Local Coverage Determination (LCD) for Positive Airway Pressure (PAP) Devices for the Treatment of Obstructive Sleep Apnea (L11518)

Contractor Information

Contractor Name	Contractor Number	Contractor Type
CGS Administrators, LLC opens in new window	18003	DME MAC

Back to Top

LCD Information

Document Information

LCD ID Number
L11518

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

Contractor's Determination Number
PAP

Primary Geographic Jurisdiction opens in new window
Alabama
Arkansas
Colorado
Florida
Georgia
Louisiana
Mississippi
North Carolina
New Mexico
Oklahoma
Puerto Rico
South Carolina
Tennessee
Texas
Virginia
Virgin Islands
West Virginia

Oversight Region
Region IV

DME Region LCD Covers
Jurisdiction C

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 10/01/2011

Revision Ending Date

CMS National Coverage Policy
CMS Pub. 100.03 (Medicare National Coverage Determination Manual), Chapter 1, Section 240.4

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 local coverage determination, the criteria for "reasonable and necessary", based on Social Security Act §1862(a)(1)(A) provisions, 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 reasonable and 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 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 sleep test (as defined below) 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 reasonable and necessary.

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 for a patient with OSA and criteria A-D are not met, it will be denied as not reasonable and necessary.

A bi-level positive airway pressure device with back-up rate (E0471) is not reasonable and necessary if the primary diagnosis is OSA. If an E0471 is billed with a diagnosis of OSA, it will be denied as not reasonable and necessary.

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).

Sleep Tests

Coverage and Payment rules for sleep tests may be found in the LCDs for the applicable Medicare Part A or Part B contractor. There may be differences between those LCDs and the DME MAC LCD. For the purposes of 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 sleep test (Type I, II, III, IV, Other) that meets the Medicare coverage criteria in effect for the date of service of the claim for the PAP device. The 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 all PAP devices, 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 all PAP devices, the sleep test, Type I - 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), Accreditation Commssion for Health Care (ACHC), or The Joint Commission (TJC, formerly the Joint Commission on Accreditation of Healthcare Organizations – JCAHO).

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 ≥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 reasonable and 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). This may be a repeat diagnostic, titration or split-night 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 Medicare 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 dates of service on or after November 1, 2008 as long as the patient continues to 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 reasonable and necessary.

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

The following table represents the usual maximum amount of accessories expected to be reasonable and 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 reasonable and necessary.

For DMEPOS items and supplies provided on a recurring basis, billing must be based on prospective, not retrospective use. For DMEPOS products (A4604, A7027-A7046) that are supplied as refills to the original order, suppliers must contact the beneficiary prior to dispensing the refill and not automatically ship on a pre-determined basis, even if authorized by the beneficiary. This shall be done to ensure that the refilled item remains reasonable and necessary, existing supplies are approaching exhaustion, and to confirm any changes/modifications to the order. Contact with the beneficiary or designee regarding refills must take place no sooner than 14 calendar days prior to the delivery/shipping date. For delivery of refills, the supplier must deliver the DMEPOS product no sooner than 10 calendar days prior to the end of usage for the current product. This is regardless of which delivery method is utilized. (CMS' Program Integrity Manual, Internet-Only Manual, CMS Pub. 100-8, Chapter 5, Section 5.2.6).

For all DMEPOS items that are provided on a recurring basis, suppliers are required to have contact with the beneficiary or caregiver/designee prior to dispensing a new supply of items. Suppliers must not deliver refills without a refill request from a beneficiary. Items delivered without a valid, documented refill request will be denied as not reasonable and necessary.

Suppliers must not dispense a quantity of supplies exceeding a beneficiary's expected utilization. Suppliers must stay attuned to changed or atypical utilization patterns on the part of their clients. Suppliers must verify with the ordering physicians that any changed or atypical utilization is warranted. Regardless of utilization, a supplier must not dispense more than a three (3)-month quantity at a time.

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.

Back to Top

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 issued as required by payer policy, individual case

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
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.

Back to Top

General Information

Documentations 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.

REFILLS

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

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

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

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

- Beneficiary's name or authorized representative if different than the beneficiary
- A description of each item that is being requested
- Date of refill request
- Quantity of each item that the beneficiary still has remaining

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

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 that both of the following issues were addressed prior to changing to an E0470 device:

A. Interface fit and comfort. An appropriate interface has been properly fit and the beneficiary is using it without difficulty. This properly fit interface will be used with the E0470 device; and,

B. E0601 pressure settings. The current pressure setting of the E0601 prevents the beneficiary from tolerating the therapy and lower pressure settings of the E0601 were tried but failed to:
   1. Adequately control the symptoms of OSA; or,
   2. Improve sleep quality; or,
   3. 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.

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 reasonable and necessary 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

Start Date of Notice Period 08/01/1993

Revision History Number 013

Revision History Explanation Revision Effective Date: 10/01/2011
INDICATIONS AND LIMITATIONS OF COVERAGE:
Added: ACHC as approved accreditation body for sleep labs

08/05/2011 - The Jurisdiction C contractor adopted a new business name. This LCD revision only includes the change from CIGNA Government Services to CGS Administrators, LLC. No coverage information was included in this revision and no provider action is needed regarding this revision.

Revision Effective Date: 08/02/2011

INDICATIONS AND LIMITATIONS OF COVERAGE:
Revised: Refills information
DOCUMENTATION SECTION:
Added: Refills documentation information

Revision Effective Date: 02/04/2011 (March 2011 Revision)
INDICATIONS AND LIMITATIONS OF COVERAGE:
Revised: Clarified language for acceptable sleep test in Initial Coverage criterion B and Sleep Test sections
Revised: Repeat sleep test specifications for failed trial

Revision Effective Date: 02/04/2011
INDICATIONS AND LIMITATIONS OF COVERAGE:
Deleted: Least costly alternative language for codes E0470 and E0471
Deleted: Prohibition on DME supplier conducting sleep test (regulatory requirement - moved to Policy Article)
HCPCS CODES AND MODIFIERS:
Revised: GA modifier
DOCUMENTATION REQUIREMENTS:
Revised: Requirements for documenting ineffective therapy on E0601 (Effective 8/1/2010)

Revision Effective Date: 04/01/2010 (February 2010 Revision)
INDICATION 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: 01/1/2010
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: 09/1/2009
INDICATIONS AND LIMITATIONS OF COVERAGE:
Added: Program Integrity Manual instructions on refills of accessories
Revised: Coverage of replacement devices and/or accessories
DOCUMENTATION REQUIREMENTS:
Revised: Documentation of replacement devices and/or accessories

Revision Effective Date: 09/1/2009
HCPCS CODES AND MODIFIERS
Added : GA and GZ modifiers
Revised: KX Modifier
DOCUMENTATION REQUIREMENTS:
Added: Information about the required use of KX, GA or GZ on claim lines for PAP devices and/or accessories

Revision Effective Date: 1/1/2009 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): 3/13/2008 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 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: 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 CIGNA Government Services (18003) LCD L11517 from DME PSC TrustSolutions (77012) LCD L11517.

Revision Effective Date: 01/01/2008
INDICATIONS AND LIMITATIONS OF COVERAGE:
Added: Usual maximum quantity parameters for new code 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 TrustSolutions (77012) from DMERC Palmetto GBA (00885)

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 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 to move definitions from Policy Article to LCD
Clarified calculation of AHI

Revision Effective Date: 07/01/2004
LMRP converted to LDC 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 A7056
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 Maintenance (annual review with new changes, formatting, etc.)

Related Documents
Article(s)
A20195 - Positive Airway Pressure (PAP) Devices for the Treatment of Obstructive Sleep Apnea - Policy Article - Effective February 2011 opens in new window

LCD Attachments
There are no attachments for this LCD.

Back to Top

All Versions

Updated on 03/08/2012 with effective dates 10/01/2011 - N/A
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Updated on 08/04/2011 with effective dates 08/05/2011 - N/A
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Updated on 12/10/2010 with effective dates 02/04/2011 - N/A
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Back to Top