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April 9, 2025

Kimberly Long
Lead Analyst
Center for Coverage and Analysis
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

Re: Noninvasive Positive Pressure Ventilation (NIPPV) in the Home for the Treatment of Chronic Respiratory Failure consequent to COPD (Tracking Number: CAG-00465N)

Dear Ms. Long,

On behalf of the American College of Chest Physicians (CHEST), we appreciate the opportunity to comment on the Centers for Medicare and Medicaid Services (CMS) proposed decision memo for "Noninvasive Positive Pressure Ventilation in the Home for the Treatment of Chronic Respiratory Failure consequent to COPD (CAG-00465N)."

CHEST supported this reconsideration request, and we would like to thank CMS for the efforts that have contributed to this national coverage analysis and the opportunity to advance evidence-based treatment. CHEST applauds CMS for developing essential improvements that will lead to optimized outcomes in the management of COPD.

CHEST would request CMS to consider the following that we feel are critical to ensuring patient access and optimizing outcomes:

Initial Coverage Criteria

High intensity mode requirement – The recommendation for high intensity ventilation in the Canadian Thoracic Society Guidelines is a conditional recommendation with low certainty evidence. A conditional recommendation indicates there is uncertainty in the benefits and that different patients may require varying approaches. As noted in the guidelines, there is no clear definition of "high intensity" ventilation. Patients often need time to acclimatize to higher intensity settings with progressive adjustments, as was seen in the studies cited in the decision memo.[1,2] A requirement to initiate patients at these high intensity settings will negatively impact patient tolerance and compliance with the device. We would suggest eliminating this requirement for initiating a RAD and to instead consider it a possible goal of therapy. While we do not feel specific settings should be specified, if this is necessary, we would suggest a goal IPAP = 18 cmH2O with a backup rate of 14 based on the cited 2014 meta-analysis.[3]

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[1] Coleman JM, et al. Noninvasive Ventilation in Chronic Obstructive Pulmonary Disease. Ann Am Thorac Soc. 2019 Sep;16(9):1091-1098.

[2] Köhnlein T, et al. Non-invasive positive pressure ventilation for the treatment of severe stable chronic obstructive pulmonary disease: a prospective, multicentre, randomised, controlled clinical trial. Lancet Respir Med. 2014 Sep;2(9):698-705.

Continuing Usage Criteria

Consistent use – We suggest consistent use in the continuing usage criteria for a RAD or HMV be defined as use of the device for an average of at least 4 hours per day on 70% of days within a 30-day period. Requiring 5 hours of usage every night for patients will be overly burdensome and is impractical. Patients may not have 100% daily usage for various reasons including acute illness or hospitalization. For example, more than 25% of patients had less than 4 hours of nightly usage at 6 and 12 months in the Murphy study.[4] We believe a criterion of 4 hours per day on 70% of days within a 30-day period will streamline implementation given it is a logical extension of current practice.

Re-evaluation for RAD – While we agree with the recommendation for re-evaluation by day 180, we feel that requiring subsequent evaluation every 6 months thereafter is overly burdensome to patients and would worsen patient access to evidence based care. There does not appear to be any citable evidence to support the need for re-evaluation every 6 months beyond the initial 180 days. We would propose eliminating the need for an evaluation every 6 months. If it is necessary to specify a time interval for re-evaluation, we would propose every 12 months as a more reasonable alternative.

Additionally, we urge CMS to consider the following comments to further strengthen and align the proposed decision memo with evidence-based treatment to improve patient outcomes and reduce barriers to implementation:

Sleep apnea – We suggest a change in the language of the criteria regarding sleep apnea, as an extension of current practice based on the current LCD: "Prior to initiating therapy, sleep apnea and treatment with a continuous positive airway 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 (OSA, CSA, and/or CompSA) as the predominant cause of awake hypercapnia or nocturnal arterial oxygen desaturation)."

Stable COPD – We suggest a change in how stable COPD is defined. Requiring a 4-week period without change in pharmacologic management will be burdensome to the patient and could delay evidence-based care. Patients requiring a RAD for chronic respiratory failure in COPD might require more frequent changes to their medication regimen to achieve better symptom control. We feel that a 2-week period without a change in pharmacologic management is more reflective of clinical practice and will be less burdensome to patients.

CHEST is confident that the adoption of these comments will advance evidence-based treatment and optimize outcomes in the management of COPD. We thank CMS for taking CHEST's comments into consideration.

Sincerely,

John Howington, MD, MBA, FCCP
CHEST President

Robert Musacchio, PhD
Chief Executive Officer/Executive Vice President

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[3] Struik FM, et al Nocturnal noninvasive positive pressure ventilation in stable COPD: a systematic review and individual patient data meta-analysis. Respir Med. 2014 Feb;108(2):329-37.

[4] Murphy PB, et al. Effect of Home Noninvasive Ventilation With Oxygen Therapy vs Oxygen Therapy Alone on Hospital Readmission or Death After an Acute COPD Exacerbation: A Randomized Clinical Trial. JAMA. 2017 Jun 6;317(21):2177-2186.