

Local Coverage Determination (LCD): External Breast Prostheses (L33317)

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Contractor Information

Contractor Name	Contract Type	Contract Number	Jurisdiction	State(s)
CGS Administrators, LLC	DME MAC	17013 -	DME MAC J-B	Illinois Indiana Kentucky Michigan Minnesota Ohio Wisconsin Alabama Arkansas Colorado Florida Georgia Louisiana Mississippi North Carolina New Mexico Oklahoma Puerto Rico South Carolina Tennessee Texas Virginia Virgin Islands West Virginia Connecticut District of Columbia Delaware Massachusetts Maryland Maine New Hampshire New Jersey New York - Entire State Pennsylvania Rhode Island Vermont Alaska American Samoa Arizona California - Entire State Guam Hawaii Iowa Idaho Kansas Missouri - Entire State Montana North Dakota Nebraska Nevada Oregon South Dakota
CGS Administrators, LLC	DME MAC	18003 -	DME MAC J-C	
Noridian Healthcare Solutions, LLC	DME MAC	16013 -	DME MAC J-A	
Noridian Healthcare Solutions, LLC	DME MAC	19003 -	DME MAC J-D	

LCD Information

Document Information

LCD ID L33317	Original Effective Date For services performed on or after 10/01/2015
Original ICD-9 LCD ID L11569 L11554 L26999 L5043	Revision Effective Date For services performed on or after 01/01/2017
LCD Title External Breast Prostheses	Revision Ending Date N/A
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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. (Reference the Diagnosis Codes that Support Medical Necessity section below.)

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 Detailed Written Order (DWO) (if applicable) must be received by the supplier before a claim is submitted. If the supplier bills for an item addressed in this policy without first receiving a completed DWO, the claim 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 ordering physicians 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.

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Coding Information

Bill Type Codes:

Contractors may specify Bill Types to help providers identify those Bill Types typically used to report this service. Absence of a Bill Type does not guarantee that the policy does not apply to that Bill Type. Complete absence of all Bill Types indicates that coverage is not influenced by Bill Type and the policy should be assumed to apply equally to all claims.

N/A

Revenue Codes:

Contractors may specify Revenue Codes to help providers identify those Revenue Codes typically used to report this service. In most instances Revenue Codes are purely advisory. Unless specified in the policy, services reported under other Revenue Codes are equally subject to this coverage determination. Complete absence of all Revenue Codes indicates that coverage is not influenced by Revenue Code and the policy should be assumed to apply equally to all Revenue Codes.

N/A

CPT/HCPCS 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:

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, REUSABLE, ANY TYPE, EACH

L8035 CUSTOM BREAST PROSTHESIS, POST MASTECTOMY, MOLDED TO PATIENT MODEL

L8039 BREAST PROSTHESIS, NOT OTHERWISE SPECIFIED

ICD-10 Codes that Support Medical Necessity

Group 1 Paragraph: The presence of an ICD-10 code listed in this section is not sufficient by itself to assure coverage. Refer to the section on "Coverage Indications, Limitations and/or Medical Necessity" for other coverage criteria and payment information.

Group 1 Codes:

ICD-10 Codes

Description

C50.011	Malignant neoplasm of nipple and areola, right female breast
C50.012	Malignant neoplasm of nipple and areola, left female breast
C50.019	Malignant neoplasm of nipple and areola, unspecified female breast
C50.111	Malignant neoplasm of central portion of right female breast
C50.112	Malignant neoplasm of central portion of left female breast
C50.119	Malignant neoplasm of central portion of unspecified female breast
C50.211	Malignant neoplasm of upper-inner quadrant of right female breast
C50.212	Malignant neoplasm of upper-inner quadrant of left female breast
C50.219	Malignant neoplasm of upper-inner quadrant of unspecified female breast
C50.311	Malignant neoplasm of lower-inner quadrant of right female breast
C50.312	Malignant neoplasm of lower-inner quadrant of left female breast
C50.319	Malignant neoplasm of lower-inner quadrant of unspecified female breast
C50.411	Malignant neoplasm of upper-outer quadrant of right female breast
C50.412	Malignant neoplasm of upper-outer quadrant of left female breast
C50.419	Malignant neoplasm of upper-outer quadrant of unspecified female breast
C50.511	Malignant neoplasm of lower-outer quadrant of right female breast
C50.512	Malignant neoplasm of lower-outer quadrant of left female breast
C50.519	Malignant neoplasm of lower-outer quadrant of unspecified female breast
C50.611	Malignant neoplasm of axillary tail of right female breast
C50.612	Malignant neoplasm of axillary tail of left female breast
C50.619	Malignant neoplasm of axillary tail of unspecified female breast
C50.811	Malignant neoplasm of overlapping sites of right female breast
C50.812	Malignant neoplasm of overlapping sites of left female breast
C50.819	Malignant neoplasm of overlapping sites of unspecified female breast
C50.911	Malignant neoplasm of unspecified site of right female breast
C50.912	Malignant neoplasm of unspecified site of left female breast
C50.919	Malignant neoplasm of unspecified site of unspecified female breast
C79.81	Secondary malignant neoplasm of breast
D05.00	Lobular carcinoma in situ of unspecified breast
D05.01	Lobular carcinoma in situ of right breast
D05.02	Lobular carcinoma in situ of left breast
D05.10	Intraductal carcinoma in situ of unspecified breast
D05.11	Intraductal carcinoma in situ of right breast
D05.12	Intraductal carcinoma in situ of left breast
D05.80	Other specified type of carcinoma in situ of unspecified breast
D05.81	Other specified type of carcinoma in situ of right breast
D05.82	Other specified type of carcinoma in situ of left breast
D05.90	Unspecified type of carcinoma in situ of unspecified breast

ICD-10 Codes	Description
D05.91	Unspecified type of carcinoma in situ of right breast
D05.92	Unspecified type of carcinoma in situ of left breast
I97.2	Postmastectomy lymphedema syndrome
Z85.3	Personal history of malignant neoplasm of breast
Z90.10	Acquired absence of unspecified breast and nipple
Z90.11	Acquired absence of right breast and nipple
Z90.12	Acquired absence of left breast and nipple
Z90.13	Acquired absence of bilateral breasts and nipples

ICD-10 Codes that DO NOT Support Medical Necessity

Group 1 Paragraph: All ICD-10 codes and diagnoses that are not specified in the preceding section.

Group 1 Codes: N/A

ICD-10 Additional Information

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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:

- Prescription (orders)
- 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 and Basis for Decision

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Revision History Information

Revision History Date	Revision History Number	Revision History Explanation	Reason(s) for Change
01/01/2017	R4	Revision Effective Date: 01/01/2017 COVERAGE INDICATIONS, INDICATIONS, LIMITATIONS AND/OR MEDICAL NECESSITY: Removed: Standard Documentation Language Added: New reference language and directions to Standard Documentation Requirements Added: General Requirements Revised: Refill Requirements DOCUMENTATION REQUIREMENTS: Removed: Standard Documentation Language Added: General Documentation Requirements Added: New reference language and directions to Standard Documentation Requirements POLICY SPECIFIC DOCUMENTATION REQUIREMENTS: Removed: Standard Documentation Language Added: Direction to Standard Documentation Requirements Removed: Information under Miscellaneous and Appendices RELATED LOCAL COVERAGE DOCUMENTS: Added: LCD-related Standard Documentation Requirements article	<ul style="list-style-type: none">Provider Education/Guidance
07/01/2016	R3	Revision Effective Date: 07/01/2016 DOCUMENTATION REQUIREMENTS: Revised: Standard documentation language for orders, added New order requirements, and Correct coding instructions; revised Refill documentation and Proof of delivery instructions (Effective 04/28/16)	<ul style="list-style-type: none">Provider Education/Guidance
07/01/2016	R2	Effective July 1, 2016 oversight for DME MAC LCDs is the responsibility of CGS Administrators, LLC 18003 and 17013 and Noridian Healthcare Solutions, LLC 19003 and 16013. No other changes have been made to the LCDs.	<ul style="list-style-type: none">Change in Assigned States or Affiliated Contract Numbers
10/01/2015	R1	Revision Effective Date: 10/31/2014 COVERAGE INDICATIONS, LIMITATIONS AND/OR MEDICAL NECESSITY: Revised: Standard Documentation Language to add covered prior to a beneficiary's Medicare eligibility DOCUMENTATION REQUIREMENTS:	<ul style="list-style-type: none">Provider Education/Guidance

Revision History Date	Revision History Number	Revision History Explanation	Reason(s) for Change
		Moved: Continued Need above Continued Use documentation Added: Instructions to the Refill Documentation section Revised: Standard Documentation Language to add who can enter date of delivery date on the POD Added: Equipment Retained from a Prior Payer	

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Associated Documents

Attachments N/A

Related Local Coverage Documents Article(s) [A52478 - External Breast Protheses - Policy Article A55426 - Standard Documentation Requirements for All Claims Submitted to DME MACs](#)

Related National Coverage Documents N/A

Public Version(s) Updated on 03/23/2017 with effective dates 01/01/2017 - N/A [Updated on 08/26/2016 with effective dates 07/01/2016 - 12/31/2016](#) [Updated on 06/07/2016 with effective dates 07/01/2016 - N/A](#) [Updated on 05/01/2015 with effective dates 10/01/2015 - 06/30/2016](#) [Updated on 04/04/2014 with effective dates 10/01/2015 - N/A](#) [Back to Top](#)

Keywords

N/A Read the [LCD Disclaimer](#) [Back to Top](#)

END OF LOCAL COVERAGE DETERMINATION

Per the Code of Federal Regulations, 42 C.F.R § 426. 325, only those portions of the currently effective Local Coverage Determination (LCD) that are based on section 1862(a)(1)(A) of the Social Security Act, may be challenged through an acceptable complaint as described in 42 C.F.R § 426.400. Also, per 42 C.F.R § 426.325 items that are not reviewable, and therefore cannot be challenged, include the Policy Article. Please note the distinction of the documents when reviewing the materials.

Local Coverage Article: External Breast Prostheses - Policy Article (A52478)

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Contractor Information

Contractor Name	Contract Type	Contract Number	Jurisdiction	State(s)
CGS Administrators, LLC	DME MAC	17013 -	DME MAC J-B	Illinois Indiana Kentucky Michigan Minnesota Ohio Wisconsin Alabama Arkansas Colorado Florida Georgia Louisiana Mississippi North Carolina New Mexico Oklahoma Puerto Rico South Carolina Tennessee Texas Virginia Virgin Islands West Virginia Connecticut District of Columbia Delaware Massachusetts Maryland Maine New Hampshire New Jersey New York - Entire State Pennsylvania Rhode Island Vermont Alaska American Samoa Arizona California - Entire State Guam Hawaii Iowa Idaho Kansas Missouri - Entire State Montana North Dakota Nebraska Nevada Oregon South Dakota
CGS Administrators, LLC	DME MAC	18003 -	DME MAC J-C	
Noridian Healthcare Solutions, LLC	DME MAC	16013 -	DME MAC J-A	
Noridian Healthcare Solutions, LLC	DME MAC	19003 -	DME MAC J-D	

Article Information

General Information

Article ID

A52478

Original Article Effective Date

10/01/2015

Original ICD-9 Article ID

[A19833](#)[A20209](#)[A47025](#)[A19801](#)**Revision Effective Date**

01/01/2017

Revision Ending Date

N/A

Article Title

External Breast Prostheses - Policy Article

Retirement Date

N/A

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Article Guidance

Article Text:**NON-MEDICAL NECESSITY COVERAGE AND PAYMENT RULES**

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. Information provided in this policy article relates to determinations other than those based on Social Security Act §1862(a)(1)(A) provisions (i.e. "reasonable and necessary").

External Breast Prostheses are covered under the Prosthetic Devices benefit (Social Security Act §1861(s)(8)). In order for a beneficiary's supplies to be eligible for reimbursement the reasonable and necessary (R&N) requirements set out in the related Local Coverage Determination must be met. In addition, there are specific statutory payment policy requirements, discussed below, that also must be met.

A mastectomy sleeve (L8010) is denied as noncovered, since it does not meet the definition of a prosthesis.

The useful lifetime expectancy for silicone breast prostheses is 2 years. The useful lifetime expectancy for a nipple prostheses is 3 months. For fabric, foam, or fiber filled breast prostheses, the useful lifetime expectancy is 6 months. Replacement sooner than the useful lifetime because of ordinary wear and tear will be denied as noncovered.

POLICY SPECIFIC DOCUMENTATION REQUIREMENTS

In addition to policy specific documentation requirements, there are general documentation requirements that are applicable to all DMEPOS policies. These general requirements are located in the DOCUMENTATION REQUIREMENTS section of the LCD.

Refer to the LCD-related Standard Documentation Requirements article, located at the bottom of this Policy Article under the Related Local Coverage Documents section for additional information regarding GENERAL DOCUMENTATION REQUIREMENTS and the POLICY SPECIFIC DOCUMENTATION REQUIREMENTS discussed below.

The diagnosis code must be included on each claim for the prosthesis or related item.

If the patient's medical condition changes, this should be documented by the patient's physician submitting a new order which explains the need for a different type of breast prosthesis. The order must be kept in the supplier's files but need not be submitted with the claim

CODING GUIDELINES

Code L8000 describes a bra with pockets that are intended to hold a mastectomy form or breast prosthesis held adjacent to the chest wall. Bras coded L8000 do not include an integrated breast prosthesis (for bras with integrated breast prosthesis, see codes L8001 and L8002). Products described by code L8000 may be constructed of any material (e.g., cotton, polyester or other materials), with any type or location of closure, any size, with or without integrated structural support (e.g., underwire).

Codes L8001 and L8002 describe a bra with integrated breast prosthesis, either unilateral or bilateral, respectively. Products described by codes L8001 and L8002 may be constructed of any material (e.g., cotton, polyester or other materials), with any type or location of closure, any size, with or without integrated structural support (e.g., underwire).

Code L8015 describes a camisole type undergarment with polyester fill used post mastectomy.

A custom fabricated prosthesis is one which is individually made for a specific patient starting with basic materials. Code L8035 describes a molded-to-patient-model custom breast prosthesis. It is a particular type of custom fabricated prosthesis in which an impression is made of the chest wall and this impression is then used to make a positive model of the chest wall. The prosthesis is then molded on this positive model.

Code A4280 should be used when billing for an adhesive skin support that attaches an external breast prosthesis directly to the chest wall.

The right (RT) and left (LT) modifiers must be used with these codes. When the same code for bilateral items (left and right) is billed on the same date of service, bill for both items on the same claim line using the RTLTLT modifiers and 2 units of service. Claims billed without modifiers RT and/or LT will be rejected as incorrect coding. Bras and similar inherently bilateral items (L8000 - L8002, L8015) are exempt from the RTLTLT requirement.

Suppliers should contact the Pricing, Data Analysis and Coding (PDAC) Contractor for guidance on the correct coding of these items. [Back to Top](#)

Coding Information

Bill Type Codes:

Contractors may specify Bill Types to help providers identify those Bill Types typically used to report this service. Absence of a Bill Type does not guarantee that the article does not apply to that Bill Type. Complete absence of all Bill Types indicates that coverage is not influenced by Bill Type and the article should be assumed to apply equally to all claims.

N/A

Revenue Codes:

Contractors may specify Revenue Codes to help providers identify those Revenue Codes typically used to report this service. In most instances Revenue Codes are purely advisory. Unless specified in the article, services reported under other Revenue Codes are equally subject to this coverage determination. Complete absence of all Revenue Codes indicates that coverage is not influenced by Revenue Code and the article should be assumed to apply equally to all Revenue Codes.

N/A

CPT/HCPCS Codes N/A

ICD-10 Codes that are Covered N/A

ICD-10 Codes that are Not Covered N/A

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Revision History Information

Revision History Date	Revision History Number	Revision History Explanation
03/02/2017	R3	Revision Effective Date: 01/01/2017 POLICY SPECIFIC DOCUMENTATION REQUIREMENTS: Added: Diagnosis and Change in Medical Condition requirements RELATED LOCAL COVERAGE DOCUMENTS: Added: LCD-related Standard Documentation Requirements Language Article
07/01/2016	R2	Revision Effective Date: 07/01/2016 Updated: Title to remove effective date
07/01/2016	R1	Effective July 1, 2016 oversight for DME MAC Articles is the responsibility of CGS Administrators, LLC 18003 and 17013 and Noridian Healthcare Solutions, LLC 19003 and 16013. No other changes have been made to the Articles.

[Back to Top](#) **Related Local Coverage Document(s)** Article(s) [A55426 - Standard Documentation Requirements for All Claims Submitted to DME MACs](#) LCD(s) [L33317 - External Breast Prostheses](#)

Related National Coverage Document(s) N/A

Statutory Requirements URL(s) N/A

Rules and Regulations URL(s) N/A

CMS Manual Explanations URL(s) N/A

Other URL(s) N/A

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[Keywords](#)

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