26 CENTURY BLVD STE ST610 | NASHVILLE, TN 37214-3685 | CGSMEDICARE.COM

Dear Physician,

Medicare provides reimbursement for bi-level positive airway pressure (PAP) devices, with and without back-up rate, for the treatment of restrictive thoracic disorders (i.e., neuromuscular diseases or severe thoracic cage abnormalities) when certain specified coverage criteria are met. Coverage is also available for beneficiaries with certain central sleep apnea (CSA), complex sleep apnea (CompSA), hypoventilation syndrome diagnoses, and chronic respiratory failure (CRF) consequent to chronic obstructive pulmonary disease (COPD). 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 restrictive thoracic disorders and neuromuscular diseases. Additional Dear Physician letters are available to address the criteria for coverage of other diagnoses.

Requirements for coverage of a RAD for restrictive thoracic disorders (i.e., neuromuscular diseases or severe thoracic cage abnormalities) are described in the following excerpt from the RAD local coverage determination (LCD).

> Restrictive Thoracic Disorders
>
> An E0470 or E0471 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 $PaCO_2$, done while awake and breathing the beneficiary's prescribed FIO_2 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 FIO_2, or
>
> c. For a neuromuscular disease (only), either i or ii,
>
> i. Maximal inspiratory pressure is less than 60 cm H_20, 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.
>
> If all of the above criteria are met, either an E0470 or an E0471 device (based upon the judgment of the treating practitioner) will be covered for the first three months of therapy.
>
> If all of the above criteria are not met, then E0470 or E0471 and related accessories will be denied as not reasonable and necessary.

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 practitioner 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 restrictive thoracic disorders (i.e., neuromuscular diseases or severe thoracic cage abnormalities). 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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