



## External Breast Prostheses Medical Necessity Guideline

Medical Necessity Guideline (MNG) Title: External Breast Prostheses		
MNG #: 074	<input checked="" type="checkbox"/> SCO <input checked="" type="checkbox"/> One Care <input checked="" type="checkbox"/> MA Medicare Premier <input checked="" type="checkbox"/> MA Medicare Value <input checked="" type="checkbox"/> RI Medicare Preferred <input checked="" type="checkbox"/> RI Medicare Value <input checked="" type="checkbox"/> RI Medicare Maximum	Prior Authorization Needed? <input checked="" type="checkbox"/> Yes (always required) <input type="checkbox"/> Yes (only in certain situations. See this MNG for details) <input type="checkbox"/> No
Clinical: <input checked="" type="checkbox"/>	Operational: <input type="checkbox"/>	Informational: <input type="checkbox"/>
Benefit Type: <input checked="" type="checkbox"/> Medicare <input checked="" type="checkbox"/> Medicaid	Approval Date: 7/1/2021;	Effective Date: 9/28/2021;
Last Revised Date: 9/1/2022;	Next Annual Review Date: 7/1/2022; 9/1/2023;	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*.

### DEFINITIONS:

**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.

### DECISION GUIDELINES:

#### Clinical Coverage Criteria:

Commonwealth Care Alliance (CCA) follows applicable Medicare and Medicaid regulations and uses InterQual Smart Sheets, when available, to review prior authorization requests for medical necessity. This Medical Necessity Guideline



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(MNG) applies to all CCA Products unless a more expansive and applicable CMS National Coverage Determinations (NCDs), Local Coverage Determinations (LCDs), or state-specific medical necessity guideline exists.

### 1. SENIOR CARE OPTIONS AND ONE CARE

Commonwealth Care Alliance (CCA) follows applicable Medicare and Medicaid regulations, contractual requirements, and uses InterQual Smart Sheets, when available, to review prior authorization requests for medical necessity. This MNG applies unless a less restrictive and applicable CMS National Coverage Determination (NCD), Local Coverage Determination (LCD), or state-specific medical necessity guideline exists.

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



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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

### **2. MEDICARE ADVANTAGE**

CCA follows applicable Medicare regulations, and InterQual Smart Sheets are used to review prior authorization requests for medical necessity.

### **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 codes is provided for reference purposes only and may not be all inclusive. Listing of a code in this guideline does not signify that 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. This Medical Necessity Guideline is subject to all applicable 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).

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HCPCS Code	Description	Applicable ICD-10-CM Codes that support Medical Necessity	SCO/One Care	Medicare Advantage
L8000	Breast prosthesis, mastectomy bra, without integrated breast prosthesis form, any size, any type	C50.011, C50.012, C50.019, C50.111, C50.112, C50.119, C50.211, C50.212, C50.219, C50.311, C50.312, C50.319, C50.411, C50.412, C50.419, C50.511, C50.512, C50.519, C50.611, C50.612, C50.619, C50.811, ,	✓	✓
L8001	Breast prosthesis, mastectomy bra, with integrated breast prosthesis form, unilateral, any size, any type	C50.812, C50.819, C50.911, C50.912, C50.919, C79.81, D05.00, D05.02, D05.10, D05.11, D05.12, D05.80, D05.81, D05.82, D05.90, D05.91, D05.92, I97.2, Z85.3, Z90.10, Z90.11, Z90.12, Z90.13	✓	✓
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
- 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 by considering the individual member's health care needs. If at any time an applicable CMS LCD or NCD or state-specific MNG is more expansive than the criteria set forth herein, the NCD, LCD, or state-specific MNG criteria shall supersede these criteria. This MNG references the specific regulations, coverage, limitations, service conditions, and/or prior authorization requirements in the following:

1. Commonwealth of Massachusetts. (2019). MassHealth provider manual series: Service codes.
2. U.S. Centers for Medicare & Medicaid. (2020). Local coverage determination (LCD): External breast prostheses



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(L33317).

3. U.S. Center for Medicare and Medicaid Services. (2020). Local coverage article: External breast prostheses – Policy article (A52478).

### **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:**

4. Commonwealth of Massachusetts. (2019). *MassHealth provider manual series: Service codes*. Retrieved from <https://www.mass.gov/doc/prosthetics-prt-subchapter-6/download>
5. Fitch, M., McAndrew, A., Harris, A., Anderson, J., Kubon, T. & McClennan, J. (2012). Perspectives of women about external breast prostheses. *Canadian Oncology Nursing Journal*, 22(3): 162-167.
6. Glaus, S. & Carlson, G. (2009). Long-term role of external breast prostheses after total mastectomy. *Breast Journal*, 15(4): 385-93.
7. Troyan, S., Fedorowicz, Z. & Aird, W. (2018). *DynaMed: Breast cancer in women*. Retrieved from <https://www.dynamed.com/topics/dmp-AN-T113654>
8. 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>
9. 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&>



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### REVISION LOG:

REVISION DATE	DESCRIPTION
12/31/23	Utilization Management Committee approval
9/1/2022	Updated template, added diagnoses to reference table, provided specific coverage criteria for ICO/SCO and Medicare Advantage.

### APPROVALS:

David Mello

Senior Medical Director, Utilization Review  
and Medical Policy

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12/31/23

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