

Home-Based Noninvasive Positive Pressure Ventilation to Treat Chronic Respiratory Failure Due to Chronic Obstructive Pulmonary Disease

Related CR Release Date: August 21, 2025	MLN Matters Number: MM14177
Effective Date: June 9, 2025	Related Change Request (CR) Number: CR 14177
Implementation Date: October 22, 2025	Related CR Transmittal Numbers: R13374CP & R13374NCD

Related CR Title: Noninvasive Positive Pressure Ventilation (NIPPV) in the Home for the Treatment of Chronic Respiratory Failure (CRF) Consequent to Chronic Obstructive Pulmonary Disease (COPD)

Affected Providers

- Physicians
- Suppliers
- Other providers billing Medicare Administrative Contractors (MACs) for DMEPOS

Action Needed

Make sure your billing staff knows about these updates effective June 9, 2025, including updated Medicare coverage guidance for:

- Respiratory assistance devices (RADs)
- Home mechanical ventilators (HMVs)





Background

RADs with bi-level capability, with or without a backup rate feature, are devices that use a non-invasive interface (mask) to deliver a higher level of airway pressure when the patient inhales compared to when they exhale. A backup rate feature enables the device to provide a prespecified respiratory rate if the patient's spontaneous respiratory rate decreases below a set number.

HMVs deliver a predetermined amount of air with each breath and typically have more monitoring, safety, alarm, and backup power features (such as batteries) than RADs.

Key Updates

Effective for services performed on or after June 9, 2025, CMS has determined that evidence is sufficient to cover RADs (see <u>National Coverage Determination (NCD) Manual, Chapter 1, Part 4</u>, section 240.9) with or without a backup rate feature and to cover HMVs in the home to deliver high-intensity noninvasive ventilation (NIV) to treat patients with chronic respiratory failure (CRF) due to chronic obstructive pulmonary disease (COPD).

RADs With a Backup Rate Feature – Initial Coverage Criteria

We cover in-home RAD with a backup rate feature for an initial 6-month period for COPD patients when they meet all these criteria:

- The patient exhibits persistent hypercapnia as demonstrated by partial pressure of carbon dioxide (PaCO2) ≥ 52 millimeters of mercury (mmHg) by arterial blood gas while awake and while breathing their prescribed fraction of inspired oxygen (FiO2)
- Sleep apnea isn't the predominant cause of the hypercapnia (we don't require formal sleep testing
 if, per the patient's clinician, the patient doesn't experience sleep apnea as the predominant cause
 of hypercapnia)
- The patient demonstrates 1 of these characteristics:
 - Stable COPD without an increase in or new onset of more than 1 respiratory symptom (cough, sputum production, sputum purulence, wheezing, or dyspnea) lasting 2 or more days and no change of pharmacological treatment during the 2-week period before initiation of NIV
 - Hypercapnia is present for at least 2 weeks post-hospitalization after resolving an exacerbation of COPD requiring acute NIV

By the end of the initial 6-month period, patients using a RAD with backup rate feature must use it as high intensity therapy, defined as a minimum inspiratory positive airway pressure ≥ 15 cm H20 and backup respiratory rate of at least 14 breaths per minute.



RADs Without a Backup Rate Feature – Initial Coverage Criteria

We cover in-home RAD without a backup rate feature for patients with CRF due to COPD who can't tolerate high-intensity NIV or for whom the backup rate feature is otherwise medically inappropriate. We cover a RAD without a backup rate feature in the home for an initial 6-month period for patients with COPD when they meet these criteria:

- The patient exhibits hypercapnia as demonstrated by PaCO2 ≥ 52 mmHg by arterial blood gas while awake and while breathing their prescribed FiO2
- Sleep apnea isn't the predominant cause of the hypercapnia (we don't require formal sleep testing
 if, per the clinician, the patient doesn't experience sleep apnea as the predominant cause
 of hypercapnia)

RAD Use Upon Hospital Discharge

We also cover in-home RAD with or without the backup rate feature immediately upon hospital discharge for an initial 6-month period for patients with acute on chronic respiratory failure due to COPD if the patient required either a RAD or ventilator within the 24-hour period prior to discharge and the clinician determines the patient is at risk of rapid symptom exacerbation or rise in PaCO2 after discharge.

RADs - Continuing Usage Criteria

Clinicians must evaluate patients at least twice within the first year after the patient initially receives a RAD. Evaluations must occur once by the end of the initial 6-month period and again during months 7–12.

During the first evaluation, the clinician must establish the patient is meeting usage criteria (at least 4 hours per 24-hour period on at least 70% of days in a 30-day period) and achieving at least 1 of these clinical outcomes:

- Normalization (< 46 mmHg) of PaCO2
- Stabilization of a rising PaCO2
- A 20% reduction in PaCO2 from baseline value
- Improvement of at least 1 of the patient symptoms associated with chronic hypercapnia, including headache, fatigue, shortness of breath, confusion, and sleep quality

In the second evaluation, the clinician must establish the patient is using the device at least 4 hours per 24-hour period on at least 70% of days in each paid rental month.

After the second evaluation, the patient must use the device at least 4 hours per 24-hour period on at least 70% of days in each remaining paid rental month and any month in which they receive accessories or supplies.



HMVs - Initial Coverage Criteria

We cover an HMV used in a volume targeted mode as treatment for patients with CRF due to COPD who exhibit certain clinical characteristics. We cover HMVs for an initial 6-month period for COPD patients when they meet these criteria:

- The patient exhibits hypercapnia as demonstrated by PaCO2 ≥ 52 mmHg by arterial blood gas while awake and while breathing their prescribed FiO2
- Sleep apnea isn't the predominant cause of the hypercapnia (we don't require formal sleep testing
 if, per the clinician, the patient doesn't experience sleep apnea as the predominant cause
 of hypercapnia)
- The patient demonstrates at least 1 of the following characteristics:
 - Requires oxygen therapy at FiO2 ≥ 36% or ≥ 4 liters nasally
 - Requires ventilatory support for more than 8 hours per 24-hour period
 - Requires the alarms and internal battery of an HMV because the patient is unable to effectively breathe on their own for more than a few hours and the unrecognized interruption of ventilatory support is likely to cause a life-threatening condition if the HMV can't alert the patient or caregiver
 - If, due to the patient's medical condition, the clinician determines that consistent RAD use with a backup feature for at least 4 hours per 24-hour period on at least 70% of days over a 30-day period won't help the patient achieve:
 - Normalization (< 46 mmHg) of PaCO2
 - Stabilization of a rising PaCO2
 - A 20% reduction in PaCO2 from baseline value
 - Improvement of at least 1 of the patient symptoms associated with chronic hypercapnia, including headache, fatigue, shortness of breath, confusion, and sleep quality

HMV Use Upon Hospital Discharge

We cover in-home HMV used in a volume targeted mode immediately upon hospital discharge for an initial 6-month period for patients with acute on chronic respiratory failure due to COPD if the patient's needs exceeded the capabilities of a RAD (with or without a backup rate feature) and required ventilator use within the 24-hour period prior to hospital discharge and the clinician determines the patient is at risk of rapid symptom exacerbation or rise in PaCO2 after discharge.

HMVs – Continuing Usage Criteria

Clinicians must evaluate patients at least twice within the first year after the patient initially receives an HMV. Evaluations must occur once by the end of the initial 6-month period and again during months 7–12.

In the first evaluation, the clinician must establish the patient is meeting usage criteria by using the HMV at least 4 hours per 24-hour period on at least 70% of days in a 30-day period.



In the second evaluation, the clinician must establish the patient is using the device at least 4 hours per 24-hour period on at least 70% of days in each paid rental month.

After the second evaluation, the patient must use the device at least 4 hours per 24-hour period on 70% of days in each paid rental month.

HMV Masks

We cover a different interface for daytime hours if patients use an HMV in a volume targeted mode for greater than 8 hours in any 24-hour period and they use an oronasal mask at night.

Note: Coverage of such supplies doesn't exclude coverage of additional supplies necessary for effective HMV use.

RAD & HMV Billing Information

To bill for RADs, use 1 of these HCPCS codes:

- E0470
- E0471

To bill for HMVs, use 1 of these HCPCS codes:

- E0465
- E0466
- E0467
- E0468

Always use the KX modifier when billing claims using E0470 and E0471. When billing for RADs or HMVs, include 1 of these ICD-10-CM codes:

- J96.12: Chronic respiratory failure with hypercaphia
- J96.22: Acute and chronic respiratory failure with hypercapnia
- J44.0: Chronic obstructive pulmonary disease with (acute) lower respiratory infection
- J44.1: Chronic obstructive pulmonary disease with (acute) exacerbation
- J44.89: Other specified chronic obstructive disease
- J44.9: Chronic obstructive pulmonary disease, unspecified

Note: For multifunction ventilators (E0467 and E0468), a patient would need to meet the ventilator criteria plus the criteria for 1 of the other functions for coverage. See details in the <u>Medicare Claims Processing Manual, Chapter 32</u>, section 413.

CR 14177 contains no coding or billing instructions for masks and additional mask-related supplies. While the NCD covers a mask at night and a different mask during the day, existing DME rules, coding, and billing instructions apply.

Note: Contractors won't search for claims processed on or after June 9, 2025, for RAD and HMV, but will adjust any claims you bring to their attention.



More Information

We issued transmittals R13374CP and R13374NCD to your MAC as the official instructions for this change. For more information, find your <u>MAC's website</u>.

Document History

Date of Change	Description
August 25, 2025	Initial article released.

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