Lower Limb Orthosis

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

February 2021

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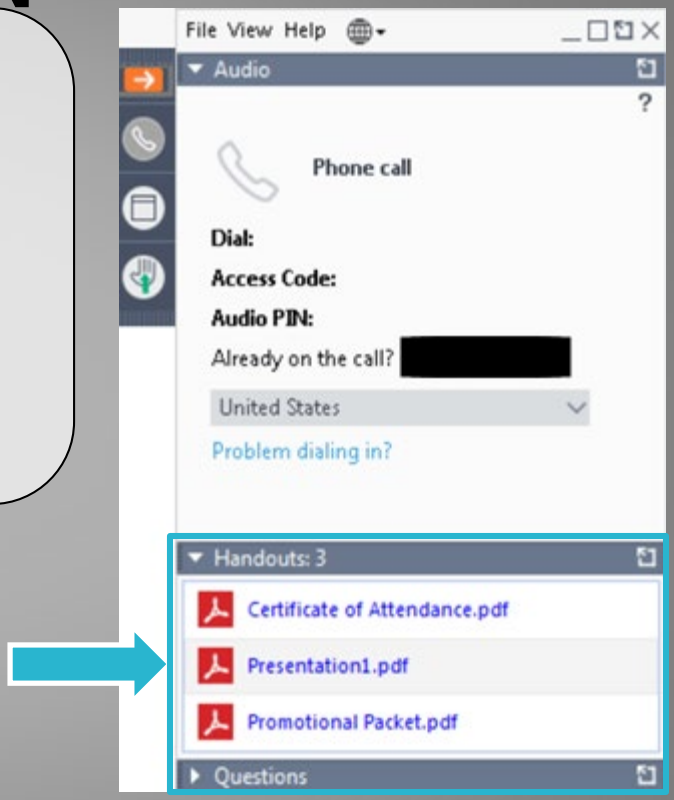
- **Palmetto GBA:** http://www.palmettogba.com/
- **WPS Government Health Administrators:** https://www.wpsgha.com/

TODAY'S PRESENTATION

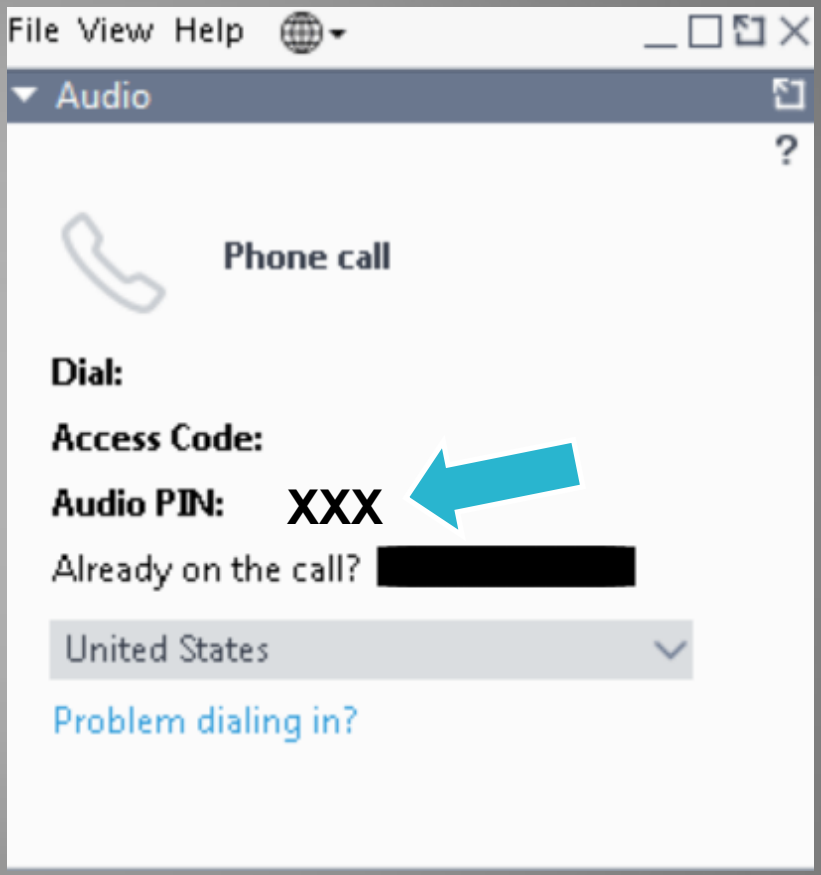
- Once you are connected to the webinar, select **Handouts**
- Select the file to download the presentation, Certificate of Attendance, and/or the Promotional Packet
- Internet Explorer may not allow you to open the attached PDFs



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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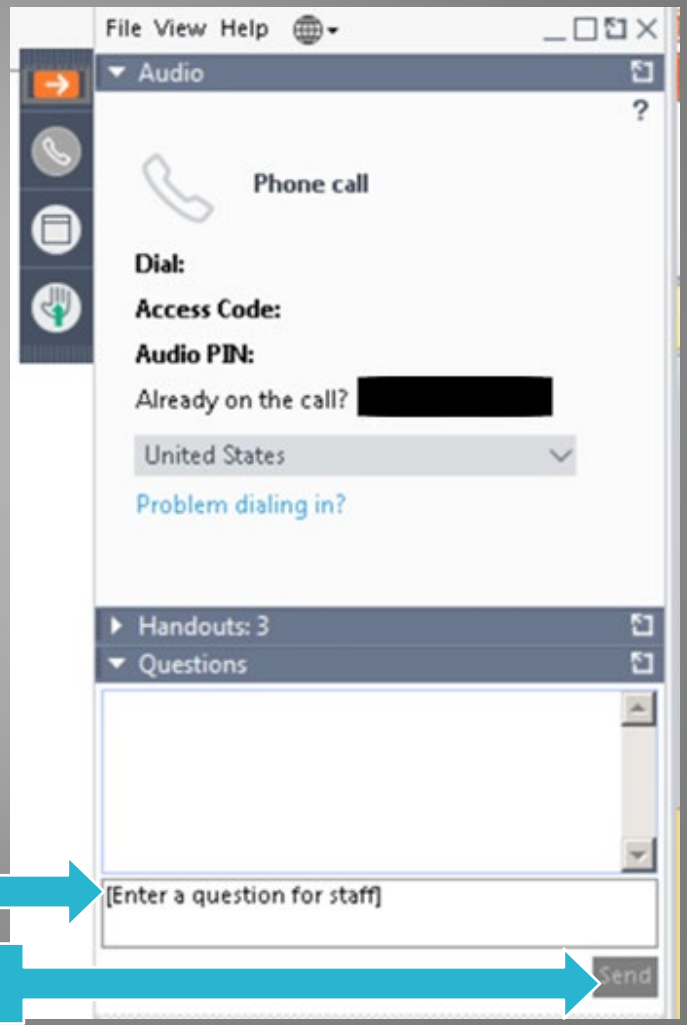

Type it here.

Hit send.

Agenda

- Definitions
- Coverage Criteria
  - Ankle Foot Orthoses/Knee Ankle Foot Orthoses
  - Knee Orthoses
- Comprehensive Error Rate Testing (CERT)
- Documentation Requirements
- Repair and Replacement
- References
- Resources

Definitions

Orthoses

- Ankle Foot Orthoses (AFO)
  - Brace, usually made of plastic, worn on lower leg and foot to support ankle, hold foot and ankle in correct position and correct foot drop
    - Abbreviated **AFO**. Also known as foot drop brace
- Knee Ankle Foot Orthoses (KAFO)
  - Long-leg orthosis that spans the knee, ankle, and foot in an effort to stabilize joints and assist the muscles of the leg
- Knee Orthoses (KO)
  - Brace that extends above and below knee joint and generally worn to support or align knee. In the case of diseases causing neurological or muscular impairment of muscles surrounding knee, KO can prevent flexion or extension instability of knee

Orthosis

- Custom Orthosis:
  - Individually made for specific beneficiary starting with basic material
  - Involves more than trimming, bending, or making other modifications to substantially prefabricated item
- 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
- 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

Coverage Criteria

Ankle Foot Orthoses (AFO) &

Knee Ankle Foot Orthosis (KAFO)

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AFO for Non-Ambulation

- 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
  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. Beneficiary has plantar fasciitis

*Also applies to replacement interface (L4392)

Replacement Interface

- Considered for coverage provided coverage criteria for a static or dynamic positioning ankle-foot orthosis has been met and continues to meet covered indications
- Denied if contracture is fixed
- Limited to one per six months

AFO for Non-Ambulation

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

AFO/KAFO During Ambulation

- AFO covered for ambulatory beneficiaries with weakness or deformity of foot and ankle, who:
  1. Require stabilization for medical reasons, and
  2. Have potential to benefit functionally

  * L4631 covered for Group 2 diagnosis codes
- Knee-ankle-foot orthoses (KAFO) are covered for ambulatory beneficiaries for whom an ankle-foot orthosis is covered and for whom additional knee stability is required
- If the basic coverage criteria for an AFO or KAFO are not met, orthosis will be denied as not reasonable and necessary

Custom AFO/KAFO

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

1. Beneficiary could not be fit with prefabricated AFO; or,
2. Condition necessitating orthosis is expected to be permanent or of longstanding duration; or,
3. Need to control knee, ankle or foot in more than one plane; or,
4. Beneficiary has documented neurological, circulatory, or orthopedic status that requires custom fabricating over model to prevent tissue injury; or,
5. Beneficiary has healing fracture which lacks normal anatomical integrity or anthropometric proportions

Orthotic Components

- Additional components may be considered for coverage if:
  1. Base orthosis is reasonable and necessary and;
  2. Specific addition is reasonable and necessary
- L-code additions to AFOs and KAFOs will be denied as not reasonable and necessary if either the base orthosis is not reasonable and necessary or the specific addition is not reasonable and necessary

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
  - Refer to Orthopedic Footwear policy
- Multiple density foot orthotics used in management of diabetic foot problems
  - Coverage limited to beneficiaries diagnosed with diabetes and qualifying foot condition
  - Refer to Therapeutic Shoes for Persons with Diabetes policy

Elastic and Similar Stretchable Materials

- Elastic or other fabric support garments with or without stays or panels do not meet statutory definition of brace because they are not rigid or semi-rigid devices
- Denied as noncovered (no Medicare benefit)
- Refer to Local Coverage Article: Ankle-Foot/Knee-Ankle-Foot Orthoses - Policy Article (A52457)

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

New Code added as of 01/01/17

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:
  1. Coverage criteria for prefabricated orthosis code L1830 met; and,
  2. General criterion for custom fabricated orthosis met

Custom Fabricated Knee Orthoses

- 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

Miscellaneous Coverage Criteria

- Heavy duty knee joint codes (L2385, L2395) covered only for beneficiaries who weigh more than 300 pounds
- Coverage of removable soft interface (K0672) is limited to maximum of two (2) per year beginning one (1) year after date of service for initial issuance of orthosis
  - Additional replacement interfaces will be denied not reasonable and necessary

Concentric Adjustable Torsion Style Mechanisms

- Concentric adjustable torsion style mechanisms (L2999) are covered under **Brace benefit** when:
  - Used to assist knee joint extension for beneficiaries who require knee extension assist in absence of any co-existing joint contracture
  - Used to assist ankle joint plantarflexion or dorsiflexion for beneficiaries who require ankle plantar or dorsiflexion assist in absence of any co-existing joint contracture
- Concentric adjustable torsion style mechanisms used for treatment of contractures, regardless of co-existing condition(s), are coded E1810 and/or E1815 and are covered under the Durable Medical Equipment benefit

Noncovered

- Orthoses used solely for prevention or treatment of pressure ulcer or pressure reduction
- Foot pressure off-loading/supportive device (A9283)
- Inversion/eversion correction device (A9285)
- Socks (L2840, L2850) used in conjunction with orthoses

Hospital or SNF Stay

- Payment for ankle-foot orthoses or knee-ankle foot orthoses are included in payment to hospital or skilled nursing facility (SNF) if:

  A. Provided prior to admission:

  - Orthosis is provided to beneficiary prior to inpatient hospital admission or Part A covered SNF stay; and,
  - Medical necessity for orthosis begins during hospital or SNF stay (e.g., after ankle, foot, or knee surgery).

OR

  B. Provided during admission:

  - Orthosis is provided to beneficiary during inpatient hospital or Part A covered 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 in either situation**

Hospital or SNF Stay

- Payment for ankle-foot orthoses or knee-ankle foot orthoses delivered to beneficiary in hospital or Part A covered SNF stay is eligible for coverage by DME MAC if:
  1. Orthosis is medically necessary for beneficiary after discharge from hospital or Part A covered SNF stay; and,
  2. Orthosis is provided to beneficiary within two days prior to discharge home; and,
  3. Orthosis is not needed for inpatient treatment or rehabilitation, but is left in room for beneficiary to take home
- Date of service is date of discharge

Comprehensive Error Rate Testing (CERT)

- 2020 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	6.3%	$25.7 B
Part A Providers (excluding Hospital Inpatient Prospective Payment System (IPPS))	6.2%	$10.9 B
Part B Providers	8.1%	$8.4 B
★**DMEPOS**	★**31.8%**	★**$2.8 B**
Hospital IPPS	3.0%	$3.6 B

CERT Denial Reasons

- Missing or inadequate documentation supporting clinical disease management for Durable Medical Equipment (DME)
- Missing signature on provider's order
- Missing or inadequate proof of delivery
- Detailed written order signed and dated after claim submission
- Missing signature required by Medicare policy
- Date of delivery not supported by submitted documentation
- Beneficiary was in Medicare Part A inpatient or SNF stay on billed date of service

Documentation Requirements

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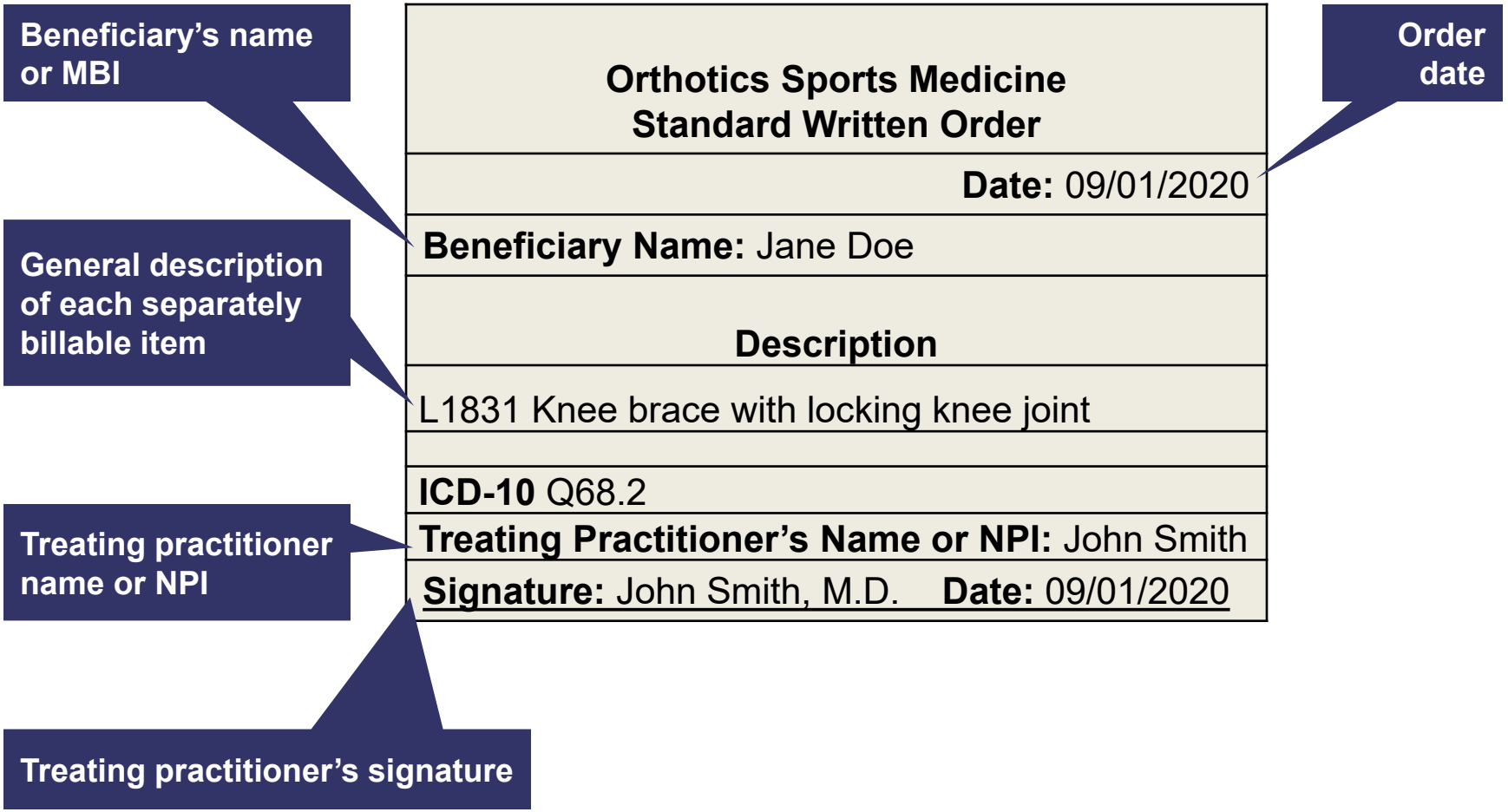
Orders

- 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

- 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., wheelchair or hospital bed), 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

Valid Standard Written Order



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 prosthetic arm, leg or 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

Supplier Records

- 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

Repair and Replacement

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Repair

- A new order is not needed for repair.
- The treating practitioner must document that the item being repaired continues to be reasonable and necessary.
- Either the treating practitioner or the supplier must document that the repair itself is reasonable and necessary.
- The supplier must maintain detailed records describing the need for and nature of all repairs Including:
  - A detailed explanation justifying the replacement of any component or part; and
  - Labor time to restore the item to its functionality.

Replacement

- Identical or similar items may be replaced in cases of:
  - Loss or irreparable damage
    - Use RA modifier on the claim
  - Reasonable Useful Lifetime (RUL)
  - Change in condition
- A new order from the treating practitioner is required to reaffirm the medical necessity for the replacement item.
- Must maintain documentation for the reason for replacement

Replacement

- Change in condition
- The medical records should demonstrate the beneficiary's change in medical/physiological condition necessitating the need for the new orthosis. A focused history and examination of the impacted body part is critical to establishing medical necessity. The medical record should include (but is not limited to):
  - the beneficiary's diagnosis
  - prognosis
  - duration of condition
  - functional limitations
  - clinical course
  - past experience with related items
  - reasons why previous orthotic devices are not functional nor appropriate for the current condition.

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

Medicare Learning Network (MLN)

- Guides
- Articles
- Educational Tools
- Booklets Brochures
- Fact Sheets
- Training Presentations
- Web-Based Training
- And more!

MLN Web page: http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNGenInfo/index.html

Competitive Bidding Implementation Contractor (CBIC)

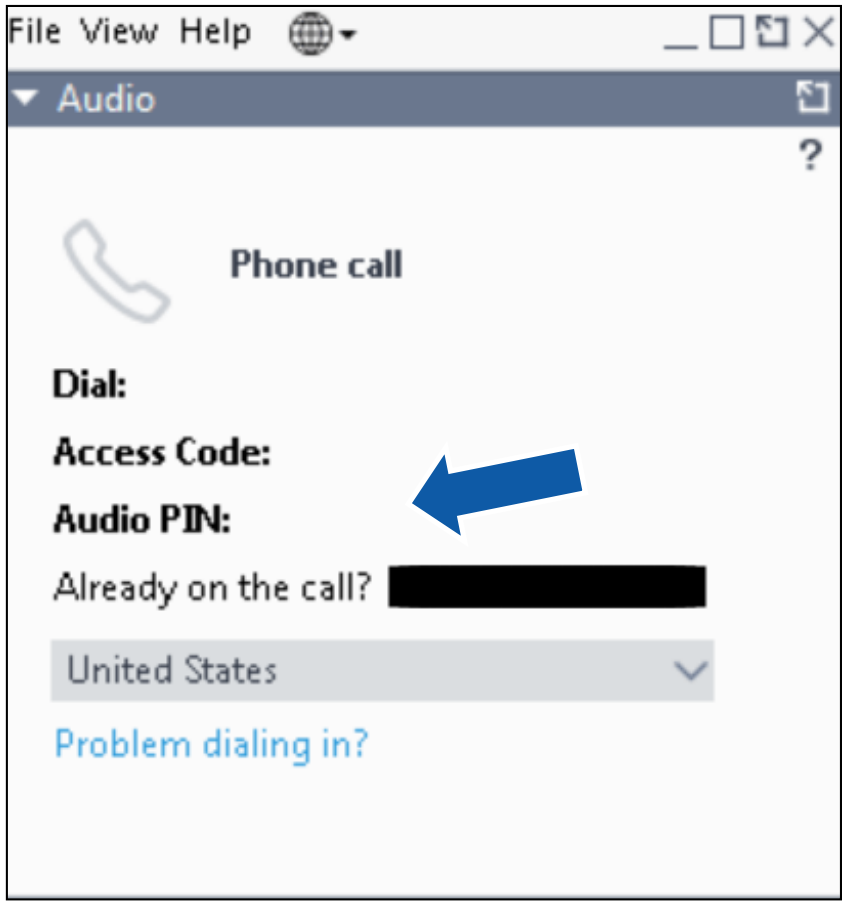
- Off The Shelf (OTS) Knee orthoses (L1812, L1830, L1833, L1836, and L1850-L1852) must be provided by a contract supplier if the beneficiary resides in an applicable Competitive Bid Area (CBA)
  - **Competitive Bidding Implementation Contractor (CBIC):** https://www.dmecompetitivebid.com/cbic/cbicr2021.nsf/DocsCat/Home
- MLN Fact Sheet -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

Other Contractor Resources

- **Pricing, Data Analysis and Coding Contractor (PDAC)**
  - 1.877.735.1326
  - http://www.dmepdac.com
- **National Supplier Clearinghouse (NSC)**
  - 1.866.238.9652
  - http://www.palmettogba.com/nsc
- **Common Electronic Data Interchange (CEDI)**
  - 1.866.311.9184
  - http://www.ngscedi.com/ngs/portal/ngscedi
  - E-mail: NGS.CEDIHelpdesk@anthem.com

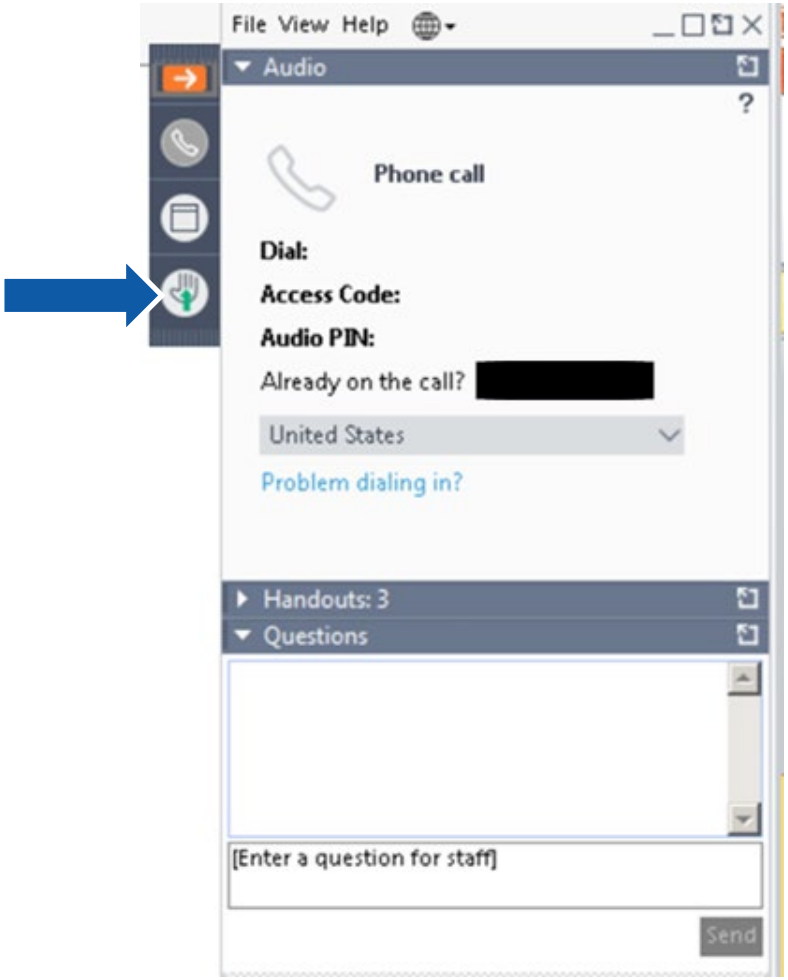
Questions?

How to Participate Today

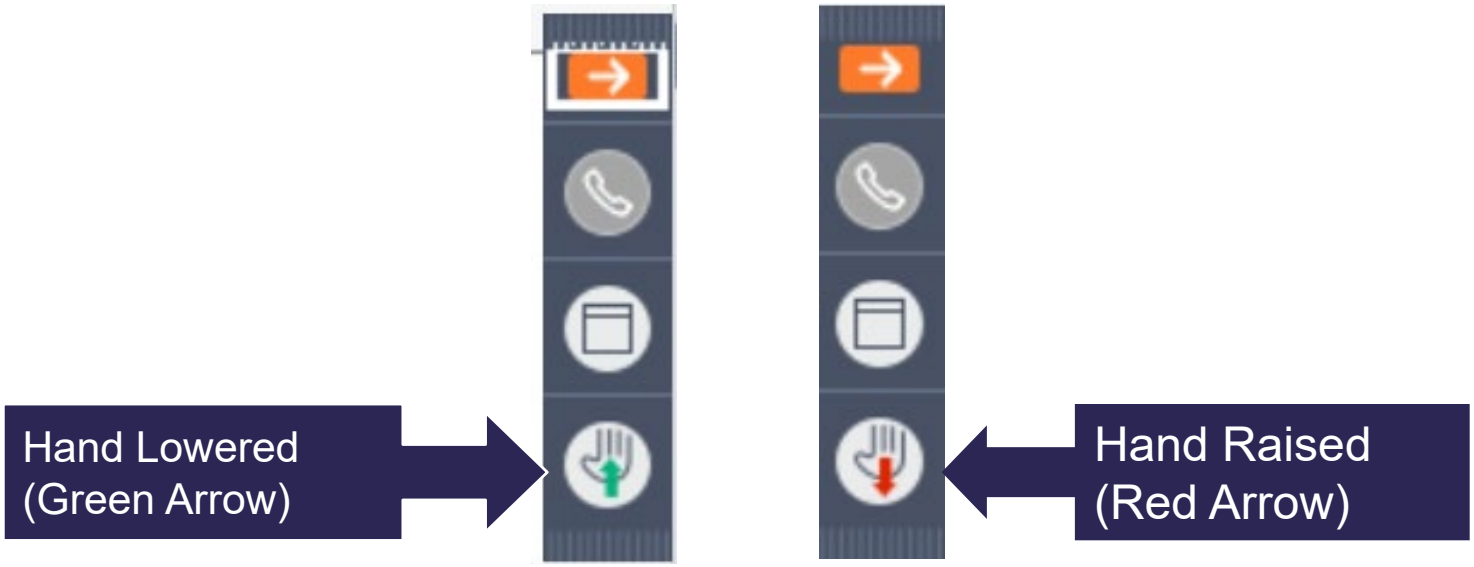


How to Participate Today

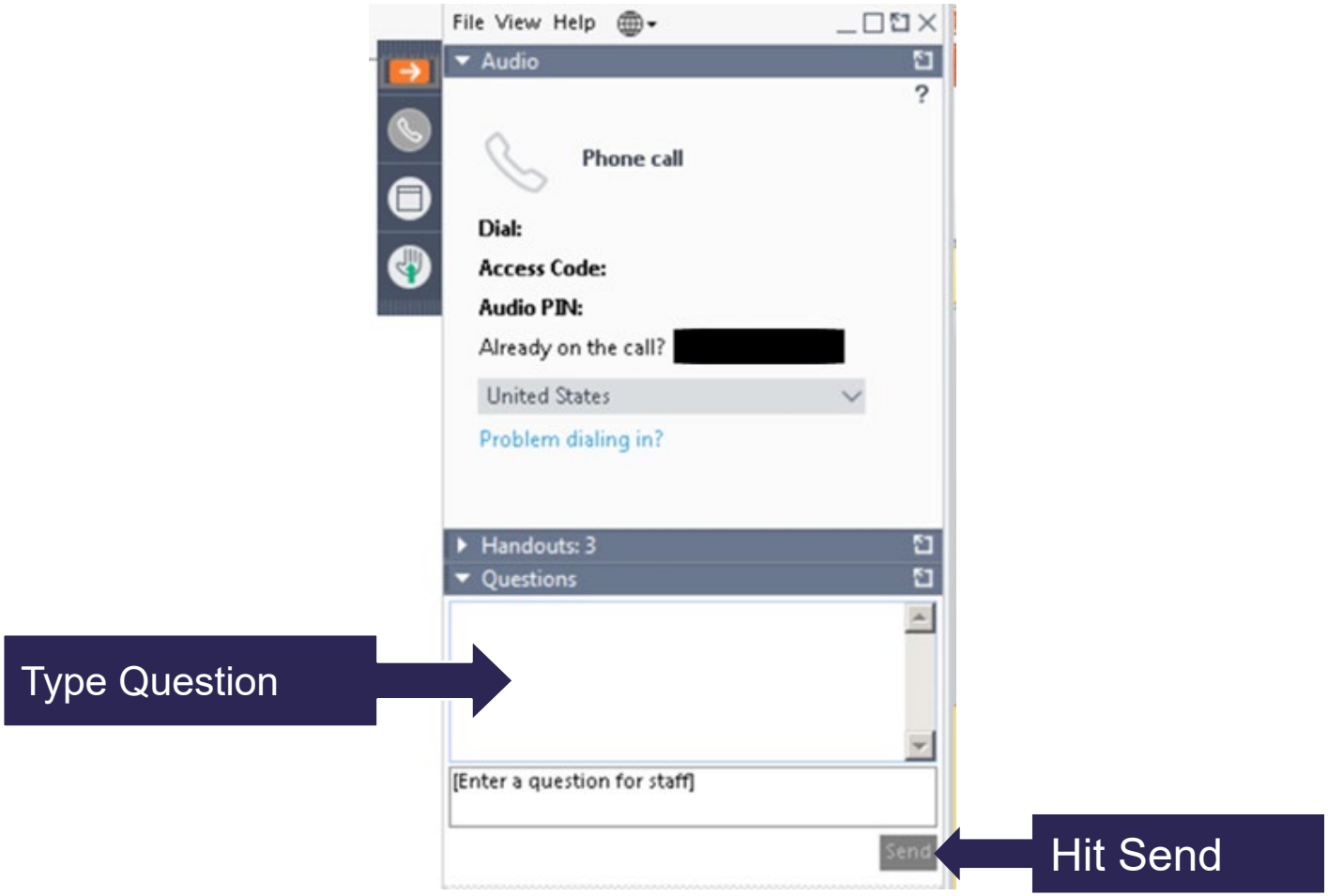
- To Ask a Verbal Question: Raise your hand
- The **Green Arrow** means your hand is not raised (Click to raise your hand)
- The **Red Arrow** means your hand is raised (Click to lower your hand)



To Ask a Question By Raising Your Hand



To Ask a Question Using the Question Box



Thank you for attending!