

Reference: L33718, A52467

PAP Devices E0470, E0471, E0601

- Face-to-Face Examination (F2F)
- Written Order Prior to Delivery (WOPD)

All PAP Accessories and Supplies

- Dispensing Order, if applicable
- Detailed Written Order (DWO)
- Refill Requirements

All PAP Devices, Accessories, and Supplies

- Beneficiary Authorization
- Proof of Delivery (POD)
 - Method 1 - Direct Delivery to the Beneficiary by the Supplier
The date the beneficiary/designee signs for the supplies is to be the date of service of the claim.
 - Method 2 - Delivery via Shipping or Delivery Service
The shipping date is to be the date of service of the claim.
- Continued Need
- Continued Use

Medical Records

Initial Coverage (First 3 Months)

Positive Airway Pressure Device - E0601

- Medical records document:
 - F2F prior to the sleep test to assess the patient for obstructive sleep apnea (OSA); **and**
 - Medicare-covered sleep test that meets either:
 - Apnea-hypopnea index (AHI) or Respiratory Disturbance Index (RDI) ≥ 15 events per hour with a minimum of 30 events; **or**
 - AHI or RDI ≥ 5 and ≤ 14 events per hour with minimum 10 events and documentation of:
 - Excessive daytime sleepiness, impaired cognition, mood disorders, or insomnia; **or**

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Hypertension, ischemic heart disease, or history of stroke, **and**

Documentation the beneficiary and/or their caregiver has received instruction from the supplier of the PAP device in the proper use and care of the equipment.

Documentation for Beneficiaries Who Fail the Initial 12 Week Trial

F2F re-evaluation to determine the etiology of the failure to respond to PAP therapy; **and**

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

Bi-level Respiratory Assist Device (RAD) without Back-up Rate (E0470)

Medical records document:

Beneficiary meets all the criteria listed above for a positive airway pressure device (E0601); **and**

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

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

A new initial F2F if E0601 has been used for more than 3 months and the beneficiary switched to E0470 (a new sleep test is not required)

PAP – Continued Coverage (Beyond the First 3 Months of Therapy)

Documentation the beneficiary is benefiting from PAP therapy as demonstrated by:

F2F re-evaluation by the treating physician 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 physician.

Adherence is defined as use of the PAP device ≥ 4 hours per night on 70% of nights during a consecutive 30 day period anytime during the first 3 months of initial use

Beneficiaries Entering Medicare

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

Clinical Evaluation – Following enrollment in FFS Medicare, the beneficiary must have a F2F which documents:

Diagnosis of OSA; **and**

The beneficiary continues to use the PAP device.

Replacement (E0601, E0470)

Replacement following the 5 year reasonable useful life (RUL) requires a F2F that documents the beneficiary continues to use and benefit from the PAP device

Non-Heated or Heated Humidifier (E0561, E0562)

Beneficiary meets PAP coverage criteria

Detailed written order includes the type of humidification

Billing Reminders

- For the first through third months of coverage, the KX modifier must be added to all codes for PAP equipment and supplies only if all PAP coverage criteria are met.
- For the fourth month's claim and any month thereafter, the KX modifier must be added to all codes for PAP equipment and supplies only if both the initial coverage and continuous coverage criteria have been met.
- A supplier can choose to hold claims for the fourth and succeeding months pending receipt of information from the treating physician that the beneficiary is demonstrating improvement in their OSA symptoms and is adhering to PAP therapy and then submit them with the KX modifier if continued coverage criteria is met.
- If the supplier chooses to hold claims for the fourth and succeeding months but learns that the beneficiary was evaluated after the 91st day and is adhering to therapy, those claims can be submitted with the KX modifier but only for dates of service following the clinical re-evaluation.
- If all the coverage criteria have not been met, the GA modifier must be added to the code(s) if a valid ABN has been obtained or a GZ modifier if a valid ABN has not been obtained.
- The ICD code for OSA must be included on all claims for PAP devices and supplies.
- A bi-level PAP device with back-up rate (E0471) billed with a diagnosis of OSA will be denied as not reasonable and necessary.

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