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## **Medicare Advantage Medical Coverage Policy**

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#### **Disclaimer**

**Change Summary** 

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# **Related Medicare Advantage Medical/Pharmacy Coverage Policies**

None

### **Related Documents**

Please refer to <a href="CMS website">CMS website</a> for the most current applicable National Coverage Determination (NCD)/Local Coverage Determination (LCD)/Local Coverage Article (LCA)/CMS Online Manual System/Transmittals.

			Jurisdiction	
Туре	Title	ID	Medicare	Applicable
		Number	Administrative	States/Territories
			Contractors (MACs)	

NCD	Breast Reconstruction Following Mastectomy	140.2		
Internet- Only Manuals (IOMs)	Chapter 16 General Exclusions from Coverage; Section 120 Cosmetic Surgery	Medicare Benefit Policy Manual		
LCD LCA	Cosmetic and Reconstructive Surgery	<u>L39051</u> <u>A58774</u>	J5, J8 - Wisconsin Physicians Service Insurance Corporation	IA, KS, MO, NE IN, MI
LCD LCA	Cosmetic and Reconstructive Surgery	<u>L39506</u> <u>A59299</u>	J15 - CGS Administrators, LLC (Part A/B MAC)	кү, он
LCD LCA	Plastic Surgery	<u>L35163</u> <u>A57221</u>	JE - Noridian Healthcare Solutions, LLC	CA, HI, NV, American Samoa, Guam, Northern Mariana Islands
LCD LCA	Billing and Coding: Plastic Surgery	L37020 A57222	JF - Noridian Healthcare Solutions, LLC	AK, AZ, ID, MT, ND, OR, SD, UT, WA, WY
LCD LCA	Cosmetic and Reconstructive Surgery	L35090 A56587	JH, JL - Novitas Solutions, Inc. (Part A/B MAC)	AR, CO, NM, OK, TX, LA, MS DE, D.C., MD, NJ, PA
LCD LCA	Cosmetic and Reconstructive Surgery  Near-Infrared Spectroscopy in Wound and Flap Management	L33428 A56658 L39385 A59158	JJ, JM - Palmetto GBA (Part A/B MAC)	AL, GA, TN NC, SC, VA, WV
LCD LCA	Cosmetic and Reconstructive Surgery	L38914 A58573	JN - First Coast Service Options, Inc. (Part A/B MAC)	FL, PR, U.S. VI

# **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 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, Fluobeam LM, Infrared 800 with Flow 800 option, Leica FL 800, PDE-Neo, PDE-Neo II, 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 (StO<sub>2</sub>), relative oxyhemoglobin (HbO<sub>2</sub>) and deoxyhemoglobin levels (Hgb) in superficial tissues and displays a two-dimensional color-coded image of tissue oxygenation. The Snapshot<sub>NIR</sub> 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 (HgbO<sub>2</sub>) and deoxyhemoglobin (Hgb) to permit real-time measurement of tissue oxygen saturation (StO<sub>2</sub>) within the selected tissue. The T.Ox and its newer modification the Intra.Ox 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 (StO<sub>2</sub>) 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.

## **Coverage Determination**

iCare follows the CMS requirements that only allows coverage and payment for services that are reasonable and necessary for the diagnosis and treatment of illness or injury or to improve the functioning of a malformed body member except as specifically allowed by Medicare.

In interpreting or supplementing the criteria above and in order to determine medical necessity consistently, iCare may consider the following criteria:

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.<sup>25,26</sup>

**Breast reconstruction** will be considered medically reasonable and necessary when the following requirements are met:

- After or in conjunction with a medically necessary mastectomy or lumpectomy (regardless of the date of the mastectomy or lumpectomy); OR
- After or in conjunction with a medically necessary prophylactic mastectomy; OR
- Due to a congenital abnormality<sup>18</sup>; OR
- Due to trauma (generally considered to be 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

### **Correction of Breast Asymmetry**

Breast reconstruction surgery to correct breast asymmetry will be considered medically reasonable and necessary when any of the following requirements are met:

A medically necessary lumpectomy that results in a deformity; OR

- After or in conjunction with a medically necessary mastectomy; OR
- Trauma (within 12 months postinjury); OR
- Complications with or removal of breast implant(s) because of any of the following:
  - Broken or failed implant
  - o Infection,
  - o Implant extrusion,
  - Siliconoma or granuloma
  - o Painful capsular contracture with disfigurement
  - Interference with diagnosis of breast cancer and/or
  - o Implant complications/removal following a medically necessary mastectomy

## Capsulectomy, Capsulotomy, Breast Implant Removal

**Capsulectomy, capsulotomy or breast implant removal** will be considered medically reasonable and necessary for the following indications:

- Painful capsular contracture; OR
- Extrusion; OR
- Confirmed broken or failed implant; OR
- Siliconoma or granuloma; **OR**
- Interference with diagnosis of breast cancer; OR
- Implant infection confirmed by either:
  - 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.<sup>3,41,42,61</sup>

**Total capsulectomy with breast implant removal** will be considered medically reasonable and necessary for either of 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) markers<sup>61</sup>; OR

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 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**

**Total capsulectomy with breast implant removal** will be considered medically reasonable and necessary for a confirmed diagnosis of breast implant associated squamous cell carcinoma.

**Reinsertion of breast implants** will be considered medically reasonable and necessary following a medically necessary removal.

The use of the criteria in this Medicare Advantage Medical Coverage Policy provides clinical benefits highly likely to outweigh any clinical harms. Services that do not meet the criteria above are not medically necessary and thus do not provide a clinical benefit. Medically unnecessary services carry risks of adverse outcomes and may interfere with the pursuit of other treatments which have demonstrated efficacy.

## **Coverage Limitations**

<u>US Government Publishing Office. Electronic code of federal regulations: part 411 – 42 CFR § 411.15 - Particular services excluded from coverage</u>

Cosmetic surgery or expenses incurred in connection with such surgery is not a covered Medicare benefit. Cosmetic surgery includes any surgical procedure directed at improving appearance, except when required for the prompt (ie, as soon as medically feasible) repair of accidental injury or for the improvement of the functioning of a malformed body member. These treatments and services fall within the Medicare program's statutory exclusion that prohibits payment for items and services that have not been demonstrated to be reasonable and necessary for the diagnosis and treatment of illness or injury (§1862(a)(1) of the Act).

Note: This exclusion does not apply to surgery for therapeutic purposes which coincidentally also serves some cosmetic purpose.<sup>24</sup>

The following <u>intraoperative assessment of tissue perfusion</u> methods will not be considered medically reasonable and necessary<sup>13,21</sup>:

- Fluorescence (fluorescent) angiography
- Multispectral imaging
- Near-infrared oximetry/spectroscopy,
- Visible light spectroscopy

**Lymphatic microvascular surgery** in conjunction with breast reconstruction to prevent lymphedema will not be considered medically reasonable and necessary.

A review of the current medical literature shows that the evidence is insufficient to determine that this service is standard medical treatment. There remains an absence of randomized, blinded clinical studies examining benefit and long-term clinical outcomes establishing the value of this service in clinical management.

#### **Summary of Evidence**

## Lymphatic Microvascular Surgery

A review of the current medical literature indicates that the existing published studies are of poor or very poor quality<sup>29</sup> due to a high risk of bias. Reasons for bias include three or more of the following: single-center focus, retrospective design, small size, and lack of randomization, blinding, and parallel controls. The only available randomized-controlled trial was performed outside of the US using data from a single center. Comparisons across studies is challenging, given the variation in how lymphedema was defined, measured and graded.<sup>38</sup>

The findings from an overall low-quality body of evidence suggest that lymphatic microvascular surgery for individuals with breast cancer who require lymph node dissection, may have a positive impact on the prevention of lymphedema<sup>29,38</sup> resulting in a relatively low incidence of transient or persistent lymphedema. Data from two recent meta-analyses also support this conclusion with a reasonable degree of uncertainty given the lack of comparative evidence and retrospective nature of many study designs. Additional experimental studies, large multicenter retrospective studies, and studies having follow-up to 5 or more years would help ascertain which patients would benefit most and establish long term safety and efficacy.<sup>38</sup>

# **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 <sup>®</sup> 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	
11971	Removal of tissue expander without insertion of implant	

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13100	Repair, complex, trunk; 1.1 cm to 2.5 cm	
13101	Repair, complex, trunk; 2.6 cm to 7.5 cm	
13102	Repair, complex, trunk; each additional 5 cm or less (List separately in addition to code for primary procedure)	
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	
14301	Adjacent tissue transfer or rearrangement, any area; defect 30.1 sq cm to 60.0 sq cm	
14302	Adjacent tissue transfer or rearrangement, any area; each additional 30.0 sq cm, or part thereof (List separately in addition to code for primary procedure)	
15650	Transfer, intermediate, of any pedicle flap (eg, abdomen to wrist, Walking tube), any location	
15740	Flap; island pedicle requiring identification and dissection of an anatomically named axial vessel	
15770	Graft; derma-fat-fascia	
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)	

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19367	Breast reconstruction; with single-pedicled transverse rectus abdominis myocutaneous (TRAM) flap			
	, , , ,			
	Breast reconstruction; with single-pedicled transverse rectus			
19368	abdominis myocutaneous (TRAM) flap, requiring separate			
	microvascular anastomosis (supercharging)			
19369	Breast reconstruction; with bipedicled transverse rectus			
15505	abdominis myocutaneous (TRAM) flap			
19370	Revision of peri-implant capsule, breast, including capsulotomy,			
19370	capsulorrhaphy, and/or partial capsulectomy			
19371	Peri-implant capsulectomy, breast, complete, including removal			
193/1	of all intracapsular contents			
	Revision of reconstructed breast (eg, significant removal of			
40200	tissue, re-advancement and/or re-inset of flaps in autologous			
19380	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	Description	Comments		
Code(s)				
No code(s) identified				
HCPCS	Description	C		
Code(s)	Description	Comments		
C1789	Prosthesis, breast (implantable)			
C9733	Nonophthalmic fluorescent vascular angiography			
L8600	Implantable breast prosthesis, silicone or equal			

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# Appendix

# **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

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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

# **Change Summary**

- 01/01/2024 New Policy.

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