



June 22, 2020

VIA E-MAIL

Medicare Evidence Development & Coverage Advisory Committee
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 MEDCAC’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; it is a home care durable medical equipment supplier that rents continuous positive airway pressure (“CPAP”) devices, bi-level positive airway pressure (“BPAP”) devices, and home mechanical ventilators (“HMs”) 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 physician and assistant professor of internal medicine in the pulmonary/critical care division at the University of Michigan, in Ann Arbor, Michigan. I have held this position since April 2018. I also serve as the Medical Director at the University of Michigan’s Assisted Ventilation Clinic in Ann Arbor, Michigan (the “Clinic”). I have held this position since April 2018. Previously, I served as a Medical Instructor at Duke University Medical Center, in Durham, North Carolina, from July 2015 to March 2018.

I graduated from the Icahn School of Medicine at Mount Sinai in 2008. 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 and critical care 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 extensive experience working with HMMVs, BPAPs, and CPAPs, and treating patients suffering from CRF consequent to COPD, neuromuscular disease, and various other conditions. 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 HMMV, BPAP, and CPAP devices, and how patients react to and are treated with such devices. I have taught, written, and spoken frequently throughout the world on the treatment of CRF consequent to COPD, and for eight years, I have treated patients who suffer from CRF consequent to COPD, including patients covered by Medicare.

The Clinic is one of the largest, if not the largest, and most comprehensive ventilator clinics in the United States. Currently, the Clinic has grown to approximately 1,100 patients requiring mechanical ventilation support. Most of the Clinic's patients have been prescribed HMMV, many of whom are in a Pressure Assist Control Mode ("PAC Mode") setting. Many Clinic patients are covered by Medicare. As the Clinic's Medical Director, I oversee the treatment and prescriptions for all of these patients. My work with and observation of patients suffering from CRF consequent to COPD, as well as my research and studies, inform my views on issues relating to HMMV treatment, including decreased mortality, decreased frequency of exacerbations requiring ER or hospital admission, increased time to hospital re-admission for respiratory related disease, and improved function and quality of life.

The Benefits of HMMV Therapy for CRF Consequent to COPD Patients

Through my research, clinical observation, and treatment of COPD patients, I have observed the positive patient health outcomes that HMMV provides in patients with CRF consequent to COPD. HMMV prescribed for such patients decreases mortality, decreases frequency of exacerbations requiring emergency room or hospital admission, increases time to hospital re-admission for respiratory related disease, and improves function and quality of life. Patients with CRF consequent to COPD develop elevated carbon dioxide (CO₂) levels in their blood due to ineffective gas exchange. HMMV helps lower CO₂ levels, ultimately putting patients at less risk of cardiovascular complications. HMMV can also decrease the work of breathing, which helps patients feel less short of breath, thereby improving quality of life. I run a weekly clinic for patients with CRF consequent to COPD. All of these patients have elevated CO₂ levels at baseline. HMMV is an effective treatment to lower these levels.

For these reasons, once a COPD patient progresses to CRF, I believe that it is appropriate to prescribe HMMV for that patient, over BPAP or CPAP. CPAP is an entirely different type of therapy that is used solely for the treatment of obstructive sleep apnea ("OSA"). As such, it is an inappropriate therapy for CRF. BPAP may be utilized earlier in the course of COPD when CO₂ levels are just mildly elevated and the disease is stable. However, as COPD progresses and

patients are repeatedly hospitalized, HMV becomes a form of life support, without which patients would have an accelerated path to death.¹

Current Usage Criteria for HMV in the Medicare Regulations

I am not aware of any current statutory or regulatory requirement that Medicare program beneficiaries for whom a ventilator, including HMV, has been prescribed must use their HMV for any specific or minimum amount of time in order for the supplier to bill or be reimbursed by Medicare for the HMV. In contrast, I am aware that durable medical equipment (“DME”) Medicare contractors (“MACs”) have published documents setting forth specific usage requirements for both CPAP and respiratory assist devices (“RAD”).

Fixed Minimum Hours-of-Usage Requirements Are Not Advisable for HMV

I believe that the Committee should recommend that CMS refrain from imposing a minimum hours-of-usage requirement for HMV prescribed to patients with CRF consequent to COPD. First, patients with CRF consequent to COPD are seriously-ill patients for whom HMV is, in my opinion, an essential aspect of their treatment regimen. CRF consequent to COPD is a chronic and progressive disease, which invariably causes the overall health of the patient to deteriorate over time. Whether or not 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 needs the device.

Second, while usage is very important for CRF consequent to COPD patients who are prescribed HMV, a minimum hours-of-usage requirement that would require a patient to use the device a certain number of hours per day or month in order to retain Medicare coverage would be detrimental to the patient. There are many reasons why a patient may not be using his or her prescribed HMV, and it is up to astute clinicians to help troubleshoot these problems. The most common reason for poor adherence early on is often the most simple. Patients are often prescribed the improper mask interface. Whether it be due to claustrophobia, or simply being prescribed a mask that is the wrong size, mask discomfort may impede usage. This problem can be easily remedied and is in no way the fault of the patient. Another barrier to patient adherence is related to settings. There are no standard pressure settings for every patient with CRF consequent to COPD. Each individual patient has different needs, so patient tolerance will vary greatly. Clinicians must make concerted efforts to adjust settings to maximize comfort and tolerance. These changes may be subtle, but can ultimately make a large difference. Given the life-threatening nature of CRF consequent to COPD, it would not be appropriate for suppliers to be forced to pick up a device because minimum usage was not met during an arbitrary time period. Responsible clinicians continually work to improve adherence to therapy. Sometimes this process is quick over the course of days or weeks. But often, this process may take many months to attain even minimal usage. In addition, the level of patient compliance with the prescribed therapy and use of the HMV may vary over time for reasons that are subjective to the patient (*e.g.*, patients may suspend usage or reduce the level of usage temporarily at times when the patient begins to “feel better” or when temporary issues relating to the patient’s ability to

¹ I use the term “life support,” not to indicate that the patient will expire immediately without use of the HMV, but to explain that CRF consequent to COPD patients prescribed HMV have a disease state where their short-term mortality is high and that HMV is an essential treatment to extend their lifespan.

tolerate the therapy arise). Nevertheless, each small step is a step towards bringing the patient to a better state of health.

I will provide a specific example from my own practice. I prescribed one of my patients HMV for CRF consequent to COPD. The patient was on maximal medical therapy with inhalers, but was frequently admitted to the hospital. The patient's CO₂ levels were twice the normal level. For months, I saw the patient regularly in clinic, but the patient could not get used to the HMV. We tried various different masks and adjusted settings, but the patient still had difficulty using it consistently. One clinic, the patient was so sick I had to directly admit the patient to the ICU. During hospitalization, we adjusted the patient's HMV settings and the patient was able to return home and utilize the HMV more frequently. The patient has not been hospitalized over the last year. If there had been an arbitrary usage requirement during those initial months, the device would have been removed from the patient's home and the patient may have suffered more severe consequences, possibly even death. But we were able to work together over the course of time to improve adherence so that the patient achieved and continued with a more stable state of health, and it is important that the patient have the device available in order to resume compliance.

Decisions to discontinue a form of life support should not be determined by a usage requirement imposed by regulators. They should be shared decisions between patient and clinician based on a patient's goals and perceived quality of life.

HMV – Including in the PAC Mode Setting – Is appropriate for Treating CRF Consequent to COPD

For patients with CRF consequent to COPD, I believe that it is important to prescribe HMV over other devices such as BPAP or CPAP. This is because HMV machines have significant benefits to patients over BPAP or CPAP machines that significantly improve outcomes for CRF consequent to COPD patients. CRF consequent to COPD is an end-stage disease, and patients with this diagnosis essentially need unending support therapy. HMV, which has additional features that neither BPAP nor CPAP can provide, is important for the treatment of such patients. These features include the following:

- HMV can provide increased pressures beyond what BPAP or CPAP can provide. While not all patients require these increased pressures, for some, particularly those with other co-morbidities including obesity, HMV may be the only method to provide adequate ventilator support.
- HMV has better monitoring capabilities than BPAP or CPAP. This is important because lung mechanics in patients with CRF consequent to COPD may change over time and during acute exacerbations. Maintaining adequate ventilation through close device monitoring is vital in trying to reduce exacerbation frequency and hospitalizations.
- HMV has an external battery backup, while BPAP and CPAP do not. This is particularly important in late stage CRF, as patients become more physiologically

dependent on HMV therapy. Both the internal and external battery allow patients to have respiratory support outside the home, which greatly improves quality of life and is extremely important for any patient-centered care.

- HMV has 40+ alarms, which are sensitive to a wider variety of developments, while BPAP and CPAP devices have fewer than 5. Therefore, HMV is able to detect far more nuanced changes in the patient's condition than can BPAP or CPAP. For patients who are increasingly dependent on HMV technology as a form of life support, this level of alarms helps alert patients and caregivers to changes in lung mechanics. By reporting these alarms to their physicians, patients may be able to have exacerbations treated preemptively at home, rather than developing into critical illness requiring hospitalization. With far fewer alarms, the ability to preemptively anticipate and treat these developing exacerbations on a BPAP or CPAP is far more limited.
- HMV also offers mouthpiece ventilation ("MPV"), which BPAP and CPAP devices do not. This is essential for a patient's use of HMV during the day, allowing the patient mobility and better quality of life. MPV allows patients to receive on demand ventilation support while being liberated from the standard nighttime mask interfaces. MPV also provides ventilation support with an expiratory pressure ("EPAP"). This makes eating and speaking much more comfortable. Without this feature, patients on BPAP or CPAP essentially are unable to leave their beds or homes when using the machine. This is impracticable and unworkable for patients with CRF consequent to COPD. Quality of life can be greatly increased by using this feature.

It is also important to note that HMV is FDA approved for treating respiratory failure. BPAP is not. BPAP is only FDA approved for treating respiratory insufficiency, not respiratory failure. If I were to prescribe a BPAP device to treat respiratory failure, I would be prescribing an off-label use of the device. I do not believe this is appropriate. BPAP devices are used to treat stable patients without chronic respiratory failure. Once a patient has chronic respiratory failure, that patient requires a level of therapy that a BPAP does not provide, but that the HMV does.

The benefits that HMV provides, which BPAP or CPAP do not, exist for multiple modes of the HMV device. For example, I prefer using positive pressure modes – which are excellent modes of HMV therapy – to volume modes in treating my patients. Volume modes are exclusively used for patients with tracheostomies requiring invasive ventilation. I have never encountered clinicians who use pure volume modes of ventilation for non-invasive HMV treatment. Volume modes have fixed flow rates that are extremely uncomfortable for patients who are spontaneously breathing. Pressure modes of ventilation have variable flow rates that are more comfortable for patients. Maximizing comfort is the key to HMV adherence.

Similarly, the PAC mode on an HMV device is also a traditional HMV therapy that provides effective ventilation for patients with CRF. I am aware of multiple physicians who

prescribe HMV in the PAC Mode to their patients, including pulmonologists. I am not aware of any pulmonologist or other physician who believes it is not appropriate to prescribe HMV in the PAC Mode to CRF patients. PAC mode allows for every breath to be equally controlled by the ventilator, whether the patient is breathing above or at the set back up rate. An inspiratory time is set so that each delivered breath is consistent. For some patients with extreme respiratory failure, the prescribing physician may want to control ventilation with a PAC mode to try to bring down CO2 levels.

I have been involved, directly or indirectly, in the care of hundreds of patients with CRF consequent to COPD. I have prescribed HMV for a majority of such patients. I routinely prescribe HMV in a PAC Mode setting for such patients. Some patients may prefer spontaneous/timed modes where they can set their own inspiratory time when breathing spontaneously. However, I have found that many patients do better when their ventilation is more controlled with a set inspiratory time in a PAC mode.

It is essential that the choice of which HMV mode is appropriate for the patient be left to the treating physician – to choose which HMV mode I believe is appropriate to treat my patients. This is particularly true of CRF patients, who are gravely ill and who need all the benefits that HMV provides them. The treating physician must have the flexibility to treat particular patients based on their individual disease-states, and restricting patients to certain modes of an HMV could have a significant negative impact on patient outcomes.

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In short, I believe that issues such as minimum usage parameters and which HMV modes are most beneficial to patients should not be addressed at the CMS level. Instead, these determinations should be left to the treating physician, who is in the best position to make them based on a particular patient's individual circumstances. I believe that any other result could have serious negative impacts for CRF consequent to COPD patients who need HMV to reduce re-hospitalizations and to prolong their life. I appreciate the opportunity to provide comments to assist in the Committee's review.

Sincerely,

A handwritten signature in black ink, appearing to read 'Philip Choi', with a stylized flourish at the end.

Philip Choi, MD, MA
Clinical Assistant Professor
Medical Director, Assisted Ventilation Clinic