breast implant may necessitate a capsulotomy (surgical opening and release of scar tissue) or capsulectomy (surgical removal of the entire capsule containing the breast implant surrounded by abnormally thick, hardened tissue).

The type of reconstruction recommended (autologous tissue or implants) depends on an individual's age, body composition, general health status, method of planned cancer treatment or other reason for reconstruction.

Breast reconstruction may require multiple surgeries, such as:

- Nipple and areola reconstruction and tattoo pigmentation
- Revision surgery involving the breast and/or donor site
- Surgery on the opposite breast to correct asymmetry

Autologous fat graft, autologous fat transplant (lipoinjection or lipomodeling) via excision lipectomy, suction lipectomy or liposuction involves the removal of adipose tissue (fat) from another area of the body (abdomen, buttocks, thighs, etc.) which is then transferred to the breast(s) during initial reconstructive surgery.

Chest wall reconstruction with flat closure is a reconstructive surgery option for an individual who is not a candidate for or has chosen not to undergo breast reconstruction with autologous tissue or an implant. The procedure may be done at the time of mastectomy or may be delayed and involves the removal and tightening of extra tissue to create a flat chest wall contour.

Oncoplastic surgery refers to integrating tumor removal and immediate breast reconstruction into the initial surgical procedure. Generally, the surgical oncologist removes the tumor, and the plastic surgeon immediately begins reconstruction.

Examples of breast reconstruction techniques (also called flaps) that use **autologous tissue** include, but may not be limited to:

- Deep circumflex iliac artery (DCIA)/Ruben's free flap
- Deep inferior epigastric perforator (DIEP)
- Gluteal artery perforator (GAP)
- Latissimus dorsi (LD)
- Profunda artery perforator (PAP)
- Superficial inferior epigastric artery (SIEA)
- Thoracodorsal artery perforator (TAP or TDAP)
- Transverse gracilis (TUG)
- Transverse rectus abdominus muscle (TRAM)

The <u>flap description and name</u> are related to the muscles or blood-supplying vessels used and involve surgically removing tissue, typically fat, skin and muscle, from one area of the body and reattaching it to the chest. Pedicled flaps are positioned with the corresponding vascular origin intact while free flaps require microsurgery to connect the tiny blood vessels needed to supply the transplanted tissue.

Other technologies used or being studied for use in conjunction with breast reconstruction procedures include, but may not be limited to:

Intraoperative tissue perfusion assessment methods have been developed to assist surgeons in determining the viability of tissue-transfer circulation during micro, plastic and reconstructive surgery. The suggested benefits involve reducing tissue necrosis (death) and decreasing the need for a second corrective procedure.

• One method, **indocyanine green (ICG) fluorescence angiography**, also referred to as **fluorescent angiography** or **spy angiography**, involves intravenous injection of ICG dye during surgery. The ICG dye binds to proteins in the blood and emits light when stimulated by a low energy laser or near infrared light. The emitted light facilitates visualization of blood flow through the operative tissue, thus

Page: 3 of 13

determining perfusion and viability. Examples of US Food & Drug Administration (FDA)-approved imaging devices or systems used to capture fluorescent images for this purpose include, but may not be limited to, Explorer Air II, FloNavi, Fluobeam LM, Infrared 800 with Flow 800 option, Leica FL 800, PDE-Gen3, SPY fluorescent imaging systems (SPY Elite, SPY-PHI) and EleVision IR Platform (including the VS3-Iridium System).

- **Multispectral imaging** involves taking several photographs under many different wavelengths of light in order to ascertain tissue oxygenation measurements for selected tissue regions. The camera determines the approximate values of oxygen saturation (StO₂), relative oxyhemoglobin (HbO₂) and deoxyhemoglobin levels (Hgb) in superficial tissues and displays a two-dimensional color-coded image of tissue oxygenation. The Snapshot_{NIR} is an example of an FDA-approved multispectral imaging device.
- Near-infrared spectroscopy (NIRS) technology is being explored to assess circulation or perfusion in tissue samples. While near-infrared light is scattered in human tissue, some structures, such as hemoglobin, absorb it. NIRS technology uses reflected light to determine the ratio of oxyhemoglobin (HgbO₂) and deoxyhemoglobin (Hgb) to permit real-time measurement of tissue oxygen saturation (StO₂) within the selected tissue. The T.Ox and its newer modifications the Intra.Ox and Intra.Ox 2.0 are examples of FDA-approved devices that measure tissue oximetry.
- Visible light spectroscopy (VLS) uses a sensor with a white LED light to illuminate target tissue and a light detector that captures reflected light. The sensor is connected to a software-based system using a range of reflected light values from visible light wavelengths. The single-use surface sensors are intended to measure percent tissue oxygen saturation (StO₂) on any skin surface to purportedly assist with monitoring skin flap perfusion after microvascular reconstructive procedures. The T-Stat is an example of an FDA-cleared device.

Lymphatic microvascular surgery is proposed in conjunction with reconstructive surgery to <u>prevent</u> the development of lymphedema that may occur following a mastectomy with axillary lymph node dissection. Lymphatic microsurgical preventive healing approach (LYMPHA) procedures include, but may not be limited to, lymphaticovenous anastomosis (LVA), lymphaticovenous bypass (LVB) or lymph node transfer. **(Refer to Coverage Limitations section)**

Coverage Determination

Requests for autologous fat graft, autologous fat transplant (lipoinjection or lipomodeling) via excision lipectomy, suction lipectomy or liposuction as stand-alone procedures (not in conjunction with other breast reconstruction techniques) require review by a medical director.

Humana members may be eligible under the Plan for **breast reconstruction** following, or in conjunction with:

• A medically necessary mastectomy or lumpectomy (regardless of the date of the mastectomy or lumpectomy); **OR**

Breast Reconstruction Page: 4 of 13

- A medically necessary prophylactic mastectomy; OR
- Trauma (within 12 months postinjury);

AND for surgical procedures including, but may not be limited to:

- Chest wall reconstruction with flat closure; OR
- Free or pedicled flap (DIEP, GAP [IGAP, SGAP], LD, PAP, Ruben's, SIEA, TAP, TDAP, TUG, TRAM, or others);
 OR
- Insertion of breast implants; **OR**
- Insertion of tissue expanders; OR
- Mastopexy (including prior to a nipple-sparing mastectomy); OR
- Nipple reconstruction and repigmentation (tattoo); OR
- Reduction mammaplasty <u>only</u> if necessary to preserve nipple viability prior to a nipple-sparing mastectomy (medical director review required)

Correction of Breast Asymmetry

Breast reconstruction surgery to correct breast asymmetry is considered cosmetic except for:

- A medically necessary lumpectomy that results in a deformity; OR
- A medically necessary mastectomy; OR
- Complications with or removal of breast implant(s) following a medically necessary mastectomy; OR
- Trauma (within 12 months postinjury)

Further modification related to achieving symmetry is subject to medical necessity and does not include procedures to fill the flap donor site.

Capsulectomy, Capsulotomy, Breast Implant Removal

Humana members may be eligible under the Plan for **capsulectomy, capsulotomy or breast implant removal** when the following criteria are met:

• Breast implants were placed in conjunction with a medically necessary (noncosmetic) surgery;

Breast Reconstruction Page: 5 of 13

AND any of the following

- Capsular contracture (<u>Baker grade</u> III or IV); OR
- o Extrusion; OR
- Rupture of saline filled, silicone gel or alternative breast implant (confirmed by imaging such as magnetic resonance imaging [MRI] or ultrasound); OR
- o Implant infection refractory to medical management (eg, antibiotics) unless contraindicated;

AND either:

- Infection confirmed by microbiological analysis of peri-implant fluid aspirate; OR
- Presence of symptoms such as fever, redness, elevated white blood cell (WBC) count

Breast Implant Associated Anaplastic Large Cell Lymphoma

Note: The following criteria applies **ONLY** to implant removal related to breast implant associated anaplastic large cell lymphoma BIA-ALCL, as total capsulectomy (complete surgical resection) is the only recommended treatment.^{3,22,23,42}

Humana members may be eligible under the Plan for **total capsulectomy with breast implant removal** for the following indications:

- Pathologic confirmation of breast implant associated anaplastic large cell lymphoma BIA-ALCL by cytological evaluation of seroma fluid or mass with Wright Giemsa stained smears and cell block immunohistochemistry/flow cytometry testing for cluster of differentiation (CD30) and anaplastic lymphoma kinase (ALK) markers⁴²; OR
- Removal of Allergan BIOCELL textured breast implants and tissue expanders (due to increased risk of breast implant-associated anaplastic large cell lymphoma [BIA-ALCL])

Breast Implant Associated Squamous Cell Carcinoma

Humana members may be eligible under the Plan for **total capsulectomy with breast implant removal** for a confirmed diagnosis of breast implant associated squamous cell carcinoma.

Humana members may be eligible under the Plan for **reinsertion of breast implants** following a medically necessary removal.

Coverage Limitations

Humana members may **NOT** be eligible under the Plan for **breast reconstruction, capsulectomy, capsulotomy or breast implant removal** procedures other than those listed above, or for any indications other than those listed above. All other indications are considered not medically necessary.

Humana members may **NOT** be eligible under the Plan for **nipple reconstruction for inverted nipples or breast reconstruction for naturally occurring breast asymmetry** as these are considered cosmetic.

Humana members may **NOT** be eligible under the Plan for **lymphatic microvascular surgery** in conjunction with breast reconstruction to prevent lymphedema. This is considered experimental/investigational as it is not identified as widely used and generally accepted for the proposed use as reported in nationally recognized peer-reviewed medical literature published in the English language.

Autologous fat graft, autologous fat transplant (lipoinjection or lipomodeling) via excision lipectomy, suction lipectomy or liposuction when performed in conjunction with other breast reconstruction techniques is considered integral to the primary procedure and not separately reimbursable.

<u>Intraoperative assessment of tissue perfusion</u> by any technology including, but not limited to, fluorescence angiography, fluorescent angiography, multispectral imaging, near-infrared spectroscopy, oximetry or visible light spectroscopy is considered integral to the primary procedure and not separately reimbursable.

Coding Information

Any codes listed on this policy are for informational purposes only. Do not rely on the accuracy and inclusion of specific codes. Inclusion of a code does not guarantee coverage and/or reimbursement for a service or procedure.

CPT® Code(s)	Description	Comments
11920	Tattooing, intradermal introduction of insoluble opaque pigments to correct color defects of skin, including micropigmentation; 6.0 sq cm or less	
11921	Tattooing, intradermal introduction of insoluble opaque pigments to correct color defects of skin, including micropigmentation; 6.1 to 20.0 sq cm	
11922	Tattooing, intradermal introduction of insoluble opaque pigments to correct color defects of skin, including micropigmentation; each additional 20.0 sq cm, or part thereof (List separately in addition to code for primary procedure)	
11970	Replacement of tissue expander with permanent implant	

Page: 7 of 13

11971	Removal of tissue expander without insertion of implant	
14000	Adjacent tissue transfer or rearrangement, trunk; defect 10 sq cm or less	
14001	Adjacent tissue transfer or rearrangement, trunk; defect 10.1 sq cm to 30.0 sq cm	
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)	
15877	Suction assisted lipectomy; trunk	
19316	Mastopexy	
19318	Breast reduction	
19325	Breast augmentation with implant	
19328	Removal of intact breast implant	
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)	
19361	Breast reconstruction; with latissimus dorsi flap	
19364	Breast reconstruction; with free flap (eg, fTRAM, DIEP, SIEA, GAP flap)	
19367	Breast reconstruction; with single-pedicled transverse rectus abdominis myocutaneous (TRAM) flap	
19368	Breast reconstruction; with single-pedicled transverse rectus abdominis myocutaneous (TRAM) flap, requiring separate microvascular anastomosis (supercharging)	
19369	Breast reconstruction; with bipedicled transverse rectus abdominis myocutaneous (TRAM) flap	
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	

Page: 8 of 13

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)			
19396	Preparation of moulage for custom breast implant			
19499	Unlisted procedure, breast			
76499	Unlisted diagnostic radiographic procedure			
CPT [®] Category III Code(s)	Description	Comments		
No code(s) i	No code(s) identified			
HCPCS Code(s)	Description	Comments		
C1789	Prosthesis, breast (implantable)			
L8600	Implantable breast prosthesis, silicone or equal			
S2066	Breast reconstruction with gluteal artery perforator (GAP) flap, including harvesting of the flap, microvascular transfer, closure of donor site and shaping the flap into a breast, unilateral			
S2067	Breast reconstruction of a single breast with "stacked" deep inferior epigastric perforator (DIEP) flap(s) and/or gluteal artery perforator (GAP) flap(s), including harvesting of the flap(s), microvascular transfer, closure of donor site(s) and shaping the flap into a breast, unilateral			
S2068	Breast reconstruction with deep inferior epigastric perforator (DIEP) flap or superficial inferior epigastric artery (SIEA) flap, including harvesting of the flap, microvascular transfer, closure of donor site and shaping the flap into a breast, unilateral			

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Page: 10 of 13

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Page: 11 of 13

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Appendix

Appendix A – Baker Grading Scale⁴¹

Grade	Breast appearance
Grade I	Breast is normally soft and appears natural
Grade II	Breast is firm but appears normal
Grade III	Breast is firm and appears abnormal
Grade IV	Breast is hard, painful and appears abnormal

Appendix B – Autologous Tissue Procedures

Flap Name	Description
Deep circumflex iliac artery (DCIA), also called Ruben's flap	Tissue overlying or just above the iliac crest (hip) along with a DCIA perforator vessel are harvested for use in cases when the abdominal tissue is insufficient due to a previous abdominoplasty or TRAM procedure
Deep inferior epigastric perforator (DIEP)	Fat and skin are moved to the chest from the lower abdominal wall with the vessel in the transplanted tissue reconnected to a vessel under the arm to provide blood supply
Gluteal artery perforator (GAP)	Tissue is harvested from the buttocks with perforating vessels from either the superior gluteal artery (SGAP) or inferior gluteal artery (IGAP) as the blood supply for the transplanted tissue
Latissimus dorsi (LD)	Harvested tissue (skin and muscle) from the back is tunneled through the axilla (underarm) with the blood supplying vessels (the thoracodorsal artery and vein) intact
Profunda artery perforator (PAP)	Skin, fat and blood vessels from the back of the upper thigh are transplanted to the chest
Superficial inferior epigastric artery (SIEA)	Uses the same abdominal tissue as the DIEP flap but different blood supplying vessels
Thoracodorsal artery perforator (TAP or TDAP)	Tissue retrieved from the same anatomical area as the LD flap however, only skin and subcutaneous tissue are harvested, leaving the latissimus dorsi muscle intact
Transverse gracilis (TUG) flap	Tissue retrieved from the upper posterior thigh and lower buttock area for individuals with insufficient lower abdominal fat
Transverse rectus abdominus muscle (TRAM)	Skin, fat, blood vessels and at least one abdominal muscle are moved from the lower abdomen to the chest area and the tissue volume is often sufficient enough to shape the breast without an implant

Page: 13 of 13

Change Summary

01/01/2025 New Policy.