BlueCross BlueShield of Arizona
An Independent Licensee of the Blue Cross and Blue Shield Association

MEDICAL COVERAGE GUIDELINES
SECTION: SURGERY

ORIGINAL EFFECTIVE DATE: 02/19/19
LAST REVIEW DATE:
LAST CRITERIA REVISION DATE:
ARCHIVE DATE:

BREAST RECONSTRUCTION/REMOVAL AND REPLACEMENT OF IMPLANTS

Non-Discrimination Statement and Multi-Language Interpreter Services information are located at the end of this document.

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.

This Medical Coverage Guideline provides information related to coverage determinations only and does not imply that a service or treatment is clinically appropriate or inappropriate. The provider and the member are responsible for all decisions regarding the appropriateness of care. Providers should provide BCBSAZ complete medical rationale when requesting any exceptions to these guidelines.

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

Autologous fat grafting to the breast has been used as an adjunct to reconstructive breast surgery, for post mastectomy pain and in irradiated skin. Adipose-derived stem cells (ADSCs) have been investigated as a supplement to the fat graft in an attempt to improve graft survival, although, a complete understanding of the mechanisms of any possible role ADSCs may have in tumorigenesis remains unknown.

Skin Substitutes:
Acellular dermal matrix derived from human skin tissue that may be used in breast reconstruction. Substitutes include:
- AlloDerm®
- AlloMend®
- Cortiva® (AlloMax™)
- DermACELL™
- DermaMatrix™
- FlexHD®
- FlexHD® Pliable™
- Graftjacket® Regenerative Tissue Matrix (also called Graftjacket Skin Substitute)

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

Criteria:

For Alloderm®, Allomax™, AlloMend®, DermACELL™, DermaMatrix, FlexHD®, FlexHD® Pliable™, Graftjacket® Regenerative Tissue Matrix (also called Graftjacket Skin Substitute), Graftjacket® Xpress, and Strattice™ used for indications other than breast reconstruction surgery, see BCBSAZ Medical Coverage Guideline #O673, *"Bio-Engineered Skin and Soft Tissue Substitutes"*.

For surgical treatments for breast cancer-related lymphedema, see BCBSAZ Medical Coverage Guideline #O1066, *"Surgical Treatments for Breast Cancer-Related Lymphedema"*.

Breast Reconstruction:

Breast reconstruction following prophylactic mastectomy will be reviewed by the medical director(s) and/or clinical advisor(s).

- 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. AlloMend®
  3. Cortiva® (AlloMax™)
  4. DermACELL™
  5. DermaMatrix™
  6. FlexHD®
  7. FlexHD® Pliable™
  8. Graftjacket® Regenerative Tissue Matrix (also called Graftjacket Skin Substitute)

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

Criteria: (cont.)

Breast Reconstruction: (cont.)

- 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.

  Skin substitutes include, *but are not limited to:*

  - Graftjacket® Xpress (injectable product)
  - Strattice™

- Breast reconstruction utilizing adipose-derived stem cells in autologous fat grafting 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***.

- Liposuction for autologous fat grafting for contouring of breast as part of breast reconstruction following breast cancer treatment is considered ***medically necessary***.

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

Criteria: (cont.)

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 non-cosmetic, medical complication or consequence, whether immediate or delayed, that arises from a prior cosmetic breast implant is considered ***medically necessary*** and ***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 or placed for breast augmentation related to the surgical treatment of gender dysphoria.

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

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) or placed for breast augmentation related to the surgical treatment of gender dysphoria.

- 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***.

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

Resources:

Literature reviewed 03/20/18. We do not include marketing materials, poster boards and non-published literature in our review.

The BCBS Association Medical Policy Reference Manual (MPRM) policy is included in our guideline review. References cited in the MPRM policy are not duplicated on this guideline.

Resources prior to 03/20/18 may be requested from the BCBSAZ Medical Policy and Technology Research Department.

1. 7.01.22 BCBS Association Medical Policy Reference Manual. Reconstructive Breast Surgery/Management of Breast Implants. Re-issue 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 02/08/2018, issue date 12/13/2007.

3. 7.01.153 BCBS Association Medical Policy Reference Manual. Adipose-Derived Stem Cells in Autologous Fat Grafting to the Breast. Re-issue date 09/14/2017, issue date 10/15/2015.

4. InterQual® Care Planning Procedures. Breast Reconstruction.

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

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

Non-Discrimination Statement:

Blue Cross Blue Shield of Arizona (BCBSAZ) complies with applicable Federal civil rights laws and does not discriminate on the basis of race, color, national origin, age, disability or sex. BCBSAZ provides appropriate free aids and services, such as qualified interpreters and written information in other formats, to people with disabilities to communicate effectively with us. BCBSAZ also provides free language services to people whose primary language is not English, such as qualified interpreters and information written in other languages. If you need these services, call (602) 864-4884 for Spanish and (877) 475-4799 for all other languages and other aids and services.

If you believe that BCBSAZ has failed to provide these services or discriminated in another way on the basis of race, color, national origin, age, disability or sex, you can file a grievance with: BCBSAZ's Civil Rights Coordinator, Attn: Civil Rights Coordinator, Blue Cross Blue Shield of Arizona, P.O. Box 13466, Phoenix, AZ 85002-3466, (602) 864-2288, TTY/TDD (602) 864-4823, crc@azblue.com. You can file a grievance in person or by mail or email. If you need help filing a grievance BCBSAZ's Civil Rights Coordinator is available to help you. You can also file a civil rights complaint with the U.S. Department of Health and Human Services, Office for Civil Rights electronically through the Office for Civil Rights Complaint Portal, available at https://ocrportal.hhs.gov/ocr/portal/lobby.jsf, or by mail or phone at: U.S. Department of Health and Human Services, 200 Independence Avenue SW., Room 509F, HHH Building, Washington, DC 20201, 1–800–368–1019, 800–537–7697 (TDD). Complaint forms are available at http://www.hhs.gov/ocr/office/file/index.html

Multi-Language Interpreter Services:

Spanish: Si usted, o alguien a quien usted está ayudando, tiene preguntas acerca de Blue Cross Blue Shield of Arizona, tiene derecho a obtener ayuda e información en su idioma sin costo alguno. Para hablar con un intérprete, llame al 602-864-4884.

Navajo: Díí kwe'é atah nílínigíí Blue Cross Blue Shield of Arizona haada yit'éego bína'ídíłkidgo éí doodago Háida bíjá anilyeedígíí t'áadoo le'é yína'ídíłkidgo beehaz'áanii hóló díí t'áá hazaadk'ehjí háká a'doowołgo bee haz'ą doo bąąh íłínígóó. Ata' halne'ígíí kojį' bich'į' hodíilnih 877-475-4799.

Chinese: 如果您，或是您正在協助的對象，有關於插入項目的名稱 Blue Cross Blue Shield of Arizona 方面的問題，您有權利免費以您的母語得到幫助和訊息。洽詢一位翻譯員，請撥電話 在此插入數字 877-475-4799。

Vietnamese: Nếu quý vị, hay người mà quý vị đang giúp đỡ, có câu hỏi về Blue Cross Blue Shield of Arizona quý vị sẽ có quyền được giúp và có thêm thông tin bằng ngôn ngữ của mình miễn phí. Để nói chuyện với một thông dịch viên, xin gọi 877-475-4799.

Arabic:
إن كان لديك أو لدى شخص تساعده أسئلة بخصوص Blue Cross Blue Shield of Arizona، فلديك الحق في الحصول على المساعدة والمعلومات الضرورية بلغتك من دون اية تكلفة .للتحدث مع مترجم اتصل ب 877-475-4799.

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

Multi-Language Interpreter Services: (cont.)

Tagalog: Kung ikaw, o ang iyong tinutulangan, ay may mga katanungan tungkol sa Blue Cross Blue Shield of Arizona, may karapatan ka na makakuha ng tulong at impormasyon sa iyong wika ng walang gastos. Upang makausap ang isang tagasalin, tumawag sa 877-475-4799.

Korean: 만약 귀하 또는 귀하가 돕고 있는 어떤 사람이 Blue Cross Blue Shield of Arizona 에 관해서 질문이 있다면 귀하는 그러한 도움과 정보를 귀하의 언어로 비용 부담없이 얻을 수 있는 권리가 있습니다. 그렇게 통역사와 얘기하기 위해서는 877-475-4799 로 전화하십시오.

French: Si vous, ou quelqu'un que vous êtes en train d'aider, a des questions à propos de Blue Cross Blue Shield of Arizona, vous avez le droit d'obtenir de l'aide et l'information dans votre langue à aucun coût. Pour parler à un interprète, appelez 877-475-4799.

German: Falls Sie oder jemand, dem Sie helfen, Fragen zum Blue Cross Blue Shield of Arizona haben, haben Sie das Recht, kostenlose Hilfe und Informationen in Ihrer Sprache zu erhalten. Um mit einem Dolmetscher zu sprechen, rufen Sie bitte die Nummer 877-475-4799 an.

Russian: Если у вас или лица, которому вы помогаете, имеются вопросы по поводу Blue Cross Blue Shield of Arizona, то вы имеете право на бесплатное получение помощи и информации на вашем языке. Для разговора с переводчиком позвоните по телефону 877-475-4799.

Japanese: ご本人様、またはお客様の身の回りの方でも、Blue Cross Blue Shield of Arizona についてご質問がございましたら、ご希望の言語でサポートを受けたり、情報を入手したりすることができます。料金はかかりません。通訳とお話される場合、877-475-4799 までお電話ください。

Farsi:
اگر شما، یا کسی که شما به او کمک میکنید ، سوال در مورد Blue Cross Blue Shield of Arizona ، داشته باشید حق این را دارید که کمک و
اطلاعات به زبان خود را به طور رایگان دریافت نمایید 877-475-4799
[تماس حاصل نمایید.

Assyrian:
[illegible] Blue Cross Blue Shield of Arizona [illegible]
[illegible] 877-475-4799.

Serbo-Croatian: Ukoliko Vi ili neko kome Vi pomažete ima pitanje o Blue Cross Blue Shield of Arizona, imate pravo da besplatno dobijete pomoć i informacije na Vašem jeziku. Da biste razgovarali sa prevodiocem, nazovite 877-475-4799.

Thai: หากคณ หรอคนทคณกาลงชวยเหลอมคาถามเกยวกบ Blue Cross Blue Shield of Arizona
คณมสทธทจะไดรบความชวยเหลอและขอมลในภาษา ของคณไดโดยไมมคาใชจาย พดคยกบลาม โทร 877-475-4799