Reliable RESPIRATORY
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**Initial RAD Respiratory Assist Device: Documentation Needed to Meet Medicare Guidelines**

**Qualification Criteria is listed per Diagnosis**

1. **Prescription (must include):**
   - □ Order date
   - □ Patient name
   - □ MD name printed (MD signing the order must be identified if more than one MD listed)
   - □ MD signature (stamps are not accepted)
   - □ MD signature date
   - □ MD NPI
   - □ Length of need (usually 99 or Lifetime)
   - □ Pap type: specific type of pap must be indicated (ie: checked or circled), pressure settings and heated humidifier
   - □ Supplies: must be specific by description or HCPC code & include qty and frequency.
     Mask and Tubing cannot list both types on one RX or it will become a dispensing order.
     Dispensing orders are used when items are listed generically, are listed as "all supplies" or items are specific but missing qty and frequency.
     {If an item is not listed on the RX, it cannot be added to the sales order unless "all supplies" is listed on the RX}
     - A7030 Full Face Mask
     - A7031 Full Face Cushion
     - A7034 Nasal Mask
     - A7032 Nasal Cushion
     - A7033 Nasal Pillow
     - A7035 Headgear
     - A4604 Tubing - Heated
     - A7037 Tubing – Regular
     - A7038 Filter – Disposable
     - A7039 Filter – Non Disposable
     - A7046 Water Chamber
   - □ Date stamp (completed by Reliable Respiratory representative)

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**CENTRAL SLEEP APNEA:**

1. **Face to Face Evaluation (prior to a diagnostic sleep study):**
   *Prior to a diagnostic sleep study, the physician must assess the patient for obstructive sleep apnea and document the findings in the office chart notes*
   - □ Face to face chart notes dated prior to the diagnostic sleep study cannot be more than 1 year old (patient will need to requalify if this is the case).
   - □ Document the patient was evaluated for sleep apnea and why a sleep study is warranted
   - □ The presence of at least one of the following:
     - Sleepiness, Difficulty initiating or maintaining sleep, frequent awakenings, or non-Restorative sleep, Awakening short of breath, Snoring OR Witnessed apneas
   - □ There is no evidence of daytime or nocturnal hypoventilation
   - □ Face to face chart notes within 6 months of the prescription (if the face to face evaluation prior to the diagnostic study is older than 6 months, in addition, patient needs a new recent face to face encounter discussing sleep and/or plan)
   - □ Signed and dated by MD
   - □ Date stamp (completed by Reliable Respiratory representative)

2. **Diagnostic Sleep Study:**
   - □ The study must be performed after the initial face to face evaluation
   - □ Must meet ALL of the following criteria:
     - An apnea-hypopnea index (AHI) greater than or equal to 5
     - The sum total of central apneas plus central hypopneas is greater than 50% of the total of all apneas and hypopneas; and
     - A central apnea-central hypopnea index (CAHI) is greater than or equal to 5 per hour;
     - There is no evidence of daytime or nocturnal hypoventilation
   - □ Signed and dated by MD
   - □ Patient cannot qualify for Central Sleep Apnea with a Home Sleep Study
   - □ Date stamp (completed by Reliable Respiratory representative)

3. **Titration Study:**
   - □ A titration study is then needed on the unit being ordered, Bipap (E0470) or the Bipap with backup rate (E0471), to show improvement of the Central Sleep Apnea.

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**COMPLEX SLEEP APNEA:**

1. **Face to Face Evaluation (prior to a diagnostic sleep study):**
   *Prior to a diagnostic sleep study, the physician must assess the patient for obstructive sleep apnea and document the findings in the office chart notes*
   - □ Face to face chart notes dated prior to the diagnostic sleep study cannot be more than 1 year old (patient will need to requalify if this is the case).
   - □ Document the patient was evaluated for sleep apnea and why a sleep study is warranted
   - □ The presence of at least one of the following:
     - Sleepiness, Difficulty initiating or maintaining sleep, frequent awakenings, or non-Restorative sleep, Awakening short of breath, Snoring OR Witnessed apneas
   - □ There is no evidence of daytime or nocturnal hypoventilation
   - □ Face to face chart notes within 6 months of the prescription (if the face to face evaluation prior to the diagnostic study is older than 6 months, in addition, patient needs a new recent face to face encounter discussing sleep and/or plan)
   - □ Signed and dated by MD
   - □ Date stamp (completed by Reliable Respiratory representative)

2. **Diagnostic Sleep Study:**
   - □ The study must be performed after the initial face to face evaluation
   - □ Must meet one of the following criteria:
     - The apnea-hypopnea index (AHI) is greater than or equal to 15 events per hour OR
     - The AHI is greater than or equal to 5 and less than or equal to 14 events per hour and documentation of at least one of the following:
       Excessive daytime sleepiness, impaired cognition, mood disorders, insomnia, hypertension, ischemic heart disease, or history of stroke
   - □ Signed and dated by MD
   - □ If patient has a home sleep study, a copy of the instruction form indicating the patient was shown how to properly use the sleep monitor must be provided by the entity (sleep lab) conducting the home sleep test. It must be signed on or before date of study by the sleep tech, patient or doctor.
   - □ Date stamp (completed by Reliable Respiratory representative)

3. **Titration Study on Cpap or Bipap with No backup Rate:**
   - □ Must meet ALL of the following criteria:
     - With use of Cpap (E0601) or Bipap no backup rate (E0470), titrated to the point where obstructive events have been effectively treated (obstructive AHI less than 5 per hour)
     - 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; and
     - After resolution of the obstructive events, a central apnea-central hypopnea index (CAHI) greater than or equal to 5 per hour.

**RESTRICTIVE THORACIC DISORDER:**

**Bipap (E0470) or Bipap with backup rate (E0471) device is covered when criteria A-C are met.**

A. There is documentation in the beneficiary'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 PaCO2, done while awake and breathing the beneficiary's prescribed FIO2 is greater than or equal to 45 mm Hg, or
    b. Sleep oximetry demonstrates oxygen saturation less than or equal to 88% for greater than or equal to 5 minutes of nocturnal recording time (minimum recording time of 2 hours), done while breathing the beneficiary's prescribed recommended FIO2, or
    c. For a neuromuscular disease (only), either i or ii,
    i. Maximal inspiratory pressure is less than 60 cm H20, or
    ii. Forced vital capacity is less than 50% predicted
C. Chronic obstructive pulmonary disease does not contribute significantly to the beneficiary's pulmonary limitation.

**HYPOVENTILATION SYNDROME:**

**Bipap (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
B. Spirometry shows an FEV1/FVC greater than or equal to 70%. (Refer to SEVERE COPD (above) for information about device coverage for beneficiaries with FEV1/FVC less than 70%.)
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 (above).
D. A facility-based PSG or HST demonstrates oxygen saturation less than or equal to 88% for greater than or equal to 5 minutes of nocturnal recording time (minimum recording time of 2 hours) that is not caused by obstructive upper airway events – i.e., AHI less than 5.

**Bipap with backup rate (E0471) device is covered for hypoventilation syndrome if both criteria A, B, and either criterion C or D are met:**

A. A covered E0470 device is being used.
B. Spirometry shows an FEV1/FVC greater than or equal to 70%. (Refer to SEVERE COPD (above) for information about device coverage for beneficiaries with FEV1/FVC less than 70%).
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 7 mm HG compared to the ABG result performed to qualify the beneficiary for the E0470 device (criterion A under E0470).
D. A facility-based PSG or HST demonstrates oxygen saturation less than or equal 88% for greater than or equal to 5 minutes of nocturnal recording time (minimum recording time of 2 hours) that is not caused by obstructive upper airway events – i.e., AHI less than 5 while using an E0470 device.

**SEVERE COPD:**
**Bipap (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.
B. Sleep oximetry demonstrates oxygen saturation less than or equal to 88% for greater than or equal to a cumulative 5 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).
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).

**Bipap with backup rate (E0471) device will be covered for COPD in either of the two situations below, depending on the testing performed to demonstrate the need.**

**Situation 1**. For Group II beneficiaries (COPD) who qualified for an E0470 device, an E0471 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 PaCO2, done while awake and breathing the beneficiary's prescribed FIO2, shows that the beneficiary's PaCO2 worsens greater than or equal to 7 mm HG compared to the original result from criterion A, (above).
B. A facility-based PSG demonstrates oxygen saturation less than or equal to 88% for greater than or equal to a cumulative 5 minutes of nocturnal recording time (minimum recording time of 2 hours) while using an E0470 device that is not caused by obstructive upper airway events – i.e., AHI less than 5.

**Situation 2**. For Group II beneficiaries (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 PaCO2 is done while awake and breathing the beneficiary's prescribed FIO2, still remains greater than or equal to 52 mm Hg.
B. Sleep oximetry while breathing with the E0470 device, demonstrates oxygen saturation less than or equal to 88% for greater than or equal to a cumulative 5 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].