**DOCUMENTATION CHECKLIST FOR POSITIVE AIRWAY PRESSURE (PAP) DEVICES**

**Policy References:**
- Local Coverage Determination (LCD) (L33718)
- Policy Article (A52467)

**Documentation References:** Standard Documentation Requirements Policy Article (A55426)

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

- Standard Written Order (SWO)
- Refill Requirements
- Beneficiary Authorization
- Proof of Delivery (POD)
- Continued Need
- Continued Use
- Medical records from treating practitioner as noted below

**Medical records should contain:**

**Initial Coverage (First Three Months)**

**Positive Airway Pressure Device - E0601**

- Face-to-face (F2F) prior to the sleep test to assess the beneficiary 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
    - 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)**

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 three months and the beneficiary switched to E0470 (a new sleep test is not required)

**PAP – Continued Coverage (Beyond the First Three 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 ≥ four hours per night on 70% of nights during a consecutive 30-day period anytime during the first three 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 five-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; and
- Standard written order includes the type of humidification