LCD for Positive Airway Pressure (PAP) Devices for the Treatment of Obstructive Sleep Apnea (L11528)

Contractor Information

Contractor Name

NHIC

Contractor Number

16003

Contractor Type

DME MAC

LCD Information

LCD ID Number

L11528

LCD Title

Positive Airway Pressure (PAP) Devices for the Treatment of Obstructive Sleep Apnea

Contractor's Determination Number

PAP

AMA CPT / ADA CDT Copyright Statement

CMS National Coverage Policy

CMS Pub. 100-03, (Medicare National Coverage Determinations Manual), Chapter 1, Section 240.4

Primary Geographic Jurisdiction

Connecticut
District of Columbia
Delaware
Massachusetts
Maryland
Maine
New Hampshire
New Jersey
New York - Entire State
Pennsylvania
Rhode Island
Vermont

Oversight Region

Region III

DME Region LCD Covers

Jurisdiction A

Original Determination Effective Date

For services performed on or after 10/01/1993

Original Determination Ending Date

Revision Effective Date

For services performed on or after 03/13/2008

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" are 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.

INITIAL COVERAGE:

A single level continuous positive airway pressure (CPAP) device (E0601) is covered for the treatment of obstructive sleep apnea (OSA) if criteria A - C are met:

A. The patient has a face-to-face clinical evaluation by the treating physician prior to the sleep test to assess the patient for obstructive sleep apnea.

B. The patient has a Medicare-covered sleep test that meets either of the following criteria (1 or 2):

    1. The apnea-hypopnea index (AHI) or Respiratory Disturbance Index (RDI) is greater than or equal to 15 events per hour with a minimum of 30 events; or,

    2. The AHI or RDI is greater than or equal to 5 and less than or equal to 14 events per hour with a minimum of 10 events and documentation of:

        a. Excessive daytime sleepiness, impaired cognition, mood disorders, or insomnia; or,

        b. Hypertension, ischemic heart disease, or history of stroke.

C. The patient and/or their caregiver has received instruction from the supplier of the CPAP device and accessories in the proper use and care of the equipment.

If a claim for a CPAP (E0601) is submitted and all of the criteria above have not been met, it will be denied as not medically necessary.

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.

The respiratory disturbance index (RDI) is defined as the average number of apneas plus hypopneas per hour of recording without the use of a positive airway pressure device.

If the AHI or RDI is calculated based on less than 2 hours of sleep or recording time, the total number of recorded events used to calculate the AHI or RDI (repectively) must be at least the number of events that would have been required in a 2 hour period (i.e., must reach $\geq$ 30 events without symptoms or $\geq$ 10 events with symptoms).

Respiratory Assist Devices (RAD)

A RAD without backup rate (E0470) is covered for those patients with OSA who meet criteria A-C above, in addition to criterion D:

D. A single level (E0601) positive airway pressure device has been tried and proven ineffective, based on a therapeutic trial conducted in either a facility or in a home setting.

If E0470 is billed and criterion D is not met, payment will be based on the allowance for the least costly medically appropriate alternative, E0601.

A RAD with backup rate (E0471) is not medically necessary if the primary diagnosis is OSA; therefore, if E0471 is billed with a diagnosis of OSA, the following payment rules apply:

1. If criteria A - D above are met, payment will be based on the allowance for the least costly medically appropriate alternative, E0470; or,

2. If criteria A-C above are met but not criterion D, payment will be based on the allowance for the least costly medically appropriate alternative, E0601.

If a CPAP device is tried and found ineffective during the initial 3 month home trial, substitution of a RAD does not require a new initial face-to-face clinical evaluation or a new sleep test.

If a CPAP device has been used for more that 3 months and the patient is switched to a RAD, a new initial face-to-face clinical evaluation is required, but a new sleep test is not required. A new 3 month trial would begin for use of the RAD.

Coverage, coding and documentation requirements for the use of RADs for diagnoses other than OSA are addressed in the RAD policy.

Sleep Tests

Coverage and Payment rules for sleep tests may be found in the local coverage determinations (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 coverage of PAP therapy, the DME MAC coverage, coding and payment rules take precedence.

Coverage of a PAP device for the treatment of OSA is limited to claims where the diagnosis of OSA is based upon a Medicare-covered sleep test (Type I, II, III, IV). A Medicare-covered sleep test must be either a polysomnogram performed in a facility-based laboratory (Type I study) or a home sleep test (HST) (Types II, III, or IV.) 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.

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 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 that allows calculation of an AHI or RDI as defined above. Devices that record channels that do not allow direct calculation of an AHI or RDI may be considered as acceptable alternatives if 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. This determination will be made on a device by device basis. Currently there is no device that indirectly measures AHI or RDI that meets this criterion.

For PAP devices with initial dates of service on or after November 1, 2008, all 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.

Patient 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.

For PAP devices with initial dates of service on or after November 1, 2008, all HSTs (Type II, III, or IV) must be interpreted by a physician who holds either:

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) or The Joint Commission (formerly the Joint Commission on Accreditation of Healthcare Organizations - JCAHO).

For PAP devices with initial dates of service on or after January 1, 2010, physicians interpreting facility-based polysomnograms (Type I) must meet one of the requirements listed above (1-4) for credentialing.

No aspect of an HST, including but not limited to delivery and/or pickup of the device, may be performed by a DME supplier. This prohibition does not extend to the results of studies conducted by hospitals certified to do such tests.

CONTINUED COVERAGE BEYOND THE FIRST THREE MONTHS OF THERAPY:

Continued coverage of a PAP device (E0470 or E0601) beyond the first three months of therapy requires that, no sooner than the 31st day but no later than the

91st day after initiating therapy, the treating physician must conduct a clinical re-evaluation and document that the beneficiary is benefiting from PAP therapy.

For PAP devices with initial dates of service on or after November 1, 2008, documentation of clinical benefit is demonstrated by:

1. Face-to-face clinical re-evaluation by the treating physician with documentation that symptoms of obstructive sleep apnea are improved; and,

2. Objective evidence of adherence to use of the PAP device, reviewed by the treating physician.

Adherence to therapy is defined as use of PAP $\geq$ 4 hours per night on 70% of nights during a consecutive thirty (30) day period anytime during the first three (3) months of initial usage.

If the above criteria are not met, continued coverage of a PAP device and related accessories will be denied as not medically necessary.

Beneficiaries who fail the initial 12 week trial are eligible to requalify for a PAP device but must have both:

1. Face-to-face clinical re-evaluation by the treating physician to determine the etiology of the failure to respond to PAP therapy; and,

2. Repeat sleep test in a facility-based setting (Type 1 study).

If the physician re-evaluation does not occur until after the 91st day but the evaluation demonstrates that the patient is benefiting from PAP therapy as defined in criteria 1 and 2 above, continued coverage of the PAP device will commence with the date of that re-evaluation.

If a CPAP device is tried and found ineffective during the initial 3 month home trial, substitution of a RAD (E0470) does not change the length of the trial unless there is less than 30 days remaining in the trial period. If more than 30 days remain in the trial period, the clinical re-evaluation would still occur between the 31st and 91st day following the initiation of CPAP.

If a CPAP device was used for more that 3 months and the patient was switched to a RAD, then the clinical re-evaluation would occur between the 31st and 91st day following the initiation of the RAD. There would also need to be documentation of

adherence to therapy during the 3 month trial with the RAD.

If there is discontinuation of usage of a PAP device at any time, the supplier is expected to ascertain this and stop billing for the equipment and related accessories and supplies.

For a PAP device dispensed prior to November 1, 2008, if the initial coverage criteria in effect at the time were met and the criteria for coverage after the first 3 months that were in effect at the time were met, the device will continue to be covered for PAP devices with initial dates of service on or after November 1, 2008 as long as the patient continues to compliantly use the device.

ACCESSORIES:

Accessories used with a PAP device are covered when the coverage criteria for the device are met. If the coverage criteria are not met, the accessories will be denied as not medically necessary.

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

A4604 - 1 per 3 months
A7027 - 1 per 3 months
A7028 - 2 per 1 month
A7029 - 2 per 1 month
A7030 - 1 per 3 months
A7031 - 1 per 1 month
A7032 - 2 per 1 month
A7033 - 2 per 1 month
A7034 - 1 per 3 months
A7035 - 1 per 6 months
A7036 - 1 per 6 months
A7037 - 1 per 3 months
A7038 - 2 per 1 month
A7039 - 1 per 6 months
A7046 - 1 per 6 months

Quantities of supplies greater than those described in the policy as the usual maximum amounts will be denied as not medically necessary.

Either a non-heated (E0561) or heated (E0562) humidifier is covered when ordered by the treating physician for use with a covered PAP (E0470 or E0601) 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.

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)
E0601	CONTINUOUS AIRWAY PRESSURE (CPAP) DEVICE

ACCESSORIES

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

The presence of an ICD-9 code listed in this section is not sufficient by itself to assure coverage. Refer to the section on Indications and Limitation of Coverage and/or Medical Necessity for other coverage criteria and payment information.

327.23 – Obstructive Sleep Apnea (Adult) (Pediatric)

Diagnoses that Support Medical Necessity

All diagnoses that are specified in the preceding section.

ICD-9 Codes that DO NOT Support Medical Necessity

All ICD-9 codes that are not specified in the preceding section.

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

Diagnoses that DO NOT Support Medical Necessity
All diagnoses that are not specified in the preceding section.

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 healthcare 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 made 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.

The ICD-9 code that justifies the need for the item must be included on the claim.

Physicians shall document the face-to-face clinical evaluations and re-evaluations in a detailed narrative note in their charts in the format that they use for other entries. For the initial evaluation, the report would commonly document pertinent information about the following elements, but may include other details. Each element would not have to be addressed in every evaluation.

History

- Signs and symptoms of sleep disordered breathing including snoring, daytime sleepiness, observed apneas, choking or gasping during sleep, morning headaches;
- Duration of symptoms
- Validated sleep hygiene inventory such as the Epworth Sleepiness Scale (see Appendices)

Physical Exam

- Focused cardiopulmonary and upper airway system evaluation

- Neck circumference
- Body mass index (BMI)

The re-evaluation must take place within the first 3 months of treatment; however, formal assessment of improvement cannot be documented before the 31st day. The re-evaluation must document both improvement in subjective symptoms of OSA and objective data related to adherence to PAP therapy.

Documentation of adherence to PAP therapy shall be accomplished through direct download or visual inspection of usage data with documentation provided in a written report format to be reviewed by the treating physician and included in the beneficiary's medical record. This information does not have to be submitted with the claim but must be available upon request.

Many suppliers have created forms which have not been approved by CMS which they send to physicians and ask them to complete. Even if the physician completes this type of form and puts it in his/her chart, this supplier-generated form is not a substitute for the comprehensive medical record as noted above. Suppliers are encouraged to help educate physicians on the type of information that is needed to document a patient's need for PAP therapy.

Proper use of the KX modifier is discussed below. The KX modifier must not be used on claims submitted until the requirements outlined in the documentation section have been met.

INITIAL COVERAGE (FIRST THREE MONTHS):

On claims for the first through third months, suppliers must add a KX modifier to codes for PAP equipment (E0470 or E0601) and accessories only if all of the criteria in the "Indications and Limitations of Coverage and/or Medical Necessity" section of this policy ("Initial Coverage") have been met.

CONTINUED COVERAGE BEYOND THE FIRST THREE MONTHS OF THERAPY:

On the fourth month's claim (and any month thereafter), the supplier must add a KX modifier to codes for PAP equipment (E0470 or E0601) and accessories only if both the "Initial Coverage" criteria and the "Continued Coverage" criteria in the "Indications and Limitations of Coverage and/or Medical Necessity" section of this policy have been met.

If the supplier does not obtain information from the physician that the beneficiary has demonstrated improvement in their OSA symptoms and is adhering to PAP therapy 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.

If the supplier chooses to hold claims for the fourth and succeeding months

pending receipt of information from the treating physician that the beneficiary received a clinical re-evaluation between the 31st and 91st day, had documented improvement in OSA symptoms and is adhering to PAP therapy, those claims may then be submitted with the KX modifier.

If the supplier chooses to hold claims for the fourth and succeeding month pending receipt of information from the treating physician but learns that the beneficiary did not receive a clinical re-evaluation between the 31st and 91st day but rather was re-evaluated at a later date and had documented improvement in OSA symptoms and is adhering to PAP therapy, those claims may then be submitted with the KX modifier but only for dates of service following the date of the clinical re-evaluation.

For a PAP device dispensed prior to November 1, 2008, if the initial coverage criteria in effect at the time were met and the criteria for coverage after the first 3 months that were in effect at the time were met, the KX modifier may be added to claim with dates of service on or after November 1, 2008 as long as the patient continues to use the device.

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

Appendices

EPWORTH SLEEPINESS SCALE

How likely are you to doze off or fall asleep in the following situations, in contrast to feeling just tired? This refers to your usual way of life in recent times. Even if you have not done some of these things recently try to work out how they would have affected you.

Use the following scale to choose the most appropriate number for each situation:

0 = would never doze or sleep.
1 = slight chance of dozing or sleeping
2 = moderate chance of dozing or sleeping
3 = high chance of dozing or sleeping

Situation	Chance of Dozing or Sleeping
Sitting and reading	____
Watching TV	____
Sitting inactive in a public place	____
Being a passenger in a motor vehicle for an hour or more	____
Lying down in the afternoon	____
Sitting and talking to someone	____

Sitting quietly after lunch (no alcohol)	____
Stopped for a few minutes in traffic while driving	____
Total score (add the scores up) (This is your Epworth score)	____

0-9 – Average score, normal population

Epworth Sleepiness Scale reprinted with permission of the Associated Professional Sleep Societies (Johns MW; A New Method for Measuring Daytime Sleepiness: The Epworth Sleepiness Scale. SLEEP 1991;14(6):540-545).

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

Sources of Information and Basis for Decision
1.The Centers for Medicare & Medicaid Services (CMS). Coverage Decision Memorandum for Continuous Positive Airway Pressure (CPAP) Therapy for Obstructive Sleep Apnea (OSA) (CAG-00093R2) (Acessed on June 22, 2008 at http://www.cms.hhs.gov/mcd/viewdecisionmemo.asp?id=204)

2.Collop NA, Anderson WM, Boehlecke B, et. al. Clinical guidelines for the use of unattended portable monitors in the diagnosis of obstructive sleep apnea in adult patients. J Clin Sleep Med 2007;3(7):737-747.

3.Standards of Accreditation of Sleep Disorders Centers. American Academy of Sleep Medicine. 2007. (Accessed May 22, 2008 at http://aasmnet.org/resources/PDF/CenterStandards.pdf)

4.Kushida CA, Littner MR, Morgenthaler T, et. al. Practice parameters for the indications for Polysomnography and related procedures: an update for 2005. Sleep 2005;28:499-521.

5.Kribbs NB, Pack AI, Kiln LR, et. al. Objective measurement of patters of nasal CPAP use by patients with obstructive sleep apnea. Am Rev Respir Dis. 1993;147:887-895.

6.Hui DS, Choy DK, Li TS, et. al. Determinants of continuous positive airway pressure compliance in a group of Chinese patients with obstructive sleep apnea. Chest 2001;120:170-176.

7.Massie CA, Hart RW, Perzlez K, Richards GN. Effects of humidification on nasal symptoms and compliance in sleep apnea patients using continuous positive airway

pressure. Chest 1999;116:403-408.

8.McArdle N, Devereux G, heidarnejad H, et. al. Long-term use of CPAP therapy for sleep apnea/hypopnea syndrome. Am J Respir Crit Care Med. 1999;159:1108-1114.

9.Nieto FJ, Young TB, Lind BK, et. al. Association of sleep disordered breathing, sleep apnea and hypertension in a large community-based study. JAMA 2000;283:1829-1836.

10.Agency for Healthcare Research and Quality. Home diagnosis of obstructive sleep apnea-hypopnea syndrome. 2007. Accessed June 12, 2008 at http://www.cms.hhs.gov/determinationprocess/downloads/id48TA.pdf

11.Waldhorn RE, Herrick TW, Nguyen MC, et. al. Long-term compliance with nasal continuous positive airway pressure therapy of obstructive sleep apnea. Chest 1990;97:33-38.

12.Popescu G, Latham M, Allgar V, et. al. Continuous positive airway pressure for sleep apnoea/hypopnea syndrome: usefulness of a 2-week trial to identify factors associated with long term use. Thorax 2001;56:727-733.

13.Campos-Rodriquez F, Peña-Griñan N, Reyes-Nuñez N, et. al. Mortality in obstructive sleep apnea-hypopnea patients treated with positive airway pressure. Chest 2005;128:624-633.

14.American Board of Internal Medicine board certification information may be found at http://www.abim.org/certification/policies/imss/sleep.aspx

Advisory Committee Meeting Notes

Start Date of Comment Period
04/30/1993

End Date of Comment Period
06/14/1993

Start Date of Notice Period
08/01/1993

Revision History Number
CPAP011

Revision History Explanation
Revision Effective Date (September Revision): 03/13/2008 except where noted otherwise in the LCD.
INDICATIONS AND LIMITATIONS OF COVERAGE:

Revised: Coverage criteria for documentation of initial evaluation and moved to Documentation section
Revised: Clarified extrapolation of AHI and RDI results
Revised: Definition of Type IV device
Revised: Extended implementation dates for credentialing of physicians interpreting home sleep tests and facility-based polysomnograms.
Revised: Requirement for beneficiary education by entity conducting home sleep test
Revised: Expanded dates during which patients must be re-evaluated for documenting benefit from PAP therapy.
Revised: Expanded dates for patients switched from CPAP to RAD with less than 30 days remaining in initial trial period
Added: Requalifying after failed initial 12 week trial of PAP therapy
DOCUMENTATION:
Revised: Expanded dates for documentation of benefit from PAP therapy.
Revised: Documentation of adherence to PAP therapy to allow visual inspection of usage data.

Revision Effective Date (July Revision): 03/13/2008 except where noted otherwise in the LCD.
Changed LCD title from Continuous Positive Airway Pressure System (CPAP) to Positive Airway Pressure (PAP) Devices for the Treatment of OSA to reflect addition of coverage for RADs.
INDICATIONS AND LIMITATIONS OF COVERAGE:
Added: Revised coverage criteria for CPAP to include home sleep testing and face-to-face clinical evaluation and re-evaluation.
Moved: Use of RADs (E0470 and E0471) for OSA from the Respiratory Assist Devices LCD to this LCD.
Added: Coverage criteria for changing from a CPAP to RADs both before and after the first three months of PAP therapy.
Added: Definition of adherence.
Added: Criteria for portable sleep monitoring devices.
Added: Requirements for administering and interpreting home sleep studies.
Added: Grandfathering criteria.
Moved: Information previously contained in Appendices.
DOCUMENTATION:
Added: Information about documenting adherence and clinical re-evaluation.
Added: Grandfathered patients and the use of the KX modifier.
Revised: Use of KX modifier for claims in fourth and subsequent months.
APPENDICES
Added: Epworth Sleepiness Scale.

3/1/2008- In accordance with Section 911 of the Medicare Modernization Act, this policy was transitioned to DME MAC NHIC (16003) LCD L11528 from DME PSC TriCenturion (77011) LCD L11528.

Revision Effective Date: 01/01/2008
INDICATIONS AND LIMITATIONS OF COVERAGE:
Added: Usual maximum quantity parameters for new codes A7027, A7028, A7029

HCPCS CODES:
Added: A7027, A7028, A7029
Removed: K0553, K0554, K0555

Revision Effective Date: 07/01/2007
INDICATIONS AND LIMITATIONS OF COVERAGE:
Removed: DMERC references.
Revised: Usual maximum quantity parameter for A7037.
Added: Usual maximum quantity parameters for new HCPCS codes – K0553, K0554 and K0555.
HCPCS CODES AND MODIFIERS:
Added: K0553, K0554 and 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).

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
HCPCS CODES:
Added: A4604
Revised: A7032, A7033
INDICATIONS AND LIMIITATIONS OF COVERAGE:
Accessories:
Added frequency guideline for A4604, A7030 and A7046
Added clarification regarding Full Face Mask Seals (A7031)
DOCUMENTATION:
Revised requirements for documenting excess quantities of supplies.
APPENDICES:
Revised definition of apnea-hypopnea index (AHI) to reflect NCD.

Revision Effective Date: 01/01/2005
HCPCS CODES AND MODIFIERS:
Added code A7045
APPENDICES:
Clerical correction to move definitions from Policy Article to LCD Clarified calculation of AHI

Revision Effective Date: 07/01/2004
LMRP converted into LCD and Policy Article
INDICATIONS AND LIMITATIONS OF COVERAGE AND/OR MEDICAL NECESSITY:
Clarified how accessories are denied when medical necessity is not met.

Revision Effective Date: 01/01/2004

HCPCS CODES AND MODIFIERS:
Crosswalked codes K0268 and K0531 to E0561 and E0562, respectively.Added new code A7046
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 hour of recorded sleep.

Revision Effective Date: 04/01/2003
HCPCS CODES AND MODIFIERS:
Added: A7030 – A7039, A7044, EY
Discontinued: K0183 – K0189
INDICATIONS ANDLIMITATIONS OF COVERAGE:
Adds standard language concerning coverage of items without an order.
Updated utilization table to incorporate new A codes which were crosswalked from K codes.
Removed reference to RDI in definitions section.
DOCUMENTATION REQUIREMENTS:
Adds standard language concerning use of EY modifier for items without an order.

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

07/01/2002 – Revised language regarding who is a qualified provider of polysomnographic studies.

04/01/2002 – Updated Coverage and Payment Rules section to reflect National Coverage Decision to cover CPAP based on apnea-hypopnea index. Eliminated Certificate of Medical Necessity requirement. Added KX modifier to indicate coverage criteria met. Revised verbiage of HCPCS code K0184. Allowed coverage of either heated or non-heated humidifier with a covered CPAP device.

10/01/1995 – Added HCPCS codes for accessories.

12/01/1993 – Corrected typo from HAO to HA0 in the Documentation section.

Reason for Change

Last Reviewed On Date

Related Documents
Article(s)
A19815 - Positive Airway Pressure (PAP) Devices for the Treatment of Obstructive Sleep Apnea (September 2008 Revision) - Policy Article - Effective March 2008

LCD Attachments
There are no attachments for this LCD

Article for Positive Airway Pressure (PAP) Devices for the Treatment of Obstructive Sleep Apnea (September 2008 Revision) - Policy Article - Effective March 2008 (A19815)

Contractor Information

Contractor Name

NHIC

Contractor Number

16003

Contractor Type

DME MAC

Article Information

Article ID Number

A19815

Article Type

Article

Key Article

Yes

Article Title

Positive Airway Pressure (PAP) Devices for the Treatment of Obstructive Sleep Apnea (September 2008 Revision) - Policy Article - Effective March 2008

AMA CPT / ADA CDT Copyright Statement

Primary Geographic Jurisdiction

Connecticut

District of Columbia
Delaware
Massachusetts
Maryland
Maine
New Hampshire
New Jersey
New York - Entire State
Pennsylvania
Rhode Island
Vermont

DME Region Article Covers

Jurisdiction A

Original Article Effective Date

07/01/2004

Article Revision Effective Date

03/13/2008

Article Text

NON-MEDICAL NECESSITY COVERAGE AND PAYMENT RULES

Accessories are separately reimbursable at the time of initial issue and when replaced.

CODING GUIDELINES

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

A continuous positive airway pressure (CPAP) device (E0601) delivers a constant level of positive air pressure (within a single respiratory cycle) 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.

For auto-titrating CPAP devices use HCPCS code E0601.

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 RAD with backup rate (E0471) delivers adjustable, variable levels (within a single respiratory cycle) of positive air pressure by way of tubing and a noninvasive

interface (such as a nasal or oral facial mask) to assist spontaneous respiratory efforts and supplement the volume of inspired air into the lungs. In addition, it has a timed backup feature to deliver this air pressure whenever sufficient spontaneous inspiratory efforts fail to occur.

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

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

Code A7033 is used for a replacement nasal cannula-type interface. This interface extends a short distance into the nostrils. The unit of service for this code is “pair”. For some products, there are two physically separate cushions or “pillows” – one for each nostril. Two cushions/pillows equals 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. One unit of service for A7027 includes both the oral and the nasal components.

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

Coverage Topic

Durable Medical Equipment

Coding Information

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

Other Information

Other Comments

3/1/2008- In accordance with Section 911 of the Medicare Modernization Act, this policy was transitioned to DME MAC NHIC (16003) Article A19815 from DME PSC TriCenturion (77011) Article A19815.

Revision History Explanation

Revision Effective Date (September Revision): 03/13/2008

Revised: Clarified UOS for code A7027
Revised: Changed SADMERC to PDAC

Revision Effective Date: 03/13/2008
Changed title to reflect change in LCD title as a result of including RADs for the treatment of OSA.
Added Non-Medical Necessity Coverage and Payment Rules section.
CODING GUIDELINES:
Added definition of a respiratory cycle.
Added: Definitions for RADs.
Moved: Reimbursement rules for accessories to Non-Medical Necessity Coverage and Payment Rules section.

3/1/2008- In accordance with Section 911 of the Medicare Modernization Act, this policy was transitioned to DME MAC NHIC (16003) Article A19815 from DME PSC TriCenturion (77011) Article A19815.

Revision Effective Date: 01/01/2008
CODING GUIDELINES:
Substituted: New code A7027

Revision Effective Date: 07/01/2007
CODING GUIDELINES:
Added: Narrative definition for new HCPCS code K0553.

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).

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

Revision Effective Date: 01/01/2006
CODING GUIDELINES:
Added definitions for tubing with a heated wire (A4604) and replacement nasal interfaces (A7032, A7033).

Revision Effective Date: 01/01/2005
Clerical correction to move definitions from Policy Article to LCD

Revision Effective Date: 07/01/2004
LMRP converted into LCD and Policy Article

Related Documents

LCD(s)
L11528 - Positive Airway Pressure (PAP) Devices for the Treatment of Obstructive Sleep Apnea