

## **MEDCAC Presentation**

**Presented by:**

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### **I. Define Patient Selection Criteria**

We believe clearly defined and easily measured standards to establish medical necessity for NIV coverage are essential for patients, payors, and suppliers

Traditionally, most patients treated with home NIV have had hypercapnic chronic respiratory failure (HC-CRF). In fact, the current literature includes only patients with HC- CRF, so little is known about the effects of NIV on other phenotypes of COPD-CRF such as hypoxic CRF, CRF defined by PFT abnormalities, or CRF defined by clinical criteria.

Partly to investigate this issue, we performed two large, retrospective studies using the Medicare Limited Data Set (LDS) on COPD-CRF patients and saw robust, statistically significant reductions in mortality, hospitalization rates, and ER visits associated with HMV use (1,2). Less than 12% of these patients were coded as having HC-CRF. While this may well underestimate the true incidence of hypercapnia, it seems improbable that all or even most of these patients had HC-CRF. The improved outcomes seen in these studies of “all comers” with COPD-CRF suggest that HMV may be beneficial in CRF phenotypes other than just those with hypercapnia. We are planning another Medicare LDS study to assess the role of hypercapnia as an independent predictor of HMV benefit in COPD-CRF.

In light of this recent data, we propose the following medical necessity standards to approve HMV use in Medicare COPD-CRF patients.

1. Hypercapnia defined as a pCO<sub>2</sub> of > 45 mmHg with appropriate pH compensation to define CRF and/or
2. Clinical characteristics consistent with the Global Initiative for Obstructive Lung Disease (GOLD) stage D COPD, defined as at least 2 COPD exacerbations or at least one COPD related hospitalization in the past year (3) and/or
3. Pulmonary function test results showing an FEV<sub>1</sub> of < 30% with a FEV<sub>1</sub>/FVC of <70% (GOLD stage 4, very severe obstruction)

### **II. Hours of Usage Criteria**

We believe all patients should be strongly encouraged to use NIV as much as possible. However, we also recognize that no available studies have established a minimum amount of time that NIV must be used to show benefit in COPD-CRF patients. In representative studies reporting positive outcomes, the average hours of daily NIV use ranges from than 3.9 hours to 5.9 hours with large variations among individual participants who showed benefit (4,5,6). Anecdotally, we are aware of many patients who use NIV as rescue treatment for respiratory

distress and report powerful symptom relief and a decrease in the need for ER/hospital utilization using this strategy.

Therefore, in light of the paucity of objective data on minimum NIV use necessary for benefit, we propose the following usage criteria.

1. Continuing coverage for NIV should not be dependent on an arbitrary hours of use criterion

### **III. Concomitant Service for COPD-CRF patients on NIV**

Patients with COPD-CRF are a chronically ill and vulnerable population. For many of these patients, NIV is an intimidating and confusing intervention which is poorly suited for a “drop ship” approach. NIV provision is considered by CMS to require frequent and substantial services. We believe this should include both initial and ongoing support by highly trained healthcare providers such as respiratory therapists or nurses. Such support should be a part of routine follow-up and should also be immediately available 24 hours a day. This support should include phone calls, video conferencing, patient engagement platforms, and in-person home visits as deemed necessary by the patient and their NIV provider. While we believe a high touch care model is best for patients, we also recognize that no clinical studies have validated this approach.

We propose the following concomitant care standards for NIV provision.

1. COPD-CRF patients using NIV should have easy access to both routine and emergent follow-up from respiratory therapists or nurses provided by their NIV supplier.

### **IV. Equipment Parameters for NIV**

Since the introduction of bi-level positive airway pressure/respiratory assist devices (BPAP/RADS) nearly 30 years ago, many clinicians have used them off-label to treat COPD-CRF. This was often done in a compassionate use scenario since treatment options were so limited for these patients. Following the introduction of true non-invasive home mechanical ventilators (HMV) around 2012, Medicare claims data show that the large majority of COPD-CRF patients treated with NIV are now using HMV (1,2). However, the legacy of BPAP/RADS use and the confusing nomenclature where devices with the same trade name have very different capabilities depending whether they are used in the hospital or in the home, has led to a great deal of confusion.(footnote 1) Unfortunately, a recent meta-analysis (7) has only added to this confusion. This analysis purported to show that BPAP/RADS devices were equal to or even better than HMV in treating COPD-CRF, but the results were fatally flawed by erroneously assigning a study with poor outcomes to the HMV group when it actually belonged in the BPAP/RADS group (8).

The two studies mentioned above that we recently completed using the Medicare LDS from 2012 to 2018 (1,2) looked at outcomes in COPD-CRF using HMV and found important reductions in mortality, hospitalizations, and ER visits associated with HMV use. We attempted

to look for outcomes associated with BPAP/RADS, but their use to treat COPD-CRF in the Medicare population from 2012 to 2018 was too infrequent to allow for meaningful analysis.

*[footnote 1: For instance, Philips Respironics manufactures a BPAP/RADS for home use trade named BiPAP. They also manufacture a hospital grade mechanical ventilator trade named the V60 BiPAP. The home BiPAP and hospital BiPAP have very different performance characteristics, technical specifications, and clinical indications.]*

HMV differs from BPAP/RADS in several important ways including the maximum level of inspiratory positive airway pressure (IPAP) that can be generated, by the peak flows achievable, and by the array of alarms to name a few. These differences make sense when one remembers that BPAP/RADS devices were designed and are indicated to treat complex sleep apnea while HMV devices were designed and are indicated to treat respiratory failure.

Additionally, we can conceive of no safe way to apply a strategy of requiring BPAP/RADS failure before allowing COPD-CRF patients to receive HMV. How would one define a patient's failure on BPAP/RADS? Would this be clinical deterioration, a hospitalization or even death? The risks of such an approach are much too high. Until head to head studies are available proving that BPAP/RADS is as safe and effective as HMV, we believe that patient safety concerns dictate that HMV be the sole NIV equipment used to treat COPD-CRF.

Therefore, we propose the following equipment parameters for treating COPD-CRF.

1. NIV for COPD-CRF should be solely provided by home mechanical ventilators.

## **References:**

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