April 30, 2026

The Honorable Mehmet Oz, M.D., M.B.A.
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
7500 Security Blvd
Baltimore, MD 21244

The Honorable Kimberly Brandt, J.D., M.A.
Deputy Administrator & Chief Operating Officer
Centers for Medicare & Medicaid Services
Department of Health and Human Services
7500 Security Blvd
Baltimore, MD 21244

RE: National Coverage Determination (NCD) for Noninvasive Positive Pressure Ventilation in the Home for the Treatment of Chronic Respiratory Failure consequent to COPD (CAG-00465N)

Dear Administrator Oz and Deputy Administrator Brandt,

On behalf of the American College of Chest Physicians (CHEST), the American Academy of Sleep Medicine, and the American Association for Respiratory Care, we appreciate CMS's thoughtful and evidence-based approach in the final National Coverage Determination (NCD) for Noninvasive Positive Pressure Ventilation in the Home for the Treatment of Chronic Respiratory Failure consequent to COPD (CAG-00465N). CHEST remains supportive of CMS's efforts to ensure evidence-based access to noninvasive ventilation (NIV) for patients with COPD. As we have undertaken efforts to enhance implementation of the new guidance, our clinical experts have identified two areas of concern. We are writing to request CMS address these issues pertaining to the continuing usage criteria and high-intensity therapy as outlined in the NCD in order to decrease barriers to access and optimize patient tolerance and compliance.

Continuing Usage Criteria

We appreciate CMS's adoption of an adherence threshold of at least 4 hours per 24-hour period on at least 70% of days for continuing usage for a Respiratory Assist Device (RAD) or Home Mechanical Ventilator (HMV). The NCD requires this threshold to be achieved during a 30-day period in the 6 months leading up to the first evaluation, a criterion we agree with and support. However, the subsequent threshold requirement to achieve this level of usage in each paid rental month does not reflect real-world clinical practice. Patients with COPD often require extended time to acclimate to NIV therapy, particularly when higher pressures are used. For example, more than 25% of patients were unable to achieve 4 hours of usage within the first 12 months in the Murphy study, with a majority of these falling just short of the goal (Murphy et al, 2017). As noted in the NCD, current clinical practice guidelines recognize the clinical benefit of NIV for COPD patients even when not achieving this targeted adherence (Ergan et al, 2019). Additionally, adherence may vary over time due to various factors, such as acute exacerbations and intercurrent illness, despite overall clinical benefit from therapy. Requiring strict adherence in each individual month does not account for these expected variations and may

result in inappropriate loss of coverage for patients who are otherwise benefiting from treatment.

A more flexible approach would better support patient adherence over time and align with the realities of managing chronic respiratory disease. We urge CMS to consider a change to the adherence criterion, **using a representative 30-day period within a broader timeframe (e.g. 120 or 180 days) or through rolling or averaged adherence**, which would be consistent with established clinical practice and other CMS policies (e.g., LCD 33718). This modification would reduce unnecessary burden, improve implementation, and better ensure sustained access to NIV therapy for patients with COPD. Additionally, this model has been successfully implemented in other clinical settings, is familiar to clinicians and suppliers, and appropriately balances adherence expectations with real-world variability.

High-Intensity Therapy

We applaud the rationale and inclusion of high-intensity therapy being the goal by the end of the initial 6-month period of therapy. This reflects the scientific evidence and the need for patients to acclimatize to higher intensity settings with progressive adjustments (Kohnlein, et al 2014, Murphy, et al 2017, Coleman et al, 2019). However, some clarification is needed to ensure compliance with the criterion in real world situations. It is unclear whether this criterion would be met in certain situations where device settings are configured to deliver an inspiratory peak airway pressure (IPAP) of ≥15 cmH_2O during therapy or a range of pressures that include this target. For example, if a patient requires a volume assured pressure support mode, the range of pressures set might include an IPAP of ≥15 cmH_2O but it is unclear if this would be sufficient to maintain qualification. We believe the intent of NCD is meant to **require the device to be programmed to deliver a high-intensity therapy to include a goal of IPAP of ≥15 cmH_2O in the programmed range**, but this requires clarification to ensure patients receiving benefit from this therapy can continue to appropriately have access to it.

CHEST strongly supports CMS's goal of ensuring that NIV therapy is both clinically appropriate and beneficial to patients. We believe that our suggested changes will better align the policy with real-world clinical practice, reduce unintended barriers to care, and ultimately improve patient outcomes. We appreciate CMS's consideration of these comments and its ongoing commitment to patient-centered, evidence-based policy development. If you have any questions or would like to follow up, please contact Jonathan Iaccarino, MD, CHEST Senior Director, Science and Policy, at jiaccarino@chestnet.org.

Sincerely,

American College of Chest Physicians
American Academy of Sleep Medicine
American Association for Respiratory Care

References:

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Ergan, B, et al. European Respiratory Society guidelines on long-term home non-invasive ventilation for management of COPD. Eur Respir J. 2019 Sep;54(3):1901003.

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