

June 22, 2020

The Honorable Alex M. Azar
Secretary
Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

The Honorable Seema Verma
Administrator
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

Re: Virtual Meeting of the Medicare Evidence Development and Coverage Advisory Committee—July 22, 2020

Dear Secretary Azar and Administrator Verma:

On behalf of the Council for Quality Respiratory Care (CQRC), I want to thank you for providing the opportunity to share comments related to the Medicare Evidence Development & Coverage Advisory Committee (MEDCAC/Committee) meeting about the home use of noninvasive positive pressure ventilation (NIV) in patients with chronic respiratory failure (CRF) consequent to chronic obstructive pulmonary disease (COPD).¹

The CQRC is a coalition of the nation's seven leading home oxygen and sleep therapy providers and manufacturing companies. Together we provide in-home patient services and respiratory equipment to more than 600,000 of the more than one million Medicare patients who rely upon home oxygen therapy to maintain their independence and enhance their quality of life. Similarly, we provide homecare services, equipment and supplies to more than one million Medicare patients with Obstructive Sleep Apnea (OSA).

The CQRC wants to thank CMS again for removing non-invasive positive pressure ventilation (NIV) from the Competitive Bidding Program (CBP) Round 2021. As CMS recognizes, removing NIV from the CBP means that any Medicare-enrolled supplier can furnish NIV. If NIV had been left in the CBP, the number of suppliers who could furnish this life-saving, life-sustaining equipment, by definition, would be limited to winning bidders. The number of suppliers selected would be based on a projected utilization (capacity) amount that CMS and its contractors made nearly a year ago, before anyone anticipated the pandemic and the increased need for home NIV therapy.

The CQRC also appreciates the interest in identifying characteristics to define patient selection and usage criteria, concomitant services, and equipment parameters necessary to best achieve positive patient health outcomes in patients with CRF consequent to COPD who use NIV. It is important that CMS coverage and reimbursement policies ensure that the right patients receive the right treatment at the right time. In this letter, we

¹CMS, "Medicare Program; Virtual Meeting of the Medicare Evidence Development and Coverage Advisory Committee—July 22, 2020" 85 *Fed. Reg.* 35933 (June 12, 2020).

offer a few overarching suggestions about how to protect access to this therapy for the patients who truly need it, while simultaneously protecting the integrity of the Medicare program. Specifically, we ask that MEDCAC consider including in its recommendations the following points.

- **Any coverage requirements should be clear and objective to allow for straight-forward documentation requirements supporting claims.** For example, with regard to NIV, we suggest using objective clinical criteria, such as the diagnosis of a specific condition (*e.g.*, hypercapnia, COPD, CRF caused by pulmonary fibrosis, thoracic restrictive diseases (such as kyphoscoliosis), neuromuscular diseases (NMD), and obesity hypoventilation), specific levels of PaCO₂, or specific FEV1 levels. While clinical judgement is essential to prescribing any home medical equipment, criteria that are subjective often result in confusion for prescribers, as well as increased audits and denials that can threaten access to the therapies. For example, the CMS 2019 CERT Report indicates that the improper payment rate for oxygen caused by insufficient prescriber documentation was 79.8 percent, but only 0.6 percent of the claims were denied because of a lack of medical necessity. We urge MEDCAC not to make recommendations that would create a problem like this for patients who require NIV therapy.
- **Based on the Agency for Healthcare Research and Quality (AHRQ) Technical Assessment, the CQRC suggests that MEDCAC recommend that CMS convene a Technical Expert Panel (TEP)** to identify the specific criteria that could be used to revise the existing National Coverage Determination and/or create Local Coverage Determinations, if CMS were to select such pathways. It should be representative of the home respiratory community, including patients and caregivers; clinical experts (including pulmonologists, nurses, respiratory therapists, other clinicians, and researchers); suppliers; manufacturers; and experts in reimbursement and medical necessity documentation requirements. The TEP would allow CMS to engage directly with experts to develop consensus around the characteristics that define patient selection and usage criteria, concomitant services, and equipment parameters to best achieve positive patient outcomes, particularly with regard to the chronic respiratory failure (CRF) indication. (Please see section I below as well). For example, it will be important to ensure that the experts in both the clinical and billing areas can provide recommendations about defining specific patient criteria.²

²For example, from a documentation perspective, including “acute” chronic respiratory failure as a covered condition would recognize that admitting medical records include “Acute Respiratory Failure” in the records because the inpatient setting is treating an acute exacerbation of the chronic respiratory failure condition. Contractors reviewing such records are likely to deny the coverage by focusing on the acute condition that

- **We also suggest that MEDCAC and CMS consider CPAP and BPAP (i.e., the respiratory assist devices (RAD) policy) along with NIV.** A review of the coverage criteria for these devices as well could provide needed clarity to this area by establishing objective clinical criteria and eliminating the requirement for patients to use the device for a specified length or amount of time (related to CPAP or BPAP)³ to protect patient access to these devices. Examining the NIV criteria along with the RAD policy would allow for a more complete discussion that recognizes the interaction that could occur once the policies are implemented. It is equally important that such a review not create a “tried and failed” approach before Medicare will cover a patient’s NIV.
- **Finally, we encourage MEDCAC to avoid any recommendations that would result in time-based criteria.** We recognize in the past that some stakeholders have suggested length or frequency of usage as a criterion. The clinical literature does not support a “usage” criterion and adopting an “average” usage requirement does not reflect a patient-centered approach to care. Putting an arbitrary usage hurdle in place for NIV could reduce utilization, but also could increase patient mortality. For example, the difference between CPAP being paid for or not by Medicare is literally two minutes per day. If a patient averages 3 hours and 59 minutes of use per day, Medicare will not pay for the CPAP after 90 days; however, if a patient averages 4 hours and 1 minute of use per day Medicare will cover the CPAP. In 2015, CMS was right to abandon a time-based approach for NIV. We believe that by abandoning a time-based criteria, CMS avoided premature termination of NIV for patients with chronic and progressive diseases, thus improving and prolonging their lives, as well as reducing costly hospital admissions. Relying upon time-based criteria would place patients’ access at risk.

In addition, we offer the following comments on the four questions outlined in the *Federal Register*.

relates directly to the underlying chronic one. Excluding the “acute” language would result in patient access problems that could be addressed prospectively through appropriately defining the coverage criteria.

³ As opposed to RAD devices, there are no usage or minimum usage requirements for NIV devices.

I. Questions 1 and 4:

How confident are you that the evidence is sufficient to determine the patient selection criteria that will improve health outcomes when used with any category of home NIPPV device?

How confident are you that the evidence is sufficient to provide the patient usage parameters that are necessary to achieve the successful patient outcomes in Q2?

The CQRC members are suppliers and manufacturers, so we do not believe it is appropriate for the organization to opine on the specific clinical selection criteria. However, as evidenced by the Technical Assessment published by the AHRQ⁴ and the “European Respiratory Society Guideline on Long- term Home Non-Invasive Ventilation for Management of Chronic Obstructive Pulmonary Disease,”⁵ the benefits of NIV are persuasive and clear in most instances, but the clinical criteria for defining objectively which patients will benefit most from the therapy suggest additional evaluation is necessary.⁶ The AHRQ wrote:

Currently, substantial variability exists regarding the usage, prescribing patterns, policies, and guidelines for noninvasive HMs, BPAPs, and CPAPs. While a number of guidelines address home use of BPAPs and HMs, there is marked variability in the conclusions, recommendations, and evidence basis for these guidelines. With current practice guideline variability, there is a clear need to synthesize the best available evidence to guide prescribing.⁷

The European Guidelines suggest similar variability:

Due to limitations in the certainty of the available evidence, all four PICO recommendations are weak/conditional, and therefore require consideration of individual preferences, resource considerations, technical expertise, and clinical circumstances prior to implementation in clinical practice. While we have tried to consider a wide spectrum of such factors when making recommendations, we cannot account for all conditions. For each recommendation, we discuss evidence limitations, issues when moving from evidence to recommendations, and implementation concerns. By reading these guidelines, and considering their applicability to their current situation, we hope these ERS guidelines will help patients, clinicians, policy

⁴AHRQ, “Noninvasive Positive Pressure Ventilation in the Home Technical Assessment” (Feb. 4, 2020).

⁵Ergan B, Oczkowski S, Rochweg B, *et al.* European Respiratory Society Guideline on Long-term Home Non-Invasive Ventilation for Management of Chronic Obstructive Pulmonary Disease. *Eur Respir J* 2019; in press (<https://doi.org/10.1183/13993003.01003-2019>).

⁶See, *e.g.*, AHRQ *supra* note 4 at ix; European Guidelines *supra* note 5 at 9 and 12.

⁷AHRQ *supra* note 4 at ES-1.

makers, and other health-care stakeholders to make rational, evidence-based, decisions with regard to the use of LTH-NIV in COPD, across a variety of settings.⁸

In light of the current state of evidence, we encourage MEDCAC to recommend to CMS that it convene a Technical Expert Panel (TEP) that would focus on objective criteria, such as:

- Specific disease/condition diagnoses
- Specific levels of PaCO₂
- Specific FEV1 levels or other objective criteria

and identify specific, clinically objective definitions or test result ranges on which to base coverage. As the entities that CMS tasks to collect documentation created by prescribers, we know first-hand how important having objective criteria is to ensuring patient access to home respiratory therapies. Conclusions that rely upon prescriber notes or other subjective criteria will likely result in patients not being able to obtain NIV therapy. Subjective criteria will lead to a substantial number of denied claims that will not support optimum patient outcomes. A TEP that includes clinicians, as well as experts in submitting and documenting claims, would be able to work through the clinical literature and develop recommendations that ensure adequate documentation can be obtained to support the claims submission process.

II. Questions 2 and 3:

How confident are you that the evidence is sufficient to determine the NIPPV equipment parameters necessary to promote successful patient-related outcomes?

How confident are you that any improved patient-related outcomes noted above made with any type of NIPPV device in the home, can be attributed to the use of the equipment alone as opposed to the concomitant provision of other support services like home respiratory therapists, home medication reconciliation and repeated elective hospital admissions?

Although the CQRC members are not clinicians, the evidence demonstrates that NIV leads to successful patient-related outcomes, particularly decreased mortality, decreased frequency of exacerbations requiring ER or hospital admission, increased time to hospital re-admission for respiratory related disease, and improved physical function and quality of life. We also maintain high confidence in the data that improved patient-related outcomes are attributable to the use of NIV.

⁸European Guidelines *supra* note 5 at 12.

NIV has shown enormous value to both the Medicare patients who require the therapy and the Medicare program as a whole. Ventilation is not optional for patients who medically require it; in some cases, it is the only option for sustaining their life. Previously, patients received ventilator therapy primarily in an institutional setting, but recent innovative technological advances now allow more patients to use these devices in the home setting. Although utilization of home ventilation therapy has increased, clinical experts believe that this increase, particularly in non-invasive ventilation therapy, is due to the expanded diagnostic categories for which these devices have been prescribed based on positive clinical research results. The primary diagnostic categories for which there is clinical evidence of improved patient outcomes when using home ventilation therapy are: neuromuscular disorders (e.g., Amyotrophic Lateral Sclerosis (ALS), Inherited Muscular Dystrophies, Myopathies, and Spinal Muscular Atrophy); restrictive thoracic diseases (e.g., scoliosis, obesity hypoventilation syndrome in which there is hypercapnia or for individuals for whom CPAP fails); and chronic respiratory failure consequent to chronic obstructive pulmonary disease.

Access to home ventilation therapy has allowed patients with these disorders/diseases to experience significant quality of life improvements as these devices have the life-giving effect of “freeing” patients from their hospital beds to return home. This shift to the home setting has corresponded with a significant reduction in Part A costs. In fact, a leading respiratory provider observed an approximately 70 percent reduction in preventable respiratory hospital admissions, along with clinically significant quality of life improvements in more than half of the patients in the first 6 months of its non-invasive ventilation program.⁹ Research demonstrates that these Medicare patients are also subject to lower rates of morbidity and mortality and that they receive enhanced clinical benefits stemming from use of non-invasive ventilators.

The benefits to patients and the program are clearly substantial. As King has explained in her study:

The preferred location for long-term mechanical ventilation is in the home, because costs are reduced, quality of life is enhanced, and integration into the community is maximized. The indications for both invasive and noninvasive mechanical ventilatory support in the home are increasing as technology and infrastructure support improves.¹⁰

This researcher warned also that even in 2012 “reimbursement constraints make it challenging to provide home ventilator patients with the optimal equipment and services

⁹Julian Husbands, MD, “Striving for Stability in Chronic Respiratory Failure Patients Using an Innovative, Home-Based Approach,” 6 *Readmissions News* 10, 1 (Oct. 2017).

¹⁰King, A.C., “Long-Term Home Mechanical Ventilation in the United States,” 57 *Respir. Care* 921-30, 929 (2012).

required” and recommended the creation of a central registry to “allow for the development and monitoring of national home mechanical ventilator patient outcomes.”¹¹ This population is clearly a vulnerable one, which not only requires the unique services provided through home ventilation therapy, but also deserves special attention to ensure that the risk of inadequate reimbursement threatening access, already presented in 2012, does not become a reality.

III. Conclusion

The CQRC appreciates the opportunity to provide comments and suggestions about the MEDCAC review of the home use of noninvasive positive pressure ventilation in patients with CRF consequent to COPD. Given the short timeline for providing comments, we encourage CMS to provide additional commenting opportunities to supplement the materials MEDCAC reviews before making its recommendations.

We would welcome the opportunity to provide additional information, clarify our suggestions, or discuss any questions you might have before or after the July meeting. Please do not hesitate to reach out to the CQRC’s Executive Director, Kathy Lester. She can be reached at (202) 534-1773 or klester@lesterhealthlaw.com. Again, we appreciate your attention to the issues and encourage you make sure that the recommendations do not create unnecessary barriers to Medicare patients being able to access these life-saving and life-sustaining treatment options.

Sincerely,

Crispin Teufel
Chairman, Council for Quality Respiratory Care

¹¹*Id.*