

External Breast Prostheses

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Introduction

External breast prostheses (EBP) are addressed by this guideline.

Health Equity Consideration

Health equity is the highest level of health for all individuals; health inequity is the avoidable difference in health status or distribution of health resources due to the social conditions in which individuals are born, grow, live, work, and age. Social determinants of health are the conditions in the environment that affect a wide range of health, functioning, and quality of life outcomes and risks. Examples include the following: safe housing, transportation, and neighborhoods; racism, discrimination, and violence; education, job opportunities, and income; access to nutritious foods and physical activity opportunities; access to clean air and water; and language and literacy skills.

Criteria

External Breast Prosthesis

An external breast prosthesis (HCPCS L8020-L8039) is medically necessary following a mastectomy for **any** of the following:

- As a permanent external breast prosthesis.
- As an alternative to a mastectomy bra.
- As an alternative to a mastectomy bra and external breast prosthesis.
- While waiting for breast reconstruction surgery.

External Breast Prosthesis Garments

A mastectomy bra (HCPCS L8000, L8001) may be medically necessary when the individual has had a mastectomy and **both** of the following:

- The individual has a covered mastectomy form (HCPCS L8020) or silicone (or equal) external breast prosthesis (HCPCS L8030).
- The pocket of the bra is used to hold the form/external breast prosthesis.

An external breast prosthesis garment with mastectomy form (HCPCS L8015) is medically necessary when **any** of the following apply:

- The device is needed for use in the post-operative period prior to a permanent external breast prosthesis.
- The device is needed as an alternative to a mastectomy bra and external breast prosthesis.

Additional Modifiers

- When indicated, the right (RT) and/or left (LT) modifiers must be used with these codes. Bras and similar inherently bilateral items (L8000 - L8002, L8015) are exempt from the RT and LT requirement.
- Only one external breast prosthesis per side is allowed for the reasonable useful lifetime of the prosthesis.
- Two external breast prostheses, one per side, are allowed for those individuals who have had bilateral mastectomies. More than one external breast prosthesis per side will be denied as not reasonable and necessary.

Usual Maximum Quantity Limits*

HCPSC Code	Quantity Allowed ≤ 12 Months Post Mastectomy	Quantity allowed > 13 Months Post Mastectomy
L8000, L8001, L8002, L8010, L8015	Up to four (4)	Up to two (2) every 12 months
L8020, L8039	Two (2) within 12 months for fabric, foam, or fiber-filled breast prostheses per affected side OR One (1) within 24 months for silicone prostheses per affected side	Two (2) every 12 months for fabric, foam, or fiber-filled breast prostheses per affected side OR One (1) every 24 months for silicone prostheses per affected side
L8030	One (1) per affected side within 24 months	One (1) per affected side every 24 months
L8032, L8033	One (1) per affected side every three (3) months	One (1) per affected side every three (3) months

*Additional supplies may be allowed for when the documentation substantiates medical necessity.

Not Covered

The following items are considered not medically necessary, not primarily medical in nature, and/or convenience items:

- HCPCS L8031 (breast prosthesis, silicone or equal, with integral adhesive).
- HCPCS L8035 (custom breast prosthesis, post mastectomy, molded to patient model).

Definitions

Mastectomy is the removal of all or part of a breast, and is typically performed as a treatment for cancer, or in some cases for the treatment of benign disease.

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.

Evidence Discussion

Purpose of technology/description of device

Mastectomy not only affects physical health, but also psychological health. A qualitative, descriptive study stated that using external breast prostheses can help improve body image and body posture. The Women's Health and Cancer Rights Act (WHCRA) of 1998 (Public Law #105-277) mandates that all insurance companies provide coverage for breast "prostheses and physical complications of mastectomy including lymphedemas."

Medical background

The United States Food and Drug Administration (FDA) considers external breast prostheses to be Class I devices (FDA, 2001). As such, they are considered to be of low to moderate risk, and manufacturers are not required to complete premarket notifications prior to marketing the devices. Manufacturers of external breast prostheses and forms available in the United States include Amoena®, Kinex®, Kosemed Orthopedics, Prosthetic Illusions, and Proteor®.

Literature review

- A 2024 study by Deshong and colleagues described the utilization of external breast prostheses (EBP) among women diagnosed with breast cancer who have had a mastectomy. The review included 22 journal articles and evaluated six themes including: patient satisfaction, comfort, quality of life, knowledge about external breast

prostheses, cost, and material. The authors reported that the literature had fifteen (68%) publications on patient satisfaction, sixteen (73%) on comfort, twenty (91%) on quality of life, and fifteen (67%) on materials. Of note, the authors reported that issues such as body image and self-esteem were important factors when reviewing mastectomy. Moreover, results showed that factors such as weight and temperature may lead to patient dissatisfaction or issues with comfort. Emerging research involves both 3-D technology and temperature-controlled EBPs to address overall patient satisfaction. The authors found comprehensive literature on quality of life and EBP use, with reported benefits of maintenance of physical appearance, self-esteem, confidence, femininity, normality, and body image. The review acknowledged a relative lack of information on knowledge and cost with only eleven (50%) and eight (36%) articles respectively. The authors concluded that EBPs significantly enhanced the body image and self-esteem of post-mastectomy women, and offered an improved quality of life.

- Qiu et al. (2020) reported a randomized controlled study that compared the physical and psychological effects of different temperature-controlled breast prostheses on the quality of life of patients after mastectomy. The study randomized 30 patients who underwent unilateral mastectomy due to breast cancer to an intervention or a control group. In the first six weeks, the intervention group used self-adhesive breast prostheses and the control group used conventional (non-adhesive) breast prostheses. In the latter six weeks, the treatment groups were switched. The study utilized questionnaires and evaluated the following parameters at both six and 12 weeks: skin condition, perception of breast prosthesis, feelings when wearing breast prosthesis, quality of life, and body image. The authors found no significant difference in quality of life and body image between the two groups during 6th and 12th week. In summary, the authors concluded that patients were satisfied with the temperature-controlled breast prosthesis and were more willing to choose self-adhesive breast prostheses.
- A qualitative, descriptive study by Jetha and colleagues (2017) identified the experiences of breast cancer patients using external breast prostheses (EBP). The study included 15 women with a history of breast cancer who were post-mastectomy and using EBP. The study utilized questionnaires that addressed topics such as reasons for using EBP, feelings about EBP, challenges associated with using EBP, and coping with the absence of breasts. The authors concluded that mastectomy may not only affect physical health but also psychological health. Moreover, the authors opined that using EBP may help post-mastectomy patients improve body image and body posture.
- Hojan, K. (2020) performed an observational study to evaluate daily functioning and activity in women post-mastectomy who use external breast prostheses (EBP). Questionnaires were administered to 125 women who had undergone unilateral mastectomy. In addition, the author analyzed current objective studies about the implementation of EBP in body motion assessments. The analysis indicated that

participants used their first EBP approximately six months after mastectomy and replaced it every two years. The method of choosing EBP had a significant impact on satisfaction with EBP, as well as on the weight of the prosthesis. In summary, the author concluded that EBP played an important role in the daily functioning and activity of women with breast cancer who have undergone unilateral mastectomy. Moreover, the weight of EBP was not deemed an important factor in an objective analysis of body motion in this patient population.

- Hojan and Manikowska (2017) performed an observational study to determine if the weight of an external breast prosthesis (EBP) affects the biomechanics of the trunk during functional movement. Fifty-one women with unilateral mastectomy were evaluated with surface electromyographic (SEMG) activity of the erector spinae muscles (ES) both with and without external breast prostheses during functional body movement testing. In addition, range of motion measurements were taken for forward bending, backward bending, lateral bending, and rotation. The results of the study demonstrated that the mean level of the ES activity in the lumbar region was not affected by the weight of the EBP during most of the functional body tests ($P > .05$). Thus, the authors concluded that the weight of an EBP for women after mastectomy may not affect posture or trunk biomechanics.
- A study by Hojan and Manikowska (2014) aimed to determine whether wearing an external breast prosthesis (EBP) affects gait in women after a mastectomy. The study included 40 women with a history of unilateral mastectomy after breast cancer. The participants were between the ages of 37 and 70 years old, and were divided into two age subgroups: subgroup A, 37 to 54 years old; and subgroup B, 55 to 70 years old. The control group consisted of 38 healthy women between the ages of 38 and 69 years old. Gait parameters were assessed with and without the EBP, including walking velocity, cadence, step length, step time, and left-right step time asymmetry. The results of the study demonstrated that the younger group of patients (subgroup A) walked faster with the EBP than without the EBP ($P < .05$); however, younger women with an EBP walked slower than those in the control group ($P < .001$). No significant differences were found in the women of the older group (subgroup B) with and without the EBP. In summary, the authors concluded that the gait parameters of the younger age group were closer to those of the healthy control group when they were wearing an EBP. Thus, the authors opined that the functional status of women after mastectomy was improved with an EBP.
- A study by Glaus and Carlson (2009) evaluated long-term satisfaction among external breast prosthesis (EBP) wearers. A questionnaire was administered to 59 women who had undergone total mastectomy without breast reconstruction. The majority of participants (68%) were at least five years out from mastectomy. The results indicated that frequent and prolonged prosthesis use was prevalent among the study participants, with 64% reporting prosthesis use all the time, six to seven days per week. Moreover, participants showed high rates (83%) of overall satisfaction, which increased over time, as women who were greater than five years out from

mastectomy were more satisfied than women less than five years post-mastectomy (90% versus 67%, $P = .05$). In conclusion, the authors found that a majority of women were satisfied with their external breast prosthesis several years after mastectomy, which reinforces the long-term importance of EBP for women who have undergone mastectomy.

Codes addressed in this guideline

HCPSC code	Description
A4280	Adhesive skin support attachment for use with external breast prosthesis, each
A6549	Gradient compression garment, not otherwise specified, for daytime use, each
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
L8031	Breast prosthesis, silicone or equal, with 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
L8039	Breast prosthesis, not otherwise specified

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