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Understanding CMS Rules and Medicare Compliance

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POWER 2024 RETAIL
Providing Opportunities for Wellness, Education & Renewal
March 11-13, 2024 | Las Vegas

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CMS Website (https://www.cms.gov)

Agenda

- Coverage Criteria for External Breast Prostheses
- Documentation Requirements
- Coverage Criteria for Lymphedema Compression Treatment Items
- Resources
- Questions & Answers

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EXTERNAL BREAST PROSTHESES

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Coverage Criteria: External Breast Prostheses

- Covered under Prosthetic Devices benefit (Social Security Act §1861(s)(8))
- Reasonable and necessary criteria
  - Local Coverage Determination (LCD): External Breast Prostheses (L33317)
  - https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?LCDId=33317
- Covered for beneficiary who has had mastectomy

Diagnosis Codes

- In addition to mastectomy:
  - Covered ICD-10 diagnosis code must be included on each claim for prosthesis or related items.
  - List of covered ICD-10-CM diagnosis codes located in Local Coverage Article: External Breast Prostheses - Policy Article (A52478) https://www.cms.gov/medicare-coverage-database/details/article-details.aspx?articleId=52478&ContrID=140.
  - An ICD-10 diagnosis code is not sufficient by itself to assure coverage.
    - Must be supported by documentation in medical record

External Breast & Nipple Prostheses

HCPCS Code	Description
L8020	Breast prosthesis mastectomy form
L8030	Breast prosthesis, silicone or equal, w/o integral adhesive
L8039	Breast prosthesis, not specified Additional information required: • Product name • Manufacturer's name and suggested price • Documentation of medical necessity for item
L8032	Nipple prosthesis, prefabricated, reusable, any type, each

External Prostheses Garment

HCPCS Code	Description
L8015	External prosthesis garment w/mastectomy form • Post-operative prior to permanent prosthesis **or** • Alternative to mastectomy bra and breast prosthesis

Mastectomy Bras

HCPCS Code	Description
L8000	Breast prosthesis, mastectomy bra, w/o integrated breast prosthesis form, any size, any type • Covered for beneficiary who has a covered mastectomy form or prostheses (L8020 or L8030) when bra pocket is used to hold prosthesis adjacent to chest wall
L8001	Breast prosthesis, unilateral mastectomy bra with integrated breast prosthesis form
L8002	Breast prosthesis, bilateral mastectomy bra with integrated breast prosthesis form

Mastectomy Bra Utilization

- LCD does not limit number of bras that can be ordered.
- Physician determines frequency and number of bra refills.
- Medically Unlikely Edits (MUEs) apply.
  - https://www.cms.gov/index.php/Medicare/Coding/NationalCorrectCodInitEd/MUE

Not Reasonable and Necessary

- More than one external breast prosthesis per side will be denied as not reasonable and necessary.
- **L8031:** Breast prosthesis, silicone or equal, with integral adhesive
  - No clinical advantage over those without integral adhesive
- **L8035:** Custom breast prosthesis
  - Medical necessity for additional features of custom fabricated prosthesis compared to prefabricated silicone breast prosthesis has not been established
- **L8033:** Nipple prosthesis, custom fabricated, reusable
  - Follows criteria for L8035

Non-covered: Mastectomy sleeve

- Mastectomy sleeve (**L8010**) denied as non-covered, does not meet definition of prosthesis.
- For any item to be covered, it must be eligible for a defined Medicare benefit category.

Hospital or Skilled Nursing Facility (SNF)

- Payment for HCPCS codes in External Breast Prosthesis policy included in payment to hospital or SNF if:
  - Item provided to beneficiary during an inpatient hospital or SNF stay prior to day of discharge; and
  - Beneficiary uses item for medically necessary inpatient treatment or rehabilitation
- Do not submit claim to DME MAC

Reasonable Useful Lifetime (RUL)

- Replacement sooner than RUL due to ordinary wear and tear will deny as non-covered.

Item	Length
Silicone breast prostheses	2 years
Nipple prostheses	3 months
Fabric, foam, or fiber filled breast prostheses	6 months

Prostheses Replacement

1. Reasonable Useful Lifetime:

- RUL - Ordinary wear and tear according to standard life span of item

2. Lost or irreparably damaged:

- Example of loss: item was in beneficiary's lost or stolen luggage
- Example of irreparable damage: damage sustained in a fire or flood

SAME TYPE OF ITEM

3. Change in medical condition:

- Additional surgery/surgeries
- Weight gain or loss, etc.

DIFFERENT TYPE OF ITEM

Replacement Requirements

- New order
- RA modifier
  - Replacement due to loss or irreparable damage
  - Include reason for replacement in Item 19 of a paper claim or in the NTE 2400 segment of an electronic claim
- Do **NOT** use RA modifier when item is being **replaced:**
  - After reasonable useful lifetime *or*
  - Due to change in the beneficiary's medical condition, because the item is not a replacement of the original item but a new order for a different HCPCS

External Breast Prostheses: RT & LT Modifiers

- **RT** = Right
- **LT** = Left
- Bilateral prostheses
  - Bill each item on two separate claim lines using RT and LT modifiers and 1 unit of service (UOS) on each claim line
- Bras and similar inherently bilateral items (L8000 - L8002, L8015)
  - DO NOT require RT and LT modifiers

Modifiers with Advance Beneficiary Notice (ABN)

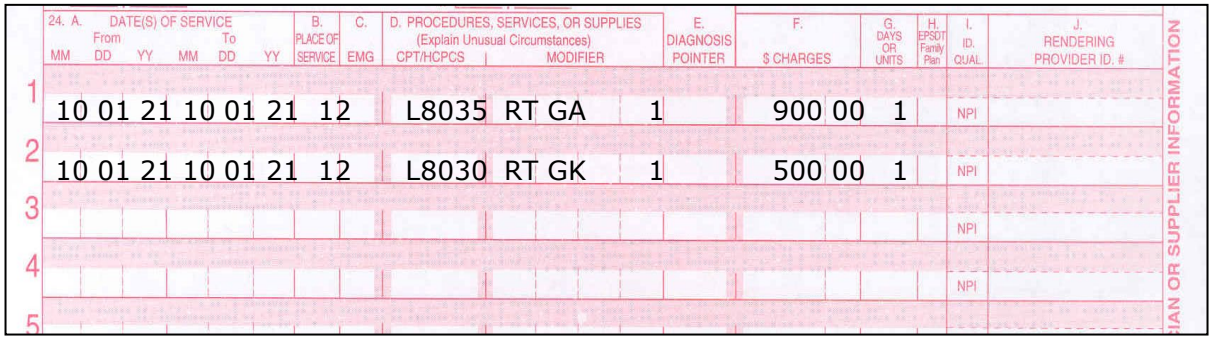
- Use form CMS-R-131 (Exp. 01/31/2026).
  - https://www.cms.gov/Medicare/Medicare-General-Information/BNI/ABN
- Ensure section E is completed accurately.
  - Example: “Medicare will only pay for breast prostheses without integral adhesive for your condition. Breast prostheses with integral adhesive are not reasonable and necessary.”
- Make sure beneficiary understands financial responsibility.
- GA = Valid ABN on file
- GZ = No ABN obtained

Upgrade Modifiers

Modifier	Description
GK	Reasonable and necessary item/service associated with GA or GZ modifier
GL	Medically unnecessary upgrade provided instead of standard item, no charge, no Advance Beneficiary Notice of Noncoverage (ABN)

Claim Submission Example: Upgrade

- Supplier collects additional charge
  - L8030 RTGK (reasonable and necessary or “standard” item)
  - L8035 RTGA (upgraded item/ABN on file)

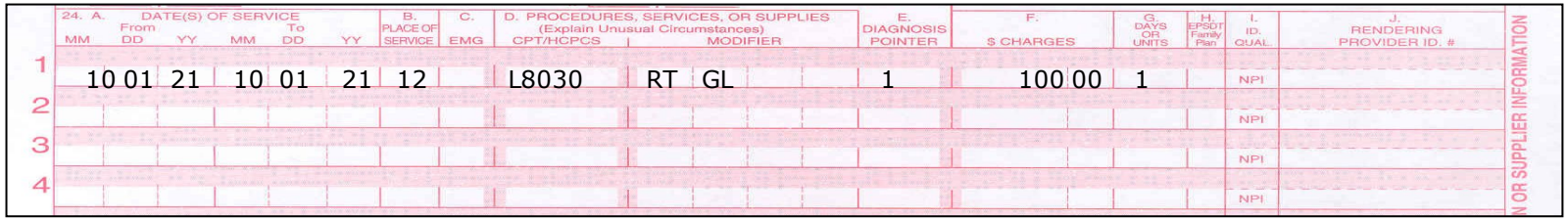


	24. A. DATE(S) OF SERVICE From MM	DD	YY	To MM	DD	YY	B. PLACE OF SERVICE	C. EMG	D. PROCEDURES, SERVICES, OR SUPPLIES (Explain Unusual Circumstances) CPT/HCPCS	MODIFIER	E. DIAGNOSIS POINTER	F. $ CHARGES	G. DAYS OR UNITS	H. EPSDT Family Plan	I. ID. QUAL.	J. RENDERING PROVIDER ID. #
1	10	01	21	10	01	21	12		L8035	RT GA	1	900 00	1		NPI	
2	10	01	21	10	01	21	12		L8030	RT GK	1	500 00	1		NPI	
3															NPI	
4															NPI	
5																

AN OR SUPPLIER INFORMATION

Claim Submission Example: Free Upgrade

- Supplier provides free upgrade
  - GL = Medically unnecessary upgrade provided instead of non-upgraded item, no charge, no ABN
  - Example: L8030 RTGL
    - Specify make and model of item furnished (upgraded item) and describe why item is an upgrade in Item 19 of a paper claim or in NTE field of electronic claim



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1	10	01	21	10	01	21	12		L8030	RT GL	1	100 00	1		NPI	
2															NPI	
3															NPI	
4															NPI	

N OR SUPPLIER INFORMATION

Mastectomy Bras: Upgrades

- May not be upgraded because upgrades cannot be provided within same HCPCS code
- HCPCS code describes any size, any type
- Assigned claims
  - Limited to Medicare fee schedule amount
  - ABN may NOT be used to collect additional fees
- Non-assigned Claims – may bill beneficiary supplier's fee for item

DOCUMENTATION REQUIREMENTS

Standard Documentation Requirements

- Standard Documentation Policy Article (A55426) https://www.cms.gov/medicare-coverage-database/details/article-details.aspx?articleid=55426
  - Standard Written Order (SWO)
  - Medical records
  - Proof of delivery (POD)
  - Beneficiary authorization
  - Continued need/use
  - Refill requirements
    - Mastectomy bras dispensed on periodic basis

Authorized to Order

Practitioner	Orders	Criteria
Physician	All	MD or DO treating beneficiary
Nurse Practitioner	• Give dispensing order • Sign the SWO	• Treating beneficiary for condition for which the item is needed • Practicing independently of a physician • Billing Medicare using their own provider number • Permitted in the state where services rendered
Clinical Nurse Specialist	• Give dispensing order • Sign the SWO	• Treating beneficiary for condition for which the item is needed • Practicing independently of a physician • Billing Medicare using their own provider number • Permitted in the state where services rendered
Physician Assistant (PA)	• Give dispensing order • Sign the SWO	• Meet the definition of physician assistant found in §1861(aa)(5)(A) of the Act • Treating beneficiary for condition for which the item is needed • Practicing under the supervision of a Doctor of Medicine or Doctor of Osteopathy • Have their own NPI • Permitted in accordance with state law.

Requirements of New Orders

- New order is required:
  - For all claims for purchases or initial rentals;
  - If there is a change in the DMEPOS order/prescription e.g., quantity;
  - When an item is replaced;
  - When there is a change in the supplier, and the new supplier is unable to obtain a copy of a valid order/prescription for the DMEPOS item from the transferring supplier.

Medical Records

- Substantiate medical necessity for item and quantity ordered and frequency of use
- Should include (but not limited to)
  - Diagnosis
  - Duration of condition
  - Clinical course
  - Prognosis
  - Functional limitations
  - Past experience with related items

Continued Need and Use

- Timely:
  - Within preceding 12 months
  - Required for resupply of items on a periodic basis

Acceptable Examples
Recent order by treating practitioner for mastectomy bras
Recent change in prescription
Timely documentation in medical record showing usage of items Medical record mentions use of prostheses or mastectomy bra

Request for Refill

- Request for refill documentation when delivering or shipping items must include
  - Beneficiary's name
  - Description of each item being requested
  - Date of refill request
- Exception: Beneficiary picks up items at supplier's retail store
  - Signed delivery ticket serves as sufficient documentation of request for refill
  - Must be clear on delivery ticket that item(s) were picked up

Refill Documentation Requirements: Final Rule CMS1780-F

Obtained In Person @ Retail Store	Delivered Refill Communications
Signed delivery slip or copy of itemized sales receipt	Beneficiary name and/or authorized representative *(Suggested: if someone other than the beneficiary, include this person's relationship to the beneficiary)*
Delivery slip/receipt should indicate items were picked up at store front	
For dates of service **on or after** January 1, 2024	Date of Request
	Description of each item requested
	Documentation of affirmative response indicating a need for the refill
	Contact must occur no sooner than 30 calendar days prior to the expected end of the current supply
	Shipment/delivery no sooner than 10 calendar days prior to expected end of current supply

Delivery Documentation

Method #1: Direct Delivery

- Beneficiary's name
- Delivery address
- Qty delivered
- A description of items being delivered. The description can be either a narrative description (e.g., lightweight wheelchair base), a HCPCS code, the long description of the HCPCS code or a brand name/model number.
- Delivery Date
- Signature of person accepting delivery
- Relationship to beneficiary

Method #2: Shipped/Mail Order Tracking Slip

Shipping Invoice

- Beneficiary's name
- Delivery address
- Description of items being delivered; either a narrative (e.g., lightweight wheelchair base), a HCPCS code, the long description of the HCPCS code or a brand name/model number.
- Qty delivered

Tracking Slip

- References each individual package
- Delivery address
- Package ID # number
- Date shipped
- Date delivered
- A common reference number (package ID #, PO#, etc.) links the invoice and tracking slip (may be handwritten on one or both forms by the supplier)

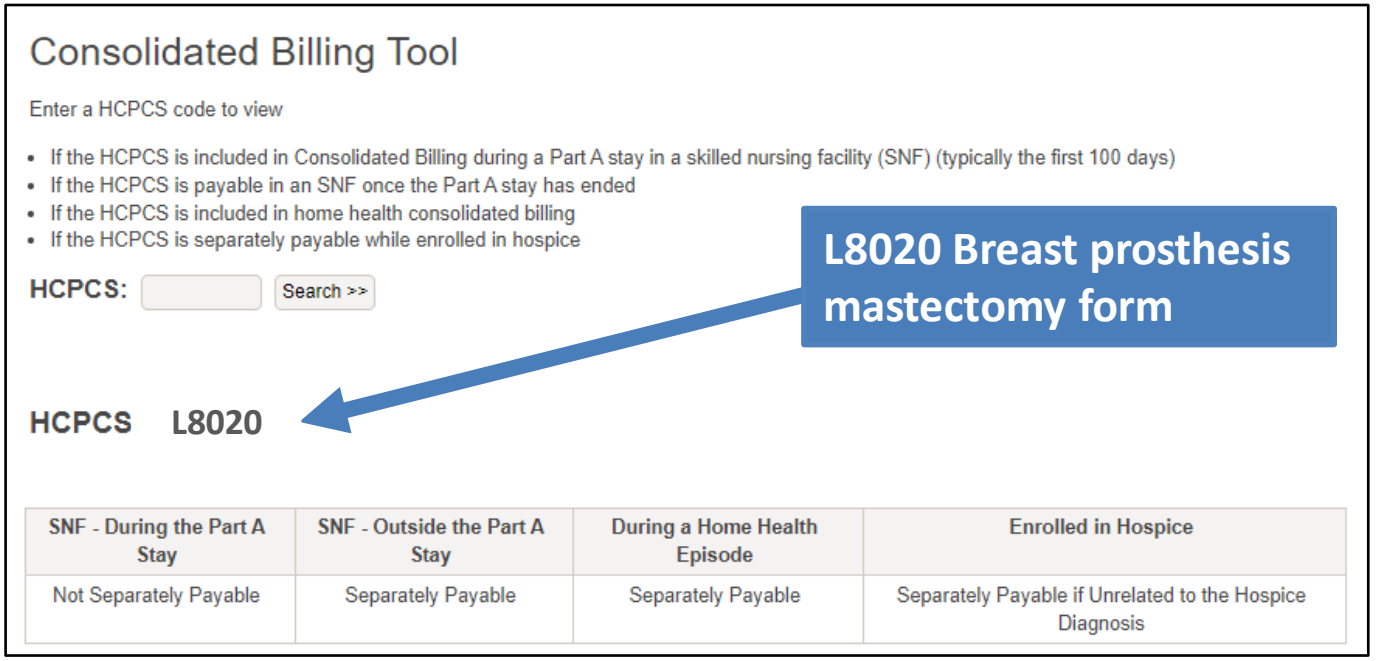
Date of Service: Anticipation of Discharge

- **Delivery to Facility**
  - Delivered for purpose of fitting/training
  - Two days prior discharge from hospital or nursing facility
  - DOS = Discharge Date
  - POS = 12 (Beneficiary's Home)
  - Add narrative to delivery documentation indicating delivered two days prior to discharge
- **Delivery to Home**
  - Two days prior discharge from hospital or nursing facility
  - DOS = Discharge Date
  - POS = 12 (Beneficiary's Home)
  - Add narrative to delivery documentation indicating delivered two days prior to discharge

Beneficiaries in a SNF or Nursing Facility

- For beneficiaries in a Part A covered stay, the claim must be billed by the SNF to the fiscal intermediary
  - No payment from Part B is available when treatment items are furnished to a beneficiary in a covered Part A stay
- If a beneficiary is NOT in covered by Part A, lymphedema compression treatment items may be billed to the DME MAC by either the SNF or an outside supplier

Consolidated Billing Tool



LYMPHEDEMA COMPRESSION TREATMENT ITEMS

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New DMEPOS Benefit Category

Background:

- Initial Article: November 13, 2023
  - https://www.cms.gov/files/document/mm13286-lymphedema-compression-treatment-items-implementation.pdf
- No planned Local Coverage Determination (LCD) or Policy Article (PA)
- DMEPOS Fee Schedule Indicator (Category): LC

Items Included:

- Standard fit compression garments
- Custom fit compression garments
- Additional lymphedema compression treatment items

Lymphedema Coverage Criteria

- Treatment of lymphedema diagnosis
  - Lymphedema, not elsewhere classified (I89.0)
  - Hereditary Lymphedema (Q82.0)
  - Postmastectomy Lymphedema Syndrome (I97.2)
  - Other postprocedural complications and disorders of the circulatory system, not elsewhere classified (I97.89)
- Non-lymphedema diagnosis prohibited
- Claims will deny without proper diagnosis

Gradient Compression Garments & Accessories

- Standard daytime gradient compression garments
- Custom daytime gradient compression garments
- Nighttime gradient compression garments
- Gradient compression wraps
- Accessories necessary for effective use of gradient compression garment/wrap
  - Zippers
  - Linings
  - Padding
  - Fillers
- Compression bandaging systems/supplies

Supplier Responsibilities: Furnishing Lymphedema Garments

- Regardless of the method of delivery, suppliers are responsible for all aspects of furnishing lymphedema garments or may make arrangements with an external fitter to perform the following services:
  - Taking measurements of the patient's affected body area
  - Performing necessary fitting services
  - Training the patient how to take the treatment item on and off
  - Showing the patient how to take care of the treatment item
  - Adjusting the treatment item, if needed
- https://www.cms.gov/medicare/payment/fee-schedules/dmepos-fee-schedule/lymphedema-compression-treatment-items

Custom Compression Garments/Wraps

- **Custom Fitted**
  - Medicare covers custom fitted gradient compression garments
    - Custom or non-standard
  - Unique in size and shape to fit the exact dimensions of the affected extremity
    - Provides accurate gradient compression to treat lymphedema
  - Beneficiary must have a qualifying diagnosis
  - Medical records must justify the medical necessity
    - Custom vs. off-the-shelf garment

- **Situations in which a beneficiary would require a custom garment**
  - If the circumference of the proximal portion of the limb is significantly greater than the distal limb
  - If the skin/tissue has folds or contours requiring a specific type of knitting pattern
  - Beneficiary is unable to tolerate the fabric composition of a standard garment

Daytime vs. Nighttime Garments

- **Daytime compression garments (with adjustable straps)**
  - Payment allowed for more than one body part/area
  - Higher level of compression
  - Three per affected extremity or part of body
  - Payment once every six months

- **Nighttime compression garments**
  - Payment allowed for more than one body part/area
  - Milder level of compression
  - Less snug against skin
  - Two per extremity or body part
  - Payment once every two years

Gradient Compression: Phase I & Phase II

- Compression bandaging supplies furnished during Phase 1 (acute or decongestive therapy) and Phase 2 (maintenance phase of therapy):
  - Covered when medically necessary for the treatment of lymphedema
  - Therapists and other suppliers furnishing bandaging systems must be enrolled as DMEPOS suppliers to be paid for furnishing these items
  - Justification for the quantity of supplies needed and the frequency of replacement must be documented in the beneficiary's medical record
    - The documentation must be available to the DME MAC when requested

Frequency of Garments

Garment type	Frequency
Daytime garments or wraps	A quantity of three (3) daytime garments or wraps per body area are allowed once every 6 months
Nighttime garments or wraps	A quantity of two (2 nighttime garments per body area) are allowed once every two (2) years (24 months).

- Claims in excess of the frequency limitations will be denied as not reasonable and necessary unless replacements are needed due to:
  - Lost, stolen, or irreparably damaged *or*
  - Change in medical/physical condition requiring a new size or type of garment or wrap

All HCPCS Lymphedema Benefit

- The complete list of codes covered under the Lymphedema Benefit:
  - A6520 – A6530
  - A6533 – A6541
  - A6549
  - A6552 – A6589
  - A6593 – A6610

For a complete list of codes with descriptors:
https://cgsmedicare.com/jc/pubs/news/2023/12/cope147943.html

Covered HCPCS Codes: Surgical Dressings

HCPCS	Description
A6531	Gradient compression stocking • Below knee • **30-40 mmHg** • Used as a surgical dressing, each
A6532	Gradient compression stocking • Below knee • **40-50 mmHg** • Used as a surgical dressing, each
A6545	Gradient compression wrap • Non-elastic • Below knee • **30 - 50 mmHg** • Used as a surgical dressing, each

Existing codes under the Surgical Dressings Benefit:

- Description has been modified to add "used as a surgical dressing"
- Requires AW modifier
- These codes are **NOT** covered under the Lymphedema policy.

New Lymphedema Codes

HCPCS	Description
A6552	Gradient compression stocking Below knee **20 - 40 mmHg** Each
A6554	Gradient compression stocking Below knee **40 mmHg or greater** Each
A6583	Gradient compression wrap w/adjustable straps Below knee **30-50 mmHg** Each

- New codes for use with lymphedema compression treatment items only
- Effective January 01, 2024

Not Otherwise Specified HCPCS

HCPCS	Description
A6549	Gradient Compression Garment • Not Otherwise Specified
A6584	Gradient Compression Wrap with Adjustable Straps • Not Otherwise Specified
A6593	Accessory for Gradient Compression Garment or Wrap with Adjustable Straps • Not Otherwise Specified
A6609	Gradient Compression Bandaging Supply • Not Otherwise Specified

All Not Otherwise Specified codes:

- Must be billed on separate claim line
- Must include appropriate units of service
- Narrative must include:
  - Description of item
  - Manufacturer name
  - Product name and number
  - Supplier price list
  - HCPCS of related item (where applicable)

Lymphedema Garments: RT & LT Modifiers

- Required when the same code is used to identify an item that can be provided for either the left and/or the right side (unilateral items).
- LT/RT is not required for bilateral items (items that have two sides, i.e., pantyhose)
- Same code billed on same date of service (DOS):
  - Bill on two separate lines using one unit of service each
  - Use of RTLT on same claim line with two units of service will be rejected

Garment Replacement

If lost, stolen or irreparably damaged:

- **Daytime Garment or Wrap**
  - Append RA Modifier
  - Payment allowed for three gradient compression garments or wraps with adjustable straps per affected extremity/body part
  - Frequency limitation once every six months
  - Six months restarts on replacement DOS
- **Nighttime Garment**
  - Append RA Modifier
  - Payment allowed for two garments)
  - Restarts based on replacement DOS

NOTE: If beneficiary has a change in medical or physical condition, do not use the RA modifier

Payment

- Payment for all necessary services associated with providing gradient compression garments and wraps, including fitting and measurements, is included in the national payment amounts made to the supplier for the item(s)
  - **DMEPOS Fee Schedules**
    - Jurisdiction A: https://med.noridianmedicare.com/web/jadme/fees-news/fee-schedules
    - Jurisdiction B: https://www.cgsmedicare.com/medicare_dynamic/fees/jb/search.asp
    - Jurisdiction C: https://www.cgsmedicare.com/medicare_dynamic/fees/jc/search.asp
    - Jurisdiction D: https://med.noridianmedicare.com/web/jddme/fees-news/fee-schedules

RESOURCES

CMS Resources

- **CMS Internet Only Manuals (IOMs)**
  - https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Internet-Only-Manuals-IOMs

- **MLN Publications**
  - https://www.cms.gov/training-education/medicare-learning-network/newsletter

Noridian Healthcare Solutions: Jurisdiction A

- **Website:** https://med.noridianmedicare.com/web/jadme
- **IVR, Supplier Contact Center, and Telephone Reopenings:** 1.866.419.9458
- **Noridian Medicare Portal (NMP)**
  https://med.noridianmedicare.com/web/jadme/topics/nmp
- **LCDs and Policy Articles:**
  https://med.noridianmedicare.com/web/jadme/policies/lcd/active

CGS Jurisdiction B

- **Website:** http://www.cgsmedicare.com/jb
- **IVR Unit:** 1.877.299.7900
- **myCGS Web Portal:** http://www.cgsmedicare.com/jb/mycgs/index.html
- **Customer Service:** 1.866.590.6727
- **Telephone Re-openings:** 1.844.240.7490
- **LCDs and Policy Articles:** http://www.cgsmedicare.com/jb/coverage/lcdinfo.html

CGS Jurisdiction C

- **Website:** http://www.cgsmedicare.com/jc
- **IVR Unit:** 1.866.238.9650
- **myCGS Web Portal:** http://www.cgsmedicare.com/jc/mycgs/index.html
- **Customer Service:** 1.866.270.4909
- **Telephone Re-openings**: 1.866.813.7878
- **LCDs and Policy Articles**: http://www.cgsmedicare.com/jc/coverage/lcdinfo.html

Noridian Healthcare Solutions: Jurisdiction D

- **Website:** https://med.noridianmedicare.com/web/jddme/
- **IVR, Supplier Contact Center, and Telephone Reopenings:** 1.877.320.0390
- **Noridian Medicare Portal (NMP)**
  https://med.noridianmedicare.com/web/jddme/topics/nmp
- **LCDs and Policy Articles**
  https://med.noridianmedicare.com/web/jddme/policies/lcd/active

Other Contractor Resources

- **Pricing, Data Analysis and Coding Contractor (PDAC)**
  - 1.877.735.1326
  - http://www.dmepdac.com

- **Common Electronic Data Interchange (CEDI)**
  - 1.866.311.9184
  - https://www.ngscedi.com/
  - E-mail: NGS.CEDIHelpdesk@anthem.com

National Provider Enrollment (NPE)

- **NPE – West (west of Mississippi)**
  - Palmetto GBA
  - 1.866.238.9652
  - https://www.palmettogba.com/palmetto/npewest.nsf
- **NPE – East (east of Mississippi)**
  - Novitas Solutions
  - 1.866.520.5193
  - https://www.novitas-solutions.com/webcenter/portal/DMEPOS

QUESTIONS

THANK YOU!