Co-Branded Positive Airway Pressure (PAP) Devices Webinar

Welcome to the Co-Branded Positive Airway Pressure (PAP) Devices webinar

- The webinar will begin shortly
- Follow the prompts on your GoToWebinar screen to ensure you have audio capability
- You must dial in via your telephone and enter your Audio PIN # in your telephone keypad to participate in the Q&A portion
- The PDF version of the PowerPoint Presentation, Promotional Package and Certificate of Attendance will be available to all attendees in the Handouts section of your GoToWebinar control panel

Disclaimer

This presentation was current at the time it was published or uploaded onto the Web. Medicare policy changes frequently so links to the source documents have been provided within the document for your reference.

This presentation was prepared as a tool to assist providers and is not intended to grant rights or impose obligations. Although every reasonable effort has been made to assure the accuracy of the information within these pages, the ultimate responsibility for the correct submission of claims and response to any remittance advice lies with the provider of services.

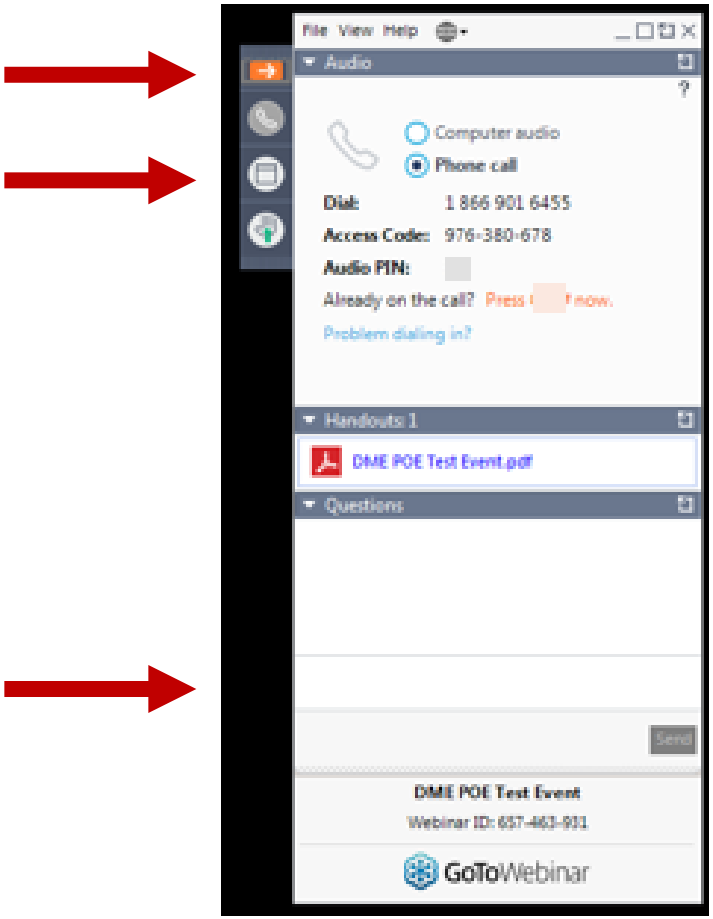
The Centers for Medicare & Medicaid Services (CMS) employees; agents, including CGS and its staff; and CMS' staff make no representation, warranty, or guarantee that this compilation of Medicare information is error free and will bear no responsibility or liability for the results or consequences of the use of this guide. This publication is a general summary that explains certain aspects of the Medicare Program but is not a legal document. The official Medicare Program provisions are contained in the relevant laws, regulations, and rulings.

This presentation may not be recorded for any purpose by attendees. However, CGS may record webinars for encore presentation purposes.

- Noridian Medicare Website (https://med.noridianmedicare.com)
- CGS Medicare Website (https://www.cgsmedicare.com)
- CMS Website (https://www.cms.gov)

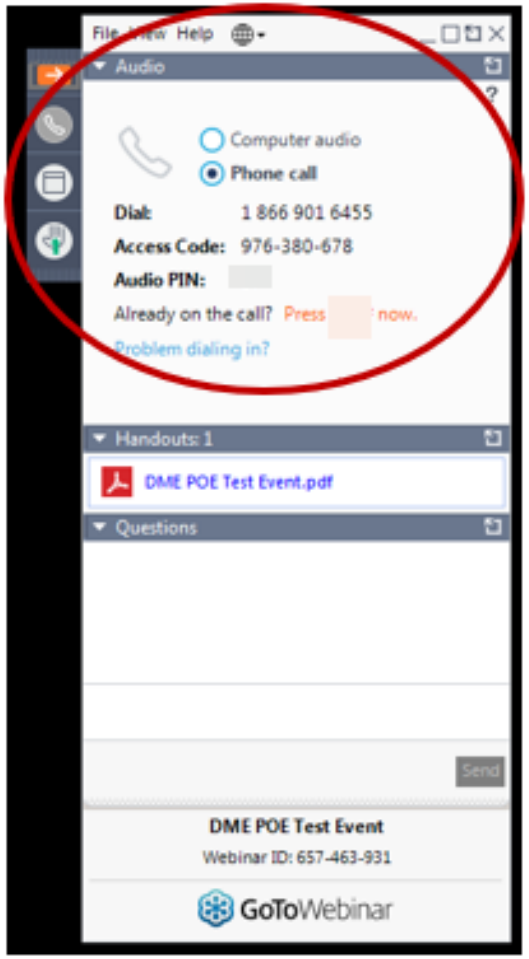
Webinar Product Navigation

- Open/Close the access panel
- Full screen mode
- Submit written questions



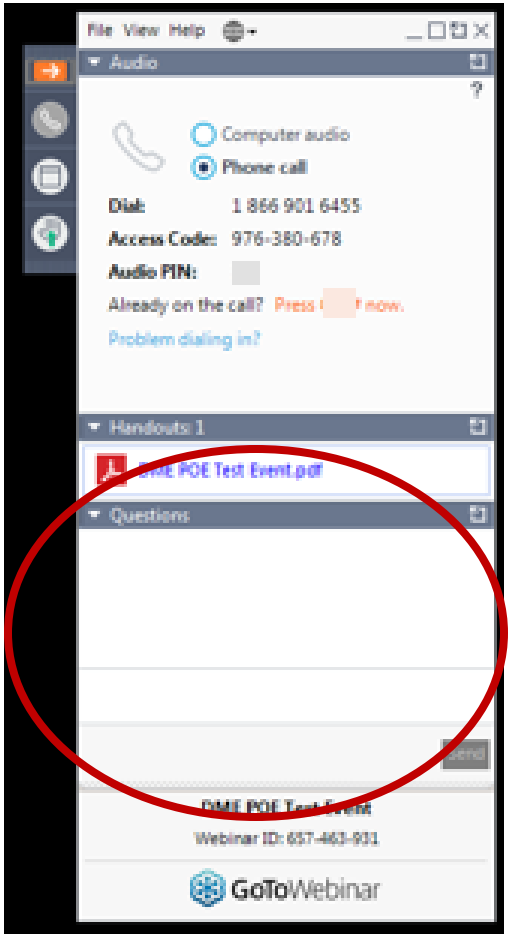
Join the Audio Conference

- Dial the toll-free number
- Enter the access code when prompted
- Enter your audio PIN when prompted
  - This is required in order to ask verbal questions later in the presentation



How to Ask a Written Question

- From the access panel
- Type your question into the Questions field
  - Be concise
- Click “Send”



Encore Events

- Is there one particular webinar from CGS Provider Outreach and Education (POE) you found especially helpful?
- Perhaps you learned something during a webinar that enlightened you about the Medicare process.
- Want to share the webinar with your colleagues, but missed the date on which it was held?

CGS POE will now be holding Encore Events. These are webinars POE has presented in the past that remain very popular among the supplier community. Encore webinars will be updated to keep information the most current.

- JB: https://www.cgsmedicare.com/jb/education/encore.html
- JC: https://www.cgsmedicare.com/jc/education/encore.html

CGS®
A CELERIAN GROUP COMPANY

noridian
Healthcare Solutions

CMS
CENTERS FOR MEDICARE & MEDICAID SERVICES

Positive Airway Pressure (PAP) Devices

Co-Branded Education

Revised: March 2022

Acronyms

- ABN: Advance Beneficiary Notice of Noncoverage
- AHI: Apnea-Hypopnea Index
- CERT: Comprehensive Error Rate Testing
- NSC: National Supplier Clearinghouse
- OSA: Obstructive Sleep Apnea
- PAP: Positive Airway Pressure
- Public Health Emergency (PHE)
- PSG: Polysomnogram
- RAD: Respiratory Assist Device
- RDI: Respiratory Disturbance Index
- RUL: Reasonable Useful Lifetime

Agenda

- Definitions
- Coverage Criteria
- Documentation
- Modifier Usage and Billing
- Comprehensive Error Rate Testing (CERT)
- COVID-19 Public Health Emergency (PHE)
- Resources
- Questions & Answers

Definitions

Obstructive Sleep Apnea (OSA)

- **Apnea**
  - Cessation of airflow for at least 10 seconds
    - Breathing stops
- **Hypopnea**
  - Abnormal respiratory event lasting at least 10 seconds associated with at least a 30% reduction in thoraco-abdominal movement or air flow as compared to baseline and with at least a 4% decrease in oxygen saturation
    - Low/slow breathing
    - Length of time when there is not chest or diaphragm movement

Apnea/Hypopnea Index
Respiratory Disturbance Index

- **Apnea-Hypopnea Index (AHI)**
  - The average number of episodes of apnea and hypopnea per hour of sleep without the use of a positive airway pressure device
- **Respiratory Disturbance Index (RDI)**
  - The average number of apneas plus hypopneas per hour of recording without the use of a positive airway pressure device
  - **Note:** For the purposes of this policy, respiratory effort related arousals (RERAs) are not included in the calculation of either AHI or RDI

Continuous Positive Airway Pressure Device (E0601)

- **Delivers a constant level of positive air by way of tubing and a noninvasive interface**
  - Within a single respiratory cycle
    - An inspiration followed by an expiration
  - Assists spontaneous respiratory efforts
  - Supplements volume of inspired air in the lungs
- **Includes auto-titrating single-level CPAP device**
  - **Note:** In this policy, the term PAP device will refer to both E0601 and E0470 when it is used in the treatment of obstructive sleep apnea (OSA)

Respiratory Assist Devices (RAD)

- **RAD without backup (E0470) delivers adjustable, variable levels of positive air pressure by way of tubing and a noninvasive interface**
  - Within a single respiratory cycle
  - Assists spontaneous respiratory efforts
  - Supplements volume of inspired air in the lungs
- **RAD with backup (E0471) delivers adjustable, variable levels of positive air pressure by way of tubing and a noninvasive interface**
  - Within a single respiratory cycle
  - Assists spontaneous respiratory efforts
  - Supplements volume of inspired air in the lungs
  - Includes a timed backup feature when spontaneous inspiratory efforts fail to occur
- **Claims for E0471 will be denied as not reasonable and necessary**

PAP Coverage Criteria

National Coverage Determination (240.4)
Local Coverage Determination (L33718)
Policy Article (A52467)
Standard Documentation Requirements Policy Article (A55426)

Revised: March 2022

Initial Coverage

An E0601 device is covered for the treatment of obstructive sleep apnea (OSA) if criteria A – C are met:

A. In-person clinical evaluation by treating practitioner prior to a sleep test to assess beneficiary for OSA.

B. Sleep test that meets either one of the following criteria:

   1. AHI or RDI is greater than or equal to 15 events per hour with a minimum of 30 events; or
   2. AHI or RDI is greater than or equal to 5 and less than or equal to 14 events per hour with a minimum of 10 events and documentation of:
      a. Excessive daytime sleepiness, impaired cognition, mood disorders, or insomnia; OR
      b. Hypertension, ischemic heart disease, or history of stroke.

C. Beneficiary or caregiver received instruction from the supplier in the proper use and care of the PAP device.

Treating Practitioner's Initial Evaluation

- **For the initial in-person evaluation, the report would commonly document pertinent information about the following elements:**
  - **History**
    - Signs and symptoms of sleep disordered breathing including snoring, daytime sleepiness, observed apneas, choking or gasping during sleep, morning headaches
    - Duration of symptoms
    - Validated sleep hygiene inventory such as the Epworth Sleepiness Scale
  - **Physical Exam**
    - Focused cardiopulmonary and upper airway system evaluation
    - Neck circumference
    - Body mass index (BMI)
- May include other details
- Each element would not have to be addressed in every evaluation

Sleep Tests

Coverage and Payment rules for diagnostic sleep tests may be found in the CMS National Coverage Determination (NCD) 240.4.1 (CMS Pub.100-03, Chapter 1, Part 4), the applicable A/B MAC LCDs and Billing and Coding articles.

- The sleep test must be either a polysomnogram performed in a facility-based laboratory (Type I study) or an inpatient hospital-based or home-based sleep test (HST) (Types II, III, IV, Other).
  - A sleep test (Type I, II, III, IV, Other) that meets the Medicare requirements for a valid sleep test as outlined in NCD 240.4.1 and the applicable A/B MAC LCD and Billing and Coding article; and,
  - A sleep test that is approved by the Food and Drug Administration (FDA) as a diagnostic device; and,
  - The sleep test results meet the coverage criteria in effect for the date of service of the claim for the PAP device; and,
  - The sleep test is ordered by the beneficiary's treating practitioner; and,
  - The sleep test is conducted by an entity that qualifies as a Medicare provider of sleep tests and is in compliance with all applicable state regulatory requirements

No Supplier Involvement with Home Sleep Test

- No aspect of a home sleep test, including but not limited to delivery and/or pickup of the device, may be performed by a DME supplier.
- This prohibition does not extend to the results of studies conducted by hospitals certified to conduct such tests or to tests conducted in facility-based sleep laboratories

Coverage for RAD Without Backup (E0470)

An E0470 device is covered for those beneficiaries with OSA who meet criteria A-C above, and D:

D. An E0601 has been tried and proven ineffective based on a therapeutic trial conducted in either a facility or in a home setting

- Ineffective is defined as documented failure to meet therapeutic goals using an E0601 during the titration portion of a facility-based study or during home use despite optimal therapy (i.e., proper mask selection and fitting and appropriate pressure settings)

Coverage for RAD Without Backup (E0470)

- If an E0601 device is tried and found ineffective during the initial facility-based titration or home trial, substitution of an E0470 does not require a new initial in-person clinical evaluation or a new sleep test
- If an E0601 device has been used for more than 3 months and the beneficiary is switched to an E0470, a new initial in-person clinical evaluation is required, but a new sleep test is not required
  - **A new 3-month trial would begin for use of the E0470**

Respiratory Assist Devices Policy

- **A bi-level positive airway pressure device with back-up rate (E0471) is not reasonable and necessary if the primary diagnosis is OSA**
  - **If an E0471 is billed with a diagnosis of OSA, it will be denied as not reasonable and necessary**
- Coverage, coding and documentation requirements for the use of E0470 and E0471 for diagnoses other than OSA are addressed in the ***Respiratory Assist Devices (RAD) LCD and related Policy Article***

Continued Coverage: Beyond First Three Months of Therapy

Continued coverage of a PAP device (E0470 or E0601) beyond the first 3 months of therapy requires:

- No sooner than the 31st day but no later than the 91st day after initiating therapy, the treating practitioner must conduct a clinical re-evaluation and document that the beneficiary is benefiting from PAP therapy
- **Documentation of clinical benefit is demonstrated by**
  - In-person clinical re-evaluation by the treating practitioner with documentation that symptoms of OSA are improved; and,
  - Objective evidence of adherence to use of the PAP device, reviewed by the treating practitioner
    - Used greater than or equal to 4 hours per night 70% of nights during a consecutive 30-day period anytime during the first 3 months of initial usage

Re-evaluations Occurring After 91st Day

- **If the treating practitioner in-person re-evaluation does not occur until after the 91st day:**
  - **Continued coverage of the PAP device will commence with the date of the in-person re-evaluation if the physician documents:**
    - That the beneficiary is benefiting from PAP therapy, and
    - Objective evidence of adherence
      - » Used greater than or equal to 4 hours per night 70% of nights during a consecutive 30-day period anytime during the first 3 months of initial usage

Failing the Initial 12 Week Trial

- **Beneficiaries who fail the initial 12-week trial are eligible to re-qualify for a PAP device but must have both:**
  - In-person clinical re-evaluation by the treating practitioner to determine the etiology of the failure to respond to PAP therapy; and,
  - Repeat sleep test in a facility-based setting (Type 1 study)
    - This may be a repeat diagnostic, titration or split-night study

Failing the Initial 12 Week Trial

- In addition to a new in-person clinical exam and repeat sleep test; there must be ***objective evidence of adherence*** prior to billing:
- **Correct Billing – Continued Coverage for Positive Airway Pressure (PAP) Devices for the Treatment of Obstructive Sleep Apnea**
  - JA: https://med.noridianmedicare.com/web/jadme/policies/dmd-articles/2019/correct-billing-continued-coverage-for-positive-airway-pressure-pap-devices-for-the-treatment-of-obstructive-sleep-apnea
  - JB: https://www.cgsmedicare.com/jb/pubs/news/2019/05/cope12486.html
  - JC: https://www.cgsmedicare.com/jc/pubs/news/2019/05/cope12486.html
  - JD: https://med.noridianmedicare.com/web/jddme/policies/dmd-articles/2019/correct-billing-continued-coverage-for-positive-airway-pressure-pap-devices-for-the-treatment-of-obstructive-sleep-apnea

Ineffective CPAP Therapy

- **Treating practitioner documented the following issues were addressed prior to changing to an E0470:**
  - Interface fit and comfort
    - Beneficiary is using appropriately fit interface without difficulty
    - This appropriately fit interface will be used with the E0470 device
  - **E0601 pressure settings. The current pressure setting of the E0601 prevents the beneficiary from tolerating the therapy and lower pressure settings of the E0601 were tried but failed to:**
    - Adequately control the symptoms of OSA; or,
    - Improve sleep quality; or,
    - Reduce the AHI/RDI to acceptable levels.

Ineffective Therapy: Switching From E0601 to E0470

If an E0601 device is tried and found ineffective during the initial facility-based titration or home trial:

- **More than 30 days remain:**
  - Trial length remains same
  - Re-evaluation between 31st and 91st day
  - Adherence to therapy on the RAD prior to 91st day
- **Less than 30 days remain:**
  - Re-evaluation must occur before the 120th day
  - Adherence to therapy on the RAD before the 120th day

Ineffective Therapy: Switching From E0601 to E0470

- **After the initial 3-month trial of the E0601**
- New evaluation
- **New 3-month trial with the RAD**
  - Clinical re-evaluation between 31st and 91st day with RAD
  - Adherence to therapy with RAD

Discontinued Usage

- Supplier is expected to know if beneficiary is using device
- Stop billing for equipment and supplies if not in use
- Recommend continuous follow-up with beneficiary through 13th month

Concurrent Use of Oxygen With PAP Therapy

- **Testing must be done in a chronic stable state**
- Both oxygen LCD and PAP LCD must be followed
- OSA sufficiently treated and lung disease unmasked
- **Overnight oximetry during home sleep test are not eligible to be used for oxygen qualification**
- **Testing may only occur during a titration sleep study:**
  - Minimum 2 hours
  - During titration specific reduction in AHI/RDI criteria met
  - Only performed after optimal PAP settings determined
  - Nocturnal oximetry conducted during PSG shows less than or equal to 88% for 5 minutes

Replacement PAP

PAP initially provided and covered through Medicare FFS:

- If a PAP device is replaced during the 5-year RUL due to loss, theft, or irreparable damage:
  - No new clinical evaluation, sleep test or trial
- **If replaced following the 5-year RUL, there must be an in-person evaluation by treating practitioner that documents:**
  - Beneficiary continues to use and benefit from device
  - No requirement for a new sleep study or trial period

Beneficiaries Entering Medicare

Beneficiary seeking rental or replacement PAP and/or accessories must meet the following requirements:

- Sleep test prior to FFS Medicare that meets AHI/RDI criteria in effect at the time a replacement PAP and/or accessories are needed, and
- **In-person evaluation following enrollment in FFS Medicare by treating practitioner that documents**
  - Diagnosis of OSA; and
  - Beneficiary continues to use the PAP device

Accessories for Beneficiary-Owned CPAP Devices and RADs

- **If Medicare paid for the base CPAP or RAD initially (that is, for 13 months of continuous use), the medical necessity for the beneficiary-owned base CPAP or RAD is assumed to have been established**
- Documentation needed:
  - Continued need for the base item
  - The medical necessity of the replacement of specific accessories or furnishing of new accessories and whether they are essential for the effective use of the base DME

https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/Downloads/MM9741.pdf

CPAP vs Ventilators

- Ventilators (E0465, E0466, and E0467) fall under the Frequent and Substantial Servicing (FSS) payment category, and payment policy requirements preclude FSS payment for devices used to deliver continuous and/or intermittent positive airway pressure, regardless of the illness treated by the device. (Social Security Act 1834(a)(3)(A))
- **A ventilator is not eligible for reimbursement for Obstructive Sleep Apnea (OSA) described in the PAP LCD even though the ventilator equipment may have the capability of operating in a positive pressure or bi-level pressure (E0601, E0470) mode.**
- **Claims for ventilators used to provide CPAP or bi-level PAP therapy for conditions described in the PAP policy will be denied as not reasonable and necessary.**
- **Claims for ventilators billed using the CPAP (E0601) or bi-level PAP (E0470) device HCPCS codes will be denied as incorrect coding.**

Continued Medical Need

For ongoing supplies, accessories and PAP device rental:

- In addition to information that justifies the initial provision of the item(s) and/or supplies, there must be information in the beneficiary's medical record to support that the item continues to remain reasonable and necessary
- Information used to justify continued medical need must be timely for the date of service under review
- Any of the following may serve as documentation justifying continued medical need:
  - A recent order/prescription by the treating practitioner for refills of supplies used with the PAP device
  - A recent change in an order/prescription
  - Timely documentation in the beneficiary's medical record showing usage of the item
    - A record in the preceding 12 months

Documentation

Authorized to Order

- **Treating Practitioner:**
  - Doctor of Medicine (MD)
  - Doctor of Osteopathy (DO)
  - Nurse Practitioner (NP)
  - Clinical Nurse Specialist (CNS)
  - Physician Assistant (PA)
- The treating practitioner must be enrolled in Medicare

Standard Written Order (SWO)

- **Must contain All the following:**
  - Beneficiary's name or Medicare Beneficiary Identifier (MBI)
  - Order Date
  - General description of the item
  - Quantity to be dispensed, if applicable
  - Treating practitioner name or NPI
  - Treating practitioner's signature

SWO must be completed and signed prior to billing Medicare

SWO: Description

- **The description** can be either a general description (e.g., PAP device), 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 order/prescription may include all concurrently ordered supplies that are separately billed (List each separately)

When is a New Order Required?

- For all claims for purchases or initial rentals
- **If there is a change in the 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 item from the transferring supplier

Expected Accessory Utilization

HCPCS	Usual Max	HCPCS	Usual Max
A4604	1 per 3 months	A7027	1 per 3 months
A7028	2 per 1 month	A7029	2 per 1 month
A7030	1 per 3 months	A7031	1 per 1 month
A7032	2 per 1 month	A7033	2 per 1 month
A7034	1 per 3 months	A7035	1 per 6 months
A7036	1 per 6 months	A7037	1 per 3 months
A7038	2 per 1 month	A7039	1 per 6 months
A7046	1 per 6 months		

Claim Narrative for 90 Day Supply

- Most DMEPOS accessory/supply items provided on a recurring basis can be dispensed with a three-month supply.
- Review the REFILL REQUIREMENTS section of each individual LCD.
- **When billing more than one month's supply of these items, include a narrative in the NTE segment of the electronic claim indicating the number of months you are billing.**
  - For example, if you bill a three-month supply of PAP accessories (i.e., filter, pillows, cushions), you must add “90-day supply” or “three-month supply.”

Refill Requirements

- **For all supply items and accessories supplied as refills to the original order:**
  - Suppliers must contact the beneficiary prior to dispensing
  - Suppliers must not automatically ship on pre-determined basis
  - Contact no sooner than 14 calendar days prior to delivery/shipping
  - Supplier must deliver the items no sooner than 10 calendar days prior to the end of usage of the current product
- **The refill request must occur and be documented before shipment**
- A retrospective attestation statement by the supplier or beneficiary is not sufficient

Documentation of Request for a Refill

- **For items obtained at a retail store, the signed delivery slip or copy of itemized sales receipt is sufficient documentation of request for refill**
  - Signed delivery slip or
  - Copy of the itemized sales receipt
- **For items that are delivered to the beneficiary, documentation of a request for refill must be either:**
  - A written document received from the beneficiary or
  - Contemporaneous written record of a phone conversation/contact between the supplier and beneficiary

Refill Documentation: Items Shipped/Delivered

- **The refill record must include:**
  - Beneficiary's name or authorized representative if different from the beneficiary
  - A description of each item that is being requested
  - Date of refill request
  - Quantity of consumable supplies remaining, or functional condition of the non-consumable supply item

Refill Requirements: Non-Consumable Supplies

- **Non-consumables: supply items that are more durable in nature, but may require periodic replacement**
  - **Examples:** PAP supplies, nebulizer supplies, RAD supplies
  - Does the item remain functional? Replacement should be provided only when the item is no longer functional
  - If replaced, document the condition of the item in sufficient detail to indicate why the replacement is necessary at that time
- **Consumable: Quantity of each item remaining (will it be exhausted by time for refill?)**

Delivery: Direct to Beneficiary

- **Delivery slip must include:**
  - Beneficiary's name
  - Delivery address
  - Date delivered
  - The quantity delivered
  - A description of the item(s) being delivered. The description can be either a narrative description, a HCPCS code, the long description of a HCPCS code, or a brand name/model number
  - Beneficiary's/Beneficiary designee's signature
  - **Date of Service = Date of Delivery**

Delivery: Shipping Service

- **The Proof of Delivery (POD) must include:**
  - Beneficiary's name
  - Delivery address
  - ***Delivery service's package ID number, supplier invoice number*** **or alternative method that links supplier's delivery documents with delivery service's records**
  - Detailed description identifying item(s) being delivered - can be either a narrative description, a HCPCS code, the long description of a HCPCS code, or a brand name/model number
  - Quantity delivered
  - Date delivered
  - **Evidence of delivery**

Date of Service for Shipping Service Delivery

- **If a supplier utilizes a shipping service or mail order, suppliers have two options for the DOS to use on the claim:**
  - Suppliers may use the shipping date as the DOS
    - The shipping date is defined as the date the delivery/shipping service label is created or the date the item is retrieved by the shipping service for delivery. However, such dates should not demonstrate significant variation.
  - Suppliers may use the date of delivery as the DOS on the claim

Date of Service = Shipping Date, Shipping Label Creation Date, or Date of Delivery

Equipment Retained From a Prior Payer

- **Proof of delivery is required**
  - Suppliers may use standard delivery template used for other items
- *Or*
  - **The supplier record must document:**
    - A statement, signed and dated by the beneficiary (or beneficiary's designee), that the supplier has examined the item, meets the POD requirements; and
    - A supplier attestation that the item meets Medicare requirements

Modifier Usage and Billing Issues

KX Modifier

- **Requirements specified in the medical policy have been met**
- Usage on claims for first 3 months:
  - All criteria in the LCD ("Initial Coverage") have been met
- **Usage on claims beyond first 3 months:**
  - Both "***Initial Coverage***" criteria and "***Continued Coverage***" criteria in the LCD have been met
    - Supplier must obtain documentation from the treating practitioner that the beneficiary has demonstrated improvement in their OSA symptoms and is adhering to PAP therapy
    - Supplier may choose to hold claims for the 4th and succeeding months pending receipt of information

Effects of Late Re-Evaluations

- **Scenario 1:** In-person clinical re-evaluation demonstrating continued coverage criteria occurred before the 91st day, but the supplier was not provided the documentation of the visit
  - **Subsequent supplier claims must be held until documentation is received**
- **Scenario 2:** In-person clinical re-evaluation does **not** occur by 91st day and subsequent re-evaluation demonstrates continued coverage criteria is met:
  - **Coverage resumes beginning with the date of re-evaluation**

ABN for Continued Coverage Criteria

- **Supplier has knowledge beneficiary is not making efforts to meet policy criteria for continued coverage, or if there is other reason to anticipate that continued coverage will be denied:**
  - Beginning on day 61 of the trial period a mandatory ABN may be issued
  - The beneficiary should choose an option box and sign and date the ABN
  - This ABN should advise the beneficiary that if, by the 90th day of therapy, they do not meet the policy criteria for continue coverage (e.g., adherent to therapy and obtain a follow-up in-person evaluation), Medicare may deny subsequent claim(s) and the beneficiary will be liable for payment
- Medicare Claims Processing Manual, Chapter 30, Section 50

Required Modifiers: GA, GZ, or KX

- **All PAP devices, accessories and supplies:**
  - **EY, GA, GZ, or KX**
    - **EY:** No physician or other licensed health care provider order for this item or service
    - **GA**: Item expected to deny as not reasonable and necessary and a properly executed ABN is on file
    - **GZ**: Item expected to be denied as not reasonable or necessary (no valid ABN)
    - **KX:** Specific coverage criteria is met

Required Rental Modifiers

- **E0601 and E0470:**
  - **RR and KH, KI, or KJ**
    - **RR:** Rental
    - **KH:** 1st rental month
    - **KI:** 2nd and 3rd rental months
    - **KJ:** 4th through 13th rental months
- **Inexpensive or Routinely Purchased**
  - Accessories, i.e., mask, tubing, humidifier
    - **NU –** new purchased item

Multi-Function Ventilator (E0467)

- Effective for claims with dates of service on or after January 1, 2019:
  - E0467 - Home ventilator, multi-function respiratory device
  - Also performs any or all of the additional functions of oxygen concentration, drug nebulization, aspiration, and cough stimulation, includes all accessories, components and supplies for all functions.

Multi-Function Ventilator (E0467)

- Effective for claims with dates of service on or after January 1, 2019:
  - The following items are included in the functionality of code E0467:
    - Ventilators
    - Oxygen equipment
    - Cough stimulator (multiple products)
    - Aspirator (suction device)
    - Mechanical In-Exsufflation devices and related accessories
    - Nebulizers and related accessories
    - High Frequency Chest Wall Oscillation Devices
    - Positive airway pressure devices (PAP and RAD)
    - Oral Appliance

Multi-Function Ventilator (E1399) Without All Four Functions

- Multi-function ventilators without all four additional functions listed below must be billed as E1399:
  - Oxygen concentrator
  - Nebulizer
  - Aspirator
  - Cough stimulator

Comprehensive Error Rate Testing (CERT) Results

Comprehensive Error Rate Testing (CERT)

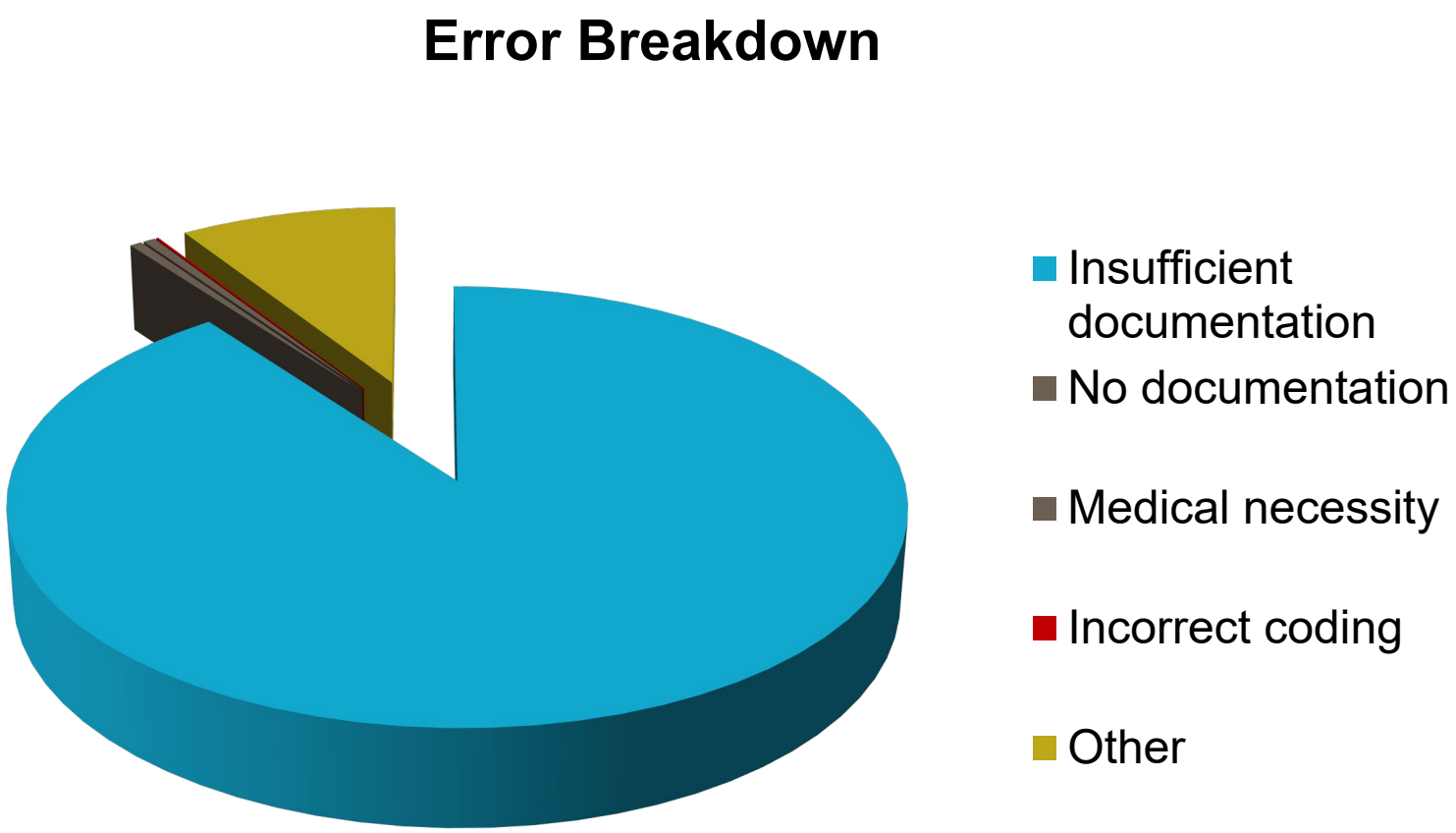
- 2021 Improper Payment Rates and Projected Improper Payment
- CERT: https://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/Improper-Payment-Measurement-Programs/CERT

Service Type	Improper Payment Rate	Projected Improper Payment Amount
Overall	6.3%	$25 B
Part A Providers (excluding Hospital Inpatient Prospective Payment System (IPPS))	6.3%	$11.6 B
Part B Providers	8.5%	$8.5 B
DMEPOS	**28.6%**	**$2.4 B**
Hospital IPPS	2.4%	$2.6 B

Improper Payment Rates for CPAP

- November 2021 report period: Claims submitted 7/1/2019 – 6/30/2020
- Number of CPAP claims reviewed by the CERT contractor during their 2021 reporting period: 814
- **Overall error rate for CPAP: 30.8%**
- CPAP projected improper payments: $319,776,813.

2021 CERT Data: CPAP Errors



Top CERT Errors for CPAP

- **Order missing or invalid**
- **Medical records:**
  - Documentation does not include a clinical evaluation by the treating practitioner prior to sleep test to assess for OSA
  - Documentation does not include a valid sleep study that meets LCD requirements
  - Documentation was not timely (within preceding 12 months) to support continued need
  - Medical record documentation is not authenticated (handwritten or electronic) by the author
  - Medical record documentation does not document a confirmed diagnosis of OSA
- **Ordering practitioner NPI reported on the claim is not the same practitioner who signed the order**
- **Proof of delivery missing or invalid**

CERT Contact Information

- **AdvanceMed** is the CERT Documentation Center
- CERT Resources and Contacts
  - **Customer Service:** 1.443.663.2699 or 1.888.779.7477
  - **Fax:** 1.804.261.8100
  - **E-mail:** CERTProvider@nciinc.com
  - **Website:** https://c3hub.certrc.cms.gov

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
    1510 East Parham Road
    Henrico, VA 23228
  - **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
    - CERTMail@nciinc.com

Appeal Rights from CERT Audits

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

COVID-19
Public Health Emergency (PHE)

Revised: March 2022

Clinical Indications for Coverage: COVID-19 Public Health Emergency

Effective for claims with dates of service on or after March 1, 2020, and for the duration of this COVID-19 PHE, clinical indications for coverage found in the Positive Airway Pressure Devices for the Treatment of Obstructive Sleep Apnea (L33718) Local Coverage Determination (LCD) are not being enforced

- **Treating practitioners and suppliers must still:**
  - Provide a Standard Written Order (SWO) for all items
  - Ensure that the items or services are reasonable and necessary
  - Continue documenting the medical necessity for all services
  - Make documentation available, upon request
    - **This enforcement discretion will only apply during the COVID-19 PHE**

Proof of Delivery- Direct to Beneficiary: COVID-19 Public Health Emergency

- In response to the COVID-19 pandemic CMS is waiving signature requirements on proof of delivery documentation for dates of service within the PHE for the COVID-19 pandemic
- Given the nature of the pandemic and the inability to collect signatures during this time, CMS will not be enforcing the signature requirement
  - **Proof of Delivery (POD) - Direct to Beneficiary**
    - **Signature requirements for DMEPOS delivered directly to a beneficiary are being waived during the COVID-19 PHE**
    - **During the PHE, suppliers should document the appropriate date of delivery and that a signature was not able to be obtained because of COVID-19**
    - **Append CR modifier to the claim line items and the COVID-19 narrative to the NTE 2400 (line note) or NTE 2300 (claim note) segments**

COVID-19 Public Health Emergency: Claim Instructions

- Additionally, suppliers should continue to use the appropriate modifiers, including the **KX** and/or CG modifiers for which LCDs' clinical indications of coverage are not being enforced
- Suppliers are reminded to append a ***CR modifier*** and **include a *narrative of "COVID-19"*** to all claims that are affected by the COVID-19 PHE
  - ***The narrative should be entered into the NTE 2400 (line note) or NTE 2300 (claim note) segments*** of the American National Standard Institute (ANSI X12) format, field 390-BM of the National Council for Prescription Drug Program (NCPDP) format, or Item 19 of paper claims

Resources

Philips Respironics Respiratory: Products Recall

- On June 14, 2021, Philips Respironics announced the voluntary, global recall of an estimated 4 million continuous positive airway pressure (CPAP) devices, bilevel respiratory assist devices (RADs), and ventilators
- Suppliers of impacted devices should work with their Philips Respironics sales representative to obtain replacement PAP, RAD, or ventilator products for their Medicare beneficiaries
- Suppliers should refer to the Philips Respironics website for additional information and to begin registration process: https://www.usa.philips.com/healthcare/e/sleep/communications/src-update

Philips Respironics Respiratory: Products Recall Joint Publications

Frequently Asked Questions (FAQs) *Philips Respironics Respiratory Products Recall* published on DME MAC website sites

- JA: https://med.noridianmedicare.com/web/jadme/policies/dmd-articles/2021/frequently-asked-questions-philips-respironics-respiratory-products-recall-revised
- JB: https://www.cgsmedicare.com/jb/pubs/news/2021/07/cope22777.html
- JC: https://www.cgsmedicare.com/jc/pubs/news/2021/07/cope22777.html
- JD: https://med.noridianmedicare.com/web/jddme/policies/dmd-articles/2021/frequently-asked-questions-philips-respironics-respiratory-products-recall-revised

CGS Resources for PAPs

- **Dedicated PAP resource pages for Jurisdictions B and C:**
  - Jurisdiction B: https://www.cgsmedicare.com/jb/mr/pap.html
  - Jurisdiction C: https://www.cgsmedicare.com/jc/mr/pap.html
- **These resource pages include:**
  - **Documentation Checklists**
    - Positive Airway Pressure (PAP) Accessories and Supplies
    - Positive Airway Pressure (PAP) Devices for the Treatment of OSA
  - FAQs
  - PAP Denial Help Aid
  - **"Dear Physician" Letters**

Local Coverage Determinations and Policy Articles

- Positive Airway Pressure (PAP) Devices for the Treatment of Obstructive Sleep Apnea
  - LCD (L33718): https://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?LCDId=33718&ContrID=140
  - Policy Article (A52467) https://www.cms.gov/medicare-coverage-database/details/article-details.aspx?articleId=52467&ContrID=140
- Standard Documentation Requirements for All Claims Submitted to DME MACs (A55426) https://www.cms.gov/medicare-coverage-database/details/article-details.aspx?articleid=55426
- Oxygen and Oxygen Equipment
  - LCD (L33797):https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?LCDId=33797&ContrID=140
  - Policy Article (A52514): https://www.cms.gov/medicare-coverage-database/view/article.aspx?articleid=52514&ver=40&

Related LCDs and Policy Articles

- Oral Appliances for Obstructive Sleep Apnea
  - LCD: https://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?LCDId=33611&ContrID=140
  - Policy Article: https://www.cms.gov/medicare-coverage-database/details/article-details.aspx?articleId=52512&ContrID=140
- Respiratory Assist Devices
  - LCD: https://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?LCDId=33800&ContrID=140
  - Policy Article: https://www.cms.gov/medicare-coverage-database/details/article-details.aspx?articleId=52517&ContrID=140

CGS Connect

- CGS Connect™ is available for:
  - CPAP (E0601)
  - CPAP Accessories (A7030/A7034)
- You may request clinical review of your pre-claim documentation.
- If the documentation review is being requested after the equipment has been delivered, CGS will respond in writing within 15 days.
- You will be notified that the documentation is either "supported" or "unsupported" and you will be provided with information about why the documentation didn't meet Medicare guidelines.
- If the documentation review is being requested before the equipment has been delivered, CGS will attempt to respond with a phone call and a letter within 10 days.
- JB: https://www.cgsmedicare.com/jb/mr/cgsconnect.html
- JC: https://www.cgsmedicare.com/jc/mr/cgsconnect.html

Jurisdiction B Resources

Interactive Voice Response (IVR) Unit:	1.877.299.7900
Customer Service:	1.866.590.6727 (Monday – Friday, 8:00 a.m. – 5:00 p.m. ET)
Telephone Reopenings:	1.844.240.7490 (Monday – Friday, 8:00 a.m. – 5:00 p.m. ET)
Paper Claim Submission:	CGS PO Box 20013 Nashville, TN 37202
Redetermination Requests, Adjustment Requests (Reopenings), EFT Form Submission, and Written Inquiries Address:	**FAX:** 1.616.660.5976 **Mail:** CGS PO Box 20007 Nashville, TN 37202
Overpayment Appeals:	**Fax:** 1.615.782.4514 **Mail:** CGS Overpayment Appeals PO Box 23070 Nashville, TN 37202
Paperwork (PWK) Segment Submission	**Fax:** 1.615.782.4511 **Mail:** CGS PO Box 20007 Nashville, TN 37202

Jurisdiction C Resources

Interactive Voice Response (IVR) Unit:	1.866.238.9650
Customer Service:	1.866.270.4909 (Monday – Friday, 7:00 a.m. – 5:00 p.m. CT)
Telephone Reopenings:	1.866.813.7878 (Monday – Friday, 7:00 a.m. – 5:00 p.m. CT)
Paper Claim Submission, Adjustment Requests (Reopenings), EFT Form Submission, and Written Inquiries Address:	CGS PO Box 20010 Nashville, TN 37202
Redetermination Requests:	**Fax:** 1.615.782.4630 **Mail:** CGS PO Box 20009 Nashville, TN 37202
Overpayment Appeals:	**Fax:** 1.615.664.5907 **Mail:** CGS Overpayment Appeals PO Box 23917 Nashville, TN 37202
Paperwork (PWK) Segment Submission	**Fax:** 1.615.664.5954 **Mail:** CGS PO Box 20010 Nashville, TN 37202

Other Contractor Resources

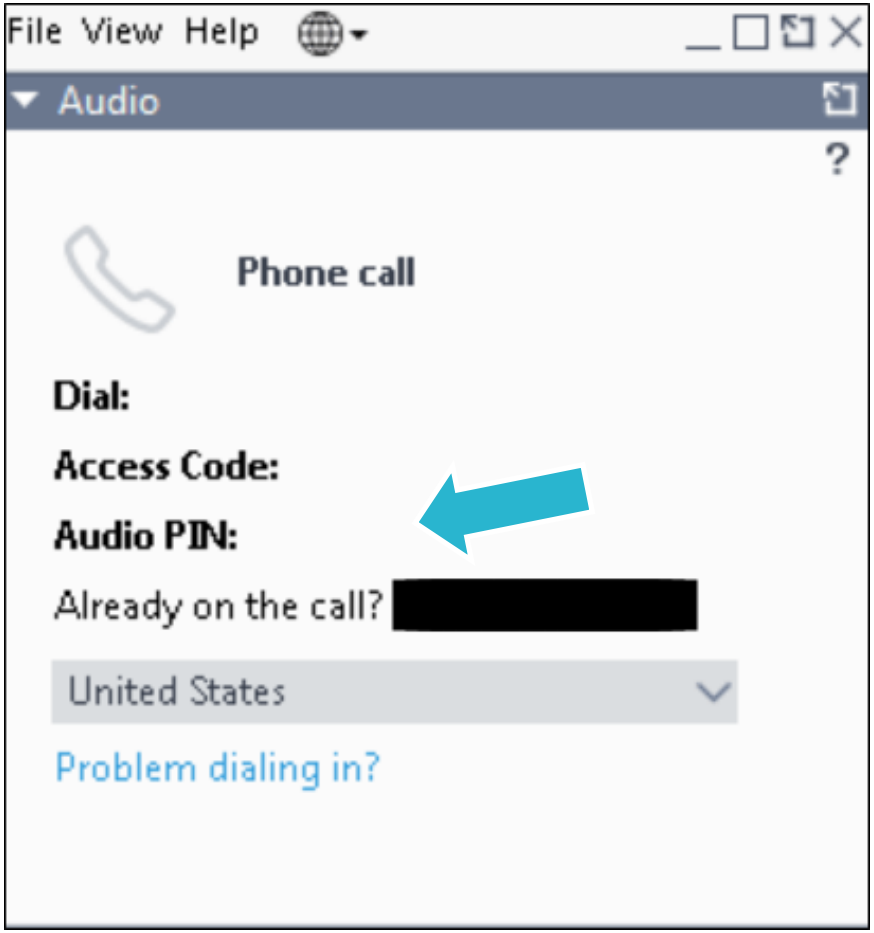
- **Pricing, Data Analysis, Coding (PDAC)**
  - 1.877.735.1326
  - https://www.dmepdac.com
- **National Supplier Clearinghouse (NSC)**
  - 1.866.238.9652
  - https://www.palmettogba.com/nsc
- **Common Electronic Data Interchange (CEDI)**
  - 1.866.311.9184
  - https://www.ngscedi.com
  - NGS.CEDIHelpdesk@anthem.com

CGS Electronic Mailing List

- **Stay up to date on DME MAC Jurisdictions B and C news!**
- Please sign up for the DME MAC Jurisdiction B or C Electronic Mailing List:
  - https://www.cgsmedicare.com/email.html
- Simply follow these steps:
  - Enter your email, first and last name, phone number, complete address and company.
  - You must select one or more Medicare contract email list.
  - Click **Sign Up.**

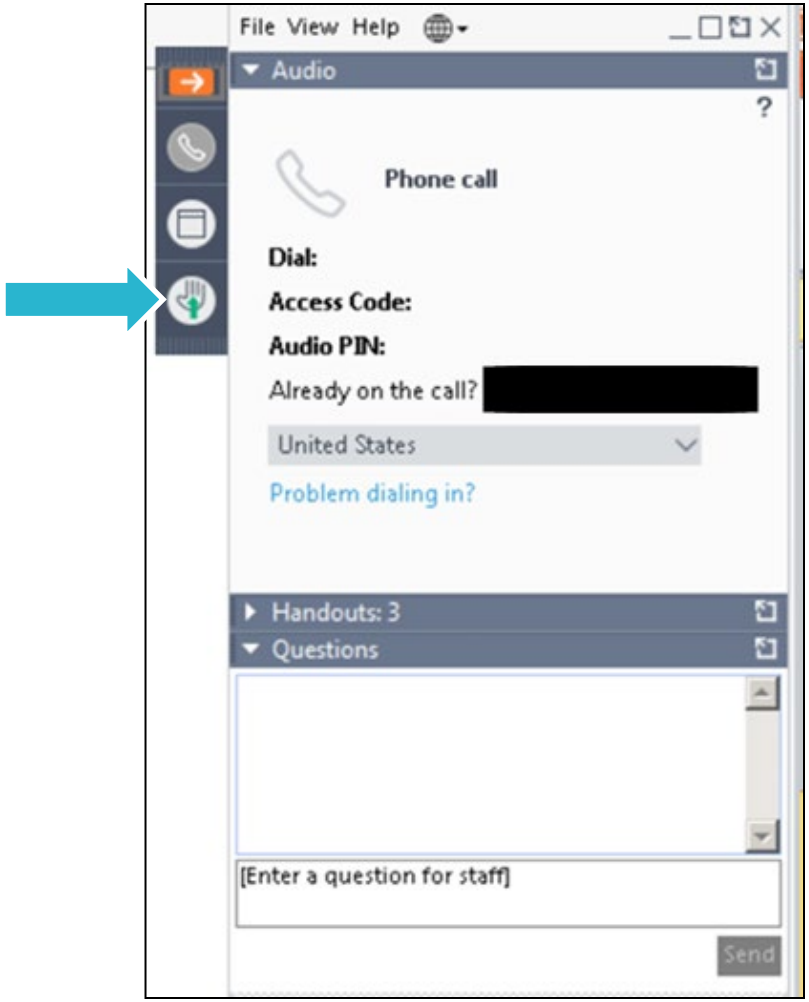
Questions?

How to Participate Today

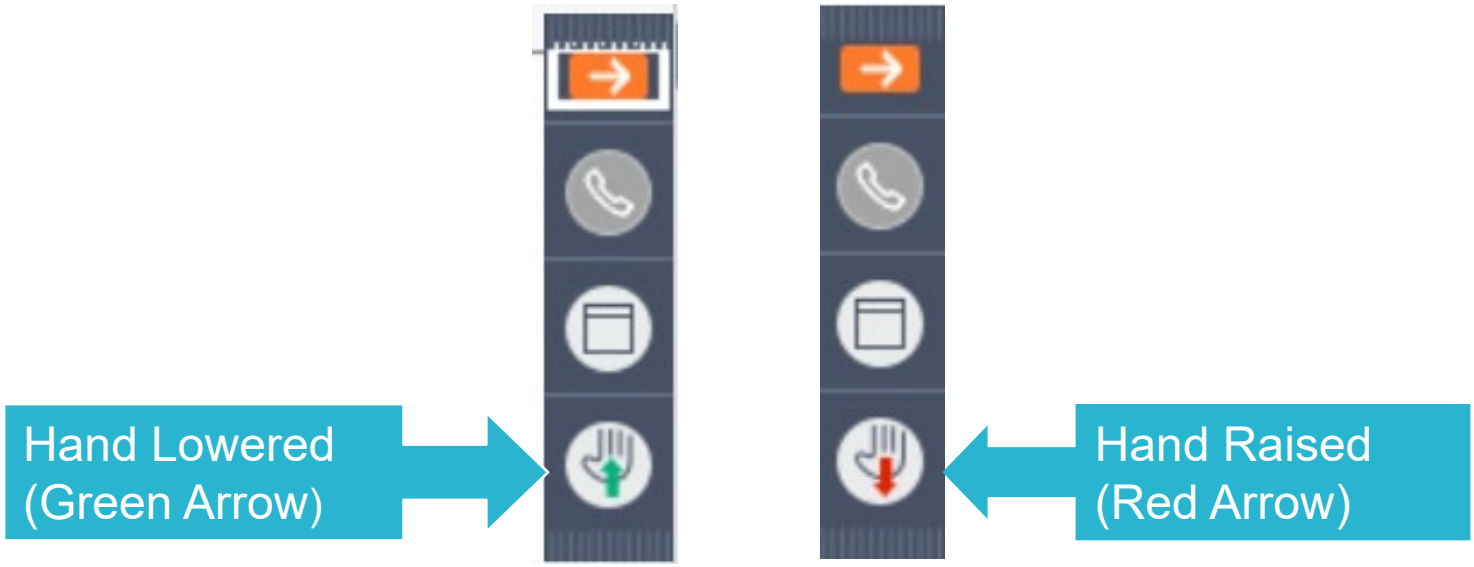


How to Participate Today

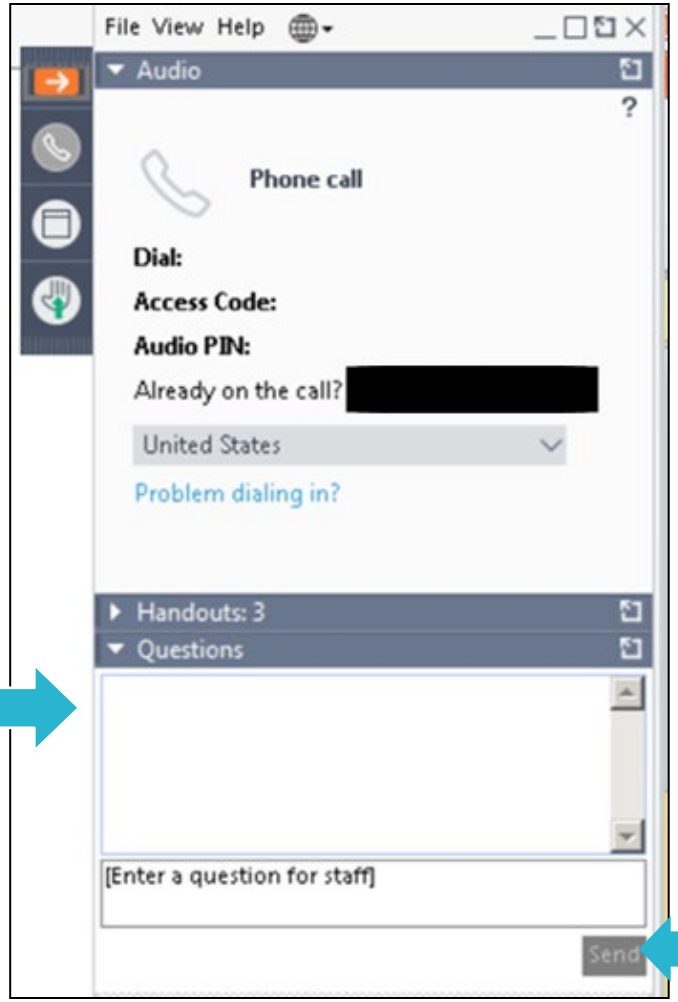
- To Ask a Verbal Question: Raise your hand
- The **Green Arrow** means your hand is not raised (Click to raise your hand)
- The **Red Arrow** means your hand is raised (Click to lower your hand)



To Ask a Question By Raising Your Hand



To Ask a Question
Using the Question Box



Type Question

Hit Send

Thank you for attending!