

## Respiratory Assist Device (RAD)

The following documentation is required to be in clinic visit/therapy notes from the treating provider within 12 months of the prescription for consideration of payment.

The following documentation is required by Medicare to be in clinic visit note for consideration of payment. Documentation from the medical record should indicate the diagnosis responsible for the needed equipment and support all the following criteria:

### **Initial coverage criteria for E0470 and E0471 devices for the first three months of therapy:**

For a respiratory assistive device (RAD) to be covered, the treating physician must fully document in the patient's medical record symptoms characteristic of sleep-associated hypoventilation, such as daytime hypersomnolence, excessive fatigue, morning headache, cognitive dysfunction, dyspnea, etc.

A RAD (E0470, E0471) is covered for those patients with clinical disorder groups characterized as (I) restrictive thoracic disorders (i.e., neuromuscular diseases or severe thoracic cage abnormalities), (II) severe chronic obstructive pulmonary disease (COPD), (III) central sleep apnea (CSA) or complex sleep apnea (Comp SA), or (IV) hypoventilation syndrome, and who also meet the following criteria:

#### **I. Restrictive Thoracic Disorders**

An E0470 or E0471 device is covered when criteria A–C are met.

- A. There is documentation in the patient's medical record of a neuromuscular disease (for example, amyotrophic lateral sclerosis) or a severe thoracic cage abnormality (for example, post-thoracoplasty for TB).
- B. One of the following:
  - a. An arterial blood gas PaCO<sub>2</sub>, done while awake and breathing the patient's prescribed FIO<sub>2</sub> is  $\geq$  45 mm Hg,  
or
  - b. Sleep oximetry demonstrates oxygen saturation  $\leq$  88% for  $\geq$  five minutes of nocturnal recording time

or

- c. For a neuromuscular disease (only), either i or ii,
  - i. Maximal inspiratory pressure is  $<$ 60 cm H<sub>2</sub>O or
  - ii. Forced vital capacity is  $<$ 50 percent predicted.
- C. Chronic obstructive pulmonary disease does not contribute significantly to the patient's pulmonary limitation.

#### **II. Severe COPD:**

An E0470 device (BiPAP without a back-up rate) is covered if criteria A-C are met,

- A. An arterial blood gas PaCO<sub>2</sub>, done while awake and breathing the patient's prescribed FIO<sub>2</sub>, is  $\geq$  52 mm Hg.
- B. Sleep oximetry demonstrates oxygen saturation  $\leq$  88 percent for  $\geq$  five minutes of nocturnal recording time (minimum recording time of two hours), done while breathing oxygen at two LPM or the patient's prescribed FIO<sub>2</sub> (whichever is higher).
- C. Prior to initiating therapy, Obstructive Sleep Apnea (OSA) and treatment with a continuous positive airway pressure device (CPAP) has been considered and ruled out. Formal sleep testing is not required if there is sufficient information on the MR to demonstrate that they do not suffer from sleep apnea.

An E0471 device will be covered for a patient with COPD in either of the two situations below, depending on the testing performed to demonstrate the need.

Situation one. For Group II patients (COPD) who qualified for an E0470 device, an E0471 (BiPAP with a back-up rate) started any time after a period of initial use of an E0470 device is covered if both criteria A and B are met.

- A. An arterial blood gas PaCO<sub>2</sub>, done while awake and breathing the patient's prescribed FIO<sub>2</sub>, shows that the beneficiary's PaCO<sub>2</sub> worsens  $\geq$ 7

### **Our Locations**

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Madison · 4639 Hammersley Road · 800-924-2773  
Reedsburg · 164 Second Street · 800-924-2273

(minimum recording time of two hours), done while breathing the patient's prescribed recommended FIO<sub>2</sub>,

mm HG compared to the original result from criterion A, (above).

- B. A facility-based PSG demonstrates oxygen saturation  $\leq 88$  percent for  $\geq$  five minutes of nocturnal recording time (minimum recording time of two hours) while using an E0470 device that is not caused by obstructive upper airway events – i.e., AHI  $< 5$ . (Refer to the Positive Airway Pressure Devices LCD for information about E0470 coverage for obstructive sleep apnea).

Situation 2. For Group II patients (COPD) who qualified for an E0470 device, an E0471 device will be covered if, at a time no sooner than 61 days after initial issue of the E0470 device, both of the following criteria A and B are met:

- A. An arterial blood gas PaCO<sub>2</sub> is done while awake and breathing the patient's prescribed FIO<sub>2</sub>, still remains  $\geq 52$  mm Hg.
- B. Sleep oximetry while breathing with the E0470 device, demonstrates oxygen saturation  $\leq 88$  percent for  $\geq$  five minutes of nocturnal recording time (minimum recording time of two hours), done while breathing oxygen at 2 LPM or the patient's prescribed FIO<sub>2</sub> [whichever is higher].

### III. Central Sleep Apnea

Central sleep apnea (CSA) is defined by all of the following:

1. An apnea-hypopnea index (AHI) greater than or equal to 5
2. The sum total of central apneas plus central hypopneas is greater than 50% of the total apneas and hypopneas
3. A central apnea-central hypopnea index (CAHI) is greater than or equal to 5 per hour
4. The presence of at least one of the following: sleepiness; difficulty initiating or maintaining sleep; frequent awakenings; non-restorative sleep; awakening short of breath; snoring; or witnessed apneas
5. There is no evidence of daytime or nocturnal hypoventilation.
6. There is significant improvement of the sleep-associated hypoventilation with the use of an E0470 or E0471 device on the settings that will be prescribed for initial use at home, while breathing the beneficiary's prescribed FiO<sub>2</sub>.

### IV. Complex Sleep Apnea

1. With use of a positive airway pressure device without a backup rate (E0601 or E0470), the polysomnogram (PSG) shows a pattern of apneas and hypopneas that demonstrates the persistence or emergence of central apneas or central hypopneas upon exposure to CPAP (E0601) or a bi-level device without backup rate (E0470) device when titrated to the point where obstructive events have been effectively treated (obstructive AHI less than 5 per hour).
2. After resolution of the obstructive events, the sum total of central apneas plus central hypopneas is greater than 50% of the total apneas and hypopneas
3. After resolution of the obstructive events, a central apnea-central hypopnea index (CAHI) greater than or equal to 5 per hour
4. If the AHI or CAHI is calculated based on less than 2 hours of continuous recorded sleep, the total number of recorded events used to calculate the AHI or CAHI must be at least the number of events that would have been required in a 2-hour period (i.e., greater than or equal to 10 events).
5. There is significant improvement of the sleep-associated hypoventilation with the use of an E0470 or E0471 device on the settings that will be prescribed for initial use at home, while breathing the beneficiary's prescribed FiO<sub>2</sub>.

### V. Hypoventilation Syndrome

An E0470 device is covered if criteria one, two, and either three or four are met.

1. An initial arterial blood gas PaCO<sub>2</sub>, done while awake and breathing the patient's prescribed FIO<sub>2</sub>, is  $\geq 45$  mm Hg.
2. Spirometry shows an FEV<sub>1</sub>/FVC  $\geq 70$  percent.
3. An initial arterial blood gas PaCO<sub>2</sub>, done during sleep or immediately upon awakening, and breathing the patient's prescribed FIO<sub>2</sub>, shows the beneficiary's PaCO<sub>2</sub> worsened  $\geq 7$  mm Hg compared to the original result in criterion 1 (above).
4. A PSG or HST (home test) demonstrates oxygen saturation  $\leq 88$  percent for  $\geq$  five minutes of nocturnal recording time (minimum recording time of 2 hours) that is not caused by obstructive upper airway events – i.e., AHI  $< 5$ . (Refer to the Positive Airway Pressure Devices LCD for information about E0470 coverage for obstructive sleep apnea).

**An E0471 device is covered for a patient with hypoventilation syndrome if criteria A, B and either C or D are met:**

- A. A covered E0470 device is being used.
- B. Spirometry shows an FEV1/FVC  $\geq$ 70 percent.
- C. An arterial blood gas PaCO<sub>2</sub>, done while awake, and breathing the patient's prescribed FIO<sub>2</sub>, shows that the beneficiary's PaCO<sub>2</sub> worsens  $\geq$ 7 mm Hg compared to the ABG result performed to qualify the patient for the E0470 device.
- D. A PSG or HST (home test) demonstrates oxygen saturation  $\leq$ 88 percent for  $\geq$ five minutes of nocturnal recording time (minimum recording time of 2 hours) that is not caused by obstructive upper airway events (i.e., AHI  $<$ five) while using an E0470 device. (Refer to the Positive Airway Pressure Devices LCD for information about E0470 coverage for obstructive sleep apnea.).

**Continued coverage criteria for E0470 and E0471 devices beyond the first three months of therapy:**

Patients covered for the first three months of an E0470 or an E0471 device must be re-evaluated no sooner than 61 days after initiating therapy to establish the medical necessity of continued coverage by Medicare beyond the first three months.

There must be documentation in the patient's medical record about the progress of relevant symptoms and patient usage of the device up to that time. Failure of the patient to be consistently using the E0470 or E0471 device for an average of four hours per 24 hour period by the time of the re-evaluation (on or after 61 days after initiation of therapy) would represent non-compliant utilization for the intended purposes and expectations of benefit of this therapy. This would constitute reason for Medicare to deny continued coverage as not medically necessary.

A signed and dated statement completed by the treating physician no sooner than 61 days after initiating use of the device, declaring that the patient is compliantly using the device (an average of four hours per 24 hour period) and that the patient is benefiting from its use must be obtained by the supplier of the device for continued coverage beyond three months.