

October 11, 2023

To champion the prevention,
diagnosis, and treatment of chest
diseases through education,
communication, and research.

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Susan Miller, M.D.
Medical Officer
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 Dr. Miller,

The American College of Chest Physicians (CHEST) appreciates the opportunity to comment on the Centers for Medicare and Medicaid Services (CMS) national coverage analysis (NCA) for Noninvasive Positive Pressure Ventilation in the Home for the Treatment of Chronic Respiratory Failure consequent to COPD (CAG-00465N). CHEST is a professional medical society representing 22,000 pulmonologists, critical care, and sleep medicine clinicians that seeks to advance the best health outcomes for patients with lung disease through education, advocacy, research, and philanthropy. A key aspect of advancing best health outcomes requires ensuring that our members have confidence that the therapies and interventions they prescribe will be appropriately accessible to their patients without challenge.

It is for this reason that CHEST was a signatory on the September 2021 reconsideration request, which derived its recommendations from the CHEST-convened Technical Expert Panel Report on Optimal NIV Medicare Access Promotion.¹ We thank CMS for initiating this national coverage analysis (NCA) in an opportunity to improve patient access to evidence-based treatment, improve health equity, and optimize outcomes in the management of Chronic Obstructive Pulmonary Disease (COPD).

CHEST would request CMS to consider the following comments with regards to this national coverage analysis:

¹ Gay PC, Owens RL; ONMAP Technical Expert Panel. Executive Summary: Optimal NIV Medicare Access Promotion: A Technical Expert Panel Report From the American College of Chest Physicians, the American Association for Respiratory Care, the American Academy of Sleep Medicine, and the American Thoracic Society. *Chest*. 2021 Nov;160(5):1808-1821. doi: 10.1016/j.chest.2021.05.074. Epub 2021 Jul 30. PMID: 34339685

1 - Health Equity: The current national coverage determination (NCD) for noninvasive ventilation (NIV) in COPD requires overnight oximetry saturation \leq 88% for > 5 minutes with a minimum of nocturnal recording on 2 L/min of supplemental oxygen or the patient's prescribed level, whichever is higher. This requirement has no medical basis and is not physiologically sound - patients with COPD have persistent hypercapnic respiratory failure with or without supplemental oxygen to treat hypoxemia.

Additionally, recent evidence² has shown clear bias in the measurement of oxygen levels with pulse oximetry, overestimating oxygen saturation in patients with darker skin. Including hypoxemia as measured by pulse oximetry as a criterion for NIV for COPD would only serve to exacerbate further inequities in COPD management. Furthermore, many COPD patients that could benefit from NIV may not have access to some of the tests required in the current NCD (e.g., polysomnography, sleep oximetry). We strongly urge CMS to remove the overnight oximetry criterion to prevent further exacerbating disparities in patient care.

2- Interrelation of Devices: As highlighted in the COPD article in the broader report,³ strongly encourage CMS to consider a comprehensive policy that that ensures patient access to the correct device in a timely manner. Patients with chronic respiratory failure consequent to COPD should be considered for a bilevel positive airway pressure (BPAP) device with backup rate or home mechanical ventilator. There should be no requirement to first trial a BPAP device without a backup rate, as the studies showing benefit of NIV in these patients used BPAP devices with a backup rate. BPAP devices without a backup rate may not provide the necessary ventilatory support to treat the hypercapnic respiratory failure in these patients. Furthermore, patients with severe COPD that require a home mechanical ventilator should have access to these directly without having to first trial devices already known to be incapable of providing the support needed to treat their level of respiratory failure.

3- Pathway: We are aware that DME MACs is currently reviewing the LCDs for respiratory assist devices (RADS) and would encourage CMS to develop a comprehensive policy that ensures patient access to the most effective device based on their individual needs and requirements. The path forward needs to reconsider the system as a whole, integrating the RAD program with the HMV program so there is a more cohesive plan that ensures patients have access to

² Jamali H, Castillo LT, Morgan CC, et al. Racial Disparity in Oxygen Saturation Measurements by Pulse Oximetry: Evidence and Implications. *Ann Am Thorac Soc.* Dec 2022;19(12):1951-1964. doi:10.1513/AnnalsATS.202203-270CME

³ Hill NS, Criner GJ, Branson RD, Celli BR, MacIntyre NR, Sergew A; ONMAP Technical Expert Panel. Optimal NIV Medicare Access Promotion: Patients With COPD: A Technical Expert Panel Report From the American College of Chest Physicians, the American Association for Respiratory Care, the American Academy of Sleep Medicine, and the American Thoracic Society. *Chest.* 2021 Nov;160(5):e389-e397. doi: 10.1016/j.chest.2021.06.082. Epub 2021 Jul 30. PMID: 34339684

the type of device that will optimize their outcomes. We are concerned that changing the E0466 criteria without updating the current RAD criteria could cause catastrophic inequities and access limitations for the most vulnerable patient populations.

In closing, we thank CMS for responding to the reconsideration request and for working with the community to create a pathway to treatment of chronic respiratory failure consequent to COPD that takes easing current barriers as its goal. At the same time, as acknowledged in the 2021 publication "Executive Summary Optimal NIV Medicare Access Promotion: A Technical Expert Panel Report From the American College of Chest Physicians, the American Association for Respiratory Care, the American Academy of Sleep Medicine, and the American Thoracic Society,"¹ the coverage of NIV for people suffering from other diseases, including thoracic restrictive diseases, hypoventilation syndromes, central sleep apnea, and obstructive sleep apnea remains equally burdensome. CHEST looks forward to collaborating with CMS to ensure the appropriate provision of physician-prescribed devices to all populations who benefit.

Sincerely,

Jack D. Buckley, MD, MPH, FCCP
CHEST President

Robert Musacchio, PhD
Chief Executive Officer/Executive Vice President