Medical Necessity Guideline

Medical Necessity Guideline (MNG) Title: External Breast Prostheses		
MNG #: 74	**☒SCO ☒One Care**	**Prior Authorization Needed? ☒Yes ☐No**
Clinical: ☒	**Operational: ☐**	**Informational: ☐**
Medicare Benefit: ☒Yes ☐No	**Approval Date: 7/1/2021**	**Effective Date:** 9/28/2021
Last Revised Date:	**Next Annual Review Date: 7/1/2022**	**Retire Date:**

OVERVIEW:
Breast cancer is the most common type of malignant tumor and is associated with physical, emotional, and psychosocial effects for women. Surgical treatments (like *mastectomies*) have improved long-term survival rates; however, the loss of or alteration in the appearance of the breast have been reported to have negative impacts on the women's self-image, psychophysiological health, and quality of life.

One option that has been demonstrated to reduce the sense of disfigurement, to help women regain self-esteem, and to restore breast symmetry is the use of external breast prostheses. An external breast prosthesis (EBP) is an artificial breast form that is created to replace the natural breast and restore the natural shape to the body following a complete or partial mastectomy. Following surgery, there may be as many as 90% of women who will decide to wear an EBP permanently or while they are waiting for *breast reconstruction*. Patients may either opt to get *standard off-the-shelf EBPs* or *custom-fitted EBPs*. The choice depends on comfort, cost, appearance, ease of cleaning, movement with the body, weight, durability, and fit.

DEFINITIONS:
Breast Cancer: Malignancy of the breast tissue. It may be classified as (1) carcinoma in situ where the cancer cells have not invaded past the basement membrane of the duct or lobule, and (2) invasive breast cancer where the cancer cells have invaded past the basement membrane and into the adjacent breast parenchyma.

Breast Reconstruction: A surgical option for patients following a unilateral or bilateral mastectomy, or after breast conservation therapy by using a breast expander/prosthetic implant or autologous tissues to restore the breast.

Conventional External Breast Prosthesis: External Breast Prosthesis that come in standardized sizes, and can be worn inside a specialized bra.

Custom-fitted External Breast Prosthesis: External Breast Prosthesis that are individually designed to conform to the surface of the skin. They are based on the tissue record (or impression) of the patient's mastectomy site and held in place using various methods.

Mastectomy: One surgical option for the risk reduction or surgical treatment of breast cancer that involves the partial or complete removal of the breast tissue and potentially the underlying fascia of the pectoralis major muscle.
DECISION GUIDELINES:

Medical Necessity Guideline

Clinical Coverage Criteria:
Commonwealth Care Alliance may authorize the **initial coverage** of external breast prostheses, when all of the following criteria are met:

- Documented past mastectomy and/or absence of breast(s) related to breast cancer within the preceding 12 months,
- Documented valid and complete written order by or under the direction of a prescribing physician, AND
- The EBP will be used in the post-operative period following a mastectomy under the following conditions:
    - As a permanent breast prosthesis,
    - As an alternative to a mastectomy bra,
    - As an alternative to a mastectomy bra and breast prosthesis, OR
    - While waiting for breast reconstruction surgery

Commonwealth Care Alliance may cover, under the conditions outlined, the following external breast prostheses:

- Breast prosthesis with or without mastectomy bra,
- Custom breast prosthesis,
- Mastectomy form with or without mastectomy bra,
- Breast prosthesis garment,
- Mastectomy bra, AND
- Nipple prosthesis

Commonwealth Care Alliance may authorize the **replacement coverage** of external breast prostheses or garment of the **same type**, if the following conditions are met:

- There is documented justified continued medical need for an EBP,
- It has been ≥ 6 months since the last EBP was supplied, AND
- If the EBP is lost,
- If the EBP is irreparably damaged, OR
- If the EBP exceeds its useful lifetime expectancy

Commonwealth Care Alliance may authorize the **replacement coverage** of external breast prostheses of a **different type**, if the following conditions are met:

- New documented valid and complete written order by or under the direction of a prescribing physician, AND
- Documented change in the member's medical condition or reason that necessitates a different type of EBP

Commonwealth Care Alliance may cover, under the conditions outlined and based on the useful lifetime expectancy, the following replacement external breast prostheses:

- One breast prosthesis per side for the useful lifetime of the prosthesis,
- Two breast prostheses, one per side, for persons who have had bilateral mastectomies,
- One silicone breast prostheses every 24 months,
- One fabric, foam, or fiber-filled breast prostheses every 6 months, AND
- Nipple prostheses every 3 months

Medical Necessity Guideline

LIMITATIONS/EXCLUSIONS:
Commonwealth Care Alliance will not cover the following, including but not limited to:

- Mastectomy sleeves as they do not meet the definition of a prosthesis,
- Breast prosthesis, silicone or equal, with integral adhesive as there is no demonstrated clinical advantage over those without integral adhesives,
- Replacements sooner than the useful lifetime expectancy due to ordinary wear and tear, OR
- Use of EBP to correct breast symmetry from other conditions not related to post-mastectomy

Benefit coverage for health services is determined by the member specific benefit plan document* and applicable laws (including the Plan's applicable government program contracts) that may require coverage for a specific service. The member specific benefit plan document identifies which services are covered, which are excluded, and which are subject to limitations.

External breast prostheses related to Gender Affirming Surgery will be reviewed for medical necessity under CCA MNG 054: Gender Affirming Surgery and Related Procedures.

AUTHORIZATION:
The following list(s) of procedure and/or diagnosis codes is provided for reference purposes only and may not be all inclusive. Listing of a code in this policy does not signify whether the service described by the code is a covered or non-covered health service. Benefit coverage for health services is determined by the member specific benefit plan document and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment. Other Policies and Coverage Determination Guidelines may apply. This Medical Necessity Guideline is subject to all applicable laws and regulations, Plan Policies and Guidelines, including requirements for prior authorization and other requirements in Provider's agreement with the Plan (including complying with Plan's Provider Manual specifications).

HCPCS Code	Description
L8000	Breast prosthesis, mastectomy bra, without integrated breast prosthesis form, any size, any type
L8001	Breast prosthesis, mastectomy bra, with integrated breast prosthesis form, unilateral, any size, any type
L8002	Breast prosthesis, mastectomy bra, with integrated breast prosthesis form, bilateral, any size, any type
L8015	External breast prosthesis garment, with mastectomy form, post mastectomy
L8020	Breast prosthesis, mastectomy form
L8030	Breast prosthesis, silicone or equal, without integral adhesive
L8032	Nipple prosthesis, prefabricated, reusable, any type, each
L8033	Nipple prosthesis, custom fabricated, reusable, any material, any type, each
L8035	Custom breast prosthesis, post mastectomy, molded to patient model

Documentation Requirements:

- Completed CCA Standard Prior Authorization Form

Medical Necessity Guideline

- Standard Written Order (SWO)
- Letter of Medical Necessity (LMN) and/or Medical Record Information (including continued need/use if applicable)

REGULATORY NOTES:

Medical Necessity Guidelines are published to provide a better understanding of the basis upon which coverage decisions are made. CCA makes coverage decisions on a case-by-case basis considering the individual member's health care needs. Pharmacy Medical Necessity Guidelines are developed for selected therapeutic classes or drugs found to be safe, but proven to be effective in a limited, defined population of patients or clinical circumstances. They include concise clinical coverage criteria based on current literature review, consultation with practicing physicians in the servicearea who are medical experts in the appropriate field, review of FDA and other government agency policies, and standards adopted by national accreditation organizations. The plan revises and updates Pharmacy Medical Necessity Guidelines annually, or more frequently if new evidence becomes available that suggests needed revisions. If at any time a CMS Local or National Coverage Determination (LCD or NCD) is published that conflicts with the criteria set forth herein, the NCD or LCD criteria shall supersede these criteria.

Disclaimer:

This Medical Necessity Guideline is not a rigid rule. As with all of CCA's criteria, the fact that a member does not meet these criteria does not, in and of itself, indicate that no coverage can be issued for these services. Providers are advised, however, that if they request services for any member who they know does not meet our criteria, the request should be accompanied by clear and convincing documentation of medical necessity. The preferred type of documentation is the letter of medical necessity, indicating that a request should be covered either because there is supporting science indicating medical necessity (supporting literature (full text preferred) should be attached to the request), or describing the member's unique clinical circumstances, and describing why this service or supply will be more effective and/or less costly than another service which would otherwise be covered. Note that both supporting scientific evidence and a description of the member's unique clinical circumstances will generally be required.

RELATED REFERENCES:

1. Commonwealth of Massachusetts. (n.d.). *114.3 CMR: Division of healthcare finance and policy ambulatory care.* Retrieved from https://www.mass.gov/doc/1143-cmr-40-rates-for-services-under-mgl-c152-workers-compensation-act/download
2. Commonwealth of Massachusetts. (2019). *MassHealth provider manual series: Service codes*. Retrieved from https://www.mass.gov/doc/prosthetics-prt-subchapter-6/download
3. Fitch, M., McAndrew, A., Harris, A., Anderson, J., Kubon, T. & McClennan, J. (2012). Perspectives ofwomen about external breast prostheses. Canadian Oncology Nursing Journal, 22(3): 162-167.
4. Glaus, S. & Carlson, G. (2009). Long-term role of external breast prostheses after total mastectomy. *Breast Journal, 15*(4): 385-93.
5. InterQual. (2021). *2021, Apr. 2021 Release medicare: Durable medical equipment – External breastprostheses.* Noridian/CGS.
6. Kubon, T., McClennen, J., Fitch, M., McAndrew, A. & Anderson, J. (2012). A mixed-methods cohort study to determine perceived patient benefit in providing custom breast prostheses. *Curr Oncol, 19*(2):e43-e52.

7. Kwong, A. & Sabel, M. (2020). *UpToDate: Mastectomy.* Retrieved from https://www.uptodate.com/contents/mastectomy?search=mastectomy&source=search_result&selectedTitle=1~150&usage_type=default&display_rank=1
8. Nahabedian, M. (2021). *UpToDate: Overview of breast reconstruction.* Retrieved from https://www.uptodate.com/contents/overview-of-breast-reconstruction?search=mastectomy&topicRef=14981&source=related_link
9. Thijs-Boer, F., Thijs, J. & Van de Wiel, H. (2001). Conventional or adhesive external breast prosthesis? A prospective study of the patients' preference after mastectomy. *Cancer Nurs, 24*(3): 227-30.
10. Troyan, S., Fedorowicz, Z. & Aird, W. (2018). *DynaMed: Breast cancer in women.* Retrieved from https://www.dynamed.com/topics/dmp-AN-T113654
11. Qiu, J., Tang, L., Huang, L., Hou, S. & Zhou, J. (2020). Physical and psychological effects of different temperature-controlled breast prostheses on patients with breast cancer during rehabilitation: A randomized controlled study. *Medicine (Baltimore), 99*(13): 1-9.
12. U.S. Centers for Medicare & Medicaid. (2020). *Local coverage determination (LCD): External breast prostheses (L33317).* Retrieved from https://med.noridianmedicare.com/documents/2230703/7218263/External+Breast+Prostheses+LCD+and+PA
13. U.S. Center for Medicare and Medicaid Services. (2020). *Local coverage article: External breast prostheses – Policy article (A52478).* Retrieved from https://www.cms.gov/medicare-coverage-database/details/article-details.aspx?articleId=52478&ver=20&LCDId=33317&NCDId=297&ncdver=2&CoverageSelection=Both&ArticleType=All&PolicyType=Final&s=All&KeyWord=Breast&KeyWordLookUp=Title&KeyWordSearchType=And&bc=gAAAACgAIAAA&
14. U.S. Center for Medicare and Medicaid Services. (2021). *Women's health and cancer rights act (WHCRA).* Retrieved from https://www.cms.gov/CCIIO/Programs-and-Initiatives/Other-Insurance-Protections/whcra_factsheet
15. U.S. Centers for Medicare & Medicaid. (2018). *Ordering external breast prostheses and supplies.* Retrieved from https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/Downloads/ExternalBreastProsthesis-MLN3754874.pdf
16. U.S. Food and Drug Administration. (2020). *Code of federal regulations title 21: Part 878 – General and plastic surgery devices.* Retrieved from https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm?fr=878.3800
17. U.S. National Library of Medicine (U.S.). (2021, Jan-2022, Feb). Quality of life in patients with standard external compared to custom-made breast prosthesis (Meavanti). *Identifier NCT03981263*. Retrieved from https://clinicaltrials.gov/ct2/show/NCT03981263
18. Zohra, J., Raisa, G. & Sharifa, L. (2017). Women experiences of using external breast prosthesis after mastectomy. *Asia-Pacific Journal of Oncology Nursing, 4*(3): 250-258.

ATTACHMENTS:

EXHIBIT A:	
EXHIBIT B	

Medical Necessity Guideline

REVISION LOG:

REVISION DATE	DESCRIPTION

APPROVALS:

Douglas Hsu, MD, MPH	Vice President, Medical Policy and Utilization Review
CCA Senior Clinical Lead [Print]	**Title [Print]**
	7/1/2021
Signature	**Date**
Click here to enter text.	
CCA Senior Operational Lead [Print]	**Title [Print]**
Signature	**Date**
Lori Tishler, MD	Senior Vice President, Medical Services
CCA CMO or Designee [Print]	**Title [Print]**
	7/1/2021
Signature	**Date**