

Respiratory Assist Devices for Chronic Obstructive Pulmonary Disease

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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 chronic obstructive pulmonary disease (COPD) when certain specified coverage criteria are met. Coverage is also available for beneficiaries with certain central sleep apnea (CSA), complex sleep apnea (CompSA), restrictive thoracic disorders (i.e., neuromuscular diseases or severe thoracic cage abnormalities) 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 COPD. Additional Dear Clinician letters are available to address the criteria for coverage of other diagnoses.

Requirements for coverage of a RAD for COPD are described in the following excerpt from the RAD local coverage determination (LCD).

Severe COPD

AnE0470 device is covered if criteria A - C are met.

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

If all of the above criteria for beneficiaries with COPD are met, an E0470 device will be covered for the first three months of therapy.

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

An E0471 device will be covered for a beneficiary with COPD in either of the two situations below, depending on the testing performed to demonstrate the need.

Situation 1. For severe COPD beneficiaries 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 beneficiary's prescribed FIO₂, shows that the beneficiary'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. (Refer to the Positive Airway Pressure (PAP) Devices for the Treatment of Obstructive Sleep Apnea LCD for information about E0470 coverage for obstructive sleep apnea).

Situation 2. For severe COPD beneficiaries 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 beneficiary'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 beneficiary's prescribed FIO₂ [whichever is higher].

If E0471 is billed but the criteria described in either situation 1 or 2 are not met, it 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 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 COPD. 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,

Noridian Healthcare Solutions Medical Directors	CGS Administrators Medical Directors
Smitha M. Ballyamanda, MD, CAQSM Medical Director, DME MAC, Jurisdictions A Noridian Healthcare Solutions, LLC	Robert D. Hoover, Jr., MD, MPH, FACP Medical Director, DME MAC, Jurisdiction C CGS Administrators, LLC
Peter J. Gurk, MD, CPE, CHCQM Medical director, DME MAC, Jurisdiction D Noridian Healthcare Solutions, LLC	Stacey V. Brennan, MD, FAAFP Medical Director, DME MAC, Jurisdictions B CGS Administrators, LLC