



June 22, 2020

Ms. Tara Hall
Coordinator, Medicare Evidence Development and Coverage Advisory Committee
Office of Clinical Standards and Quality
Centers for Medicare and Medicaid Services
Mail Stop: 3-02-01
7500 Security Boulevard
Baltimore, MD 21244

Re: MEDCAC on Noninvasive Positive Pressure Ventilation in Patients with Chronic Respiratory Failure (CRF) Consequent to Chronic Obstructive Pulmonary Disease (COPD)

MEDCAC members,

Thank you for the opportunity to respond to the Centers for Medicare and Medicaid Services' request for comments on the upcoming MEDCAC meeting on Noninvasive Positive Pressure Ventilation in Patients with Chronic Respiratory Failure (CRF) Consequent to Chronic Obstructive Pulmonary Disease (COPD). Hillrom appreciates the CMS' willingness to conduct the MEDCAC meeting to gather input from the clinical community and DME industry on this important topic.

Hill-Rom is a leading worldwide manufacturer and provider of medical technologies and related services for the health care industry. Headquartered in Chicago, Illinois, Hill-Rom is the industry leader in patient support system, respiratory devices, consumable surgical products, surgical positioning systems, patient lifts and medical equipment management services. Hillrom's Respiratory Health division manufactures and supplies patients with Non-Invasive Ventilators (NIV), High Frequency Chest Wall Oscillation (HFCWO) Devices and Mechanical In-Exsufflation (MIE) devices. Hill-Rom draws on a heritage of more than 85 years of innovation and excellence to provide solutions enhancing the lives of our patients and their care givers.

Hillrom supports CMS in the development of clear policies regarding coverage for ventilators for the Chronic Respiratory Failure (CRF) Consequent to Chronic Obstructive Pulmonary Disease (COPD) patients. In development of any new policies, Hillrom would also ask CMS to ensure prescribers maintain flexibility to select the device best suited for the patient's long-term needs, given the complexity of this patient population.

Patient Selection / Clinical Indications

Patients with Chronic Respiratory Failure consequent to COPD suffer from a disruption of the normal process in the lungs to exchange oxygen and carbon dioxide. As a result, an adequate amount of oxygen cannot reach the patient's brain, heart and other parts of the body. According to the GOLD standards¹, patients with CRF consequent to COPD typically have lung function less than 50% of normal and are considered Stage IV COPD patients. This condition is

categorized by the patient being short of breath or “breathless”, however the underlying cause of the condition can vary from patient to patient. These patients are medically fragile and require a significant amount of clinical treatment and on-going support to help manage their chronic condition in the home. Therefore, it is critical to determine the most appropriate treatment and therapies to improve the patient's outcomes and quality of life.

Non-Invasive ventilators (NIV) are designed to both oxygenate the patient and remove carbon dioxide from the patient's lungs. NIV devices support patients with or without the ability to spontaneously breathe.

Hillrom appreciates CMS and the MEDCAC allowing the clinical community to provide feedback on the application of noninvasive positive pressure ventilation devices to best determine coverage for this patient population. While the Technology Assessment by AHRQ referenced by CMS in the MEDCAC session announcement is a metanalysis of available clinical data related to the use of Noninvasive Positive Pressure Ventilation devices for patients with CRF consequent to COPD, Hillrom notes there are other important clinical & health economics studies that may be impactful to the analysis, including, but not limited to:

1. Coughlin, et al. Retrospective Assessment of Home Ventilation to Reduce Rehospitalization in Chronic Obstructive Pulmonary Disease. Journal of Clinical Sleep Medicine, Vol. 11, No. 6, 2015

This retrospective study of a quality improvement initiative involved 397 COPD patients who had experienced two or more hospitalizations in the prior year. Patients were placed on advanced modality, life-support, NIPPV therapy (non-invasive positive pressure ventilation), and followed up in the home by regular RT-led respiratory care visits over the course of one year.

At the conclusion of the study, the number of COPD patients who experienced two or more hospitalizations had decreased from 100% (397 out of 397) in the year prior to 2.2% (9 out of 397) in the year following initiation of therapy.

2. Coughlin, et al. Cost Savings from Reduced Hospitalizations with Use of Home Noninvasive Ventilation for COPD. Value in Health 20 (2017) 379 - 387

An economic model was developed to calculate savings associated with the use of Advanced NIV versus either no NIV or a respiratory assist device with bilevel pressure capacity in patients with severe COPD from two distinct perspectives: the hospital and the payer. The model examined hospital savings over 90 days and payer savings over 3 years.

Results:

- The hospital base case (250 patients) revealed cumulative savings of \$402,981 and \$449,101 over 30 and 90 days, respectively, for Advanced NIV versus both comparators.
- For the payer base case (100,000 patients), 3-year cumulative savings with Advanced NIV were \$326 million versus no NIV and \$1.04 billion versus respiratory assist device.

Conclusions: This model concluded that adoption of home Advanced NIV, as part of a multifaceted intervention program, presents an opportunity for hospitals to reduce COPD readmission-related costs and for payers to reduce costs associated with managing patients with severe COPD on the basis of reduced admissions.

Additionally, the analysis performed by AHRQ did not account for the analysis performed by Global Strategy for the Diagnosis, Management and Prevention of Chronic Obstructive Pulmonary Disease, as published in the 2020 report.

While we understand there may be conflicting clinical results for the various Noninvasive Positive Pressure Ventilation devices covered in this MEDCAC session, Hillrom urges CMS and the MEDCAC to evaluate all Clinical and Health Economic data available prior to making any coverage decisions for this complex patient population.

Based on our extensive review of clinical research, interactions with prescribers of NIV and our experience providing NIV devices to patients with Chronic Respiratory Failure consequent to COPD, Hillrom believes the patients who would benefit from NIV devices could be identified by either a PaCO₂ ≥ 50 and/or FEV1 < 50% of predicted.

Currently, CMS covers Non-Invasive ventilators for two additional patient indications, other than Chronic Respiratory Failure consequent to COPD: Neuromuscular Disease and Restrictive Thoracic Diseases. Should CMS consider changes in ventilator coverage for these two clinical indications, Hillrom would encourage CMS to engage in similar outreach to the clinical community, manufacturers and DME providers for input prior to finalizing any potential coverage changes.

Usage Requirements

Non-Invasive ventilators not only support Chronic Respiratory Failure consequent to COPD patients during night-time use, but are critical to these patients for day-time use. Given a primary symptom for this condition is shortness of breath, having a device to support the patients during the day and particularly during times of activity is important to the patient's clinical outcomes.

Clinical data has demonstrated the importance of mobility to the outcomes of COPD patients, including the following:

- Activity for two hours/week reduces hospital admissions & respiratory mortality by 30% – 40%²
- Outdoor activity increases four-year survival 35% vs 15% for oxygen-dependent patients³
- For every 0.14 decrease in physical activity level (PAL), the relative risk of death is more than doubled⁴
- For every 1,000 daily steps increase at low-average intensity, COPD hospitalization risk decreases by 20%⁵



For patients requiring support of a Non-Invasive Ventilator, daytime use (particularly during periods of activity) has been found to be as important as overall total hours of use.

Device Parameters

CMS has indicated they are interested in gathering feedback on device parameters, as well. Specific to Ventilators, Hillrom would encourage CMS to refer to the internationally recognized ISO standards for Home Ventilators, ISO 80601-2-72. This ISO standard has very specific requirements for basic safety and the essential performance of home healthcare environment ventilators for ventilator-dependent patients. The FDA recognizes devices that meet this ISO standard with a product classification of "NOU".

Lastly, as a provider of highly specialized Respiratory DME devices, Hill-Rom is concerned about the timing of the MEDCAC meeting and the limited time allowed for response for the following reasons:

1. CMS announced the meeting on June 11th with a response due on June 22nd. Given the very complex nature of the CRF / COPD clinical condition, as well as the inclusion of multiple devices (NIV, BiPAP and CPAP), this short timeframe for response does not adequately allow for a thorough analysis of all the clinical data available.
2. Most importantly, given the country is currently in the midst of the COVID19 pandemic, Hillrom is concerned pulmonologists and other clinical experts, will not be able to adequately respond to the requests for participation (either via written response or during the July 22nd session) as they are currently focused on treating a significant number of COVID19 patients and identifying the best treatment protocols for the virus.

Hillrom supports efforts CMS may undertake to better clarify coverage, usage and documentation requirements for ventilators for this patient population, while maintaining flexibility for prescribers to select the device best suited for the patient's long-term needs.

Hill-Rom appreciates the opportunity to comment and respectfully requests that CMS delay the MEDCAC meeting to allow appropriate time for a thorough analysis and response from the Clinical community. Should you require any additional information or have questions regarding our position, please contact me at 800-426-4224.

Sincerely,

A handwritten signature in black ink that reads 'Andy Reding'. The signature is written in a cursive, flowing style.

Andy Reding
Vice President and General Manager of Hill-Rom Respiratory Care



References

1. Global Strategy for the Diagnosis, Management and Prevention of Chronic Obstructive Pulmonary Disease, 2020
2. Garcia-Aymerich J, Lange P, Benet M, et al. *Thorax*. 2006 Sep; 61(9): 772–778.
3. Ringbaek TJ, Lage P. *Clin Rehabil*. 2005 May;19(3):331-8.
4. Waschki B, Kristen A, Holz O, et al. August 2011. Volume 140, Issue 2, Pages 331–342
5. Donaire-Gonzalez D, Gimeno-Santos E, Balcells E, et al. *European Respiratory Journal* 2015 46: 1281-1289