BOSTON MEDICAL CENTER HEALTHNet PLAN

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WELL SENSE HEALTH PLAN

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Medical Policy

Breast Reconstruction

Policy Number: OCA 3.43
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Product Applicability	☒ **All Plan+ Products**
Well Sense Health Plan ☒ Well Sense Health Plan	**Boston Medical Center HealthNet Plan** ☒ MassHealth ACO ☒ MassHealth MCO ☒ Qualified Health Plans/ConnectorCare/Employer Choice Direct ☒ Senior Care Options ◊

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 member (i.e., 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 when applicable Plan criteria are met, as specified in the Medical Policy Statement section of this Plan policy. Prior authorization is required.

In accordance with Massachusetts state-mandated benefits, the Plan covers medically necessary treatment to correct or repair disturbances of body composition caused by HIV-associated lipodystrophy syndrome for a BMC HealthNet Plan member (i.e., Massachusetts resident enrolled in the Plan's MassHealth, Qualified Health Plans, or Senior Care Options product). 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's *Cosmetic, Reconstructive, and Restorative Services* medical policy, 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 lipectomy, autologous fat grafts, reconstructive breast procedures, 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.

It will be determined during the Plan's prior authorization process if the service is considered medically necessary for the requested use. The *Medically Necessary* medical policy, policy number OCA 3.14, includes the Plan's product-specific definitions of medically necessary treatment. Refer to the following Plan policies for information regarding additional breast procedures: *Breast Reduction Surgery* medical policy, policy number OCA 3.44; *Gynecomastia Surgery* medical policy, policy number OCA 3.48; *Mastopexy* medical policy, policy number OCA 3.717; and *Skin Substitutes in the Outpatient Setting* medical policy, policy number OCA 3.710.

Breast reconstruction for the treatment of 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 the Plan's *Gender Affirmation Surgeries* medical policy, policy number OCA 3.11, rather than this Plan medical policy to determine the medical necessity of chest reconstructive procedures used to treat gender dysphoria (e.g., treatment of gender dysphoria with breast augmentation, mastectomy, breast reconstruction with flaps, mastopexy, and/or breast reduction surgery). Review criteria in the Medical Policy Statement section of this policy (rather than the criteria included in the *Gender Affirmation Surgeries* medical policy) for Plan prior authorization guidelines for the medically necessary surgical removal of breast implants and/or the replacement of breast implants after implant explantation (including when the implant was initially inserted as a component of a gender affirmation 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 a gender affirmation 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 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 **medically necessary** when the procedure is included in breast reconstruction for breast cancer treatment in the affected and/or contralateral breast when no native breast tissue is present and Plan prior authorization is obtained. 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 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 surgery 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 surgery 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):

(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 for with the treatment of 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 the Plan's *Gender Affirmation Surgeries* 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 Affirmation Surgeries* 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 a gender affirmation surgery). 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.

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):

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 (4):

(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) Member 40 years of age or older has had a mammogram within 12 calendar months from the date of the planned procedure in both breasts; AND

(4) 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

◊ Note: 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 **medically necessary** when the procedure is included in breast reconstruction for breast cancer treatment in the affected and/or contralateral breast and Plan prior authorization is obtained for the breast reconstruction.

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 (4):

(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

(3) Member 40 years of age or older has had a mammogram of both breasts within 12 calendar months from the date of the planned procedure; AND

(4) 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 (4):

(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) Member 40 years of age or older has had a mammogram of both breasts within 12 calendar months from the date of the planned reduction surgery; AND

(4) 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's *Cosmetic, Reconstructive, and Restorative Services* medical policy, 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 d:

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 necessity 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 medical necessity 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 which is related to contractures or rupture; 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 medical necessity criteria are NOT met), 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. Member 40 years of age or older has had a mammogram of both breasts within 12 calendar months from the date of the planned breast procedure; AND

d. 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 medically 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.

Review the Plan's *Gender Affirmation Surgeries* medical policy, policy number OCA 3.11, for prior authorization guidelines for breast augmentation or mastectomy as gender affirmation surgery(ies) rather than other Plan medical policies related to the requested breast procedures. The *Gynecomastia Surgery* medical policy, policy number OCA 3.48, includes the Plan's 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's *Cosmetic, Reconstructive, and Restorative Services* medical policy, 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 lipectomy, 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 and/or the use of soft tissue fillers (i.e., injections using free silicone or other substances) that are NOT approved by the U. S. Food and Drug Administration (FDA) for the specified use are considered experimental and investigational (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 treatment in the affected and/or contralateral breast and Plan prior authorization is obtained. 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's *Cosmetic, Reconstructive, and Restorative Services* medical policy, 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 unproven 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 f:

    a. Systemic symptoms attributed to autoimmune diseases and/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. Pain which is NOT related to contractures or rupture; OR

f. 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.

8. Plan Medical Director review is required for breast reconstruction when related to an adverse effect of a cosmetic breast procedure/treatment (e.g., the use of soft tissue fillers administered with injections of free silicone or other substances), the member has had NO diagnosis of breast cancer, and applicable criteria have NOT been met in the Medical Policy Statement section of this policy. To determine the medical necessity of breast reconstruction of the affected breast, the treating provider must provide the following medical record documentation: description of member's medical condition supporting the member's plan of care; applicable past medical/surgical history; prior treatments with clinical outcomes, complications, and adverse effects (including timeline of symptoms); diagnostic clinical findings; and the requested surgical procedure(s). When breast reconstruction is requested on the contralateral unaffected breast, medical record documentation must support the medical necessity of breast reconstruction for the contralateral breast in addition to the affected breast.

9. Breast reconstruction for a member with persistent, well-documented gender dysphoria may include the surgical removal or implants and/or the replacement of breast implants after implant explantation (when the implant was initially inserted as a component of a gender affirmation surgery); these procedures are considered medically necessary when the Plan's applicable medical necessity criteria are met, as specified in the Medical Policy Statement section of this policy. See the Plan's *Gender Affirmation Surgeries* medical policy, policy number OCA 3.11, rather than this policy to determine the medical necessity of chest reconstructive procedures used to treat gender dysphoria (e.g., treatment of gender dysphoria with breast augmentation, mastectomy, breast reconstruction with flaps, mastopexy, and/or breast reduction surgery).

Review the following Plan medical policies for guidelines and product-specific definitions of cosmetic, reconstructive, medically necessary, and/or experimental and investigational services: *Cosmetic, Reconstructive, and Restorative Services* medical policy, policy number OCA 3.69; *Medically Necessary* medical policy, policy number OCA 3.14; and *Experimental and Investigational Treatment* medical policy, policy number OCA 3.12.

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, 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 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 an 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 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 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). Since 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 the Plan's *Skin Substitutes in the Outpatient Setting* medical policy, 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. The *Breast Reduction Surgery* medical policy, policy number OCA 3.44, includes the Plan's medical necessity criteria and applicable coding for mammoplasty when related to breast reconstruction after lumpectomy or mastectomy or for any other indication. Review the Plan's *Mastopexy* medical policy, 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.

CPT Codes	**Description: Services considered medically necessary.** 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 when applicable criteria are met 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 when applicable criteria are met in the Medical Policy Statement section.
11920	Tattooing, intradermal introduction of insoluble opaque pigments to correct color defects of skin, including micropigmentation; 6.0 sq. cm or less Plan note: This CPT code must be billed with a primary diagnosis code related to breast cancer. The service 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. Requests for other indications require Plan Medical Director review to determine the medical necessity of treatment.

11921	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) Plan note: This CPT code must be billed with a primary diagnosis code related to breast cancer. The service 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. Requests for other indications require Plan Medical Director review to determine the medical necessity of treatment.
11970	Replacement of tissue expander with permanent implant
11971	Removal of tissue expander(s) without insertion of implant
15769	Grafting of autologous soft tissue, other, harvested by direct excision (e.g., fat, dermis, fascia)
15771	Grafting of autologous fat harvested by liposuction technique to trunk, breasts, scalp, arms, and/or legs; 50 cc or less injectate Plan notes: 1. This procedure code is considered medically necessary when used to bill for autologous fat grafting (AFG) for breast reconstruction when billed with a primary diagnosis code related to breast cancer. AFG is 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. 2. When AFG is NOT included in a breast reconstruction procedure for breast cancer treatment in the affected and/or contralateral breast, the Plan considers the use of AFG or adipose-derived stem cells (included in fat harvested from donor sites for AFG) for reconstruction of the breast to be experimental and investigational. Requests for other indications require Plan Medical Director review to determine the medical necessity of treatment. Questions remain regarding the safety of the procedure; 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. 3. See the Plan's *Cosmetic, Reconstructive, and Restorative Services* medical policy, policy number OCA 3.12, for the Plan's guidelines on the use autologous fat grafts for the medically necessary treatment of HIV-associated lipodystrophy syndrome according to Massachusetts mandated benefits, as specified in Chapter 233 of the Acts of 2016, An Act Relative to HIV Associated Lipodystrophy Syndrome Treatment.
15772	Grafting of autologous fat harvested by liposuction technique to trunk, breasts, scalp, arms, and/or legs; each additional 50 cc injectate, or part thereof (List separately in addition to code for primary procedure) Plan notes: 1. This procedure code is considered medically necessary when used to bill for autologous fat grafting (AFG) for breast reconstruction when billed with a primary diagnosis code related to breast cancer. AFG is 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. 2. When AFG is NOT included in a breast reconstruction procedure for breast cancer treatment in the affected and/or contralateral breast, the Plan considers the use of AFG or adipose-derived stem cells (included in fat harvested from donor sites for AFG) for reconstruction of the breast to be experimental and investigational. Requests for other indications require Plan Medical Director review to determine the medical necessity of treatment. Questions remain regarding the safety of the procedure; 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. 3. See the Plan's *Cosmetic, Reconstructive, and Restorative Services* medical policy, policy number OCA 3.12, for the Plan's guidelines on the use autologous fat grafts for the medically necessary treatment of HIV-associated lipodystrophy syndrome according to Massachusetts mandated benefits, as specified in Chapter 233 of the Acts of 2016, An Act Relative to HIV Associated

	Lipodystrophy Syndrome Treatment.
15777	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)
19325	Breast augmentation with implant
19328	Removal of intact breast implant
19330	Removal of ruptured breast implant , including implant contents (e.g., saline, silicone gel)
19340	Insertion of breast implant on same day of mastectomy (i.e., immediate)
19342	Insertion or replacement of implant on separate day from mastectomy
19350	Nipple/areola reconstruction
19355	Correction of inverted nipple Plan note: This CPT code must be billed with a primary diagnosis code related to breast cancer. The service 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.
19357	Tissue expander placement in breast reconstruction, including subsequent expansion(s)
19361	Breast reconstruction with latissimus dorsi flap
19364	Breast reconstruction with free flap(e.g., fTRAM, DIEP, SIEA, GAP flap)
19367	Breast reconstruction with single-pedicled transverse rectus abdominis myocutaneous (TRAM) flap
19368	Breast reconstruction with single-pedicled transverse rectus abdominis myocutaneous (TRAM) , requiring separate microvascular anastomosis (supercharging)
19369	Breast reconstruction with bipedicled transverse rectus abdominis myocutaneous (TRAM) flap
19370	Revision of peri-implant capsule, breast, including capsulotomy, capsulorrhaphy, and/or partial capsulectomy
19371	Peri-implant capsulectomy, breast, complete, including removal of all intracapsular contents
19380	Revision of reconstructed breast (e.g., significant removal of tissue, re-advancement and/or re-inset of flaps in autologous reconstruction or significant capsular revision combined with soft tissue excision in implant-based reconstruction)
19396	Preparation of moulage for custom breast implant

HCPCS Code	Description: Service considered medically necessary
L8600	Implantable breast prosthesis, silicone or equal Plan note: This code is considered medically necessary when applicable criteria are met in the Medical Policy Statement section of this policy. When criteria are NOT met, Plan Medical Director review is required for individual consideration.

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 surgery.

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.

Early detection with imaging studies can prevent the development of life-threatening breast cancer. Mammography, ultrasonography, and/or magnetic resonance imaging (MRI) may be recommended before performing a breast procedure to detect breast cancer. There is no industry-wide consensus on breast cancer screening criteria, but guidelines are endorsed by the American Cancer Society (ACS), American College of Obstetricians and Gynecologists (ACOG), American College of Physicians (ACP), American College of Radiology (ACR), American Medical Association (AMA), National Cancer Institute (NCI), National Comprehensive Cancer Network (NCCN), and the United States Preventive Services Task Force (USPSTF)

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 Mammaplasty (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.

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Policy History

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

*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

Policy Revisions History			
Review Date	**Summary of Revisions**	**Revision Effective Date and Version Number**	**Approved by**
02/06/07	Updated references.	Version 2	02/06/07: Q&CMC
12/01/07	No changes.	Version 3	01/08/08: MPCTAC 01/22/08: Utilization Management Committee (UMC)
12/01/08	No changes to clinical criteria. Updated references.	Version 4	02/19/08: Quality Improvement Committee (QIC) 01/27/09: MPCTAC 01/27/09: UMC 02/25/09: QIC
12/01/09	Updated clinical criteria to include functional impairment, reconstructive and restorative language.	Version 5	12/23/09: MPCTAC 02/24/10: QIC
12/01/10	Updated coding and references.	Version 6	12/28/10: MPCTAC 01/26/11: QIC
12/01/11	Added language to include criteria for male and female breast reconstruction and treatment of lymphedema. Updated coding.	Version 7	12/12/11: MPCTAC 12/20/11: QIC
07/01/12	Off cycle review for Well Sense Health Plan. Revised Summary statement, reformatted Clinical Guideline Statement, updated coding, revised references.	Version 8	08/03/12: MPCTAC 09/05/12: QIC
12/01/12	Updated Summary section. Revised language in the Applicable Coding section and revised the applicable code list (by deleting CPT codes 19316 and 19318). Revised introductory sentence in Clinical Guideline Statement section and reformatted criteria. Referenced the following Plan policies: *Breast Reduction Mammoplasty in Females, Mastopexy, Surgical Treatment for Male Gynecomastia*, *Medically Necessary, and Skin Substitutes in the Outpatient Setting*. Changed name of policy category from "Clinical Coverage Guidelines" to "Medical Policy."	Version 9	12/19/12: MPCTAC 01/31/13: QIC

Policy Revisions History			
04/01/13	Review for effective date 08/01/13. Updated and added references. Revised introductory sentence in Medical Policy Statement section (formerly titled Clinical Guideline Statement section) and Clinical Background Information section. Revised applicable code list and text in Applicable Coding section. Referenced policy's Definitions section within the clinical criteria. Added limitations and referenced *Experimental and Investigational Treatment* policy.	08/01/13 Version 10	04/17/13: MPCTAC 05/16/13: QIC
06/01/13	Ad hoc review for effective date of 10/01/13. Revised language in Applicable Coding section and removed CPT code 19318 from the applicable code list.	10/01/13 Version 11	06/19/13: MPCTAC 07/18/13: QIC
04/01/14	Review for effective date 08/01/14. Deleted CPT code 19499 as an experimental and investigational code for breast reconstruction because the code is used for indications not related to this Plan policy. Revised Plan note for CPT code 19366. Added CPT code 19355 as an applicable code. Updated references.	08/01/14 Version 12	04/16/14: MPCTAC 05/14/14: QIC
06/01/15	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 and Limitations sections.	09/01/15 Version 13	06/01/15: MPCTAC (electronic vote) 06/10/15: QIC
11/25/15	Review for effective date 01/01/16. Updated template with list of applicable products and notes. Revised language in the Applicable Coding section.	01/01/16 Version 14	11/18/15: MPCTAC 11/25/15: MPCTAC (electronic vote) 12/09/15: QIC
04/01/16	Review for effective date 08/01/16.	08/01/16	04/20/16: MPCTAC

Policy Revisions History			
	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.	Version 15	05/23/16: QIC
07/05/16	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.	10/01/16 Version 16	07/05/16: MPCTAC (electronic vote) 07/13/16: QIC
09/28/16	Review for effective date 11/01/16. Administrative changes made to clarify language related to gender.	11/01/16 Version 17	09/30/16: MPCTAC (electronic vote) 10/12/16: QIC
04/01/17	Review for effective date 05/08/17. Administrative changes made to the Medical Policy Statement and 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.	05/08/17 Version 18	04/19/17: MPCTAC
03/01/18	Review for effective date 06/01/18. Updated Policy Summary, References, and Other Applicable Policies sections. Administrative change made to the Medical Policy Statement section. Revised criteria in the Limitations section. Clarified guidelines in the Applicable Coding section related to indications for autologous fat grafting. Updated applicable code list.	06/01/18 Version 19	03/21/18: MPCTAC
04/01/19	Review for effective date 07/01/19. Administrative changes made to the Clinical Background Information, References, Other Applicable Policies, and Reference to Applicable Laws and Regulations sections. Criteria revised in	07/01/19 Version 20	04/18/19: MPCTAC (electronic vote)

Policy Revisions History			
	the Medical Policy Statement and Limitations sections.		
01/01/20	Review for effective date 02/01/20. Industry-wide code updates effective 01/01/20 made to the Applicable Coding section. Plan notes revised in the Applicable Coding section. Updated the References section.	02/01/20 Version 21	01/15/20: MPCTAC
04/01/20	Review for effective date 05/01/20. Administrative changes made to the Applicable Coding, References, and Reference to Applicable Laws and Regulations sections.	05/01/20 Version 22	04/15/20: MPCTAC
12/01/20	Review for effective date 01/01/21. Industry-wide update to code descriptions in the Applicable Coding section. Administrative changes made to the Policy Summary, Medical Policy Statement, Limitations, Clinical Background Information, and Other Applicable Policies sections.	01/01/21 Version 23	Not applicable because industry-wide code changes; 12/16/20: MPCTAC review
04/01/21	Review for effective date 05/01/21. Administrative changes made to the Policy Summary, Medical Policy Statement, Limitations, and References sections.	05/01/21 Version 24	04/21/21: MPCTAC

Last Review Date

04/01/21

Next Review Date

04/01/22

Authorizing Entity

MPCTAC

Other Applicable Policies

Medical Policy - *Breast Reduction Surgery,* 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 Affirmation Surgeries*, 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 - *Ambulatory Surgical Center - Facility*, policy number SCO 4.114
Reimbursement Policy - *Ambulatory Surgery Center,* policy number WS 4.31
Reimbursement Policy - *Anesthesia*, policy number 4.103
Reimbursement Policy - *Anesthesia*, policy number SCO 4.103
Reimbursement Policy - *Anesthesia*, policy number WS 4.11
Reimbursement Policy - *Bilateral and Multiple Procedure Reductions*, policy number 4.607
Reimbursement Policy - *Bilateral and Multiple Procedure Reductions*, policy number SCO 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 SCO 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 SCO 4.018
Reimbursement Policy - *General Clinical Editing and Payment Accuracy Review Guidelines*, policy number WS 4.18
Reimbursement Policy - *Hospital*, policy number WS 4.21
Reimbursement Policy - *Inpatient Hospital*, policy number 4.110
Reimbursement Policy - *Inpatient Hospital*, policy number SCO 4.110
Reimbursement Policy - *Non-Participating Provider*, policy number WS 4.5
Reimbursement Policy - *Non-Reimbursed Codes*, policy number 4.38
Reimbursement Policy - *Non-Reimbursed Codes*, policy number WS 4.38
Reimbursement Policy - *Outpatient Hospital*, policy number 4.17
Reimbursement Policy - *Outpatient Hospital*, policy number SCO 4.17
Reimbursement Policy - *Physician and Non-Physician Practitioner Services*, policy number 4.608
Reimbursement Policy - *Physician and Non-Physician Practitioner Services*, policy number SCO 4.608
Reimbursement Policy - *Physician and Non-Physician Practitioner Services*, policy number WS 4.28
Reimbursement Policy - *Professional Bilateral and Multiple Procedure Reductions*, policy number WS 4.24
Reimbursement Policy - *Provider Preventable Conditions and Serious Reportable Events*, policy number 4.610
Reimbursement Policy - *Provider Preventable Conditions and Serious Reportable Events*, policy number SCO 4.610
Reimbursement Policy - *Provider Preventable Conditions and Serious Reportable Events*, policy number WS 4.29

Reference to Applicable Laws and Regulations

78 FR 48164-69. Federal Register. Centers for Medicare & Medicaid Services (CMS). Medicare Program. Revised Process for Making National Coverage Determinations. 2013 Aug 7.

130 CMR 410.00. Code of Massachusetts Regulations. Division of Medical Assistance. Outpatient Hospital Services.

130 CMR 415.000. Code of Massachusetts Regulations. Division of Medical Assistance. Acute Inpatient Hospital Services.

130 CMR 433.000. Code of Massachusetts Regulations. Division of Medical Assistance. Physician Services.

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He-W 500. New Hampshire Code of Administrative Rules. Medical Assistance.

He-W 530.01(e). New Hampshire Code of Administrative Rules. Medical Assistance. Service Limits, Co-Payments, and Non-Covered Services. Definitions. Medically Necessary.

He-W 531. New Hampshire Code of Administrative Rules. Medical Assistance. Physician Services.

He-W 543. New Hampshire Code of Administrative Rules. Medical Assistance. Hospital Services.

MGL c 233. Massachusetts General Laws. Chapter 233: An Act Relative to HIV-Associated Lipodystrophy Syndrome Treatment.

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RSA Chapter 417-D:2-b. New Hampshire Revised Statutes. Insurance. Women's Health Care. Reconstructive Surgery.

RSA Chapter 420-E. New Hampshire Revised Statutes. Insurance. Licensure of Medical Utilization Review Entitles.

U.S. Women's Health and Cancer Right Act of 1998.

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.