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 PaCO₂, done while awake and breathing the prescribed FIO₂, 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

The content of this document was prepared as an educational tool and is not intended to grant rights or impose obligations. Use of this document is not intended to take the place of either written law or regulations. Suppliers are reminded to review the Local Coverage Determination and Policy Article for specific documentation guidelines.
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 PaCO2 is $\geq 52$ mm Hg while beneficiary is awake and breathing the prescribed FIO2; and
- Sleep oximetry study demonstrates oxygen saturation $\leq 88\%$ for $\geq 5$ 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); 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 $\geq 7$ mm Hg compared to original result above; and
  - A facility based polysomnogram (PSG) demonstrates oxygen saturation $\leq 88\%$ for $\geq 5$ 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 $\geq 52$ mm Hg; and
  - Sleep oximetry while breathing with the E0470 demonstrates oxygen saturation $\leq 88\%$ for $\geq 5$ 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 $\geq 45$ mm Hg; and
  - Spirometry shows an FEV1/FVC $\geq 70\%$; 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