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### **VIA E-MAIL**

Medicare Evidence Development & Coverage Advisory Committee  
[MedCACpresentations@cms.hhs.gov](mailto:MedCACpresentations@cms.hhs.gov)

**RE: Comments for the Virtual Meeting of the Medicare Evidence Development  
and Coverage Advisory Committee – July 22, 2020 [CMS-3395-N]**

Dear Sir or Madam:

I am writing to provide comments concerning the virtual public meeting of the Medicare Evidence Development & Coverage Advisory Committee (“MEDCAC” or the “Committee”) to be held on Wednesday, July 22, 2020, focusing on the home use of noninvasive positive pressure ventilation in patients with chronic respiratory failure (“CRF”) consequent to chronic obstructive pulmonary disease (“COPD”). I understand that the Centers for Medicare & Medicaid Services (“CMS”) is seeking the Committee’s recommendations regarding the characteristics that define those patient selection and usage criteria, concomitant services, and equipment parameters necessary to best achieve positive patient health outcomes in beneficiaries with CRF consequent to COPD. I am writing to provide comments concerning these questions.

### **Financial Interest Statement**

Although these comments are my own, I note that I have a currently ongoing consulting relationship with Apria Healthcare LLC (“Apria”) to consult with respect to the rental of noninvasive positive pressure ventilation to patients with CRF consequent to COPD, neuromuscular diseases, and thoracic restrictive diseases covered by the Medicare Program. Apria is not a manufacturer, but a home care durable medical equipment company that rents continuous positive airway pressure (“CPAP”) devices, bi-level positive airway pressure (“BPAP”) devices, and home mechanical ventilators (“HMV”) to beneficiaries of commercial and governmental insurance, including Medicare beneficiaries. At this point in time, I have a “minor association” with Apria, as defined by MEDCAC (“< \$10,000”).

### **Background and Qualifications**

I am a practicing physician, pulmonologist and intensivist. I have been a partner at Chevy Chase Pulmonary Associates since July 2000. I have also been the Chief of the Pulmonary Section at Sibley Memorial Hospital in Washington, D.C., since January 2005. I continue to hold both of these positions. Previously, I served as the Vice-Chairman of Sibley’s

Internal Medicine department from January 2010 to 2013. And I served as an Assistant Professor of Medicine in the Pulmonary and Critical Care Division of the Medical College of Virginia from 1998 to 2000. I am or have been a Fellow or Board Member of multiple respiratory or medical organizations, including the American College of Physicians, the American College of Chest Physicians, the Society of Critical Care Medicine, and the European Respiratory Society. A more complete description of my academic, clinical, and administrative experience is contained in my CV, attached as Exhibit A.

I am board certified in pulmonary disease, internal medicine, critical care medicine, and hospice and palliative medicine. I specialize in pulmonary and critical care medicine, including chronic non-invasive and invasive ventilator management, and I regularly practice in this field.

I have experience working with HMMs, BPAPs, and CPAPs, and treating patients suffering from CRF consequent to COPD, restrictive lung and neuromuscular diseases. I am very familiar with these diseases, the typical conditions of patients who require noninvasive ventilation for treatment, the functionality, modes, and treatments offered by HMM, BPAP, and CPAP devices, and how patients react to and are treated with such devices. I have spoken on the treatment of CRF due to COPD and other conditions, and for 22 years, I have treated patients who suffer from chronic respiratory failure, including patients covered by Medicare.

Both in my own practice, and while treating patients at Sibley and suburban hospitals in the Washington Metropolitan region, I have treated patients with CRF consequent to COPD for whom I prescribed home mechanical ventilation. My work and observation of patients suffering from CRF, and my review of the literature, inform my views on issues relating to HMM treatment, including decreased mortality, decreased frequency of exacerbations requiring ER or hospital admission, increased time to hospital re-admission for respiratory related disease, and frequently, improved function and quality of life. In my experience, patients with chronic respiratory failure benefit from HMM and are able to reduce the frequency of hospitalizations and exacerbations, and there is a tangible mortality benefit as supported by clinical trials.<sup>1</sup>

### **HMM Therapy Is an Important Treatment for CRF Consequent to COPD Patients**

Through my research, clinical observation, and treatment of COPD patients in my practice, I have observed the positive patient health outcomes that HMM provides in patients with CRF consequent to COPD. HMM prescribed for such patients decreases mortality, frequency of exacerbations requiring emergency room visits, and hospital admissions, and increases time to hospital re-admission for respiratory-related disease. It frequently improves function and quality of life as well. Indeed, HMM can be a very important treatment for CRF patients. I have seen very sick CRF patients with little to no ability to engage in everyday activities improve dramatically, breaking the cycle of CO<sub>2</sub> retention and chronic respiratory acidosis related nefarious symptoms (headache, sleepiness, difficulty concentrating and frequently pulmonary cachexia) through HMM treatment. HMM helps lower elevated carbon

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<sup>1</sup> Köhnlein T, Windisch W, Köhler D, 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;2:698-705 (among others). As reviewed by CMS on their February 2020 publication, 36 studies have been identified addressing this important matter.

<https://www.cms.gov/Medicare/Coverage/DeterminationProcess/downloads/id108TA.pdf>

dioxide in patients, decreasing the work of breathing. It can greatly improve patients' quality of life. At times, I have seen it allow sick patients to regain some sense of normalcy in their lives, including interacting with friends and family and even leaving the home. Some of those patients were bedridden, with poor quality of life, and HMV was an important intervention to help alleviate the burden of their disease.

Moreover, it is essential that CRF patients who have been prescribed HMV have their device available to them to treat their condition, especially during acute decompensations that may occur. CRF is a dynamic disease state. Patients' conditions – while often continuously deteriorating over the long term – vary in acuity during particular weeks or months. There may be times when the patient needs the HMV to avoid hospitalization or even death, even if the patient had not used the HMV in the preceding week or month. Further, the use of the device benefits a patient, even if the use is infrequent. Patients with COPD have notorious variability in the degree of airway inflammation and bronchospasm, which may precipitate acute on chronic respiratory failure that may ensue over the course of days or hours. Having access to HMV for these types of acute decompensations is highly beneficial, resulting in decreased frequency of returns to emergency departments and admissions, which we know is associated with a very high case fatality rate.

For these reasons, once a COPD patient's disease state progresses to CRF, I believe that it is appropriate to prescribe HMV over CPAP or BPAP. CPAP is used to treat obstructive sleep apnea, and it does not properly treat CRF patients. As for BPAP therapy, it may be used early on as an assistive mode, to help support patients with respiratory insufficiency, but the inability to ascertain a proper minute ventilation, the lack of a mandatory rate, and the absence of many important features found on an HMV (discussed below) frequently make BPAP inadequate to treat patients with chronic respiratory failure. HMV is the better treatment for CRF patients and provides the level of therapy, monitoring, and features that are needed to treat very sick CRF patients who otherwise face a much greater risk of hospitalization or death.<sup>2</sup>

### **Lack of Current Usage Criteria for HMV**

I am not aware of any current statutory or regulatory requirement that requires Medicare patients prescribed HMV to use their HMV for any specific or minimum amount of time before the supplier can bill for it or be reimbursed by Medicare for it. This is different than other pieces of durable medical equipment ("DME"), where Medicare contractors have published specific usage requirements for both BPAP and CPAP devices.

### **Fixed Minimum Hours-of-Usage Requirements Should Not Be Imposed for HMV**

I believe that a minimum hours-of-usage requirement should not be imposed for HMV prescribed to treat patients with CRF consequent to COPD. Patients with CRF due to COPD are seriously-ill patients for whom HMV is, in my opinion, an essential aspect of their treatment regimen. Advanced COPD with associated CRF is a chronic and, frequently, a progressive disease, which inevitably causes the patient's condition to deteriorate over time. Whether or not

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<sup>2</sup> The RESCUE trial from The Netherlands and the Kohnlein et Al. study from Germany and Austria (cited below) support these conclusions.

such a patient uses his or her HMV during any given period of time does not change the patient's underlying diagnosis or the reasons why the patient may need the device, as indicated above.

Moreover, a fixed minimum hours-of-usage requirement would be detrimental to patients and interfere with our ability to treat patients. How much a patient needs to use his or her HMV device depends on the particular circumstances of the patient and his or her disease state. Some patients must use the device frequently to obtain the benefits that they need. But for others, even minimal use provides benefits and may decrease both hospitalizations and recurrent acute respiratory decompensations. It is extremely difficult to preset a usage requirement for every patient without taking into account each patient's different circumstances and situation. Proper levels of usage should be determined on an individual level between a physician and his patient through individualized treatment plans. Making minimum level of usage a reimbursement requirement would seriously interfere with our ability to treat patients.

I believe it is inappropriate to set up the DME companies to "police" the treatment of our patients. If a fixed minimum hours-of-usage requirement were imposed, then DME companies would be forced to cancel equipment orders for patients not meeting those requirements. In my opinion, this is not the proper function of a DME company. Of course, there should be a critical review of the equipment prescribed, to determine if there is indeed ongoing clinical benefit. But this review should be done by the physician, not the DME company. If the physician determines that there has been no improvement or benefit to the patient from his or her HMV, then we can make an objective assessment and cancel the device. This determination should be up to the physician observing and treating the patient. It seems arbitrary and potentially risky for an administrator working for the government (who has never seen the patient) or the DME company (which is not the treating physician) to make those decisions. Requiring DME companies to "police" our patients and pick up the equipment based on a "one-size-fits-all" hours-of-usage requirement inverts the treatment process. DME companies are supposed to be providing a service for physicians and patients, not dictating when or how physicians can treat their patients. Any usage requirement has the potential to seriously impact our patients and increases the possibility of hospitalization or death for those patients.

In my experience, some patients start off with limited initial use of their HMV and over time transition to more frequent usage. This is sometimes a slow process that often takes months. But each small increase in usage is a step toward increasing the patient's health, helping to compensate chronic respiratory acidosis and extending life. If the devices were to be removed, it would not be possible for patients to gradually increase usage or to use the HMV to avoid acute decompensations that might otherwise result in hospitalization or death.

As a treating physician, it is my responsibility to critically evaluate the benefit of any recommended treatment and cancel the intervention if non-beneficial. In patients with CRF, we try to encourage and increase a patient's usage over time. Removal of the device as a result of failing to meet a usage requirement would have severe consequences for patients, placing them at greater risk of re-hospitalization and potentially death, as we know that each hospitalization with acute hypercarbic respiratory failure is associated with high mortality.

## **HMV Is appropriate for Treating CRF Consequent to COPD**

For patients with CRF consequent to COPD, there is a critical role for HMV. HMV machines provide significant benefits to patients over BPAP or CPAP machines that may improve outcomes for COPD patients with CRF. Patients with advanced COPD and CO<sub>2</sub> retention live in constant risk of acute and catastrophic respiratory decline. Once CO<sub>2</sub> rises and chronic respiratory acidosis develops, acute decompensations due to pulmonary, thoracic or even extra-thoracic problems may precipitate acute on chronic respiratory failure, possibly leading to a cycle of CO<sub>2</sub> narcosis and further respiratory acidosis. HMV, which can ascertain a minute ventilation, is more likely to assist those patients with the most severe respiratory failure.

HMV devices have several features that make them superior to standard BPAP. These include the ability to provide higher pressures; better monitoring capabilities; an external battery backup; minute ventilation alarms and many others. Some devices allow for the adjustment of up to forty alarms, which are sensitive to a wider variety of developments, while a BPAP only has five. These features are potentially important for CRF patients, particularly some who do not have access to adequate home support or supervision. Alarms can help alert patients and physicians to preemptively anticipate significant episodes, giving the patient time to obtain potentially life-saving treatment before it is too late. Considering the potentially devastating consequence of such acute decompensations, it also is important that CRF patients have a device with battery backup. Given the severity of CRF patients' disease state, these features can truly mean the difference between life and death for the patient.

HMV offers mouthpiece ventilation (which BPAP or CPAP do not), which may facilitate intermittent diurnal use and greater mobility, independence, and potentially better quality of life. Without this feature, patients on BPAP or CPAP essentially are unable to leave their homes when using the machine.

In patients with respiratory failure consequent to COPD and severe respiratory acidosis, most pulmonologists prefer the use of HMV through pressure modes with a back-up rate and a minimal minute ventilation to ascertain adequate compensation and CO<sub>2</sub> elimination. Pressure modes tend to be more comfortable for patients and less likely to lead to patient-ventilator dyssynchrony or ventilator related complications, such as barotrauma and pulmonary injury in patients with limited reserve and frail pulmonary tissues.

The Pressure Assist Control mode ("PAC mode") (pressure assist ventilation) is a traditional mode of pressure control ventilation in which the HMV supports a breath initiated by the patient, but also may provide a guaranteed minute ventilation. This mode of ventilation is considered a traditional ventilator intervention and is frequently used by treating pulmonologists. PAC mode maintains a set inspiratory time that helps control the inspiratory and expiratory time of each breath for the patient. Controlling a patient's breath in this way can be beneficial for some patients who have excessive dead space ventilation, have severe obstruction, or may need a longer expiratory time to be able to deflate properly and achieve adequate ventilation limiting auto-PEEP and dangerous hyperinflation in patients with excessive lung compliance.

As a practicing clinician, I think that it is important to be able to analyze the evidence and to be able to tailor the patient's pathology and patho-physiology (*i.e.*, treatment) to the anticipated most effective device.

Advances in ventilator technology have complicated matters, as more options have rushed ahead before clinical studies become available to support their adoption. We should remember that enhanced minute ventilation is likely to lead to better outcomes, as demonstrated by most of the evidence available. The potential comfort benefits of new devices are also likely to improve compliance and adherence with the consequent improved outcomes.

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In short, I commend the Committee for considering these issues. But I believe it is critically important that many of the issues that the Committee is considering, including usage parameters and the decision to prescribe HMV versus BPAP, be left to the sound discretion of the treating physician. Physicians are in the best position to make these determinations based on their judicious and objective review of each individual patient. Setting global and sometimes arbitrary parameters that might preclude a patient from obtaining an HMV that he or she needs has the potential to result in poor outcomes, including excess hospitalizations and death for such patients. Patients with CRF consequent to COPD are seriously ill and frequently not in a position to advocate for themselves. We should ensure they have access to a potentially life-saving or life-extending therapy without additional arbitrary hurdles that may result in poor and premature outcomes.

Sincerely,

A handwritten signature in black ink, reading "Carlos E. Picone". The signature is fluid and cursive, with the first name "Carlos" and last name "Picone" clearly distinguishable.

Carlos E. Picone, MD, FCCP, FACP  
Pulmonary Medicine – Critical Care Medicine – Palliative Medicine

**References:**

Struik FM, Sprooten RT, Kerstjens HA, et al. Nocturnal non-invasive ventilation in COPD patients with prolonged hypercapnia after ventilatory support for acute respiratory failure: a randomized, controlled, parallel-group study. *Thorax* 2014;69:826-34. RESCUE trial. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4739968/pdf/jtd-08-02-255.pdf>

Köhnlein T, Windisch W, Köhler D, et al. Non-invasive positive pressure ventilation for the treatment of severe stable chronic obstructive pulmonary disease: a prospective, multicenter, randomized, controlled clinical trial. *Lancet Respir Med* 2014;2:698-705.

Murphy PB, Rehal S, Arbane G, 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 06 06;317(21):2177-86. doi: <https://dx.doi.org/10.1001/jama.2017.4451>

Jan Hendrik Storre, et al. Home noninvasive ventilatory support for patients with chronic obstructive pulmonary disease: patient selection and perspectives. *Int J Chron Obstruct Pulmon Dis*. 2018; 13: 753–760. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5836655/pdf/copd-13-753.pdf>

CMS – Technology Assessment Program: Noninvasive Positive Pressure Ventilation in the Home <https://www.cms.gov/Medicare/Coverage/DeterminationProcess/downloads/id108TA.pdf>