BREAST RECONSTRUCTION/REMOVAL AND REPLACEMENT OF IMPLANTS

Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Medical Coverage Guideline must be read in its entirety to determine coverage eligibility, if any.

The section identified as “Description” defines or describes a service, procedure, medical device or drug and is in no way intended as a statement of medical necessity and/or coverage.

The section identified as “Criteria” defines criteria to determine whether a service, procedure, medical device or drug is considered medically necessary or experimental or investigational.

State or federal mandates, e.g., FEP program, may dictate that any drug, device or biological product approved by the U.S. Food and Drug Administration (FDA) may not be considered experimental or investigational and thus the drug, device or biological product may be assessed only on the basis of medical necessity.

Medical Coverage Guidelines are subject to change as new information becomes available.

For purposes of this Medical Coverage Guideline, the terms "experimental" and "investigational" are considered to be interchangeable.

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Description:

Surgical procedures to restore the normal appearance of the breast following surgery, injury or trauma. The most common indication for breast reconstruction is following a mastectomy for the treatment of breast cancer. Breast reconstruction may be performed at the time of mastectomy or at a later date. Breast reconstruction also includes surgery on the contralateral breast to achieve symmetry with the reconstructed breast. Contralateral breast surgery includes breast augmentation and reduction mammoplasty.
BREAST RECONSTRUCTION/REMOVAL AND REPLACEMENT OF IMPLANTS
(cont.)

**Description:** (cont.)

Breast reconstruction techniques include:

- Breast implants, silicone-gel or saline
- Deep Inferior Epigastric Perforator (DIEP) flap, using autologous abdominal skin and fat with microvascular dissection of the blood vessels to preserve the muscle tissue
- Gluteal artery flaps using autologous skin and tissue from the upper or lower buttocks including the superior gluteal artery perforator (SGAP) flap or inferior gluteal artery perforator (IGAP)
- Latissimus dorsi flap, using autologous skin, tissue and latissimus dorsi muscle from beneath the shoulder blade
- Nipple/areola reconstruction or nipple tattooing
- Superficial Inferior Epigastric Artery (SIEA) flap, similar to the DIEP flap with blood supply from the superficial inferior epigastric vessels
- Transverse Rectus Abdominus Myocutaneous (TRAM) flap, using autologous skin, tissue and rectus muscle from the abdomen

Novel techniques have been investigated for breast reconstruction which include, *but are not limited to*:

- Adipose derived stem cells
- Autologous fat grafting

**Skin Substitutes:**

Acellular dermal matrix derived from human skin tissue that may be used in breast reconstruction. Substitutes include:

- AlloDerm®
- AlloMax®
- DermaMatrix™
- FlexHD®
- GraftJacket®
- Strattice™
BREAST RECONSTRUCTION/REMOVAL AND REPLACEMENT OF IMPLANTS (cont.)

Criteria:

Breast Reconstruction:

- Breast reconstruction following a mastectomy for breast cancer or fibrocystic disease is considered medically necessary utilizing ANY of the following:
  1. Breast implant
  2. DIEP flap
  3. Latissimus dorsi flap
  4. TRAM flap
  5. SIEA flap
  6. SGAP or IGAP flap
  7. Nipple/areola reconstruction or nipple tattooing
  8. Contralateral breast surgery to achieve symmetry

- The following skin substitutes used in breast reconstruction following a mastectomy for breast cancer or fibrocystic disease are considered medically necessary:
  1. AlloDerm
  2. AlloMax
  3. DermaMatrix
  4. FlexHD
  5. GraftJacket
  6. Strattice

- All other skin substitutes used in breast reconstruction following a mastectomy for breast cancer or fibrocystic disease or if above criteria not met is considered experimental or investigational based upon:
  1. Insufficient scientific evidence to permit conclusions concerning the effect on health outcomes, and
  2. Insufficient evidence to support improvement of the net health outcome, and
  3. Insufficient evidence to support improvement of the net health outcome as much as, or more than, established alternatives, and
  4. Insufficient evidence to support improvement outside the investigational setting.
BREAST RECONSTRUCTION/REMOVAL AND REPLACEMENT OF IMPLANTS
(cont.)

Criteria: (cont.)

- Breast reconstruction utilizing autologous fat grafting with or without adipose-derived stem cells is considered experimental or investigational based upon insufficient scientific evidence to permit conclusions concerning the effect on health outcomes.

- Breast reconstruction for any complication or consequence, whether immediate or delayed, that arises from a prior non-covered breast condition or surgery is considered a complication of a non-covered service and not eligible for coverage.

- Breast reconstruction for all other indications not listed above to improve breast appearance is considered cosmetic and not eligible for coverage.

Removal of Breast Implants:

- Removal of a breast implant that was originally implanted for reconstruction following a mastectomy for breast cancer or fibrocystic disease or related to a complication of a covered medical condition (e.g., abscess, injury, trauma, prior chest surgery with deformity) is considered medically necessary.

- Removal of a cosmetic breast implant as an adjunct to the surgical treatment for breast cancer is considered medically necessary.

- Removal of a breast implant for any complication or consequence, whether immediate or delayed, that arises from a prior cosmetic breast implant is considered a complication of a non-covered service and not eligible for coverage.

Replacement of Breast Implants:

- Replacement of a breast implant following removal is considered medically necessary only when the original implant was placed for reconstruction following a mastectomy for breast cancer or fibrocystic disease.

- Replacement of a breast implant for any complication or consequence, whether immediate or delayed, that arises from a prior cosmetic breast implant is considered a complication of a non-covered service and not eligible for coverage.
BREAST RECONSTRUCTION/REMOVAL AND REPLACEMENT OF IMPLANTS
(cont.)

Criteria: (cont.)

Capsulectomy/Capsulotomy:

- Capsulectomy and/or capsulotomy is considered *medically necessary only* when the original implant was placed for reconstruction following a mastectomy for breast cancer or fibrocystic disease or related to a complication of a covered medical condition (e.g., abscess, injury, trauma, prior chest surgery with deformity).

- Capsulectomy and/or capsulotomy for any complication or consequence, whether immediate or delayed, that arises from a prior cosmetic breast implant is considered a complication of a non-covered service and not eligible for coverage.

Resources:


BREAST RECONSTRUCTION/REMOVAL AND REPLACEMENT OF IMPLANTS
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Resources: (cont.)


BREAST RECONSTRUCTION/REMOVAL AND REPLACEMENT OF IMPLANTS
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Resources: (cont.)


BREAST RECONSTRUCTION/REMOVAL AND REPLACEMENT OF IMPLANTS
(cont.)

Resources: (cont.)


FDA 510 K Summary for Strattice:

- FDA-approved indication: Soft tissue patch to reinforce soft tissue where weakness exists and for the surgical repair of damaged or ruptured soft tissue membranes. Indications for use include the repair of hernias and breast recon and/or body wall defects which require the use of reinforcing or bridging material to obtain the desired surgical outcome.