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

Contractor Information

Contractor Name

NHIC, Corp.

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

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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

LCD Information

New York - Entire State
Pennsylvania
Rhode Island
Vermont

Oversight Region

Region I

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 04/01/2010

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" 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.

DEFINITIONS:

Apnea is defined as the cessation of airflow for at least 10 seconds.

Hypopnea is defined as an abnormal respiratory event lasting at least 10 seconds associated with at least a 30% reduction in thoracoabdominal movement or airflow as compared to baseline, and with at least a 4% decrease in oxygen saturation.

The apnea-hypopnea index (AHI) is defined as the average number of episodes of apnea and

hypopnea per hour of sleep without the use of a positive airway pressure device. For purposes of this policy, respiratory effort related arousals (RERAs) are not included in the calculation of the AHI. Sleep time can only be measured in a Type I (facility based polysomnogram) or Type II sleep study (see descriptions below).

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. For purposes of this policy, respiratory effort related arousals (RERAs) are not included in the calculation of the RDI. The RDI is reported in Type III, Type IV, and Other home sleep studies.

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 (respectively) must be at least the number of events that would have been required in a 2 hour period (i.e., must reach ≥30 events without symptoms or ≥10 events with symptoms).

INITIAL COVERAGE:

In this policy, the term PAP (positive airway pressure) device will refer to both a single-level continuous positive airway pressure device (E0601) and a bi-level respiratory assist device without back-up rate (E0470) when it is used in the treatment of obstructive sleep apnea.

I. An E0601 device device 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 device in the proper use and care of the equipment.

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

LCD Information

II. An E0470 device is covered for those patients with OSA who meet criteria A-C above, in addition to criterion D:

D. An E0601 has been tried and proven ineffective based on a therapeutic trial conducted in either a facility or in a home setting.

Ineffective is defined as documented failure to meet therapeutic goals using an E0601 during the titration portion of a facility-based study or during home use despite optimal therapy (i.e., proper mask selection and fitting and appropriate pressure settings).

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 bi-level positive airway pressure device with back-up 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 an E0601 device is tried and found ineffective during the initial facility-based titration or home trial, substitution of an E0470 does not require a new initial face-to-face clinical evaluation or a new sleep test.

If an E0601 device has been used for more than 3 months and the patient is switched to an E0470, 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 E0470.

Coverage, coding and documentation requirements for the use of E0470 and E0471 for diagnoses other than OSA are addressed in the Respiratory Assist Devices (RAD) Local Coverage Determination (LCD) and Policy Article (PA).

<u>Sleep Tests</u>

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, Other). 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, IV, Other). The test must be ordered by the beneficiary's treating physician and conducted by an entity that qualifies as a Medicare provider of sleep tests and is in compliance with all applicable state regulatory requirements.

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, one of which is airflow; or,

D. Other - Devices that monitor and record a minimum of three (3) channels that include actigraphy, oximetry and peripheral arterial tone and for which there is substantive clinical evidence in the published peer-reviewed medical literature that demonstrates that the results accurately and reliably correspond to an AHI or RDI as defined above. This determination will be made on a device by device basis (See Appendix B for list of approved devices in this category).

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, IV, Other) 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 coverage based on a facility-based polysomnogram (Type I) performed on or after January 1, 2010, the interpreting physician 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.

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.

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 an E0601 device is tried and found ineffective during the initial facility-based titration or home trial, substitution of an 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 an E0601 and

objective documentation of adherence on the E0470 would need to occur prior to the 91st day following initiation of the E0601. If less than 30 days remain in the trial period, the clinical re-evaluation and objective documentation of adherence must occur before the 120th day following the initiation of the E0601.

If an E0601 device was used for more that 3 months and the patient was then switched to an E0470, the clinical re-evaluation must occur between the 31st and 91st day following the initiation of the E0470. There would also need to be documentation of adherence to therapy during the 3 month trial with the E0470.

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.

REPLACEMENT:

This section applies to PAP devices initially provided and covered while the beneficiary was in Medicare fee-for-service (FFS).

If a PAP device is replaced during the 5 year reasonable useful lifetime (RUL) because of loss, theft, or irreparable damage due to a specific incident, there is no requirement for a new clinical evaluation, sleep test, or trial period.

If a PAP device is replaced following the 5 year RUL, there must be a face-to-face evaluation by their treating physician that documents that the beneficiary continues to use and benefit from the PAP device. There is no requirement for a new sleep test or trial period.

BENEFICIARIES ENTERING MEDICARE

For beneficiaries who received a PAP device prior to enrollment in fee for service (FFS) Medicare and are seeking Medicare coverage of either rental of the device, a replacement PAP device and/or accessories, both of the following coverage requirements must be met:

1. Sleep test – There must be documentation that the beneficiary had a sleep test, prior to FFS Medicare enrollment, that meets the Medicare AHI/RDI coverage criteria in effect at the time that the beneficiary seeks Medicare coverage of a replacement PAP device and/or accessories; and,

2. Clinical Evaluation – Following enrollment in FFS Medicare, the beneficiary must have a face-to-face evaluation by their treating physician who documents in the beneficiary's medical record that:

    a. The beneficiary has a diagnosis of obstructive sleep apnea; and,

    b. The beneficiary continues to use the PAP device.

If either criteria 1 or 2 above are not met, the claim will be denied as not medically necessary.

In these situations, there is no requirement for a clinical re-evaluation or for objective documentation of adherence to use of the device.

LCD Information

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.

A supplier must not dispense more than a 3-month quantity of PAP accessories at a time.

Suppliers should stay attuned to atypical utilization patterns of their clients. A beneficiary or their caregiver must specifically request refills of PAP accessories before they are dispensed. The supplier must not automatically dispense a quantity of supplies on a predetermined regular basis, even if the beneficiary has "authorized" this in advance. As referenced in the Program Integrity Manual (Internet-Only Manual, CMS Pub. 100-8, Chapter 4.26.1) “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 when ordered by the treating physician for use with a covered PAP (E0470 or E0601) device.

Coding Information

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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

Coding Information

GA - Waiver of liability statement issued, as required by payer policy

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

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

Coding Information

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)

For beneficiaries changing from an E0601 to E0470 due to ineffective therapy while on E0601 (either during a facility-based titration or in the home setting), the treating physician must document:

- The beneficiary tried but was unsuccessful with attempts to use the E0601 device; and,
- Multiple interface options have been tried and the current interface is most comfortable to the beneficiary; and,
- The work of exhalation with the current pressure setting of the E0601 prevents the beneficiary from tolerating the therapy; and,
- Lower pressure settings of the E0601 fail to adequately control the symptoms of OSA or reduce the AHI/RDI to acceptable levels.

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.

MODIFIERS:

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.

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.

BENEFICIARIES ENTERING MEDICARE

For beneficiaries who received a PAP device prior to enrollment in fee for service (FFS) Medicare and are seeking Medicare coverage of either rental of the device, a replacement device or accessories, the supplier may add the KX modifier only if both of the criteria listed in the "Indications and Limitations of Coverage and/or Medical Necessity" for "Beneficiaries Entering Medicare" section have been met.

The supplier may hold claims, pending confirmation that the above requirements are met, and then submit claims with the KX modifier beginning with the date of FFS Medicare enrollment.

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 PAP equipment 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.

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

Appendices

Appendix A: 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).

Appendix B: List of Approved Other Devices that Indirectly Measure AHI/RDI
Watch-PAT devices (Itamar Medical)

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
04/30/1993

End Date of Comment Period
06/14/1993

General Information

Start Date of Notice Period
08/01/1993

Revision History Number
CPAP011

Revision History Explanation
Revision Effective Date: 04/01/2010
INDICATIONS AND LIMITATIONS OF COVERAGE:
Added: Program Integrity Manual instructions on refills of accessories.
Added: Replacement instructions for beneficiaries already in Medicare.
Revised: Types of sleep tests.
Revised: Coverage of replacement devices and/or accessories.
Revised: Beneficiaries entering Medicare instructions.
DOCUMENTATION REQUIREMENTS:
Added: Replacement instructions for beneficiaries already in Medicare.
Revised: Documentation of replacement devices and/or accessories.
Revised: Beneficiaries entering Medicare instructions.

Revision Effective Date: 01/01/2010
INDICATIONS AND LIMITATIONS OF COVERAGE:
Revised: PAP device coverage when based on facility-based PSG – coverage based on date of PSG not DOS of device for credentialing requirement.

Revision Effective Date: 09/01/2009
HCPCS CODES AND MODIFIERS:
Added: GA and GZ modifiers.
Revised: KX modifier.
DOCUMENTATION REQUIREMENTS:
Added: Information about the required use of GA, GZ, or KX on claim lines for PAP devices and/or accessories.

Revision Effective Date: 01/01/2009 (except where noted otherwise in the LCD)
INDICATIONS AND LIMITATIONS OF COVERAGE:
Revised: Criteria for Type IV home sleep test device.
Added: Coverage requirements for beneficiaries enrolling in Medicare and needed replacement PAP device and/or accessories.
DOCUMENTATION REQUIREMENTS:
Added: Requirements for beneficiaries enrolling in Medicare and needed replacement PAP device and/or accessories.
APPENDICES:
Added: List of approved Type IV devices that do not report AHI/RDI based on direct measurement of airflow or thoracoabdominal movement.
Covered Type IV device list to include Watch-PAT devices.

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

General Information

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 REQUIREMENTS:
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 REQUIREMENTS:
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.

03/01/2008
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).

General Information

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 AND MODIFIERS:
Added: A4604
Revised: A7032, A7033
INDICATIONS AND LIMITATIONS OF COVERAGE:
Accessories:
Added: Frequency guideline for A4604, A7030 and A7046.
Added: Clarification regarding Full Face Mask Seals (A7031).
DOCUMENTATION REQUIREMENTS:
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: Moved 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: 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 modifier.
Discontinued: K0183 – K0189
INDICATIONS AND LIMITATIONS OF COVERAGE:
Added: 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:
Added: 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.

General Information

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 - Policy Article - Effective April 2010

LCD Attachments
There are no attachments for this LCD

All Versions

Article for Positive Airway Pressure (PAP) Devices for the Treatment of Obstructive Sleep Apnea - Policy Article - Effective April 2010 (A19815)

Contractor Information

Contractor Name

NHIC, Corp.

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 - Policy Article - Effective April 2010

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Primary Geographic Jurisdiction

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

Article Information

DME Region Article Covers

Jurisdiction A

Original Article Effective Date

07/01/2004

Article Revision Effective Date

04/01/2010

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 single-level 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 single-level CPAP devices, use HCPCS code E0601.

A bi-level respiratory assist device without backup rate (E0470) allows independent setting of inspiratory and expiratory pressures to deliver positive airway 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.

A bi-level respiratory assist device with backup rate (E0471) allows independent setting of inspiratory and expiratory pressures to deliver positive airway pressure within a single respiratory cycle 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, E0471 devices have 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.

Article Information

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

Coding Information

Other Information

Revision History Explanation

Revision Effective Date: 04/01/2010
Revised: Use of RAD term.
Revised: Definition of E0470 and E0471.

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.

03/01/2008 - 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).

Other Information

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