Local Coverage Determination (LCD)

Respiratory Assist Devices

L33800

Contractor Information

Contractor Name	Contract Type	Contract Number	Jurisdiction	States
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	States
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

LCD Title
Respiratory Assist Devices

Proposed LCD in Comment Period
N/A

Source Proposed LCD
DL33800

Original Effective Date
For services performed on or after 10/01/2015

Revision Effective Date
For services performed on or after 01/01/2024

Revision Ending Date
N/A

Retirement Date
N/A

Notice Period Start Date
06/24/2021

Notice Period End Date
08/07/2021

Issue

Issue Description

The LCD is revised to align refill requirements with CMS Final Rule CMS-1780-F. This revision allows contact with the beneficiary regarding refills to take place no sooner than 30 calendar days prior to the end of the current supply and to document an affirmative response.

Issue - Explanation of Change Between Proposed LCD and Final LCD

No proposed LCD issued.

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.

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 PaCO2, done while awake and breathing the beneficiary's prescribed FIO2 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 FIO2, or
c. For a neuromuscular disease (only), either i or ii,
    i. Maximal inspiratory pressure is less than 60 cm H20, 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 PaCO2, done while awake and breathing the beneficiary's prescribed FIO2, 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 FIO2 (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 severe COPD beneficiaries 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 PaCO2, done while awake and breathing the beneficiary's prescribed FIO2, shows that the beneficiary's PaCO2 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 (PAP) Devices for the Treatment of Obstructive Sleep Apnea LCD for information about E0470 coverage for obstructive sleep apnea).

Situation 2. For severe COPD beneficiaries 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 PaCO2 is done while awake and breathing the beneficiary's prescribed FIO2, 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 FIO2 [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 FIO2.

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 PaCO2, done while awake and breathing the beneficiary's prescribed FIO2, is greater than or equal to 45 mm Hg
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 PaCO2, done during sleep or immediately upon awakening, and breathing the beneficiary's prescribed FIO2, shows the beneficiary's PaCO2 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 (PAP) Devices for the Treatment of Obstructive Sleep Apnea 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 PaCO2, done while awake, and breathing the beneficiary's prescribed FIO2, shows that the beneficiary's PaCO2 worsens greater than or equal to 7 mm Hg compared to the arterial blood gas (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 (PAP) Devices for the Treatment of Obstructive Sleep Apnea 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.

VENTILATORS

The Centers for Medicare & Medicaid Services (CMS) National Coverage Determinations Manual (CMS Pub. 100-03) in Chapter 1, Part 4, Section 280.1 stipulates that ventilators (E0465, E0466, and E0467) 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 beneficiary to beneficiary. For conditions such as these, the specific treatment plan for any individual beneficiary 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, E0466, or E0467 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, or E0467) 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.

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, and document an affirmative response, 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 expected to end, and to confirm any changes or modifications to the order. Contact with the beneficiary or designee regarding refills must take place no sooner than 30 calendar days prior to the expected end of the current supply. For delivery of refills, the supplier must deliver the DMEPOS product no sooner than 10 calendar days prior to the expected end of the current supply. 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 and document an affirmative response, prior to dispensing a new supply of items. Suppliers must not deliver refills without a refill request and an affirmative response 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 e.g., oximetry, sleep testing, or spirometry, 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 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.

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).

Coverage of a RAD device for the treatment of sleep-disordered breathing is limited to claims where the diagnosis is based on all of the following:

1. 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,
2. A sleep test that is approved by the Food and Drug Administration (FDA) as a diagnostic device; and,
3. The sleep test results meet the coverage criteria in effect for the date of service of the claim for the RAD device; and,
4. The sleep test is ordered by the beneficiary's treating practitioner; and,
5. 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.

Summary of Evidence
N/A

Analysis of Evidence (Rationale for Determination)
N/A

Coding Information

CPT/HCPCS Codes

Group 1 (2 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 (19 Codes)

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
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

Code	Description
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

Revision History Information

Revision History Date	Revision History Number	Revision History Explanation	Reasons for Change
01/01/2024	R9	**Revision Effective Date: 01/01/2024** COVERAGE INDICATIONS, LIMITATIONS, AND/OR MEDICAL NECESSITY: Added: “and document an affirmative response” to language that pertains to contact with the beneficiary or caregiver/designee for DMEPOS products supplied as refills Revised: “approaching exhaustion” to “expected to end” in regard to existing supplies Revised: “Contact with the beneficiary or designee regarding refills must take place no sooner than 14 calendar days prior to the delivery/shipping date.” to “Contact with the beneficiary or designee regarding refills must take place no sooner than 30 calendar days prior to the expected end of the current supply.” Revised: “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.” to “For delivery of refills, the supplier must deliver the DMEPOS product no sooner than 10 calendar days prior to the expected end of the current supply.” SUMMARY OF EVIDENCE: Removed: Summary of evidence information, due to not being applicable to the non-discretionary changes ANALYSIS OF EVIDENCE (RATIONALE FOR DETERMINATION): Removed: Analysis of evidence information, due to not being applicable to the non-discretionary changes *12/14/2023: Pursuant to the 21st Century Cures Act, these revisions do not require notice and comment because the revisions are non-discretionary updates to refill requirement information per CMS Final Rule CMS-1780-F.*	• Provider Education/Guidance • Other (CMS Final Rule CMS-1780-F)

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08/08/2021	R8	**REVISION EFFECTIVE DATE: 08/08/2021** COVERAGE INDICATIONS, LIMITATIONS AND/OR MEDICAL NECESSITY: Removed: 'etc.' from initial coverage statement for E0470 or an E0471 RAD Revised: Situation 1 and 2 revised "Group II" to "severe COPD" beneficiaries Revised: Situation 1 criterion B to proper LCD title, Positive Airway Pressure (PAP) Devices for the Treatment of Obstructive Sleep Apnea for E0471 Revised: Hypoventilation Syndrome criterion D to proper LCD title, Positive Airway Pressure (PAP) Devices for the Treatment of Obstructive Sleep Apnea for E0470 and E0471 Revised: Header from "VENTILATOR WITH NOINVASIVE INTERFACES" to "VENTILATOR" Revised: The CMS manual reference to CMS Pub. 100-03 Added: HCPCS code E0467 to ventilator code listings Revised: "Patient" to "beneficiary" Removed: Statement of claim line rejection if billed without GA, GZ or KX modifier Removed: "etc." from BENEFICIARIES ENTERING MEDICARE section Revised: SLEEP TESTS section to point to NCD 240.4.1 and applicable A/B MAC LCDs and Billing and Coding articles SUMMARY OF EVIDENCE: Added: Information related to diagnostic sleep testing ANALYSIS OF EVIDENCE: Added: Information related to diagnostic sleep testing RELATED LOCAL COVERAGE DOCUMENTS: Added: Response to Comments (A58822)	• Reconsideration Request

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01/01/2020	R7	**Revision Effective Date: 01/01/2020** COVERAGE INDICATIONS, LIMITATIONS AND/OR MEDICAL NECESSITY: Revised: “physician” to “practitioner” GENERAL: Revised: Order information as a result of Final Rule 1713 REFILL REQUIREMENTS: Revised: “ordering physicians” to “treating practitioners” REPLACEMENT: Revised: “physician” to “treating practitioner” BENEFICIARIES ENTERING MEDICARE: Revised: “physician” to “treating practitioner” SLEEP TESTS: Revised: “physician” to “practitioner” 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" DOCUMENTATION REQUIREMENTS: Revised: “physician’s” to “treating practitioner’s” GENERAL DOCUMENTATION REQUIREMENTS: Revised: “Prescriptions (orders)” to “SWO” POLICY SPECIFIC DOCUMENTATION REQUIREMENTS: Revised: “physician” updated to “treating practitioner” *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.*	• Provider Education/Guidance • Other
01/01/2017	R6	No changes have been made to this LCD *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.*	• Other

Revision History Date	Revision History Number	Revision History Explanation	Reasons for Change
01/01/2017	R5	**Revision Effective Date: 01/01/2017** COVERAGE INDICATIONS, INDICATIONS, LIMITATIONS AND/OR MEDICAL NECESSITY: Clarified: Distinction between coverage of RAD devices and ventilators with non-invasive interfaces 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	• Provider Education/Guidance
07/01/2016	R4	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.	• Change in Assigned States or Affiliated Contract Numbers
01/01/2016	R3	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)	• Provider Education/Guidance • Revisions Due To CPT/HCPCS Code Changes

Revision History Date	Revision History Number	Revision History Explanation	Reasons for Change
10/01/2015	R2	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 who can enter date of delivery date on the POD Added: Instructions for Equipment Retained from a Prior Payer Added: Repair/Replacement section	• Provider Education/Guidance
10/01/2015	R1	**Revision Effective Date: 10/01/2015** 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	• Provider Education/Guidance • Reconsideration Request

Associated Documents

Attachments

N/A

Related Local Coverage Documents

Articles

A52517 - Respiratory Assist Devices - Policy Article

A58822 - Response to Comments: Respiratory Assist Devices - DL33800

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

Related National Coverage Documents

NCDs

N/A

Public Versions

Updated On	Effective Dates	Status	
12/07/2023	01/01/2024 - N/A	Currently in Effect	You are here

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

Keywords

N/A