Nebulizers and Inhalation Medication

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

June 4, 2024

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Participants

- **CGS Administrators, LLC**
- **First Coast Service Options, Inc.**
- **National Government Services**
- **Noridian Healthcare Solutions, LLC**
- **Novitas Solutions**
- **Palmetto GBA**
- **WPS Government Health Administrators**

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Agenda

- Coverage Criteria
- Documentation Requirements
- Audit Data – Top CERT Errors
- Resources
- Questions

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Coverage Criteria

Nebulizers

Local Coverage Determination (LCD) L33370

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Coverage Criteria: Small Volume Nebulizers A7003-A7005

Approved Drugs	Medical Necessity	Codes
Albuterol, arformoterol, budesonide, cromolyn, formoterol, ipratropium, levalbuterol, metaproterenol, revefenacin	Obstructive pulmonary disease	Group 8
Dornase alfa	Cystic fibrosis	Group 9
Tobramycin	Cystic fibrosis Bronchiectasis	Group 10
Pentamidine	HIV, pneumocystosis, or organ transplants complications	Group 4
Acetylcysteine	Persistent thick or tenacious pulmonary secretions	Group 7

- Compressor E0570 can be used with any of the small volume nebulizers A7003 – A7005, for all the group codes in the chart.
- The LCD references “Group Code 3” for the E0570 because it is a combination of all the group codes above: 4, 7, 8 ,9, and 10

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Coverage Criteria: Large Volume Nebulizers

Covered HCPCS	Approved for	Medical Necessity	Codes
A7007, A7017: nebulizer **E0565, E0572**: compressor **A4217, A7018**: water or saline **E0585:** nebulizer w/compressor & heater	Humidity for thick, tenacious secretions	Cystic fibrosis Bronchiectasis Tracheostomy Tracheobronchial stent	Group 5
A7006: filtered nebulizer **E0565, E0572**: compressor	Pentamidine	HIV Pneumocystosis Organ transplant w/ complications	Group 1

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Coverage Criteria: E0574 Small Volume Ultrasonic

Claims for E0574 used with other inhalation solutions will be denied as not reasonable and necessary.

Covered HCPCS	Approved for	Medical Necessity	Codes
E0574: small volume, ultrasonic nebulizer and Related accessories	Treprostinil inhalation solution J7686	Pulmonary hypertension	Group 11

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Coverage Criteria: J7686 Treprostinil (1)

Considered for coverage when either criteria 1-3 are met; or criterion 4 is met:

1. Pulmonary artery hypertension (Group 11 Codes); and
2. Pulmonary hypertension not secondary to pulmonary venous hypertension (e.g., left sided atrial or ventricular disease, left sided valvular heart disease; or respiratory disorders other than interstitial lung disease (see criterion 4) (e.g., chronic obstructive pulmonary disease, obstructive sleep apnea or other sleep disordered breathing, alveolar hypoventilation disorders); and

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Coverage Criteria: J7686 Treprostinil(2)

3. Primary pulmonary hypertension or pulmonary hypertension secondary to **one** of the following: connective tissue disease, HIV infection, cirrhosis, anorexigens or congenital left-to-right shunts.

   - If these conditions are present, **all** the following criteria (a-d) must be met:

     a. Pulmonary hypertension has progressed despite maximal medical and/or surgical treatment of the identified condition; **and**

     b. The mean pulmonary artery pressure is > 25 mm Hg at rest or > 30 mm Hg with exertion; **and**

     c. The beneficiary has significant symptoms from the pulmonary hypertension (i.e., severe dyspnea on exertion, and either fatigability, angina, or syncope); **and**

     d. Treatment with oral calcium channel blocking agents has been tried and failed or has been considered and ruled out.

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Coverage Criteria: J7686 Treprostinil(3)

4. The beneficiary has a diagnosis of pulmonary hypertension associated with interstitial lung disease (Group 11 Codes) and **all** the following criteria (a-e) are met:

   a. Presence of interstitial lung disease confirmed by high-resolution CT scan of the chest; **and**

   b. Mean pulmonary artery pressure is ≥ 25mm Hg; **and**

   c. Pulmonary capillary wedge pressure or left ventricular end-diastolic pressure is ≤ 15mm Hg; **and**

   d. Pulmonary vascular resistance is ≥ 3 Wood Units at rest; **and**

   e. Significant symptoms of pulmonary hypertension (e.g., dyspnea on exertion, fatigability)

If the above criteria are not met (either* criteria 1-3 or criterion 4*), code E0574 and the related drug treprostinil will be denied as not reasonable and necessary.

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Coverage Criteria: K0730

A controlled-dose inhalation drug delivery system (K0730) is considered for coverage when:

- It is reasonable and necessary to administer iloprost (Q4074) to beneficiaries with pulmonary hypertension only (Group 14 Codes).
- Claims for code K0730 for use with other inhalation solutions will be denied as not reasonable and necessary.
- If all the criteria listed in the LCD are not met, code K0730 and the related drug Q4074 will be denied as not reasonable and necessary.

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Coverage Criteria: Q4074 Iloprost (1)

Considered for coverage when all the following criteria 1-3 are met:

1. The beneficiary has a diagnosis of pulmonary artery hypertension (Group 14 Codes); **and**
2. Pulmonary hypertension not secondary to pulmonary venous hypertension, or respiratory system disorders (e.g., chronic obstructive pulmonary disease, interstitial lung disease, obstructive sleep apnea or other sleep disordered breathing, alveolar hypoventilation disorders); **and**

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Coverage Criteria: Q4074 Iloprost (2)

3. The beneficiary has primary pulmonary hypertension or pulmonary hypertension secondary to one of the following conditions: connective tissue disease, HIV infection, cirrhosis, anorexigens or congenital left to right shunts. If these conditions are present, then all the following criteria (a-d) must be met:

   a. Pulmonary hypertension has progressed despite maximal medical and/or surgical treatment of the identified condition; and

   b. Mean pulmonary artery pressure is > 25 mm Hg at rest or > 30 mm Hg with exertion; and

   c. Beneficiary has significant symptoms from pulmonary hypertension (i.e., severe dyspnea on exertion, and either fatigability, angina, or syncope); and

   d. Treatment with oral calcium channel blocking agents has been tried and failed or has been considered and ruled out

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Coverage Criteria: E0575 Large Volume Ultrasonic

A large volume ultrasonic nebulizer (E0575) offers no proven clinical advantage over a pneumatic compressor and nebulizer and will be denied as not reasonable and necessary.

For all inhalation medications in the Nebulizers LCD:

- If the drugs used with nebulizer are not covered, the nebulizer, compressor, and other related accessories/supplies will be denied as not reasonable and necessary.

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Coverage Criteria: Accessories

Accessories are separately payable if the related compressor and accessories are reasonable and necessary.

- The following table lists the compressor/generator, which is related to the accessories described:

Compressor/Generator	Related Accessories
E0565	A4619, A7006, A7007, A7010, A7012, A7013, A7014, A7015, A7017, A7525, E1372
E0570	A7003, A7004, A7005, A7006, A7013, A7015, A7525
E0572	A7006, A7007, A7014, A7017
E0574	A7013, A7014, A7016
E0585	A4619, A7006, A7010, A7012, A7013, A7014, A7015, A7525
K0730	A7005

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Accessories and Frequencies

- **A4619**: 1 per month
- **A7003:** 2 per month
- **A7004:** 2 per month
  - *in addition to A7003*
- **A7005:** 1 per 6 months
- **A7005:** 1 per 3 months
  - *only with K0730*
- **A7006:** 1 per month
- **A7007:** 2 per month
- **A7010:** 1 unit per 2 months
- **A7012:** 2 per month
- **A7013:** 2 per month
- **A7014**: 1 per 3 months
- **A7015**: 1 per month
- **A7016**: 2 per year
- **A7017**: 1 per 3 years
- **A7525**: 1 per month
- **E1372**: 1 per 3 years

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Inhalation Drugs and Solutions

- **Acetylcysteine**
  - up to 74 g/month
- **Albuterol**
  - up to 465 mg/ month*
- **Albuterol/Ipratropium combination**
  - up to 186 units/month*
- **Arformoterol**
  - up to 930 mcg/month – 62 units/month
- **Budesonide**
  - up to 62 units/month
- **Cromolyn sodium**
  - up to 2480 mg/month
- **Dornase alfa**
  - up to 78 mg/month
- **Formoterol**
  - up to 1240 mcg/month – 62 units/month
- **Ipratroprium bromide**
  - up to 93mg/month
- **Levalbuterol**
  - up to 232.5 mg/month – 465 units/month *****
- **Metaproterenol**
  - up to 2800 mg/month – 280 units/month *
- **Pentamidine**
  - up to 300 mg/month
- **Revefenacin**
  - 5250 mcg/month
- **Treprostinil**
  - up to 31 units/month
- **Sterile saline or water, 10ml/unit (A4216, A4218)**
  - up to 56 units/month
- **Distilled water, sterile water, or sterile saline in large volume nebulizer**
  - up to 18 liters/month

see exceptions on the next slide

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Inhalation Drugs and Solutions

- When albuterol, levalbuterol, or metaproterenol are prescribed as rescue/supplemental medication for beneficiaries who are taking formoterol or arformoterol, the maximum milligrams/month that are reasonably billed are:

Inhalation Drugs and Solutions	Maximum Milligrams/Month
Albuterol	78 mg/month
Albuterol/Ipratroprium combination	31 units/month
Levalbuterol	39 mg/month – 78 units/month
Metaproterenol	470 mg/month – 47 units/month

- Claims for more than these amounts of drugs will be denied as not reasonable and necessary.

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Coverage Criteria Notes(1)

- When a "concentrated form" of an inhalation drug is covered, separate saline solution (A4216 or A4218 [metered dose]) used to dilute it will be separately reimbursed.
  - Saline dispensed for the dilution of concentrated nebulizer drugs must be billed on the same claim as the drug(s) being diluted.
- Albuterol, levalbuterol, or metaproterenol is covered if it is used as a rescue/supplemental medication in addition to the long-acting beta-adrenergic agonist drug, formoterol or arformoterol.
- **NOTE: Compounded inhalation solutions and compounded solutions billed with J7699 will be denied as not reasonable and necessary**.

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Coverage Criteria Notes(2)

- Albuterol, levalbuterol, and metaproterenol are all short-acting bronchodilators with beta-adrenergic stimulatory effect.
  - It is not reasonable and necessary for a beneficiary to use more than one of these at a time.
  - The use of more than one of these drugs at the same time will be denied as not reasonable and necessary.
- Revefenacin is a long-acting muscarinic antagonist. If a long-acting muscarinic antagonist (revefenacin) is used, the short-acting muscarinic antagonist (ipratropium bromide) will be denied as not reasonable and necessary.

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New ICD-10 Codes

Revision Effective Date: 10/01/2023

ICD-10-CM CODES THAT SUPPORT MEDICAL NECESSITY

Added ICD-10 Codes:	To Groups:
J12.82, U07.1 and U09.9	3, 8, 12
J15.61 and J15.69	2, 3, 7, 12, and 13
J44.81 and J44.89	2, 3, 6, 7, 8, 12, and 13

Removed ICD-10 Codes:	From Groups:
J15.6	2, 3, 7, 12, and 13

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Non-Coverage

- Large volume pneumatic nebulizer (E0580) and water or saline (A4217 or A7018) are not separately payable when used with oxygen equipment.
- If a large volume nebulizer, related compressor/generator, and water or saline are used predominantly to provide room humidification, the item(s) will be denied as noncovered.
- Prefilled disposable large volume nebulizer (A7008) is noncovered under the Durable Medical Equipment (DME) benefit because it is a convenience item.
- Kits and concentrates for use in cleaning respiratory equipment will be denied as noncovered.
- Disposable equipment or equipment in which a major component required for their function is disposable do not meet the definition of durable medical equipment and must be billed using code A9270 (noncovered item or service).

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Documentation Requirements

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Medical Record Documentation

Medical Records:

- Treating physician/practitioner office notes
- Hospital notes/records
- Nursing facilities records
- Home health records
- Other health care professionals without financial motive

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Reasonable and Necessary

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Continued Need Documentation

Acceptable Examples
▪ A recent order by the treating physician/practitioner for refills
▪ Recent order by treating practitioner for repairs
▪ A recent change in prescription
▪ Timely documentation in the medical record showing usage of items

TIMELY: Within the preceding 12 months

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Continued Use Documentation

Acceptable Examples
▪ Timely documentation in the medical record showing usage of items
▪ Supplier records documenting requests for refill/replacement
▪ Supplier records documenting beneficiary's confirmation of continued use of a rental item

TIMELY: Within the preceding 12 months

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Standard Written Order (SWO)

- Beneficiary's name or Medicare Beneficiary Identifier (MBI)
- Order Date
- General description of the item
  - Can be either a general description (e.g., nebulizer), 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

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SWO Quantity

- Base items do not require quantity unless ordering more than one
- Quantity to be dispensed is required for items provided on a periodic basis
  - Accessories and supplies
    - Examples: 120 per month, 2 boxes, etc.
  - Drugs
    - Must indicate the amount prescribed
      - » Examples: 31 units per month and as needed, 465 mg per month, etc.

Quantity to be dispensed ≠ **Total # of units per refill**
"Per month" or "30 days"

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SWO and Frequency

Frequency of use is not required on the Standard Written Order.

- However, if audited, the medical records must support the frequency provided and billed.

Frequency of use ≠ **Daily usage**
"every 4 hours" or "4 per day"

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New Order Requirements

New prescription (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

Note: Be aware of state law/statute requirements

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Proof of Delivery (POD): Direct to Beneficiary

- Delivery slip must include:
  - Beneficiary's name
  - Delivery address
  - Sufficiently detailed description to identify the item(s) being delivered, narrative description, brand name/model number, HCPCS code, or long narrative HCPCS description
  - Quantity delivered
  - Date delivered
  - Beneficiary (or designee) signature

Date of Service
=
Date of Delivery

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POD: Shipping or Delivery Service(1)

- The POD must include:
  - Beneficiary's name
  - Delivery address
  - Delivery service's package identification number, supplier invoice number, or alternative method that links the supplier's delivery documents with the delivery service's records
  - A description of the item(s) being delivered. The description can be either a narrative description (e.g., lightweight wheelchair base), a HCPCS code, the long description of a HCPCS code, or a brand name/model number
  - Quantity delivered
  - Date delivered
  - Evidence of delivery

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POD: Shipping or Delivery Service(2)

Two options for the date of service (DOS) 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.
    - Note: 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
or
Date of Delivery

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POD: Retained From a Prior Payer

POD is required for all items, even those in the beneficiary's possession provided by another insurer prior to Medicare eligibility

- Suppliers may utilize the standard delivery template used for other DMEPOS items; or,
- POD can be satisfied in the form of:
  - A statement, signed and dated by the beneficiary (or beneficiary's designee), that the supplier has examined the item; and
  - A supplier attestation that the item meets Medicare requirements.

Date of Service
=
1st day of the 1st rental month in which Medicare payments are made for the item

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Refill Requests: Final Rule CMS1780-F

Final Rule CMS1780-F: https://www.cms.gov/medicare/medicare-fee-service-payment/homehealthpps/home-health-prospective-payment-system/cms-1780-f:

- **For refill requests on or after January 1, 2024:**
  - **Suppliers must obtain documentation of beneficiary's affirmative response indicating a need for the refill**
    - Removed: Suppliers must document quantity/functional condition of each item remaining
  - **Suppliers must document the beneficiary has confirmed their need for refill no sooner than 30 calendar days prior to the expected end of the current supply**
    - Removed: Contact with the beneficiary or designee regarding refills must take place no sooner than 14 calendar days prior to the delivery/shipping date

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Refill Documentation Requirements: Final Rule CMS1780-F

Refill Documentation Requirements for dates of service **on or after** January 1, 2024

Obtained In Person @ Retail Store	**Delivered Refill Communications**
Signed delivery slip or copy of itemized sales receipt	Beneficiary name and/or authorized representative *(Suggested: if someone other than the beneficiary include this person's relationship to the beneficiary)*
Delivery slip/receipt should indicate items were picked up at store front	
	Date of Request
	Description of each item requested
	Documentation of affirmative response indicating a need for the refill
	Contact must occur no sooner than 30 calendar days prior to the expected end of the current supply
	Shipment/delivery occur no sooner than 10 calendar days prior to expected end of current supply

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Top CERT Errors

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CERT Error Rates for 2023

The 2023 CERT Improper Payment Data Report

- The overall DMEPOS CERT Error Rate was **22.5%**
- The overall projected improper payment amount **$1.9 Billion**

Nebulizers, accessories and related inhalation drugs had an improper payment error rate of 13.2% for 2023.

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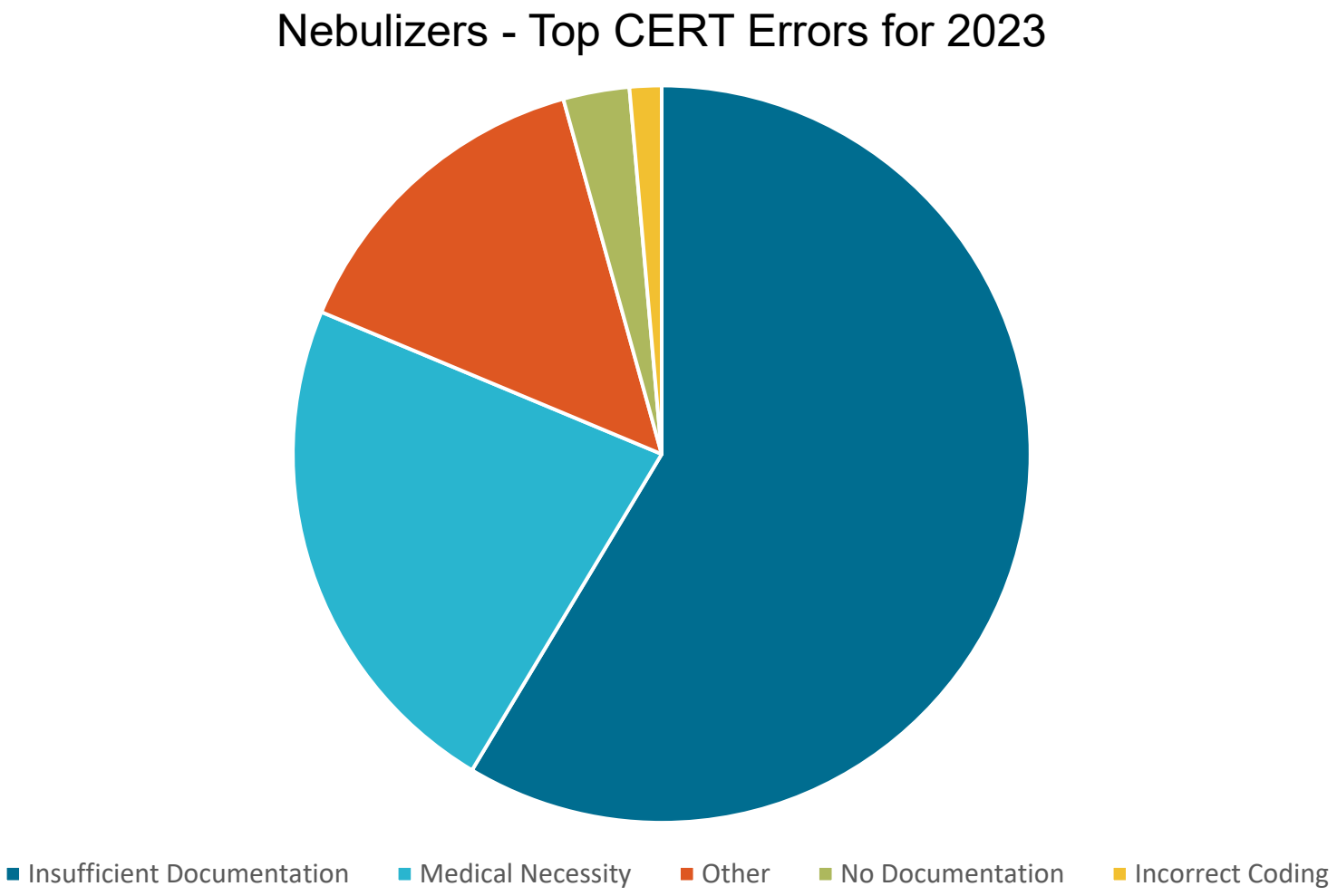
CERT
Improper Payment Rates by Type of Error



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Thank you for attending!

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