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

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### Contractor Information

<table>
<thead>
<tr>
<th>Contractor Name</th>
<th>Contract Type</th>
<th>Contract Number</th>
<th>Jurisdiction(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Noridian Healthcare Solutions, LLC</td>
<td>DME MAC</td>
<td>19003 - DME MAC J-D</td>
<td>Alaska, American Samoa, Arizona, California - Entire State, Guam, Hawaii, Iowa, Idaho, Kansas, Missouri - Entire State, Montana, North Dakota, Nebraska, Nevada, Oregon, South Dakota</td>
</tr>
</tbody>
</table>
LCD Information

Document Information

LCD ID
L33800

Original ICD-9 LCD ID
L11493

LCD Title
Respiratory Assist Devices

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

Revision Effective Date
For services performed on or after 01/01/2016

Revision Ending Date
N/A

Retirement Date
N/A

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. For the items addressed in this local coverage determination, the criteria for "reasonable and necessary", based on Social Security Act §1862(a)(1)(A) provisions, are defined by the following coverage indications, limitations and/or medical necessity.
Medicare does not automatically assume payment for a durable medical equipment, prosthetics, orthotics and supplies (DMEPOS) item that was covered prior to a beneficiary becoming eligible for the Medicare Fee For Service (FFS) program. When a beneficiary receiving a DMEPOS item from another payer (including Medicare Advantage plans) becomes eligible for the Medicare FFS program, Medicare will pay for continued use of the DMEPOS item only if all Medicare coverage, coding and documentation requirements are met. Additional documentation to support that the item is reasonable and necessary, may be required upon request of the DME MAC.

PREScriptions

For an item to be covered by Medicare, a detailed written order (DWO) must be received by the supplier before a claim is submitted. If the supplier bills for an item addressed in this policy without first receiving the completed DWO, the item will be denied as not reasonable and necessary.

For some items in this policy to be covered by Medicare, a written order prior to delivery (WOPD) is required. Refer to the DOCUMENTATION REQUIREMENTS section of this LCD and to the NON-MEDICAL NECESSITY COVERAGE AND PAYMENT RULES section of the related Policy Article for information about WOPD prescription requirements.

General

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:
  1. An apnea-hypopnea index (AHI) greater than or equal to 5; and
  2. The sum total of central apneas plus central hypopneas is greater than 50% of the total apneas and hypopneas; and
  3. A central apnea-central hypopnea index (CAHI) is greater than or equal to 5 per hour; and
  4. 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
  5. 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 physician must fully document in the beneficiary’s medical record symptoms characteristic of sleep-associated hypoventilation, such as daytime hypersomnia, 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 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 H2O, 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 physician) 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 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 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 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 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
physician) 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 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 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 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 disease groups may appear to overlap conditions described in the Respiratory Assist Devices LCD but they are not overlapping. Choice of an appropriate device i.e., a ventilator versus a bi-level PAP device is made based upon the severity of the condition. CMS distinguished the use of respiratory product types in a National Coverage Analysis Decision Memo (CAG-00052N) in June 2001 saying that RAD is “distinguished from ventilation in a patient for whom interruption or failure of respiratory support leads to death.”

The conditions described in the Respiratory Assistance Devices (RAD) local coverage determination are not life-threatening conditions where interruption of respiratory support would quickly lead to serious harm or death. These policies describe clinical conditions that require intermittent and relatively short durations of respiratory support. Thus, any type ventilator would not be eligible for reimbursement for any of the conditions described in the RAD LCD even though the ventilator equipment may have the capability of operating in a bi-level PAP (E0470, E0471) mode. Bi-level PAP devices (E0470, E0471) are considered as reasonable and necessary in those clinical scenarios.

Claims for ventilators (E0465, E0466) used for the treatment of conditions described in the RAD LCD will be denied as not reasonable and necessary.

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 physician. 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 physician 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:

<table>
<thead>
<tr>
<th>Item</th>
<th>Frequency</th>
</tr>
</thead>
<tbody>
<tr>
<td>A4604</td>
<td>1 per 3 months</td>
</tr>
<tr>
<td>A7027</td>
<td>1 per 3 months</td>
</tr>
<tr>
<td>A7028</td>
<td>2 per 1 month</td>
</tr>
<tr>
<td>A7029</td>
<td>2 per 1 month</td>
</tr>
</tbody>
</table>
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 physician for use with a covered E0470 or E0471 RAD.

REFILL REQUIREMENTS

For Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (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. (CMS Program Integrity Manual, Internet-Only Manual, CMS Pub. 100-08, Chapter 5, Section 5.2.8-9).

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 ordering physicians 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 a face-to-face evaluation by their treating physician 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 or face-to-face evaluation by their treating physician 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 physician 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 physician 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 physician 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 physician 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).

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**Coding Information**

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.
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)

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)

TUBING WITH INTEGRATED HEATING ELEMENT FOR USE WITH POSITIVE AIRWAY PRESSURE DEVICE

COMBINATION ORAL/NASAL MASK, USED WITH CONTINUOUS POSITIVE AIRWAY PRESSURE DEVICE, EACH

ORAL CUSHION FOR COMBINATION ORAL/NASAL MASK, REPLACEMENT ONLY, EACH

NASAL Pillows FOR COMBINATION ORAL/NASAL MASK, REPLACEMENT ONLY, PAIR

FULL FACE MASK USED WITH POSITIVE AIRWAY PRESSURE DEVICE, EACH

FACE MASK INTERFACE, REPLACEMENT FOR FULL FACE MASK, EACH

CUSHION FOR USE ON NASAL MASK INTERFACE, REPLACEMENT ONLY, EACH

PILLOW FOR USE ON NASAL CANNULA TYPE INTERFACE, REPLACEMENT ONLY, PAIR

NASAL INTERFACE (MASK OR CANNULA TYPE) USED WITH POSITIVE AIRWAY PRESSURE DEVICE, WITH OR WITHOUT HEAD STRAP

HEADGEAR USED WITH POSITIVE AIRWAY PRESSURE DEVICE

CHINSTRAP USED WITH POSITIVE AIRWAY PRESSURE DEVICE

TUBING USED WITH POSITIVE AIRWAY PRESSURE DEVICE

FILTER, DISPOSABLE, USED WITH POSITIVE AIRWAY PRESSURE DEVICE

FILTER, NON DISPOSABLE, USED WITH POSITIVE AIRWAY PRESSURE DEVICE

ORAL INTERFACE USED WITH POSITIVE AIRWAY PRESSURE DEVICE, EACH

EXHALATION PORT WITH OR WITHOUT SWIVEL USED WITH ACCESSORIES FOR POSITIVE AIRWAY DEVICES, REPLACEMENT ONLY

WATER CHAMBER FOR HUMIDIFIER, USED WITH POSITIVE AIRWAY PRESSURE DEVICE, REPLACEMENT, EACH

HUMIDIFIER, NON-HEATED, USED WITH POSITIVE AIRWAY PRESSURE DEVICE

HUMIDIFIER, HEATED, USED WITH POSITIVE AIRWAY PRESSURE DEVICE
ICD-10 Codes that Support Medical Necessity N/A

ICD-10 Codes that DO NOT Support Medical Necessity N/A
ICD-10 Additional Information

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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 physician'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.

PRESCRIPTION (ORDER) REQUIREMENTS

GENERAL (PIM 5.2.1)

All items billed to Medicare require a prescription. An order for each item billed must be signed and dated by the treating physician, kept on file by the supplier, and made available upon request. Items dispensed and/or billed that do not meet these prescription requirements and those below must be submitted with an EY modifier added to each affected HCPCS code.

DISPENSING ORDERS (PIM 5.2.2)

Equipment and supplies may be delivered upon receipt of a dispensing order except for those items that require a written order prior to delivery. A dispensing order may be verbal or written. The supplier must keep a record of the dispensing order on file. It must contain:

- Description of the item
- Beneficiary's name
- Prescribing physician's name
- Date of the order
- Physician signature (if a written order) or supplier signature (if verbal order)

For the "Date of the order" described above, use the date the supplier is contacted by the physician (for verbal orders) or the date entered by the physician (for written dispensing orders).

In some cases, the physician may specify a future start date for therapy that is different from the date of the order. This start date does not impact the date of service (DOS) entered on the claim, Medicare-required forms (e.g., CMN, DIF) or refill/delivery timelines. As long as the supplier has a properly completed prescription with a correctly determined prescription date, an item may be shipped or delivered on or after the prescription date (except for items that require written orders prior to delivery).

Signature and date stamps are not allowed. Signatures must comply with the CMS signature requirements outlined in PIM 3.3.2.4.
The dispensing order must be available upon request.

For items that are provided based on a dispensing order, the supplier must obtain a detailed written order before submitting a claim.

WRITTEN ORDERS PRIOR TO DELIVERY (PIM 5.2.4)

ACA 6407 requires a written order prior to delivery (WOPD) for the HCPCS codes specified in the table contained in the Policy Specific Documentation Requirements Section below. The supplier must have received a complete WOPD that has been both signed and dated by the treating physician and meets the requirements for a DWO before dispensing the item. Refer the related Policy Article NON-MEDICAL NECESSITY COVERAGE AND PAYMENT RULES section for information about the statutory requirements associated with a WOPD.

DETAILED WRITTEN ORDERS (PIM 5.2.3)

A detailed written order (DWO) is required before billing. Someone other than the ordering physician may produce the DWO. However, the ordering physician must review the content and sign and date the document. It must contain:

- Beneficiary's name
- Physician's name
- Date of the order
- Detailed description of the item(s) (see below for specific requirements for selected items)
- Physician signature and signature date

For items provided on a periodic basis, including drugs, the written order must include:

- Item(s) to be dispensed
- Dosage or concentration, if applicable
- Route of Administration, if applicable
- Frequency of use
- Duration of infusion, if applicable
- Quantity to be dispensed
- Number of refills, if applicable

For the "Date of the order" described above, use the date the supplier is contacted by the physician (for verbal orders) or the date entered by the physician (for written dispensing orders).

With respect to the date on the DWO/WOPD:

1. If the prescriber creates a complete and compliant DWO/WOPD, only a single date - the “order date” - is required. This order date may be the date that the prescriber signs the document (either wet signature or electronic signature).

2. If someone other than the prescriber (e.g., DME supplier) creates the DWO/WOPD then the prescription must be reviewed and, “...personally signed and dated...” by the prescriber. In this scenario two (2) dates are required: an “order date” and a prescriber-entered “signature date”.
In some cases, the physician may specify a future start date for therapy that is different from the date of the order. This start date does not impact the date of service (DOS) entered on the claim, Medicare-required forms (e.g., CMN, DIF) or refill/delivery timelines. As long as the supplier has a properly completed prescription with a correctly determined prescription date, an item may be shipped or delivered.

Frequency of use information on orders must contain detailed instructions for use and specific amounts to be dispensed. Reimbursement shall be based on the specific utilization amount only. Orders that only state "PRN" or "as needed" utilization estimates for replacement frequency, use, or consumption are not acceptable. (PIM 5.9)

The detailed description in the written order may be either a narrative description or a brand name/model number.

Signature and date stamps are not allowed. Signatures must comply with the CMS signature requirements outlined in PIM 3.3.2.4.

The DWO must be available upon request.

A prescription is not considered as part of the medical record. Medical information intended to demonstrate compliance with coverage criteria may be included on the prescription but must be corroborated by information contained in the medical record. (PIM 5.2.3)

**MEDICAL RECORD INFORMATION**

**GENERAL (PIM 5.7 - 5.9)**

The **Coverage Indications, Limitations and/or Medical Necessity** section of this LCD contains numerous reasonable and necessary (R&N) requirements. The **Non-Medical Necessity Coverage and Payment Rules** section of the related Policy Article contains numerous non-reasonable and necessary, benefit category and statutory requirements that must be met in order for payment to be justified. Suppliers are reminded that:

- Supplier-produced records, even if signed by the ordering physician, and attestation letters (e.g. letters of medical necessity) are deemed not to be part of a medical record for Medicare payment purposes.

- Templates and forms, including CMS Certificates of Medical Necessity, are subject to corroboration with information in the medical record.

Information contained directly in the contemporaneous medical record is the source required to justify payment except as noted elsewhere for prescriptions and CMNs. The medical record is not limited to physician’s office records but may include records from hospitals, nursing facilities, home health agencies, other healthcare professionals, etc. (not all-inclusive). Records from suppliers or healthcare professionals with a financial interest in the claim outcome are not considered sufficient by themselves for the purpose of determining that an item is reasonable and necessary.

**CONTINUED MEDICAL NEED**

For all Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) items, the initial justification for medical need is established at the time the item(s) is first ordered; therefore, beneficiary medical records demonstrating that the item is reasonable and necessary are created just prior to, or at the time of, the creation of the initial prescription. For purchased items, initial months of a rental item or for initial months of ongoing supplies or drugs, information justifying reimbursement will come from this initial time period. Entries in the beneficiary’s medical record must have been created prior to, or at the time of, the initial date of service (DOS) to establish whether the initial reimbursement was justified based upon the applicable coverage policy.

For ongoing supplies and rental DME items, in addition to information described above that justifies the initial provision of the item(s) and/or supplies, there must be information in the beneficiary’s medical record to support that the item continues to be used by the beneficiary and remains reasonable and necessary. Information used to justify continued medical need must be timely for the DOS under review. Any of the following may serve as documentation justifying continued medical need:

- A recent order by the treating physician for refills

- A recent change in prescription
• A properly completed CMN or DIF with an appropriate length of need specified
• Timely documentation in the beneficiary's medical record showing usage of the item

Timely documentation is defined as a record in the preceding 12 months unless otherwise specified elsewhere in the policy.

CONTINUED USE

Continued use describes the ongoing utilization of supplies or a rental item by a beneficiary. Suppliers are responsible for monitoring utilization of DMEPOS rental items and supplies. No monitoring of purchased items or capped rental items that have converted to a purchase is required. Suppliers must discontinue billing Medicare when rental items or ongoing supply items are no longer being used by the beneficiary.

Beneficiary medical records or supplier records may be used to confirm that a DMEPOS item continues to be used by the beneficiary. Any of the following may serve as documentation that an item submitted for reimbursement continues to be used by the beneficiary:

• Timely documentation in the beneficiary's medical record showing usage of the item, related option/accessories and supplies
• Supplier records documenting the request for refill/replacement of supplies in compliance with the Refill Documentation Requirements (This is deemed to be sufficient to document continued use for the base item, as well)
• Supplier records documenting beneficiary confirmation of continued use of a rental item

Timely documentation is defined as a record in the preceding 12 months unless otherwise specified elsewhere in this policy.

REFILL DOCUMENTATION (PIM 5.2.7-9)

A routine refill prescription is not needed. A new prescription is needed when:

• There is a change of supplier
• There is a change in the item(s), frequency of use, or amount prescribed
• There is a change in the length of need or a previously established length of need expires
• State law requires a prescription renewal

For items that the beneficiary obtains in-person at a retail store, the signed delivery slip or a copy of the itemized sales receipt is sufficient documentation of a request for refill.

For items that are delivered to the beneficiary, documentation of a request for refill must be either a written document received from the beneficiary or a contemporaneous written record of a phone conversation/contact between the supplier and beneficiary. The refill request must occur and be documented before shipment. A retrospective attestation statement by the supplier or beneficiary is not sufficient. The refill record must include:

• Beneficiary's name or authorized representative if different than the beneficiary
• A description of each item that is being requested
• Date of refill request
For consumable supplies, i.e., those that are used up (e.g., ostomy or urological supplies, surgical dressings, etc.) - the supplier should assess the quantity of each item that the beneficiary still has remaining, to document that the amount remaining will be nearly exhausted on or about the supply anniversary date.

For non-consumable supplies, i.e., those more durable items that are not used up but may need periodic replacement (e.g., PAP and RAD supplies) - the supplier should assess whether the supplies remain functional, providing replacement (a refill) only when the supply item(s) is no longer able to function. Document the functional condition of the item(s) being refilled in sufficient detail to demonstrate the cause of the dysfunction that necessitates replacement (refill).

This information must be kept on file and be available upon request.

PROOF OF DELIVERY (PIM 4.26, 5.8)

Proof of delivery (POD) is a Supplier Standard and DMEPOS suppliers are required to maintain POD documentation in their files. For medical review purposes, POD serves to assist in determining correct coding and billing information for claims submitted for Medicare reimbursement. Regardless of the method of delivery, the contractor must be able to determine from delivery documentation that the supplier properly coded the item(s), that the item(s) delivered are the same item(s) submitted for Medicare reimbursement and that the item(s) are intended for, and received by, a specific Medicare beneficiary.

Suppliers, their employees, or anyone else having a financial interest in the delivery of the item are prohibited from signing and accepting an item on behalf of a beneficiary (i.e., acting as a designee on behalf of the beneficiary). The signature and date the beneficiary or designee accepted delivery must be legible.

For the purpose of the delivery methods noted below, designee is defined as any person who can sign and accept the delivery of durable medical equipment on behalf of the beneficiary.

Proof of delivery documentation must be available to the Medicare contractor on request. All services that do not have appropriate proof of delivery from the supplier will be denied and overpayments will be requested. Suppliers who consistently fail to provide documentation to support their services may be referred to the OIG for imposition of Civil Monetary Penalties or other administrative sanctions.

Suppliers are required to maintain POD documentation in their files. For the items addressed in this policy, there are two methods of delivery:

1. Delivery directly to the beneficiary or authorized representative
2. Delivery via shipping or delivery service

Method 1—Direct Delivery to the Beneficiary by the Supplier

Suppliers may deliver directly to the beneficiary or the designee. In this case, POD to a beneficiary must be a signed and dated delivery document. The POD document must include:

- Beneficiary's name
- Delivery address
- Sufficiently detailed description to identify the item(s) being delivered (e.g., brand name, serial number, narrative description)
- Quantity delivered
- Date delivered
- Beneficiary (or designee) signature

The date delivered on the POD must be the date that the DMEPOS item was received by the beneficiary or
designee. The date of delivery may be entered by the beneficiary, designee or the supplier. When the supplier’s delivery documents have both a supplier-entered date and a beneficiary or beneficiary’s designee signature date on the POD document, the beneficiary or beneficiary’s designee-entered date is the date of service.

In instances where the supplies are delivered directly by the supplier, the date the beneficiary received the DMEPOS supply must be the date of service on the claim.

**Method 2—Delivery via Shipping or Delivery Service Directly to a Beneficiary**

If the supplier utilizes a shipping service or mail order, the POD documentation must be a complete record tracking the item(s) from the DMEPOS supplier to the beneficiary. An example of acceptable proof of delivery would include both the supplier's own detailed shipping invoice and the delivery service's tracking information. The supplier's record must be linked to the delivery service record by some clear method like the delivery service's package identification number or supplier's invoice number for the package sent to the beneficiary. The POD document must include:

- Beneficiary's name
- Delivery address
- Delivery service’s package identification number, supplier invoice number or alternative method that links the supplier's delivery documents with the delivery service's records
- Sufficiently detailed description to identify the item(s) being delivered (e.g., brand name, serial number, narrative description)
- Quantity delivered
- Date delivered
- Evidence of delivery

If a supplier utilizes a shipping service or mail order, suppliers must use the shipping date as the date of service on the claim.

Suppliers may also utilize a return postage-paid delivery invoice from the beneficiary or designee as a POD. This type of POD document must contain the information specified above.

**EQUIPMENT RETAINED FROM A PRIOR PAYER**

When a beneficiary receiving a DMEPOS item from another payer (including a Medicare Advantage plan) becomes eligible for the Medicare FFS program, the first Medicare claim for that item or service is considered a new initial Medicare claim for the item. Even if there is no change in the beneficiary’s medical condition, the beneficiary must meet all coverage, coding and documentation requirements for the DMEPOS item in effect on the date of service of the initial Medicare claim. There are special requirements for this category described under “BENEFICIARIES ENTERING MEDICARE” in the “Coverage Indications, Limitations, and/or Medical Necessity” section of this LCD.

A POD is required for all items, even those in the beneficiary’s possession provided by another insurer prior to Medicare eligibility. To meet the POD requirements for a beneficiary transitioning to Medicare, the supplier:

1. Must obtain a new POD as described above under “Methods of Delivery” (whichever method is applicable); or,
2. Must obtain a statement, signed and dated by the beneficiary (or beneficiary’s designee), attesting that the supplier has examined the DMEPOS item, it is in good working order and that it meets Medicare requirements.

For the purposes of reasonable useful lifetime and calculation of continuous use, the first day of the first rental month in which Medicare payments are made for the item (i.e., date of service) serves as the start date of the reasonable useful lifetime and period of continuous use. In these cases, the proof of delivery documentation serves as evidence that the beneficiary is already in possession of the item.
1. The treating physician must document that the DMEPOS item being repaired continues to be reasonable and necessary (see Continued Medical Need section above); and,

2. Either the treating physician or the supplier must document that the repair itself is reasonable and necessary.

The supplier must maintain detailed records describing the need for and nature of all repairs including a detailed explanation of the justification for any component or part replaced as well as the labor time to restore the item to its functionality.

A physician's order and/or new Certificate of Medical Necessity (CMN), when required, is needed to reaffirm the medical necessity of the item for replacement of an item.

POLICY SPECIFIC DOCUMENTATION REQUIREMENTS

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 this policy 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 this policy have been met and the treating physician'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 Physician 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 used. 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.

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

MISCELLANEOUS:

The physician 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.

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

**AFFORDABLE CARE ACT (ACA) 6407 REQUIREMENTS**

ACA 6407 contains provisions that are applicable to certain specified items in this policy. In this policy the specified items are:

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<thead>
<tr>
<th>Revision History Date</th>
<th>Revision History Number</th>
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<tbody>
<tr>
<td>01/01/2016</td>
<td>R3</td>
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| 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) |

| 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) |

These items require an in-person or face-to-face interaction between the beneficiary and their treating physician prior to prescribing the item, specifically to document that the beneficiary was evaluated and/or treated for a condition that supports the need for the item(s) of DME ordered. A dispensing order is not sufficient to provide these items. A Written Order Prior to Delivery (WOPD) is required. Refer to the related Policy Article NON-MEDICAL NECESSITY COVERAGE AND PAYMENT RULES section for information about these statutory requirements.

The DMEPOS supplier must have documentation of both the face-to-face visit and the completed WOPD in their file prior to the delivery of these items.

Suppliers are reminded that all Medicare coverage and documentation requirements for DMEPOS also apply. There must be sufficient information included in the medical record to demonstrate that all of the applicable coverage criteria are met. This information must be available upon request.

**Appendices**

PIM citations above denote references to CMS Program Integrity Manual, Internet Only Manual 100-08

**Utilization Guidelines**

Refer to Coverage Indications, Limitations and/or Medical Necessity

**Sources of Information and Basis for Decision**

N/A

**Revision History Information**

Please note: Most Revision History entries effective on or before 01/24/2013 display with a Revision History Number of "R1" at the bottom of this table. However, there may be LCDs where these entries will display as a separate and distinct row.

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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)

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<tr>
<td>Provider Education/Guidance</td>
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<td>Revisions Due To CPT/HCPCS Code Changes</td>
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10/01/2015 R2

Revision Effective Date: 12/01/2014 (May 2015 Publication)

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## Associated Documents

**Attachments** N/A

**Related Local Coverage Documents Article(s)** A52517 - Respiratory Assist Devices - Policy Article

**Related National Coverage Documents** N/A

**Public Version(s)** Updated on 02/26/2016 with effective dates 01/01/2016 - N/A

Updated on 05/07/2015 with effective dates 10/01/2015 - 12/31/2015

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Updated on 04/04/2014 with effective dates 10/01/2015 - N/A

**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.

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**Contractor Information**

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<th>Contract Type</th>
<th>Contract Number</th>
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<td>DME MAC</td>
<td>18003 - DME MAC J-C</td>
<td>Alabama, Arkansas, Colorado, Florida, Georgia, Louisiana, Mississippi, North Carolina, New Mexico, Oklahoma, Puerto Rico, South Carolina, Tennessee, Texas, Virginia, Virgin Islands, West Virginia</td>
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<td>CGS Administrators, LLC</td>
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**Contractor Name**
Noridian Healthcare Solutions, LLC

**Contract Type**
DME MAC

**Contract Number**
19003 - DME MAC J-D

**Jurisdiction**
- Vermont
- Alaska
- American Samoa
- Arizona
- California - Entire State
- Guam
- Hawaii
- Iowa
- Idaho
- Kansas
- Missouri - Entire State
- Montana
- North Dakota
- Nebraska
- Nevada
- Oregon
- South Dakota
- Utah
- Washington
- Wyoming
- Northern Mariana Islands

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**Article Information**

**General Information**

**Article ID**
A52517

**Original Article Effective Date**
10/01/2015

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11/05/2015

**Revision Ending Date**
N/A

**Retirement Date**
N/A

**Article Title**
Respiratory Assist Devices - Policy 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).

AFFORDABLE CARE ACT (ACA) 6407 REQUIREMENTS

ACA 6407 contains provisions that are applicable to specified items in this policy. In this policy the specified items are:

<table>
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<td>E0470</td>
<td>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)</td>
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<td>E0471</td>
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Face-to-Face Visit Requirements:

As a condition for payment, Section 6407 of the Affordable Care Act (ACA) requires that a physician (MD, DO or DPM), physician assistant (PA), nurse practitioner (NP) or clinical nurse specialist (CNS) has had a face-to-face examination with a beneficiary that meets all of the following requirements:

- The treating physician must have an in-person examination with the beneficiary within the six (6) months prior to the date of the written order prior to delivery (WOPD).
- This examination must document that the beneficiary was evaluated and/or treated for a condition that supports the need for the item(s) of DME ordered.
A new face-to-face examination is required each time a new prescription for one of the specified items is ordered. A new prescription is required by Medicare:

- For all claims for purchases or initial rentals.
- When there is a change in the prescription for the accessory, supply, drug, etc.
- If a local coverage determination (LCD) requires periodic prescription renewal (i.e., policy requires a new prescription on a scheduled or periodic basis)
- When an item is replaced
- When there is a change in the supplier

The first bullet, "For all claims for purchases or initial rentals”, includes all claims for payment of purchases and initial rentals for items not originally covered (reimbursed) by Medicare Part B. Claims for items obtained outside of Medicare Part B, e.g. from another payer prior to Medicare participation (including Medicare Advantage plans), are considered to be new initial claims for Medicare payment purposes.

Prescription Requirements:

A WOPD is a standard Medicare Detailed Written Order, which must be completed, including the prescribing physician’s signature and signature date, and must be in the Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) supplier’s possession BEFORE the item is delivered. The WOPD must include all of the items below:

- Beneficiary’s name,
- Physician’s name
- Date of the order
- The prescribing practitioner's National Provider Identifier (NPI),
- The signature of the ordering practitioner
- Signature date

For any of the specified items provided on a periodic basis, including drugs, the written order must include, in addition to the above:

- Item(s) to be dispensed
- Dosage or concentration, if applicable
- Route of Administration, if applicable
- Frequency of use
- Duration of infusion, if applicable
- Quantity to be dispensed
- Number of refills, if applicable

Note that prescriptions for these specified DME items require the National Provider Identifier to be included on the
prescription. Prescriptions for other DMEPOS items do not have this NPI requirement. Suppliers should pay particular attention to orders that include a mix of items, to assure that these ACA order requirements are met.

The treating practitioner that conducted the face-to-face examination does not need to be the prescriber for the DME item. However the prescriber must:

- Verify that the in-person visit occurred within the 6-months prior to the date of their prescription, and
- Have documentation of the face-to-face examination that was conducted, and
- Provide the DMEPOS supplier with copies of the in-person visit records.

Date and Timing Requirements

There are specific date and timing requirements:

- The date of the face-to-face examination must be on or before the date of the written order (prescription) and may be no older than 6 months prior to the prescription date.
- The date of the face-to-face examination must be on or before the date of delivery for the item(s) prescribed.
- The date of the written order must be on or before the date of delivery.
- The DMEPOS supplier must have documentation of both the face-to-face visit and the completed WOPD in their file prior to the delivery of these items.

A date stamp (or similar) is required which clearly indicates the supplier’s date of receipt of both the face-to-face record and the completed WOPD with the prescribing physician’s signature and signature date. It is recommended that both documents be separately date-stamped to avoid any confusion regarding the receipt date of these documents.

Claim Denial

Claims for the specified items subject to ACA 6407 that do not meet the requirements specified above will be denied as statutorily non-covered – failed to meet statutory requirements.

If the supplier delivers the item prior to receipt of a written order, it will be denied as statutorily non-covered. If the written order is not obtained prior to delivery, payment will not be made for that item even if a written order is subsequently obtained. If a similar item is subsequently provided by an unrelated supplier who has obtained a written order prior to delivery, it will be eligible for coverage.

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”.

Note: Coding guidelines and requirements may vary based on specific insurance policies and regulations. Always consult with the payer’s guidelines and policy documents for the most accurate information.
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.

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

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**Coding Information**

**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 article does not apply to that Bill Type. Complete absence of all Bill Types indicates that coverage is not influenced by Bill Type and the article 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 article, 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 article should be assumed to apply equally to all Revenue Codes.
### Revision History Information

Please note: The Revision History information included in this Article prior to 06/20/2013 will now display with a Revision History Number of "R1" at the bottom of this table. All new Revision History information entries completed on or after 06/20/2013 will display as a row in the Revision History section of the Article and numbering will begin with "R2".

<table>
<thead>
<tr>
<th>Revision Date</th>
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<tbody>
<tr>
<td>11/05/2015</td>
<td>R3</td>
<td>NON-MEDICAL NECESSITY COVERAGE AND PAYMENT RULES: Revised: Standard Documentation language to remove start date verbiage from Prescription Requirements</td>
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<tr>
<td>10/01/2015</td>
<td>R2</td>
<td>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</td>
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<tr>
<td>10/01/2015</td>
<td>R1</td>
<td>Revision Effective Date: 10/01/2015 NON-MEDICAL NECESSITY COVERAGE AND PAYMENT RULES: Added: ACA 6407 prescriber requirements</td>
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**Related Local Coverage Document(s)** 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

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### Keywords

N/A Read the [Article Disclaimer](#) Back to Top