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LCD for Respiratory Assist Devices (L27228)

Contractor Information

Contractor Name

National Government Services, Inc.

Contractor Number

17003

Contractor Type

DME MAC

LCD Information

LCD ID Number

L27228

LCD Title

Respiratory Assist Devices

Contractor's Determination Number

RAD

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CMS National Coverage Policy**Primary Geographic Jurisdiction**

Illinois
Indiana
Kentucky
Michigan
Minnesota
Ohio
Wisconsin

Oversight Region

Region V

DME Region LCD Covers

Jurisdiction B

Original Determination Effective Date

For services performed on or after 10/01/1999

Original Determination Ending Date**Revision Effective Date**

Revision Effective Date

For services performed on or after 02/01/2010

Revision Ending Date**Indications and Limitations of Coverage 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 medical policy, the criteria for "reasonable and necessary" is defined by the following indications and limitations of coverage and/or medical necessity.

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. 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.

GENERAL:

FIO₂ is the fractional concentration of oxygen delivered to the patient for inspiration. For the purpose of this policy, the patient's prescribed FIO₂ refers to the oxygen concentration the patient normally breathes when not undergoing testing to qualify for coverage of a Respiratory Assist Device (RAD). That is, if the patient 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.

A polysomnogram (PSG) 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. For the purpose of this policy, the polysomnogram 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 regulatory requirements.

Central sleep apnea (CSA) is defined as:

1. An apnea-hypopnea index (AHI) greater than 5, and
2. Central apneas/hypopneas greater than 50% of the total apneas/hypopneas, and
3. Central apneas or hypopneas \geq 5 times per hour, and
4. Symptoms of either excessive sleepiness or disrupted sleep.

Complex sleep apnea (CompSA) is a form of central apnea specifically identified by the persistence or emergence of central apneas or hypopneas upon exposure to CPAP or an E0470 device when obstructive events have disappeared. These patients have predominately obstructive or mixed apneas during the diagnostic sleep study occurring at \geq 5 times per hour. With use of a CPAP or E0470, they show a pattern of apneas and hypopneas that meets the definition of CSA described above.

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.

If the AHI is calculated based on less than 2 hours of continuous recorded sleep, the total number of recorded events used to calculate the AHI must be at least the number of events that would have been required in a 2-hour period (i.e., \geq 10 events).

For the purpose of this policy, the arterial blood gas, sleep oximetry study or polysomnogram 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 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 patient's medical record symptoms characteristic of sleep-associated hypoventilation, such as daytime hypersomnolence, excessive fatigue, morning headache, cognitive dysfunction, dyspnea, etc.

A RAD (E0470, E0471) is covered for those patients with clinical disorder groups characterized as (I) restrictive thoracic disorders (i.e., neuromuscular diseases or severe thoracic cage abnormalities), (II) severe chronic obstructive pulmonary disease (COPD), (III) central sleep apnea (CSA) or complex sleep apnea (Comp SA), or (IV) hypoventilation syndrome, and who also meet the following criteria:

- I. Restrictive Thoracic Disorders:

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

- A. There is documentation in the patient's medical record of a neuromuscular disease (for

- A. There is documentation in the patient'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:
- An arterial blood gas PaCO₂, done while awake and breathing the patient's prescribed FIO₂ is ≥ 45 mm Hg, **or**
 - Sleep oximetry demonstrates oxygen saturation ≤ 88% for ≥ 5 minutes of nocturnal recording time (minimum recording time of 2 hours), done while breathing the patient's prescribed recommended FIO₂, **or**
 - For a neuromuscular disease (only), either i or ii,
 - Maximal inspiratory pressure is <60 cm H₂O **or**
 - Forced vital capacity is <50% predicted.
- C. Chronic obstructive pulmonary disease does not contribute significantly to the patient'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 medically necessary.

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

II. Severe COPD:

An E0470 device is covered if criteria A–C are met,

- An arterial blood gas PaCO₂, done while awake and breathing the patient's prescribed FIO₂, is ≥ 52 mm Hg.
- Sleep oximetry demonstrates oxygen saturation ≤ 88% for ≥ 5 minutes of nocturnal recording time (minimum recording time of 2 hours), done while breathing oxygen at 2 LPM or the patient's prescribed FIO₂ (whichever is higher).
- Prior to initiating therapy, Obstructive Sleep Apnea (OSA) and treatment with a continuous positive airway pressure device (CPAP) has been considered and ruled out.

If all of the above criteria for patients 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 medically necessary.

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

Situation 1. For Group II patients (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.

- An arterial blood gas PaCO₂, done while awake and breathing the patient's prescribed FIO₂, shows that the beneficiary's PaCO₂ worsens ≥7 mm HG compared to the original result from criterion A, (above).
- A facility-based PSG demonstrates oxygen saturation ≤88% for ≥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 <5. (Refer to the Positive Airway Pressure Devices LCD for information about E0470 coverage for obstructive sleep apnea).

Situation 2. For Group II patients (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:

- An arterial blood gas PaCO₂ is done while awake and breathing the patient's prescribed FIO₂, still remains ≥ 52 mm Hg.
- Sleep oximetry while breathing with the E0470 device, demonstrates oxygen saturation ≤ 88% for ≥ 5 minutes of nocturnal recording time (minimum recording time of 2 hours), done while breathing oxygen at 2 LPM or the patient's prescribed FIO₂ [whichever is higher].

If E0471 is billed and the criteria for an E0470 device are met, it will be paid as the least costly medically appropriate alternative, E0470.

If E0471 is billed and the criteria for an E0470 device are not met, it will be denied as not medically necessary.

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

III. 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)

- The diagnosis of central sleep apnea (CSA) or complex sleep apnea (CompSA); **and**
- 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 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 patients 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 medically necessary.

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

IV. Hypoventilation Syndrome:

An E0470 device is covered if criteria 1, 2, **and** either 3 or 4 are met.

1. An initial arterial blood gas PaCO₂, done while awake and breathing the patient's prescribed FIO₂, is ≥45 mm Hg.
2. Spirometry shows an FEV1/FVC ≥70% and an FEV1 ≥50% of predicted. (Refer to II. SEVERE COPD (above) for information about device coverage for patients with FEV1/FVC <70% or FEV1 <50% of predicted).
3. An initial arterial blood gas PaCO₂, done during sleep or immediately upon awakening, and breathing the patient's prescribed FIO₂, shows the beneficiary's PaCO₂ worsened ≥7 mm Hg compared to the original result in criterion 1 (above).
4. A facility-based PSG demonstrates oxygen saturation ≤88% for ≥5 minutes of nocturnal recording time (minimum recording time of 2 hours) that is not caused by obstructive upper airway events – i.e., AHI <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 medically necessary.

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

- A. A covered E0470 device is being used.
- B. Spirometry shows an FEV1/FVC ≥70% and an FEV1 ≥50% of predicted. (Refer to II. SEVERE COPD (above) for information about device coverage for patients with FEV1/FVC <70% or FEV1 <50% of predicted).
- C. An arterial blood gas PaCO₂, done while awake, and breathing the patient's prescribed FIO₂, shows that the beneficiary's PaCO₂ worsens ≥7 mm Hg compared to the ABG result performed to qualify the patient for the E0470 device.
- D. A facility-based PSG demonstrates oxygen saturation ≤88% for ≥5 minutes of nocturnal recording time (minimum recording time of 2 hours) that is not caused by obstructive upper airway events (i.e., AHI <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 paid at the least costly medically appropriate alternative, E0740.

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

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

Patients 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 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 fourth and succeeding months of 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.

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 must be obtained by the supplier of the device for continued coverage beyond three months.

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

ACCESSORIES:

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

CODE	USUAL MAXIMUM AMOUNT
A4604	1 per 3 months
A7027	1 per 3 months
A7028	2 per 1 month
A7029	2 per 1 month

A7030	1 per 3 months
A7031	1 per 1 month
A7032	2 per 1 month
A7033	2 per 1 months
A7034	1 per 3 months
A7035	1 per 6 months
A7036	1 per 6 months
A7037	1 per 3 months
A7038	2 per 1 month
A7039	1 per 6 months
A7046	1 per 6 months

the patient has nearly exhausted the supply on hand prior to dispensing any additional items. CMS' *Program Integrity Manual* (Internet-Only Manual, CMS Pub. 100-08, Chapter 4, section 4.26.1) requires, "Contact with the beneficiary or designee regarding refills should take place no sooner than approximately 7 days prior to the delivery/shipping date. For subsequent deliveries of refills, the supplier should deliver the DMEPOS product no sooner than approximately 5 days prior to the end of usage for the current product."

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.

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.

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.

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.

GA - Waiver of liability statement on file.

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

KX - Requirements specified in the medical policy have been met.

HCPCS CODES:

EQUIPMENT:

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

ACCESSORIES

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

A7030	FULL FACE MASK USED WITH POSITIVE AIRWAY PRESSURE DEVICE, EACH
A7031	FACE MASK INTERFACE, REPLACEMENT FOR FULL FACE MASK, EACH
A7032	CUSHION FOR USE ON NASAL MASK INTERFACE, REPLACEMENT ONLY, EACH
A7033	PILLOW FOR USE ON NASAL CANNULA TYPE INTERFACE, REPLACEMENT ONLY, PAIR
A7034	NASAL INTERFACE (MASK OR CANNULA TYPE) USED WITH POSITIVE AIRWAY PRESSURE DEVICE, WITH OR WITHOUT HEAD STRAP
A7035	HEADGEAR USED WITH POSITIVE AIRWAY PRESSURE DEVICE
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.

CODE	DESCRIPTION
XX000	Not Applicable

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." 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 health care professionals and test reports. This documentation must be available upon request.

An order for each item billed must be signed and dated by the treating physician, kept on file by the supplier, and be available upon request. Items billed 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.

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 patients in Groups I-IV in the Indications and 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 Indications and Limitations and/or Medical Necessity section of this policy have been met and the treating physician's signed and dated statement described in the Indications and 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 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 Indications and Limitations of Coverage 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 patients 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 more information on documentation requirements

Appendices

Utilization Guidelines

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

Sources of Information and Basis for Decision

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

12

Revision History Explanation

Revision Effective Date: 02/01/2010

INDICATIONS AND LIMITATIONS OF COVERAGE:

Moved definitions contained in section III to the GENERAL section with the other definitions.

Changed term "usual" to "prescribed" in the descriptor for FIO₂ testing throughout.

Added early coverage criteria for E0471 to COPD section.

Moved late coverage criteria for E0471 to COPD section from CONTINUED COVERAGE section.

Added Hypoventilation Syndrome as a covered indication.

Removed Medicare Beneficiary Statement requirement

Added supply/accessory quantity monitoring requirement.

DOCUMENTATION REQUIREMENTS:

Removed Beneficiary Statement requirements.

ATTACHMENTS:

Substituted beneficiary statement indicating that it was retired.

Revision Effective Date: 09/01/2009

INDICATIONS AND LIMITATIONS OF COVERAGE:

Removed term "progressive" from general coverage criteria of neuromuscular diseases

HCPCS CODES AND MODIFIERS:

Added: GA and GZ modifiers

Revised: KX modifier

DOCUMENTATION REQUIREMENTS:

Added: Instructions for the use of GA and GZ modifiers

Revision Effective Date: 03/13/2008

INDICATIONS AND LIMITATIONS OF COVERAGE:

Inserted definitions from APPENDICES section.

Removed indication IV. Obstructive Sleep Apnea section and moved to Positive Airway Pressure (PAP)

Devices for the Treatment of Obstructive Sleep Apnea LCD

Deleted NPPRA acronym

HCPCS CODES AND MODIFIERS:

Removed E0472

DOCUMENTATION REQUIREMENTS:

Corrected KX modifier statement about accessories.

APPENDICES:

Moved definitions to Indications and Limitations of Coverage section.

Revision Effective Date: 03/01/2008

In accordance with Section 911 of the Medicare Modernization Act, this policy was transitioned to DME MAC National Government Services (17003) LCD L27228 from DME PSC TriCenturion (77011) LCD L11504.

Revision Effective Date: 01/01/2008

INDICATIONS AND LIMITATIONS OF COVERAGE:

Revised Least Costly Alternative statements for E0471 and E0470 to reflect changed payment category for E0471.

Removed 1999 transition criteria.

Added A7027-A7029 to usual quantities table

Removed K0553-K0555 from usual quantities table.

Added E0471 to humidifier coverage statement.

HCPCS CODES AND MODIFIERS:

Added A7027-A7029

Removed K0553-K0555

DOCUMENTATION REQUIREMENTS:

Removed 1999 transition requirements.

Revision Effective Date: 07/01/2007

INDICATIONS AND LIMITATIONS OF COVERAGE:

Added K0553-K0555 to usual quantities table.

Removed DMERC references

Revised maximum amount for A7037.

HCPCS CODES AND MODIFIERS:

Added codes K0553-K0555

DOCUMENTATION REQUIREMENTS:

Removed DMERC references

06/01/2007 - In accordance with Section 911 of the Medicare Modernization Act of 2003, Virginia and West Virginia were transitioned from DME PSC TriCenturion (77011) to DME PSC TrustSolutions (77012).

Revision Effective Date: 04/01/2006

CMS NATIONAL COVERAGE POLICY:

Deleted reference to National Coverage Determinations Manual.

INDICATIONS AND LIMITATIONS OF COVERAGE:

Revised least costly medically appropriate language for E0471 to reflect new payment category.

Moved statement concerning separate payment for accessories to the Policy Article.

APPENDICES:

Moved definitions of NPPRA and FIO₂ from the Policy Article.

Moved definition of respiratory cycle to the Policy Article.

03/01/2006 - In accordance with Section 911 of the Medicare Modernization Act of 2003, this policy was transitioned to DME PSC TriCenturion (77011) from DMERC Tricenturion (77011).

Revision Effective Date: 01/01/2006

INDICATIONS AND LIMITATIONS OF COVERAGE:

Revised coverage criteria for central sleep apnea.

Added frequency guidelines for A4604, A7030, A7031 and A7046.

HCPCS CODES:

Added: A4604

Revised: A7032, A7033

DOCUMENTATION:

Revised requirements for documenting excess quantities of supplies.

APPENDICES:

Added definitions for central sleep apnea and complex sleep apnea.

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: 04/01/03

HCPCS CODES AND MODIFIERS:

HCPCS CODES AND MODIFIERS:

Added: A7030–A7039, A7044, EY modifier to HCPCS modifier array.

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.

07/01/2002 – The revised policy states: "Where permitted, the KX [modifier] must be added to codes K0532, E0471, and codes for accessories used with K0532."

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 PaCO₂ 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 FIO₂,"

– 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.

Reason for Change**Last Reviewed On Date****Related Documents****Article(s)**

[Article for Respiratory Assist Devices – Policy Article – Effective September 2009 \(A47231\)](#)

LCD Attachments

[Medicare Beneficiary Statement – Retired February 2010 PDF](#) (912 KB)

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