

Helpful hints for filing

Positive Airway Pressure (PAP) devices (E0601 and E0470) and related accessories

Overview

The following information describes coverage and payment information regarding positive airway pressure (PAP) devices and accessories. Coverage criteria for a respiratory assist device (RAD) used for the treatment of obstructive sleep apnea (OSA) are now reflected in this Helpful Hints and the Medicare Durable Medical Equipment (DME) Medicare Administrative Contractor (MAC) PAP Local Coverage Decision (LCD). Coding, coverage, payment, and documentation guidelines are listed on the following pages. This is to be used as a guide.

For an item to be covered by Medicare, the following conditions apply: (1) item must be eligible for a defined Medicare benefit category; (2) item must 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) the item must meet all applicable Medicare statutory and regulatory requirements.[1] Please refer to your supplier manual or contact your DME MAC medical director or provider helpline for specific instructions.

CPAP and Auto-CPAP devices (with and without pressure relief technology) (HCPCS E0601) are classified in the payment policy category "Capped Rental." Medicare will pay on a rental basis for continuous use up to 13 months, after which the title and ownership of the equipment will pass to the beneficiary. Accessories required for items in the "Capped Rental" category are reimbursed separately by Medicare unless specifically noted otherwise.

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[1]Section 1862 (a)1(A) of Title XVIII of the Social Security Act.

General coverage guidelines

On March 13, 2008, the National Coverage Decision (NCD) was updated, allowing coverage of a PAP device based upon a diagnosis of OSA by home sleep testing (HST). Additionally, the NCD was updated to remove the requirements that an individual have moderate-to-severe OSA and that surgery is a likely alternative.

Definitions

- Apnea – A cessation of airflow for at least 10 seconds.

- Apnea-Hypopnea Index (AHI) – 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.

- Continuous Positive Pressure Airway device (CPAP) – A device which provides a flow of positive pressure air at a constant level to the upper airway by way of tubing and a noninvasive interface to splint the airway open during sleep.

- Home Sleep Test (HST) – Is performed unattended in a home using a portable monitoring device, and must monitor and record a minimum of three channels that allow for direct calculation of AHI or RDI.

- Hypopnea – An abnormal respiratory event lasting at least 10 seconds with at least a 30% reduction in thorocoabdominal movement or airflow as compared to baseline, and with at least a four percent oxygen desaturation.

- Nasal application device – Nasal, nasal/oral, or facial mask.

- Obstructive Sleep Apnea (OSA) – Frequent and prolonged episodes in which breathing stops during sleep. Diagnosis is confirmed by monitoring the patient during sleep for periods of apnea and lowered blood oxygen levels. OSA results from the obstruction of the upper airway.

- Polysomnography (PSG) – A polysomnography is distinguished from a sleep study by the inclusion of sleep staging. Sleep staging is defined to include a 1-4 lead electroencephalogram (EEG), an electrooculogram (EOG), a submental electromyogram and a electrocardiogram (ECG). This study may either be conducted as a whole-night or split-night study.

- Respiratory Distress Index (RDI) – 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.

- Sleep study – Continuous and simultaneous recording of physiological and pathophysiological parameters of sleep with physician review, interpretation, and report. The recorded parameters are airflow, respiratory effort, and oxygen saturation by oximetry.

General coverage guidelines

For the purpose of the policy, a Medicare-covered sleep test must be either:

- A polysomnogram performed in a facility-based sleep laboratory or unattended using a home sleep monitoring device of Types II, III and IV (must monitor and record at least three channels that allow for direct calculation of AHI or RDI). The test must be ordered by the beneficiary's treating physician and conducted by a laboratory that qualifies as a Medicare provider of sleep tests and complies with all applicable state regulatory requirements.

- Not performed by a DME supplier or any entity with a significant financial relationship to the DME supplier. This exclusion does not apply to results of studies from hospitals certified to perform such tests.

If a patient discontinues usage of an E0601 or E0470 device at any time, the supplier is expected to ascertain the device, and stop billing for the equipment and related accessories and supplies.

Clinical coverage guidelines

Initial coverage: PAP devices are covered under Medicare when ordered and prescribed by the licensed treating physician to be used for adult patients with OSA or for beneficiaries diagnosed with OSA whose OSA improved as a result of CPAP therapy during the initial 12-week period. Criteria A-C as outlined on the following page must be met in order to be considered for coverage.

I. Initial coverage criteria for CPAP (first three months)

Criterion 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. Effective November 1, 2008, the clinical evaluation may include the following:

1. Sleep history and symptoms including, but not limited to, snoring, daytime sleepiness, observed apneas, choking or gasping during sleep, morning headaches.
2. Epworth Sleepiness Scale.
3. Physical examination that documents body mass index, neck circumference, and a focused cardiopulmonary and upper airway system evaluation.

and

Criterion B1

Medicare-covered sleep test where the AHI or RDI is ≥ 15 events per hour with a minimum of 30 events.

or

Criterion B2

Medicare-covered sleep test where the AHI or RDI is ≥ 5 and ≤ 14 events per hour with a minimum of 10 events and documented symptoms of excessive daytime sleepiness, impaired cognition, mood disorders or insomnia; or hypertension, ischemic heart disease or history of stroke.

and

Criterion C

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

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

and

Criterion 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 a CPAP device is tried and found to be ineffective during the initial three-month home trial, substitution of a RAD does not require a new initial face-to-face clinical evaluation or a new sleep test. However, the treating physician must document both of the following:

- The interface being used with CPAP that will also be used with the RAD fits properly and the beneficiary is using it without difficulty.
- The patient could not tolerate the current pressure setting and lower settings were not adequate to do one of the following:
  - Adequately control the symptoms of OSA
  - Improve sleep quality
  - Reduce the AHI/RDI to acceptable levels

Please refer to the detailed criteria provided in the Continued Coverage: Failure of CPAP section of this Helpful Hints.

If a CPAP device has been used for more than three 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 three-month trial would begin for use of the RAD.

Payment: least costly alternative

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. However, effective for initial claims on or after February 4, 2011, if criterion D is not met, the claim will be denied as not medically necessary. 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 two payment rules apply:

If criteria A-D above are met, payment will be based on the allowance for the least costly medically appropriate alternative, E0470. For initial claims on or after February 4, 2011, if E0471 is billed with a diagnosis of OSA, the claim will be denied as not medically necessary.

or

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. For initial claim dates on or after February 4, 2011, if E0471 is billed with a diagnosis of OSA, the claim will be denied.

Coverage, coding, and documentation requirements for the use of a RAD device for diagnoses other than OSA are addressed in the RAD Helpful Hints and Medicare policy.

Note: The following flow charts illustrate the clinical guidelines for coverage. For the documentation requirements for continued coverage, refer to the Documentation section on the next page.

II. Continued coverage of CPAP (beyond first three months)

Continued coverage of a PAP device (E0470 or E0601) may continue for beneficiaries who meet the following criteria:

Criterion A
OSA improves as a result of the initial 12-week PAP device use.

and

Criterion B
Between the 31st and 91st day after initiating therapy, the treating physician must conduct a face-to-face clinical re-evaluation documenting the benefit from PAP therapy.

and

Criterion C
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 percent of nights during a consecutive 30-day period anytime during the first three months of initial usage.

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 B and C above, continued coverage of the PAP device will commence with the date of that re-evaluation.

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

III. Failure of CPAP: continued coverage (beyond first three months)

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

Criterion A
Face-to-face clinical re-evaluation by the treating physician to determine the etiology of the failure to respond to PAP therapy.

and

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

IV. New Medicare beneficiaries: continued coverage

For new Medicare Fee-for-Service (FFS) beneficiaries who received a PAP device prior to becoming eligible for Medicare, and need coverage for either a replacement PAP device and/or accessories, both of the following requirements must be met:

Criterion A
Documentation that the beneficiary had a sleep test, prior to Medicare FFS enrollment, that meets the Medicare AHI or RDI coverage criteria in effect at the time that the beneficiary seeks a replacement PAP device and/or accessories.

and

Criterion B
After becoming eligible for the Medicare FFS program, the beneficiary must have a face-to-face evaluation by their treating physician who documents in the beneficiary's medical record that the beneficiary has a diagnosis of obstructive sleep apnea and continues to use the PAP device.

Initiation to RAD for the treatment of OSA

If a CPAP device is tried and found ineffective during the initial three-month home trial, substitution of a RAD (E0470) does not change the length of the trial (three months) unless there are less than 30 days remaining in the trial period. Depending upon where the beneficiary is in the trial, the following criteria would apply for a clinical re-evaluation:

More than 30 days remain in trial
The clinical re-evaluation would still occur between the 31st and 91st day following the initiation of CPAP.

or

Less than 30 days remain in trial
The clinical re-evaluation must occur before the 120th day following the initiation of CPAP.

or

Post initial three-month trial
The clinical re-evaluation would occur between the 31st and 91st day following the initiation of the RAD with documentation of adherence to therapy during the three-month trial with the RAD.

For a PAP device dispensed prior to November 1, 2008, if the initial coverage criteria in effect at that time was met, and the criteria for coverage after the first three months in effect were met, coverage for the PAP device will continue on or after November 1, 2008, assuming patient compliance with the PAP device.

Sleep tests

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, or 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.

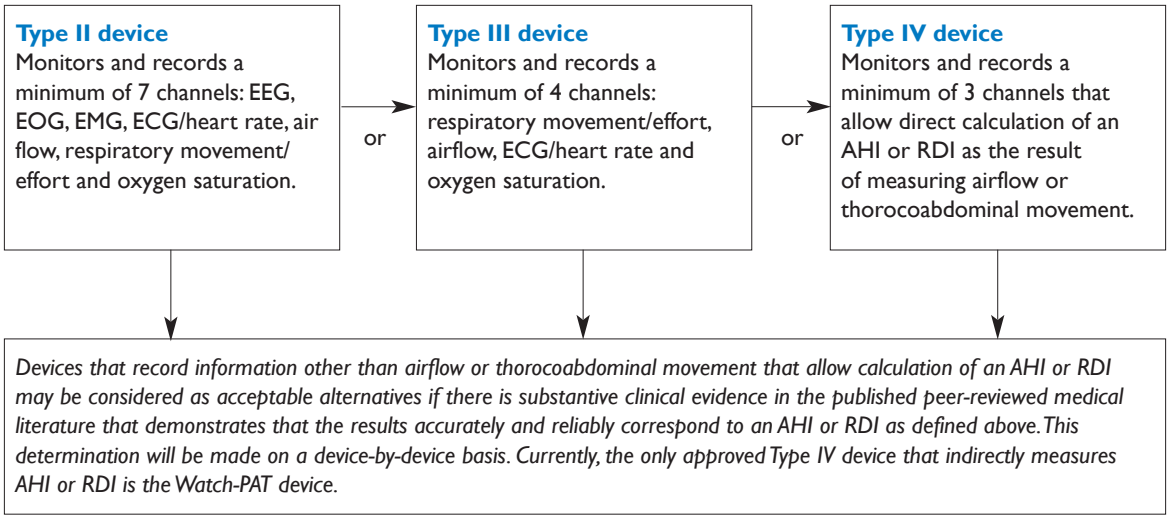
Facility-based sleep test

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), electrooculogram (EOG), submental electromyogram (EMG) and electrocardiogram (ECG). It must also include at least the following additional parameters of sleep:

- Airflow
- Respiratory effort
- Oxygen saturation by oximetry
- Performed as either a whole night study for diagnosis only or a split night study to diagnose and initially evaluate treatment

Home sleep test (HST)

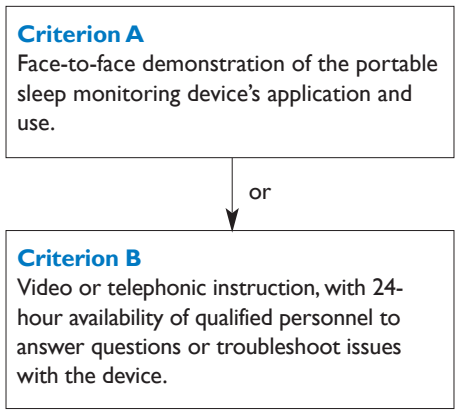
An HST is performed unattended in the beneficiary's home using a portable monitoring device. A portable monitoring device for conducting an HST must meet one of the following criteria:



HST requirements

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:



Physician credentials

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 physician credential requirements (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.

Billing for CPAP accessories

Accessories are separately reimbursable according to the frequencies outlined below.

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."

HCPCS code	Description	Maximum replacement allowance*
A4604	Tubing with integrated heating element for use with positive airway pressure device	1 per 3 months
A7030	Full face mask used with positive airway pressure device, each	1 per 3 months
A7031	Face mask interface, replacement for full face mask, each	1 per 1 month
A7032	Cushion for use on nasal mask interface, replacement only, each	2 per 1 month
A7033	Pillow for use on nasal cannula type interface, replacement only, pair	2 per 1 month
A7034	Nasal interface (mask or cannula type), used with positive airway pressure device, with or without head strap	1 per 3 months
A7035	Headgear	1 per 6 months
A7036	Chinstrap	1 per 6 months
A7037	Tubing	1 per 3 months
A7038	Filter, disposable	2 per 1 month
A7039	Filter, non-disposable	1 per 6 months
A7045	Exhalation port with or without swivel, replacement	Not specified in DME MAC policy
A7046	Water chamber for humidifier, replacement, each	1 per 6 months
A9279	Monitoring feature/device, stand-alone or integrated, any type, includes all accessories, components and electronics, not otherwise classified	No current fee schedule allowance
E0561	Humidifier, non-heated	N/A; purchased item
E0562	Humidifier, non-heated	N/A; purchased item

*Quantities of supplies greater than those outlined in DME MAC policy as the usual maximum amounts will be denied as not medically necessary, in the absence of clear documentation supporting the medical necessity for the higher utilization. This information must be attached to a hard copy claim or entered into the narrative field of an electronic claim. Documentation in the patient record must corroborate the order and medical necessity of the items and quantities billed.

Humidifier coverage

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. Suggestions include:

- Document medical necessity and maintain in patient file
- Candidates for heated humidity may include:
  - Patients prone to mouth leaks
  - Patients with chronic nasal symptoms (including conditions existing prior to initiation of CPAP treatment)
  - Elderly patients; as a person ages, the likelihood of nasal complaints, increased nasal resistance and/or impairment of the mucociliary function of the nose increases
  - Patients taking medications that may result in dryness of the nasal mucosa (i.e., anti-hypertensives, antidepressants)

Device replacement after five-year reasonable useful lifetime

Original device provided by Medicare – Patient must have a face-to-face evaluation by the treating physician that documents that the patient continues to use, and benefits from, the PAP device. A new sleep test or trial period is NOT required.

Original device provided by payer other than Medicare – Patient's sleep test prior to Medicare meets the current AHI / RDI requirements and a face-to-face evaluation with the treating physician once on Medicare confirms a diagnosis of OSA and the patient's continued use of the device. A trial period is NOT required. These requirements apply to the need for a device or supplies and accessories.

Documentation requirements

A Certificate of Medical Necessity (CMN) is not required for PAP claims. However, the supplier is required to keep appropriate documentation on file, including:

- An order for all equipment and accessories signed and dated by the treating physician
- Documentation of medical necessity

–EY modifier

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.

–KX modifier

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 have been met.

Continued coverage (beyond first three months)

For claims beginning with the fourth month of rental, and including all subsequent monthly rental claims, the supplier must add a –KX modifier to codes for equipment (E0470 or E0601) and accessories only if both the initial coverage and continued coverage criteria have been met. Suppliers must maintain documentation in their records that these criteria have been met and this must be available to the DME MAC upon request.

- 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 used.

- Claims may be held 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, with the –KX modifier. However, if the beneficiary received a clinical re-evaluation at a later date (after the 91st day), claims can be submitted with the –KX modifier for dates of service following the date of clinical re-evaluation.

- For a PAP device dispensed prior to November 1, 2008, if initial coverage criteria in effect at the time were met and criteria for coverage after the first three months of initial coverage was met, the –KX modifier may be added to the claim on or after November 1, 2008, if the beneficiary continues to use the device.

- For beneficiaries who received a PAP device prior to enrollment in the Medicare FFS program and are seeking Medicare coverage of either a replacement PAP device and/or accessories, the supplier may add the –KX modifier only if all of the criteria have been met. The supplier may hold claims, pending confirmation that the requirements were met, and may submit claims with the –KX modifier beginning with the date of enrollment.

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