

RESPIRATORY ASSIST DEVICES FOR CENTRAL SLEEP APNEA OR COMPLEX SLEEP APNEA

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Dear Clinician,

Medicare provides reimbursement for bi-level positive airway pressure (PAP) devices, with and without back-up rate, for the treatment of Central Sleep Apnea (CSA) or Complex Sleep Apnea (CompSA) when certain specified coverage criteria are met. Coverage is also available for beneficiaries with certain restrictive thoracic disorders (i.e., neuromuscular diseases or severe thoracic cage abnormalities), chronic obstructive pulmonary disease (COPD) and hypoventilation syndrome diagnoses. The information in this letter is intended to assist you in documenting that your patient meets Medicare criteria for initial coverage of a respiratory assist device (RAD) for your patient with CSA or CompSA. Additional Dear Clinician letters are available to address the criteria for coverage of other diagnoses.

Requirements for coverage of a RAD for CSA or CompSA are described in the following excerpt from the RAD local coverage determination (LCD). A RAD is covered for a patient who meets both criteria A and B:

- A. The diagnosis of CSA or CompSA; and
 1. CSA is defined by all of the following:
 - a. An apnea-hypopnea index (AHI) greater than or equal to 5; and
 - b. The sum total of central apneas plus central hypopneas is greater than 50% of the total apneas and hypopneas; and
 - c. A central apnea-central hypopnea index (CAHI) is greater than or equal to 5 per hour; and
 - d. The presence of at least one of the following:
 - i. Sleepiness, difficulty initiating or maintaining sleep, frequent awakenings, or non-restorative sleep, awakening short of breath, snoring, witnessed apneas
 - e. There is no evidence of daytime or nocturnal hypoventilation
 2. CompSA is a form of central apnea specifically identified by all of the following:
 - a. With use of a PAP 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).
- b. 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
 - c. After resolution of the obstructive events, the CAHI is greater than or equal to 5 per hour.
- B. 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 FIO₂.

In the event of an audit, your medical record may be used to demonstrate that the criteria above are met for your patient. We encourage you to thoroughly address the applicable requirements in your records at the time you prescribe the RAD.

In addition to the initial coverage requirements discussed above, all beneficiaries using RAD must have a re-evaluation during the third month of use. The evaluation must be documented in your records for Medicare to continue to pay for a RAD after the third month. The re-evaluation requirements are:

- No sooner than the 61st day after initiating therapy, you must conduct a clinical re-evaluation and document that your patient is compliantly using and benefiting from RAD therapy. This is demonstrated by:
 - An in-person or Medicare-approved telehealth visit with your patient on or after the 61st day of the trial (not before the 61st day) that documents:
 - Medical record documentation about the progress of relevant symptoms and beneficiary usage of the device up to that time.
 - A signed and dated statement completed by the treating clinician no sooner than 61 days after initiating use of the device, declaring that the beneficiary is compliantly using the device (an average of 4 hours per 24-hour period) and that the beneficiary is benefiting from its use.

It is important to stay in communication with your patient's durable medical equipment (DME) supplier or track compliance yourself so that a follow-up visit can be scheduled no sooner than 61 days after initiating therapy.

This letter provides only limited details on the coverage of RAD for CSA and CompSA. Refer to the Respiratory Assist Devices LCD, LCD-related Policy Article, and Standard Documentation Requirements for All Claims Submitted to DME MACs for additional information regarding Medicare coverage, coding, and documentation requirements.

Sincerely,

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