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 diagnostic sleep test scored at 4% and 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