Medicare Respiratory Assist Device (RAD) Qualifications- Severe COPD

Prescription

- Patient's Name
- Date of Order
- General Description of the item(s) BIPAP, BIPAP ST, BIPAP ASV
- Pressure Settings
- For supplies, list each separately (e.g., mask 1/3 months; headgear 1/6 months; tubing 1/3 months, filters, disposable 2/month; filter, reusable, 1/6 months; water chamber 1/6 months; cushion, nasal or pillow, 2/month; full face cushion 1/month)
- Physician's Signature
- Physician's Name Printed or NPI

Chart Notes

- Medical records fully document symptoms characteristic of sleep associated hypoventilation (daytime hypersomnolence, excessive fatigue, morning headache, cognitive dysfunction, etc.)
- Medical record must meet all the coverage criteria of the appropriate diagnosis. Chart Notes must be signed and dated by the practitioner.

Severe COPD without a backup rate

A BIPAP (E0470) device is covered if criteria A - C are met.

A. An arterial blood gas PaCO2, done while awake and breathing the patient'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 patient'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 the patient does not suffer from some form of sleep apnea (OSA, CSA and/or CompSA) as the predominant cause of awake hypercapnia or nocturnal arterial oxygen desaturation).

Severe COPD with a backup rate

A BIPAP (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 1: For severe COPD patients 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 patient's prescribed FIO2, shows that the patient'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 severe COPD patients 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 patient'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 patient's prescribed FIO2 [whichever is higher].

Medicare Respiratory Assist Device (RAD) Qualifications- Central/Complex Sleep Apnea

Prescription

- Patient's Name
- Date of Order
- General Description of the item(s) BIPAP, BIPAP ST, BIPAP ASV
- Pressure Settings
- For supplies, list each separately (e.g., Full face mask, nasal mask, headgear, disposable filter, non-disposable filter, chinstrap, tubing, heated tubing, humidifier, humidifier chamber, replacement face mask interface, cushion for nasal mask, pillow for nasal mask)
- Physician's Signature
- Physician's Name Printed or NPI

Chart Notes

- Medical records fully document symptoms characteristic of sleep associated hypoventilation (daytime hypersomnolence, excessive fatigue, morning headache, cognitive dysfunction, etc.)
- Medical record must meet all the coverage criteria of the appropriate diagnosis. Chart Notes must be signed and dated by the practitioner.

Central Sleep Apnea

- An apnea-hypopnea index (AHI) greater than or equal to 5; and
- The sum total of central apneas plus central hypopneas is greater than 50% of the total apneas and hypopneas; and
- A central apnea-central hypopnea index (CAHI) is greater than or equal to 5 per hour; and
- 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
    - Witnessed apneas
- There is no evidence of daytime or nocturnal hypoventilation.

Complex Sleep Apnea

With use of a positive airway pressure device without a backup rate (CPAP or BIPAP), 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 or a bi-level device without backup rate device when titrated to the point where obstructive events have been effectively treated (obstructive AHI less than 5 per hour).

1. 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
2. After resolution of obstructive events, a central apnea-central hypopnea index (CAHI) is greater than or equal to 5 per hour.

Central Sleep Apnea or Complex Sleep Apnea

A BIPAP, BIPAP ST, and BIPAP ASV device is covered when, prior to initiating therapy, a complete facility-based, attended PSG is performed documenting the following (A and B):

A. The diagnosis of CSA or CompSA; and
B. Significant improvement of the sleep-associated hypoventilation with the use of an BIPAP, BIPAP ST and BIPAP ASV device on the settings that will be prescribed for initial use at home, while breathing the patient's prescribed FIO2.

Current as of February 2024

Medicare Respiratory Assist Device (RAD) Qualifications- Hypoventilation

Prescription

- Patient's Name
- Date of Order
- General Description of the item(s) BIPAP, BIPAP ST, BIPAP ASV
- Pressure Settings
- For supplies, list each separately (e.g., mask 1/3 months; headgear 1/6 months; tubing 1/3 months, filters, disposable 2/month; filter, reusable, 1/6 months; water chamber 1/6 months; cushion, nasal or pillow, 2/month; full face cushion 1/month)
- Physician's Signature
- Physician's Name Printed or NPI

Chart Notes

- Medical records fully document symptoms characteristic of sleep associated hypoventilation (daytime hypersomnolence, excessive fatigue, morning headache, cognitive dysfunction, etc.)
- Medical record must meet all the coverage criteria of the appropriate diagnosis. Chart Notes must be signed and dated by the practitioner.

Hypoventilation Syndrome – without a backup rate

A BIPAP device is covered if both criteria A and B and either criterion C or D are met.

A. An initial arterial blood gas $PaCO_2$, done while awake and breathing the patient's prescribed FIO_2, 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 patients with FEV1/FVC less than 70%.)
C. An arterial blood gas $PaCO_2$, done during sleep or immediately upon awakening, and breathing the patient's prescribed FIO_2, shows the patient's $PaCO_2$ 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.

A BIPAP ST or BIPAP ASV device is covered for a patient with hypoventilation syndrome if both criteria A, B, and either criterion C or D are met:

A. A covered BIPAP device is being used.
B. Spirometry shows an FEV1/FVC greater than or equal to 70%. (Refer to SEVERE COPD) for information about device coverage for patients with FEV1/FVC less than 70%).
C. An arterial blood gas $PaCO_2$, done while awake, and breathing the patient's prescribed FIO_2, shows that the patient's $PaCO_2$ worsens greater than or equal to 7 mm Hg compared to the arterial blood gas (ABG) result performed to qualify the patient for the E0470 device (criterion A under BIPAP).
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. (Refer to the Positive Airway Pressure (PAP) Devices for Treatment of Obstructive Sleep Apnea LCD for information about E0470 coverage for obstructive sleep apnea.)

Current as of February 2024

Scan For PAP Qualification Guidelines

Medicare Respiratory Assist Device (RAD) Qualifications- Restrictive Thoracic Disorder

Prescription

- Patient's Name
- Date of Order
- General Description of the item(s) BIPAP, BIPAP ST, BIPAP ASV
- Pressure Settings
- For supplies, list each separately (e.g., mask 1/3 months; headgear 1/6 months; tubing 1/3 months, filters, disposable 2/month; filter, reusable, 1/6 months; water chamber 1/6 months; cushion, nasal or pillow, 2/month; full face cushion 1/month)
- Physician's Signature
- Physician's Name Printed or NPI

Chart Notes

- Medical records fully document symptoms characteristic of sleep associated hypoventilation (daytime hypersomnolence, excessive fatigue, morning headache, cognitive dysfunction, etc.)
- Medical record must meet all the coverage criteria of the appropriate diagnosis. Chart Notes must be signed and dated by the practitioner.

Restrictive Thoracic Disorder

A BIPAP, BIPAP ST or BIPAP ASV device is covered when criteria A – C are met.

A. There is documentation in the patient's medical record of a neuromuscular disease (i.e., amyotrophic lateral sclerosis) or a severe thoracic cage abnormality (i.e., post-thoracoplasty for TB).
B. One of the following:
    a. An arterial blood gas PaCO2, done while awake and breathing the patient'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 patient'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 patient's pulmonary limitation.

Current as of February 2024

Scan For PAP Qualification Guidelines