

1150 18th Street, N.W. Suite 300
Washington, D.C. 20036
Phone: 202-296-9770 Fax: 202-296-9776
thoracic.org

Raed A. Dweik, MD, MBA, ATSF
President

Michelle Ng Gong, MD, MS, ATSF
President-elect

Irina Petrache, MD, ATSF
Immediate Past President

Jesse Roman, MD, ATSF
Secretary

Gregory Tino, MD, ATSF, FCCP, FACP
Treasurer

Karen J. Collishaw, MPP, CAE
Chief Executive Officer

*American Journal of Respiratory
and Critical Care Medicine*

*American Journal of Respiratory Cell and
Molecular Biology*

Annals of the American Thoracic Society

ATS Scholar

*ATS 2026
International Conference*

April 24, 2026

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

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.

Re: Implementation of NIV Coverage for COPD (CAG-00465N)

Dear Dr. Oz and Ms. Brandt,

On behalf of the American Thoracic Society (ATS), we appreciate CMS's efforts to expand access to noninvasive ventilation (NIV) for patients with chronic respiratory failure due to chronic obstructive pulmonary disease (COPD). We write to highlight important implementation considerations to ensure that coverage policies align with clinical realities and support sustained patient benefit.

As background, the American Thoracic Society is a medical professional society of over 20,000 physicians, scientist, nurses and respiratory therapists dedicated to the prevention, detection, treatment and cure of pulmonary disease, critical care illness and sleep disordered breathing. In short, we are lung experts. As lung experts, we offer the following comments regarding implementation of the recent NIV Coverage for COPD (CAG-00465N).

Our primary concern relates to the requirement that patients demonstrate use of ≥ 4 hours per night on $\geq 70\%$ of days, both during the initial 6-month period and as a monthly requirement during months 7–12. While adherence metrics can provide a useful framework during therapy initiation, strict application of these thresholds as binary determinants of coverage does not fully reflect the clinical course of COPD.

During the initial 6 months, patients often require variable periods of acclimation as therapy is titrated and tolerance

evolves. Early adherence does not reliably predict long-term use or clinical benefit. Rigid interpretation of these thresholds—even in the early phase—may lead to premature classification of patients as non-adherent despite ongoing clinical engagement and potential for benefit. These observations are supported by clinical trial data demonstrating that meaningful clinical benefit may occur even when strict adherence thresholds are not consistently met.

These concerns are more pronounced in the maintenance phase (months 7–12), where requiring adherence thresholds to be met in each individual month is particularly misaligned with the fluctuating nature of COPD. Patients frequently experience exacerbations, hospitalizations, and intercurrent illnesses, as well as non-medical life events such as loss of electricity from a weather event, sleeplessness from having to provide care to a family member, or acute grief from death of a spouse that may temporarily disrupt use but do not indicate treatment failure. A single month of sub-threshold usage should not result in loss of access to therapy, which remains clinically beneficial.

Emerging data further underscore that early or intermittent non-adherence does not reliably predict long-term outcomes, and that many patients continue to use and benefit from NIV over time despite not consistently meeting rigid thresholds.

We respectfully recommend that CMS consider a more flexible, longitudinal approach to adherence assessment, including:

- Evaluating adherence over broader time windows (e.g., rolling or averaged periods), rather than individual months
- Allowing continued coverage when there is documented clinical benefit or ongoing physician-directed management.

These modifications would better align policy with the realities of COPD care while preserving CMS's goals of ensuring appropriate and effective therapy.

We appreciate CMS's commitment to patient-centered, evidence-based policy and would welcome the opportunity to further discuss these considerations.

Sincerely,



Neomi Shah, MD, MPH, MSc, ATSF
Chair, Sleep and Respiratory Neurobiology (SRN) Assembly
American Thoracic Society

Raed Dweik

Raed A. Dweik MD, MBA, ATSF
President
American Thoracic Society

References

- Murphy PB, Rehal S, Arbane G, et al. *Effect of Home Noninvasive Ventilation With Oxygen Therapy vs Oxygen Therapy Alone on Hospital Readmission or Death After an Acute COPD Exacerbation*. JAMA. 2017;317(21):2177–2186.
- Köhnlein T, Windisch W, Köhler D, et al. *Non-invasive positive pressure ventilation for the treatment of severe stable chronic obstructive pulmonary disease: a prospective, multicentre, randomised controlled trial*. Lancet Respir Med. 2014;2(9):698–705.
- Ergan B, Oczkowski S, Rochweg B, et al. *European Respiratory Society guidelines on long-term home non-invasive ventilation for management of COPD*. Eur Respir J. 2019;54(3):1901003.
- Coleman JM, et al. *Noninvasive Ventilation in Chronic Obstructive Pulmonary Disease*. Ann Am Thorac Soc. 2019;16(9):1091–1098.