Lower Limb Orthoses

A Collaboration Webinar
presented by the
A/B and DME Medicare
Administrative Contractors

December 17 , 2024

Disclaimer

The A/B and DME MAC Provider Outreach and Education (POE) staff have produced this material as an informational reference for providers furnishing services in our contract jurisdictions to Medicare beneficiaries.

Although every reasonable effort has been made to assure the accuracy of the information within these pages at the time of publication, the Medicare program is constantly changing, and it is the responsibility of each provider to remain abreast of the Medicare program requirements. Any regulations, policies and/or guidelines cited in this publication are subject to change without further notice. Current Medicare regulations can be found on the Centers for Medicare & Medicaid Services (CMS) website at http://www.cms.gov.

As a reminder, CMS does not allow recording of education opportunities such as this.

Participants

- **CGS Administrators, LLC:** http://www.cgsmedicare.com
- **First Coast Service Options, Inc.:** https://medicare.fcso.com/
- **National Government Services:** http://www.ngsmedicare.com/
- **Noridian Healthcare Solutions, LLC:** http://www.noridianmedicare.com/
- **Novitas Solutions:** https://www.novitas-solutions.com/
- **Palmetto GBA:** http://www.palmettogba.com/
- **WPS Government Health Administrators:** https://www.wpsgha.com/

Agenda

- Medical Records
- Coverage Criteria
  - Ankle-Foot & Knee Ankle-Foot Orthoses
  - Knee Orthoses
- Documentation Requirements
- Prior Authorization
- Comprehensive Error Rate Testing (CERT)
- Resources

Medical Records

Medical Records(1)

Before submitting a claim to Medicare, the DMEPOS supplier must have on file:

- A Standard Written Order (SWO) or Written Order Prior to Delivery (WOPD)
- Information from the treating practitioner concerning the patient's diagnosis, and any information required for the use of specific modifiers or attestation statements
  - The supplier should obtain as much documentation from the patient's medical record to assure themselves that coverage criteria for an item have been met.
  - If the information in the patient's medical record does not adequately support the medical necessity for the item, the supplier is liable for the dollar amount involved

Medical Records(2)

The medical record must contain sufficient documentation of the medical condition to substantiate the necessity for the items

- The information should include:
  - Diagnosis
  - Other pertinent information including, but not limited to:
    - Duration of the beneficiary's condition
    - Clinical course of treatment
    - Prognosis
    - Functional limitations
    - Other therapeutic interventions and results
    - Past experience with related items.

Coverage Criteria

Ankle-Foot & Knee Ankle-Foot Orthoses

AFO for Non-Ambulation(1)

- L4396/L4397 (Static or dynamic positioning ankle-foot orthosis) is covered if either all of criteria 1-4 or criterion 5 is met:

  1. Plantar flexion contracture of the ankle (Group 1 Diagnosis Codes) with dorsiflexion on passive range of motion testing of at least 10 degrees (i.e., a nonfixed contracture)
  2. Reasonable expectation of ability to correct contracture
  3. Contracture interference with functional abilities
  4. Used as a component of a therapy program

  OR

  5. The beneficiary has plantar fasciitis (Group 1 Diagnosis Codes) (Also applies to replacement interface L4392)

AFO for Non-Ambulation(2)

- If L4396 or L4397 is covered, replacement interface (L4392) is covered if the beneficiary continues to meet indications and coverage rules for the splint
- Maximum of 1 per 6 months
  - Additional interfaces will be denied not reasonable and necessary
- Not reasonable and necessary: L4396 or L4397 and replacement interface (L4392)
  - If contracture is fixed
- L4396, L4397 and L4392:
  - Beneficiary with a foot drop but without an ankle flexion contracture
  - Component of a static/dynamic AFO that is used to address positioning of the knee or hip
    - Effectiveness isn't established

AFO for Non-Ambulation(3)

- Medicare does not reimburse for a foot drop splint/recumbent positioning device (L4398) or replacement interface (L4394).
  - Denied as not reasonable and necessary in a beneficiary with foot drop who is nonambulatory because there are other more appropriate treatment modalities.
  - Denied as noncovered (no Medicare benefit) when they are used solely for the prevention or treatment of a pressure ulcer (it does not meet the definition of a brace).

Coverage During Ambulation

AFOs Used During Ambulation

- Covered for ambulatory beneficiaries with weakness or deformity of the foot and ankle, who:
  - Require stabilization for medical reasons, and
  - Have the potential to benefit functionally

KAFOs Used During Ambulation

- Covered for ambulatory beneficiaries with weakness or deformity of the foot and ankle, who:
  - Require stabilization for medical reasons, and
  - Have the potential to benefit functionally
  - Additional knee stability is required

Not reasonable or necessary: Basic coverage criteria for AFO/KAFO aren't met

Custom-Fabricated AFO/KAFO

AFOs and KAFOs that are custom-fabricated are covered for ambulatory beneficiaries when the basic coverage criteria are met and one of the following criteria are met:

- Beneficiary could not be fit with a prefabricated AFO; or,
- Condition necessitating the orthosis is expected to be permanent or of longstanding duration (more than 6 months); or,
- A need to control the knee, ankle or foot in more than one plane; or,
- Beneficiary has a documented neurological, circulatory, or orthopedic status that requires custom fabricating to prevent tissue injury; or,
- Beneficiary has a healing fracture which lacks normal anatomical integrity or anthropometric proportions

Custom fabricated orthoses: Not reasonable and necessary when basic coverage criteria and any above criteria aren't met

Miscellaneous Coverage Criteria

Concentric Adjustable Torsion-style Mechanisms:

HCPC	Benefit/Coverage
L2999	Covered under **Brace Benefit:** Used to assist knee joint extension in absence of any co-existing joint contracture, **or** Used to assist ankle joint plantarflexion or dorsiflexion assist in the absence of any co-existing joint contracture
E1810 *(Custom Fit)*	Covered under **DME Benefit:** Used to treat contractures; Dynamic adjustable knee extension/flexion device, includes soft interface material
E1815 *(Custom Fit)*	Covered under **DME Benefit:** Used to treat contractures; Dynamic adjustable ankle extension/flexion device, includes soft interface material

Shoe/Foot Orthotics

- Foot orthotics are shoe inserts that do not extend above the ankle
- Beneficiaries without diabetes:
  - Coverage may be considered if shoe is an integral part of the brace
    - Shoes which are incorporated into a brace must be billed by the same supplier billing for the brace
  - Refer to the Orthopedic Footwear policy https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?LCDId=33641&ContrID=140
- Multiple density foot orthotics used in the management of diabetic foot problems
  - Coverage limited to beneficiaries diagnosed with diabetes and qualifying foot condition
  - Refer to the Therapeutic Shoes for Persons with Diabetes policy https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?LCDId=33369&ContrID=140

Knee Orthoses

Prefabricated Knee Orthoses(1)

- Knee orthosis with joints (L1810, L1812) or knee orthosis with condylar pads and joints with or without patellar control (L1820) are covered for:
  - Ambulatory beneficiaries who have weakness or deformity of the knee and
  - Require stabilization
- A knee orthosis with a locking knee joint (L1831) or a rigid knee orthosis (L1836) is covered for:
  - Beneficiaries with flexion or extension contractures of the knee with movement on passive range of motion testing of at least 10 degrees (i.e., a nonfixed contracture)
  - Requires covered Group 1 diagnosis code

Prefabricated Knee Orthoses(2)

HCPCS	Description	Covered for:
L1830 *(off-the-shelf)*	Knee immobilizer without joints	Path 1
L1833 *(off-the-shelf)* **L1832** *(custom fit)*	Knee orthosis with adjustable knee joints	Either Path 1 or Path 2
L1843 *(custom fit)* **L1845** *(custom fit)* **L1851** *(off-the-shelf)* **L1852** *(off-the-shelf)*	Knee orthosis, with an adjustable flexion and extension joint that provides both medial-lateral and rotation control	Either Path 1 or Path 2

Path 1:

- Recent injury or surgical procedure to knee(s); and
- Group 2 or Group 4 diagnosis codes

Path 2:

- Ambulatory; and
- Objective description of joint laxity; and
- Knee instability due to condition specified in the Group 4 diagnosis codes

Prefabricated Knee Orthoses(3)

- Swedish type (L1850) covered
  - Ambulatory; and,
  - Knee instability
    - Genu recurvatum – hyperextended knee
      - » Congenital or acquired
  - Requires covered Group 5 diagnosis code

Documentation of Knee Instability

- Knee instability must be documented by
  - Examination of the beneficiary and
  - Objective description of joint laxity
    - e.g., varus/valgus instability, anterior/posterior Drawer test
- When the beneficiary doesn't meet coverage criteria
  - Claims will be denied as not reasonable and necessary
    - Example: Only pain or a subjective description of joint instability is documented
- A covered diagnosis code alone
  - Not enough to meet coverage criteria

Custom Fabricated Knee Orthoses – General Coverage Requirements

L1834, L1840, L1844, L1846, L1860

- Must have documented physical characteristic which requires use of custom fabricated instead of prefabricated
- Examples:
  - Deformity of leg or knee;
  - Size of thigh and calf;
  - Minimal muscle mass upon which to suspend an orthosis
- Consider prefabricated alternatives
- Not reasonable and necessary in treatment of knee contractors for non-ambulatory beneficiaries

Custom-Fabricated Knee Orthoses

HCPCS	Description	Covered:
L1834	Immobilizer w/out joints	Meets criteria for L1830 & custom-fabricated
L1840	Derotation orthosis	Instability due to internal ligamentous disruption Group 3 ICD-10 Codes
L1844	Adjustable flexion/ extension joint w/medial-lateral and rotation control	▪ Meets criteria for L1843, L1845, L1851, and L1852 ▪ Meets criteria for custom-fabricated Group 4 ICD-10 Codes
L1846	Adjustable flexion/ extension joint w/medial-lateral and rotation control	▪ Meets criteria for L1843, L1845, L1851, and L1852 ▪ Meets criteria for custom-fabricated Group 4 ICD-10 Codes
L1860	Modified supracondylar prosthetic socket	▪ Ambulatory ▪ Knee instability due to hyperextended knee ▪ Meets criteria for custom-fabricated Group 5 ICD-10 Codes

Local Coverage Determinations (LCDs) and Policy Articles (PAs)

Detailed information in the LCDs and PAs provides coverage criteria and Medicare requirements Information

- Ankle-Foot/Knee-Ankle-Foot Orthosis
  - LCD: https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?LCDId=33686&ContrID=140
  - PA: https://www.cms.gov/medicare-coverage-database/view/article.aspx?articleId=52457&ContrID=140
- Knee Orthoses
  - LCD: https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?LCDId=33318&ContrID=140
  - PA: https://www.cms.gov/medicare-coverage-database/view/article.aspx?articleId=52465&ContrID=140
- Standard Documentation Requirements for All Claims Submitted to DME MACs
  - https://www.cms.gov/medicare-coverage-database/view/article.aspx?articleid=55426

Documentation Requirements

Authorized to Order

Treating Practitioner:

- Doctor of Medicine (MD)
- Doctor of Osteopathy (DO)
- Nurse Practitioner (NP)
- Clinical Nurse Specialist (CNS)
- Physician Assistant (PA)

Program Integrity Manual Chapter 5 https://www.cms.gov/regulations-and-guidance/guidance/manuals/downloads/pim83c05.pdf

Standard Written Order (SWO) / Written Order Prior to Delivery (WOPD)

- Beneficiary's name or Medicare Beneficiary Identifier (MBI)
- Order date
- General description of item
- Quantity to be dispensed, if applicable
- Treating practitioner name or NPI
- Treating practitioner's signature

SWO/WOPD: Description

- **Description** – General description (e.g., PAP device), HCPCS code, HCPCS code narrative, or brand name/model number
- **For equipment** – In addition to description of base item, SWO may include all concurrently ordered options, accessories or additional features that are separately billed (list each separately)
- **For supplies** – In addition to description of base item, SWO may include all concurrently ordered supplies that are separately billed (List each separately)

SWO must be completed and signed prior to billing Medicare

WOPD must be completed and signed prior to delivery of the item

New Order Required

- All claims for purchases or initial rentals
- Change the order
- On regular basis (even if there no change) only if specified in a particular medical policy
- When an item is replaced
- Change in supplier and new supplier unable to obtain copy of valid order from transferring supplier

Required Face-to-Face and Written Order Prior to Delivery List

- CMS maintains the Required Face-to-Face Encounter and Written Order Prior to Delivery (WOPD) List: https://www.cms.gov/files/document/required-face-face-encounter-and-written-order-prior-delivery-list.pdf
- Knee Orthosis: L1832, L1843, L1845, L1851, and L1852
  - Ankle-Foot/Knee- Ankle Foot Orthosis: L1932, L1940, L1951, L1960, L1970, L2005, and L2036
- Items on this list require:
  - Face-to-face encounter within six months preceding the order, and
  - Written Order Prior to Delivery (WOPD)

Written Order Prior to Delivery (WOPD)

A WOPD is a completed SWO that is communicated to the supplier before delivery of the item

- Items appearing on the Required List require a Face-to-Face (F2F) encounter and WOPD
- The date of the WOPD shall be on or before the date of delivery
  - Must be completed within 6 months after the required F2F encounter

Face-to-Face Encounter

- The treating practitioner must document and communicate to the DMEPOS supplier that they had a face-to-face encounter with the patient within the 6 months before the date on the written order/prescription
  - The 6-month timing requirement doesn't replace other CMS policies
- In-person or telehealth encounter between the treating practitioner and the patient
  - Telehealth encounter must meet the requirements of 42 CFR 410.78 and 42 CFR 414.65
- Supporting documentation includes subjective and objective information associated with diagnosing, treating, or managing a clinical condition for the DMEPOS item ordered
- Suppliers must maintain the written order/prescription, and the supporting documentation provided by the treating practitioner to support payment for the item(s) of DMEPOS and make them available to CMS or its contractors upon request

Treating Practitioner is Also the Supplier

In those limited instances in which the treating practitioner is also the supplier and is permitted to furnish specific items and has fulfilled the role of the supplier in accordance with any applicable laws and policies:

- A separate SWO is not required
  - However, the medical record must still contain all the required SWO elements

Documentation Requirements

For any DMEPOS item to be covered by Medicare, the medical record must contain sufficient documentation of the patient's medical condition to substantiate the necessity for the type and quantity of items ordered and for the frequency of use or replacement

- Detailed documentation in treating practitioner's records supporting:
  - Medical necessity of item billed
  - Diagnosis code that is billed on the claim
- Medical information intended to demonstrate compliance with coverage criteria may be included on prescription but must be corroborated by information contained in medical record

Proof of Delivery (POD)

Method 1: Direct Delivery to Beneficiary	Method 2: Shipping/Delivery Service	Method 3: Delivery to Skilled Nursing Facility

▪ Beneficiary's name
▪ Delivery address
▪ A description of the item(s) being delivered
  • Narrative description (e.g., ankle foot orthosis), ***or***
  • HCPCS code, ***or***
  • Long description of HCPCS code, ***or***
  • Brand name/model number
▪ Quantity delivered
▪ Date delivered
▪ Beneficiary (or designee) signature
▪ ***IF the item is custom fit or custom fabricated this is the only method of delivery***
	▪ Beneficiary's name
	▪ Delivery address
	▪ A description of the item(s) being delivered
	  • Narrative description (e.g., ankle foot orthosis), ***or***
	  • HCPCS code, ***or***
	  • Long description of HCPCS code, ***or***
	  • Brand name/model number
	▪ Quantity delivered
	▪ Delivery service's package ID number, supplier invoice number or alternative method which links supplier's delivery documents with delivery services' records
	▪ Date delivered
	▪ Evidence of delivery
		▪ Documentation demonstrating delivery of the item(s) to the facility by the supplier or delivery entity; ***and***
		▪ Documentation from the nursing facility demonstrating receipt and/or usage of the item(s) by the beneficiary
		▪ The quantities delivered and used by the beneficiary must justify the quantity billed

Date of Service (DOS) = Date of Delivery	***DOS= Shipping Date or Date of Delivery***	***DOS = Shipping Date or Date of Delivery***

Prior Authorization

Prior Authorization (PA)

Lower Limb Orthoses that require PA

Effective Date	HCPCS code(s)
October 10, 2022	L1832, *L1833, and L1851
August 12, 2024	L1843, L1845, L1951 *L1833 no longer requires PA

- These claim types are excluded from any PA program as described in the Operational Guide:
  - Veterans Affairs
  - Medicare Advantage
  - Part A and Part B Demonstrations
  - Indian Health Services
- https://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/Medicare-FFS-Compliance-Programs/DMEPOS/Downloads/Operational-Guide-for-DMEPOS-PA-current.pdf

PA Decisions and Delivery

DME MAC will complete review and provide a response:

Type of PAR Request	Timeframe for response
Initial	Within 5 business days
Resubmissions	Within 5 business days
Expedited	Within 2 business days (necessity of expedited request at DME MAC's discretion)

- Validation Period – PAR decisions are valid for 60 calendar days following "affirmed" decision
  - If you don't provide the item within sixty (60) days, you must submit a new PAR

Acute Situations: Prior Authorization

- When the beneficiary's health or life is jeopardized without the use of the orthotic device within the expedited review time frame, (e.g., when a beneficiary suffers an acute injury to the knee or spine)
  - You can bypass prior authorization, provide item, and bill claim with ST modifier.
  - ST modifier – Related to trauma or injury
- Claims submitted with the ST modifier are subject to prepayment review

Comprehensive Error Rate Testing (CERT)

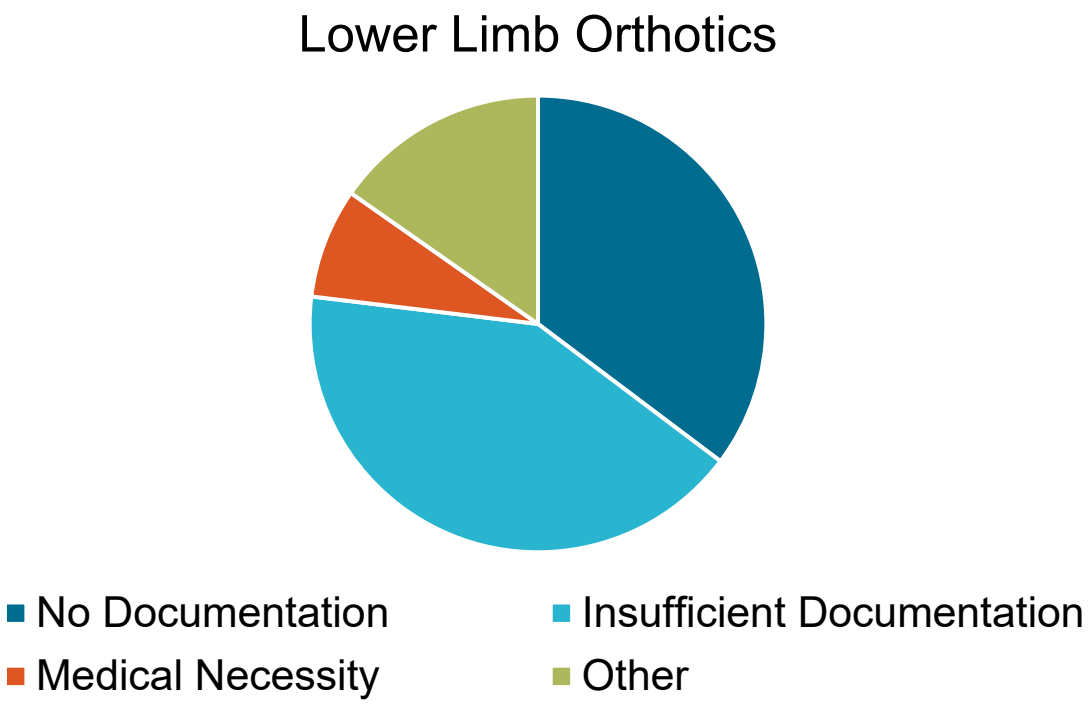
2023 Comprehensive Error Rate Testing (CERT)

- 2023 Improper Payment Rates and Projected Improper Payment
- CERT: https://www.cms.gov/https/wwwcmsgov/data-research/monitoring-programs/improper-payment-measurement-programs/2023-medicare-fee-service-supplemental-improper-payment-data

Service Type	Improper Payment Rate	Projected Improper Payment Amount
Overall	7.4%	$31.2 B
Part A Providers (excluding Hospital Inpatient Prospective Payment System (IPPS))	7.8%	$14.2 B
Part B Providers	10.0%	$11.0 B
DMEPOS	**22.5%**	**$1.9 B**
Hospital IPPS	3.4%	$4.1 B

CERT 2023 - Lower Limb Orthoses – Type of Errors

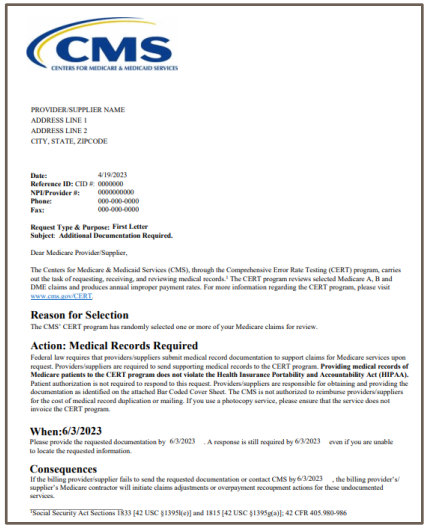
- Improper payment rate of 36.6% on the 2023 report



Responding to a CERT Request

There are five ways to respond to a request from the CERT contractor.

- Fax: 1.804.261.8100
- Mail: CERT Documentation Center
  8701 Park Central Drive, Suite 400-A
  Richmond, VA 23227
- esMD: https://www.cms.gov/esMD
- Encrypted CD: Must be in TIFF or PDF format
- Encrypted email: Attachment must be in TIFF or PDF format



CMS
CENTERS FOR MEDICARE & MEDICAID SERVICES

PROVIDER/SUPPLIER NAME
ADDRESS LINE 1
ADDRESS LINE 2
CITY, STATE, ZIPCODE

Date: 4/19/2023
Reference ID: CID #: 0000000
NPI/Provider #: 0000000000
Phone: 000-000-0000
Fax: 000-000-0000

Request Type & Purpose: First Letter
Subject: Additional Documentation Required.

Dear Medicare Provider/Supplier,

The Centers for Medicare & Medicaid Services (CMS), through the Comprehensive Error Rate Testing (CERT) program, carries out the task of requesting, receiving, and reviewing medical records.[1] The CERT program reviews selected Medicare A, B and DME claims and produces annual improper payment rates. For more information regarding the CERT program, please visit www.cms.gov/CERT.

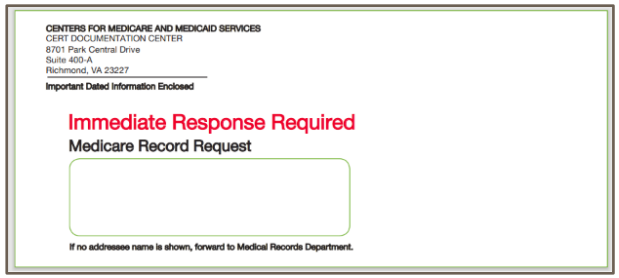
Reason for Selection
The CMS' CERT program has randomly selected one or more of your Medicare claims for review.

Action: Medical Records Required
Federal law requires that providers/suppliers submit medical record documentation to support claims for Medicare services upon request. Providers/suppliers are required to send supporting medical records to the CERT program. **Providing medical records of Medicare patients to the CERT program does not violate the Health Insurance Portability and Accountability Act (HIPAA).** Patient authorization is not required to respond to this request. Providers/suppliers are responsible for obtaining and providing the documentation as identified on the attached Bar Coded Cover Sheet. The CMS is not authorized to reimburse providers/suppliers for the cost of medical record duplication or mailing. If you use a photocopy service, please ensure that the service does not invoice the CERT program.

When:6/3/2023
Please provide the requested documentation by 6/3/2023 . A response is still required by 6/3/2023 even if you are unable to locate the requested information.

Consequences
If the billing provider/supplier fails to send the requested documentation or contact CMS by 6/3/2023 , the billing provider's/supplier's Medicare contractor will initiate claims adjustments or overpayment recoupment actions for these undocumented services.

[1]Social Security Act Sections 1833 [42 USC §1395l(e)] and 1815 [42 USC §1395g(a)]; 42 CFR 405.980-986



CENTERS FOR MEDICARE AND MEDICAID SERVICES
CERT DOCUMENTATION CENTER
8701 Park Central Drive
Suite 400-A
Richmond, VA 23227

Important Dated Information Enclosed

Immediate Response Required
Medicare Record Request

If no addressee name is shown, forward to Medical Records Department.

Resources

CMS

DME MACs

Other Related Contractors

CMS Resources

- MLN Matters Article SE20007: https://www.cms.gov/files/document/se20007.pdf
- Standard Documentation Requirements for All Claims Submitted to DME MACs: https://www.cms.gov/medicare-coverage-database/view/article.aspx?articleid=55426
- Ankle-Foot/Knee-Ankle-Foot Orthosis:
  - LCD: https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?LCDId=33686&ContrID=140
  - PA: https://www.cms.gov/medicare-coverage-database/view/article.aspx?articleId=52457&ContrID=140
- Knee Orthoses:
  - LCD: https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?LCDId=33318&ContrID=140
  - PA: https://www.cms.gov/medicare-coverage-database/view/article.aspx?articleId=52465&ContrID=140

Noridian Healthcare Solutions Jurisdiction A Resources

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

CGS Administrators, LLC Jurisdiction B Resources

- **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

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CGS Administrators, LLC Jurisdiction C Resources

- **Website:** https://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

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Noridian Healthcare Solutions Jurisdiction D Resources

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

noridian Healthcare Solutions

Other Contractor Resources

- **Pricing, Data Analysis and Coding Contractor (PDAC)**
  - 1.877.735.1326
  - http://www.dmepdac.com
- **CEDI**
  - 1.866.311.9184
  - https://www.ngscedi.com/web/ngscedi/home
  - E-mail: NGS.CEDIHelpdesk@anthem.com

National Provider Enrollment (NPE)

- NPE East: Novitas Solutions:
  - https://www.novitas-solutions.com/webcenter/portal/DMEPOS
  - 1.866.520.5193
- NPE West: Palmetto GBA:
  - https://www.palmettogba.com/palmetto/npewest.nsf
  - 1.866.238.9652

Thank you for attending!