BlueCross BlueShield of Arizona
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MEDICAL COVERAGE GUIDELINES
SECTION: SURGERY

ORIGINAL EFFECTIVE DATE: 06/16/09
LAST REVIEW DATE: 05/13/14
LAST CRITERIA REVISION DATE: 05/13/14
ARCHIVE DATE:

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.

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:

1. 7.01.22 BCBS Association Medical Policy Reference Manual. Reconstructive Breast Surgery/Management of Breast Implants. Archived date 01/12/2012, issue date 12/01/1995

2. 7.01.113 BCBS Association Medical Policy Reference Manual. Bio-Engineered Skin and Soft Tissue Substitutes. Re-issue date 02/13/2014, issue date 12/13/2007

3. 7.01.129 BCBS Association Medical Policy Reference Manual. Autologous Fat Grafting to the Breast and Adipose-derived Stem Cells. Re-issue date 4/10/2014, issue date 06/09/2011

4. Arnez ZM, Khan U, Pogorelec D, Planinsek F. Breast reconstruction using the free superficial inferior epigastric artery (SIEA) flap. *Br J Plast Surg.* 1999 Jun;52(4):276-279

5. Beahm EK, Walton RL. The efficacy of bilateral lower abdominal free flaps for unilateral breast reconstruction. *Plast Reconstr Surg.* 2007 Jul;120(1):41-54

6. Breuing KH, Warren SM. Immediate bilateral breast reconstruction with implants and inferolateral AlloDerm slings. *Ann Plast Surg.* 2005 Sep;55(3):232-239

7. Cahan A, Palaia, D., Rosenberg, M., Bonnanno, P.,. The Aesthetic Mastecomy Utilizing a Non-Nipple-Sparing Portal Approach. *Annals of Plasty Surgery.* 2011;66(No. 5):424-428

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

Resources: (cont.)

8. Cohn AB, Walton RL. Immediate autologous breast reconstruction using muscle-sparing TRAM flaps with superficial epigastric system turbocharging: a salvage option. *J Reconstr Microsurg.* 2006 Apr;22(3):153-156

9. DellaCroce, F. Breast Reconstruction, Perforator Flap. Updated 02/01/2007, accessed 06/19/2008 & 07/07/2008

10. Deutsch MF. Breast Reconstruction, Other Free Flaps. *eMedicine.* June 26, 2005

11. Faleris J, Hernandez R, et al. In-vivo and in-vitro histological evaluation of two commercially available acellular dermal matrices. *Hernia.* 2011;15:147-156.

12. Gamboa-Bobadilla, G, M. Implant breast reconstruction using acellular dermal matrix. *Ann Plast Surg.* 2006 Jan;56(1):22-25

13. Gautam AK, Allen RJJ, LoTempio MM, et al. Congenital breast deformity reconstruction using perforator flaps. *Ann Plast Surg.* 2007 Apr;58(4):353-358

14. Granzow JW, Levine JL, Chiu ES, Allen RJ. Breast reconstruction using perforator flaps. *J Surg Oncol.* 2006 Nov 1;94(6):441-454

15. Holm C, Mayr M, Hofter E, Ninkovic M. The versatility of the SIEA flap: a clinical assessment of the vascular territory of the superficial epigastric inferior artery. *J Plast Reconstr Aesthet Surg.* 2007;60(8):946-951

16. InterQual ® Care Planning Procedures. Breast Reconstruction.

17. InterQual ® Care Planning Procedures. Breast Implant Removal.

18. Keller A. The deep inferior epigastric perforator free flap for breast reconstruction. *Ann Plast Surg.* 2001 May;46(5):474-479; discussion 479-480

19. Kroll, SS. Fat necrosis in free transverse rectus abdominis myocutaneous and deep inferior epigastric perforator flaps. *Plast Reconstr Surg.* 2000 Sep;106(3):576-583

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

Resources: (cont.)

20. Kroll SS, Reece GP, Miller MJ, et al. Comparison of cost for DIEP and free TRAM flap breast reconstructions. *Plast Reconstr Surg.* 2001 May;107(6):1413-1416; discussion 1417-1418

21. LifeCell Corporation. Breast Reconstruction Postmastectomy. Accessed 08/22/2007

22. LifeCell Corporation. Regenerative Human Acellular Tissue Matrix (AlloDerm®) as Tissue Supplement in Immediate Breast Reconstruction Postmastectomy- A Technical Perspective. 2005

23. Losken A. Early Results Using Sterilized Acellular Human Dermis (NeoForm) in Postmastectomy Tissue Expander Breast Reconstruction *Plas Reconstr Surg.* 2009;123:1654-1658.

24. Nahabedian MY, Momen B, Galdino G, Manson PN. Breast Reconstruction with the free TRAM or DIEP flap: patient selection, choice of flap, and outcome. *Plast Reconstr Surg.* 2002 Aug;110(2):466-475; discussion 476-467

25. Public Law. Women's Health and Cancer Rights Act. Effective 10/21/1998, accessed 07/12/2006

26. Public Law. Women's Health and Cancer Rights Act of 1998, Section 713. Effective 11/01/1998:1077

27. Rawlani V, Buck DW, 2nd, Johnson SA, Heyer KS, Kim JY. Tissue expander breast reconstruction using prehydrated human acellular dermis. *Ann Plast Surg.* Jun 2011;66(6):593-597

28. Rizzuto RP, Allen RJ. Reconstruction of a partial mastectomy defect with the superficial inferior epigastric artery (SIEA) flap. *J Reconstr Microsurg.* 2004 Aug;20(6):441-445; discussion 446

29. Rosenberg M, Palaia, D., Cahan, A., DeChiara, S., Arthur, K., et al,. Immediate Single-Stage Reconstruction of the Breast Utilizing FlexHD and Implant Following Skin-Sparing Mastectomy. *The American Journal of Cosmetic Surgery.* 2011;28(No. 3):145-155

30. Salzberg CA. Nonexpansive immediate breast reconstruction using human acellular tissue matrix graft (AlloDerm). *Ann Plast Surg.* 2006 Jul;57(1):1-5

31. Topol BM, Dalton EF, Ponn T, Campbell CJ. Immediate single-stage breast reconstruction using implants and human acellular dermal tissue matrix with adjustment of the lower pole of the breast to reduce unwanted lift. *Ann Plast Surg.* Nov 2008;61(5):494-499

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

Resources: (cont.)

32. Tutor EG, Auba C, Benito A, Rabago G, Kreutler W. Easy venous superdrainage in DIEP flap breast reconstruction through the intercostal branch. *J Reconstr Microsurg.* 2002 Oct;18(7):595-598

33. Venturi ML, Mesbahi AN, Boehmler JH, AJ. M. Evaluating Sterile Human Acellular Dermal Matrix in Immediate Expander-Based Breast Reconstruction: A Multi-centered Prospective Cohort Study. *Plast Reconstr Surg.*

34. Vesely J, Stupka I, Drazan L, Holusa P, Licata P, Corradini B. DIEP flap breast reconstruction--new experience. *Acta Chir Plast.* 2001;43(1):3-6

35. Zienowicz RJ, Karacaoglu E. Implant-based breast reconstruction with allograft. *Plast Reconstr Surg.* 2007 Aug;120(2):373-381

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.