



RESPIRATORY ASSIST DEVICE (RAD)

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There are four different clinical groups characterized as:

GROUP I: Restrictive Thoracic Disorders

GROUP II: Severe Chronic Obstructive Pulmonary Disease (COPD)

GROUP III: Central Sleep Apnea (CSA) or Complex Sleep Apnea (Comp SA)

GROUP IV: Hypoventilation Syndrome

FOR INITIAL COVERAGE:

GROUP I: Restrictive Thoracic Disorders

1. Neuromuscular disease or severe thoracic cage abnormality **AND**
2. One of the following
 - A. Arterial blood gas PaCO₂, while awake and breathing patient's prescribed FiO₂ is greater than 45 mm Hg, **OR**
 - B. Sleep oximetry demonstrates oxygen saturation less than 88 percent for more than 5 minutes nocturnal, while breathing prescribed FiO₂, **OR**
 - C. For neuromuscular disease (only)
 - i. Maximal inspiratory pressure less than 60 cm H₂O **OR**
 - ii. Forced vital capacity less than 50 percent predicted
3. COPD does not contribute significantly to patient's pulmonary function.

GROUP II: Severe COPD

Standard BiPAP without backup (E0470):

1. ABG PaCO₂, while awake and breathing patient's prescribed FiO₂ greater than 52 mm HG; **AND**
2. Sleep oximetry demonstrates oxygen saturation of less than or equal to 88 percent for at least 5 minutes nocturnal, done while breathing at 2 lpm or the patient's prescribed FiO₂ (whichever is higher); **AND**
3. 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 Comp SA) as the predominant cause of awake hypercapnia or nocturnal arterial oxygen desaturation).

DID YOU KNOW!

- The overnight oximetry can be performed at anytime during the hospital stay. It is not necessary to do 2 days before discharge for BiPAP. It's best to do the test while patient is most sick; i.e. upon admission.
- If OSA is a component to the patient's problems, then a sleep study **MUST** be done first.
- If your patient's diagnosis is Restrictive Thoracic Disorder, Central Sleep Apnea (CSA), or Complex Sleep Apnea (Comp SA), or Hypoventilation syndrome your patient can qualify for BiPAP without a sleep study, call for details. **1-866-366-7599**
- Trilogy is still an option for patients with chronic respiratory failure from COPD, Neuromuscular disease, and Thoracic Restrictive Disease.



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BiPAP with backup (E0471):

Covered for COPD in following two situations:

Situation 1 – BiPAP with backup started any time after a period of initial use of BiPAP without backup if both A and B are met:

- A.** ABG PaCO₂, while awake and breathing beneficiary's prescribed FiO₂, shows that the beneficiary's PaCO₂ worsens greater than or equal to 7 mm Hg compared to original result from #1 above.
- B.** Facility-based PSG demonstrates oxygen saturation less than or equal to 88 percent for at least five minutes nocturnal (minimum recording 2 hours) while using BiPAP without backup that is not caused by obstructive upper airway event.

Situation 2 – BiPAP with backup no sooner that 61 days after initial issue of BiPAP without backup if both A and B are met:

- A.** ABG PaCO₂ done while awake and breathing beneficiary's prescribed FiO₂, still remains greater than or equal to 52 mm Hg **AND**
- B.** Sleep oximetry, while breathing with BiPAP without backup, demonstrates oxygen saturation less than or equal to 88 percent for at least five minutes nocturnal, (minimum recording time of two hours) while breathing oxygen at 2 lpm or prescribed FiO₂, whichever is higher.

GROUP III: Central Sleep Apnea or Complex Sleep Apnea

Prior to initiating therapy, a complete, facility-based, attended polysomnogram must be performed documenting both A and B:

- A.** Diagnosis of central sleep apnea (CSA) or complex sleep apnea (CompSA), **AND**
- B.** Significant improvement of the sleep-associated hypoventilation with the BiPAP with or without backup while breathing prescribed FiO₂

Central sleep apnea (CSA) is defined as:

- 1.** An apnea-hypopnea index (AHI) greater than or equal to five, **AND**
- 2.** The sum total of central apneas plus central hypopneas is greater than 50% of the total apneas an hypopneas, **AND**
- 3.** A central apnea-central hypopnea index (CAHI) is greater than or equal to 5 per hour, **AND**
- 4.** Presence of at least one of the following:
 - Sleepiness
 - Difficulty initiating or maintaining sleep, frequent awakenings, or nonrestorative sleep
 - Awakening short of breath
 - Snoring
 - Witnessed apneas
- 5.** There is no evidence of daytime or nocturnal hypoventilation



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Complex sleep apnea (CompSA) is a form of central apnea specifically identified by all of the following:

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; and
 3. After resolution of the obstructive events, a central apnea-central hypopnea index (CAHI) greater than or equal to 5 per hour.
- For diagnosis of CSA, the central apnea-central hypopnea index (CAHI) is defined as the average number of episodes of central apnea and central hypopnea per hour of sleep without the use of a positive airway pressure device. For CompSA, the CAHI is determined during the use of a positive airway pressure device after obstructive events have disappeared.
 - 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).

GROUP IV: Hypoventilation Syndrome

BiPAP without backup covered if 1, 2 and either 3 or 4 are met:

1. ABG PaCO₂, done while awake breathing prescribed FiO₂ is greater than or equal to 45 mm Hg.
2. Spirometry shows FEV1/FVC greater than or equal to 70 percent.
3. ABG PaCO₂ done during sleep or immediately upon awaking breathing prescribed FiO₂ shows the beneficiary's PaCO₂ worsened greater than or equal to 7 mm Hg compared to result in criterion 1 above.
4. PSG demonstrates oxygen saturation less than or equal to 88 percent for at least 5 minutes nocturnal (minimum recording time of two hours) not caused by obstructive upper airway events.

BiPAP with backup covered if 1, 2, and either 3 or 4 are met:

1. BiPAP without backup is being used
2. Spirometry shows FEV1/FVC greater than or equal to 70 percent.
3. ABG PaCO₂ done while awake breathing prescribed FiO₂ shows the beneficiary's PaCO₂ worsens greater than or equal to 7 mm Hg compared to ABG performed to qualify for BiPAP without backup.
4. PSG demonstrates oxygen saturation less than or equal to 88 percent for at least 5 minutes nocturnal (minimum recording time of 2 hours) that is not caused by obstructive upper airway events.

Continued coverage beyond the first three months:

Must be re-evaluated by treating practitioner no sooner than 61st day after initial therapy.

- Documenting that patient is compliant with the device. Compliance is using the machine for at least four hours per a 24-hour period.
- Documentation that patient is benefiting from use of the therapy.
- Make sure it's signed and dated by treating practitioner.