BOSTON MEDICAL CENTER HEALTHNet PLAN

bmchp.org | 888-566-0008

WELL SENSE HEALTH PLAN

wellsense.org | 877-957-1300

Medical Policy

Breast Reconstruction

Policy Number: OCA 3.43
Version Number: 25
Version Effective Date: 12/01/21

Product Applicability	☒ **All Plan+ Products**
WellSense Health Plan	**Boston Medical Center HealthNet Plan**
☒ NH Medicaid	☒ MassHealth ACO
☒ NH Medicare Advantage	☒ MassHealth MCO
	☒ Qualified Health Plans/ConnectorCare/Employer Choice Direct
	☒ Senior Care Options

+ Note: Disclaimer and audit information is located at the end of this document.

Policy Summary

The Plan considers breast reconstruction medically necessary when applicable Plan medical criteria are met after the diagnosis of breast cancer or for other indications. The Plan defines breast reconstruction as surgical procedures 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. Prior authorization is required.

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 at the same time as the surgical treatment for breast cancer (oncoplastic breast reconstruction) or at a later time (delayed breast reconstruction). The Plan complies with coverage guidelines for all applicable state-mandated benefits and federally-mandated benefits that are medically necessary for

+ *Plan* refers to Boston Medical Center Health Plan, Inc. and its affiliates and subsidiaries offering health coverage plans to enrolled members. The Plan operates in Massachusetts under the trade name Boston Medical Center HealthNet Plan and in other states under the trade name WellSense Health Plan.

the member's condition. Review the Plan's *Cosmetic, Reconstructive, and Restorative Services* medical policy, policy number OCA 3.12 for guidelines on the use autologous fat grafts to treat 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. Other applicable medical policies include: *Breast Reduction Surgery* medical policy, policy number OCA 3.44; *Gender Affirmation Services* medical policy, policy number OCA 3.11; *Gynecomastia Surgery* medical policy 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.

Clinical Criteria

Breast reconstruction is considered medically necessary when applicable criteria are met and documented in the member's medical record, as stated below in item A or item B:

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

Applicable criteria must be met in EITHER item 1 or item 2 below:

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

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 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 when the patient has **no native breast tissue present**; these ASPS guidelines do not reference the safety of AFG with breast conserving therapy (i.e., lumpectomy, quadrantectomy, partial mastectomy, or segmental mastectomy) rather than a mastectomy.

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 and/or contralateral surgery for the member's unaffected breast. Reconstructive surgery may involve one (1) or

more of the following methods: Breast reconstruction using prosthetic implants/breast augmentation, tissue expanders, autologous tissue reconstruction, autologous fat grafting, areola reconstruction, mastopexy, and/or breast reduction surgery to restore the normal appearance of the breast; 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 treat a medical condition which may include but is not limited to ANY of the following listed 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 related to breast cancer treatment or 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 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 affected breast) and related to breast cancer reconstruction, **implant replacement in the contralateral unaffected breast is also covered**; OR

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

Preoperative photographs may be requested by the Plan for prior authorization. At least ONE (1) of the following applicable criteria specified below in items a through c must be met:

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 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

∞ Note: Review the Plan's *Gender Affirmation Services* medical policy, policy number OCA 3.11, for medically necessary indications for breast/chest procedures to treat gender dysphoria.

(2) The 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) and not related to breast cancer treatment/reconstruction, treatment in the contralateral unaffected breast is covered ONLY when performed at the same time as the affected breast; OR

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

ALL of the following criteria must be met when the initial implantation was unrelated to breast cancer treatment/reconstruction, as specified below in items (1) through (4):

(1) There is documented evidence of a significant physical functional and at least ONE (1) of the following criteria is met, 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 (i.e., the breast is firm and looks abnormal) or Baker Grade IV (i.e., the breast is hard, painful, and looks abnormal); 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 in item i or item ii:

i. Partial or complete rupture of silicone gel-filled breast implant confirmed with MRI or other conclusive imaging study; OR

ii. Rupture of saline-filled breast implant confirmed with conclusive imaging study (e.g., MRI) and functional physical impairment such as significant capsular contracture (pain with Baker Grade III or IV) or persistent infection refractory to medical management with 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 for removal of a breast implant that was inserted for breast reconstruction, implant removal in the contralateral unaffected breast is ONLY covered 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 (e.g., component of gender affirmation surgery to treat gender dysphoria); AND

(2) The initial breast implant was removed for a medically necessary condition that meets Plan criteria for breast implant removal, as specified above; 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, **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, as specified below in items 1 through 3:

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

Cosmetic services (including devices, drugs, and procedures) are NOT considered medically necessary by the Plan, as stated 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, 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; OR

2. **Breast Implant Removal in Affected Breast Only (After Cosmetic Breast Augmentation Surgery):**

When the initial breast implant surgery is cosmetic and NOT related to breast reconstruction, **breast implant removal in the contralateral unaffected breast is NOT medically necessary**. Each breast implant removal must independently meet criteria for breast implant explantation and ALL of the following criteria must be met, as specified below in items a through c:

a. There is documented evidence of a significant physical functional impairment and at least ONE (1) of the following criteria is met in the affected breast 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; OR

(2) Implant removal is required to treat a capsular contracture and ALL of the following criteria are 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 an intracapsular or extracapsular ruptured breast implant of the affected breast only when ONE (1) of the following criteria is met in item (a) or (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 conclusive imaging study (e.g., MRI) with a functional physical impairment 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 and has had a mammogram of both breasts within 12 calendar months from the date of the planned breast procedure; 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, the Plan considers the replacement of breast implant(s) to NOT be 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.

Limitations and Exclusions

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 FDA approved for the specified use are considered experimental and investigational or NOT medically necessity (including breast cancer reconstruction surgery) due to limited evidence documenting the clinical utility and clinical validity of treatment.

2. Any of the following services listed below in items a through e are considered medically necessary ONLY when a component of breast reconstruction for breast cancer treatment (or has a history of breast cancer) in the affected and/or contralateral breast:

    a. The use of autologous fat grafting (AFG) or adipose-derived stem cells (included in fat harvested from donor sites for AFG); OR

    b. Augmentation mammoplasty to enlarge small but otherwise normal breasts or to create symmetry between normal breasts; OR

    c. Nipple inversion correction; OR

    d. Tattooing to correct color defects of skin; OR

    e. Explantation of intact breast implant(s) when applicable Plan medical criteria are NOT met, including one (1) or more of the following conditions listed below in item (1) though (5):

        (1) Systemic symptoms attributed to autoimmune diseases and/or connective tissues diseases; OR

        (2) Suspected benefit for prophylaxis against breast cancer; OR

        (3) Patient anxiety; OR

        (4) Breast implant has repositioned/shifted; OR

        (5) Pain which is NOT related to contractures or rupture.

Variations

The Plan uses guidance from the Centers for Medicare & Medicaid Services (CMS) for medical necessity and coverage determinations for Senior Care Options (SCO) members and WellSense Medicare Advantage HMO members, including but not limited to national coverage determinations (NCDs), local coverage determinations (LCDs), local coverage articles (LCAs), and documentation included in Medicare manuals. At the time of the Plan's most recent policy review, CMS NCD 140.2 includes

nationally covered indications for breast reconstruction following mastectomy and LCD L35001 includes guidelines for reduction mammoplasty. Verify CMS guidelines in effect on the date of the prior authorization request. When there is no guidance from CMS for the requested service, Plan-adopted clinical review criteria will be used to determine the medical necessity of the service.

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.

CPT Codes	Description: Services considered medically necessary.
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.
11921	Tattooing, intradermal introduction of insoluble opaque pigments to correct color defects of skin, including micropigmentation; 6.1 to 20.0 sq. cm Plan note: This CPT code must be billed with a primary diagnosis code related to breast cancer.
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
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)
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.
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 Clinical Criteria section of this policy.

References

Agency for Healthcare Research and Quality (AHRQ). Saldanha IJ, Cao W, Broyles JM, Adam GP, Reddy Bhuma M, Mehta S, Dominici LS, Pusic AL, Balk EM. Breast Reconstruction After Mastectomy: A

Systematic Review and Meta-Analysis. Comparative Effectiveness Review Number 245. AHRQ Publication No. 21-EHC027. Contract No. 75Q80120D00001. 2021 Jul.

American Cancer Society (ACS). ACS Guidelines for the Early Detection of Cancer.

American Cancer Society (ACS), American Society of Clinical Oncology (ASCO). Runowicz CD, Leach CR, Henry NL, Henry KS, Mackey HT, Cowens-Alvarado RL, Cannady RS, Pratt-Chapman ML, Edge SB, Jacobs LA, Hurria A, Marks LB, LaMonte SJ, Warner E, Lyman GH, Ganz PA. ACS/ASCO Breast Cancer Survivorship Care Guideline. J Clin Oncol. 2016 Feb 20;34(6):611-35. doi: 10.1200/JCO.2015.64.3809. Epub 2015 Dec 7. PMID: 26644543.

American Cancer Society (ACS). Mammograms after Breast Cancer Surgery.

American Cancer Society (ACS). Mammograms for Women with Breast Implants.

The American College of Obstetricians and Gynecologists (ACOG). ACOG Practice Bulletin Number 179. Clinical Management Guidelines for Obstetrician – Gynecologists. Breast Cancer Risk Assessment and Screening in Average-Risk Women. 2017 Jul. Reaffirmed 2019.

The American College of Obstetricians and Gynecologists (ACOG). Committee on Adolescent Health Care. Breast and Labial Surgery in Adolescents. Number 686. 2017 Jan. Reaffirmed 2020.

The American Society of Breast Surgeons (ASBrS). Official Statements. Consensus Guidelines, Performance and Practice Guidelines, Quality Measures, Resource Guides.

American Society of Plastic Surgeons (ASPS). Alderman A, Gutowski K, Ahuja A, Gray D; Postmastectomy Expander Implant Breast Reconstruction Guideline Work Group. ASPS clinical practice guideline summary on breast reconstruction with expanders and implants. Plast Reconstr Surg. 2014 Oct;134(4):648e-55e. doi: 10.1097/PRS.0000000000000541. PMID: 25357060.

American Society of Plastic Surgeons (ASPS). ASPS Recommended Insurance Coverage Criteria. Breast Implant-Associated Anaplastic Large Cell Lymphoma.

American Society of Plastic Surgeons (ASPS). ASPS Recommended Insurance Coverage Criteria. Breast Reconstruction for Deformities Unrelated to Cancer Treatment.

American Society of Plastic Surgeons (ASPS). ASPS Recommended Insurance Coverage Criteria. Breast Reconstruction Following Diagnosis and Treatment for Breast Cancer.

American Society of Plastic Surgeons (ASPS). ASPS Recommended Insurance Coverage Criteria. Fat Grafting to the Breast.

American Society of Plastic Surgeons (ASPS). ASPS Recommended Insurance Coverage Criteria. Gynecomastia Surgery.

American Society of Plastic Surgeons (ASPS). ASPS Recommended Insurance Coverage Criteria. Reconstruction after Prophylactic Mastectomy.

American Society of Plastic Surgeons (ASPS). ASPS Recommended Insurance Coverage Criteria. Reduction Mammaplasty.

American Society of Plastic Surgeons (ASPS). Breast Augmentation/Augmentation Mammaplasty.

American Society of Plastic Surgeons (ASPS). Breast Reconstruction.

American Society of Plastic Surgeons (ASPS). Evidence-Based Clinical Practice Guidelines. Autologous Breast Reconstruction with DIEP or Pedicled TRAM Abdominal Flaps.

American Society of Plastic Surgeons (ASPS). Guiding Principles. Post-Mastectomy Fat Graft/Fat Transfer.

American Society of Plastic Surgeons (ASPS). Gutowski KA; ASPS Fat Graft Task Force. Current applications and safety of autologous fat grafts: A report of the ASPS Fat Graft Task Force. Plast Reconstr Surg. 2009 Jul;124(1):272-80. doi: 10.1097/PRS.0b013e3181a09506. PMID: 19346997.

Brenelli F, Rietjens M, De Lorenzi F, Pinto-Neto A, Rossetto F, Martella S, Rodrigues JR, Barbalho D. Oncological safety of autologous fat grafting after breast conservation treatment: a prospective evaluation. Breast J. 2014 Mar-Apr;20(2):159-65. doi: 10.1111/tbj.12225. Epub 2014 Jan 23. PMID: 24450421.

Centers for Medicare & Medicaid Services (CMS). The Center for Consumer Information & Insurance Oversight. Employer Initiatives.

Centers for Medicare & Medicaid Services (CMS). Local Coverage Determination (LCD) for Reduction Mammaplasty L35001. National Government Services, Inc. 2015 Oct 1.

Centers for Medicare & Medicaid Services (CMS). Manuals. Publication # 100-02. Medicare Benefit Policy Manual.

Centers for Medicare & Medicaid Services (CMS). Manuals. Publication # 100-03. Medicare National Coverage Determinations (NCD) Manual.
Centers for Medicare & Medicaid Services (CMS). Medicare Coverage Database (MCD).

Centers for Medicare & Medicaid Services (CMS). National Coverage Determination (NCD) for Breast Reconstruction Following Mastectomy 140.2. Version Number 1. 1997 Jan 1.

Centers for Medicare & Medicaid Services (CMS). National Coverage Determination (NCD) for Mammograms 220.4. Version Number 1. 1978 May 15.

Centers for Medicare & Medicaid Services (CMS). Transmittals.

Cleveland Clinic. Breastfeeding after Breast or Nipple Surgery.

Codner MA, Mejia JD, Locke MB, Mahoney A, Thiels C, Nahai FR, Hester TR, Nahai F. A 15-year experience with primary breast augmentation. Plast Reconstr Surg. 2011 Mar;127(3):1300-10. doi: 10.1097/PRS.0b013e318205f41b. PMID: 21364430.

Commonwealth of Massachusetts. Division of Insurance (DOI) Bulletins.

Commonwealth of Massachusetts. Mandatory Benefits Guide. Consumer Affairs and Business Regulation.

Commonwealth of Massachusetts. MassHealth Guidelines for Medical Necessity Determination for Breast Reconstruction and Intact Breast Implant Removal. MNG-Breast Recon. 2018 Mar 12.

Commonwealth of Massachusetts. MassHealth Guidelines for Medical Necessity Determination for Reduction Mammoplasty. MND-RM. 2019 Jul 24.

Commonwealth of Massachusetts. MassHealth Provider Bulletins.

Commonwealth of Massachusetts. MassHealth Provider Manuals.

Commonwealth of Massachusetts. MassHealth Transmittal Letters.

Florenza CG, Chou SH, Mantzoros CS. Lipodystrophy: pathophysiology and advances in treatment. Nat Rev Endocrinol. 2011 Mar;7(3):137-50. doi: 10.1038/nrendo.2010.199. Epub 2010 Nov 16. PMID: 21079616.

Gabriel A, Champaneria MC, Maxwell GP. Fat grafting and breast reconstruction: tips for ensuring predictability. Gland Surg. 2015 Jun;4(3):232–43. doi: 10.3978/j.issn.2227-684X.2015.04.18. PMID: 26161308.

Glesby MJ. Treatment of HIV-associated lipodystrophy. UpToDate. 2020 Apr 17.

Hayes. Health Technology Assessment. Autologous Fat Grafting for Breast Reconstruction After Breast Cancer Surgery. Dallas, TX: Hayes; Annual Review 2020 Oct 21.

Howes BHL, Fosh B, Watson DI. Yip JM, Eaton M, Smallman A, Dean NR. Autologous Fat Grafting for Whole Breast Reconstruction. Plast Reconstr Surg Glob Open. 2014 Apr 7;2(3):e124. doi: 10.1097/GOX.0000000000000075. eCollection 2014 Mar. PMID: 25289318.

Iwuala SO, Lesi OA, Fasanmade OA, Sabir AA, Olamoyegun MA, Okany CC. Prevalence of and Risk Factors for Lipoatrophy in Patients with HIV Infection in Nigeria. AIDS Res Treat. 2015;2015:402638. doi: 10.1155/2015/402638. Epub 2015 Mar 2. PMID: 25821597.

Jones NB, Wilson J, Kotur L, Stephens J, Farrar WB, Agnese DM. Contralateral prophylactic mastectomy for unilateral breast cancer: an increasing trend at a single institution. Ann Surg Oncol. 2009 Oct;16(10):2691-6. doi: 10.1245/s10434-009-0547-9. Epub 2009 Jun 9. PMID: 19506956.

Kamakura T, Ito K. Autologous cell-enriched fat grafting for breast augmentation. Aesthetic Plast Surg. 2011 Dec;35(6):1022-30. doi: 10.1007/s00266-011-9727-7. Epub 2011 Apr 30. PMID: 21533662.

Kasem A, Wazir U, Headon H, Mokbel K. Breast lipofilling: a review of current practice. Arch Plast Surg. 2015 Mar;42(2):126-30. doi: 10.5999/aps.2015.42.2.126. Epub 2015 Mar 16. PMID: 25798382.

Krastev T, van Turnhout A, Vriens E, Smits L, van der Hulst R. Long-term Follow-up of Autologous Fat Transfer vs Conventional Breast Reconstruction and Association With Cancer Relapse in Patients With Breast Cancer. JAMA Surg. 2019 Jan 1;154(1):56-63. doi: 10.1001/jamasurg.2018.3744. PMID: 30304330.

Lindroos B, Suuronen R, Miettinen S. The potential of adipose stem cells in regenerative medicine. Stem Cell Rev. 2011 Jun;7(2):269-91. doi: 10.1007/s12015-010-9193-7. PMID: 20853072.

Losken A, Hamdi M. Partial breast reconstruction: Current perspectives. Plast Reconstr Surg. 2009 Sep;124(3):722-36. doi:10.1097/PRS.0b013e3181b179d2. PMID: 19730292.

Macmillan RD, McCulley SJ. Oncoplastic Breast Surgery: What, When and for Whom? Curr Breast Cancer Rep. 2016;8:112-7. Epub 2016 May 3. PMID: 27330677.

Mizuno H, Hyakusoku H. Fat grafting to the breast and adipose-derived stem cells: recent scientific consensus and controversy. Aesthtic Surg J. 2010 May-Jun;30(3):381-7. doi: 10.1177/1090820X10373063. PMID: 20601560.

Nahabedian M. Overview of breast reconstruction. UpToDate. 2020 Aug 10.

National Cancer Institute (NCI). National Institutes of Health. Breast Reconstruction After Mastectomy. 2017 Feb 24.

National Comprehensive Cancer Network (NCCN). NCCN Categories of Evidence and Consensus.

National Comprehensive Cancer Network (NCCN). NCCN Clinical Practice Guidelines in Oncology. Breast Cancer.

National Comprehensive Cancer Network (NCCN). NCCN Clinical Practice Guidelines in Oncology. Breast Cancer Risk Reduction.

National Comprehensive Cancer Network (NCCN). NCCN Clinical Practice Guidelines in Oncology. Breast Cancer Screening and Diagnosis.

National Comprehensive Cancer Network (NCCN). NCCN Clinical Practice Guidelines in Oncology. Genetic/Familial High-Risk Assessment: Breast and Ovarian.

National Institute for Health and Clinical Excellence (NICE). Breast reconstruction using lipomodelling after breast cancer treatment. Interventional Procedure Guidance (IPG) 417. 2012 Jan.

National Institute for Health and Clinical Excellence (NICE). Laparoscopic mobilization of the greater omentum for breast reconstruction. Interventional Procedure Guidance (IPG) 253. 2008 Feb 27.

National Organization for Rare Disorders (NORD). Acquired Lipodystrophy.

Nava MB, Blondeel P, Botti, G, Casabona F, Catanuto, G; Clemens MW, De Fazio D, De Vita Roy, Grotting J, Hammond D, Harris P, Montemurro P, Mendonça Munhoz,A, Nahabedian M, Pompei S, Rancati A, Rigotti G, Salgarello M, Scaperrotta G, Spano A, Stan C, Rocco N. International Expert Panel Consensus on Fat Grafting of the Breast. Plast Reconstr Surg. 2019 Oct;7(10):32426. doi: 10.1097/GOX.0000000000002426. PMID: 31772879.

New Hampshire Department of Health and Human Services. Billing Manuals.

New Hampshire Department of Health and Human Services. Provider Notices.

Rancati A, Gonzalez E, Dorr J, Angrigiani C. Oncoplastic surgery in the treatment of breast cancer. Ecancermedicalscience. 2013;7:293. doi: 10.3332/ecancer.2013.293. Epub 2013 Feb 21. PMID: 23441139.

Rigotti G, Marchi A, Stringhini P, Baroni G, Galiè M, Molino AM, Mercanti A, Micciolo R, Sbarbati A. Determining the oncological risk of autologous lipoaspirate grafting for post-mastectomy breast reconstruction. Aesth Plast Surg. 2010 Aug;34(4):475-80. doi:10.1007/s00266-010-9481-2. Epub 2010 Mar 24. PMID: 20333521.

Schmauss D, Machens HG, Harder Y. Breast Reconstruction after Mastectomy. 2016 Jan 19;2:71. doi: 10.3389/fsurg.2015.00071. eCollection 2015. PMID: 26835456.

Seth AK, Hirsch EM, Kim JY, Fine NA. Long-term outcomes following fat grafting in prosthetic breast reconstruction: a comparative analysis. Plast Reconstr Surg. 2012 Nov;130(5):984-90. doi: 10.1097/PRS.0b013e318267d34d. PMID: 22777039.

Sterodimas A, de Faria J, Nicaretta B, Pitanguy I. Tissue engineering with adipose-derived stem cells (ADSCs): Current and future applications. J Plast Reconstr Aesthet Surg. 2010 Nov;63(11):1886-92. doi: 10.1016/j.bjps.2009.10.028. Epub 2009 Dec 7. PMID: 19969517.

Tabit CJ, Slack GC, Fan K, Wan DC, Bradley JP. Fat grafting versus adipose-derived stem cell therapy: distinguishing indications, techniques, and outcomes. Aesthetic Plast Surg. 2012 Jun;36(3):704-13. doi: 10.1007/s00266-011-9835-4. Epub 2011 Nov 9. PMID: 22069062.

Tan SS, Yang Ng Z, Shan W, Rozen W. Role of Adipose-derived Stem Cells in Fat Grafting and Reconstructive Surgery. J Cutan Aesthet Surg. 2016 Jul-Sep;9(3):152–6. doi: 10.4103/0974-2077.191672. PMID: 27761084.

Techanukul T, Lohsiriwat V. Stem cell and tissue engineering in breast reconstruction. Gland Surg. 2014 Feb;3(1):55–61. doi: 10.3978/j.issn.2227-684X.2014.02.11. PMID: 25083496.

United States Department of Labor. Health Plans & Benefits: Women's Health and Cancer Rights.

U. S. Food and Drug Administration (FDA). Center for Devices and Radiological Health FDA Update on the Safety of Silicone Gel-Filled Breast Implants. 2011 Jun.

U.S. Food and Drug Administration (FDA). Medical Devices. Breast Implant-Associated Anaplastic Large Cell Lymphoma (BIA-ALCL). 2019 Mar 22.

U.S. Food and Drug Administration (FDA). Medical Devices. Breast Implants. 2019 Apr 2.

U. S. Food and Drug Administration (FDA). Medical Devices. Risk of Breast Implants. 2019 Mar 22.

U. S. Food and Drug Administration (FDA). Medical Devices. Types of Breast Implants. 2019 Mar 22.

U.S. Food and Drug Administration (FDA). News & Events. FDA Statement: Statement from Binita Ashar, M.D., of the FDA's Center for Devices and Radiological Health on agency's commitment to studying breast implant safety. 2018 Sep 14.

U.S. Preventive Services Task Force (USPSTF). Breast Cancer Recommendation Statement From the U.S. Preventive Services Task Force. Erratum for Screening for Breast Cancer: U.S. Preventive Services Task Force Recommendation Statement. [Ann Intern Med. 2016]. Ann Intern Med. 2016 Mar 15;164(6):448. doi: 10.7326/L16-0404. PMID: 26974722.

U.S. Preventive Services Task Force (USPSTF). Siu AL; USPSTF. Screening for breast cancer: U.S. Preventive Services Task Force recommendation statement. 2016 Feb 16;164(4):279-96. doi: 10.7326/M15-2886. Epub 2016 Jan 12. PMID: 26757170.

Weathers WM, Wolfswinkel EM, Hatef DA, Lee EI, Hollier LH, Brown RH. Implant-associated anaplastic large cell lymphoma of the breast: Insight into a poorly understood disease. Can J Plast Surg. 2013 Summer;21(2):95-8. PMID: 24431950.

Wilson A, Butler PE, Seifalian AM. Adipose-derived stem cells for clinical applications: a review. Cell Prolif. 2011 Feb;44(1):86-98. doi: 10.1111/j.1365-2184.2010.00736.x. PMID: 21199013.

Zhong T, McCarthy CM, Price AN, Pusic AL. Evidence-based medicine: breast reconstruction. Plast Reconstr Surg. 2013 Dec;132(6):1658-69. doi: 10.1097/PRS.0b013e3182a80836. PMID: 24281592.

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: 01/01/12
*Effective Date for the WellSense New Hampshire Medicaid Product: 01/01/13
*Effective Date for the Senior Care Options Product: 01/01/16
*Effective Date for the WellSense Medicare Advantage HMO Product: 01/01/22

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

Policy Revisions History			
			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 WellSense 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
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

Policy Revisions History			
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. 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.	08/01/16 Version 15	04/20/16: MPCTAC 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	10/01/16 Version 16	07/05/16: MPCTAC (electronic vote) 07/13/16: QIC

Policy Revisions History			
	References sections. Revised the applicable code list and added Plan notes for specific codes.		
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 the Medical Policy Statement and Limitations sections.	07/01/19 Version 20	04/18/19: MPCTAC (electronic vote)
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

Policy Revisions History			
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
11/01/21	Review for effective date 12/01/21. Adopted new medical policy template; removed administrative sections, the Medical Policy Statement section renamed the Clinical Criteria section, and the Limitations section renamed the Limitations and Exclusions section. Added WellSense Medicare Advantage HMO as an applicable product effective 01/01/22. Administrative changes made to the Policy Summary, Clinical Criteria, Limitations and Exclusions, Applicable Coding, and References sections.	12/01/21 Version 25	11/17/21: MPCTAC

Authorizing Entity

MPCTAC

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.