DOCUMENTATION CHECKLIST FOR RESPIRATORY ASSIST DEVICE (RAD)

Policy References:

- Local Coverage Determination (LCD) (L33800)
- Policy Article (A52517)

Documentation References: Standard Documentation Requirements Policy Article (A55426)

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

Medical records for E0470, E0471, accessories, and supplies should contain:

Initial Coverage

- ☐ Symptoms characteristic of sleep-associated hypoventilation, such as:
  - ☐ Daytime hypersomnolence;
  - ☐ Excessive fatigue;
  - ☐ Morning headache;
  - ☐ Cognitive dysfunction;
  - ☐ Dyspnea, etc.; and
- ☐ Beneficiary has one of the following disorders and meets all coverage criteria for that disorder:

Restrictive Thoracic Disorder

- ☐ Neuromuscular disease (i.e., amyotrophic lateral sclerosis) or a severe thoracic cage abnormality (i.e., post-thoracoplasty for TB); **and**
- ☐ Arterial blood gas PaC02, done while awake and breathing the prescribed FI02, is ≥ 45 mm Hg; **or**

- ☐ Sleep oximetry demonstrates oxygen saturation ≤ 88% for ≥ five minutes of nocturnal recording time (minimum recording time of two hours), done while breathing the beneficiary's prescribed recommended FIO2; **or**
- ☐ For a neuromuscular disease only, maximal inspiratory pressure is < 60 cm H2O or forced vital capacity is < 50% predicted; **and**
- ☐ Chronic Obstructive Pulmonary Disease (COPD) does not contribute significantly to the beneficiary's pulmonary limitation.

Severe COPD

An E0470 device is covered if criteria A - C are met:

- ☐ A. An arterial blood gas PaCO2, done while awake and breathing the beneficiary's prescribed FIO2, is greater than or equal to 52 mm Hg; **and**
- ☐ B. Sleep oximetry demonstrates oxygen saturation less than or equal to 88% for greater than or equal to a cumulative five minutes of nocturnal recording time (minimum recording time of two hours), done while breathing oxygen at 2 LPM or the beneficiary's prescribed FIO2 (whichever is higher); **and**
- ☐ C. Prior to initiating therapy, sleep apnea and treatment with a continuous positive airway pressure device (CPAP) has been considered and ruled out. (Note: Formal sleep testing is not required if there is sufficient information in the medical record to demonstrate that the beneficiary does not suffer from some form of sleep apnea (Obstructive Sleep Apnea (OSA), CSA and/or CompSA) as the predominant cause of awake hypercapnia or nocturnal arterial oxygen desaturation).

Situation one: E0471 started any time after a period of initial use of E0470 is covered if:

- ☐ An arterial blood gas PaCO2, done while awake and breathing the beneficiary's prescribed FIO2, shows the beneficiary's PaCO2 worsens ≥ 7mm Hg compared to original result above; **and**
- ☐ A facility based polysomnogram (PSG) demonstrates oxygen saturation ≤ 88% for ≥ five cumulative minutes of nocturnal recording time (minimum recording time of two hours) while using an E0470 that is not caused by obstructive upper airway events (AHI < 5).

Situation two: E0471 will be covered no sooner than 61 days after initial issue of the E0470 if:

- ☐ An arterial blood gas PaCO2 is done while awake and breathing the beneficiary's prescribed FIO2, still remains ≥ 52 mm Hg; **and**
- ☐ Sleep oximetry while breathing with the E0470 demonstrates oxygen saturation ≤ 88% for ≥ five cumulative minutes of nocturnal recording time (minimum recording time of two hours), done while breathing oxygen at 2 LPM or the beneficiary's prescribed FIO2 (whichever is higher).

Central Sleep or Complex Sleep Apnea

Prior to initiating therapy, a complete facility-based, attended PSG was performed documenting:

☐ Diagnosis of either central (CSA) or complex sleep apnea (CompSA); **and**

☐ Significant improvement of the sleep-associated hypoventilation with use of an E0470 or E0471 on the settings the physician prescribed for initial use at home while breathing the prescribed FIO2.

Hypoventilation Syndrome

E0470 device is covered if both criteria A **and** B **and** either criterion C **or** D are met.

☐ A. An initial arterial blood gas PaCO2, done while awake and breathing the beneficiary's prescribed FIO2, is greater than or equal to 45 mm Hg; **and**

☐ B. Spirometry shows an FEV1/FVC greater than or equal to 70%.; **and**

☐ C. An arterial blood gas PaCO2, done during sleep or immediately upon awakening, and breathing the beneficiary's prescribed FIO2, shows the beneficiary's PaCO2 worsened greater than or equal to 7 mm Hg compared to the original result in criterion A; **or**

☐ D. A facility-based PSG or HST demonstrates oxygen saturation less than or equal to 88% for greater than or equal to five minutes of nocturnal recording time (minimum recording time of two hours) that is not caused by obstructive upper airway events – i.e., AHI less than five.

E0471 device is covered if both criteria A, B, **and** either criterion C **or** D are met:

☐ A. A covered E0470 device is being used; **and**

☐ B. Spirometry shows an FEV1/FVC greater than or equal to 70%; **and**

☐ C. An arterial blood gas PaCO2, done while awake, and breathing the beneficiary's prescribed FIO2, shows that the beneficiary's PaCO2 worsens greater than or equal to 7mm Hg compared to the arterial blood gas (ABG) result performed to qualify the beneficiary for the E0470 device (criterion A under E0470); **or**

☐ D. A facility-based PSG or HST demonstrates oxygen saturation less than or equal 88% for greater than or equal to five minutes of nocturnal recording time (minimum recording time of two hours) that is not caused by obstructive upper airway events – i.e., AHI less than five while using an E0470 device.

Continued Coverage (Beyond the First Three Months of Therapy) – E0470 or E0471

☐ Medical records document beneficiary was re-evaluated on/after the 61st day of therapy:

- ☐ Progress of relevant symptoms; **and**
- ☐ Beneficiary usage of the device (average four hours per 24 hours).

Documentation in supplier's records:

- ☐ Signed and dated physician statement completed no sooner than 61 days after initiating use of the device declaring:
  - ☐ Beneficiary is consistently using device an average of four hours per 24-hour period; **and**
  - ☐ Beneficiary is benefiting from its use.

Replacement of E0470 or E0471

Following the five-year reasonable useful lifetime (RUL), there must be:

- ☐ A F2F that documents the beneficiary continues to use and benefit from the device; **and**
- ☐ A new prescription is required.

Beneficiaries Entering Medicare

- ☐ Qualification test – Documentation that the beneficiary had testing prior to FFS Medicare enrollment, that meets the current coverage criteria in effect at the time that the beneficiary seeks Medicare coverage of a replacement device and/or accessory; **and**
- ☐ Clinical evaluation – Following enrollment in FFS Medicare, the beneficiary must have a F2F documenting all of the following:
  - ☐ Beneficiary has the qualifying medical condition for the applicable scenario; **and**
  - ☐ Testing performed, date of the testing used for qualification and results; **and**
  - ☐ Beneficiary continues to use the device; **and**
  - ☐ Beneficiary is benefiting from the treatment.

Ventilators with Noninvasive Interfaces (E0465 and E0466)

Covered for the following conditions:

- ☐ Neuromuscular disease
- ☐ Thoracic restrictive disease
- ☐ Chronic respiratory failure consequent to COPD