Positive Airway Pressure Devices Coverage and Documentation Checklist

Dispensing Order
Positive airway pressure (PAP) equipment, supplies, and accessories may be delivered upon receipt of a dispensing order. A dispensing order may be verbal or written. The supplier must keep a record of the dispensing order on file. It must contain:

- Description of the item(s)
- Beneficiary’s name
- Prescribing Physician’s name
- Date of the order and the start date, if the start date is different from the date of the order
  - Use the date the supplier is contacted by the physician (for verbal orders) or the date entered by the physician (for written dispensing orders)
- Physician signature (if a written order) or supplier signature (if verbal order)

New Order Requirements
A new order is required if:

- There is a change in supplier
- 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 prescription renewal

Coverage Criteria for an E0601 Device
Documentation that all the following coverage criteria are met:

- A face-to-face clinical evaluation by the treating physician prior to the sleep study test to assess the patient for obstructive sleep apnea
- A Medicare-covered sleep test that meets either of the following criteria:
  - The apnea-hypopnea index (AHI) (on facility-based polysomnograms) or respiratory disturbance index (RDI) (on home sleep tests) is greater than or equal to 15 events with a minimum of 30 events; or
  - The AHI or RDI is greater than or equal to five and less than or equal to 14 events per hour with a minimum of ten events and documentation of:
    - Excessive daytime sleepiness, impaired cognition, mood disorders, or insomnia; or
    - Hypertension, ischemic heart disease, or history of stroke
- The patient and/or their caregiver have received instruction from the supplier of the PAP device and accessories in the proper use and care of the equipment

Coverage for an E0470 Device
Documentation that supports the patient meets all the criteria for an E0601 device and the following:

- An E0601 has been tried and proven ineffective based on a therapeutic trial either during a facility-based titration or in a home setting
There must be documentation in the patient’s medical record that both of the following issues were addressed:

☐ Interface fit and comfort. Beneficiary is using current interface without difficulty and it will be used with the E0470 device.
☐ E0601 pressure settings. The current pressure setting of the E0601 prevents the beneficiary from tolerating the therapy and lower pressure setting of the E0601 were tried but failed to adequately control the symptoms of OSA, improve sleep quality, or reduce the AHI/RDI to acceptable levels.

**Continued Coverage for an E0601 and E0470 Beyond First Three Months of Therapy**

The treating physician must perform a clinical reevaluation no sooner than the 31st day, but no later than the 91st day after initiating therapy, which documents the following:

☐ A face-to-face clinical reevaluation by the treating physician with documentation that symptoms of obstructive sleep apnea are improved; and
☐ Objective evidence of adherence to use of the PAP device, reviewed by the treating physician (adherence to therapy is defined as use of the PAP ≥ four hours per night on 70 percent of nights during a consecutive 30-day period anytime during the first three months of initial use).

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.

**Continued Use/Medical Need**

Ongoing supplies and rental durable medical equipment (DME) items require documentation in the beneficiary’s medical record to support that the item continues to be used by the beneficiary and remains reasonable and necessary. Information used to justify continued medical need must be timely for the date of service. Timely, documentation is defined as a record in the preceding 12 months unless otherwise specified in the policy.

☐ Any of the following may serve as documentation justifying continued medical need:
☐ A recent order by the treating physician for refills
☐ A recent change in prescription
☐ Timely documentation in the beneficiary’s medical record showing usage of the item

**Refill Documentation**

*A routine refill prescription is not needed.*

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

Suppliers are required to have contact with the beneficiary no sooner than 14 calendar days prior to the delivery/shipping date of a new supply PAP supplies. 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. 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

For delivery of refills, the supplier must deliver the product no sooner than ten calendar days prior to the end of usage for the current product. This is regardless of which delivery method is utilized.

Regardless of utilization, a supplier must not dispense more than a three-month quantity at a time.

**Proof of Delivery**

Suppliers are required to maintain proof of delivery (POD) in their files.

**Method 1:** Direct Delivery to the Beneficiary by the Supplier. Suppliers may deliver directly to the beneficiary or the designee. In this case, POD to a beneficiary must be a signed and dated delivery slip. The POD record must include:

- Beneficiary’s name
- Delivery address
- Sufficiently detailed description to identify the item(s) being delivered (e.g., brand name, serial number, narrative description)
- Quantity delivered
- Date delivered
- Beneficiary (or designee) signature
- Date of signature

The date of signature on the delivery slip must be the date that the item was received by the beneficiary or designee.

In instances where the supplies are delivered directly by the supplier, the date the beneficiary received the DMEPOS supply must be the date of service on the claim.

**Method 2:** Delivery via Shipping or Delivery Service. If using a shipping service or mail order, the POD record must include:

- Beneficiary’s name
- Delivery address
- Delivery service’s package identification number, supplier invoice number or alternative method that links the supplier’s delivery service’s records
- Sufficiently detailed description to identify the item(s) being delivered (e.g., brand name, serial number, narrative description)
- Quantity delivered
- Date delivered
- Evidence of delivery

If a utilizing a shipping service or mail order, suppliers must use the shipping date as the date of service on the claim.

Suppliers may also utilize a return postage-paid delivery invoice from the beneficiary or designee as a POD. This type of POD record must contain the information specified above.
Reminders

Beneficiaries entering Medicare that have already been on a PAP device are only required to have a previous qualifying sleep study and after Medicare eligibility a face-to-face examination. They are not required to meet the 90-day adherence nor the reevaluation.

Replacement of a PAP device prior to the five-year reasonable useful life (RUL) must be due to the item being lost, stolen, or irreparably damaged (not due to normal wear and tear). A new face-to-face is not required in this case.

Replacement of a PAP device after the five year RUL does require a new face-to-face examination and new order but does not require that the beneficiary meet the continued coverage criteria again.