



Reimbursement Fast Facts: PAP for OSA Treatment

Understanding Medicare coding and coverage

In this guide, the term “PAP (positive airway pressure) device” will refer to auto-titrating and single-level continuous positive airway pressure devices (E0601) as well as bilevel devices without back-up rate (E0470), all of which are indicated for patients with obstructive sleep apnea (OSA). ResMed’s PAP devices are designed to deliver effective therapy as quietly and comfortably as possible.

| Device | Description | HCPCS | Medicare Reimbursement |
|---|--|-------|--|
| CPAP | Continuous Positive Airway Pressure devices (e.g. AirSense™ 10). Includes automatic positive airway pressure (APAP) devices (e.g. AirSense 10 AutoSet™) | E0601 | Fee Schedule Lookup Tool |
| Bilevel (Bilevel to treat restrictive thoracic disorders, COPD, central/complex sleep apnea and hypoventilation is covered under a separate Medicare policy. See PN 1010293) | Respiratory assist device, bilevel 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) (e.g. AirCurve™ 10 VAuto, AirCurve 10 S, VPAP COPD) | E0470 | |

PAP Billing Criteria

Home use of PAP equipment is eligible for Medicare reimbursement only when the patient meets all of the requirements set out in the PAP devices for the treatment of OSA Local Coverage Determination (LCD) and related Policy Article (PA).¹

E0601 Initial coverage (first three months)

An E0601 device is covered for the treatment of OSA if criteria A – C are met:

- A.** The patient has an in-person clinical evaluation by the treating practitioner prior to the sleep test to assess the patient for OSA. NOTE: The evaluation would generally include documentation of sleep history and OSA symptoms, physical exam and sleep questionnaire in the patient’s medical record.
- B.** The patient has a sleep test that meets either of the following criteria:
 - 1.** The apnea-hypopnea index (AHI) or respiratory disturbance index (RDI)* is ≥ 15 events per hour with minimum of 30 events; or

- 2.** The AHI or RDI is ≥ 5 and ≤ 14 events per hour with 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.

E0470 Initial coverage (first three months)

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 a home setting. NOTE: Ineffective is defined as **documented** (in the medical record) 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).

| Requirement | BILEVEL (E0470) SUBSTITUTION OCCURS | | |
|-------------------------------------|---------------------------------------|-------------------------------------|------------------------------------|
| | During initial 3-month trial of E0601 | | Post 3-month trial of E0601 |
| | > 30 days remaining in trial period | < 30 days remaining in trial period | after 3-month trial on E0601 |
| Trial period | • remains the same (no change) | • extended to 120 days | • new 3-month trial with bilevel |
| Clinical re-evaluation | • between 31-91st day | • prior to 120th day | • between 31-91st day with bilevel |
| Compliance | • on bilevel prior to 91st day | • on bilevel prior to 120th day | • on bilevel prior to 91st day |
| Initial in-person evaluation | • not required for E0470 | • not required for E0470 | • required for E0470 |
| New sleep test | • not required | • not required | • not required |
| Standard Written Order | • required for E0470 | • required for E0470 | • required for E0470 |
| Proof of Delivery | • required for E0470 | • required for E0470 | • required for E0470 |

* The RDI is defined as the average number of apneas plus hypopneas per hour of recording without the use of a PAP 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.



Key Coverage Criteria for Sleep Tests

- Covered sleep tests include Type I, II, III or IV
- For home-based sleep test (HST), patients must receive instruction, prior to having the test, on how to properly apply the device. This instruction must be provided by the entity conducting the HST and **may not be performed by a DME supplier.**
- All sleep tests must be interpreted by a practitioner 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 member board of American Board of Medical Specialists (ABMS) or American Osteopathic Association (AOA); or
 3. Completed training by ABMS or AOA member board and completed all requirements for subspecialty certification in sleep except exam itself; or
 4. Active staff membership of a sleep center or lab accredited by the American Academy of Sleep Medicine (AASM), Accreditation Commission for Health Care (ACHC), or The Joint Commission (TJC).

Continued Coverage Beyond the First Three Months of Therapy

Medical records include:

- Documentation that the patient is benefiting from PAP therapy as demonstrated by:
 - In-person re-evaluation by the treating practitioner between the 31st and 91st day **after initiating therapy** documenting that symptoms of OSA are improved; **and**
 - Objective evidence of adherence to use of the PAP device reviewed by treating practitioner.

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

PAP Requalification Post-Failing 12-week Trial Period

- In-person clinical re-evaluation by the treating practitioner to determine the etiology of the failure to respond to PAP therapy; **and**,
- Repeat sleep test in a facility-based setting (Type 1 study). This may be a repeat diagnostic, titration or split-night study.
- Billing may resume at month four with documentation that patient met new adherence to therapy.

Documentation Requirements:

The supplier must be able to provide all of these items upon request:

- Standard Written Order (SWO)
- Medical Record Information (including continued need/use if applicable)
- Patient authorization
- Proof of Delivery
- Refill documentation (if applicable)

Q & A

Q: Does the treating practitioner who completes the initial in-person exam have to write the order for the PAP therapy?

No, the treating practitioner who does the initial in-person exam does not have to be the same practitioner who orders the PAP. For example, the PAP device can be ordered by a practitioner from the sleep lab if also engaged in diagnosing or treating the patient for sleep-disordered breathing.

Q: If a patient was diagnosed with OSA and received a PAP device paid for by private insurance, and the patient is now enrolled in Fee-For-Service (FFS) Medicare and needs a replacement device, what is required for coverage?

Prior to FFS Medicare enrollment, the patient must have had a sleep test that meets the FFS Medicare AHI/RDI coverage criteria in effect at the time that the patient seeks a replacement PAP device and/or accessories. Following enrollment, the patient must also have an in-person evaluation by their treating physician that documents in the medical record a diagnosis of OSA and that the patient continues to use the PAP device. In these situations, there is no requirement for a clinical re-evaluation or for objective documentation of adherence to use of the device.

Q: Can results from a sleep study be used to qualify patients for home oxygen?

Coverage of home oxygen therapy requires that the patient be tested in the "chronic stable state." For patients with OSA to be considered in the chronic, stable state, OSA must be sufficiently treated such that the underlying severe lung disease is unmasked. Please see Medicare's FAQ on Oxygen Use in Beneficiaries with OSA.²

Q: What does a Medicare prescription need to include to authorize billing of a DME item?

A standard written order (SWO) must be communicated to the supplier prior to claim submission.

A SWO must contain all of the following elements:

- Beneficiary's name or Medicare Beneficiary Identifier (MBI)
- Order date
- General description of the item
 - The description can be either a general description (e.g. CPAP), a HCPCS code, a HCPCS code narrative, or a brand name/model number
 - For equipment: In addition to the description of the base item, the SWO may include all concurrently ordered options, accessories or additional features that are separately billed or require an upgraded code (list each separately)
 - For supplies: In addition to the description of the base item, the DMEPOS order/prescription may include all concurrently ordered supplies that are separately billed (list each separately)
- Quantity to be dispensed, if applicable
- Treating practitioner's name or NPI
- Treating practitioner's signature

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1 Centers for Medicare & Medicaid Services, "PAP Devices for the Treatment of OSA" (L33718), U.S. Department of Health and Human Services (revision effective date 01/01/2020)

2 FAQ: Oxygen Use in Beneficiaries with Obstructive Sleep Apnea, 11/22/13

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