Breast Reconstruction

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Medicare Advantage Medical Coverage Policy

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Related Medicare Advantage Medical/Pharmacy Coverage Policies

None

Related Documents

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

<table>
<thead>
<tr>
<th>Type</th>
<th>Title</th>
<th>ID Number</th>
<th>Jurisdiction Medicare Administrative Contractors (MACs)</th>
<th>Applicable States/Territories</th>
</tr>
</thead>
</table>
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 **flap description and name** 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 ($StO_2$), relative oxyhemoglobin ($HbO_2$) 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 ($HgbO_2$) and deoxyhemoglobin ($Hgb$) to permit real-time measurement of tissue oxygen saturation ($StO_2$) 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 ($StO_2$) 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 prevent 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.  

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; 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 only 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
  - Infection,
  - Implant extrusion,
  - Siliconeoma or granuloma
  - Painful capsular contracture with disfigurement
  - Interference with diagnosis of breast cancer and/or
  - 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
• Siliconeoma 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.\(^{3,41,42,61}\)

**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\(^{61}\); 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**

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**

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

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.24

The following *intraoperative assessment of tissue perfusion* methods will not be considered medically reasonable and necessary13,21:

- 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 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.

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 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.

**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.

<table>
<thead>
<tr>
<th>CPT® Code(s)</th>
<th>Description</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>11920</td>
<td>Tattooing, intradermal introduction of insoluble opaque pigments to correct color defects of skin, including micropigmentation; 6.0 sq cm or less</td>
<td></td>
</tr>
<tr>
<td>11921</td>
<td>Tattooing, intradermal introduction of insoluble opaque pigments to correct color defects of skin, including micropigmentation; 6.1 to 20.0 sq cm</td>
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<tr>
<td>11922</td>
<td>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)</td>
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</tr>
<tr>
<td>11970</td>
<td>Replacement of tissue expander with permanent implant</td>
<td></td>
</tr>
<tr>
<td>11971</td>
<td>Removal of tissue expander without insertion of implant</td>
<td></td>
</tr>
<tr>
<td>Code</td>
<td>Description</td>
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<tr>
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<td>-----------------------------------------------------------------------------</td>
<td></td>
</tr>
<tr>
<td>13100</td>
<td>Repair, complex, trunk; 1.1 cm to 2.5 cm</td>
<td></td>
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<tr>
<td>13101</td>
<td>Repair, complex, trunk; 2.6 cm to 7.5 cm</td>
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<tr>
<td>13102</td>
<td>Repair, complex, trunk; each additional 5 cm or less (List separately in addition to code for primary procedure)</td>
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<tr>
<td>14000</td>
<td>Adjacent tissue transfer or rearrangement, trunk; defect 10 sq cm or less</td>
<td></td>
</tr>
<tr>
<td>14001</td>
<td>Adjacent tissue transfer or rearrangement, trunk; defect 10.1 sq cm to 30.0 sq cm</td>
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<tr>
<td>14301</td>
<td>Adjacent tissue transfer or rearrangement, any area; defect 30.1 sq cm to 60.0 sq cm</td>
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</tr>
<tr>
<td>14302</td>
<td>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)</td>
<td></td>
</tr>
<tr>
<td>15650</td>
<td>Transfer, intermediate, of any pedicle flap (eg, abdomen to wrist, Walking tube), any location</td>
<td></td>
</tr>
<tr>
<td>15740</td>
<td>Flap; island pedicle requiring identification and dissection of an anatomically named axial vessel</td>
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<tr>
<td>15770</td>
<td>Graft; derma-fat-fascia</td>
<td></td>
</tr>
<tr>
<td>15771</td>
<td>Grafting of autologous fat harvested by liposuction technique to trunk, breasts, scalp, arms, and/or legs; 50 cc or less injectate</td>
<td></td>
</tr>
<tr>
<td>15772</td>
<td>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)</td>
<td></td>
</tr>
<tr>
<td>15877</td>
<td>Suction assisted lipectomy; trunk</td>
<td></td>
</tr>
<tr>
<td>19316</td>
<td>Mastopexy</td>
<td></td>
</tr>
<tr>
<td>19318</td>
<td>Breast reduction</td>
<td></td>
</tr>
<tr>
<td>19325</td>
<td>Breast augmentation with implant</td>
<td></td>
</tr>
<tr>
<td>19328</td>
<td>Removal of intact breast implant</td>
<td></td>
</tr>
<tr>
<td>19330</td>
<td>Removal of ruptured breast implant, including implant contents (eg, saline, silicone gel)</td>
<td></td>
</tr>
<tr>
<td>19340</td>
<td>Insertion of breast implant on same day of mastectomy (ie, immediate)</td>
<td></td>
</tr>
<tr>
<td>19342</td>
<td>Insertion or replacement of breast implant on separate day from mastectomy</td>
<td></td>
</tr>
<tr>
<td>19350</td>
<td>Nipple/areola reconstruction</td>
<td></td>
</tr>
<tr>
<td>19355</td>
<td>Correction of inverted nipples</td>
<td></td>
</tr>
<tr>
<td>19357</td>
<td>Tissue expander placement in breast reconstruction, including subsequent expansion(s)</td>
<td></td>
</tr>
<tr>
<td>19361</td>
<td>Breast reconstruction; with latissimus dorsi flap</td>
<td></td>
</tr>
<tr>
<td>19364</td>
<td>Breast reconstruction; with free flap (eg, fTRAM, DIEP, SIEA, GAP flap)</td>
<td></td>
</tr>
<tr>
<td>Code</td>
<td>Description</td>
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<td></td>
</tr>
<tr>
<td>19367</td>
<td>Breast reconstruction; with single-pedicled transverse rectus abdominis myocutaneous (TRAM) flap</td>
<td></td>
</tr>
<tr>
<td>19368</td>
<td>Breast reconstruction; with single-pedicled transverse rectus abdominis myocutaneous (TRAM) flap, requiring separate microvascular anastomosis (supercharging)</td>
<td></td>
</tr>
<tr>
<td>19369</td>
<td>Breast reconstruction; with bipedicled transverse rectus abdominis myocutaneous (TRAM) flap</td>
<td></td>
</tr>
<tr>
<td>19370</td>
<td>Revision of peri-implant capsule, breast, including capsulotomy, capsulorrhaphy, and/or partial capsulectomy</td>
<td></td>
</tr>
<tr>
<td>19371</td>
<td>Peri-implant capsulectomy, breast, complete, including removal of all intracapsular contents</td>
<td></td>
</tr>
<tr>
<td>19380</td>
<td>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)</td>
<td></td>
</tr>
<tr>
<td>19396</td>
<td>Preparation of moulage for custom breast implant</td>
<td></td>
</tr>
<tr>
<td>19499</td>
<td>Unlisted procedure, breast</td>
<td></td>
</tr>
<tr>
<td>76499</td>
<td>Unlisted diagnostic radiographic procedure</td>
<td></td>
</tr>
</tbody>
</table>

**References**


Appendix B – Autologous Tissue Procedures

<table>
<thead>
<tr>
<th>Flap Name</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Deep circumflex iliac artery (DCIA), also called Ruben’s flap</td>
<td>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</td>
</tr>
<tr>
<td>Deep inferior epigastric perforator (DIEP)</td>
<td>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</td>
</tr>
<tr>
<td>Gluteal artery perforator (GAP)</td>
<td>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</td>
</tr>
<tr>
<td>Latissimus dorsi (LD)</td>
<td>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</td>
</tr>
<tr>
<td>Profunda artery perforator (PAP)</td>
<td>Skin, fat and blood vessels from the back of the upper thigh are transplanted to the chest</td>
</tr>
<tr>
<td>Superficial inferior epigastric artery (SIEA)</td>
<td>Uses the same abdominal tissue as the DIEP flap but different blood supplying vessels</td>
</tr>
<tr>
<td>Thoracodorsal artery perforator (TAP or TDAP)</td>
<td>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</td>
</tr>
<tr>
<td>Transverse gracilis (TUG) flap</td>
<td>Tissue retrieved from the upper posterior thigh and lower buttock area for individuals with insufficient lower abdominal fat</td>
</tr>
<tr>
<td>Transverse rectus abdominus muscle (TRAM)</td>
<td>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</td>
</tr>
</tbody>
</table>

**Change Summary**

- 01/01/2024 New Policy.