

**LCD for Respiratory Assist Devices (L11482)****Contractor Information**

<b>Contractor Name</b>	AdminaStar Federal, Inc.
<b>Contractor Number</b>	00635
<b>Contractor Type</b>	DMERC

**LCD Information**

<b>LCD Database ID Number</b>	L11482
<b>LCD Title</b>	Respiratory Assist Devices
<b>Contractor's Determination Number</b>	RAD
<b>AMA CPT / ADA CDT Copyright Statement</b>	CPT codes, descriptions and other data only are copyright 2004 American Medical Association (or such other date of publication of CPT). All Rights Reserved. Applicable FARS/DFARS Clauses Apply. CDT-4 codes and descriptions are © 2004 American Dental Association. All rights reserved.
<b>CMS National Coverage Policy</b>	CMS Pub. 100-3 (Medicare National Coverage Determination Manual), Chapter 1, Section 280.1
<b>Primary Geographic Jurisdiction</b>	DC IL IN MD MI MN OH VA WI WV
<b>Oversight Region</b>	Region V
<b>CMS Consortium</b>	Midwest

<b>DMERC Region LCD Covers</b>	Region B
<b>Original Determination Effective Date</b>	For services performed on or after 10/01/1999
<b>Original Determination Ending Date</b>	
<b>Revision Effective Date</b>	For services performed on or after 01/01/2005
<b>Revision Ending Date</b>	
<b>Indications and Limitations of Coverage and/or Medical Necessity</b>	<p>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 medical policy, the criteria for "reasonable and necessary" is defined by the following indications and limitations of coverage and/or medical necessity.</p> <p>For an item to be covered by Medicare, a written signed and dated order must be received by the supplier before a claim is submitted to the DMERC. If the supplier bills for an item addressed in this policy without first receiving the completed order, the item will be denied as not medically necessary.</p> <p>GENERAL:</p> <ul style="list-style-type: none"> <li>- The "treating physician" must be one who is qualified by virtue of experience and training in non-invasive respiratory assistance, to order and monitor the use of respiratory assist devices. Physicians who treat patients for other medical conditions may or may not be so qualified, and if not, though they may be the treating physician of the beneficiary for other conditions, they are not considered the "treating physician" for the administration of NPPRA therapy.</li> </ul> <p>For the purpose of this policy, polysomnographic studies must be performed in a sleep study laboratory, and not in the home or in a mobile facility. It must comply with all applicable state</p>

regulatory requirements.

- For the purpose of this policy, arterial blood gas, sleep oximetry and polysomnographic studies may not be performed by a DME supplier. A DME supplier is not considered a qualified provider or supplier of these tests for purposes of this policy's coverage and payment guidelines. This prohibition does not extend to the results of studies conducted by hospitals certified to do such tests.

- 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 (First Three Months):

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

- A respiratory assist device (E0470, E0471) used to administer NPPRA therapy is covered for those patients with clinical disorder groups characterized as (I) restrictive thoracic disorders (i.e., progressive neuromuscular diseases or severe thoracic cage abnormalities), (II) severe chronic obstructive pulmonary disease (COPD), (III) central sleep apnea (CSA), or (IV) obstructive sleep apnea (OSA) (E0470 only) and who also meet the following criteria:

##### I) Restrictive Thoracic Disorders:

A) There is documentation in the patient's medical record of a progressive neuromuscular disease (for example, amyotrophic lateral sclerosis) or a severe thoracic cage abnormality (for example, post-thoracoplasty for TB), and

B) 1) An arterial blood gas PaCO<sub>2</sub>, done while awake and breathing the patient's usual FIO<sub>2</sub> is greater than or equal to 45 mm Hg, or

2) Sleep oximetry demonstrates oxygen saturation less than or equal to 88% for at least five continuous minutes, done while breathing the patient's usual FIO<sub>2</sub>, or,

3) For a progressive neuromuscular disease (only), maximal inspiratory pressure is less than 60 cm H<sub>2</sub>O or forced vital capacity is less than 50% predicted, and

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

If all of the above criteria are met, either a E0470 or E0471 device (based upon the judgment of the treating physician) will be covered for patients within this group of conditions for the first three months of NPPRA therapy (see below for continued coverage after the initial three months). If all of the above criteria are not met, then E0470 or E0471 and related accessories will be denied as not medically necessary.

II) Severe COPD:

A) 1) An arterial blood gas PaCO<sub>2</sub>, done while awake and breathing the patient's usual FIO<sub>2</sub>, is greater than or equal to 52 mm Hg, and

2) Sleep oximetry demonstrates oxygen saturation less than or equal to 88% for at least five continuous minutes, done while breathing oxygen at 2 LPM or the patient's usual FIO<sub>2</sub> (whichever is higher), and

B) Prior to initiating therapy, OSA (and treatment with CPAP) has been considered and ruled out.

If all of the above criteria for patients with COPD are met, a E0470 device will be covered for the first three months of NPPRA therapy (see below for continued coverage after the initial three months). A E0471 device will not be covered for a patient with COPD during the first two months, because therapy with a E0470 device with proper adjustments of the device's settings and patient accommodation to its use will usually result in sufficient improvement without the need of a back-up rate. (See below for coverage of a E0471 device for COPD after 2 month's use of a E0470 device.)

If all of the above criteria are not met, E0470 and related accessories will be denied as not medically necessary. If E0471 is billed, even if the criteria for a E0470 device are met, since the E0471 is in a different payment category than E0470 and a least costly medically appropriate alternative payment cannot be made, it will be denied as not medically necessary.

III) Central Sleep Apnea (i.e., apnea not due to airway obstruction):

Prior to initiating therapy, a complete facility-based, attended polysomnogram must be performed documenting the following:

A) The diagnosis of central sleep apnea (CSA), and

- B) The exclusion of obstructive sleep apnea (OSA) as the predominant cause of sleep-associated hypoventilation, and
- C) The ruling out of CPAP as effective therapy if OSA is a component of the sleep-associated hypoventilation, and
- D) Oxygen saturation less than or equal to 88% for at least five continuous minutes, done while breathing the patient's usual FIO<sub>2</sub>, and
- E) 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 patient's usual FIO<sub>2</sub>.

If all of the above criteria are met, either an E0470 or E0471 device (based upon the judgment of the treating physician) will be covered for patients with documented CSA conditions for the first three months of NPPRA therapy (see below for continued coverage after the initial three months). If all of the above criteria are not met, then E0470 or E0471 and related accessories will be denied as not medically necessary.

#### IV) Obstructive Sleep Apnea (OSA):

Criteria (A) and (B) are both met:

A) A complete facility-based, attended polysomnogram, has established the diagnosis of obstructive sleep apnea according to the following criteria:

1) The apnea-hypopnea index (AHI) is greater than or equal to 15 events per hour, or

2) The AHI is from 5 to 14 events per hour with documented symptoms of:

a) Excessive daytime sleepiness, impaired cognition, mood disorders, or insomnia, or

b) Hypertension, ischemic heart disease, or history of stroke, and

B) A single level device (E0601, Continuous Positive Airway Pressure Device, CPAP) has been tried and proven ineffective.

If the above criteria are met, an E0470 device will be covered for the first three months of NPPRA therapy (see below for continued coverage after the initial three months). If E0470 is billed and these criteria are not met but the coverage criteria in

the DMERC policy for Continuous Positive Airway Pressure System (CPAP) are met, payment will be based on the allowance for the least costly medically appropriate alternative, E0601.

A E0471 device is not medically necessary if the primary diagnosis is OSA. If E0471 is billed, since the E0471 is in a different payment category than E0470 and E0601 and a least costly medically appropriate alternative payment cannot be made, it will be denied as not medically necessary.

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

Patients covered for the first 3 months of an E0470 or E0471 device must be re-evaluated to establish the medical necessity of continued coverage by Medicare beyond the first three months. While the patient 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 4th and succeeding months of NPPRA therapy until this re-evaluation has been completed.

There must be documentation in the patient's medical record about the progress of relevant symptoms and patient usage of the device up to that time. Failure of the patient 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 medically necessary.

The following items of documentation must be obtained by the supplier of the device for continuation of coverage beyond three months:

- 1) A signed and dated statement completed by the treating physician no sooner than 61 days after initiating use of the device, declaring that the patient is compliantly using the device (an average of 4 hours per 24 hour period) and that the patient is benefiting from its use, and
- 2) A Medicare beneficiary statement completed by the patient no sooner than 61 days after initiating use of the device (see below).

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

not medically necessary.

For Group II patients (COPD) who qualified for an E0470 device, if at a time no sooner than 61 days after initial issue and compliant use of an E0470 device, the treating physician believes the patient requires an E0471 device, the E0471 device will be covered if the following criteria are met:

- 1) An arterial blood gas PaCO<sub>2</sub>, repeated no sooner than 61 days after initiation of compliant use of the E0470, done while awake and breathing the patient's usual FIO<sub>2</sub>, still remains greater than or equal to 52 mm Hg, and
- 2) A sleep oximetry, repeated no sooner than 61 days after initiation of compliant use of an E0470 device, and while breathing with the E0470 device, demonstrates oxygen saturation less than or equal to 88% for at least five continuous minutes, done while breathing oxygen at 2 LPM or the patient's usual FIO<sub>2</sub> [whichever is higher], and
- 3) A signed and dated statement from the treating physician, completed no sooner than 61 days after initiation of the E0470 device, declaring that the patient has been compliantly using the E0470 device (an average of 4 hours per 24 hour period) but that the patient is NOT benefiting from its use, and
- 4) A Medicare beneficiary statement completed by the patient, no sooner than 61 days after initiation of the E0470 device.

If the above criteria for an E0471 are not met, since the E0471 is in a different payment category than E0470 and a least costly medically appropriate alternative payment cannot be made, it will be denied as not medically necessary.

#### PATIENTS ON AN E0470 OR E0741 DEVICE PRIOR TO OCTOBER 1, 1999:

For patients in Groups I, II and III started on E0470 or E0471 respiratory assist devices at any time (and in Group IV, 3 months or less) prior to October 1, 1999, the supplier must obtain the following for continued coverage:

- 1) A signed and dated statement from the treating physician declaring that the patient continues to compliantly use the device (an average of 4 hours per 24 hour period) and that the patient is benefiting from its use, and
- 2) A Medicare beneficiary statement completed by the patient.

For patients in Group IV started on E0470 devices greater than 3 months prior to October 1, 1999, the requirements listed in the

previous paragraph do not apply. Coverage will be continued. E0471 devices have not been covered for the treatment of patients in Group IV (OSA) even prior to October 1, 1999 and will continue to be denied as not medically necessary for this group of patients.

If the above criteria for continued coverage are not met, E0470 and E0471 devices and their accessories will be denied as not medically necessary.

#### MEDICARE BENEFICIARY STATEMENT:

For continued coverage of an E0470 or E0471 device, the supplier must obtain a signed and dated statement from the beneficiary documenting that the device is currently being used for 4 or more hours per 24 hour period, that it has been used for at least 2 months at the time of the statement's completion, that the beneficiary plans to continue using the device in the future, and that the person completing the statement was not the supplier. A suggested form for collecting this information is attached (whatever form is used must contain all of the questions contained on the attached suggested form). All of the questions on any Medicare beneficiary statement must be answered by the beneficiary, or a family member or caregiver, but may not be completed by the supplier. The completed statement documenting that the criteria for continued coverage have been met must be obtained by the supplier in order for the fourth and succeeding months' claims to be eligible for coverage.

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

#### ACCESSORIES:

Accessories (A7030-A7039, A7044, A7046, E0561, E0562) used with E0471 or E0472 are not separately billable or reimbursable since E0471 and E0472 are in the frequent and substantially serviced payment category. These items are separately reimbursable when used with E0470.

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

A7034 - 1 per 3 months  
A7032 or A7033 - 2 per 1 month  
A7035 - 1 per 6 months  
A7036 - 1 per 6 months  
A7037 - 1 per 1 month  
A7038 - 2 per 1 month  
A7039 - 1 per 6 months

Billing for quantities of supplies greater than those described in the policy as the usual maximum amounts, in the absence of documentation clearly explaining the medical necessity of the excess quantities, will be denied as not medically 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 respiratory assist device.

**Coverage Topic** Durable Medical Equipment

### Coding Information

#### CPT/HCPCS Codes

**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.**

**KX - Specific required documentation on file.**

#### HCPCS CODES:

#### EQUIPMENT:

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)

E0472 RESPIRATORY ASSIST DEVICE, BI-LEVEL PRESSURE CAPABILITY, WITH BACKUP RATE FEATURE, USED WITH INVASIVE INTERFACE, E.G., TRACHEOSTOMY TUBE (INTERMITTENT ASSIST DEVICE WITH CONTINUOUS POSITIVE AIRWAY PRESSURE DEVICE)

#### ACCESSORIES:

A7030 FULL FACE MASK USED WITH POSITIVE AIRWAY PRESSURE DEVICE, EACH

A7031 FACE MASK INTERFACE, REPLACEMENT FOR FULL FACE

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

**ICD-9 Codes that Support Medical Necessity**

Not specified.

**Diagnoses that Support Medical Necessity**

Not specified.

**ICD-9 Codes that DO NOT Support Medical Necessity** Not specified.

**ICD-9 Codes that DO NOT Support Medical Necessity Asterisk Explanation**

**Diagnoses that DO NOT Support Medical Necessity** Not specified.

### General 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" (42 U.S.C. section 1395l(e)). It is expected that the patient's medical records will reflect the need for the care provided. The patient'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 to the DMERC upon request.

An order for each item billed must be signed and dated by the treating physician, kept on file by the supplier, and made available to the DMERC upon request. Items billed to the DMERC before a signed and dated order has been received by the supplier must be submitted with an EY modifier added to each affected HCPCS code.

Proper use of the KX modifier is discussed below. Where permitted KX must be added to codes E0470, E0471, and codes for accessories used with E0470. The KX modifier must not be used on claims submitted to the DMERC until the required documentation has actually been obtained and entered into the supplier's files.

**FOR PATIENTS PLACED ON AN E0470 OR E0471 DEVICE AFTER OCTOBER 1, 1999:**

On claims for the first through third months, suppliers must add a KX modifier if all of the criteria for patients in Groups I-IV in the Coverage and Payment Rules section of this policy have been met. If the requirements for the KX modifier are not met, the supplier may submit additional documentation with the claim to justify coverage, but 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 and Payment Rules section of this policy have been met and the following additional documentation has been obtained for the supplier's files:

For all patients on an E0470 or E0471 device, the supplier must obtain:

- 1) The treating physician's signed and dated statement described in the Coverage and Payment Rules Section above, and
- 2) A Medicare beneficiary statement, completed and obtained according to the criteria stated in the Coverage and Payment Rules section.

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

In addition, for patients in Group II (COPD), when an E0471 device is being billed, the following additional documentation requirements must be met:

- 3) Repeat arterial blood gas PaCO<sub>2</sub> and
- 4) Repeat sleep oximetry,

both of which must meet the criteria described in the Coverage and Payment Rules section above.

FOR PATIENTS PLACED ON AN E0470 OR E0471 DEVICE PRIOR TO OCTOBER 1, 1999:

- A) All patients on an E0470 or E0471 device 90 days or less prior to October 1, 1999:

For the first through third rental months' claims, a KX modifier must be added if there is a physician's order in the supplier's file, and documentation in the patient's medical record of a covered diagnosis.

On the fourth rental month's claim (and any month thereafter), a KX modifier must be added if all the "Initial Coverage" criteria in the Coverage and Payment Rules section of this policy have been

met and the supplier has obtained the documentation described in (1) and (2) of the previous section (treating physician and beneficiary statements).

B) Patients in Groups I-III on an E0470 or E0471 device greater than 90 days prior to October 1, 1999:

A KX modifier must be added if the supplier has obtained the documentation described in (1) and (2) of the previous section (treating physician and beneficiary statements).

C) Patients in Group IV (OSA) on an E0470 device greater than 90 days prior to October 1, 1999:

The KX must be added on these claims if there is a physician's order in the supplier's file, and documentation in the patient's medical record of a covered diagnosis. A KX must not be added to claims for an E0471 used to treat Group IV patients (OSA).

#### MISCELLANEOUS:

The physician and beneficiary statements for patients on E0470 or E0471 devices must be kept on file by the supplier, but should not be sent in with the claim. The DMERC may request copies of this documentation at its discretion.

When billing for quantities of accessories for E0470 that are greater than those described in the policy as the usual maximum amounts, each claim must include documentation supporting the medical necessity for the higher utilization. This information must be attached to a hard copy claim or entered in the narrative field of an electronic claim. Additionally, there must be clear documentation in the patient's medical records corroborating the medical necessity of this amount. The DMERC may request copies of the patient's medical records that corroborate the order and any additional documentation that pertains to the medical necessity of items and quantities billed.

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

#### Appendices

A respiratory cycle is defined as an inspiration, followed by an expiration.

Polysomnography is the continuous and simultaneous monitoring and recording of various physiological and pathophysiological parameters of sleep with physician review, interpretation, and report. It must include sleep staging, which is defined to include a 1-4 lead electroencephalogram (EEG), and electro-oculogram (EOG), and a submental electromyogram (EMG). 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.

Apnea is defined as the cessation of airflow for at least 10 seconds documented on a polysomnogram.

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 apneas and hypopneas per hour of sleep. The polysomnogram must be based on a minimum of two hours of recording time without the use of a positive airway pressure device, reported by polysomnogram. The AHI may not be extrapolated or projected. For example, the total recording time off of a device for the polysomnogram is 150 minutes of which 60 minutes are spent in sleep. During those 150 minutes, the patient experienced 10 apneas and 20 hypopneas. The polysomnogram is considered valid because it meets the two hour minimum requirement for total recording time (150 minutes = 2.5 hours). The AHI is calculated using the 1 hour of sleep (60 minutes = 1 hour) and dividing that number into the 30 total respiratory events (10 apneas + 20 hypopneas = 30 events). The resultant AHI is 30 (30 events divided by 1 hour = 30).

**Utilization  
Guidelines**

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

**Sources of  
Information and  
Basis for Decision**

Reserved for future use.

**Advisory  
Committee Meeting  
Notes**

**Start Date of  
Comment Period**

**End Date of**

**Comment Period**

**Start Date of Notice Period** 06/01/1999

**Revision History Number** 004

**Revision History Explanation**

Revision Effective Date: 01/01/2005  
 LMRP converted to LCD and Policy Article  
 HCPCS CODES & MODIFIERS:  
 Added A7045  
 APPENDICES:  
 Added example of how the AHI is calculated.

Revision Effective Date: 01/01/2004  
 HCPCS CODES & MODIFIERS  
 Added: A7046, E0470, E0471, E0472, E0561, E0562  
 Deleted: K0532, K0533, K0534, K0268, K0531  
 INDICATIONS & LIMITATIONS OF COVERAGE:  
 Added references to new codes.  
 CODING GUIDELINES:  
 Added references to new codes.  
 OTHER COMMENTS:  
 Revised the definition of AHI to require a minimum of two hours of recording time without the use of the device rather than two hours of recorded sleep.

Revision effective date: 04/01/2003  
 HCPCS CODES and MODIFIERS:  
 Added: A7030-A7039, A7044, EY modifier  
 Deleted: K0183-K0189  
 INDICATIONS AND LIMITATIONS OF COVERAGE:  
 Updated table to reflect the new codes usual maximum amount.  
 Added standard language concerning coverage of items without an order.  
 DOCUMENTATION:  
 Added standard language concerning use of EY modifier for items without an order.  
 OTHER COMMENTS:  
 Definitions of NPPRA, respiratory cycle, polysomnography, FIO2, apnea, hypopnea and AHI moved here.

The revision dates listed below are the dates the revisions were published and not necessarily the effective dates for the revisions.

07/01/2002 - The corrected policy states: Where permitted, the KX [modifier] must be added to codes K0532, K0533, and codes for

accessories used with K0532.

04/01/2002 - New criteria for obstructive sleep apnea, involving an apnea-hypopnea index. Liberalization of documentation requirements for the beneficiary and physician compliance statements. Liberalization extending coverage and separate payment for heated humidifiers (K0531) when prescribed for use with a covered RAD without backup rate (K0532). RAD with backup rate used with invasive interface (K0534) added to explain when to bill this code. Replaced ZX with KX modifier.

01/01/2000 - Elements of the Respiratory Assist Device policy have been revised as outlined below:

- The PaCO<sub>2</sub> coverage and payment criterion for "Group II Chronic Obstructive Pulmonary Disease" (COPD) is reduced from greater than or equal to 55 mm Hg to greater than or equal to 52 mm Hg.
- Two elements (B and D) of the coverage and payment criteria for "Group III Central Sleep Apnea" have also been revised. The revised criteria now read:

"B. The exclusion of obstructive sleep apnea (OSA) as the predominant cause of sleep-associated hypoventilation," and

"D. Oxygen saturation less than or equal to 88 percent for at least five continuous minutes, done while breathing the patient's usual FIO<sub>2</sub>,"

- The Respiratory Assist Devices (RAD) DMERC Medical Review policy contains several provisions to reimburse code K0533 (Respiratory assist device, bi-level pressure capability, with backup rate feature, used with noninvasive interface) comparable to the least costly medically appropriate alternative code K0532 (Respiratory assist device, bi-level pressure capability, without backup rate feature, used with noninvasive interface) when various coverage and payment criteria are not met. Since the K0533 is in the "Frequent and Substantial Servicing" payment category and K0532 is in the "Capped Rental" payment category, a least costly medically appropriate alternative payment cannot be made. Consequently, K0533 will be denied as not medically necessary when the policy criteria are not met.

These revisions are effective with the original effective date of the policy.

**Related Documents Article(s)**

A23860 - Respiratory Assist Devices - Policy Article - Effective January 2005

**LCD Attachments**    There are no attachments for this LCD

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**Article for Respiratory Assist Devices - Policy Article - Effective January 2005 (A23860)****Contractor Information**

<b>Contractor Name</b>	AdminaStar Federal, Inc.
<b>Contractor Number</b>	00635
<b>Contractor Type</b>	DMERC

**Article Information**

<b>Article Database ID Number</b>	A23860
<b>Article Type</b>	Article
<b>Key Article</b>	Yes
<b>Article Title</b>	Respiratory Assist Devices - Policy Article - Effective January 2005
<b>Primary Geographic Jurisdiction</b>	DC IL IN MD MI MN OH VA WI WV
<b>DMERC Region Article Covers</b>	Region B
<b>Article Start Date</b>	01/01/2005
<b>Article Revision Effective Date</b>	
<b>Article Text</b>	<b>CODING GUIDELINES</b>

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 (i.e., NPPRA).

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 (i.e., NPPRA). In addition, it has a timed backup feature to deliver this air pressure

whenever sufficient spontaneous inspiratory efforts fail to occur.

Accessories that are used to deliver air pressure to the patient's nose and/or mouth, and which do not involve an invasive delivery technique such as tracheostomy, are represented by codes A7030-A7039, A7044, A7046, E0561, and E0562. While these codes have represented accessories used with continuous positive airway pressure devices (CPAP), the same accessories are also used in the application of other forms of NPPRA therapy.

If a respiratory assist device is used to apply NPPRA therapy that does not have the timed backup feature, bill using code E0470; if it has a timed backup feature and is used with a noninvasive interface, bill using code E0471. Only bill for a E0472 if a RAD with a timed backup feature is being used with an invasive interface, e.g., tracheostomy tube.

Suppliers should contact the Statistical Analysis Durable Medical Equipment Regional Carrier (SADMERC) for guidance on the correct coding of these items.

As referenced in this policy, noninvasive positive pressure respiratory assistance (NPPRA) is the administration of positive air pressure, using a nasal and/or oral mask interface which creates a seal, avoiding the use of more invasive airway access (e.g., tracheostomy). It may sometimes be applied to assist insufficient respiratory efforts in the treatment of conditions that may involve sleep-associated hypoventilation. It is to be distinguished from the invasive ventilation administered via a securely intubated airway, in a patient for whom interruption or failure of ventilatory support would lead to imminent demise of the patient.

FIO<sub>2</sub> is the fractional concentration of oxygen delivered to the patient for inspiration. For the purpose of this policy, the patient's usual FIO<sub>2</sub> refers to the oxygen concentration the patient normally breathes when not undergoing testing to qualify for coverage of NPPRA therapy. That is, if the patient does not normally use supplemental oxygen, their usual FIO<sub>2</sub> is that found in room air.

**Coverage Topic** Durable Medical Equipment

### Coding Information

**No Coding Information has been entered in this section of the article.**

### Other Information

#### Revision History Explanation

Effective Date: 01/01/2005  
LMRP converted to LCD and Policy Article

#### Related Documents

LCD(s) L11482 - Respiratory Assist Devices