

# Local Coverage Determination (LCD): Respiratory Assist Devices (L33800)

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## Contractor Information

CONTRACTOR NAME	CONTRACT TYPE	CONTRACT NUMBER	JURISDICTION	STATE(S)
CGS Administrators, LLC	DME MAC	17013 - DME MAC	J-B	Illinois Indiana Kentucky Michigan Minnesota Ohio Wisconsin
CGS Administrators, LLC	DME MAC	18003 - DME MAC	J-C	Alabama Arkansas Colorado Florida Georgia Louisiana Mississippi New Mexico North Carolina Oklahoma Puerto Rico South Carolina Tennessee Texas Virgin Islands Virginia West Virginia
Noridian Healthcare Solutions, LLC	DME MAC	16013 - DME MAC	J-A	Connecticut Delaware District of Columbia Maine Maryland Massachusetts New Hampshire New Jersey New York - Entire State Pennsylvania Rhode Island Vermont

CONTRACTOR NAME	CONTRACT TYPE	CONTRACT NUMBER	JURISDICTION	STATE(S)
Noridian Healthcare Solutions, LLC	DME MAC	19003 - DME MAC	J-D	Alaska American Samoa Arizona California - Entire State Guam Hawaii Idaho Iowa Kansas Missouri - Entire State Montana Nebraska Nevada North Dakota Northern Mariana Islands Oregon South Dakota Utah Washington Wyoming

## LCD Information

### Document Information

**LCD ID**

L33800

**Original Effective Date**

For services performed on or after 10/01/2015

**LCD Title**

Respiratory Assist Devices

**Revision Effective Date**

For services performed on or after 01/01/2020

**Proposed LCD in Comment Period**

N/A

**Revision Ending Date**

N/A

**Source Proposed LCD**

N/A

**Retirement Date**

N/A

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**Notice Period Start Date**

N/A

**Notice Period End Date**

N/A

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## **CMS National Coverage Policy**

N/A

### **Coverage Guidance**

#### **Coverage Indications, Limitations, and/or Medical Necessity**

For any item to be covered by Medicare, it must 1) be eligible for a defined Medicare benefit category, 2) be reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member, and 3) meet all other applicable Medicare statutory and regulatory requirements.

The purpose of a Local Coverage Determination (LCD) is to provide information regarding “reasonable and necessary” criteria based on Social Security Act § 1862(a)(1)(A) provisions.

In addition to the “reasonable and necessary” criteria contained in this LCD there are other payment rules, which are discussed in the following documents, that must also be met prior to Medicare reimbursement:

- The LCD-related Standard Documentation Requirements Article, located at the bottom of this policy under the Related Local Coverage Documents section.

- The LCD-related Policy Article, located at the bottom of this policy under the Related Local Coverage Documents section.
- Refer to the Supplier Manual for additional information on documentation requirements.
- Refer to the DME MAC web sites for additional bulletin articles and other publications related to this LCD.

For the items addressed in this LCD, the "reasonable and necessary" criteria, based on Social Security Act § 1862(a)(1)(A) provisions, are defined by the following coverage indications, limitations and/or medical necessity.

## DEFINITIONS

For purposes of this policy the following definitions are used:

- FIO2 is the fractional concentration of oxygen delivered to the beneficiary for inspiration. The beneficiary's prescribed FIO2 refers to the oxygen concentration the beneficiary normally breathes when not undergoing testing to qualify for coverage of a Respiratory Assist Device (RAD). That is, if the beneficiary does not normally use supplemental oxygen, their prescribed FIO2 is that found in room air.
- FEV1 is the forced expired volume in 1 second.
- FVC is the forced vital capacity.
- Central sleep apnea (CSA) is defined by all of the following:
  - An apnea-hypopnea index (AHI) greater than or equal to 5; and
  - The sum total of central apneas plus central hypopneas is greater than 50% of the total apneas and hypopneas; and
  - A central apnea-central hypopnea index (CAHI) is greater than or equal to 5 per hour; and
  - The presence of at least one of the following:
    - Sleepiness
    - Difficulty initiating or maintaining sleep, frequent awakenings, or non-restorative sleep
    - Awakening short of breath
    - Snoring
    - Witnessed apneas
  - There is no evidence of daytime or nocturnal hypoventilation
- Complex sleep apnea (CompSA) is a form of central apnea specifically identified by all of the following:
  1. With use of a positive airway pressure device without a backup rate (E0601 or E0470), the polysomnogram (PSG) shows a pattern of apneas and hypopneas that demonstrates the persistence or emergence of central apneas or central hypopneas upon exposure to CPAP (E0601) or a bi-level device without backup rate (E0470) device when titrated to the point where obstructive events have been effectively treated (obstructive AHI less than 5 per hour).
  2. After resolution of the obstructive events, the sum total of central apneas plus central hypopneas is greater than 50% of the total apneas and hypopneas; and
  3. After resolution of the obstructive events, a central apnea-central hypopnea index (CAHI) greater than or equal to 5 per hour.

- Apnea is defined as the cessation of airflow for at least 10 seconds.
- Hypopnea is defined as an abnormal respiratory event lasting at least 10 seconds associated with at least a 30% reduction in thoracoabdominal movement or airflow as compared to baseline, and with at least a 4% decrease in oxygen saturation.
- The apnea-hypopnea index (AHI) is defined as the average number of episodes of apnea and hypopnea per hour of sleep without the use of a positive airway pressure device.
- For diagnosis of CSA, the central apnea-central hypopnea index (CAHI) is defined as the average number of episodes of central apnea and central hypopnea per hour of sleep without the use of a positive airway pressure device. For CompSA, the CAHI is determined during the use of a positive airway pressure device after obstructive events have disappeared.
- If the AHI or CAHI is calculated based on less than 2 hours of continuous recorded sleep, the total number of recorded events used to calculate the AHI or CAHI must be at least the number of events that would have been required in a 2-hour period (i.e., greater than or equal to 10 events).
- See the Sleep Tests section below for a discussion of (PSG) and portable home sleep testing (HST).
- If there is discontinuation of usage of an E0470 or E0471 device at any time, the supplier is expected to ascertain this, and stop billing for the equipment and related accessories and supplies.

#### INITIAL COVERAGE CRITERIA FOR E0470 AND E0471 DEVICES FOR THE FIRST THREE MONTHS OF THERAPY:

For an E0470 or an E0471 RAD to be covered, the treating practitioner must fully document in the beneficiary's medical record symptoms characteristic of sleep-associated hypoventilation, such as daytime hypersomnolence, excessive fatigue, morning headache, cognitive dysfunction, dyspnea, etc.

A RAD (E0470, E0471) is covered for those beneficiaries with one of the following clinical disorders: restrictive thoracic disorders (i.e., neuromuscular diseases or severe thoracic cage abnormalities), severe chronic obstructive pulmonary disease (COPD), CSA or CompSA, or hypoventilation syndrome, as described in the following section.

#### Restrictive Thoracic Disorders

An E0470 or E0471 device is covered when criteria A – C are met.

- A. There is documentation in the beneficiary's medical record of a neuromuscular disease (for example, amyotrophic lateral sclerosis) or a severe thoracic cage abnormality (for example, post-thoracoplasty for TB).
- B. One of the following:
  - a. An arterial blood gas PaCO<sub>2</sub>, done while awake and breathing the beneficiary's prescribed FIO<sub>2</sub> is greater than or equal to 45 mm Hg, or
  - b. Sleep oximetry demonstrates oxygen saturation less than or equal to 88% for greater than or equal to 5 minutes of nocturnal recording time (minimum recording time of 2 hours), done while breathing the beneficiary's prescribed recommended FIO<sub>2</sub>, or
  - c. For a neuromuscular disease (only), either i or ii,
    - i. Maximal inspiratory pressure is less than 60 cm H<sub>2</sub>O, or
    - ii. Forced vital capacity is less than 50% predicted

C. Chronic obstructive pulmonary disease does not contribute significantly to the beneficiary's pulmonary limitation.

If all of the above criteria are met, either an E0470 or an E0471 device (based upon the judgment of the treating practitioner) will be covered for the first three months of therapy.

If all of the above criteria are not met, then E0470 or E0471 and related accessories will be denied as not reasonable and necessary.

See CONTINUED COVERAGE CRITERIA FOR E0470 AND E0471 DEVICES BEYOND THE FIRST THREE MONTHS for information on more than three months use.

#### Severe COPD

An E0470 device is covered if criteria A - C are met.

- A. An arterial blood gas PaCO<sub>2</sub>, done while awake and breathing the beneficiary's prescribed FIO<sub>2</sub>, is greater than or equal to 52 mm Hg.
- B. Sleep oximetry demonstrates oxygen saturation less than or equal to 88% for greater than or equal to a cumulative 5 minutes of nocturnal recording time (minimum recording time of 2 hours), done while breathing oxygen at 2 LPM or the beneficiary's prescribed FIO<sub>2</sub> (whichever is higher).
- C. Prior to initiating therapy, sleep apnea and treatment with a continuous positive airway pressure device (CPAP) has been considered and ruled out. (Note: Formal sleep testing is not required if there is sufficient information in the medical record to demonstrate that the beneficiary does not suffer from some form of sleep apnea (Obstructive Sleep Apnea (OSA), CSA and/or CompSA) as the predominant cause of awake hypercapnia or nocturnal arterial oxygen desaturation).

If all of the above criteria for beneficiaries with COPD are met, an E0470 device will be covered for the first three months of therapy.

If all of the above criteria are not met, E0470 and related accessories will be denied as not reasonable and necessary.

An E0471 device will be covered for a beneficiary with COPD in either of the two situations below, depending on the testing performed to demonstrate the need.

Situation 1. For Group II beneficiaries (COPD) who qualified for an E0470 device, an E0471 started any time after a period of initial use of an E0470 device is covered if both criteria A and B are met.

- A. An arterial blood gas PaCO<sub>2</sub>, done while awake and breathing the beneficiary's prescribed FIO<sub>2</sub>, shows that the beneficiary's PaCO<sub>2</sub> worsens greater than or equal to 7 mm HG compared to the original result from criterion A, (above).
- B. A facility-based PSG demonstrates oxygen saturation less than or equal to 88% for greater than or equal to a cumulative 5 minutes of nocturnal recording time (minimum recording time of 2 hours) while using an E0470 device that is not caused by obstructive upper airway events – i.e., AHI less than 5. (Refer to the Positive Airway Pressure Devices LCD for information about E0470 coverage for obstructive sleep apnea).

Situation 2. For Group II beneficiaries (COPD) who qualified for an E0470 device, an E0471 device will be covered if, at a time no sooner than 61 days after initial issue of the E0470 device, both of the following criteria A and B are met:

- A. An arterial blood gas PaCO<sub>2</sub> is done while awake and breathing the beneficiary's prescribed FIO<sub>2</sub>, still remains greater than or equal to 52 mm Hg.
- B. Sleep oximetry while breathing with the E0470 device, demonstrates oxygen saturation less than or equal to 88% for greater than or equal to a cumulative 5 minutes of nocturnal recording time (minimum recording time of 2 hours), done while breathing oxygen at 2 LPM or the beneficiary's prescribed FIO<sub>2</sub> [whichever is higher].

If E0471 is billed but the criteria described in either situation 1 or 2 are not met, it will be denied as not reasonable and necessary.

See CONTINUED COVERAGE CRITERIA FOR E0470 AND E0471 DEVICES BEYOND THE FIRST THREE MONTHS for information on more than three months use.

### Central Sleep Apnea or Complex Sleep Apnea

An E0470 or E0471 device is covered when, prior to initiating therapy, a complete facility-based, attended PSG is performed documenting the following (A and B):

- A. The diagnosis of CSA or CompSA; and
- B. Significant improvement of the sleep-associated hypoventilation with the use of an E0470 or E0471 device on the settings that will be prescribed for initial use at home, while breathing the beneficiary's prescribed FIO<sub>2</sub>.

If all of the above criteria are met, either an E0470 or an E0471 device (based upon the judgment of the treating practitioner) will be covered for beneficiaries with documented CSA or CompSA for the first three months of therapy.

If all of the above criteria are not met, then E0470 or E0471 and related accessories will be denied as not reasonable and necessary.

See CONTINUED COVERAGE CRITERIA FOR E0470 AND E0471 DEVICES BEYOND THE FIRST THREE MONTHS for information on more than three months use.

### Hypoventilation Syndrome

An E0470 device is covered if both criteria A and B and either criterion C or D are met.

- A. An initial arterial blood gas PaCO<sub>2</sub>, done while awake and breathing the beneficiary's prescribed FIO<sub>2</sub>, is greater than or equal to 45 mm Hg
- B. Spirometry shows an FEV<sub>1</sub>/FVC greater than or equal to 70%. (Refer to SEVERE COPD (above) for information about device coverage for beneficiaries with FEV<sub>1</sub>/FVC less than 70%.)
- C. An arterial blood gas PaCO<sub>2</sub>, done during sleep or immediately upon awakening, and breathing the beneficiary's prescribed FIO<sub>2</sub>, shows the beneficiary's PaCO<sub>2</sub> worsened greater than or equal to 7 mm HG compared to the original result in criterion A (above).
- D. A facility-based PSG or HST demonstrates oxygen saturation less than or equal to 88% for greater than or

equal to 5 minutes of nocturnal recording time (minimum recording time of 2 hours) that is not caused by obstructive upper airway events – i.e., AHI less than 5. (Refer to the Positive Airway Pressure Devices LCD for information about E0470 coverage for obstructive sleep apnea.)

If the above criteria are not met, E0470 and related accessories will be denied as not reasonable and necessary.

An E0471 device is covered for a beneficiary with hypoventilation syndrome if both criteria A, B, and either criterion C or D are met:

- A. A covered E0470 device is being used.
- B. Spirometry shows an FEV1/FVC greater than or equal to 70%. (Refer to SEVERE COPD (above) for information about device coverage for beneficiaries with FEV1/FVC less than 70%).
- C. An arterial blood gas PaCO<sub>2</sub>, done while awake, and breathing the beneficiary's prescribed FIO<sub>2</sub>, shows that the beneficiary's PaCO<sub>2</sub> worsens greater than or equal to 7 mm HG compared to the ABG result performed to qualify the beneficiary for the E0470 device (criterion A under E0470).
- D. A facility-based PSG or HST demonstrates oxygen saturation less than or equal 88% for greater than or equal to 5 minutes of nocturnal recording time (minimum recording time of 2 hours) that is not caused by obstructive upper airway events – i.e., AHI less than 5 while using an E0470 device. (Refer to the Positive Airway Pressure Devices LCD for information about E0470 coverage for obstructive sleep apnea.)

If the criteria above are not met, an E0471 device will be denied as not reasonable and necessary.

See CONTINUED COVERAGE CRITERIA FOR E0470 AND E0471 DEVICES BEYOND THE FIRST THREE MONTHS for information on more than three months use.

#### VENTILATOR WITH NOINVASIVE INTERFACES

The Centers for Medicare & Medicaid Services (CMS) National Coverage Determinations Manual (Internet-Only Manual, Publ. 100-03) in Chapter 1, Part 4, Section 280.1 stipulates that ventilators (E0465, E0466) are covered for the following conditions:

“[N]euromuscular diseases, thoracic restrictive diseases, and chronic respiratory failure consequent to chronic obstructive pulmonary disease.”

Each of these disease categories are comprised of conditions that can vary from severe and life-threatening to less serious forms. These ventilator-related disease groups overlap conditions described in this Respiratory Assist Devices LCD used to determine coverage for bi-level PAP devices. Each of these disease categories are conditions where the specific presentation of the disease can vary from patient to patient. For conditions such as these, the specific treatment plan for any individual patient will vary as well. Choice of an appropriate treatment plan, including the determination to use a ventilator vs. a bi-level PAP device, is made based upon the specifics of each individual beneficiary's medical condition. In the event of a claim review, there must be sufficient detailed information in the medical record to justify the treatment selected.

Ventilators 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)) This means that products currently classified as HCPCS code E0465 or E0466 when used to provide CPAP or bi-level PAP (with or



without backup rate) therapy, regardless of the underlying medical condition, shall not be paid in the FSS payment category. A ventilator is not eligible for reimbursement for any of the conditions described in this RAD LCD even though the ventilator equipment may have the capability of operating in a bi-level PAP (E0470, E0471) mode. Claims for ventilators used to provide CPAP or bi-level CPAP therapy for conditions described in this RAD policy will be denied as not reasonable and necessary.

General principles of correct coding require that products assigned to a specific HCPCS code only be billed using the assigned code. Thus, using the HCPCS codes for CPAP (E0601) or bi-level PAP (E0470, E0471) devices for a ventilator (E0465, E0466) used to provide CPAP or bi-level PAP therapy is incorrect coding. Claims for ventilators billed using the CPAP or bi-level PAP device HCPCS codes will be denied as incorrect coding.

#### CONTINUED COVERAGE CRITERIA FOR E0470 AND E0471 DEVICES BEYOND THE FIRST THREE MONTHS OF THERAPY

Beneficiaries covered for the first three months of an E0470 or an E0471 device must be re-evaluated to establish the medical necessity of continued coverage by Medicare beyond the first three months. While the beneficiary may certainly need to be evaluated at earlier intervals after this therapy is initiated, the re-evaluation upon which Medicare will base a decision to continue coverage beyond this time must occur no sooner than 61 days after initiating therapy by the treating practitioner. Medicare will not continue coverage for the fourth and succeeding months of therapy until this re-evaluation has been completed.

There must be documentation in the beneficiary's medical record about the progress of relevant symptoms and beneficiary usage of the device up to that time. Failure of the beneficiary to be consistently using the E0470 or E0471 device for an average of 4 hours per 24 hour period by the time of the re-evaluation (on or after 61 days after initiation of therapy) would represent non-compliant utilization for the intended purposes and expectations of benefit of this therapy. This would constitute reason for Medicare to deny continued coverage as not reasonable and necessary.

A signed and dated statement completed by the treating practitioner no sooner than 61 days after initiating use of the device, declaring that the beneficiary is compliantly using the device (an average of 4 hours per 24 hour period) and that the beneficiary is benefiting from its use must be obtained by the supplier of the device for continued coverage beyond three months.

If the above criteria are not met, continued coverage of an E0470 or an E0471 device and related accessories will be denied as not reasonable and necessary.

#### ACCESSORIES

The following table represents the usual maximum amount of accessories expected to be reasonable and necessary:

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

Billing for quantities of supplies greater than those described in the policy as the usual maximum amounts, will be denied as not reasonable and necessary.

Either a non-heated (E0561) or heated (E0562) humidifier is covered and paid separately when ordered by the treating practitioner for use with a covered E0470 or E0471 RAD.

#### GENERAL

A Standard Written Order (SWO) must be communicated to the supplier before a claim is submitted. If the supplier bills for an item addressed in this policy without first receiving a completed SWO, the claim shall be denied as not reasonable and necessary.

For Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) base items that require a Written Order Prior to Delivery (WOPD), the supplier must have received a signed SWO before the DMEPOS item is delivered to a beneficiary. If a supplier delivers a DMEPOS item without first receiving a WOPD, the claim shall be denied as not reasonable and necessary. Refer to the LCD-related Policy Article, located at the bottom of this policy under the Related Local Coverage Documents section.

For DMEPOS base items that require a WOPD, and also require separately billed associated options, accessories, and/or supplies, the supplier must have received a WOPD which lists the base item and which may list all the associated options, accessories, and/or supplies that are separately billed prior to the delivery of the items. In this scenario, if the supplier separately bills for associated options, accessories, and/or supplies without first receiving a completed and signed WOPD of the base item prior to delivery, the claim(s) shall be denied as not reasonable and necessary.

An item/service is correctly coded when it meets all the coding guidelines listed in CMS HCPCS guidelines, LCDs, LCD-related Policy Articles, or DME MAC articles. Claims that do not meet coding guidelines shall be denied as not reasonable and necessary/incorrectly coded.

Proof of delivery (POD) is a Supplier Standard and DMEPOS suppliers are required to maintain POD documentation in their files. Proof of delivery documentation must be made available to the Medicare contractor upon request. All services that do not have appropriate proof of delivery from the supplier shall be denied as not reasonable and necessary.

Claim lines billed without a GA, GZ or KX modifier will be rejected as missing information.

## REFILL REQUIREMENTS

For DMEPOS items and supplies provided on a recurring basis, billing must be based on prospective, not retrospective use. For DMEPOS products that are supplied as refills to the original order, suppliers must contact the beneficiary prior to dispensing the refill and not automatically ship on a pre-determined basis, even if authorized by the beneficiary. This shall be done to ensure that the refilled item remains reasonable and necessary, existing supplies are approaching exhaustion, and to confirm any changes or modifications to the order. Contact with the beneficiary or designee regarding refills must take place no sooner than 14 calendar days prior to the delivery/shipping date. For delivery of refills, the supplier must deliver the DMEPOS product no sooner than 10 calendar days prior to the end of usage for the current product. This is regardless of which delivery method is utilized.

For all DMEPOS items that are provided on a recurring basis, suppliers are required to have contact with the beneficiary or caregiver/designee prior to dispensing a new supply of items. Suppliers must not deliver refills without a refill request from a beneficiary. Items delivered without a valid, documented refill request will be denied as not reasonable and necessary.

Suppliers must not dispense a quantity of supplies exceeding a beneficiary's expected utilization. Suppliers must stay attuned to changed or atypical utilization patterns on the part of their clients. Suppliers must verify with the treating practitioners that any changed or atypical utilization is warranted. Regardless of utilization, a supplier must not dispense more than a three (3) - month quantity at a time.

## REPLACEMENT

This section applies to E0470 and E0471 devices initially provided for the scenarios addressed in this policy and reimbursed while the beneficiary was in Medicare fee-for-service (FFS).

If an E0470 or E0471 device is replaced during the 5 year reasonable useful lifetime (RUL) because of loss, theft, or irreparable damage due to a specific incident, there is no requirement for a new clinical evaluation or testing.

If an E0470 or E0471 device is replaced following the 5 year RUL, there must be an in-person evaluation by their treating practitioner that documents that the beneficiary continues to use and benefit from the device. There is no requirement for new testing. A new prescription is required.

Refer to the repair and replacement information in the Supplier Manual for additional information.

## BENEFICIARIES ENTERING MEDICARE

For beneficiaries who received an E0470 or E0471 device prior to enrollment in fee-for-service (FFS) Medicare and are seeking Medicare reimbursement for a rental, either to continue using the existing device or for a replacement device, coverage transition is not automatic. These claims are considered to be new, initial rentals for Medicare. Therefore all current coverage and documentation requirements set out in this policy must be met with the exceptions noted below.

Qualification Testing – Use of testing performed prior to Medicare eligibility is allowed. There must be documentation that the beneficiary had the testing required by the applicable scenario i.e., oximetry, sleep testing, spirometry, etc.,

prior to FFS Medicare enrollment, that meets the current coverage criteria in effect at the time that the beneficiary seeks Medicare coverage of a replacement device and/or accessories; and

Clinical Evaluation – Following enrollment in FFS Medicare, the beneficiary must have an in-person evaluation by their treating practitioner who documents all of the following in the beneficiary’s medical record:

- The beneficiary has the qualifying medical condition for the applicable scenario; and
- The testing performed, date of the testing used for qualification and results; and
- The beneficiary continues to use the device; and
- The beneficiary is benefiting from the treatment.

## SLEEP TESTS

Coverage and Payment rules for sleep tests may be found in the LCDs for the applicable Medicare Part A or Part B contractor. There may be differences between those LCDs and the DME MAC LCD. For the purposes of payment for a RAD device, the DME MAC coverage, coding and payment rules take precedence.

Payment for a RAD device for the treatment of the conditions specified in this policy may be contingent upon an evaluation for the diagnosis sleep apnea (Obstructive Sleep Apnea, Central Sleep Apnea and/or Complex Sleep Apnea). Diagnosis of sleep apnea is based upon a sleep test that meets the Medicare coverage criteria in effect for the date of service of the claim for the RAD device. 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). The test must be ordered by the beneficiary’s treating practitioner and conducted by an entity that qualifies as a Medicare provider of sleep tests and is in compliance with all applicable state regulatory requirements.

Note: Not all types of HST are appropriate for the evaluation of Central Sleep Apnea or Complex Sleep Apnea, as they do not monitor the necessary parameters.

A Type I sleep test is the continuous and simultaneous monitoring and recording of various physiological and pathophysiological parameters of sleep with practitioner review, interpretation, and report. It is facility-based and must include sleep staging, which is defined to include a 1-4 lead electroencephalogram (EEG), electro-oculogram (EOG), submental electromyogram (EMG) and electrocardiogram (ECG). It must also include at least the following additional parameters of sleep: airflow, respiratory effort, and oxygen saturation by oximetry. It may be performed as either a whole night study for diagnosis only or as a split night study to diagnose and initially evaluate treatment.

An HST is performed unattended in the beneficiary’s home or during a hospitalization using a portable monitoring device. A portable monitoring device for conducting an HST must meet one of the following criteria:

- A. Type II device – Monitors and records a minimum of seven (7) channels: EEG, EOG, EMG, ECG/heart rate, airflow, respiratory movement/effort and oxygen saturation; or
- B. Type III device – Monitors and records a minimum of four (4) channels: respiratory movement/effort, airflow, ECG/heart rate and oxygen saturation; or
- C. Type IV device – Monitors and records a minimum of three (3) channels, one of which is airflow; or
- D. Other - Devices that monitor and record a minimum of three (3) channels that include actigraphy, oximetry and peripheral arterial tone and for which there is substantive clinical evidence in the published peer-reviewed medical literature that demonstrates that the results accurately and reliably correspond to an AHI or RDI as defined above. This determination will be made on a device-by-device basis (See Appendix B for list of

approved devices in this category).

Beneficiaries who undergo an HST must, prior to having the test, receive instruction on how to properly apply a portable sleep-monitoring device. This instruction must be provided by the entity conducting the HST and may not be performed by a DME supplier. Beneficiary instruction may be accomplished by either:

1. Face-to-face demonstration of the portable sleep monitoring device's application and use; or
2. Video or telephonic instruction, with 24-hour availability of qualified personnel to answer questions or troubleshoot issues with the device.

All sleep tests (Type I - IV, Other) must be interpreted by a practitioner who holds one of the following:

1. Current certification in Sleep Medicine by the American Board of Sleep Medicine (ABSM); or
2. Current subspecialty certification in Sleep Medicine by a member board of the American Board of Medical Specialties (ABMS); or
3. Completed residency or fellowship training by an ABMS member board and has completed all the requirements for subspecialty certification in sleep medicine except the examination itself and only until the time of reporting of the first examination for which the practitioner is eligible; or
4. Active staff membership of a sleep center or laboratory accredited by the American Academy of Sleep Medicine (AASM), Accreditation Commission for Health Care (ACHC), or The Joint Commission (TJC, formerly the Joint Commission on Accreditation of Healthcare Organizations – JCAHO).

### **Summary of Evidence**

N/A

### **Analysis of Evidence (Rationale for Determination)**

N/A

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## **Coding Information**

### **CPT/HCPCS Codes**

#### **Group 1 Paragraph:**

The appearance of a code in this section does not necessarily indicate coverage.

#### **HCPCS MODIFIERS:**

EY - No physician or other licensed health care provider order for this item or service

GA Waiver of liability statement issued as required by payer policy, individual case

GZ - Item or service expected to be denied as not reasonable and necessary

KX - Requirements specified in the medical policy have been met

**HCPCS CODES:**

EQUIPMENT

**Group 1 Codes:**

CODE	DESCRIPTION
E0470	RESPIRATORY ASSIST DEVICE, BI-LEVEL PRESSURE CAPABILITY, WITHOUT BACKUP RATE FEATURE, USED WITH NONINVASIVE INTERFACE, E.G., NASAL OR FACIAL MASK (INTERMITTENT ASSIST DEVICE WITH CONTINUOUS POSITIVE AIRWAY PRESSURE DEVICE)
E0471	RESPIRATORY ASSIST DEVICE, BI-LEVEL PRESSURE CAPABILITY, WITH BACK-UP RATE FEATURE, USED WITH NONINVASIVE INTERFACE, E.G., NASAL OR FACIAL MASK (INTERMITTENT ASSIST DEVICE WITH CONTINUOUS POSITIVE AIRWAY PRESSURE DEVICE)

**Group 2 Paragraph:**

ACCESSORIES

**Group 2 Codes:**

CODE	DESCRIPTION
A4604	TUBING WITH INTEGRATED HEATING ELEMENT FOR USE WITH POSITIVE AIRWAY PRESSURE DEVICE
A7027	COMBINATION ORAL/NASAL MASK, USED WITH CONTINUOUS POSITIVE AIRWAY PRESSURE DEVICE, EACH
A7028	ORAL CUSHION FOR COMBINATION ORAL/NASAL MASK, REPLACEMENT ONLY, EACH
A7029	NASAL PILLOWS FOR COMBINATION ORAL/NASAL MASK, REPLACEMENT ONLY, PAIR
A7030	FULL FACE MASK USED WITH POSITIVE AIRWAY PRESSURE DEVICE, EACH

CODE	DESCRIPTION
A7031	FACE MASK INTERFACE, REPLACEMENT FOR FULL FACE MASK, EACH
A7032	CUSHION FOR USE ON NASAL MASK INTERFACE, REPLACEMENT ONLY, EACH
A7033	PILLOW FOR USE ON NASAL CANNULA TYPE INTERFACE, REPLACEMENT ONLY, PAIR
A7034	NASAL INTERFACE (MASK OR CANNULA TYPE) USED WITH POSITIVE AIRWAY PRESSURE DEVICE, WITH OR WITHOUT HEAD STRAP
A7035	HEADGEAR USED WITH POSITIVE AIRWAY PRESSURE DEVICE
A7036	CHINSTRAP USED WITH POSITIVE AIRWAY PRESSURE DEVICE
A7037	TUBING USED WITH POSITIVE AIRWAY PRESSURE DEVICE
A7038	FILTER, DISPOSABLE, USED WITH POSITIVE AIRWAY PRESSURE DEVICE
A7039	FILTER, NON DISPOSABLE, USED WITH POSITIVE AIRWAY PRESSURE DEVICE
A7044	ORAL INTERFACE USED WITH POSITIVE AIRWAY PRESSURE DEVICE, EACH
A7045	EXHALATION PORT WITH OR WITHOUT SWIVEL USED WITH ACCESSORIES FOR POSITIVE AIRWAY DEVICES, REPLACEMENT ONLY
A7046	WATER CHAMBER FOR HUMIDIFIER, USED WITH POSITIVE AIRWAY PRESSURE DEVICE, REPLACEMENT, EACH
E0561	HUMIDIFIER, NON-HEATED, USED WITH POSITIVE AIRWAY PRESSURE DEVICE
E0562	HUMIDIFIER, HEATED, USED WITH POSITIVE AIRWAY PRESSURE DEVICE

## General Information

### Associated Information

### DOCUMENTATION REQUIREMENTS

Section 1833(e) of the Social Security Act precludes payment to any provider of services unless "there has been furnished such information as may be necessary in order to determine the amounts due such provider." It is expected that the beneficiary's medical records will reflect the need for the care provided. The beneficiary's medical records include the treating practitioner's office records, hospital records, nursing home records, home health agency records, records from other healthcare professionals and test reports. This documentation must be available upon request.

### GENERAL DOCUMENTATION REQUIREMENTS

In order to justify payment for DMEPOS items, suppliers must meet the following requirements:

- SWO
- Medical Record Information (including continued need/use if applicable)
- Correct Coding

- Proof of Delivery

Refer to the LCD-related Standard Documentation Requirements article, located at the bottom of this policy under the Related Local Coverage Documents section for additional information regarding these requirements.

Refer to the Supplier Manual for additional information on documentation requirements.

Refer to the DME MAC web sites for additional bulletin articles and other publications related to this LCD.

## **POLICY SPECIFIC DOCUMENTATION REQUIREMENTS**

Items covered in this LCD have additional policy-specific requirements that must be met prior to Medicare reimbursement.

Refer to the LCD-related Policy article, located at the bottom of this policy under the Related Local Coverage Documents section for additional information.

## MISCELLANEOUS

The treating practitioner statement for beneficiaries on E0470 or E0471 devices must be kept on file by the supplier, but should not be sent in with the claim. This documentation must be available upon request.

## APPENDICES

## UTILIZATION GUIDELINES

Refer to Coverage Indications, Limitations and/or Medical Necessity.

## **Sources of Information**

N/A

## **Bibliography**

N/A

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# **Revision History Information**

REVISION HISTORY DATE	REVISION HISTORY NUMBER	REVISION HISTORY EXPLANATION	REASON(S) FOR CHANGE
01/01/2020	R7	<p><b>Revision Effective Date: 01/01/2020</b>            COVERAGE INDICATIONS, LIMITATIONS AND/OR MEDICAL NECESSITY:            Revised: "physician" to "practitioner"</p>	<ul style="list-style-type: none"> <li>• Provider Education/Guidance</li> <li>• Other</li> </ul>



REVISION HISTORY DATE	REVISION HISTORY NUMBER	REVISION HISTORY EXPLANATION	REASON(S) FOR CHANGE
		<p>GENERAL: Revised: Order information as a result of Final Rule 1713</p> <p>REFILL REQUIREMENTS: Revised: "ordering physicians" to "treating practitioners"</p> <p>REPLACEMENT: Revised: "physician" to "treating practitioner"</p> <p>BENEFICIARIES ENTERING MEDICARE: Revised: "physician" to "treating practitioner"</p> <p>SLEEP TESTS: Revised: "physician" to "practitioner"</p> <p>CODING INFORMATION: Removed: Field titled "Bill Type" Removed: Field titled "Revenue Codes" Removed: Field titled "ICD-10 Codes that Support Medical Necessity" Removed: Field titled "ICD-10 Codes that DO NOT Support Medical Necessity" Removed: Field titled "Additional ICD-10 Information"</p> <p>DOCUMENTATION REQUIREMENTS: Revised: "physician's" to "treating practitioner's"</p> <p>GENERAL DOCUMENTATION REQUIREMENTS: Revised: "Prescriptions (orders)" to "SWO"</p> <p>POLICY SPECIFIC DOCUMENTATION REQUIREMENTS: Revised: "physician" updated to "treating practitioner"</p> <p><i>02/27/20: Pursuant to the 21st Century Cures Act, these revisions do not require notice and comment because they are due to non-discretionary coverage updates reflective of CMS FR-1713.</i></p>	
01/01/2017	R6	<p>No changes have been made to this LCD</p> <p><i>04/05/2018: At this time 21st Century Cures Act will apply to new and revised LCDs that restrict coverage which requires comment and notice. This revision is not a restriction to the coverage determination; and, therefore not all the fields included on the LCD are applicable as noted in this policy.</i></p>	<ul style="list-style-type: none"> <li>• Other</li> </ul>
01/01/2017	R5	<p><b>Revision Effective Date: 01/01/2017</b></p> <p>COVERAGE INDICATIONS, INDICATIONS, LIMITATIONS AND/OR MEDICAL NECESSITY: Clarified: Distinction between coverage of RAD devices and ventilators with non-invasive interfaces</p>	<ul style="list-style-type: none"> <li>• Provider Education/Guidance</li> </ul>

REVISION HISTORY DATE	REVISION HISTORY NUMBER	REVISION HISTORY EXPLANATION	REASON(S) FOR CHANGE
		<p>Removed: Standard Documentation Language  Added: New reference language and directions to Standard Documentation Requirements  Added: General Requirements  Revised: Refill Requirements  DOCUMENTATION REQUIREMENTS:  Removed: Standard Documentation Language  Added: General Documentation Requirements  Added: New reference language and directions to Standard Documentation Requirements  POLICY SPECIFIC DOCUMENTATION REQUIREMENTS:  Removed: Standard Documentation Language  Added: Direction to Standard Documentation Requirements  Removed: Supplier Manual direction under Miscellaneous  Removed: PIM citation under Appendices  RELATED LOCAL COVERAGE DOCUMENTS:  Added: LCD-related Standard Documentation Requirements article</p>	
07/01/2016	R4	<p>Effective July 1, 2016 oversight for DME MAC LCDs is the responsibility of CGS Administrators, LLC 18003 and 17013 and Noridian Healthcare Solutions, LLC 19003 and 16013. No other changes have been made to the LCDs.</p>	<ul style="list-style-type: none"> <li>• Change in Assigned States or Affiliated Contract Numbers</li> </ul>
01/01/2016	R3	<p>Revision Effective Date: 01/01/2016  COVERAGE INDICATIONS, LIMITATIONS AND/OR MEDICAL NECESSITY:  Replaced: HCPCS Codes E0450, E0460-E0464 with new HCPCS Codes E0465, E0466  DOCUMENTATION REQUIREMENTS  Revised: Standard Documentation language to remove start date verbiage from Prescription Requirements (Effective 11/05/2015)</p>	<ul style="list-style-type: none"> <li>• Provider Education/Guidance</li> <li>• Revisions Due To CPT/HCPCS Code Changes</li> </ul>
10/01/2015	R2	<p>Revision Effective Date: 12/01/2014 (May 2015 Publication)  COVERAGE INDICATIONS, LIMITATIONS AND/OR MEDICAL NECESSITY:  Revised: Standard Documentation Language to add covered prior to a beneficiary's Medicare eligibility  DOCUMENTATION REQUIREMENTS:  Revised: Standard Documentation Language to add</p>	<ul style="list-style-type: none"> <li>• Provider Education/Guidance</li> </ul>

REVISION HISTORY DATE	REVISION HISTORY NUMBER	REVISION HISTORY EXPLANATION	REASON(S) FOR CHANGE
		who can enter date of delivery date on the POD Added: Instructions for Equipment Retained from a Prior Payer Added: Repair/Replacement section	
10/01/2015	R1	<b>Revision Effective Date: 10/01/2015</b> COVERAGE INDICATIONS, LIMITATIONS AND/OR MEDICAL NECESSITY: Revised: Definitions of Central Sleep Apnea and Complex Sleep Apnea to include a CAHI index and expands signs and symptoms that describe the conditions Revised: Severe COPD to clarify that definitive testing is not necessary to exclude OSA when the clinical picture is sufficient Revised: Severe COPD to clarify that nocturnal oximetry is a cumulative 5 minutes of testing Revised: Hypoventilation Syndromes to remove FEV1 Revised: PSG testing to also include HST testing when used in the in-patient hospital setting to establish or rule out the diagnosis of OSA Added: Ventilator section based upon NCD and April 2014 coding and coverage article Added: Sleep Test coverage and payment rules	<ul style="list-style-type: none"> <li>• Provider Education/Guidance</li> <li>• Reconsideration Request</li> </ul>

## Associated Documents

### Attachments

N/A

### Related Local Coverage Documents

Article(s)

A52517 - Respiratory Assist Devices - Policy Article

A55426 - Standard Documentation Requirements for All Claims Submitted to DME MACs

### Related National Coverage Documents

N/A

### Public Version(s)

Updated on 02/21/2020 with effective dates 01/01/2020 - N/A

Updated on 03/27/2018 with effective dates 01/01/2017 - 12/31/2019

Updated on 04/12/2017 with effective dates 01/01/2017 - N/A

Some older versions have been archived. Please visit the MCD Archive Site to retrieve them.

# Keywords

N/A

**END OF LOCAL COVERAGE DETERMINATION**

Per the Code of Federal Regulations, 42 C.F.R § 426. 325, only those portions of the currently effective Local Coverage Determination (LCD) that are based on section 1862(a)(1)(A) of the Social Security Act, may be challenged through an acceptable complaint as described in 42 C.F.R § 426.400. Also, per 42 C.F.R § 426.325 items that are not reviewable, and therefore cannot be challenged, include the Policy Article. Please note the distinction of the documents when reviewing the materials.

# Local Coverage Article: Respiratory Assist Devices - Policy Article (A52517)

Links in PDF documents are not guaranteed to work. To follow a web link, please use the MCD Website.

## Contractor Information

CONTRACTOR NAME	CONTRACT TYPE	CONTRACT NUMBER	JURISDICTION	STATE(S)
CGS Administrators, LLC	DME MAC	17013 - DME MAC	J-B	Illinois Indiana Kentucky Michigan Minnesota Ohio Wisconsin
CGS Administrators, LLC	DME MAC	18003 - DME MAC	J-C	Alabama Arkansas Colorado Florida Georgia Louisiana Mississippi New Mexico North Carolina Oklahoma Puerto Rico South Carolina Tennessee Texas Virgin Islands Virginia West Virginia
Noridian Healthcare Solutions, LLC	DME MAC	16013 - DME MAC	J-A	Connecticut Delaware District of Columbia Maine Maryland Massachusetts New Hampshire New Jersey New York - Entire State Pennsylvania Rhode Island Vermont

CONTRACTOR NAME	CONTRACT TYPE	CONTRACT NUMBER	JURISDICTION	STATE(S)
Noridian Healthcare Solutions, LLC	DME MAC	19003 - DME MAC	J-D	Alaska American Samoa Arizona California - Entire State Guam Hawaii Idaho Iowa Kansas Missouri - Entire State Montana Nebraska Nevada North Dakota Northern Mariana Islands Oregon South Dakota Utah Washington Wyoming

## Article Information

### General Information

**Article ID**

A52517

**Original Effective Date**

10/01/2015

**Original ICD-9 Article ID**

[A23659](#)

[A23974](#)

[A47231](#)

[A23902](#)

**Revision Effective Date**

04/03/2020

**Revision Ending Date**

N/A

**Article Title**

Respiratory Assist Devices - Policy Article

**Retirement Date**

N/A

**Article Type**

Article

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## **Article Guidance**

### **Article Text:**

### **NON-MEDICAL NECESSITY COVERAGE & PAYMENT RULES**

For any item to be covered by Medicare, it must 1) be eligible for a defined Medicare benefit category, 2) be reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member, and 3) meet all other applicable Medicare statutory and regulatory requirements. Information provided in this policy article relates to determinations other than those based on Social Security Act §1862(a)(1)(A) provisions (i.e. "reasonable and necessary").

Respiratory assist devices are covered under the Durable Medical Equipment benefit (Social Security Act §1861(s)(6)). In order for a beneficiary's equipment to be eligible for reimbursement the reasonable and necessary (R&N) requirements set out in the related Local Coverage Determination must be met. In addition, there are specific statutory payment policy requirements, discussed below, that also must be met.



Accessories are separately reimbursable when used with E0470, E0471.

Services of a respiratory therapist are non-covered under the DME benefit.

A liner used in conjunction with a PAP mask is considered a comfort/convenience item. These products are non-covered under the DME benefit in accordance with the Medicare Benefit Policy Manual 100-02 Chapter 15 Section 110.1, and should be coded A9270 (Non-covered item or service).

## **REQUIREMENTS FOR SPECIFIC DMEPOS ITEMS PURSUANT TO Final Rule 1713 (84 Fed. Reg Vol 217)**

Final Rule 1713 (84 Fed. Reg Vol 217) requires a face-to-face encounter and a Written Order Prior to Delivery (WOPD) for specified HCPCS codes. CMS and the DME MACs provide a list of the specified codes, which is periodically updated. The link will be located here once it is available.

Claims for the specified items subject to Final Rule 1713 (84 Fed. Reg Vol 217) that do not meet the face-to-face encounter and WOPD requirements specified in the LCD-related Standard Documentation Requirements Article (A55426) will be denied as not reasonable and necessary.

If a supplier delivers an item prior to receipt of a WOPD, it will be denied as not reasonable and necessary. If the WOPD is not obtained prior to delivery, payment will not be made for that item even if a WOPD is subsequently obtained by the supplier. If a similar item is subsequently provided by an unrelated supplier who has obtained a WOPD, it will be eligible for coverage.

## **POLICY SPECIFIC DOCUMENTATION REQUIREMENTS**

### **REPLACEMENT OF ACCESSORIES FOR MEDICARE-PAID, BENEFICIARY-OWNED EQUIPMENT:**

For claims for replacement accessories (e.g., interfaces, tubing, filters, humidifier chambers), if Medicare paid for the base RAD initially (i.e., for 13 months of continuous use), the medical necessity for the beneficiary-owned base RAD is assumed to have been established. Therefore, to make a payment determination, there must only be documentation that the base DME item continues to meet medical need; and (2) The replacement of specific accessories or furnishing of new accessories remain medically necessary and are essential for the effective use of the base DME.

Documentation of continued medical need for the base item must come from the treating practitioner's records. The supplier's documentation records must support the need to replace the accessory to maintain the equipment's functionality and meet the beneficiary's medical need.

This guidance does not apply RADs when Medicare did not originally provide payment for the base item. In cases where Medicare did not originally pay for the DME item, all coverage, coding and documentation requirements in effect for the date of service (DOS) on the claim under review must be met (see below).

In addition to policy specific documentation requirements, there are general documentation requirements that are applicable to all DMEPOS policies. These general requirements are located in the DOCUMENTATION REQUIREMENTS section of the LCD.

Refer to the LCD-related Standard Documentation Requirements article, located at the bottom of this Policy Article under the Related Local Coverage Documents section for additional information regarding GENERAL DOCUMENTATION REQUIREMENTS and the POLICY SPECIFIC DOCUMENTATION REQUIREMENTS.

## **MODIFIERS**

### **KX MODIFIER:**

Proper use of modifiers is discussed below. Specific modifiers must be used and differ depending on whether or not the requirements outlined in the documentation section have been met.

Where permitted, KX must be added to codes E0470 and E0471 and codes for accessories used with E0470 and E0471. The KX modifier must not be used until the required documentation has actually been obtained and entered into the supplier's files.

On claims for the first through third months, suppliers must add a KX modifier if all of the criteria for beneficiaries in Groups I-IV in the Coverage Indications, Limitations and/or Medical Necessity section of the related LCD have been met. If the requirements for the KX modifier are not met, the KX modifier must not be used.

On the fourth month's claim (and any month thereafter), the supplier must add a KX modifier if all the "Initial Coverage" criteria in the Coverage Indications, Limitations and/or Medical Necessity section of the related LCD have been met and the treating practitioner's signed and dated statement described in the Coverage Indications, Limitations and/or Medical Necessity above, has been obtained for the supplier's files.

If the completed and signed treating practitioner statement is not in the supplier's files in time for submission of the fourth or succeeding months' claims, the supplier may still submit the claims, but a KX modifier must not be added. However, if the supplier chooses to hold claims for the fourth and succeeding months until the completed and signed forms are obtained, those claims may then be submitted with the KX modifier, so long as their answers indicate continued compliant use of and benefit from the therapy, according to the Coverage Indications, Limitations and/or Medical Necessity section.

### **GA AND GZ MODIFIERS**

In all of the situations above describing use of the KX modifier, if all of the coverage criteria have not been met, the GA or GZ modifier must be added to a claim line for the RAD equipment (E0470 or E0471) and accessories. When there is an expectation of a medical necessity denial, suppliers must enter the GA modifier on the claim line if they have obtained a properly executed Advance Beneficiary Notice (ABN) or the GZ modifier if they have not obtained a valid ABN.

## **CODING GUIDELINES**

A respiratory assist device (RAD) without backup rate (E0470) delivers adjustable, variable levels (within a single respiratory cycle) of positive air pressure by way of tubing and a noninvasive interface (such as a nasal, oral, or facial mask) to assist spontaneous respiratory efforts and supplement the volume of inspired air into the lungs. A respiratory cycle is defined as an inspiration, followed by an expiration.

A respiratory assist device (RAD) with backup rate (E0471) delivers adjustable, variable levels (within a single respiratory cycle) of positive air pressure by way of tubing and a noninvasive interface (such as a nasal or oral facial mask) to assist spontaneous respiratory efforts and supplement the volume of inspired air into the lungs. In addition, it has a timed backup feature to deliver this air pressure whenever sufficient spontaneous inspiratory efforts fail to occur.

Code A4604 describes tubing used with a heated humidifier and has a heated wire running the length of the tubing. It is designed for use with a positive airway pressure device and a non-invasive interface - i.e., nasal or face mask, nasal cannula, or oral interface.

Code A7032 is used for a replacement nasal mask interface that goes around the nose, but not into the nostrils. The unit of service for this code is "each".

Code A7033 is used for a replacement nasal cannula-type interface. This interface extends a short distance into the nostrils. The unit of service for this code is "pair". For some products, there are two physically separate cushions or "pillows" – one for each nostril. Two cushions/ pillows equal one unit of service of A7033. For other products, the interface is a single piece with two protrusions that extend into the nostrils. One of these interfaces equals one unit of service of A7033.

Code A7027 (Combination oral/nasal mask, used with continuous positive airway pressure device, each) is a two-piece system with separate elements for oral and nasal use.

A liner is a soft, flexible material, which is placed between the patient's skin and the PAP mask interface. Liners used with a PAP mask are made of cloth, silicone or other materials. Liners are not interfaces for use with a PAP mask. Consequently, liners should not be billed as replacement features of a PAP mask such as A7031 (Face mask interface, replacement for full face mask, each) or A7032 (Cushion for use on nasal mask interface, replacement only, each). Liners billed as replacement features of a PAP mask should be coded A9270 (Non-covered item or service).

Monitoring devices (integrated or modular) are capable of tracking data generated by a RAD device, which can be subsequently downloaded for further analysis by a healthcare provider, DME supplier, or beneficiary. Such technologies include, but are not limited to:

- Smart cards and readers
- USB/Thumb drive accessories
- Wired telephonic transmission modules
- Wireless modems

Suppliers who elect to bill separately for monitoring technology must use HCPCS code A9279 (MONITORING FEATURE/DEVICE, STAND-ALONE OR INTEGRATED, ANY TYPE, INCLUDES ALL ACCESSORIES, COMPONENTS AND ELECTRONICS, NOT OTHERWISE CLASSIFIED). Code A9279 is all-inclusive, and is to be used whether the monitoring technology is incorporated as part of the base item, supplied as an add-on module or is a stand-alone item.

Claims for A9279 are denied as statutorily non-covered.

Use of multiple instances of A9279 to bill separately for individual features is incorrect coding.

Claims billed for monitoring technologies using other NOC codes such as E1399 [DURABLE MEDICAL EQUIPMENT,

MISCELLANEOUS] will be denied as incorrect coding.

Code 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) describes a ventilator that integrates the function of multiple types of equipment into a single device. Code E0467 combines the function of a ventilator with those of any combination or all of the following:

- Oxygen equipment
- Nebulizer and compressor
- Aspirator (suction device)
- Cough stimulator (multiple products)
- Positive airway pressure devices (PAP and RAD)
- Custom fabricated oral appliances

The following HCPCS codes for individual items are included in the functionality of code E0467:

- HCPCS codes E0470, E0471, E0472, E0561, E0562, A4604, A7027, A7028, A7029, A7030, A7031, A7032, A7033, A7034, A7035, A7036, A7037, A7038, A7039, A7044, A7045, A7046

For E0467 claims with dates of service before April 3, 2020:

Claims for any of the HCPCS codes listed above that are submitted on the same claim or that overlap any date(s) of service for E0467 is considered to be unbundling.

In addition, any claim for repair (HCPCS code K0739 for labor and any HCPCS code for replacement items) of beneficiary-owned equipment identified by HCPCS codes listed above is considered as unbundling if the date(s) of service for the repair overlaps any date(s) of service for code E0467.

Claims for code E0467 with a date(s) of service that overlaps date(s) of service for any of the following scenarios are considered as a claim for same or similar equipment when the beneficiary:

- Is currently in a rental month for any of the items listed above
- Owns any of the equipment listed above that has not reached the end of its reasonable useful lifetime.

For E0467 claims with dates of service on or after April 3, 2020:

Any claim for repair (HCPCS code K0739 for labor and any HCPCS code for replacement items) of beneficiary-owned equipment identified by HCPCS codes listed above is considered as unbundling if the date(s) of service for the repair overlaps any date(s) of service for code E0467.

Claims for code E0467 with a date(s) of service that overlaps date(s) of service in a rental month for any of the items listed above are considered as a claim for same or similar equipment.

Suppliers should contact the Pricing, Data Analysis and Coding (PDAC) Contractor for guidance on the correct coding of these items.

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# Coding Information

## CPT/HCPCS Codes

N/A

## ICD-10 Codes that Support Medical Necessity

N/A

## ICD-10 Codes that DO NOT Support Medical Necessity

N/A

## Additional ICD-10 Information

N/A

## Bill Type Codes:

Contractors may specify Bill Types to help providers identify those Bill Types typically used to report this service. Absence of a Bill Type does not guarantee that the policy does not apply to that Bill Type. Complete absence of all Bill Types indicates that coverage is not influenced by Bill Type and the policy should be assumed to apply equally to all claims.

N/A

## Revenue Codes:

Contractors may specify Revenue Codes to help providers identify those Revenue Codes typically used to report this service. In most instances Revenue Codes are purely advisory. Unless specified in the policy, services reported under other Revenue Codes are equally subject to this coverage determination. Complete absence of all Revenue Codes indicates that coverage is not influenced by Revenue Code and the policy should be assumed to apply equally to all Revenue Codes.

N/A

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# Revision History Information

REVISION HISTORY DATE	REVISION HISTORY NUMBER	REVISION HISTORY EXPLANATION
04/03/2020	R11	<p><b>Revision Effective Date: 04/03/2020</b></p> <p>CODING GUIDELINES: Revised: Guidance for billing HCPCS code E0467 based on DOS</p> <p><i>07/16/2020: At this time 21st Century Cures Act applies to new and revised LCDs which require comment and notice. This revision is to an article that is not a local coverage determination.</i></p>
01/01/2020	R10	<p><b>Revision Effective Date: 01/01/2020</b></p> <p>NON-MEDICAL NECESSITY COVERAGE AND PAYMENT RULES: Removed: REQUIREMENTS FOR SPECIFIC DMEPOS ITEMS PURSUANT TO 42 CFR 410.38(g) section REQUIREMENTS FOR SPECIFIC DMEPOS ITEMS PURSUANT TO FINAL RULE 1713 (84 Fed. Reg Vol 217): Added: Section and related information based on Final Rule 1713</p> <p>MODIFIERS: Revised: "physician" to "practitioner"</p> <p>ICD-10 CODES THAT SUPPORT MEDICAL NECESSITY: Revised: Section header "ICD-10 Codes that are Covered" updated to "ICD-10 Codes that Support Medical Necessity"</p> <p>ICD-10 CODES THAT DO NOT SUPPORT MEDICAL NECESSITY: Revised: Section header "ICD-10 Codes that are Not Covered" updated to "ICD-10 Codes that DO NOT Support Medical Necessity"</p> <p><i>02/27/2020: At this time 21st Century Cures Act applies to new and revised LCDs which require comment and notice. This revision is to an article that is not a local coverage determination.</i></p>
01/01/2019	R9	<p><b>Revision Effective Date: 01/01/2019</b></p> <p>CODING GUIDELINES: Revised: E0467 Coding Guidelines to include custom fabricated oral appliances</p> <p><i>04/04/2019: At this time 21st Century Cures Act applies to new and revised LCDs which require comment and notice. This revision is to an article that is not a local coverage determination.</i></p>
01/01/2019	R8	<p><b>Revision Effective Date: 01/01/2019</b></p> <p>CODING GUIDELINES: Added: E0467 Coding Guidelines</p> <p><i>03/07/2019: At this time 21st Century Cures Act applies to new and revised LCDs which require comment and notice. This revision is to an article that is not a local coverage determination.</i></p>

REVISION HISTORY DATE	REVISION HISTORY NUMBER	REVISION HISTORY EXPLANATION
01/01/2017	R7	<p><b>Revision Effective Date: 01/01/2017</b>  NON-MEDICAL NECESSITY COVERAGE &amp; PAYMENT RULES:  Added: Direction for REPLACEMENT OF ACCESSORIES FOR MEDICARE-PAID, BENEFICIARY-OWNED EQUIPMENT</p> <p><i>06/14/2018: At this time 21st Century Cures Act applies to new and revised LCDs that restrict coverage, which require comment and notice. This revision is to an article that is not a local coverage determination.</i></p>
01/01/2017	R6	<p><b>Revision Effective Date: 01/01/2017</b>  NON-MEDICAL NECESSITY COVERAGE AND PAYMENT RULES  Added: 42 CFR 410.38(g) language, previously in POLICY SPECIFIC DOCUMENTATION REQUIREMENTS section.</p> <p><i>04/05/2018: At this time 21st Century Cures Act applies to new and revised LCDs that restrict coverage, which require comment and notice. This revision is to an article that is no a local coverage determination.</i></p>
01/01/2017	R5	<p>Revision Effective Date: 01/01/2017  POLICY SPECIFIC DOCUMENTATION REQUIREMENTS:  Added: 42 CFR 410.38(g) and Modifiers requirements  RELATED LOCAL COVERAGE DOCUMENTS:  Added: LCD-related Standard Documentation Requirements Language Article</p>
07/01/2016	R4	<p>Effective July 1, 2016 oversight for DME MAC Articles is the responsibility of CGS Administrators, LLC 18003 and 17013 and Noridian Healthcare Solutions, LLC 19003 and 16013. No other changes have been made to the Articles.</p>
11/05/2015	R3	<p>Revision Effective Date: 11/05/2015  NON-MEDICAL NECESSITY COVERAGE AND PAYMENT RULES:  Revised: Standard Documentation language to remove start date verbiage from Prescription Requirements</p>
10/01/2015	R2	<p>Revision Effective Date: 12/01/2014 (May 2015 Publication)  NON-MEDICAL NECESSITY COVERAGE &amp; PAYMENT RULES:  Added: Non-coverage statement for liners used in conjunction with a PAP mask  Removed: "When required by state law" from ACA new prescription requirements  CODING GUIDELINES:  Added: Coding guidelines for liners used with PAP mask based on DME MAC article posted on February 13, 2014  Added: Coding guidelines for Monitoring Technology based on DME MAC article posted on November 15, 2013</p>
10/01/2015	R1	<p><b>Revision Effective Date: 10/01/2015</b>  NON-MEDICAL NECESSITY COVERAGE AND PAYMENT RULES:  Added: ACA 6407 prescriber requirements</p>

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# Associated Documents

## **Related Local Coverage Document(s)**

Article(s)

A55426 - Standard Documentation Requirements for All Claims Submitted to DME MACs

LCD(s)

L33800 - Respiratory Assist Devices

## **Related National Coverage Document(s)**

N/A

## **Statutory Requirements URL(s)**

N/A

## **Rules and Regulations URL(s)**

N/A

## **CMS Manual Explanations URL(s)**

N/A

## **Other URL(s)**

N/A

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# Keywords

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