April 16, 2026

The Honorable Mehmet Oz, M.D., M.B.A.
Administrator
Centers for Medicare & Medicaid Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

The Honorable Kimberly Brandt, J.D., M.A.
Deputy Administrator & Chief Operating Officer
Centers for Medicare & Medicaid Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

Dear Administrator Oz and Deputy Administrator Brandt,

We are writing as a group of patient, healthcare professional, and industry organizations to request that CMS immediately issue clarifying guidance for the continuing use criteria for both home mechanical ventilators (HMV) and respiratory assist devices (RAD) for beneficiaries with chronic respiratory failure (CRF) consequent to chronic obstructive pulmonary disease (COPD). Medicare beneficiaries rely upon this respiratory equipment to remain in their homes and communities while receiving this life-sustaining therapy. Despite nearly a year of outreach and engagement with the CMS contractors and staff, there has been no clarification of these requirements. As a result, based on an informal survey of suppliers potentially more than 50 percent of beneficiaries relying on HMV and RAD devices will be required to end their therapy and return their devices, even if their physicians believe the devices remain medically necessary. We need CMS to act now to protect patients' access to these devices.

Several peer-reviewed studies using CMS data have demonstrated that patients diagnosed with CRF consequent to COPD who use a HMV fare better than patients who do not receive an HMV. The patients using the HMV therapy experience fewer emergency department visits, fewer hospitalizations, and lower mortality.[1] The most recent study found that beneficiaries who received HMV within the first week of a CRF consequent to COPD diagnosis have $2,182 lower monthly health care costs than beneficiaries with the same diagnoses who did not receive the device.[2] Adherence to NIV therapy is highly

[1] *See,* Frazier WD, Murphy R, van Eijndhoven E. Non-invasive ventilation at home improves survival and decreases healthcare utilization in Medicare beneficiaries with Chronic Obstructive Pulmonary Disease with chronic respiratory failure. Respir Med. 2021 Feb;177:106291. doi: 10.1016/j.rmed.2020.106291. Epub 2020 Dec 30. PMID: 33421940; Frazier WD, DaVanzo JE, Dobson A, Heath S, Mati K. Early Initiation of non-invasive ventilation at home improves survival and reduces healthcare costs in COPD patients with chronic hypercapnic respiratory failure: A retrospective cohort study. Respir Med. 2022 Aug-Sep;200:106920. doi: 10.1016/j.rmed.2022.106920. Epub 2022 Jun 30. PMID: 35834844.

[2] Dobson & DaVanzo. "Report Summary: Impact of Non-Invasive Ventilator at Home (NIVH billed under HCPCS E0466) on Select Outcomes for Medicare Fee-for-Service (FFS) Beneficiaries" *on file with the author* (April 2025).

dependent on appropriate clinical support, including respiratory therapist led patient education, device titration, and follow-up.

Our organizations worked together with CMS as it developed the National Coverage Determination (NCD) for non-invasive positive pressure therapy ventilation (NIPPV) for patients with CRF consequent to COPD. We supported the Administration's adoption of many of the recommendations that patient advocates, physicians, respiratory therapists, suppliers, and manufacturers had suggested in the final NCD. However, the continuing use criteria clarifications were not addressed at that time. While contractors have the authority to issue such clarifications, they have not done so. April 2026 is the month in which the first group of patients prescribed RAD and HMV devices under the NCD must demonstrate they meet the continuing use criteria.

The clarifications we request would support the Administration's intent to ensure that patients prescribed RADs and HMVs are using and benefiting from the devices in the medical opinion of their physician. Under the current NCD language, many patients narrowly miss the Medicare adherence requirement of greater than or equal to four hours per day on 70 percent of days within a single 30-day period. Current NCD policy does not directly speak to what happens if a patient shows usage but may have missed the rigid requirement or have valid clinical reasons for falling short of this threshold within a specific 30-day period.

In addition, some devices do not have a modem or the ability to track usage. While manufacturers continue to work to update device technology, as we predicted, not all devices could be updated within the NCD's timeframe.

When adherence is not met, the NCD does not allow patients to remain on the device. Physicians will be asked to write orders discontinuing therapy for patients not meeting usage requirements. However, if the physician believes that the patient is benefiting from the device, it is not appropriate, ethical, or consistent with their medical judgment to write the discontinuation order. At the same time, Medicare prohibits suppliers from continuing billing. Nor are suppliers permitted to leave the device in the home, as doing so would constitute providing non-covered services. This creates a no-win situation for patients, physicians, and suppliers.

While a longer-term solution, such as a multi-month rolling average similar to policies in other parts of the Medicare programs might be appropriate, beneficiaries, prescribers, and suppliers need clarity now - in April 2026 - to prevent beneficiaries being told they must return their devices. Specifically, we ask that CMS issue a clarification in writing that allows the prescriber of the RAD or HMV device to certify that the patient's continued use of the device is medically appropriate if the patient's actual usage in the 30-day period is less than the NCD requirement. Additionally, CMS should accept a statement

from the patient that they continue to use the device at least four hours a day when signed by the physician.

The second clarification we request relates to patient use of high-intensity settings for RAD Bi-level Pressure Capability, with Back-Up Rate Feature devices. It is currently unclear whether qualification for ongoing use requires documentation of sustained pressures greater than or equal to 15 cm H_2O during therapy or whether device settings configured to deliver pressures at or above this threshold are sufficient. We recommend that CMS clarify that the requirement is met if the device provided is programmed to deliver inspiratory pressures of 15 cmH_2O or higher, satisfying the high-intensity settings criteria.

While we understand that the contractors should be providing this guidance, they have had months to clarify the usage requirements and protect beneficiary access in these situations but have not done so. Therefore, we urge CMS to issue guidance that applies to all CMS audit contractors making these two clarifications before the end of April (and making them retroactive to April 1) so that patients who medically require these devices and benefit from them in the view of their physician can retain access to them.

Sincerely,

AAHomecare
American Association for Respiratory Therapists
The COPD Foundation
The Council for Quality Respiratory Care
The VGM Group

cc: Alec Aramanda
Kimberly Long
Connie Leonard
Daniel Schwartz