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RESPIRATORY ASSIST DEVICES (RAD) FOR HYPOVENTILATION SYNDROME

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Dear Physician,

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

Requirements for coverage of a RAD device for hypoventilation syndrome are described in the following excerpt from the RAD LCD.

Hypoventilation Syndrome

A bi-level device without backup rate (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. (Refer to the Positive Airway Pressure Devices LCD for information about E0470 coverage for obstructive sleep apnea.)

If the above criteria are not met, E0470 and related accessories will be denied as not reasonable and necessary.

A bi-level device with backup rate (E0471) device is covered for a beneficiary with hypoventilation syndrome if both criteria A, B, and either criterion C or D are met:

A. A covered E0470 device is being used.

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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. (Refer to the Positive Airway Pressure Devices LCD for information about E0470 coverage for obstructive sleep apnea.)

If the criteria above are not met, an E0471 device 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 device.

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:

• A face-to-face 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 physician 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 DME company 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 hypoventilation syndrome. Refer to the Respiratory Assist Device LCD, LCD-related Policy Article, and Standard Documentation Requirements for additional information regarding Medicare coverage, coding, and documentation.

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