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Healthcare Solutions

Documentation Checklist
Respiratory Assist Devices (RAD)

Policy References: Local Coverage Determination Respiratory Assist Device (RAD) (L33800) and Policy Article (A52517)

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

Respiratory Assist Devices (RAD) E0470 and E0471, Accessories and Supplies

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

Medical Records should contain:

For initial coverage (first three (3) months of therapy), medical records must document:

- ☐ Symptoms characteristic of sleep-associated hypoventilation i.e.:
  - ☐ Daytime hypersomnolence;
  - ☐ Excessive fatigue;
  - ☐ Morning headache;
  - ☐ Cognitive dysfunction;
  - ☐ Dyspnea, etc.; **and**
- ☐ Beneficiary has one (1) 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 ≥ 5 minutes of nocturnal recording time (minimum recording time of 2 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 – E0470

- ☐ Arterial blood gas PaC02 is ≥ 52 mm Hg while beneficiary is awake and breathing the prescribed FI02; **and**
- ☐ Sleep oximetry study demonstrates oxygen saturation ≤ 88% for ≥ 5 cumulative minutes of nocturnal recording time (minimum recording time of 2 hours), done while breathing oxygen at 2 LPM or the beneficiary's prescribed FI02 (whichever is higher); **and**
- ☐ Prior to initiating therapy, obstructive sleep apnea (OSA) and treatment with a CPAP has been considered and ruled out.

Severe COPD – E0471

- ☐ Situation one: An 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 ≥ 5 cumulative minutes of nocturnal recording time (minimum recording time of 2 hours) while using an E0470 that is not caused by obstructive upper airway events (AHI < 5).
- ☐ Situation two: An 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 ≥ 5 cumulative minutes of nocturnal recording time (minimum recording time of 2 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 is covered if the medical records support:
  - ☐ An initial arterial blood gas PaCO2, done while awake and breathing the beneficiary's prescribed FIO2, is ≥ 45 mm Hg; **and**
  - ☐ Spirometry shows an FEV1/FVC ≥ 70%; **and**

- ☐ An arterial blood gas PaCO2, done during sleep or immediately upon awakening, and while breathing the beneficiary's prescribed FIO2, shows the beneficiary's PaCO2 worsened ≥ 7mm Hg compared to the original result; **or**
- ☐ A facility based PSG or home sleep testing (HST) demonstrates oxygen saturation ≤ 88% for ≥ 5 minutes of nocturnal recording (minimum recording time of 2 hours) that is not caused by obstructive upper airway events (AHI < 5).

☐ E0471 is covered if the medical records support:

- ☐ A covered E0470 is being used; **and**
- ☐ Spirometry shows an FEV1/FVC ≥ 70% **and**
- ☐ An arterial blood gas PaCO2, done while awake and breathing the beneficiary's prescribed FIO2, shows the beneficiary's PaCO2 worsens ≥ 7 mm Hg compared to the ABG result performed to qualify the patient for the E0470 device; **or**
- ☐ A facility based PSG or HST demonstrates oxygen saturation ≤ 88% for ≥ 5 minutes of nocturnal recording time (minimum recording time of 2 hours) that is not caused by obstructive upper airway events (AHI < 5 while using an E0470).

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 4 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 4 hours per 24 hour period; **and**
  - ☐ Beneficiary is benefiting from its use.

Replacement of an E0470 or E0471

☐ Following the 5 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)

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