noridian
Healthcare Solutions

Documentation Checklist
Respiratory Assist Devices (RAD)

References: L11493, A23902 (prior to 10/01/2015); L33800, A52517 (on/after 10/01/2015)

Respiratory Assist Devices (RAD) E0470 and E0471

- ☐ Face-to-Face Examination (F2F)
  - ☐ Date stamp indicating supplier's date of receipt of F2F on or before date of delivery
- ☐ Written Order Prior to Delivery (WOPD)
  - ☐ Date stamp indicating supplier's date of receipt of WOPD on or before date of delivery

All RAD Accessories and Supplies

- ☐ Dispensing Order, if applicable
- ☐ Detailed Written Order (DWO)
- ☐ Refill Requirements

All Devices, Accessories, and Supplies

- ☐ Proof of Delivery (POD)
  - ☐ Method 1 - Direct Delivery to the Beneficiary by the Supplier
    The date the beneficiary/designee signs for the equipment or supplies is to be the date of service of the claim.
  - ☐ Method 2 - Delivery via Shipping or Delivery Service
    The shipping date is to be the date of service of the claim.
- ☐ Continued Need
- ☐ Continued Use

Medical Records

- ☐ 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

- ☐ Medical records document:
  - ☐ Progressive 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 usual 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

- ☐ Medical records document:
  - ☐ 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 usual 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 usual 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 FEV1 ≥ 50% of predicted; **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 FEV1 ≥ 50% of predicted; **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 (E0466)

☐ Medical records document on of the following conditions:

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

☐ Condition is life-threatening where interruption of respiratory support would quickly lead to serious harm or death

Billing Reminders

- Add the KX modifier to all claims for RADs and accessories for the first through third months if all the coverage criteria have been met.
- Add the KX modifier to all claims for the fourth month and thereafter if all the coverage criteria have been met **and** if the physician signed and dated a statement declaring that the beneficiary is compliantly using and is benefiting from the device.
- The signed physician statement must be obtained and kept on file by the supplier for continued coverage beyond three months.
- The signed physician statement should not be sent in with the claim but must be available upon request.
- When there is an expectation of a medical necessity denial, the GA modifier must be added to the code if a valid Advance Beneficiary Notice (ABN) has been obtained or a GZ modifier if a valid ABN has not been obtained.
- Claims for ventilators (E0465, E0466) used for the treatment of conditions described in the RAD LCD will be denied as not reasonable and necessary.

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Go Back to Front Page