Knee Orthosis

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

February 2023

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.

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Participants

- CGS Administrators, LLC: http://www.cgsmedicare.com
- First Coast Service Options, Inc.: http://www.fcso.com/
- National Government Services: http://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/

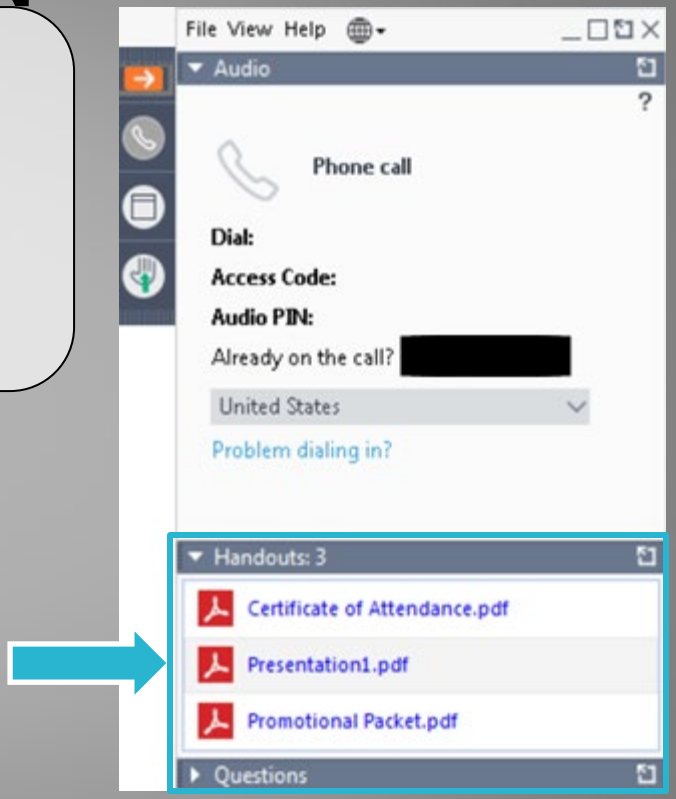
ACCESS:

All registrants received an email from: DME POE 2
customercare@gotowebinar.com

- Click on the link within the email to join the web presentation
- Using your telephone, dial into the conference call using the number and access code provided in the e-mail

TODAY'S PRESENTATION

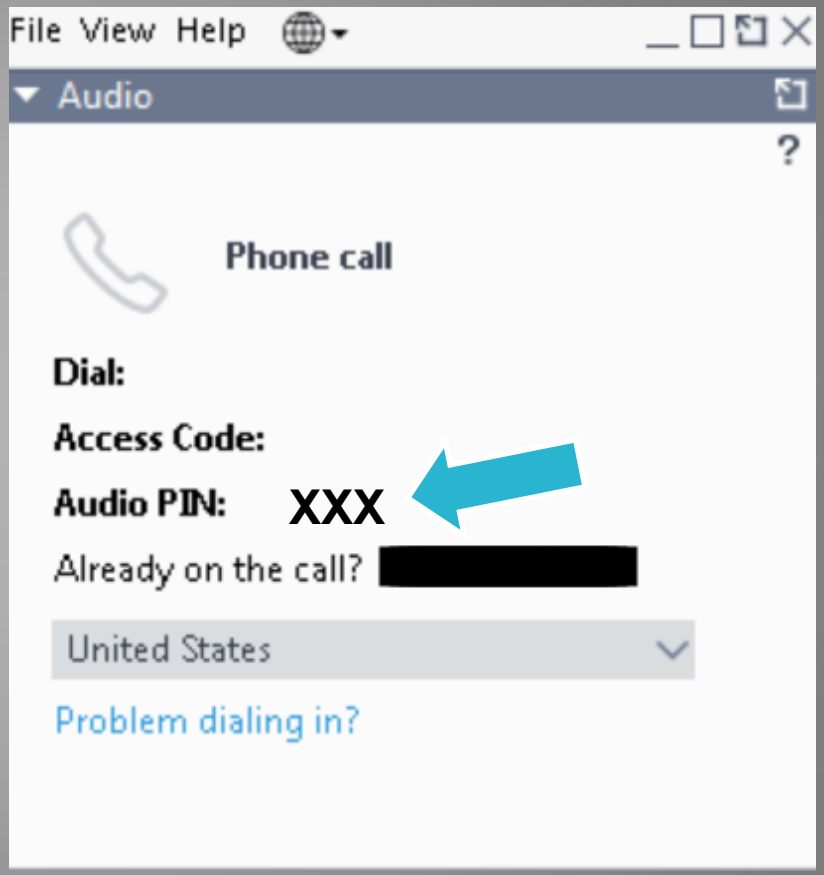
- Once you are connected to the webinar, select **Handouts**
- Select **Orthoses.pdf** to download the presentation
- Internet Explorer may not allow you to open the attached PDFs.



AUDIO

Once you are connected to the audio, the PIN displays

- Input the PIN on your screen into your telephone
- Dial-in number and PIN are unique for each attendee



QUESTION BOX

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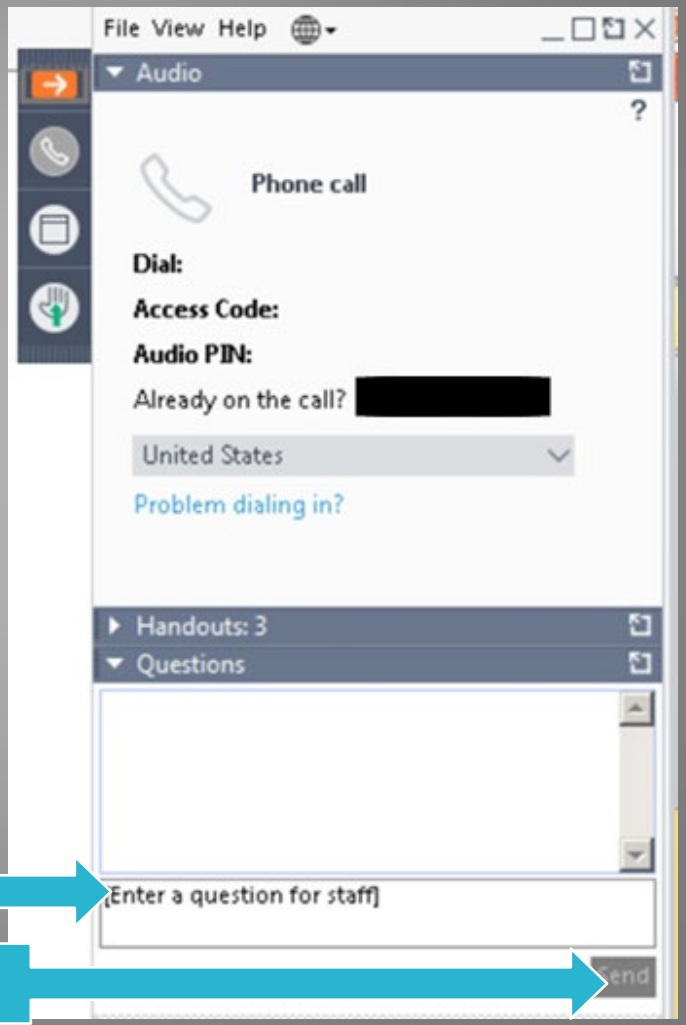

Type it here.

Hit send.

Agenda

- Definitions
- Coverage Criteria
- Comprehensive Error Rate Testing (CERT)
- Documentation Requirements
- Repair and Replacement
- References
- Resources

Definitions

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Orthoses

- Orthotic Devices:
  - Rigid or semi-rigid devices used for purpose of supporting weak or deformed body member or restricting or eliminating motion in diseased or injured part of body
- Custom Fabricated Orthosis:
  - Individually made for specific beneficiary starting with basic material
  - Involves more than trimming, bending, or making other modifications to substantially prefabricated item
- Prefabricated Orthosis:
  - Both “off-the-shelf” and custom-fit items are considered prefabricated braces for Medicare coding purposes
  - Manufactured in quantity without specific beneficiary in mind

Custom-Fabricated

- Individually-made for specific beneficiary
- Fabricated based on clinically-derived and rectified castings, tracings, measurements, and/or other images (such as X-rays) of the body part
- Requires use of basic materials including, but not limited to: plastic, metal, leather, or cloth in form of uncut or unshaped sheets, bars, or other basic forms
- Involves substantial work such as vacuum forming, cutting, bending, molding, sewing, drilling, and finishing prior to fitting on beneficiary
- Requires positive model of beneficiary

Prefabricated Orthoses

Off-the-Shelf (OTS) Orthotics	Custom-Fitted Orthotics
Prefabricated	Prefabricated
May or may not be supplied as a kit that requires some assembly	May or may not be supplied as a kit that requires some assembly
Requires **minimal self-adjustment** for fitting (by beneficiary or supplier)	Requires **more** than minimal self-adjustment at time of delivery for individualized fit
Fitting does **NOT** require expertise of certified orthotist/specialized training	Fitting at delivery **DOES** require expertise of certified orthotist/specialized training

Individuals with Expertise to Perform Customized Fit

- More than minimal self-adjustment is defined as changes made to achieve an individualized fit of the item that requires the expertise of a certified orthotist or an individual who has specialized training in the provision of orthotics in compliance with all applicable Federal and State licensure and regulatory requirements.
- Certified Orthotist is Certified by:
  - American Board for Certification in Orthotics and Prosthetics, Inc. or
  - Board for Orthotics/Prosthetist Certification

Coverage Criteria

Knee Orthoses

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Prefabricated Knee Orthoses

- Knee orthosis with joints (L1810, L1812) or knee orthosis with condylar pads and joints with or without patellar control (L1820) covered for ambulatory beneficiaries who have the following:
  - Weakness or deformity of knee; and,
  - Require stabilization.
- Knee orthosis with locking knee joint (L1831) or rigid knee orthosis (L1836) covered for beneficiaries with flexion or extension contractures of knee with movement on passive range of motion testing of at least 10 degrees (i.e., nonfixed contracture)

Prefabricated Knee Orthoses

- Knee immobilizer without joints (L1830), or knee orthosis with adjustable knee joints (L1832, L1833), or knee orthosis, with adjustable flexion and extension joint that provides both medial-lateral and rotation control (L1843, L1845, L1851, L1852), are covered if:
  - Beneficiary has had recent injury to or surgical procedure on the knee(s)
- Knee orthoses L1832, L1833, L1843, L1845, L1851 and L1852 are also covered for beneficiary who is:
  - Ambulatory; and,
  - Has knee instability due to condition specified in the policy article

Prefabricated Knee Orthoses

- Prefabricated knee orthoses (L1832, L1833, L1843, L1845, L1850, L1851, L1852) are covered for knee instability and must be documented by:
  - Examination of beneficiary; and,
  - Objective description of joint laxity
    (e.g., varus/valgus instability, anterior/posterior Drawer test)
- Will be denied as not reasonable and necessary when the beneficiary does not meet the above criteria for coverage
  - For example, they will be denied if only pain or a subjective description of joint instability is documented

Prefabricated Knee Orthoses

- Knee orthosis, Swedish type, prefabricated (L1850) covered for beneficiary who is:
  - Ambulatory; and,
  - Has knee instability due to genu recurvatum – hyperextended knee.
    - Congenital or acquired

Custom Fabricated Knee Orthoses

- Coverage for custom fabricated (L1834, L1840, L1844, L1846, L1860) requires documented physical characteristic which requires use of custom fabricated orthosis instead of prefabricated orthosis
- Examples of situations which meet criterion for custom fabricated orthosis include, but are not limited to:
  - Deformity of leg or knee
  - Size of thigh and calf
  - Minimal muscle mass upon which to suspend orthosis

Custom Fabricated Knee Orthoses

- Custom fabricated knee immobilizer without joints (L1834) covered if criteria 1 and 2 are met:
  - Coverage criteria for prefabricated orthosis code L1830 met; and,
  - General criterion for custom fabricated orthosis met
- Custom fabricated derotation knee orthosis (L1840) covered for instability due to internal ligamentous disruption of knee
- Custom fabricated knee orthosis with adjustable flexion and extension joint (L1844, L1846) is covered if:
  - Coverage criteria for prefabricated orthosis (L1843, L1845, L1851 and L1852) are met; and,
  - General criterion for custom fabricated orthosis is met

Custom Fabricated Knee Orthoses

- Custom fabricated knee orthosis with modified supracondylar prosthetic socket (L1860) covered for beneficiary who is:
  - Ambulatory, and,
  - Has knee instability due to genu recurvatum – hyperextended knee
- If a custom fabricated orthosis is provided but the medical record does not document why that item is medically necessary instead of a prefabricated orthosis, the custom fabricated orthosis will be denied as not reasonable and necessary

Comprehensive Error Rate Testing (CERT)

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Comprehensive Error Rate Testing (CERT)

- 2022 Improper Payment Rates and Projected Improper Payment
- CERT: https://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/Improper-Payment-Measurement-Programs/CERT

Service Type	Improper Payment Rate	Projected Improper Payment Amount
Overall	7.5%	$31.5 B
Part A Providers (excluding Hospital Inpatient Prospective Payment System (IPPS))	8.9%	$17.1 B
Part B Providers	8.2%	$8.8 B
★**DMEPOS**	★**25.2%**	★**$2.2 B**
Hospital IPPS	3.0%	$4.1 B

CERT Denial Reasons

- Missing or inadequate documentation supporting coverage criteria
- Missing or inadequate description of the modification to the orthotic at the time of fitting
- Missing or inadequate order
- Missing or inadequate proof of delivery
- Missing signature required by Medicare policy

Documentation Requirements

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Orders

- A written order/prescription is a written communication from a treating practitioner that documents the need for a beneficiary to be provided an item of DMEPOS. Treating practitioner means a physician, as defined in section 1861(r)(1) of the Act, or physician assistant, nurse practitioner, or clinical nurse specialist, as those terms are defined in section 1861(aa)(5) of the Act.
- All DMEPOS items require a written order/prescription from the treating practitioner for Medicare payment as a condition of payment.

Standard Written Order (SWO)

For dates of service on and after January 01, 2020, an SWO must be communicated to the supplier prior to claim submission and must contain all of the following:

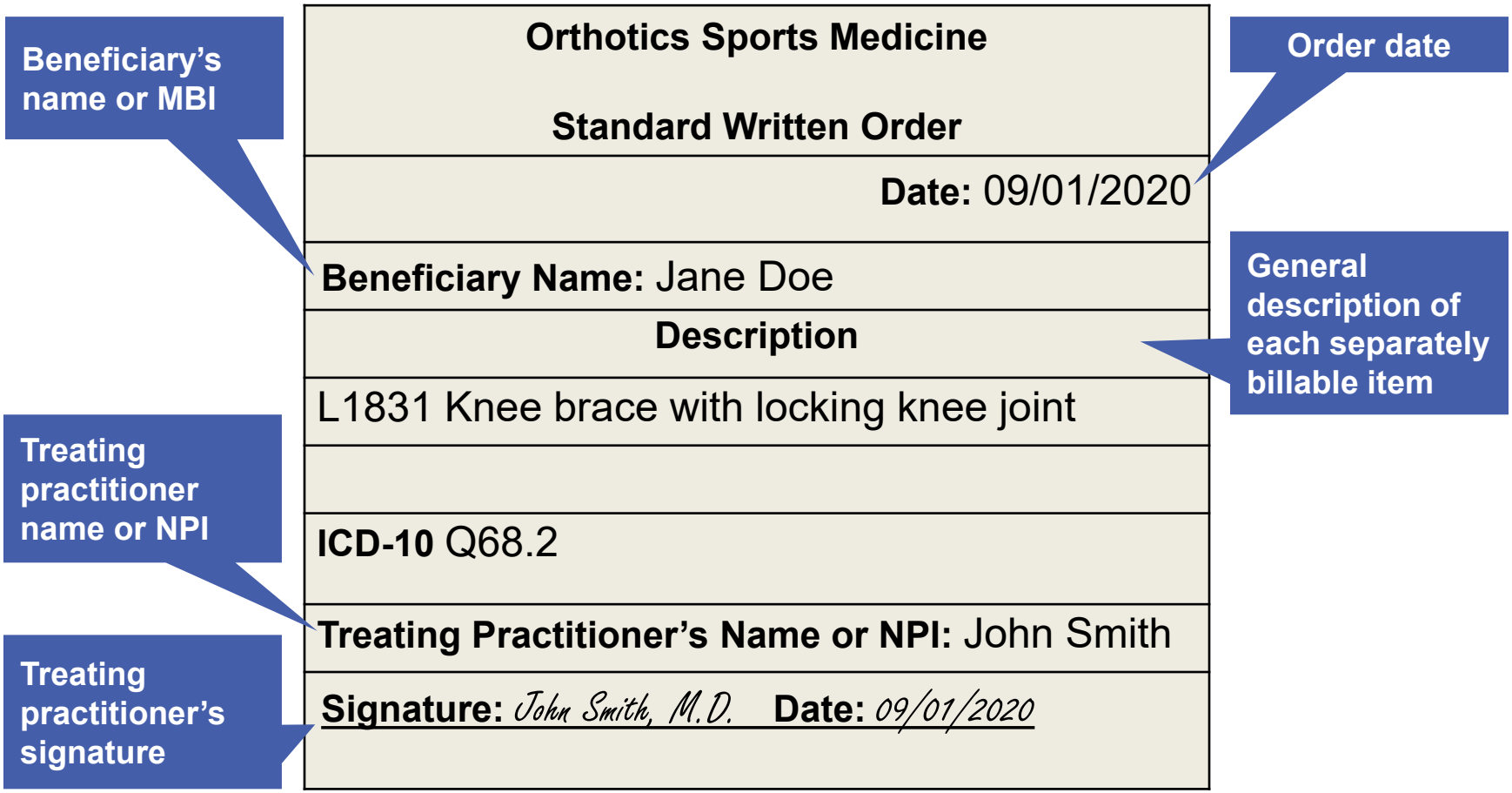
- Beneficiary's name or Medicare Beneficiary Identifier (MBI)
- Order date
- General description of the item
  - The description can be either a general description (e.g., knee orthosis), a HCPCS code, a HCPCS code narrative, or a brand name/model number
  - For equipment - In addition to the description of the base item, the SWO may include all concurrently ordered options, accessories or additional features that are separately billed or require an upgraded code (list each separately)
  - For supplies – In addition to the description of the base item, the DMEPOS order/prescription may include all concurrently ordered supplies that are separately billed (list each separately)
- Quantity to be dispensed, if applicable
- Treating practitioner name or NPI
- Treating practitioner's signature

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 fulfill 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.

Valid Standard Written Order



Written Order Prior to Delivery (WOPD) and Face to Face (F2F) Encounter

https://www.cms.gov/files/document/required-face-face-encounter-and-written-order-prior-delivery-list.pdf

- Effective April 13, 2022:
  - E0748 Osteogenesis Stimulator
  - L0648 Lumbar Sacral Orthosis
  - L0650 Lumbar Sacral Orthosis
  - L1832 Knee Orthosis
  - L1833 Knee Orthosis
  - L1851 Knee Orthosis
  - L3960 Shoulder-Elbow-Wrist-Hand Orthosis

Written Order Prior to Delivery

- A WOPD is a completed SWO that is communicated to the supplier before delivery of the item.
- Items appearing on the Required List are subject to the F2F encounter and WOPD requirements.
- 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.
- MLN Matters Number: SE20007
  https://www.cms.gov/files/document/se20007.pdf

Face-to-Face Encounter

- The treating practitioner must document and communicate to the DMEPOS supplier that they had a F2F 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

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;
- On a regular basis (even if there is no change in the order/prescription) only if it is so specified in the documentation section of a particular medical policy;
- 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.

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

Medical Records

- Orders, supplier prepared statements, and physician/practitioner attestations by themselves do NOT provide sufficient documentation of medical necessity, even if signed by the ordering physician/practitioner.
  - There must be information in the patient's medical record that supports the medical necessity for the item.
- Supplier-produced records, even if signed by prescribing physician, and attestation letters (e.g., letters of medical necessity) are deemed not to be part of medical record for Medicare payment purposes
- Templates and forms are subject to corroboration with information in medical record

Medical Records

- Documentation created by an orthotist or prosthetist shall be considered part of the individual's medical record to support documentation created by physicians and certain other non-physician practitioners
- In the event of a claim review, the Orthotics and Prosthetics (O&P) supplier may request medical records, in addition to providing their notes to the Medicare contractor
- The O&P supplier's notes are but part of the whole medical record and are considered in the context of documentation made by the physician and other healthcare practitioners to provide additional details to demonstrate that the orthotic billed to Medicare was reasonable and necessary

Documentation Requirements

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 unless a properly executed ABN of possible denial has been obtained. (Internet-Only Manual, Publication 100-08, Program Integrity Manual, Chapter 5, Section 9)

Documentation Requirements

- Physicians, please be reminded that DME suppliers must:
  - Provide the product that is specified by ordering physician
  - Be sure that ordering physician's medical record justifies need for type of product (i.e., prefabricated versus custom fabricated)
  - Only bill for HCPCS code that accurately reflects both type of orthosis and appropriate level of fitting
  - Have detailed documentation in supplier's record that justifies code selected

Documentation Requirements

- When billing for items requiring more than minimal modification by qualified practitioner:
  - Detailed description of modifications necessary at time of fitting orthosis to beneficiary
- For custom fabricated orthoses there must be detailed documentation in treating physician's records to support medical necessity of custom fabricated rather than prefabricated orthosis
  - This information will be corroborated by functional evaluation in orthotist or prosthetist's records

Prior Authorization

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Prior Authorization Affected HCPCS Codes

CMS has added the following five HCPCS codes for orthoses to the Required Prior Authorization (PA) list Effective October 10, 2022 – Nationwide:

HCPCS	Policy
L0648	Lumbar-Sacral Orthosis
L0650	Lumbar-Sacral Orthosis
L1832	**Knee Orthosis**
L1833	**Knee Orthosis**
L1851	**Knee Orthosis**

Prior Authorization Exclusions

The following claim types are excluded from any PA program described in the operational guide:

- Veterans Affairs
- Medicare Advantage
- Part A and Part B Demonstrations
- Indian Health Services

Competitive Bidding Exceptions

- Physician/Non-physician practitioners, Physical Therapists, and Occupational Therapists enrolled as DMEPOS suppliers may furnish certain Off-the-Shelf (OTS) back and knee braces to their own patients without being a Competitive Bidding Program (CBP) contract supplier.
- The exception for physicians only applies if the physician is prescribing and furnishing the orthotic on the same day as the professional service in accordance with the rules associated with the limited exception to the Physician Self-Referral, or Stark law.
  - Claims billed to the DME MACs for these items must have the same date of service as the professional office visit or physical/occupational therapy service billed to the Part B MAC.
  - To be paid for these OTS back and knee braces as a non-contract supplier, physicians and other treating practitioners should use the modifier KV and physical therapists and occupational therapists should use the modifier J5 when billing their claims.
  - Claims for L1833, and L1851 billed with modifier KV or J5 will not be subject to prior authorization requirements.

Competitive Bidding Exceptions

- Hospitals in competitive bidding areas (CBAs) can also furnish off the shelf back and knee braces under a CBP exception.
- These hospitals should use modifier J4 to bill for these off-the-shelf back and knee braces furnished under these exceptions, to bypass prior authorization.
- Claims billed with modifiers KV, J5, and J4 will be subject to prepayment medical record review as outlined in Internet Only Manual (IOM) 100-08 Ch. 3, after the item has been furnished to ensure that they are medically necessary and meet Medicare requirements.
- 10% of claims submitted using the KV, J5, or J4 modifiers for HCPCS L0648, L0650, L1833, and L1851 will be subject to prepayment review.

Acute Situations

Acute Situations

- When the beneficiary's health or life is jeopardized without the use of the orthotic device within the expedited review timeframe, (e.g., when a beneficiary suffers an acute injury to the knee or spine) certain providers and suppliers may choose to forego submitting a prior authorization request, provide the item, and bill the claim with the ST modifier.
  - ST Modifier – Related to trauma or injury
- All claims for orthoses subject to prior authorization and billed with modifier ST will be subject to prepayment medical record review by the MAC as outlined in Internet Only Manual (IOM) 100-08 Ch. 3.

Timeframes

- Initial Request
  - Decision letters will be sent with the Unique Tracking Number (UTN) within 5 business days
- Resubmitted Requests
  - Decision letters will be sent with the UTN within 5 business days
- Expedited Requests
  - DME MAC will attempt to review and communicate a decision within 2 business days
  - Based on the DME MAC determination where delays in a review and a response could jeopardize the life or health of the beneficiary

Expedited Request

Expedited review of the PAR for emergency situations:

- The request for an expedited review must provide rationale supporting the request
- The DME MAC will provide the decision to the supplier and/or beneficiary (if specifically requested by the beneficiary) via telephone, fax, or other “real-time” communication, within the requisite timeframe
  - The supplier shall hold their claim and not submit until the UTN is provided.
  - Claims that have received an affirmative PA and submitted prior to receiving the UTN must be submitted to a formal reopening to process for payment

Expedited Request

What happens when an expedited PA request is submitted?

- After the PA request is submitted, the medical records will be reviewed to confirm if the beneficiary's health/life is in jeopardy without the use of the orthotic device within the regular review timeframe (5 business days).
  - For example, this might occur when a beneficiary suffers an acute/emergent injury to the knee or spine.
- If the DME MAC substantiates the need for an expedited decision, the DME MAC will make reasonable efforts to communicate a decision (phone call and letter) within 2 business days of receipt of the expedited PA request. If the request is "affirmed," the supplier can then provide the item to the beneficiary and hold the claim until the UTN is received.
- If the need for an expedited decision is not substantiated, the DME MAC will respond in the 5-business day timeframe.

Prior Authorization (PA) Delivery Timeframe

- PA for these codes will remain valid for sixty (60) calendar days following the provisional affirmation review decision
- The supplier has up to 60 days to furnish the orthoses

Resources and Reminders

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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

CGS Administrators, LLC Jurisdiction C Resources

- **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 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

Competitive Bidding Implementation Contractor (CBIC)

- Off The Shelf (OTS) knee and spinal orthoses must be provided by a contract supplier if the beneficiary resides in an applicable Competitive Bid Area (CBA) unless an exception applies
  - Knee (L1812, L1830, L1833, L1836, and L1850-L1852) and
  - Spinal orthoses (L0450, L0455, L0457, L0467, L0469, L0621, L0623, L0625, L0628, L0641, L0642, L0643, L0648, L0649, L0650 and L0651)
- Competitive Bidding Implementation Contractor (CBIC): https://www.dmecompetitivebid.com/cbic/cbicr2021.nsf/DocsCat/Home

Competitive Bidding Implementation Contractor (CBIC)

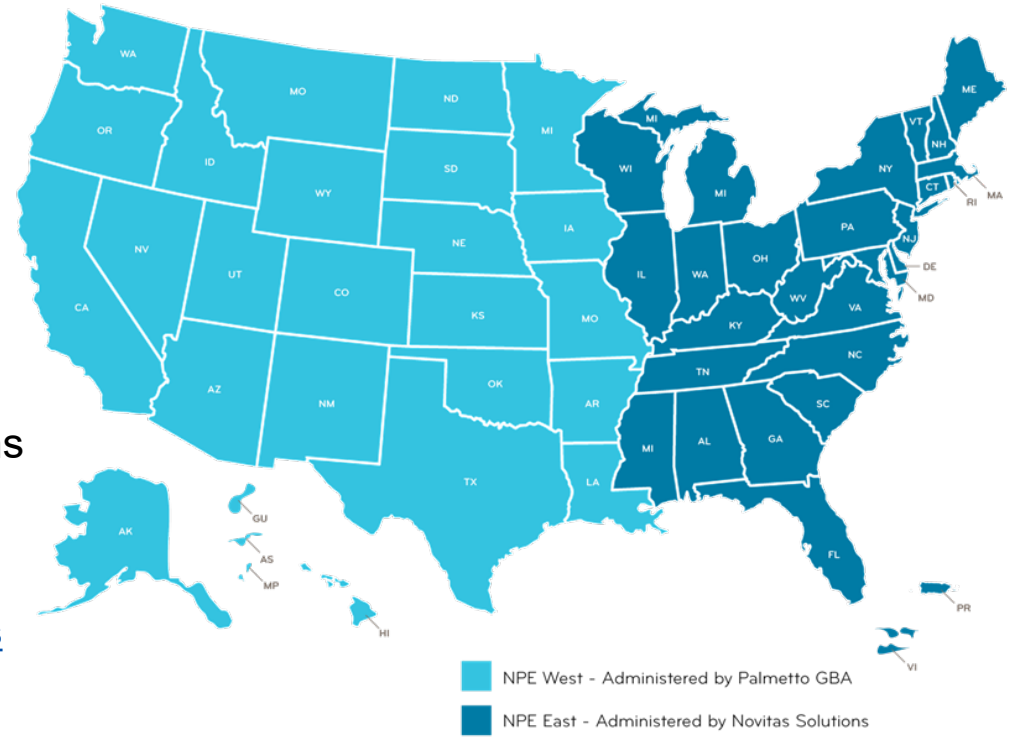
- MLN Fact Sheets
  - DMEPOS Competitive Bidding Program Referral Agents: https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/Downloads/DME_Ref_Agt_Factsheet_ICN900927.pdf
  - Physicians And Other Physicians And Other Treating Practitioners, Physical Therapists, And Occupational Therapists https://www.cms.gov/outreach-and-education/medicare-learning-network-mln/mlnproducts/downloads/dme_physicians_other_pract_factsheet_icn900926.pdf

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/web/ngscedi/home
  - E-mail: NGS.CEDIHelpdesk@wellpoint.com

DMEPOS National Provider Enrollment (NPE)

- DMEPOS Change to Enrollment Contractor
  - Effective November 7, 2022
- What has Changed?
  - 2 new contractors will process DMEPOS enrollment applications
    - NPE East: Novitas Solutions https://www.novitassolutions.com/webcenter/portal/NovitasSolutions
      - » DMEPOS activities for suppliers located east of the Mississippi River
    - NPE West: Palmetto GBA https://www.palmettogba.com/palmetto/npewest.nsf
      - » DMEPOS activities for suppliers located west of the Mississippi River



Questions?

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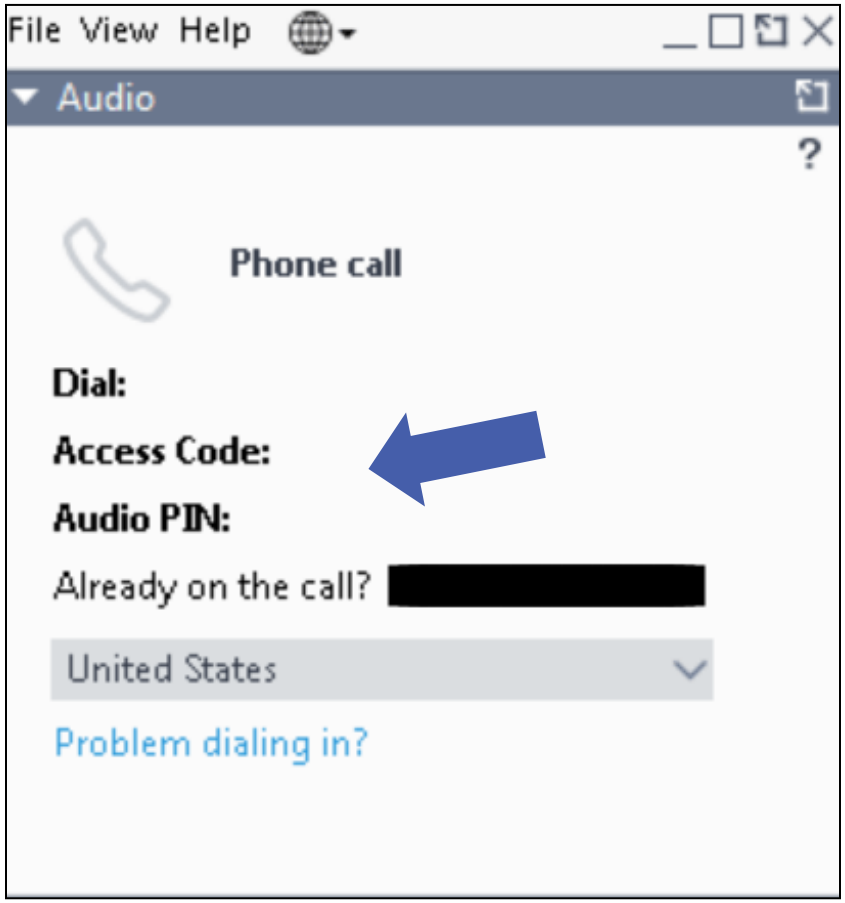
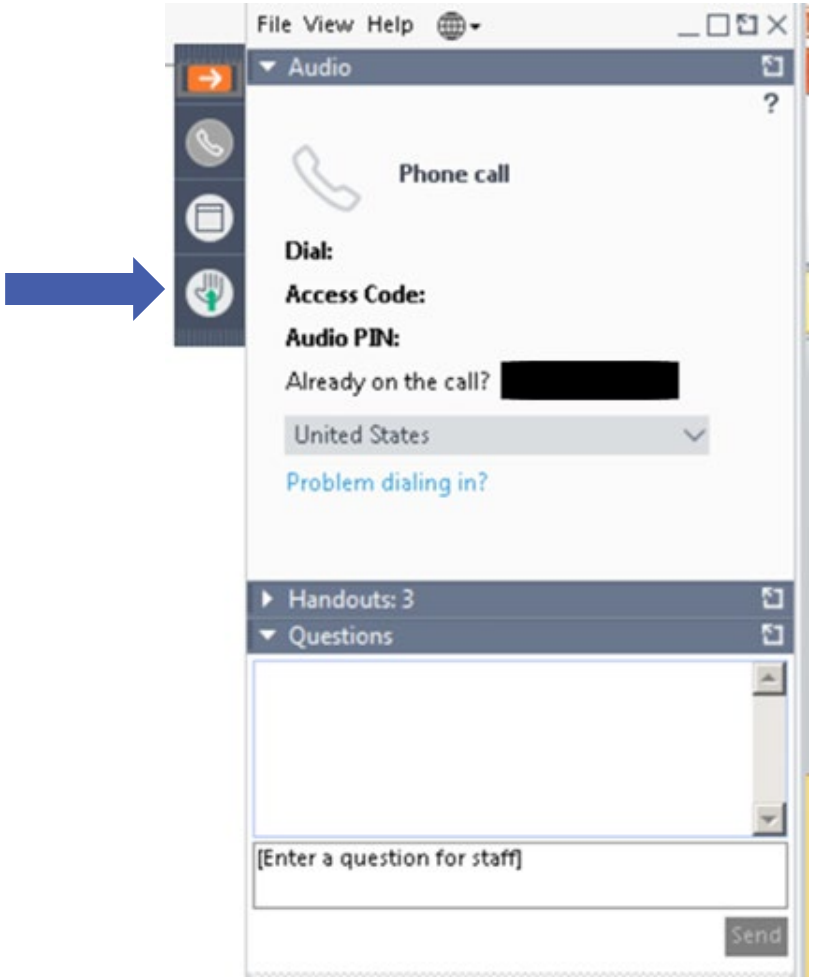
How to Participate Today

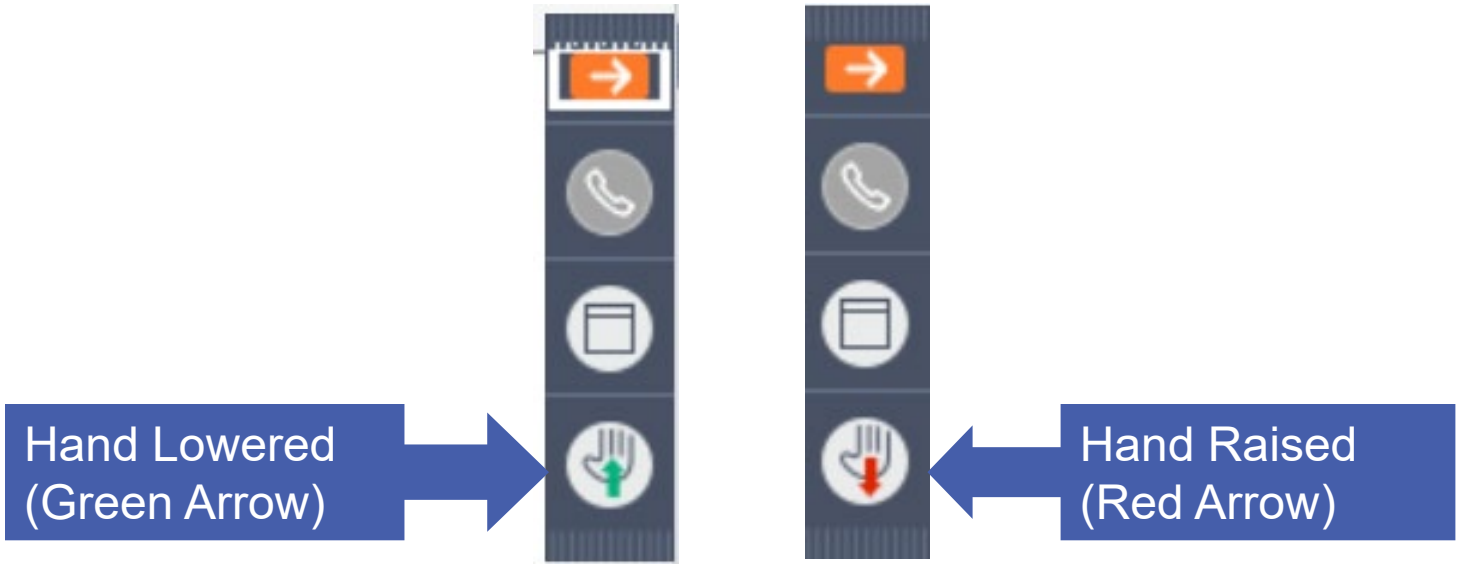


How to Participate Today

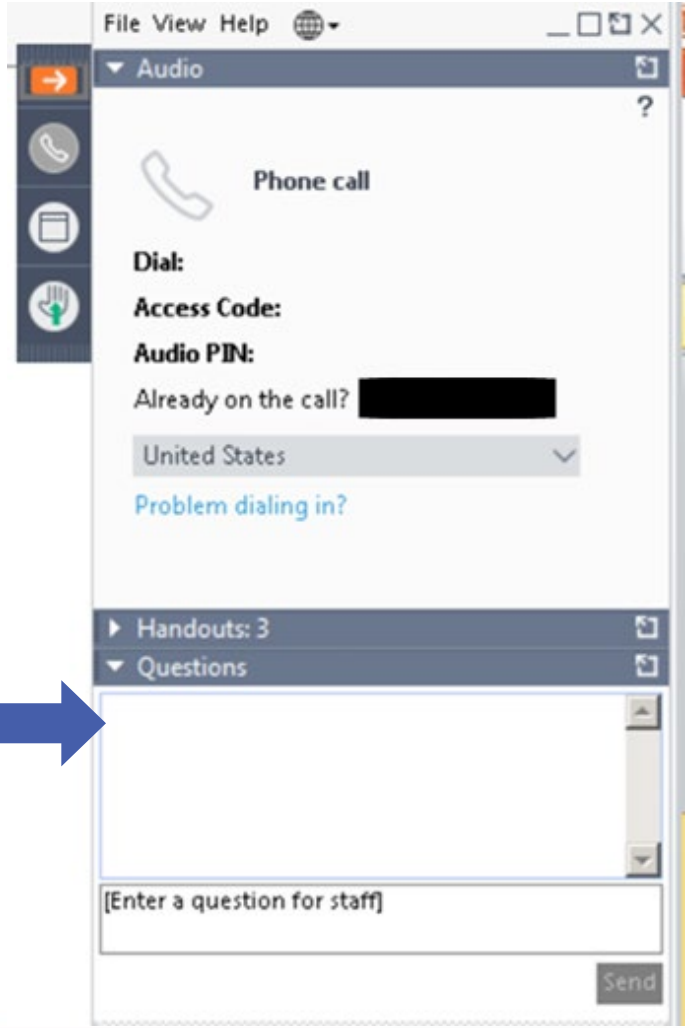
- To Ask a Verbal Question: Raise your hand
- The **Green Arrow** means your hand is not raised (Click to raise your hand)
- The **Red Arrow** means your hand is raised (Click to lower your hand)



To Ask a Question
By Raising Your Hand



To Ask a Question Using the Question Box



Type Question

Hit Send

Thank you for attending!

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