Local Coverage Determination (LCD)

External Breast Prostheses

L33317

Expand All | Collapse All

Contractor Information
LCD Information

Document Information

LCD ID
L33317
LCD Title
External Breast Prostheses
Proposed LCD in Comment Period
N/A
Source Proposed LCD
N/A
Original Effective Date
For services performed on or after 10/01/2015
Revision Effective Date
For services performed on or after 01/01/2020
Revision Ending Date
N/A
Retirement Date
N/A
Notice Period Start Date
N/A
Notice Period End Date
N/A
AMA CPT / ADA CDT / AHA NUBC Copyright Statement

CMS National Coverage Policy

None

Coverage Guidance

Coverage Indications, Limitations, and/or Medical Necessity

For any item to be covered by Medicare, it must 1) be eligible for a defined Medicare benefit category, 2) be reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member, and 3) meet all other applicable Medicare statutory and regulatory requirements.

The purpose of a Local Coverage Determination (LCD) is to provide information regarding “reasonable and necessary” criteria based on Social Security Act § 1862(a)(1)(A) provisions.

In addition to the “reasonable and necessary” criteria contained in this LCD there are other payment

rules, which are discussed in the following documents, that must also be met prior to Medicare reimbursement:

- The LCD-related Standard Documentation Requirements Article, located at the bottom of this policy under the Related Local Coverage Documents section.
- The LCD-related Policy Article, located at the bottom of this policy under the Related Local Coverage Documents section.
- Refer to the Supplier Manual for additional information on documentation requirements.
- Refer to the DME MAC web sites for additional bulletin articles and other publications related to this LCD.

For the items addressed in this LCD, the “reasonable and necessary” criteria, based on Social Security Act § 1862(a)(1)(A) provisions, are defined by the following coverage indications, limitations and/or medical necessity.

A breast prosthesis is covered for a patient who has had a mastectomy. (Refer to the ICD-10 code list in the LCD-related Policy Article for applicable diagnoses.)

An external breast prosthesis garment, with mastectomy form (L8015) is covered for use in the postoperative period prior to a permanent breast prosthesis or as an alternative to a mastectomy bra and breast prosthesis.

Breast prostheses, silicone or equal, with integral adhesive (L8031) have not been demonstrated to have a clinical advantage over those without the integral adhesive. Therefore, if L8031 is billed, it will be denied as not reasonable and necessary.

The medical necessity for the additional features of a custom fabricated prosthesis (L8035) compared to a prefabricated silicone breast prosthesis has not been established, and therefore, if an L8035 breast prosthesis is billed, it will be denied as not reasonable and necessary.

An external breast prosthesis of the same type can be replaced at any time if it is lost or is irreparably damaged (this does not include ordinary wear and tear). An external breast prosthesis of a different type can be covered at any time if there is a change in the patient's medical condition necessitating a different type of item. The Medicare program will pay for only one breast prosthesis per side for the useful lifetime of the prosthesis. Two prostheses, one per side, are allowed for those persons who have had bilateral mastectomies. More than one external breast prosthesis per side will be denied as not reasonable and necessary.

A mastectomy bra (L8000) is covered for a patient who has a covered mastectomy form (L8020) or silicone (or equal) breast prosthesis (L8030) when the pocket of the bra is used to hold the form/prosthesis.

GENERAL
A Standard Written Order (SWO) must be communicated to the supplier before a claim is submitted. If the supplier bills for an item addressed in this policy without first receiving a completed SWO, the claim shall be denied as not reasonable and necessary.
For Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) base items that require a Written Order Prior to Delivery (WOPD), the supplier must have received a signed SWO before the DMEPOS item is delivered to a beneficiary. If a supplier delivers a DMEPOS item without first receiving a WOPD, the claim shall be denied as not reasonable and necessary. Refer to the LCD-related Policy Article, located at the bottom of this policy under the Related Local Coverage Documents section.

For DMEPOS base items that require a WOPD, and also require separately billed associated options, accessories, and/or supplies, the supplier must have received a WOPD which lists the base item and which may list all the associated options, accessories, and/or supplies that are separately billed prior to the delivery of the items. In this scenario, if the supplier separately bills for associated options, accessories, and/or supplies without first receiving a completed and signed WOPD of the base item prior to delivery, the claim(s) shall be denied as not reasonable and necessary.
An item/service is correctly coded when it meets all the coding guidelines listed in CMS HCPCS guidelines, LCDs, LCD-related Policy Articles, or DME MAC articles. Claims that do not meet coding guidelines shall be denied as not reasonable and necessary/incorrectly coded.
Proof of delivery (POD) is a Supplier Standard and DMEPOS suppliers are required to maintain POD documentation in their files. Proof of delivery documentation must be made available to the Medicare contractor upon request. All services that do not have appropriate proof of delivery from the supplier shall be denied as not reasonable and necessary.

REFILL REQUIREMENTS

For DMEPOS items and supplies provided on a recurring basis, billing must be based on prospective, not retrospective use. For DMEPOS products that are supplied as refills to the original order, suppliers must contact the beneficiary prior to dispensing the refill and not automatically ship on a pre-determined basis, even if authorized by the beneficiary. This shall be done to ensure that the refilled item remains reasonable and necessary, existing supplies are approaching exhaustion, and to confirm any changes or modifications to the order. Contact with the beneficiary or designee regarding refills must take place no sooner than 14 calendar days prior to the delivery/shipping date. For delivery of refills, the supplier must deliver the DMEPOS product no sooner than 10 calendar days prior to the end of usage for the current product. This is regardless of which delivery method is utilized.

For all DMEPOS items that are provided on a recurring basis, suppliers are required to have contact with the beneficiary or caregiver/designee prior to dispensing a new supply of items. Suppliers must not deliver refills without a refill request from a beneficiary. Items delivered without a valid, documented refill request will be denied as not reasonable and necessary.

Suppliers must not dispense a quantity of supplies exceeding a beneficiary's expected utilization. Suppliers must stay attuned to changed or atypical utilization patterns on the part of their clients. Suppliers must verify with the treating practitioner that any changed or atypical utilization is warranted.

Regardless of utilization, a supplier must not dispense more than a three (3) month quantity at a time.

Summary of Evidence

NA

Analysis of Evidence (Rationale for Determination)

NA

Coding Information

CPT/HCPCS Codes

Expand All | Collapse All

Group 1

(13 Codes)

Group 1 Paragraph

The appearance of a code in this section does not necessarily indicate coverage.

HCPCS MODIFIERS:

EY – No physician or other licensed health care provider order for this item or service
LT - Left side
RT - Right side

HCPCS CODES:

Group 1 Codes

Code	Description
A4280	ADHESIVE SKIN SUPPORT ATTACHMENT FOR USE WITH EXTERNAL BREAST PROSTHESIS, 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
L8010	BREAST PROSTHESIS, MASTECTOMY SLEEVE
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

General Information

Associated Information

DOCUMENTATION REQUIREMENTS

Section 1833(e) of the Social Security Act precludes payment to any provider of services unless "there has been furnished such information as may be necessary in order to determine the amounts due such provider." It is expected that the beneficiary's medical records will reflect the need for the care provided. The beneficiary's medical records include the treating practitioner’s records, hospital records, nursing home records, home health agency records, records from other healthcare professionals and test reports. This documentation must be available upon request.

GENERAL DOCUMENTATION REQUIREMENTS

In order to justify payment for DMEPOS items, suppliers must meet the following requirements:

- SWO
- Medical Record Information (including continued need/use if applicable)
- Correct Coding
- Proof of Delivery

Refer to the LCD-related Standard Documentation Requirements article, located at the bottom of this policy under the Related Local Coverage Documents section for additional information regarding these requirements.

Refer to the Supplier Manual for additional information on documentation requirements.

Refer to the DME MAC web sites for additional bulletin articles and other publications related to this LCD.

POLICY SPECIFIC DOCUMENTATION REQUIREMENTS

Items covered in this LCD have additional policy-specific requirements that must be met prior to Medicare reimbursement.

Refer to the LCD-related Policy article, located at the bottom of this policy under the Related Local Coverage Documents section for additional information.

Miscellaneous

Appendices

Utilization Guidelines
Refer to Coverage Indications, Limitations and/or Medical Necessity
Sources of Information
N/A
Bibliography

NA

Revision History Information

Associated Documents

Attachments
N/A
Related Local Coverage Documents
Articles
A52478 - External Breast Prostheses - Policy Article
A55426 - Standard Documentation Requirements for All Claims Submitted to DME MACs

Related National Coverage Documents
N/A