MEDICAL POLICY

POLICY TITLE	RECONSTRUCTIVE BREAST SURGERY/MANAGEMENT OF BREAST IMPLANTS
POLICY NUMBER	MP-1.103

Original Issue Date (Created):	**June 21, 2004**
Most Recent Review Date (Revised):	**March 25, 2014**
Effective Date:	**June 1, 2014**

I. POLICY

Reconstructive breast surgery, including the use of prosthetic devices, may be considered **medically necessary** after a medically necessary mastectomy, accidental injury, or trauma. Medically necessary mastectomies, partial or total (see definition), are most typically done as treatment for cancer. Reconstruction may be performed by an implant –based approach or through the use of autologous tissue.

Explantation &/or capsulotomy of a ***silicone*** gel-filled breast implant may be considered **medically necessary** in all cases for any of the following indications;

- documented implant rupture;
- infection;
- extrusion;
- Baker Class IV contracture; or
- Surgical treatment of breast cancer.

Explantation &/or capsulotomy of a ***saline***-filled breast implant may be considered **medically necessary** for any of the following indications;

- infection;
- extrusion;
- Baker Class IV contracture;
- surgical treatment of breast cancer; or
- a ruptured implant if the original breast implantation was for reconstructive purposes.

[Note: Final page is signature page and is kept on file, but not issued with Policy.]

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Explantation &/or capsulotomy of a breast implant associated with a Baker Class III contracture may be considered **medically necessary** only in those patients who had originally undergone breast implantation for reconstructive purposes.

The following indications for explantation of implants or capsulotomy are considered **not medically necessary**:

- Systemic symptoms, attributed to connective tissue diseases, autoimmune diseases, etc.;
- Patient anxiety;
- Baker Class I—III contractures in patients with implants for cosmetic purposes;
- Rupture of a saline implant in patients with implants for cosmetic purposes;
- Pain not related to contractures or rupture.

Reconstructive breast surgery after explantation of an implant is considered **medically necessary** only in those patients who had originally undergone breast implantation for reconstructive purposes.

Application of the above policy regarding explantation of implants requires documentation of the original indication for implantation and the type of implant, either saline or silicone gel-filled, and the current symptoms, either local or systemic. (NOTE: See Attachment A to facilitate determination of the medical necessity of explantation).

Mastopexy or reduction mammoplasty is considered **reconstructive and medically necessary** only when performed on the unaffected breast following previous mastectomy when the purpose is to provide symmetry with the breast on which the mastectomy has been performed.

Patients who have originally undergone implantation of a cosmetic breast implant are not candidates for additional reconstructive surgery or replacement implantation following surgery.

Products for Use in Breast Reconstructive Surgery

Use of allogeneic acellular dermal matrix products* (i.e., AlloDerm®, AlloMax™, DermaMatrix™, FlexHD®, GraftJacket®) may be considered **medically necessary** for use in breast reconstructive surgery.

Cross-reference:

MP-1.002 Augmentation Mammoplasty
MP-1.004 Cosmetic and Reconstructive Surgery
MP-1.036 Prophylactic Mastectomy and Prophylactic Bilateral Oophorectomy
MP-1.013 Reduction Mammoplasty

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II. PRODUCT VARIATIONS

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[N] = No product variation, policy applies as stated
[Y] = Standard product coverage varies from application of this policy, see below

[N] Capital Cares 4 Kids
[N] PPO
[N] HMO
[N] SeniorBlue HMO
[N] SeniorBlue PPO
[N] Indemnity
[N] SpecialCare
[N] POS
[Y] FEP PPO*

* For products for use in breast reconstruction surgery, refer to FEP Medical Policy Manual MP-7.01.113 Bio-Engineered Skin and Soft Tissue Substitutes. The FEP Medical Policy manual can be found at www.fepblue.org

III. DESCRIPTION/BACKGROUND

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Reconstructive breast surgery is defined as a surgical procedure that is designed to restore the normal appearance of the breast after surgery, accidental injury, or trauma. The most common indication for reconstructive breast surgery is a prior mastectomy. In contrast, cosmetic breast surgery is defined as surgery designed to alter or enhance the appearance of a breast that has not undergone surgery, accidental injury, or trauma. Reduction mammoplasty is a common example of cosmetic breast surgery, but surgery to alter the appearance of a congenital abnormality of the breasts, such as tubular breasts, could also be considered cosmetic in nature.

The most common type of reconstructive breast surgery is insertion of a silicone gel-filled or saline-filled breast implant, either inserted immediately at the time of mastectomy or sometime afterward in conjunction with the previous use of a tissue expander. Local complications of breast implants are frequent and may require removal of the implant. Contracture is the most common local complication of breast implants. Contractures have been graded according to the Baker classification as follows:

Grade I: Augmented breast feels as soft as a normal breast

Grade II: Breast is less soft and the implant can be palpated but is not visible

Grade III: Breast is firm, palpable, and the implant (or its distortion) is visible

Grade IV: Breast is hard, painful, cold, tender, and distorted.

Other types of reconstruction include nipple/areola reconstruction, nipple tattooing, and/or the use of autologous tissue, such as a transverse rectus abdominus myocutaneous flap (TRAM procedure) or a latissimus dorsi flap. In addition, mastopexy or reduction mammoplasty on the contralateral breast may be performed to achieve symmetry with the reconstructed breast.

ACT 81 of 2002-No Time Limit on Reconstructive Surgery-is a Pennsylvania mandate which removes the 6-year time limit on mandatory insurance coverage for reconstructive surgery following mastectomy for breast cancer. Act 81 now supersedes Act 51 of 1997 (The Mastectomy Health Security Act). This act also directs that all healthcare policies: shall not require early discharge after a mastectomy. The act requires coverage for a home health care visit that the treating physician determines is necessary within forty-eight hours after discharge when the discharge occurs within forty-eight hours following admission for the mastectomy. The act requires coverage for prosthetic devices and requires coverage for physical complications from breast cancer, including lymphedema.

The Women's Health and Cancer Rights Act of 1998 is a federal mandate requiring group health plans that cover mastectomies to also cover reconstructive breast surgery following a mastectomy. In addition, reconstructive surgery and services after mastectomy, partial or total, is a mandated benefit in many states (i.e., Act 81 of 2002).

Products for Use in Breast Reconstructive Surgery

Acellular Dermal Matrix

Allograft acellular dermal matrix products derived from donated human skin tissue are supplied by U.S. AATB-compliant tissue banks using the standards of the American Association of Tissue Banks (AATB) and U.S. Food and Drug Administration's (FDA) guidelines. The processing removes the cellular components (i.e., epidermis and all viable dermal cells) that can lead to rejection and infection. Acellular dermal matrix products from human skin tissue are regarded as minimally processed and not significantly changed in structure from the natural material; the FDA classifies it as banked human tissue and therefore does not require FDA approval.

- AlloDerm® (LifeCell Corporation) is an acellular dermal matrix (allograft) tissue-replacement product that is created from native human skin and processed so that the basement membrane and cellular matrix remain intact. Originally, AlloDerm required refrigeration and rehydration prior to use. It is currently available in a ready-to-use product that is stored at room temperature. An injectable micronized form of AlloDerm (Cymetra) is also available.

- AlloMax™ Surgical Graft (Bard Davol) is an acellular non-cross-linked human dermis allograft. (AlloMax was previously marketed as NeoForm™.)

- FlexHD® (Ethicon) is an acellular hydrated dermis derived from donated human allograft skin. The Musculoskeletal Transplant Foundation acquires and processes the tissue.

- DermaMatrix™ (Synthes) is an acellular dermal matrix (allograft) derived from donated human skin tissue. DermaMatrix Acellular Dermis is processed by the Musculoskeletal Transplant Foundation® (MTF®).

- GraftJacket® Regenerative Tissue Matrix (KCI) is an acellular regenerative tissue matrix that has been processed from screened donated human skin supplied from U.S. tissue banks. The allograft is minimally processed to remove the epidermal and dermal cells, while preserving dermal structure

IV. RATIONALE

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NA

V. DEFINITIONS

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AUTOLOGOUS refers to originating within an individual; i.e., self-donation.

CAPSULOTOMY-refers to division of a capsule as around a breast implant; creation of an opening through a capsule; e.g., of a scar that might form around a foreign body.

CONTRACTURE refers to fibrosis of connective tissue in skin, fascia, muscle or a joint capsule that prevents normal mobility of the related tissue or joint.

COSMETIC SURGERY is an elective procedure performed primarily to restore a person's appearance by surgically altering a physical characteristic that does not prohibit normal function, but is considered unpleasant or unsightly.

EXPLANTATION refers to the removal of an implant**.**

MAMMOPLASTY refers to plastic reconstructive surgery of the breast.

MASTECTOMY per Act 81 is defined as: the removal of all or part of the breast for medically necessary reasons, as determined by a licensed physician. (This is NOT restricted to cancer indications.)

MASTOPEXY is the correction of a pendulous breast or surgical fixation and plastic surgery.

PROSTHETIC DEVICES refers to the initial and subsequent artificial devices to replace the removed breast or portions thereof, ordered by the patient's physician.

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RECONSTRUCTIVE SURGERY-a procedure performed to improve or correct a functional impairment, restore a bodily function or correct a deformity resulting from birth defect or accidental injury. The fact that a member might suffer psychological consequences from a deformity does not, in the absence of bodily functional impairment, qualify surgery as being reconstructive surgery.

VI. BENEFIT VARIATIONS

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The existence of this medical policy does not mean that this service is a covered benefit under the member's contract. Benefit determinations should be based in all cases on the applicable contract language. Medical policies do not constitute a description of benefits. A member's individual or group customer benefits govern which services are covered, which are excluded, and which are subject to benefit limits and which require preauthorization. Members and providers should consult the member's benefit information or contact Capital for benefit information.

VII. DISCLAIMER

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Capital's medical policies are developed to assist in administering a member's benefits, do not constitute medical advice and are subject to change. Treating providers are solely responsible for medical advice and treatment of members. Members should discuss any medical policy related to their coverage or condition with their provider and consult their benefit information to determine if the service is covered. If there is a discrepancy between this medical policy and a member's benefit information, the benefit information will govern. Capital considers the information contained in this medical policy to be proprietary and it may only be disseminated as permitted by law.

VIII. CODING INFORMATION

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Note: This list of codes may not be all-inclusive, and codes are subject to change at any time. The identification of a code in this section does not denote coverage as coverage is determined by the terms of member benefit information. In addition, not all covered services are eligible for separate reimbursement.

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Covered when medically necessary:

CPT Codes®								
11920	11921	11922	15330	15331	19300	19301	19302	19303
19304	19305	19306	19307	19316	19318	19324	19324	19328
19330	19340	19342	19350	19355	19357	19361	19364	19330
19367	19368	19369	19370	19371	19380	19396		19367

HCPCS Code	Description
C1789	PROSTHESIS, BREAST (IMPLANTABLE)
L8039	BREAST PROSTHESIS, NOS
L8600	IMPLANTABLE BREAST PROSTHESIS, SILICONE OR EQUAL
S2068	BREAST RECON DIEP FLA MVA & CLOS DONOR SITE UNI
Q4116	ALLODERM, PER SQ CM

ICD-9-CM Diagnosis Code*	Description
173.5	OTHER MALIGNANT NEOPLASM OF SKIN OF TRUNK, EXCEPT SCROTUM
174.0	MALIGNANT NEOPLASM OF NIPPLE AND AREOLA OF FEMALE BREAST
175.0	MALIGNANT NEOPLASM OF NIPPLE AND AREOLA OF MALE BREAST
198.2	SECONDARY MALIGNANT NEOPLASM OF SKIN
198.81	SECONDARY MALIGNANT NEOPLASM OF BREAST
233.0	CARCINOMA IN SITU OF BREAST
238.3	NEOPLASM OF UNCERTAIN BEHAVIOR OF BREAST
996.54	MECHANICAL COMPLICATION DUE TO BREAST PROSTHESIS
996.69	INFECTION AND INFLAMMATORY REACTION DUE TO OTHER INTERNAL PROSTHETIC DEVICE, IMPLANT, AND GRAFT
996.79	OTHER COMPLICATIONS DUE TO OTHER INTERNAL PROSTHETIC DEVICE, IMPLANT, AND GRAFT
V10.3	PERSONAL HISTORY OF MALIGNANT NEOPLASM OF BREAST
V16.3	FAMILY HISTORY OF MALIGNANT NEOPLASM OF BREAST
V45.71	ACQUIRED ABSENCE OF BREAST AND NIPPLE

*If applicable, please see Medicare LCD or NCD for additional covered diagnoses.

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The following ICD-10 diagnosis codes will be effective October 1, 2015:

ICD-10-CM Diagnosis Code*	Description
C50.111-C50.119	Malignant neoplasm of breast code range (female codes only listed)
C50.211-C50.219	Malignant neoplasm of breast code range (female codes only listed)
C50.311-C50.319	Malignant neoplasm of breast code range (female codes only listed)
C50.411-C50.419	Malignant neoplasm of breast code range (female codes only listed)
C50.511-C50.519	Malignant neoplasm of breast code range (female codes only listed)
C50.611-C50.619	Malignant neoplasm of breast code range (female codes only listed)
C50.811-C50.819	Malignant neoplasm of breast code range (female codes only listed)
C50.911-C50.919	Malignant neoplasm of breast code range (female codes only listed)

*If applicable, please see Medicare LCD or NCD for additional covered diagnoses.

IX. REFERENCES

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Attachment A

The following chart should facilitate determination of the medical necessity of explantation or capsulotomy. Yes indicates that the explantation or capsulotomy would be considered medically necessary given the symptoms, type of implant, and original indication for implantation.

Indication/Type of Implant				
Indication for Explantation	**Reconstruction/ silicone**	**Reconstruction/ saline**	**Cosmetic/ silicone**	**Cosmetic/ saline**
Systemic Illness				
Connective tissue disease	no	no	no	no
Autoimmune disease	no	no	no	no
Rheumatic conditions	no	no	no	no
Neurologic symptoms	no	no	no	no
Fibromyalgia	no	no	no	no
Chronic fatigue syndrome	no	no	no	no
Patient Anxiety	no	no	no	no
Absolute Medical Indications				
Rupture*	yes	yes	yes	no
Baker class IV contracture	yes	yes	yes	yes
Recurrent infection	yes	yes	yes	yes
Extruded implant	yes	yes	yes	yes
Surgery for breast cancer	yes	yes	yes	yes
Indication for Explantation	**Reconstruction/ silicone**	**Reconstruction/ saline**	**Cosmetic/ silicone**	**Cosmetic/ saline**
Other Indications				
Baker class III contractures	yes	yes	no	no
Pain**	no	no	no	no
Post-Explantation Procedures				
Reimplantation of implants	yes	yes	no	no
Autologous reconstruction	yes	yes	no	no

*Rupture of implants requires documentation with an imaging study, such as mammography, magnetic resonance imaging, or ultrasonography. Lack of imaging confirmation of rupture in association with persistent local symptoms requires case by case consideration.

** Pain as an isolated symptom is an inadequate indication for explantation. The pain should be related to the Baker classification or a diagnosis of rupture.

X. POLICY HISTORY

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MP 1.103	**CAC 2/24/04**
	CAC 11/30/04
	CAC 11/29/05
	CAC 11/28/06
	CAC 2/27/07
	CAC 1/29/08
	CAC 3/31/09
	CAC 3/30/10 Consensus Review
	CAC 4/26/11 Consensus
	10/12/11 FEP variation updated with FEP policy MP 7.01.113 Allograft Use in Breast Reconstruction Surgery.
	CAC 8/28/12 Consensus review. References updated. Added statement regarding methods by which reconstruction can be performed**.** **Code reviewed 8/16/12 klr**
	CAC 7/30/13 Consensus. No change to policy statements. References updated. No coding changes.
	CAC 3/25/14 Consensus. Deleted the medically necessary statement regarding use of allograft material in breast reconstructive surgery and added the following statement, " Use of allogeneic acellular dermal matrix products* (i.e., AlloDerm®, AlloMax™, DermaMatrix™, FlexHD®, GraftJacket®) may be considered **medically necessary** for use in breast reconstructive surgery." No change to other policy statements. For FEP variation - changed title of policy to match title on FEP policy.

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