Medical Policy

Breast Reconstruction

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Product Applicability

- All Plan* Products

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Notes:
+ Disclaimer and audit information is located at the end of this document.
◊ The guidelines included in this Plan policy are applicable to members enrolled in Senior Care Options only if there are no criteria established for the specified service in a Centers for Medicare & Medicaid Services (CMS) national coverage determination (NCD) or local coverage determination (LCD) on the date of the prior authorization request. Review the member’s product-specific benefit documents at www.SeniorsGetMore.org to determine coverage guidelines for Senior Care Options.

Policy Summary

The Plan considers breast reconstruction to be medically necessary for all members (regardless of gender) after mastectomy or lumpectomy when applicable Plan medical criteria are met, including reconstruction of the affected breast, reconstruction of the unaffected contralateral breast after mastectomy or lumpectomy to produce a symmetrical appearance, and/or for the treatment of physical complications of all stages of mastectomy or lumpectomy. The Plan complies with coverage guidelines for all applicable state-mandated benefits and federally-mandated benefits that are medically necessary for the member’s condition. Breast reconstruction and restorative services for a female member (including a member born with female reproductive organs and/or with typical female karyotype with two [2] X chromosomes) with a diagnosis other than breast cancer is medically necessary.

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Breast reconstruction for MtF members with persistent, well-documented gender dysphoria includes augmentation mammoplasty with implantation of breast prostheses and/or the medically necessary surgical removal of breast implants with replacement of breast implants after implant explantation. See Plan policy, Gender Reassignment Surgery medical policy, policy number OCA 3.11, (rather than this Plan medical policy) for the initial breast augmentation procedure. Review criteria in the Medical Policy Statement section of this policy (rather than the criteria included in the Gender Reassignment Surgery medical policy) for Plan prior authorization guidelines for the medically necessary surgical removal of breast implants and the replacement of breast implants after implant explantation (when the implant was initially inserted for breast reconstruction as a component of gender reassignment surgery).
Description of Item or Service

**Breast Reconstruction:** Surgical procedures that are designed to restore the normal appearance of the breast after surgery (such as mastectomy or lumpectomy), as a component of gender reassignment surgery, and/or surgical procedures used to restore, correct, or improve anatomical and/or functional impairments that result from congenital anomalies, accidental injury, previous surgery, therapeutic interventions, or disease of the breast. Breast reconstruction does NOT include cosmetic breast augmentation surgery (augmentation mammoplasty).

Medical Policy Statement

Breast surgeries, including breast reconstruction (as defined in the Description of Item or Service section of this policy) and breast implant removal (related to either breast reconstruction or cosmetic procedures), are considered medically necessary for all members (regardless of gender) for the following medical indications when applicable Plan criteria are met and documented in the member’s medical record, as specified below in item A (Breast Reconstruction and Restorative Services) or item B (Breast Procedures After Cosmetic Breast Augmentation):

A. **Breast Reconstruction and Restorative Services:**

   Applicable criteria must be met for breast reconstruction and restorative services, EITHER item 1 for breast reconstruction after a diagnosis of breast cancer or item 2 for breast reconstruction for a diagnosis other than breast cancer.

1. **Breast Reconstruction After a Diagnosis of Breast Cancer:**

   In compliance with the Women’s Health and Cancer Rights Act of 1998, the Plan covers all stages of reconstruction surgery after a diagnosis of breast cancer on the affected breast and contralateral breast; medically necessary services are determined in consultation with the attending physician and the member. Breast reconstruction may occur at the same time as the surgery to treat the breast cancer (immediate reconstruction/oncoplastic breast reconstruction) or at a later time (delayed breast reconstruction). The Post-Mastectomy Fat Graft/Fat Transfer Guiding Principles from the American Society of Plastic Surgeons (ASPS) reaffirmed in June 2015 state that autologous fat grafting (AFG) is a safe and effective modality in breast reconstruction and may result in aesthetic improvement, alleviate post-mastectomy pain syndrome, and improve the quality of irradiated skin on the post-mastectomy breast to soften the skin and restore it to non-irradiated appearance and consistency when the patient has **no native breast tissue present**; these ASPS guidelines do not reference the safety of AFG for a patient who has had breast conserving therapy (also called lumpectomy, quadrantectomy, partial mastectomy, or segmental mastectomy) rather than a mastectomy (in which the entire breast is removed, including all of the breast tissue and sometimes other nearby tissues). According to a Hayes report updated in July 2016, AFG is increasingly used as an adjunct to reconstructive surgery among patients having undergone surgery for breast cancer but there is

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very-poor-quality body of evidence demonstrating the safety and effectiveness of AFG; questions still remain regarding the safety of the procedure, with some studies indicating that adipose cells may directly stimulate tumor growth and may increase the risk of malignancy. Treating providers are expected to carefully review and comply with the most up-to-date evidence-based clinical practice guidelines for AFG in effect at the time of the member’s breast reconstruction surgery.

At least ONE (1) of the following criteria is met, as specified below in items a through c:

a. **Surgical Correction Following a Mastectomy or Lumpectomy (for Breast Cancer Treatment), Breast Cancer Reconstruction, and/or as Prophylaxis for Breast Cancer in the Affected and/or Contralateral Breast:**

   Breast reconstruction and treatment of physical complications in connection with a mastectomy or lumpectomy may include ONE (1) or more of the following treatments, as specified below in items (1) through (3):

   (1) Reconstructive surgery of the member’s affected breast (with applicable procedures specified in the Applicable Coding section of this policy). Reconstructive surgery may or may not involve one (1) or more of the following methods, as determined appropriate for the member following mastectomy or lumpectomy: Breast reconstruction using prosthetic implants/breast augmentation, skin/tissue expanders, autologous tissue reconstruction (using vascularized autologous tissue), autologous fat grafting (using non-vascularized lipoaspirate autologous fat), nipple/areola reconstruction, mastopexy, and/or breast reduction mammoplasty to restore the normal appearance of the breast; AND/OR

   (2) Contralateral surgery for the member’s unaffected breast (with applicable procedures specified in the Applicable Coding section of this policy). Contralateral surgery may or may not involve one (1) or more of the following methods, as determined appropriate for the member following mastectomy or lumpectomy: Breast reconstruction using prosthetic implants/breast augmentation, autologous tissue reconstruction (using vascularized autologous tissue), autologous fat grafting (using non-vascularized lipoaspirate autologous fat), nipple/areola reconstruction, mastopexy, and/or breast reduction mammoplasty to improve symmetry and appearance; AND/OR

   (3) Treatment of lymphedema; OR

b. **Surgical Removal of Breast Implant (Initially Inserted for Breast Cancer Reconstruction):**

   The Plan considers the surgical removal of a breast implant to be medically necessary when ALL of the following criteria are met, as specified below in items (1) through (3):

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(1) The breast implant insertion was related to breast cancer treatment or breast cancer reconstruction; AND

(2) The treating provider has determined that removal of the member’s breast implant is needed to facilitate breast cancer treatment or to treat a medical condition which may include but is not limited to ANY of the following, as specified below in items (a) through (c):

(a) A medical complication of a breast implant (e.g., implant rupture, infection, contracture, extrusion); OR

(b) Treatment or monitoring of breast cancer; OR

(c) Treatment related to breast reconstruction for breast cancer; AND

(3) When criteria are met unilaterally (in the affected breast) for removal of a breast implant and the implant was inserted for breast reconstruction (as defined in the Description of Item or Service section) related to breast cancer treatment or breast cancer reconstruction, removal of the breast implant in the contralateral unaffected breast is also covered; OR

c. Reconstructive Breast Surgery After Breast Implant Removal (Initially Inserted for Breast Cancer Treatment/Reconstruction):

The Plan considers breast reconstruction (with or without replacement of breast implant) of the affected breast and/or unaffected contralateral breast (non-diseased breast) to be medically necessary when BOTH of the following criteria are met, as specified below in items (1) and (2):

(1) Plan criteria are met for breast implant removal for a member who had a breast implant inserted after breast cancer treatment or reconstruction (as specified above in item 1b of this section); AND

(2) When criteria are met unilaterally (in the affected breast) for breast reconstruction after removal of a breast implant and the implant was inserted for breast reconstruction (as defined in the Description of Item or Service section) related to breast cancer treatment, replacement of the breast implant in the contralateral unaffected breast is also covered; OR

2. Breast Reconstruction for a Diagnosis Other Than Breast Cancer:

The member’s condition must meet the definition of breast reconstruction rather than a cosmetic procedure, as specified in the Description of Item or Service section. Breast Reconstruction

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reconstruction for MtF members with persistent, well-documented gender dysphoria includes augmentation mammoplasty with implantation of breast prostheses and/or the medically necessary surgical removal of breast implants with replacement of breast implants after implant explantation. See Plan policy, *Gender Reassignment Surgery* medical policy, policy number OCA 3.11, (rather than this Plan medical policy) for the initial breast augmentation procedure. Review criteria in the Medical Policy Statement section of this policy (rather than the criteria included in the *Gender Reassignment Surgery* medical policy) for Plan prior authorization guidelines for the medically necessary surgical removal of breast implants and the replacement of breast implants after implant explantation (when the implant was initially inserted for breast reconstruction as a component of gender reassignment surgery).

At least ONE (1) of the following applicable criteria must be met and documented in the member’s medical record (including preoperative photographs, which will be submitted as part of the prior authorization review process if requested by the Plan) for breast reconstruction, as specified below in item a (for surgical reconstructive procedures other than breast implant removal or re-implantation), item b (for breast implant removal), and/or item c (for replacement of breast implant). Utilize Plan medical criteria in item A1 of this Medical Policy Statement section (rather than this section) when the member has had a diagnosis of breast cancer.

a. **Breast Reconstructive Procedures (Except Removal or Re-implantation of Breast Implant):**

ALL of the following criteria are met, as specified below in items (1) through (3):

1. There is documented evidence of at least ONE (1) of the following conditions, as specified below in item (a) or item (b):
   
   a. Significant physical functional impairment (as specified in the Definitions section of this policy) or pain related to the diagnosis that is refractory to medical management; OR
   
   b. Severe disfigurement resulting from injury, trauma, or disease (e.g., Poland Syndrome); AND

2. The treatment (breast reconstructive and restorative service) can be reasonably expected to improve the physical functional impairment or relieve the pain; AND

3. When criteria are met unilaterally (in the affected breast) for breast reconstruction (as defined in the Description of Item or Service section) and the breast reconstruction is not related to breast cancer treatment or breast cancer reconstruction, breast reconstruction in the contralateral unaffected breast is covered ONLY when performed at the same time as the affected breast; OR

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b. **Surgical Removal of Breast Implant (Initially Inserted for Breast Reconstruction):**

ALL of the following criteria must be met for breast implant removal when the initial implantation was related to breast reconstruction (as defined in the Description of Item or Service section of this policy but not related to breast cancer treatment or breast cancer reconstruction), as specified below in items (1) through (3):

(1) There is documented evidence of a significant physical functional impairment (as specified in the Definitions section of this policy) by meeting at least ONE (1) of the following criteria, as specified below in items (a) through (d):

(a) Implant removal is required to treat a persistent or recurrent infection (local or systemic) that is secondary to the breast implant and refractory to medical management including antibiotics; OR

(b) Implant removal is required to treat a capsular contracture and BOTH of the following criteria are met, as specified below in items i and ii:

   i. Capsular contracture is categorized as Baker Grade III or Baker Grade IV; AND

   ii. Capsular contracture is causing pain; OR

(c) Implant removal is required due to breast implant exposure/extrusion; OR

(d) Implant removal of a ruptured breast implant (intracapsular or extracapsular rupture) when ONE (1) of the following criteria is met, as specified below in item i or item ii:

   i. Rupture of silicone gel-filled breast implant (i.e., partially or completely filled with silicone gel) confirmed with MRI or other conclusive imaging study; OR

   ii. Rupture of saline-filled breast implant confirmed with MRI or other conclusive imaging study with a functional physical impairment (as specified in the Definitions section of this Plan policy) such as significant capsular contracture (Baker Grade III with pain or Baker Grade IV with pain) or persistent infection refractory to medical management including antibiotics; AND

(2) The treatment can be reasonably expected to improve the physical functional impairment or relieve the pain; AND

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(3) When criteria are met unilaterally (in the affected breast) for removal of a breast implant and the implant was inserted for breast reconstruction (as defined in the Description of Item or Service section), **removal of the breast implant in the contralateral unaffected breast is covered ONLY when both breast implants are removed at the same time; OR**

c. **Replacement of Breast Implant After Implant Explantation (Initially Inserted for Breast Reconstruction):**

The Plan considers the replacement of a breast implant to be medically necessary when ALL of the following criteria are met, as specified below in items (1) through (3):

(1) The initial breast implant was placed for a medically necessary condition that meets the Plan definition of breast reconstruction (as specified in the Description of Item or Service section and medical criteria listed above in item 2a of this section); AND

(2) The initial breast implant was removed for a medically necessary condition that meets Plan criteria for breast implant removal for breast reconstruction, as specified above in item 2b of this section; AND

(3) When criteria are met unilaterally (in the affected breast) for the replacement of a breast implant listed above in item (1) and item (2) after removal of a breast implant initially inserted for breast reconstruction (as defined in the Description of Item or Service section), **replacement of the breast implant in the contralateral unaffected breast is covered ONLY when both breast implants are replaced at the same time; OR**

**B. Breast Procedures Related to Cosmetic Services:**

Applicable criteria must be met for breast procedures related to cosmetic services, as specified below in item 1, item 2, or item 3.

1. **Cosmetic Breast Procedures (Except Removal or Re-implantation of Breast Implant):**

Cosmetic services (including devices, drugs, procedures, and surgery) are considered NOT medically necessary by the Plan, as specified in the Plan policy, *Cosmetic, Reconstructive, and Restorative Services* (policy number OCA 3.69). Even if the initial breast augmentation surgery was a cosmetic procedure (and not medically necessary), removal of the breast implant may be medically necessary due to a documented medical complication in the affected breast, as specified below in item 2 (Breast Implant Removal in Affected Breast Only); OR
2. **Breast Implant Removal in Affected Breast Only (After Cosmetic Breast Augmentation Surgery):**

   ALL of the following criteria must be met for breast implant removal (when the initial implantation was a cosmetic procedure), as specified below in items a through c:

   a. There is documented evidence of a significant physical functional impairment (as specified in the Definitions section of this policy) by meeting at least ONE (1) of the following criteria, as specified below in items (1) through (4):

      (1) Implant removal is required to treat a persistent or recurrent infection (local or systemic) that is secondary to the breast implant and refractory to medical management including antibiotics (and does not include the contralateral unaffected breast when medical criteria are not met); OR

      (2) Implant removal is required to treat a capsular contracture and ALL of the following criteria are met (and does not include the contralateral unaffected breast when criteria are not met), as specified below in items (a) through (c):

         (a) Capsular contracture is categorized as Baker Grade III or Baker Grade IV; AND

         (b) Capsular contracture is causing pain; AND

         (c) Symptoms are refractory to medical management (including antibiotics); OR

      (3) Implant removal is required due to breast implant exposure/extrusion; OR

      (4) Implant removal of a ruptured breast implant (intracapsular or extracapsular rupture) when ONE (1) of the following criteria is met (and does NOT include the contralateral unaffected breast when criteria are NOT met for the unaffected breast), as specified below in item (a) or item (b):

         (a) Rupture of silicone gel-filled breast implant (i.e., partially or completely filled with silicone gel) confirmed with MRI or other conclusive imaging study; OR

         (b) Rupture of saline-filled breast implant confirmed with MRI or other conclusive imaging study with a functional physical impairment (as specified in the Definitions section of this Plan policy) such as significant capsular contracture (Baker Grade III with pain or Baker Grade IV with pain) or persistent infection refractory to medical management including antibiotics; AND

   b. The treatment can be reasonably expected to improve the physical functional impairment or relieve the pain; AND
c. When the initial breast implant surgery is cosmetic and NOT related to breast reconstruction (as defined in the Description of Item or Service section), breast implant removal in the contralateral unaffected breast is NOT medically necessary. Each breast implant removal must independently meet criteria for breast implant explantation; OR

3. Replacement of Breast Implant After Cosmetic Breast Augmentation Surgery:

When the initial breast implant surgery is cosmetic and NOT related to breast reconstruction (as defined in the Description of Item or Service section), the Plan considers the replacement of breast implant(s) to NOT be medically necessary. The replacement of the breast implant is NOT considered medical necessary for the affected breast and/or the contralateral unaffected breast, even when the breast implant removal is due to a medical complication and meets applicable Plan criteria, as specified above.

See the Gender Reassignment Surgery medical policy, policy number OCA 3.11, for Plan’s prior authorization guidelines for breast augmentation for male-to-female (MtF) members and mastectomy for female-to-male (FtM) members for gender reassignment (rather than other Plan medical policies related to the requested breast procedures). Review the Gynecomastia Surgery medical policy (policy number OCA 3.48) for medical necessity criteria for gynecomastia surgery (including but not limited to the surgical treatment for gynecomastia to reduce HIV-associated lipohypertrophy of the chest). See the Plan medical policy, Cosmetic, Reconstructive, and Restorative Services (policy number OCA 3.69), rather than this policy for medical necessity criteria for the following indications for treatment: Treatment of HIV-associated lipodystrophy when it is not associated with gynecomastia surgery (e.g., liposuction/suction assisted lpectomy, autologous fat grafts, and reconstructive breast procedures for HIV-associated lipodystrophy, and/or dermal filler injections for the treatment of facial lipoatrophy syndrome) and/or the treatment of lipodystrophy when the condition is not associated with HIV. For pharmacotherapy, see the Plan’s applicable pharmacy policies available at www.bmchp.org for BMC HealthNet Plan members and posted at www.wellsense.org for Well Sense Health Plan members; pharmacy policies include prior authorization guidelines and medical necessity criteria for the Plan’s covered drug list (categorized by medical drug name), including but not limited to the Plan’s Egrifta® pharmacy policy, policy number 9.032.

Limitations

1. Implantation of an internal breast prosthesis that is not approved by the U. S. Food and Drug Administration (FDA) is considered experimental and investigational for any indication (including breast cancer reconstruction surgery).

2. The use of autologous fat grafting (AFG) or adipose-derived stem cells (included in fat harvested from donor sites for AFG) for reconstruction of the breast is considered experimental and investigational unless the procedure is included in breast reconstruction for breast cancer

Breast Reconstruction

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Breast Reconstruction

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Plan Medical Director review is required for all other indications because questions remain regarding the safety of this type of breast reconstruction; some in vitro studies have indicated that adipocytes and their associated milieu may directly stimulate tumor growth and progression, and adipose-derived stem cells within the graft may increase the risk of malignant transformation. See the Plan medical policy, *Cosmetic, Reconstructive, and Restorative Services* (policy number OCA 3.69), rather than this policy for medical necessity criteria for the use of AFG to treat HIV-associated lipodystrophy.

In compliance with the Women’s Health and Cancer Rights Act of 1998, the Plan covers all stages of reconstruction surgery after a diagnosis of breast cancer on the affected breast and contralateral breast; medically necessary services are determined in consultation with the attending physician and the member. However, questions remain regarding the safety of AFG for some indications. The Post-Mastectomy Fat Graft/Fat Transfer Guiding Principles from the American Society of Plastic Surgeons (ASPS) reaffirmed in June 2015 state that autologous fat grafting (AFG) is a safe and effective modality in breast reconstruction when the patient has no native breast tissue present; these ASPS guidelines do not reference the safety of AFG for a patient who has had breast conserving therapy (also called lumpectomy, quadrantectomy, partial mastectomy, or segmental mastectomy) rather than a mastectomy (in which the entire breast is removed, including all of the breast tissue and sometimes other nearby tissues). According to a Hayes report updated in July 2016, AFG is increasingly used as an adjunct to reconstructive surgery among patients having undergone surgery for breast cancer but there is very-poor-quality body of evidence demonstrating the safety and effectiveness of AFG; questions still remain regarding the safety of the procedure, with some studies indicating that adipose cells may directly stimulate tumor growth and may increase the risk of malignancy. Treating providers are expected to carefully review and comply with the most up-to-date evidence-based clinical practice guidelines for AFG in effect at the time of the member’s breast reconstruction surgery.

3. Augmentation mammoplasty is NOT considered medically necessary to enlarge small but otherwise normal breasts or to create symmetry between normal breasts (unless the procedure is included in breast reconstruction for breast cancer treatment in the affected and/or contralateral breast and Plan prior authorization is obtained).

4. Nipple inversion correction is NOT considered medically necessary (unless the procedure is included in breast reconstruction for breast cancer treatment in the affected and/or contralateral breast and Plan prior authorization is obtained).

5. Tattooing to correct color defects of skin is NOT considered medically necessary (unless the procedure is included in breast reconstruction for breast cancer treatment in the affected and/or contralateral breast and Plan prior authorization is obtained).
6. One (1) or more of the following indications for explantation of intact breast implant(s) are NOT considered medically necessary (unless the member requires or has a history of breast cancer treatment and/or breast cancer reconstructive surgery), as specified below in items a through e:

a. Systemic symptoms attributed to autoimmune diseases or connective tissues diseases; OR

b. Suspected benefit for prophylaxis against breast cancer; OR

c. Patient anxiety; OR

d. Breast implant has repositioned/shifted; OR

e. When applicable Plan medical criteria (specified in the Medical Policy Statement section) are NOT met.

7. Plan Medical Director review is required for breast reconstruction of the member’s affected breast and/or contralateral breast after a diagnosis of breast cancer when Plan criteria in the Medical Policy Statement section are not met and/or the service is not specified as medically necessary in the Limitations or Applicable Coding section of this policy.

Review Plan policies, Cosmetic, Reconstructive, and Restorative Services (policy number OCA 3.69) and Medically Necessary, (policy number OCA 3.14) for Plan guidelines for medically necessary treatment and cosmetic services. See Plan policy, Experimental and Investigational Treatment (policy number OCA 3.12) for the Plan definitions of experimental or investigational treatment.

Definitions

Augmentation Mammoplasty/Breast Augmentation Surgery: Surgical placement of breast implants to increase fullness and improve symmetry of the breasts, or to restore breast volume lost after weight reduction or pregnancy. Breast implants may also be used for breast reconstruction after mastectomy or injury.

Autologous Fat Grafting (AFG): Also known as autologous fat transfer, autologous adipocyte transfer, lipoaspirate, lipoinjection, lipotransfer, liposculpture, lipectomy, lipoaugmentation, lipotransplantation, lipofilling, and lipomodelling, AFG describes the harvesting of the patient’s own body fat (from sites such as the abdomen, thighs, buttocks, or flank) using liposuction followed by its reinjection into the tissue to be corrected, contoured, or augmented after breast conserving therapy (lumpectomy) or mastectomy in the affected and/or contralateral breast, “rippling” after implant-based reconstruction and improvement of the transition zone between flap and skin, and/or preparation of the irradiated chest wall prior to breast implant placement. The patient must have several donor sites equipped with fat, because the reconstructive procedure usually takes four (4) to six (6) stages of fat grafting, with each

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A breast reconstruction procedure generally a few months apart. Autologous fat grafting is considered a natural filler, and unlike synthetic fillers will neither induce any foreign body reaction nor be resorbed completely. Risks and complications reported in the literature include bleeding, calcifications, fat embolism, fat necrosis, infection, oil cysts and graft volume loss; cases of severe complications and death appear to be extremely rare. An alternative to the use of standard AFG is the use of enriched AFG. Enriched AFG is harvested fat enriched with stem cells, platelet-rich plasma, vascular endothelial growth factors, or other biological additives.

**Baker Grades:** A classification of capsular contracture after breast implantation. The Baker grading is as follows:

1. Grade I the breast is normally soft and looks natural
2. Grade II the breast is a little firm but looks normal
3. Grade III the breast is firm and looks abnormal
4. Grade IV the breast is hard, painful, and looks abnormal

**Breast Implant Extrusion:** Lack of adequate tissue coverage or infection may result in exposure and extrusion of the breast implant through the skin. An implant may become visible at the surface of the breast as a result of the device pushing through layers of skin due to tissue breakdown (necrosis) or when the incision site fails to heal normally. Implant removal may be necessary, and permanent scar deformity may occur.

**Capsular Contraction/Capsular Contracture:** Hardening and constriction of the breast implant capsule that causes breast firmness. The capsule naturally forms around a foreign object in the body such as a breast implant. In the most severe cases of breast implant capsular contraction, it can create a painful, distorted, misshaped, or oddly positioned implant.

**HIV-associated Lipodystrophy:** Abnormal fat accumulation (lipohypertrophy), localized loss of fat tissue (lipoatrophy), or a combination of both that are associated with metabolic complications (such as dyslipidemia, glucose intolerance, and insulin resistance) and contribute to HIV-related morbidity and mortality through increased cardiovascular and cerebrovascular disease risk. The syndrome occurs in HIV-infected patients treated with antiretroviral medications (e.g., protease inhibitors and nucleoside reverse transcriptase inhibitors). HIV may be a causal factor for lipodystrophy by interfering with the way the body processes adipose tissue. Treatment for HIV-associated lipodystrophy may include conservative treatment (diet modification and exercise), pharmacotherapy, or surgical intervention when conservative treatment and drug therapy are not effective. The magnitude of fat loss determines the severity of metabolic complications and associated treatment plan.
Lipodystrophy: A medical condition resulting in abnormal fat accumulation (lipohypertrophy), localized loss of fat tissue (lipoatrophy), or a combination of both with metabolic complications (such as dyslipidemia, glucose intolerance, and insulin resistance). With lipoatrophy, there is selective, subcutaneous fat loss (either partial or near total absence of adipose tissue) from various regions of the body, generally occurring in the limbs, face, and/or buttocks. Lipohypertrophy (fat accumulation), when present, most commonly occurs in the abdomen, dorsocervical area (developing fat pad enlargement known as buffalo hump), and the breast/chest. In addition, lipomas may develop in other parts of the body. A disruption in the total amount and distribution of adipose tissue (as an active endocrine organ) contribute to metabolic abnormalities that alter hormone levels secreted by adipose tissue. The magnitude of fat loss determines the severity of metabolic complications and may result in dyslipidemia and abnormal glucose metabolism (predisposing the patient to cardiovascular disease and diabetes mellitus). The physical changes associated with the lipodystrophy syndrome can be divided into three (3) major types: lipoatrophy or fat wasting; lipohypertrophy or fat accumulation; and mixed forms with atrophy and hypertrophy coexisting in different body regions. Men tend to experience lipoatrophy and women are more likely to have lipohypertrophy. Withdrawal of antiretroviral therapy and therapeutic strategies do not achieve substantial improvements and may not be medically appropriate. Two major types of lipodystrophies are inherited (familial or genetic lipodystrophies) or secondary to a medical condition or drug treatment (e.g., HIV-associated lipodystrophy).

Oncoplastic Breast Reconstruction: The surgical management of breast cancer with complete resection of the tumor, preservation of normal tissue, immediate breast reconstruction of the affected breast at the time of the surgical treatment for breast cancer, and may also include symmetrizing surgery for the contralateral breast to improve aesthetic outcomes and patient satisfaction.

Physical Functional Impairment: A physical condition in which the normal or proper action of a body part or organ is damaged. This includes but is not limited to problems with ambulation, speech and communication, respiration and control of secretions, protection of airway, swallowing, nutrition, vision, or the alteration of skin function (e.g., some dermatologic conditions such as pemphigus that impair the fluid balance of the skin). A physical functional impairment does not include an individual’s emotional well-being or mental health.

Poland’s Syndrome: A rare congenital abnormality characterized by absence (aplasia) of chest wall muscles on one side of the body (absence of the sternocostal portion of the pectoralis major), hypoplasia of the hand and forearm, and complete or incomplete syndactyly and short fingers. Affected individuals may have variable associated features, such as under development or absence of one nipple (including the darkened area around the areola) and/or patchy absence of hair under the axilla. In females (or individuals born with female reproductive organs and/or with typical female karyotype with two [2] X chromosomes), there may be underdevelopment or absence (aplasia) of one breast and subcutaneous tissues. In some cases, associated skeletal abnormalities may also be present, such as underdevelopment or absence of upper ribs, elevation of the shoulder blade (Sprengel deformity), and/or shortening of the arm with underdevelopment of the ulna and radius.
Reconstructive and Restorative Services: (a) Those services that are performed for the primary purpose of improving, repairing, restoring, or correcting a physical functional impairment, or relieving pain, resulting from any of the following: accidental traumatic injury, post-therapeutic intervention (e.g., radiation or chemotherapy), birth abnormality, congenital defect, disease process, or anatomic variants; or (b) post-mastectomy services for eligible members.

Applicable Coding

The Plan uses and adopts up-to-date Current Procedural Terminology (CPT) codes from the American Medical Association (AMA), International Statistical Classification of Diseases and Related Health Problems, 10th revision (ICD-10) diagnosis codes developed by the World Health Organization and adapted in the United Stated by the National Center for Health Statistics (NCHS) of the Centers for Disease Control under the U.S. Department of Health and Human Services, and the Health Care Common Procedure Coding System (HCPCS) established and maintained by the Centers for Medicare & Medicaid Services (CMS). Because the AMA, NCHS, and CMS may update codes more frequently or at different intervals than Plan policy updates, the list of applicable codes included in this Plan policy is for informational purposes only, may not be all inclusive, and is subject to change without prior notification. Whether a code is listed in the Applicable Coding section of this Plan policy does not constitute or imply member coverage or provider reimbursement. Providers are responsible for reporting all services using the most up-to-date industry-standard procedure and diagnosis codes as published by the AMA, NCHS, and CMS at the time of the service.

Providers are responsible for obtaining prior authorization for the services specified in the Medical Policy Statement section and Limitation section of this Plan policy, even if an applicable code appropriately describing the service that is the subject of this Plan policy is not included in the Applicable Coding section of this Plan policy. Coverage for services is subject to benefit eligibility under the member’s benefit plan. Please refer to the member’s benefits document in effect at the time of the service to determine coverage or non-coverage as it applies to an individual member. See Plan reimbursement policies for Plan billing guidelines.

See Plan policy, Skin Substitutes in the Outpatient Setting (policy number OCA 3.710), for applicable codes for tissue-engineered skin substitutes that are considered medically necessary for breast reconstruction with Plan prior authorization. Review Plan policy, Breast Reduction Mammaplasty (policy number OCA 3.44) for medical criteria and applicable coding for mammaplasty when related to breast reconstruction after lumpectomy or mastectomy or for any other indication. See Plan policy, Mastopexy (policy number OCA 3.717), for medical criteria and applicable coding for mastopexy when related to breast reconstruction after lumpectomy or mastectomy or for any other indication.
Breast Reconstruction

Plan notes:
1. For breast reconstruction of the member’s affected breast and/or contralateral breast after a diagnosis of breast cancer, one (1) or more of the following applicable codes (and corresponding services) are considered medically necessary according to applicable criteria in the Medical Policy Statement section.
2. For breast reconstruction for a member with a diagnosis other than breast cancer, the following applicable codes (and corresponding services) are considered medically necessary only when applicable criteria are met in the Medical Policy Statement section.

<table>
<thead>
<tr>
<th>CPT Codes</th>
<th>Description: Codes covered when medically necessary.</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>
</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 (Use 11922 in conjunction with 11921)</td>
</tr>
<tr>
<td>11970</td>
<td>Replacement of tissue expander with permanent prosthesis</td>
</tr>
<tr>
<td>11971</td>
<td>Removal of tissue expander(s) without insertion of prosthesis</td>
</tr>
<tr>
<td>15777</td>
<td>Implantation of biologic implant (e.g., acellular dermal matrix) for soft tissue reinforcement (e.g., breast, trunk) (List separately in addition to code for primary procedure)</td>
</tr>
<tr>
<td>19324</td>
<td>Mammaplasty, augmentation; without prosthetic implant</td>
</tr>
<tr>
<td>19325</td>
<td>Mammaplasty, augmentation; with prosthetic implant</td>
</tr>
</tbody>
</table>

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<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
<th>Plan note:</th>
</tr>
</thead>
<tbody>
<tr>
<td>19328</td>
<td>Removal of intact mammary implant</td>
<td></td>
</tr>
<tr>
<td>19330</td>
<td>Removal of mammary implant material</td>
<td></td>
</tr>
<tr>
<td>19340</td>
<td>Immediate insertion of breast prosthesis following mastopexy, mastectomy or in reconstruction</td>
<td></td>
</tr>
<tr>
<td>19342</td>
<td>Delayed insertion of breast prosthesis following mastopexy, mastectomy or in reconstruction</td>
<td></td>
</tr>
<tr>
<td>19350</td>
<td>Nipple/areola reconstruction</td>
<td></td>
</tr>
<tr>
<td>19355</td>
<td>Correction of inverted nipple</td>
<td></td>
</tr>
<tr>
<td>19357</td>
<td>Breast reconstruction, immediate or delayed, with tissue expander, including subsequent expansion</td>
<td></td>
</tr>
<tr>
<td>19361</td>
<td>Breast reconstruction with latissimus dorsi flap, without prosthetic implant</td>
<td></td>
</tr>
<tr>
<td>19364</td>
<td>Breast reconstruction with free flap</td>
<td></td>
</tr>
<tr>
<td>19367</td>
<td>Breast reconstruction with transverse rectus abdominis myocutaneous flap (TRAM), single pedicle, including closure of donor site</td>
<td></td>
</tr>
<tr>
<td>19368</td>
<td>Breast reconstruction with transverse rectus abdominis myocutaneous flap (TRAM), single pedicle, including closure of donor site, with microvascular anastomosis (supercharging)</td>
<td></td>
</tr>
<tr>
<td>19369</td>
<td>Breast reconstruction with transverse rectus abdominis myocutaneous flap (TRAM), double pedicle, including closure of donor site</td>
<td></td>
</tr>
<tr>
<td>19370</td>
<td>Open periprosthetic capsulotomy, breast</td>
<td></td>
</tr>
<tr>
<td>19371</td>
<td>Periprosthetic capsulectomy, breast</td>
<td></td>
</tr>
<tr>
<td>19380</td>
<td>Revision of reconstructed breast</td>
<td></td>
</tr>
<tr>
<td>19396</td>
<td>Preparation of moulage for custom breast implant</td>
<td></td>
</tr>
</tbody>
</table>

**HCPCS Codes**

<table>
<thead>
<tr>
<th>HCPCS Codes</th>
<th>Description: Codes covered when medically necessary.</th>
</tr>
</thead>
</table>

Plan notes:
1. For breast reconstruction of the member’s affected breast and/or contralateral breast after a diagnosis of breast cancer, one (1) or more of the following applicable codes (and corresponding services) are considered medically necessary according to applicable criteria in the Medical Policy Statement section.
2. For breast reconstruction for a member with a diagnosis other than breast cancer, the following applicable codes (and corresponding services) are considered medically necessary only when applicable criteria are met in the...
<table>
<thead>
<tr>
<th>CPT Code</th>
<th>Description: Code may be covered or considered experimental and investigational based on indication for treatment and type of service provided.</th>
</tr>
</thead>
<tbody>
<tr>
<td>19366</td>
<td>Breast reconstruction with other technique</td>
</tr>
<tr>
<td></td>
<td>Plan notes:</td>
</tr>
<tr>
<td></td>
<td>1. Code used when billing for autologous fat grafting (AFG) for breast reconstruction or for other breast reconstruction techniques not specified in another industry-standard CPT or HCPCS procedure code.</td>
</tr>
<tr>
<td></td>
<td>2. When this code is used for AFG, the CPT code must be billed with a primary diagnosis code related to breast cancer. AFG is only covered for a member (regardless of gender) after mastectomy or lumpectomy, including reconstruction of the affected breast, reconstruction of the unaffected contralateral breast after mastectomy or lumpectomy to produce a symmetrical appearance, and/or for the treatment of physical complications of all stages of mastectomy or lumpectomy in compliance with Women’s Health and Cancer Rights Act of 1998. Treating providers are expected to carefully review and comply with the most up-to-date evidence-based clinical practice guidelines for AFG in effect at the time of the member’s breast reconstruction surgery. A summary of the American Society of Plastic Surgeons (ASPS) guidelines and Hayes report regarding the safety of AFG are included in the Medical Policy Statement and Limitations sections.</td>
</tr>
<tr>
<td></td>
<td>3. The Plan considers the use of autologous fat grafting (AFG) or adipose-derived</td>
</tr>
</tbody>
</table>
Clinical Background Information

Breast reconstruction is considered medically necessary after a mastectomy or lumpectomy to correct a deformity or re-establish symmetry secondary to previous breast surgery and/or the effects of therapeutic regimes such as radiation therapy. Breast reconstruction is medically necessary when used to restore functional impairments resulting from congenital anomalies, injury, trauma, and other diseases of the breast. Reconstruction procedures may involve multiple techniques and stages to recreate the breast mound through the use of one (1) or more of the following methods: Breast reconstruction using prosthetic implants/breast augmentation, skin/tissue expanders, autologous tissue reconstruction (using vascularized autologous tissue), autologous fat grafting (using non-vascularized lipoaspirate autologous fat), nipple/areola reconstruction, mastopexy, and/or breast reduction mammoplasty.

The Women's Health and Cancer Rights Act (WHCRA), signed into law on October 21, 1998, includes important protections for individuals who elect breast reconstruction in connection with a mastectomy. WHCRA amended the Employee Retirement Income Security Act of 1974 (ERISA) and the Public Health Service Act (PHS Act) and is administered by the Departments of Labor and Health and Human Services.

At the time of the Plan’s most recent policy review, the following applicable clinical guidelines were found from the Centers for Medicare & Medicaid Services (CMS) for breast surgery: National Coverage Determination (NCD) for Breast Reconstruction Following Mastectomy (140.2), NCD for Mammograms (220.4), Local Coverage Determination (LCD) for Cosmetic and Reconstructive Surgery (L34698), and LCD for Reduction Mammoplasty (L35001). No CMS clinical guidelines were identified specifically for mastopexy surgery or for autologous fat grafting for breast reconstruction during the policy review process. CMS guidelines for the medically necessary treatment of lipodystrophy only include dermal injections for the treatment of facial lipodystrophy syndrome (LDS) using FDA-approved dermal fillers with HIV infected beneficiaries when facial LDS caused by antiretroviral HIV treatment is a significant contributor to the patient’s depression. Verify if applicable CMS criteria are in effect for the requested breast procedure in an NCD or LCD on the date of the prior authorization request for a Senior Care Options member.
References


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Breast Reconstruction

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United States Department of Labor. FAQs About Women's Health And Cancer Rights.


*


<table>
<thead>
<tr>
<th>Original Approval Date</th>
<th>Original Effective Date* and Version Number</th>
<th>Policy Owner</th>
<th>Original Policy Approved by</th>
</tr>
</thead>
<tbody>
<tr>
<td>Regulatory Approval: N/A</td>
<td>11/06/05 Version 1</td>
<td>Medical Policy Manager as Chair of Medical Policy, Criteria, and Technology Assessment Committee (MPCTAC)</td>
<td>Quality and Clinical Management Committee (Q&amp;CMC)</td>
</tr>
<tr>
<td>Internal Approval: 09/06/05</td>
<td></td>
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</tr>
</tbody>
</table>

*Effective Date for the BMC HealthNet Plan Commercial Product(s): 01/01/12
*Effective Date for the Well Sense Health Plan New Hampshire Medicaid Product(s): 01/01/13
*Effective Date for the Senior Care Options Product(s): 01/01/16

<table>
<thead>
<tr>
<th>Review Revisions History</th>
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</thead>
<tbody>
<tr>
<td>Review Date</td>
</tr>
<tr>
<td>02/06/07</td>
</tr>
<tr>
<td>12/01/07</td>
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<tr>
<td>12/01/08</td>
</tr>
<tr>
<td>12/01/09</td>
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<tr>
<td>12/01/10</td>
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<tr>
<td>12/01/11</td>
</tr>
<tr>
<td>Date</td>
</tr>
<tr>
<td>------------</td>
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<tr>
<td><strong>07/01/12</strong></td>
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<tr>
<td><strong>12/01/12</strong></td>
</tr>
<tr>
<td><strong>04/01/13</strong></td>
</tr>
<tr>
<td><strong>06/01/13</strong></td>
</tr>
<tr>
<td><strong>04/01/14</strong></td>
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<tr>
<th>Date</th>
<th>Description</th>
<th>Effective Date</th>
<th>Reviewer</th>
</tr>
</thead>
<tbody>
<tr>
<td>06/01/15</td>
<td>Review for effective date 09/01/15. Removed Commonwealth Care, Commonwealth Choice, and Employer Choice from the list of applicable products because the products are no longer available. Updated Policy Summary, Description of Item or Service, Definitions, and References sections. Updated criteria in the Medical Policy Statement section and Limitations section.</td>
<td>09/01/15</td>
<td>06/01/15: MPCTAC (electronic vote) 06/10/15: QIC</td>
</tr>
<tr>
<td>11/25/15</td>
<td>Review for effective date 01/01/16. Updated template with list of applicable products and notes. Revised language in the Applicable Coding section.</td>
<td>01/01/16</td>
<td>11/18/15: MPCTAC 11/25/15: MPCTAC (electronic vote) 12/09/15: QIC</td>
</tr>
<tr>
<td>04/01/16</td>
<td>Review for effective date 08/01/16. Revised the Clinical Background Information, References, and Reference to Applicable Laws and Regulations sections. Added Plan notes in the Applicable Coding section. Added limitation and revised criterion in the Medical Policy Statement section.</td>
<td>08/01/16</td>
<td>04/20/16: MPCTAC 05/23/16: QIC</td>
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<tr>
<td>07/05/16</td>
<td>Review for effective date 10/01/16. Revised criteria in the Medical Policy Statement and Limitations sections. Updated Summary, Description of Item or Service, Definitions, Clinical Background Information, and References sections. Revised the applicable code list and added Plan notes for specific codes.</td>
<td>10/01/16</td>
<td>07/05/16: MPCTAC (electronic vote) 07/13/16: QIC</td>
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<tr>
<td>09/28/16</td>
<td>Review for effective date 11/01/16. Administrative changes made to clarify language related to gender.</td>
<td>11/01/16</td>
<td>09/30/16: MPCTAC (electronic vote) 10/12/16: QIC</td>
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<tr>
<td>04/01/17</td>
<td>Review for effective date 05/08/17. Administrative changes made to the Medical Policy Statement and</td>
<td>05/08/17</td>
<td>04/19/17: MPCTAC</td>
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</tbody>
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Breast Reconstruction

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### Policy Revisions History

Limitations sections. Plan notes added to the Applicable Coding section. Updated Summary, Definitions, Clinical Background Information, References, and References to Applicable Laws and Regulations sections.

### Last Review Date

04/01/17

### Next Review Date

04/01/18

### Authorizing Entity

MPCTAC

### Other Applicable Policies

Medical Policy - *Breast Reduction Mammaplasty*, policy number OCA 3.44
Medical Policy - *Cosmetic, Reconstructive, and Restorative Services*, policy number OCA 3.69
Medical Policy - *Experimental and Investigational Treatment*, policy number OCA 3.12
Medical Policy - *Gender Reassignment Surgery*, policy number OCA 3.11
Medical Policy - *Gynecomastia Surgery*, policy number OCA 3.48
Medical Policy - *Mastopexy*, policy number OCA 3.717
Medical Policy - *Medically Necessary*, policy number OCA 3.14
Medical Policy - *Skin Substitutes in the Outpatient Setting*, policy number OCA 3.710
Pharmacy Policy - *Egrifta®,* policy number 9.032
Reimbursement Policy - *Anesthesia*, policy number 4.103
Reimbursement Policy - *Bilateral and Multiple Procedure Reductions*, policy number 4.607
Reimbursement Policy - *Free Standing Surgical Facility Services*, policy number 4.114
Reimbursement Policy - *General Billing and Coding Guidelines*, policy number 4.31
Reimbursement Policy - *General Billing and Coding Guidelines*, policy number WS 4.17
Reimbursement Policy - *General Clinical Editing and Payment Accuracy Review Guidelines*, policy number 4.108
Reimbursement Policy - *General Clinical Editing and Payment Accuracy Review Guidelines*, policy number WS 4.18
Reimbursement Policy - *Outpatient Hospital*, policy number 4.17
Reimbursement Policy - *Physician and Non Physician Practitioner Services*, policy number 4.608
Reimbursement Policy - *Physician and Non Physician Practitioner Services*, policy number WS 4.28

Breast Reconstruction

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Reimbursement Policy - Professional Bilateral and Multiple Procedure Reductions, policy number: WS 4.24

Reference to Applicable Laws and Regulations


M.G.L. Chapter 233: An Act Relative to HIV-Associated Lipodystrophy Syndrome Treatment.


Breast Reconstruction

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Disclaimer Information: +

Medical Policies are the Plan’s guidelines for determining the medical necessity of certain services or supplies for purposes of determining coverage. These Policies may also describe when a service or supply is considered experimental or investigational, or cosmetic. In making coverage decisions, the Plan uses these guidelines and other Plan Policies, as well as the Member’s benefit document, and when appropriate, coordinates with the Member’s health care Providers to consider the individual Member’s health care needs.

Plan Policies are developed in accordance with applicable state and federal laws and regulations, and accrediting organization standards (including NCQA). Medical Policies are also developed, as appropriate, with consideration of the medical necessity definitions in various Plan products, review of current literature, consultation with practicing Providers in the Plan’s service area who are medical experts in the particular field, and adherence to FDA and other government agency policies. Applicable state or federal mandates, as well as the Member’s benefit document, take precedence over these guidelines. Policies are reviewed and updated on an annual basis, or more frequently as needed. Treating providers are solely responsible for the medical advice and treatment of Members.

The use of this Policy is neither a guarantee of payment nor a final prediction of how a specific claim(s) will be adjudicated. Reimbursement is based on many factors, including member eligibility and benefits on the date of service; medical necessity; utilization management guidelines (when applicable); coordination of benefits; adherence with applicable Plan policies and procedures; clinical coding criteria; claim editing logic; and the applicable Plan – Provider agreement.