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Submitted via: [Public Comment Online Portal](https://www.cms.gov/medicare-coverage-database/view/national-submit-public-comment.aspx?DocID=315&commentDocType=nca&fromPage=tracking&)

Re: Noninvasive Positive Pressure Ventilation (NIPPV) in the Home for Treatment of Chronic Respiratory Failure Consequent to COPD

Dear Ms. Long and Dr. Miller,

On behalf of the [American Association for Respiratory Care](https://www.aarc.org/) (AARC), thank you for accepting our comments on the proposed decision memo for Noninvasive Positive Pressure Ventilation (NIPPV) in the Home for the Treatment of Chronic Respiratory Failure (CRF) consequent to Chronic Obstructive Pulmonary Disease (COPD). As one of the organizations that submitted the formal [request](https://www.cms.gov/files/document/id315.pdf) to amend §280.1 of the National Coverage Determinations (NCD) Manual, (Pub. 100-03, Part 4, Chapter 1) regarding coverage of positive and negative pressure ventilators as part of the Durable Medical Equipment (DME) Reference List, we appreciate the agency opening the review of both positive and negative pressure ventilators for the treatment of chronic respiratory failure (CRF) consequent to COPD as an equipment category that is covered under the DME benefit.

The AARC is a national professional organization with a membership of over 44,000 respiratory therapists who treat patients with acute and chronic respiratory diseases such as chronic obstructive pulmonary disease (COPD) and asthma. Through our advocacy, we support more than 125,000 practicing respiratory therapists across the country.

Respiratory therapists are an integral part of the healthcare system, providing care for patients with a myriad of pulmonary diseases, including chronic obstructive pulmonary disease (COPD), asthma, bronchitis, emphysema, cystic fibrosis, and acute respiratory distress syndrome. Our members also provide therapy for patients suffering from neuromuscular diseases, including Parkinson’s disease, amyotrophic lateral sclerosis, and sleep apnea. Finally, respiratory therapists provide care for patients suffering from trauma and provide support for premature infants. Respiratory therapists treat patients of all ages, and they use their training in pulmonary medicine to provide therapeutic care to patients suffering from pulmonary disease and other conditions that impair breathing.

The AARC thanks the agency for adopting many of the recommendations outlined in our [national coverage analysis comment letter](https://www.cms.gov/medicare-coverage-database/view/ncacal-public-comments.aspx?ncaId=315&fromTracking=Y&). Additionally, the goal of the original [NCD revision request](https://www.cms.gov/files/document/id315.pdf) submitted on September 9, 2021 was to enhance access to noninvasive ventilators for patients with chronic respiratory failure due to COPD and other conditions, ensuring Medicare beneficiaries receive optimal care, and we believe that this proposed decision memo achieves that goal. The final details of the proposed decision memo are particularly important to ensure access to respiratory care by respiratory therapists by addressing the clinical needs of patients suffering from respiratory failure. We are extremely thankful to the agency for developing an NCD that meets the needs of the patients that our members treat.

Throughout this process, the AARC has continually supported the use of arterial blood gas measurement as a criterion in determining the need for an NIPPV and eliminating the requirement for nocturnal oximetry tests. We are pleased to see that CMS has adopted the use of arterial blood gas measurement of PaCO₂ ≥ 52 mm Hg as a primary clinical criterion for coverage.

Additionally, it has been our position to use bi-level positive airway pressure (BPAP) device with backup rate as the starting respiratory therapy rather than BPAP without backup. Non-invasive ventilation with a backup rate significantly reduces mortality and hospitalizations in patients with chronic hypercapnic respiratory failure from COPD. The proposed decision memo supports this position by recommending the use of BPAP-ST (spontaneous/timed) and volume-assured pressure support options. We are also pleased to see that the agency believes that device selection should be based on the patient’s specific condition (COPD, thoracic restrictive disease, etc.) and supported by clinical evidence.

We strongly urge CMS to include a grandfather clause for existing Medicare beneficiaries already using Respiratory Assist Devices (RADs) or Home Mechanical Ventilators (HMVs). Forcing these patients to requalify under newly established criteria could disrupt continuity of care and lead to unnecessary hardship. A clear transition policy will preserve therapeutic gains already achieved and maintain patient safety.

We are concerned that the proposed 5-hour nightly usage requirement places an undue burden on patients, physicians, and suppliers. This exceeds current adherence expectations for other respiratory therapies (e.g., 4 hours/night for CPAP) and may create unnecessary barriers to coverage. We recommend aligning the requirement with standard clinical practice: **4 hours per day on at least 70% of days in a 30-day period**, which strikes a balance between patient capability and therapeutic efficacy. This more practical threshold has precedent and reflects realistic patient behavior.

Finally, AARC continues to support the coverage of a second 90-day adherence trial period and are disappointed that CMS did not include this in the proposed decision memo. The coverage of a second 90-day adherence trial period would provide patients more time to demonstrate adherence and clinical improvement. Some Medicare patients may need a longer period to reach conventional adherence definitions, and coverage of a second 90-day period may be essential to reaching the required levels of adherence and more importantly to show clinical improvement. We ask that the agency reconsider and revise the decision memo to include coverage for a second 90-day trial period.

The AARC thanks the CMS for its work on the revision to NCD, and we support the agency in these efforts, and thank you for the continued collaboration. If you have questions or would like to meet to discuss our comments, please contact Miriam O’Day, Senior Vice President of Government Affairs, AARC (Miriam.oday@aarc.org).

Sincerely,