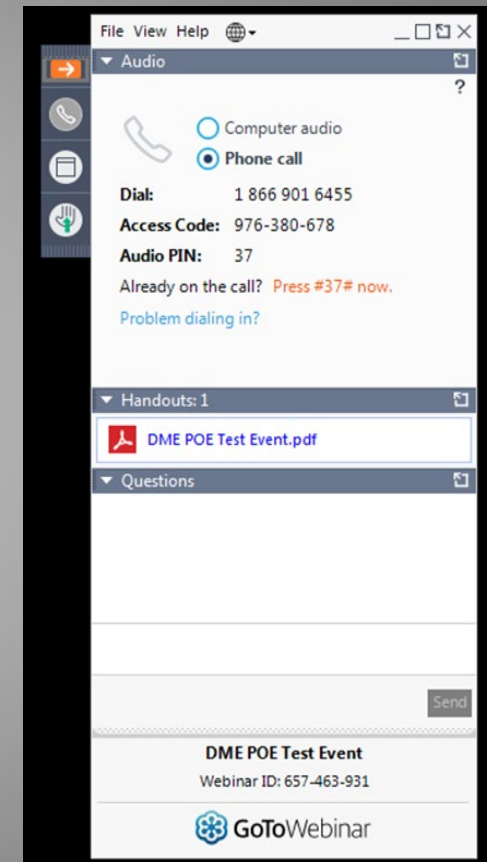


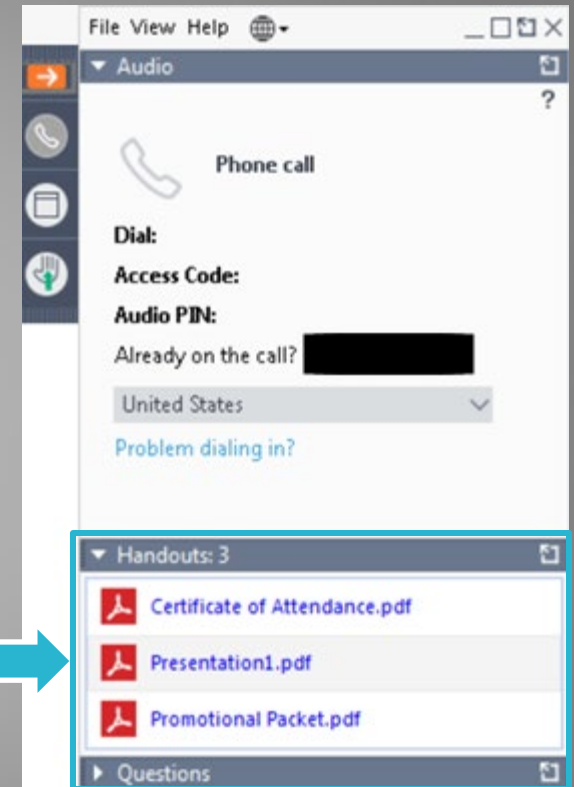
JOIN THE AUDIO CONFERENCE

- Dial the toll-free number
 - Enter the access code when prompted
 - Enter your audio PIN when prompted
 - Required for verbal questions



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



QUESTION BOX

To ask a question in the question box . . .

The screenshot shows a software interface with a top menu bar containing 'File View Help' and a globe icon. Below the menu bar is a sidebar with three icons: a right-pointing arrow, a telephone handset, and a hand with a green arrow. The main content area is titled 'Audio' and contains a 'Phone call' section with a telephone handset icon. Below this are fields for 'Dial:', 'Access Code:', and 'Audio PIN:'. The 'Audio PIN:' field has a dropdown menu showing 'United States' and a 'Problem dialing in?' link. Below the 'Audio' section is a 'Questions' section with a text input field containing the placeholder text '[Enter a question for staff]' and a 'Send' button.

Type it here.

Hit send.

Disclaimer

The DME MAC CERT Outreach and Education Task Force consists of representatives from each of the DME MACs and is independent from the CMS CERT Team and CERT Contractors, who are responsible for the calculation of the Medicare Fee-for-Service Improper Payment Rate.

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Together We Can Reduce CERT Errors

**DME CERT Outreach and Education Task Force
Therapeutic Shoes for Persons with Diabetes (TSPD)
National Webinar – November 2, 2022**

Today's Webinar Moderators and Presenters

- Jurisdiction A and D: Ruth Reese
- Jurisdiction B and C: Angie Cooper

Agenda

- Comprehensive Error Rate Testing (CERT) Errors
- Primary Care First (PCF) Model Demonstration Project
- Nurse Practitioners (NPs) and Physician Assistants (PAs) as Certifying Physicians
- Coverage Criteria
- Documentation Requirements
- References
- Questions

Comprehensive Error Rate Testing (CERT) Errors

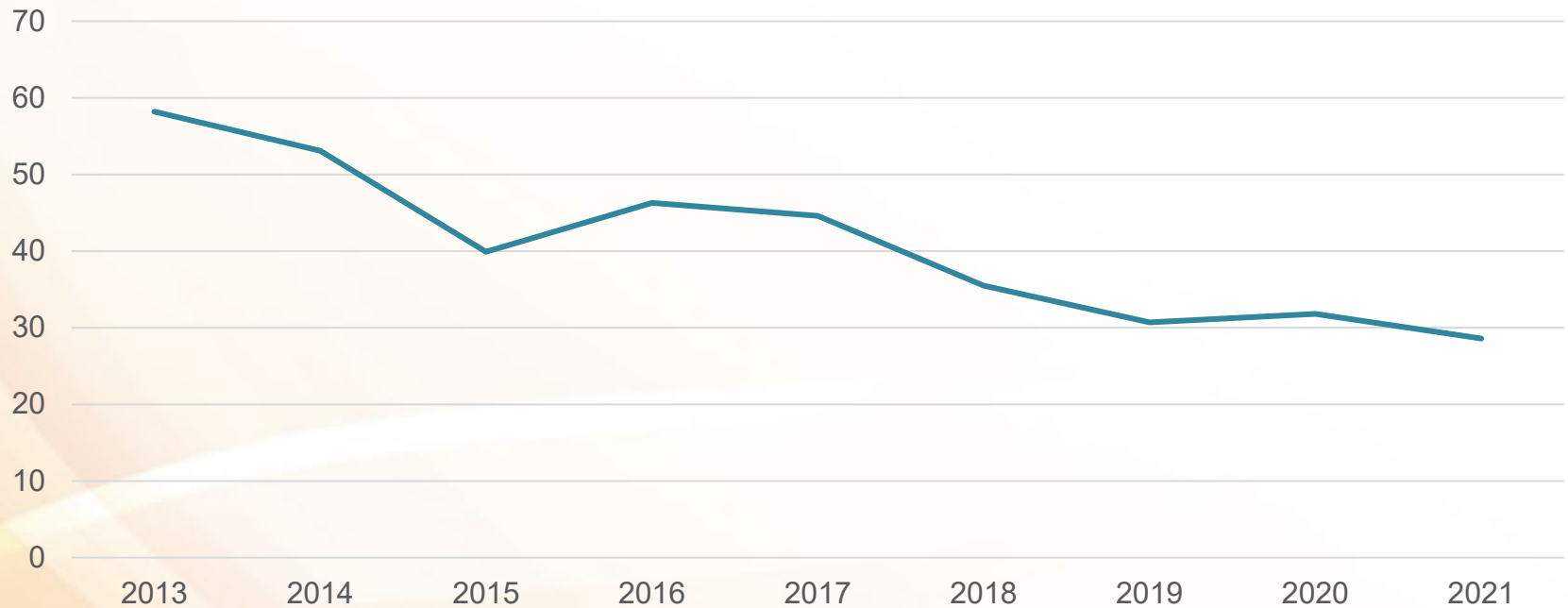
CERT

2021 Improper Payment Rates and Projected Improper Payment

<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	6.26%	\$25.03 B
DMEPOS	28.64%	\$2.38 B
Part A (excluding Hospital Inpatient Prospective Payment System (IPPS))	6.31%	\$11.58 B
Part A (Hospital IPPS)	2.39%	\$2.58 B
Part B Providers	8.49%	\$8.5 B

DMEPOS Improper Payment Rate All DME MAC Trend



Top Root Causes of Insufficient Documentation Errors in DMEPOS

- Orders – Missing or inadequate
- Documentation to support coverage criteria – Missing or inadequate
- Proof of delivery – Missing or inadequate

Improper Payment Rates for Diabetic Shoes

- November 2021 report included claims submitted between July 1, 2019 through June 30, 2020.
- Number of diabetic shoes claims reviewed by the CERT contractor during this reporting period: 129
- Diabetic shoes improper payment rate: 67.9%
- Percent of overall improper payments: 0.3%
- Diabetic shoes projected improper payments: \$70,410,351

Current Error Trends: Insufficient Supplier Documentation

- Documentation did not include an in-person evaluation of the patient's feet conducted by the supplier prior to selection of the specific items.
- Documentation did not include an in-person supplier visit at the time of delivery that assessed the fit of the shoes and inserts with the patient wearing them.

Current Error Trends: Ordering Practitioner

- The name and NPI of the ordering practitioner listed on the claim does not match the name of the practitioner who signed the order

Current Error Trends: Certifying Physician Documentation

- Medical record documentation does not include a clinical foot evaluation either conducted by the certifying physician or approved, initialed, and dated by the certifying physician
- The file does not include medical records from the certifying physician
- The medical records do not verify that the certifying physician is managing the patient's diabetes
- Documentation did not include a Statement of Certifying Physician

CERT Documentation Requests

- Documentation may be submitted the following ways:
 - **Fax:** 804.261.8100
 - Use the barcoded cover sheet as the only coversheet.
 - Do not add your own cover sheet as this slows down the receipt and identification process.
 - Send a separate fax transmission for each individual claim.
 - **Mail:** CERT Documentation Center
8701 Park Central Drive, Suite 400-A
Richmond, VA 23227
 - **Electronic Submission of Medical Documentation (esMD):**
 - Include a CID# or Claim number and the barcoded cover sheet in your file transmission.
 - Information on esMD can be found at <https://www.cms.gov/esMD>.

(continued on next slide)

CERT Documentation Requests

- **Via CD:**

- Images should be encrypted per HIPAA security rules.
- If encrypted, password and CID# must be provided via email to CERTMail@nciinc.com or via fax to 804.261.8100
- Must contain only images in TIFF or PDF format.

- **Via Email Attachment:**

- Email attachment(s) should be encrypted per HIPAA security rules.
- If encrypted, password and CID# must be provided via phone to 888.779.7477 or via fax to 1.804.261.8100
- Must contain only attachments in TIFF or PDF format.

CERT Contact Information

■ CERT Documentation Center

- Customer Service: 1.443.663.2699
- Toll Free: 1.888.779.7477
- Email: certprovider@nciinc.com
- Website: <https://c3hub.certrc.cms.gov/>

■ DME MAC CERT Resources

- JA: <https://med.noridianmedicare.com/web/jadme/cert-reviews/cert>
- JB: <https://www.cgsmedicare.com/jb/claims/cert/index.html>
- JC: <https://www.cgsmedicare.com/jc/claims/cert/index.html>
- JD: <https://med.noridianmedicare.com/web/jddme/cert-reviews/cert>



Appeal Rights from CERT Audits

- If CERT contractor finds errors with claim in question, supplier will receive an Overpayment Demand Letter and revised Medicare Remittance Advice (MRA) statement
- If supplier does not agree with outcome of CERT review, they should file an appeal to the Redeterminations department of their DME MAC within 120 days of date on demand letter or MRA
 - If a redetermination is filed to appropriate DME MAC within 30 days of overpayment demand letter, all recoupment activities will cease until redetermination decision is made

Primary Care First (PCF) Model Demonstration Project

PCF Model Demonstration Project

- January 1, 2021 through December 31, 2025
 - CMS will utilize PCF model
 - Allow NPs to certify an order for diabetic shoes
- Only Nurse practitioners (NPs) participating in PCF demonstration eligible to serve as certifying physician
 - Participants are listed with a group or organization
- Information on PCF model <https://innovation.cms.gov/innovation-models/primary-care-first-model-options>

Nurse Practitioners (NPs) and Physician Assistants (PAs) as Certifying Physicians

NPs and PAs as Certifying Physician for Therapeutic Shoes and Inserts

- CMS guidance to DME MACs with respect to delegation of
 - Certifying physician (MD or DO) for comprehensive management of diabetes responsibilities to NP and PA
- Clarification specific to NPs/PAs practicing under supervision of MD or DO, i.e., “incident to”
<https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/bp102c15.pdf>
 - Does not extend to NPs who practice independently (i.e., bill under their own NPI)
- Joint DME MAC Article posted November 5, 2020

NP or PA as certifying physician 2

NP Participant of PCF model demonstration project	NP or PA practicing “incident to” certifying physician
Acts as certifying physician	Acts as certifying physician
Performs exam	Performs exam
Documents in medical record	Documents in medical record, certifying physician signs, dates and indicates agreement
Completes certification statement	Completes certification statement, certifying physician co-signs

Coverage Criteria for TSPD

Coverage Criteria

1. Beneficiary has diabetes mellitus
2. Certifying physician documented in beneficiary's medical record one or more
 - a. Previous amputation of other foot, or part of either foot, or
 - b. History of previous foot ulceration of either foot, or
 - c. History of pre-ulcerative calluses of either foot, or
 - d. Peripheral neuropathy with evidence of callus formation of either foot, or
 - e. Foot deformity of either foot, or
 - f. Poor circulation in either foot; and
3. Certifying physician has certified that indications (1) and (2) are met and he/she is treating beneficiary under comprehensive plan of care for his/her diabetes and beneficiary needs diabetic shoes
 - Have an in-person visit with beneficiary during which diabetes management is addressed within 6 months prior to delivery of shoes/inserts
 - Sign certification statement on or after date of in-person visit and within 3 months prior to delivery of shoes/inserts

Coverage Criteria

4. Prior to selecting items, supplier must conduct in-person evaluation of beneficiary
5. At time of in-person delivery of items selected, supplier must conduct objective assessment of fit of shoes and inserts and document results. Beneficiary's subjective statements regarding fit does not meet this criteria

If criteria 1-5 are not met, the therapeutic shoes, inserts and/or modifications will be denied as noncovered.

Conditions 2A-2F

- A. Previous amputation of other foot, or part of either foot, or
- B. History of previous foot ulceration of either foot, or
- C. History of pre-ulcerative calluses of either foot, or
- D. Peripheral neuropathy with evidence of callus formation of either foot, or
- E. Foot deformity of either foot, or
- F. Poor circulation in either foot; and

**Documentation must clearly indicate
condition is of feet or foot**

Custom Molded Shoe (A5501)

- Covered when beneficiary has foot deformity that cannot be accommodated by a depth shoe
 - Nature and severity of deformity must be documented in supplier records
 - Record must be available on request
- If custom molded shoe provided but medical record does not support why item is medically necessary, it will deny not reasonable and necessary

Allowance Per Calendar Year

One pair of custom molded shoes (A5501) and two additional pairs of inserts (A5512, A5513, A5514)

or

One pair of depth shoes (A5500) and three pairs of inserts (A5512, A5513, A5514)

- Not including non-customized removable inserts provided with shoes

Calendar year: January through December

Modifications

- Modification may be covered as substitute for insert
- Common modifications may include
 - Rigid rocker bottoms (A5503)
 - Roller bottoms (A5503)
 - Wedges (A5504)
 - Metatarsal bars (A5505)
 - Offset heels (A5506)
 - Not otherwise specified therapeutic modification (A5507)
 - Include flared heels
 - Line-item narrative describing modification

Documentation Requirements

Standard Written Order (SWO)

- SWO elements
 - Beneficiary's name or Medicare Beneficiary Identifier (MBI)
 - Order Date
 - General description of the item
 - Description can be either general description (e.g., diabetic shoes and inserts), HCPCS code, HCPCS code narrative, or brand name/model number
 - Quantity to be dispensed
 - Treating practitioner name or National Provider Identifier (NPI)
 - Treating practitioner's signature
- If prescriber is also supplier, a separate order is not required.
 - Items provided must be clearly noted in medical record

Physician/Practitioner Documentation

- From the Certifying Physician:
 - Medical record of an in-person visit with beneficiary during which diabetes management is addressed within 6 months prior to delivery of shoes/inserts
 - Medical record of an in-person visit documenting one of covered foot conditions (criteria 2A-F) within 6 months prior to delivery of shoes/inserts
 - Certifying physician not practitioner that performs examination, certifying physician must obtain, initial, sign, date and indicate agreement with practitioner that performed exam prior to or on same day as signing certification statement
 - Statement of Certifying Physician signed on or after date of in-person visit and within 3 months prior to delivery of shoes/inserts
- Prescribing Practitioner
 - Medical record of an in-person visit within 6 months prior to delivery of shoes/inserts
 - Standard Written Order (SWO)

Documentation of Diabetes Management

- Support diagnosis of diabetes mellitus
- Document a comprehensive plan of care
 - This is more than a diagnosis in medical record.
 - Numerous guidelines from clinical organizations related to diabetes care provide detailed information about various elements of care plan for persons with diabetes.
- Must occur within 6 months prior to delivery of shoes/inserts
- Certification Statement by itself does not meet this requirement for documentation in medical records

Who May Conduct the Evaluation for Diabetes Management

- MD or DO who is responsible for diagnosing and treating beneficiary's diabetic systemic condition through a comprehensive plan of care
- Nurse practitioner practicing independently under Primary Care First Model Demonstration Project
- NP or PA practicing under supervision of an MD or DO “incident to”
 - Supervising physician has documented patient is diabetic and has been, and continues to provide, patient follow-up under a comprehensive management program of that condition
 - Supervising physician must review and verify (sign and date) all NP or PA notes in medical record pertaining to provision of therapeutic shoes, acknowledging their agreement with actions of NP or PA

Documentation of Covered Foot Condition

- The “certifying physician” has documented in beneficiary’s medical record one or more of the following conditions:
 - Previous amputation of the other foot, or part of either foot
 - History of previous foot ulceration on either foot
 - History of pre-ulcerative calluses of either foot
 - Peripheral neuropathy with evidence of callus formation of either foot
 - Foot deformity of either foot
 - » Include a description of the deformity
 - Poor circulation in either foot
 - » Documented evidence of poor circulation
- Certification Statement by itself does not meet this requirement for documentation in medical records

Certifying Physician's Responsibility for the Foot Examination

- Certifying physician must either:
 - Personally document one or more of criteria 2a – f in medical record of an in-person visit within 6 months prior to delivery and prior to or on same day as signing certification statement
 - NP or PA practicing “incident to” a supervising physician
 - » The supervising physician (MD or DO) must review, sign and date acknowledging agreement
 - Obtain, initial, date (prior to signing certification statement), and indicate agreement with information from medical records of an in-person visit that is within 6 months prior to delivery of shoes/inserts, and that documents one or more of criteria 2a-f
 - Medical records of an in-person visit may be with:
 - » Podiatrist (DPM),
 - » Other MD or DO
 - » PA, NP or CNS

Statement of Certifying Physician

- Certifying physician has certified
 - Indications (1) and (2) are met
 - They are treating beneficiary for diabetes and beneficiary needs diabetic shoes
 - Has an in-person visit with beneficiary during which diabetes management is addressed within six (6) months prior to delivery
 - Signs and dates certification statement on or after date of in-person visit and within three (3) months prior to delivery of shoes/inserts
 - NP or PA practicing “incident to” a supervising physician
 - NP or PA completes, signs and dates statement
 - Supervising physician (M.D. or D.O.) must review and verify (sign and date) acknowledging agreement
- Certification statement is not sufficient to meet requirement for documentation in medical record

Example of Statement of Certifying Physician

https://downloads.cms.gov/medicare-coverage-database/lcd_attachments/33369_18/certifyingphysiciantherapeuticshoesrevised2018.pdf

Statement of Certifying Physician for Therapeutic Shoes for Persons with Diabetes

Patient Name: _____

MBI: _____

I certify that all of the following statements are true:

1. This patient has diabetes mellitus.
2. This patient has one or more of the following conditions. (Circle all that apply):
 - a. History of partial or complete amputation of the foot.
 - b. History of previous foot ulceration.
 - c. History of pre-ulcerative callus.
 - d. Peripheral neuropathy with evidence of callus formation.
 - e. Foot deformity.
 - f. Poor circulation.
3. I am treating this patient with a comprehensive plan of care for his/her diabetes.
4. This patient needs special shoes (depth or custom-molded shoes) because of his/her diabetes.

Physician signature: _____

Date signed: _____

Physician name (printed – MUST BE AN M.D. OR D.O.): _____



Supplier Documentation – Criteria 4

In-person evaluation at time of selecting items

- Examination of feet including description of abnormalities
- For all shoes, measurements of feet
- For custom molded shoes and inserts
 - Conducting and documenting
 - Taking impressions
 - Making casts
 - Obtaining CAD-CAM images of feet that will be used in creating positive model

Supplier Documentation – Criteria 5

In-person evaluation at time of delivery

- Conducted with beneficiary wearing the shoes and inserts
- Must document that the shoes/inserts/modifications fit properly
- A beneficiary's subjective statements regarding fit as the sole documentation of the in-person delivery does not meet this criterion.

Proof of Delivery

- Delivery documentation must include:
 - Beneficiary's name
 - Delivery address
 - Sufficiently detailed description of item(s) being delivered (e.g., brand name, serial number, narrative description)
 - Quantity delivered
 - Date delivered
 - Beneficiary (or designee) signature
- Date of Service is date of delivery
- In-person delivery by the supplier is required

Activity Timeline

Activity	Responsible Person	Requirements
Visit to document diabetes mellitus management	Certifying MD/DO NP/PA “incident to” NP PCF Demonstration Project	Within six months prior to delivery
Visit to document qualifying foot condition	Certifying MD/DO, other MD/DO, Podiatrist, PA, NP, CNS	Within six months prior to delivery
Complete Certification Statement	Certifying MD/DO NP/PA “incident to” supervising MD/DO must verify (sign/date) NP PCF Demonstration Project	<ul style="list-style-type: none"> • Within three months prior to delivery • Signed on or after visit(s) to document diabetes management and foot condition
Sign SWO	Treating Practitioner: Certifying MD/DO, other MD/DO, Podiatrist, PA, NP, CNS	<ul style="list-style-type: none"> • After visit with treating practitioner

Activity Timeline 2

Activity	Responsible Person	Requirements
Selection Visit	Supplier	Prior to selecting specific items that will be provided
Fit Assessment/Delivery Visit	Supplier	After selection visit
Claim Submission	Supplier	<ul style="list-style-type: none">• After delivery• After receiving SWO• After receiving certification statement

Resources

TSPD Resources

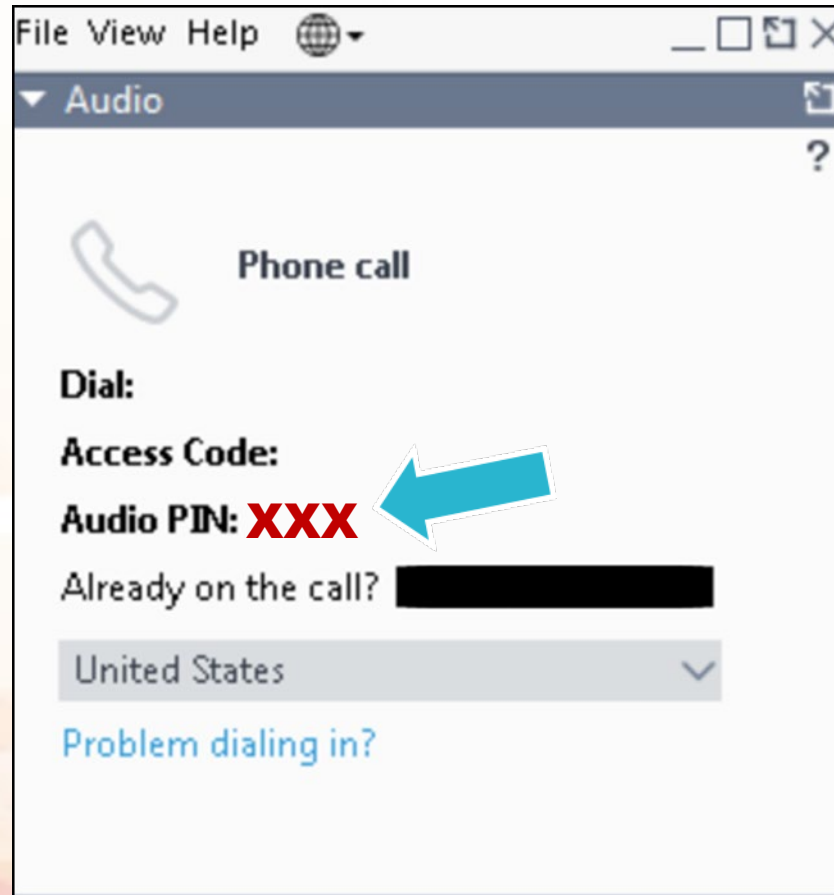
- Local Coverage Determination (LCD): Therapeutic Shoes for Persons with Diabetes (L33369)
<https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?LCDId=33369>
- Local Coverage Article: Therapeutic Shoes for Persons with Diabetes - Policy Article (A52501)
<https://www.cms.gov/medicare-coverage-database/view/article.aspx?articleId=52501>
- Local Coverage Article: Standard Documentation Requirements for All Claims Submitted to DME MACs (A55426)
<https://www.cms.gov/medicare-coverage-database/details/article-details.aspx?articleid=55426>

Resources

- Jurisdiction DME MAC Websites:
 - Jurisdiction A – <https://med.noridianmedicare.com/web/jadme/>
 - Jurisdiction B – <https://www.cgsmedicare.com/jb>
 - Jurisdiction C – <https://www.cgsmedicare.com/jc>
 - Jurisdiction D – <https://med.noridianmedicare.com/web/jddme/>

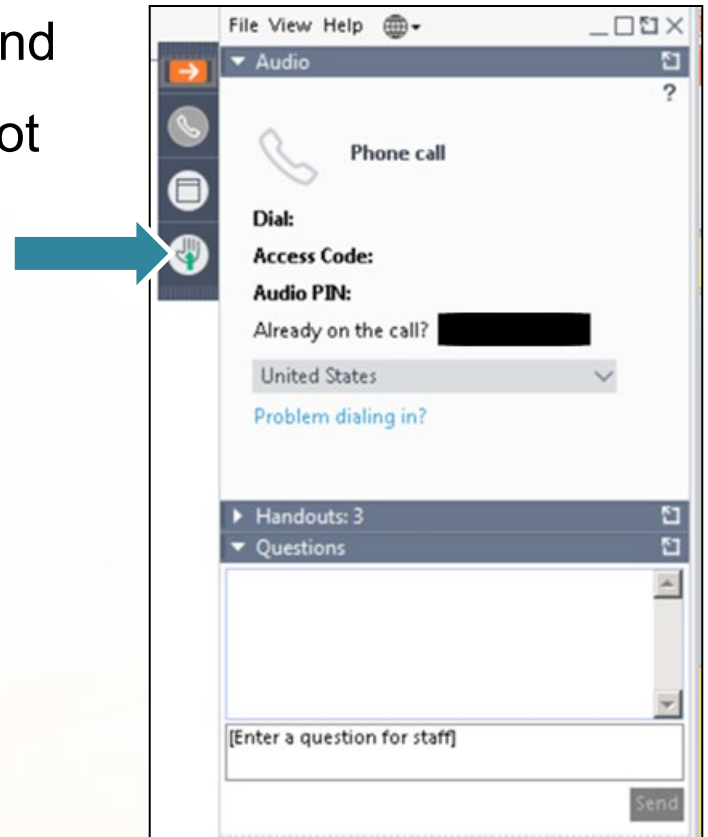
Questions?

How to Participate

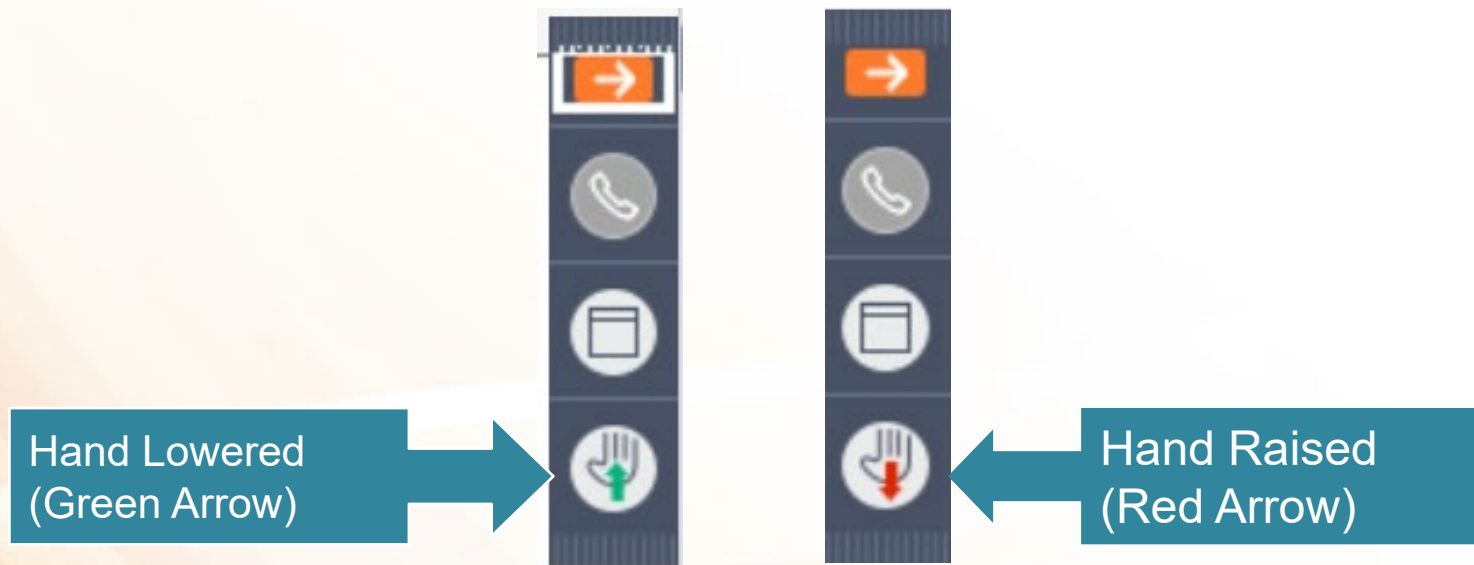


How to Participate Today

- 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

