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**A FORMAL REQUEST FOR NCD RECONSIDERATION FOR  
HOME MECHANICAL VENTILATORS, INCLUDING BI-LEVEL DEVICES**

**Decision Request for Home Mechanical Ventilators, including Bi-Level Devices**

On behalf of the American Association of Respiratory Care, CHEST/American College of Chest Physicians and the National Association for Medical Direction of Respiratory Care, please consider this formal submission as a request for a reconsideration of the current National Coverage Determination for home mechanical ventilators found in the *Medicare National Coverage Determinations Manual (Publication #103) at Chapter 1, Part 4, 280.1, Durable Medical Equipment Reference List (Effective May 5, 2005)*.

Current Medicare policy covers ventilators, both positive and negative pressure types, for the treatment of neuromuscular diseases, thoracic restrictive diseases, and chronic respiratory failure consequent to chronic obstructive pulmonary disease. We believe that the clinical relationship between home mechanical ventilators and bi-level devices (identified as respiratory assist devices by CMS) are so strongly inter-related that any comprehensive policy addressing home mechanical ventilation must also address these corollary devices. In this request, we provide numerous vignettes to illustrate this inter-relationship, acknowledging that some Medicare beneficiaries may warrant a home mechanical ventilator without any previous use of a bi-level device; likewise, some Medicare beneficiaries may never warrant genuine home mechanical ventilation. But there is a portion of the Medicare population that does experience a shift in need for the level of mechanical support as their illness(es) progress. We recognize this particular scenario can be confusing and complicated. Therefore, as noted above, we are providing a series of vignettes to illustrate these common clinical scenarios in order to ensure appropriate policy decision making based on clinical considerations.

For clinicians, the term “respiratory assist device” continues to be particularly mystifying as it is not a term used by the FDA nor does it appear anywhere in the clinical literature. The day-to-day application of a moving, non-specific definition is frustrating. We would hope that CMS determines that use of common, well accepted terms to describe devices in this category of

non-life support ventilators is a better approach than use of terms that are extremely challenging and frustrating to the medical community.

Based on detailed scientific evidence presented in this document that both invasive and noninvasive home mechanical ventilation are integral to the treatment of chronic respiratory failure, **we request that CMS implement the following policies in priority order listed below:**

- 1) Establish specific clinical definitions for chronic respiratory failure, mechanical ventilator and mechanical ventilation;**
- 2) Recognize specific categories of mechanically ventilated patients that acknowledge chronic respiratory failure may occur intermittently, nocturnally, or on an ongoing basis; and,**
- 3) Meld the current LCDs for “respiratory assist devices” into the revised NCD for home mechanical ventilators with three notable changes:**
  - a. Use medical terminology, i.e., bi-level devices/mechanical ventilators for use in treatment of respiratory insufficiency, recognized by the medical community and the Food & Drug Administration to address coverage of devices for treatment of respiratory insufficiency.**
  - b. Eliminate the current requirement for oximetry testing in certain specified scenarios as there is no scientific basis for this requirement.**
  - c. Eliminate the current requirement for a Medicare beneficiary to “fail” therapy of a device without using a backup rate as there is no scientific basis for this requirement.**

NOTE: This request does not affect nor is it intended to address any treatment policy or recommendations regarding patients with straightforward obstructive sleep apnea as outlined in local coverage decision document 33718 (LCD 33718). Our focus is strictly directed toward the 2001 Decision Memo language regarding home mechanical ventilator coverage and related coverage criteria and guidelines contained within the current LCD for bi-level devices (LCD L33800).

## **Part B Benefit Category**

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As noted above, ventilators are covered under Medicare’s Part B Durable Medical Equipment benefit category (§1861(n)) and as a medical or other health service under §1861(s)(6) of the Social Security Act [the Act]).

## **Description of the Item or Service/FDA Labeled Indications/Medicare Population**

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In accordance with the *Federal Register* notice of August 7, 2013, to be considered a complete NCD reconsideration request the document must include a detailed description of the item or service. Although ventilators are already covered under Medicare and we are not requesting a

specific device be covered, to comply with the requirements we are providing the following information.

Ventilators are indicated by FDA to provide continuous or intermittent ventilator support for the care of individuals who require mechanical ventilation. The devices are intended to be used in the home, hospitals and institutions and may be used for both invasive and noninvasive ventilation. Ventilators are classified by the FDA as Class II devices which are moderate to high risk devices with general controls and special controls, the latter of which are generally device-specific. In the case of ventilators, the controls are related to performance standards. Importantly as best we can determine, FDA does distinguish between mechanical ventilators intended to provide life support (removal of the device would lead to significant patient harm and eventual death) and mechanical ventilators to provide support for respiratory insufficiency. Devices with the CBK approval are approved for life support (respiratory failure) while ventilators classified as MNT or MNS are approved to treat respiratory insufficiency.

For the purpose of this reconsideration request, we recognize we are addressing two broad categories of ventilators – those used to treat respiratory failure AND those ventilators/bi-level devices used to treat documented respiratory insufficiency. Bi-level devices without a backup rate deliver adjustable, variable levels of positive pressure via tubing and a noninvasive interface, whereby such devices with backup include a timed backup feature to deliver air pressure whenever sufficient spontaneous inspiratory efforts fail.

As noted above, it is critically important to recognize that chronic respiratory failure may occur intermittently, nocturnally, or on an ongoing/continuous basis. The targeted Medicare populations affected may suffer from a range of diseases, most notably neuromuscular diseases, thoracic restrictive diseases and chronic obstructive pulmonary disease.

### **Reconsideration of Current Coverage**

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In reconsidering an NCD, CMS requires that the **requesters show arguments that “our conclusion materially misinterpreted the existing evidence at the time the NCD was decided.”** In this particular case, the NCD itself is simply an acknowledgement in the DME Reference List that ventilators, both negative and positive pressure types, are covered for certain conditions. However, revisions by the Durable Medical Equipment Medicare Administrative Contractors (DME MACs) to their local coverage determinations (LCDs) on respiratory assist devices in December 2014 and again in October 2015 have had substantial negative consequences for access to home mechanical ventilation and have prompted this request for reconsideration.

On June 29 2001, CMS posted a non-binding Decision Memo for Noninvasive Positive Pressure Devices (CAG-00052N) that includes an extremely problematic statement regarding home mechanical ventilation. The Decision Memo states that noninvasive ventilation is “distinguished from the invasive ventilation administered via a securely intubated airway, in a

patient for whom interruption or failure of respiratory support leads to death.” The distinction was made in conjunction with CMS’s review of whether direct placement of a bi-level device with backup was demonstrated for patients with severe COPD without first undergoing a trial with a bi-level device without backup.

The likelihood that interruption or failure of respiratory support will lead to death is not determined by the type of ventilation but rather the clinical status of the patient. Regardless of the type of ventilator, patients with little or no vital capacity will die rapidly if ventilator support is interrupted whereas those with reserve ventilator capacity and in need of just intermittent or nocturnal ventilator assistance may live for weeks or even months after removal of the ventilator. **Additionally, there is nothing in the current FDA labeled indications that infers that the use of invasive mechanical ventilation is associated with life support which, upon removal of that support, leads to death.**

In fact, as long as chronic respiratory failure is documented, there is little need to distinguish between invasive and noninvasive ventilation for Medicare coverage purposes. Virtually all devices approved by the Food and Drug Administration (FDA) for treatment of respiratory failure can provide ventilation through either approach, a clinical decision understandably made by the ordering physician, the Medicare beneficiary and his/her family.

Nevertheless, the DME MACs now cite that descriptive language in the 2001 Decision Memo as the basis for denying coverage of home mechanical ventilators to a range of patients with neuromuscular, thoracic restrictive diseases and chronic respiratory failure because there is insufficient information in the medical record to indicate that removal of the ventilator will lead to death.

### **Information regarding relevance, usefulness, and medical benefits of home mechanical ventilation**

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As discussed further in this document, the state-of-the-art of home mechanical ventilation has experienced dramatic technological advances since the 2001 CMS Decision Memo. Thus, these waves of current denials reflect a lack of understanding of the technologies readily available to treat chronic respiratory failure, an unnecessary recurring distinction between invasive and noninvasive home mechanical ventilation and a failure to comprehend the nature of chronic respiratory failure. Further, there is a cadre of scientific evidence that was not available at the time the CMS Decision Memo was written that now supports a change in the current NCD for ventilators as discussed in this reconsideration request.

Additionally, we believe it is imperative for a revised NCD for home mechanical ventilation to provide specific clarification that home mechanical ventilation is integral to the standard of care for treatment of chronic respiratory failure and such mechanical ventilation may understandably vary from several hours per day to continuous usage. Removal of the device

may lead to deterioration of health, but the concept that removal of a home mechanical ventilator leads to death as stated in the 2001 Decision Memo has no scientific validity. Permitting contractors to implement such policies goes well beyond the verbiage of the current NCD and is unacceptable to the pulmonary medical community.

### **Current Overlap between Home Mechanical Ventilators and Bi-level/Respiratory Assist Devices**

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As discussed below, it is impossible to focus on home mechanical ventilation without acknowledging the difficult distinction, particularly related to bi-level devices, that separates treatment for documented chronic respiratory failure from documented respiratory insufficiency and related diagnoses/disorders. Because the same device can be used to treat both clinical scenarios, it is absolutely critical to draw clear clinical distinctions between these uses to ensure appropriate use by Medicare beneficiaries as well as provide reasonable guidance to clinicians and suppliers.

Home mechanical positive pressure ventilation emerged with FDA approval of a portable volume targeted ventilator (home mechanical ventilator or HMV) in 1977 that focused upon ventilator dependent pediatric patients with tracheostomies.<sup>1</sup> With the development of bi-level pressure (BPAP) targeted devices for patients with persistent sleep disordered breathing and hypoventilation despite optimal CPAP therapy, a new opportunity for treatment with non-invasive ventilation (NIV) assist devices in the home became available.<sup>2,3</sup> Subsequently, BPAP equipment was specifically addressed in the **Federal Register** and defined by CMS as “respiratory assist devices” or “RADs”. Prior to 1999, RADs were termed by Medicare as “*intermittent assist devices with continuous positive airway pressure*”. There was no distinction in the Healthcare Common Procedure Coding System (HCPCS) as to whether or not a backup rate feature was employed. Effective January 1, 1992, code E0453 with the description of “therapeutic ventilator; suitable for use 12 hours or less per day” was added to the HCPCS. This code was added to describe ventilators used on a part-time basis by patients who are dependent on stationary ventilators for less than 12 hours a day.

The DMERC/DMEMAC medical review policies on respiratory assist devices were implemented on October 1, 1999 after a consensus conference organized by NAMDRG addressed the clinical issues related to ventilator assistance for patients with neuromuscular disease (NMD), COPD,

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<sup>1</sup> Edwards JD, Kun SS, Keens TG. Outcomes and causes of death in children on home mechanical ventilation via tracheostomy: an institutional and literature review. *J Pediatr* 2010; 157(6):955-959.

<sup>2</sup> Sanders MH, Kern N. Obstructive sleep apnea treated by independently adjusted inspiratory and expiratory positive airway pressures via nasal mask. Physiologic and clinical implications. *Chest* 1990; 98(2):317-24.

<sup>3</sup> Strumpf DA, Carlisle CC, Millman RP, Smith KW, Hill NS. An evaluation of the Respironics BiPAP Bi-level CPAP device for delivery of assisted ventilation. *Resp Care* 35:415-422, 1990.

and other hypoventilation syndromes (HS).<sup>4</sup> The separate, specific acknowledgment of a backup rate was initially warranted because utilization of a BPAP with backup rate was clinically and financially more similar to that of an HMV. Consequently, use of a BPAP backup rate was regarded as a more sophisticated therapy and therefore recognized as a ventilator by the FDA, resulting in need for a more ‘frequent and substantial servicing’ (FSS) payment classification by Medicare. In August 2003, the reimbursement ruling was changed to ensure that all BPAPs, even when used as a ventilator with a backup rate, were nevertheless paid as a capped rental (CR) item. As later clarified in 2006 (*Federal Register*/Vol. 71, No. 18, p. 4519-22/ January 27, 2006 /Rules and Regulations), “Ventilators that are excluded from the FSS payment category are paid in accordance with section 1834(a)(7) of the Act under the CR category on a rental basis.” This ruling clarified reimbursement policy for BPAPs vs. H MVs, but did not help identify the clinical situations most appropriate for FSS or CR category equipment.

While we acknowledge that payment issues are not part of this reconsideration process, it is important to note that newer studies on all three of the recognized hypercapnic respiratory failure disease categories (NMD, COPD and other HS) have emerged that now call for a re-examination of the BPAP and H MV policies related to management of these patients.

Now, some 15 years later, the two categories of devices (BPAPs and H MVs) used to treat patients with chronic hypercapnic alveolar hypoventilation (chronic hypercarbic respiratory failure) have overlapped. The lines began to blur as H MVs with expanded capabilities made it possible to treat patients with the same diagnosis, ***but with different degrees of severity***, as either a “BPAP” or a “H MV” device using the same mode of flow delivery and even with the same settings. In short, these newer H MVs now have the capability of delivering therapy with BPAP settings as well as volume targeted modes. It is now more difficult to tie appropriate device code assignment to medically necessary treatment plans chosen for one patient or another when BPAP settings are deliverable with either a “bi-level” or an H MV. Essentially, the same BPAP settings can be provided in the home with devices in both of these broad categories, but with very different coding implications that impact Medicare payment.

A separate clinical issue is the lack of provision for the expertise of a respiratory therapist in the home which may necessitate transfer of some patients with more complex severe chronic respiratory failure to a chronic care facility in order to provide access to sufficient clinical management of their ventilator device (“bi-level device” or H MV). The problem is that the current reimbursement policy creates a disconnect between the patient’s clinical status/needs and reimbursement because payment policies focus on devices rather than the clinical situation. This dilemma was well summarized in a cogent review by Angela C King in the

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<sup>4</sup> Clinical Indications for Noninvasive Positive Pressure Ventilation in Chronic Respiratory Failure Due to Restrictive Lung Disease, COPD, and Nocturnal Hypoventilation—A Consensus Conference Report. *Chest* 1999; 116:521–53.

discussion section of *Long-Term Home Mechanical Ventilation in the United States*.<sup>5</sup> We do acknowledge that this gap in care is driven by gaps in the Medicare statute.

This request also provides expert consensus opinion regarding the use of home mechanical ventilation in adults, attempting to describe different clinical scenarios that dictate the need for different levels of ventilator assistance and support. It is not intended to address these issues in the context of CMS reimbursement. As expert clinicians, we continue to recognize the intrinsic differences among patients with chronic hypercapnic respiratory failure due to neuromuscular disease (NMD), COPD and other hypoventilation syndromes. Consequently, sections in this document separately address those three patient categories.

### **RECOMMENDATION: Establish a Specific Definition for Chronic Respiratory Failure, Home Mechanical Ventilator and Home Mechanical Ventilation**

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In considering policy revisions that reflect the standard of care today with respect to mechanical ventilation, it is important to first propose definitions for both respiratory failure and a mechanical ventilator including the process of mechanical ventilation. Adoption of these recommendations necessitates replacement of the 2001 Decision Memo with a more accurate policy of the state-of-the-art of home mechanical ventilation and also provides specific guidance to Medicare contractors regarding home mechanical ventilation for treatment of both chronic respiratory failure (HMs) and respiratory insufficiency (bi-level devices).

#### **Definition of Respiratory Failure** <sup>6,7,8</sup>

Respiratory failure is the inability of the respiratory system to maintain gas exchange within normal limits. The degree of respiratory failure may range from mild to severe with the severity determining the urgency and extent of treatment. It is generally divided into 2 forms:

- 1) Oxygenation failure – inability to maintain PaO<sub>2</sub> of 60 mm Hg or greater on room air and,
- 2) Ventilatory failure – inability to maintain PaCO<sub>2</sub> of 45 mm Hg or below

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<sup>5</sup> King A. Long-Term Home Mechanical Ventilation in the United States. *Resp Care* 2012. 57: 921-30.

<sup>6</sup> Hill NS. Chapter 99. Ventilatory Failure in Murray and Nadel's Textbook of Respiratory Medicine 6<sup>th</sup> Edition Broaddas VC et al, eds. Saunders, Philadelphia 2015

<sup>7</sup> Grippe M. Respiratory Failure in Fishman's Pulmonary Diseases and Disorders 5<sup>th</sup> edition. Grippe, Elias, Fishman eds. McGraw Hill 2015.

<sup>8</sup> Fletcher EC, Lockett RA, Goodnight-White S, et al. A double-blind trial of nocturnal supplemental oxygen for sleep desaturation in patients with chronic obstructive pulmonary disease and a daytime PaO<sub>2</sub> above 60 mm Hg. *Am Rev Respir Dis*. 1992. 145(5):1070-6.

**Rationale:** With a definition of “respiratory failure” as the primary qualifying criterion to warrant home mechanical ventilation, physicians and suppliers will have clear pathways for appropriate use of home mechanical ventilators. The PaO<sub>2</sub> threshold of 60 mmHg was based on early well accepted criteria to enroll patients with chronic stable COPD in studies regarding the development of pulmonary hypertension. The PaCO<sub>2</sub> level is derived from standard accepted lab values upper limit of normal.

Respiratory failure can be acute, chronic or acute-on chronic. Oxygenation failure is related to the duration and rate of deterioration. Patients with acute oxygenation failure deteriorate over hours to days. Chronic oxygenation failure denotes relatively stable hypoxemia over months or years; acute-on chronic oxygenation failure means chronic oxygenation failure deteriorates over hours or days. Acute hypercapnic respiratory failure follows the same time course as acute oxygenation failure, but is differentiated from chronic by the pH level, which is compensated by bicarbonate retention in the case of chronic. Compensation is partial in the case of acute-on chronic hypercapnic respiratory failure.

Oxygenation and ventilator (hypercapnic respiratory) failure may coexist. In the presence of severe CO<sub>2</sub> retention in a patient breathing room air, hypoxemia is inevitable due to the effect of hypercapnia on alveolar gas exchange. Patients with milder respiratory failure may be able to maintain normal or near normal gas exchange under stable, resting conditions while awake, but gas exchange deteriorates when they are asleep, exercising or experience an exacerbation, often due to infections. These patients have restrictive or obstructive ventilatory or central respiratory drive defects that lead to oxygen desaturations (SaO<sub>2</sub> < 89%) with exercise or nocturnally.

### **Definition of Mechanical Ventilator**

A mechanical ventilator is a device capable of delivering pressurized gas (either through a secured artificial airway or through a mask or mouthpiece) in a manner that repeatedly supplies a physiological tidal volume to the lungs sufficient to improve or fully sustain respiration.

### **Definition of Mechanical Ventilation**

Mechanical ventilation is the use of a mechanical ventilator on a patient in whom interruption or failure of this device can reasonably be expected to lead to eventual or rapid clinical deterioration leading to medical harm or even death.

**Rationale:** After nearly two decades of use of the term “respiratory assist device” by CMS, confusion still abounds in the clinical community because these devices do not appear in the peer reviewed clinical literature or medical textbooks. CMS rejection of classifications by the Food & Drug Administration amplifies this confusion. Therefore, it is important to have concise

definitions of what constitutes a mechanical ventilator – the well accepted standard of care as part of a treatment plan for respiratory failure.

In essence, respiratory failure marks a progression from mild respiratory failure to a more serious life threatening condition. These are patients who are without the respiratory reserve needed to overcome minor insults to the respiratory system that a patient with normal physiology would possess. These patients require mechanical assistance with breathing in order to maintain their arterial blood gases at or close to their normal compensated state. Without this mechanical assistance these patients could experience exacerbation of symptoms such as fatigue, hypersomnolence and morning headache, and conditions such as heart failure, respiratory arrest, or death.

### **RECOMMENDATION: Recognize Specific Usage Categories of Mechanically Ventilated Patients in the Home**

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**Rationale:** The need for mechanical ventilation crosses a spectrum of patients including those with neuromuscular disease, COPD and other hypoventilatory syndromes. Such need can range from sporadic to continuous as chronic respiratory failure is not always a constant, 24 hour, ever present condition. Therefore, it is reasonable to acknowledge subcategories of care related to home mechanical ventilation. We propose the recognition of three distinct categories of mechanically ventilated patients as outlined below.<sup>9,10,11,12</sup> The references provide an overview of these conditions with the more precise data from randomized trials discussed in detail below. This recognition will assist physicians and suppliers as well as Medicare contractors in recognizing that chronic respiratory failure, as defined and documented, occurs within different Medicare populations and, despite the variance in actual need, the need is nevertheless reasonable and necessary, in accordance with Medicare statute and regulations.

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<sup>9</sup> Simonds A. Recent advances in respiratory care for neuromuscular disease. *Chest* 2006; 130: 1879–1876.

<sup>10</sup> COPD Working Group. Noninvasive positive pressure ventilation for chronic respiratory failure patients with stable chronic obstructive pulmonary disease (COPD): an evidence-based analysis. *Ont Health Technol Assess Ser* [Internet]. 2012; 12(9): 1–51.

<sup>11</sup> Struik FM, Lacasse Y, Goldstein R, Kerstjens HA, Wijkstra PJ. Nocturnal non-invasive positive pressure ventilation for stable chronic obstructive pulmonary disease. *Cochrane Database of Systematic Reviews* 2013, Issue 6. Art. No.: CD002878.

<sup>12</sup> Mokhlesi B, Kryger MH, Grunstein RR. Assessment and management of patients with obesity hypoventilation syndrome. *Proceedings of the American Thoracic Society* 2008; 5:218-25.

**NOTE:** We recognize that the Coverage & Analysis Group does not address payment issues for DME. We are **not** recommending different payment amounts for use of a home mechanical ventilator for treatment of chronic respiratory failure. However, we do believe the distinction of these three categories, when matched with an appropriate device, will dramatically improve the guidance to physicians on device selection and, in our view, actually reduce Medicare outlays if CMS concurs with the principles of our corollary request for integration into this policy specific policy guidance related to the use of bi-level devices. As those devices become more available to Medicare beneficiaries, demand for home mechanical ventilation will, in our view, lessen.

### **Subcategory #1: Extended/Continuous use of a mechanical ventilator**

**Patient Vignette:** A 65 year old man recovering from a major motor vehicle trauma with high cervical neck injuries was weaned from the ventilator and after accommodating to non-invasive mechanical ventilator support, his tracheostomy tube was removed. He was not able to tolerate being off the ventilator more than minutes at a time so was introduced to a home mechanical ventilator and transferred home to the care of his family.

**Rationale:** This classification of beneficiary would include but is not limited to patients with advanced cardiorespiratory or neuromuscular disease such as severe COPD, cystic fibrosis, muscular dystrophy, demyelinating diseases such as amyotrophic lateral sclerosis, diaphragm failure, primary and secondary inflammatory lung disease such as interstitial pneumonitis or related to complications of pre- and post-lung transplant. These patients may have co-morbidities such as heart and kidney failure further contributing to the respiratory condition requiring nearly continuous ventilatory support.

**This scenario** invariably covers the patient who may have been treated with an artificial airway two decades ago, but today the standard of care is to treat the patient with noninvasive ventilation allowing reduced costs, greater independence, mobility, and care in the home environment. Incidentally, the effort to obtain coverage for home mechanical ventilation actually emerged from efforts to transition children with a tracheostomy and ventilator

dependent from a permanent hospital setting to the home with their families.<sup>13,14,15</sup> At this time these patients are a small segment of the broad mechanical ventilation population.

The concept of removal of these devices leading to death (CAG 00052N) is problematic and needs to be amended. The concern is that when “leading to death” is interpreted as immediate or imminent death by the DME MACs in their LCDs, then many patients who are in appropriate need of sophisticated devices that require frequent and substantial servicing will not receive them. For example, a patient who requires ventilator support for much of the day as well as nocturnally is ***inherently not stable without ventilator support*** and is likely to die within days or weeks without this support, with the time to death becoming more immediate as the requirement for ventilator support approaches 24/7.

Today, many if not most of these patients are receiving noninvasive ventilation and to reserve home mechanical ventilators for only patients “with a securely intubated airway” ignores the reality that many such patients today are receiving noninvasive ventilation at home. It would place them at undue risk in the event of ventilator interruption. An example is a patient (provided by one of the authors to the DME MAC medical directors, per their request, one year ago) with muscular dystrophy who had received 24/7 noninvasive ventilation for 10 years and died two years ago when the RAD she was using became inadvertently disconnected from the power supply. The device, which her DME provided because the supplier believed she only qualified for RAD devices, had no ‘loss of power alarm’ and the problem was not detected until it was too late. Had this patient been provided a home mechanical ventilator with an internal backup battery and appropriate power alarms, it is likely that she would be alive today.

A policy that creates roadblocks for these devices because a patient is being ventilated noninvasively, or is not at threat of imminent death if there is a sudden interruption of ventilator support, threatens a narrow but specific patient population. This is especially true of patients with neuromuscular disease. If denials of home mechanical ventilators to this Medicare population due to a failure to meet the “leading to death” criterion, the policy assuredly leads to the deaths of some of these patients due to the circumstances in the patient scenario described above.

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<sup>13</sup> King A. Long-Term Home Mechanical Ventilation in the United States. *Resp Care* 2012. 57: 921-30.

<sup>14</sup> Bach JR, Intinola P, Alba AS, Holland IE. The ventilator-assisted individual: cost analysis of institutionalization vs rehabilitation and in-home management. *Chest* 1992; 101(1):26-30.

<sup>15</sup> Windisch W on behalf of the quality of life in home mechanical ventilation study group. Impact of home mechanical ventilation on health-related quality of life. *Eur Respir J* 2008; 32: 1328–1336.

This recommendation is also in line with criteria used in France<sup>16</sup> with its long-established and excellent home ventilator program. Patients on more hours of ventilator support during the day and night are provided not only with sophisticated home ventilator, but also qualify for a backup ventilator in view of the recognition that these patients are at high risk for deterioration if their primary device fails.

### **Subcategory #2: Mechanical ventilator use more than nocturnally alone**

**Patient Vignette:** A 65 year old woman with neuromuscular disease who was wheelchair bound presented with daytime hypersomnolence. The patient was noting progressive weakness and after tolerating nocturnal ventilation alone for some months, began to develop worsening hypercapnia and dyspnea during the day. She was introduced to optimal non-invasive nocturnal ventilatory support but also required daytime periods of assistance with a mouthpiece using a home mechanical ventilator.

**Rationale:** Patients in this subcategory require ventilators treatment but the patient is not in need of the ventilator support described with the same intensity as subcategory #1. These patients may have the same diagnoses as those listed in the first category above but their need for ventilator support is not as great. Nonetheless, they generally need more than just nocturnal support, often supplementing for a few hours intermittently during the daytime. Without this additional support, clinicians can reasonably expect insidious deterioration leading eventually to hospitalization or a greater clinical catastrophe. The amount of time on daytime ventilation increases depending on the rate of progression of the underlying process. Daytime mouthpiece ventilation is safe and has been associated with favorable survival rates and stabilization of vital capacity in patients with muscular dystrophy.<sup>17</sup> Although some of these patients may receive adequate support from a bi-level device via a nasal interface, they may require a specialized ventilator if mouthpiece ventilation is needed for optimal support.

Therefore, special consideration should be given to the broadly accepted clinical practice of using a ventilator capable of providing mouthpiece or 'sip' ventilation or equivalent type of support as is commonly used in patients with neuromuscular disease who suffer from severe

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<sup>16</sup> [http://www.codage.ext.cnamts.fr/cgi/tips/cgi-fiche?p\\_code\\_tips=1163030&p\\_date\\_jo\\_arrete=%25&p\\_menu=FICHE&p\\_site=AMELI](http://www.codage.ext.cnamts.fr/cgi/tips/cgi-fiche?p_code_tips=1163030&p_date_jo_arrete=%25&p_menu=FICHE&p_site=AMELI)

[www.codage.ext.cnamts.fr/codif/tips/index.php?p\\_site=AMELI](http://www.codage.ext.cnamts.fr/codif/tips/index.php?p_site=AMELI)

<sup>17</sup> Toussaint M, Steens M, Wasteels G, Soudon P. Diurnal ventilation via mouthpiece: survival in end-stage Duchenne patients. *Eur Respir J.* 2006 Sep; 28(3):549-55.

daytime dyspnea and persistent hypercapnia and this treatment mode is not available with a bi level device.<sup>18,19</sup> Although there have been no outcome studies regarding diurnal mouthpiece or equivalent assistance accessory, the benefit and convenience reported by patients and clinicians is well known. The only equipment that offers this type of ventilatory mode falls into the home mechanical ventilator category.

### **Subcategory #3: Nocturnal only use of a mechanical ventilator not successfully treated with a bi-level device**

**Patient Vignette:** A 72 year old moderately obese man with oxygen dependent COPD and mild OSA was hospitalized for COPD exacerbation and was initially treated with non-invasive ventilation and then stabilized. Repeated attempts to optimize the patient's nocturnal gas exchange condition were met with poor sleep, daytime dyspnea, and continued hypercapnia with a bi-level device. The patient was transitioned to a home mechanical ventilator using a volume targeted mode with a backup rate and improved allowing discharge to home.

**Rationale:** These clinical and coverage criteria may well be described in the current LCD 33800 and supporting clinical literature. As described in more detail in the bi-level coverage criteria discussed below, we take special issue however with the inappropriate restriction on the use of a bi-level with a backup rate. For patients using mechanical ventilation in this fashion (and the vast majority are on noninvasive ventilation), bi-level devices are generally sufficient; however, for both the complex mixed disease patient with recent exacerbation and the chronic home dwelling patient failing a bi-level regimen, a home mechanical ventilator may be needed.

Several studies have examined the routine use of a bi-level device without a backup rate after an acute hospitalization in severe COPD patients and have generally failed to demonstrate reduction in readmission rates beyond 3 months.<sup>20,21</sup> These reports also fail to make attempts at higher pressure delivery and larger guaranteed minute ventilation levels. **For more specific**

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<sup>18</sup> Cleary S, Misiaszek, J., Wheeler, S., Kalra, S., & Johnston, W. Using Lung Volume Recruitment Therapy to Improve Swallowing and Airway Protection for Individuals with ALS Amyotrophic Lateral Sclerosis *Amyotrophic Lateral Sclerosis*. 2010; 11(1):58-9.

<sup>19</sup> Khirani S, Ramirez A, Delord V, Leroux K, Lofaso F, Hautot S, et al. Evaluation of ventilators for mouthpiece ventilation in neuromuscular disease. *Respir Care* 2014; 59(9):1329-37.

<sup>20</sup> Casanova C, Celli B, Tost L, et al. D Long-term controlled trial of nocturnal nasal positive pressure ventilation in severe COPD. *Chest* 2000.118; 1582-1590.

<sup>21</sup> Galli, JA, Krahnke JS, Mamary J, Shenoy K, Zhao H and Criner GJ. Home noninvasive ventilation use following acute hypercapnic respiratory failure in COPD. *Resp Med* 2014; 108: 722-728.

**comments, please review our recommendations regarding bi-level devices integral to this reconsideration request.**

Although our priorities are to establish the three initial subcategories described above, there is an additional sub-category of patients who potentially need access to a mechanical ventilator, namely those patients who experience persistent hypercapnia and clinical deterioration on a bi-level device with or without a backup rate despite attempts at optimal use. Home mechanical ventilation devices are more akin to hospital ventilators in capabilities. The Kohnlein study<sup>22</sup> published last year demonstrated the value of targeting a certain reduction in PaCO<sub>2</sub> that was associated with a very impressive reduction in 1 year mortality rate from 33% in controls to 12% in ventilated patients. These authors utilized high pressures and a high back-up rate, termed high-intensity ventilation, which were set to improve or even normalize hypercapnia. Prior studies in COPD patients that have not demonstrated improvements in CO<sub>2</sub> levels when using NIV have not shown the same improvements in physiological endpoints or survival.

The same adverse outcomes associated with failure to improve CO<sub>2</sub> in COPD patients are almost certainly true for other forms of hypercapnic respiratory failure including advanced or complicated obesity hypoventilation, overlap syndrome (COPD and OSA), or neuromuscular disease patients using bi-level devices. As such, we believe that patients in category 3 should have initial access to a bi-level device with a backup rate as described further below but some may still need a home mechanical ventilator if this is documented to be inadequate.

If, after a reasonable trial period in hospital or at home (30 days) of a bi-level device used for at least 4 hours daily and at the highest pressures tolerated (minimum >12 cm H<sub>2</sub>O), there is no improvement in hypercapnia, or before that period of time the patient's hypercapnia clinically deteriorates (rise of >5mmHg), then the patient should be eligible for a trial of a home mechanical ventilator. These devices offer many more options than bi level devices that can provide more effective ventilator support and are more likely to improve or even normalize CO<sub>2</sub> through the delivery of higher pressures, greater levels of pressure support, synchronized expiratory phasing and enhanced modes such as targeted tidal volume ventilation.

### **Conclusion Addressing Home Mechanical Ventilators**

The recommendations above should not be difficult to implement. Using existing technology imbedded in the devices, usage is easily determined. This is a reasonable requirement for CMS and its contractors to consider and the medical societies submitting this request support a requirement that an ordering physician must specify subcategory usage and document the

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<sup>22</sup> Kohnlein T, Windisch W, Kohler D, et al. Non-invasive positive pressure ventilation for the treatment of severe stable chronic obstructive pulmonary disease: a prospective, multicentre, randomized, controlled clinical trial. *Lancet* 2014; Vol 2 (9): 698–705

clinical reasons for the recommendation. Usage technology is virtually omnipresent and would not be a burden to beneficiaries, physicians, or suppliers.

Adopting the clinical parameters suggested above, in tandem with documented usage, would add clarity and important guidance to physicians and suppliers. Furthermore, if adopted, these suggestions should enable appropriate use of more sophisticated frequent and substantially serviced equipment to recipients who stand to benefit from it and not arbitrarily denying it to the noninvasively ventilated group who are clearly in just as much need for more sophisticated equipment as the invasively ventilated patients.

**RECOMMENDATION: Meld the current LCDs for “respiratory assist devices” into the revised NCD for home mechanical ventilators, with three changes, one of which is related to technical verbiage and the remaining two changes are specifically clinical in nature.**

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- a. **Use medical terminology i.e. bi-level devices/mechanical ventilators for use in treatment of respiratory insufficiency, recognized by the medical community and the Food & Drug Administration to address coverage of devices for treatment of respiratory insufficiency;**
- b. **Eliminate the current requirement for oximetry testing in certain specified scenarios as there is no scientific basis for this requirement;**
- c. **Eliminate the current requirement for a Medicare beneficiary to “fail” therapy of a device without using a backup rate as there is no scientific basis for this requirement.**

### **Background**

The Durable Medical Equipment Medicare Administrative Contractors (DME MACs) have promulgated several identical local coverage determinations (LCDs) for respiratory assist devices, the most recent version dated October 1, 2015 (L33800). While many portions of these LCDs are sound, there are several specific provisions that have no scientific basis and are problematic to the appropriate treatment of certain Medicare beneficiaries. Ongoing efforts with the DME MACs to modify those problematic provisions have been fruitless. As noted in detail above, the relationship between these bi-level devices for treatment of respiratory insufficiency and home mechanical ventilators for treatment of chronic respiratory failure are inextricably linked.

### **Establish Description of Bi-Level Devices (MNT or MNS FDA classified ventilators) for Treatment of Respiratory Insufficiency**

While we acknowledge that both the CMS Central Office and its contractors refer to these devices as “respiratory assist devices (RADs),” the pulmonary medicine community refers to the verbiage of the Food & Drug Administration (FDA) as well as the peer reviewed clinical literature and medical textbooks which cite these devices as bi-level devices or mechanical ventilators for treatment of respiratory insufficiency. The term “respiratory assist device” is a creation of CMS, is not found anywhere in the clinical literature, and is confusing to the medical community because there are no specific definitions for identification of these devices in the LCDs promulgated to address these devices.

Here are excerpts from various user manuals for bi-level devices and we should emphasize several points:

Some bi-level devices are approved for treatment of OSA while others have multi-function approval. It is the progression of some diseases that can legitimately shift a device from one function to another.

- The device is indicated for the treatment of obstructive sleep apnea (OSA) in patients weighing more than 66 lbs. (30 kg). It is intended for home and hospital use.
- The device is indicated for the treatment of patients weighing more than 66 lbs. (30 kg) with obstructive sleep apnea (OSA), central and/or mixed apneas, or periodic breathing. It is intended for home and hospital use.
- The device is indicated to provide noninvasive ventilation for patients weighing more than 30 lbs. (13 kg) with respiratory insufficiency such as that associated with hypercapnic chronic obstructive pulmonary disease (COPD) or obstructive sleep apnea (OSA). The device is intended for home and hospital use.

**Justification for elimination of current requirements for oximetry testing in certain scenarios and elimination of current requirement for a Medicare beneficiary to “fail” therapy of a device without using a backup rate**

As noted above, we do accept the major policy decisions embedded in the current LCDs for bi-level devices. Therefore, we are not providing detailed information regarding the clinical appropriateness of use of these devices as those considerations are not being challenged. However, we do believe that specific changes to those policies would improve access to these devices and promote a stronger, less confusing environment for clinicians and equipment suppliers.

1. The most problematic obstacle to proper delivery of care to beneficiaries under the current guidelines is the restricted access to a backup rate device. There is new level I evidence supporting the initial use of a backup rate in COPD patients as explained below and this pathway is not permitted under the present coverage criteria. There is certainly supportive albeit lower level retrospective evidence for initial use of a backup rate also

in patients with hypoventilation syndromes as explained separately in that section below. We feel that if the long troublesome distinction between devices with vs without a backup rate is removed and decision-making left to the treating physician, appropriate initial treatment with a backup rate would be available to patients. This would further simplify the coverage criteria under these conditions as can be seen in this suggested revised policy.

2. An additional priority revision we are seeking is the elimination of any oximetry criteria for these same two categories of patients. As explained below, these patients are not suffering primarily from failed oxygenation but rather from failed ventilation, which is only indirectly and poorly assessed by oximetry, especially in patients on supplemental oxygen. Thus, the present criteria make little physiologic sense but can result in barriers to appropriate therapy for beneficiaries when oximetry criteria are not satisfied. There are no data to offer regarding the use of oximetry as necessary criteria to justify use of these ventilatory devices. We are suggesting that these criteria be removed altogether which, again, simplifies coverage criteria.

For ease of review, here are the specific changes we are recommending to the current LCDs for bi-level devices. **Revisions are noted in *italics*.**

### **Restrictive Thoracic Disorders**

In this category of patients, bi-level devices E0470 or E0471 are covered when criteria A – C are met. Based on our comments below, the current oximetry requirement “while breathing the beneficiary’s prescribed FIO<sub>2</sub>” in criteria B a. and b. (e.g., arterial blood gas and sleep oximetry) should be removed; the minimum recording time relative to documenting certain sleep oximetry oxygen saturation rates should be revised from 2 hours to 30 minutes; and criterion C should be clarified to emphasize the role of the treating physician in the decision-making process. With these changes, the suggested revisions to the category should read as follows:

An E0470 or E0471 device is covered when criteria A – C are met.

- A. There is documentation in the beneficiary’s medical record of a neuromuscular disease (for example, amyotrophic lateral sclerosis) or a severe thoracic cage abnormality (for example, post-thoracoplasty for TB).
- B. One of the following:
  - a. An arterial blood gas PaCO<sub>2</sub> *done while awake is greater than or equal to 45mm Hg, or*
  - b. Sleep oximetry demonstrates oxygen saturation less than or equal to 88% for greater than or equal to 5 minutes of nocturnal recording time (*minimum recording time of 30 minutes*), or

- c. For a neuromuscular disease (only), either i or ii,
  - i. Maximal inspiratory pressure is less than 60 cm H<sub>2</sub>O, or
  - ii. Forced vital capacity is less than 50% predicted
- C. *In the opinion of the treating physician*, chronic obstructive pulmonary disease does not contribute significantly to the beneficiary's pulmonary limitation.

**Rationale:** This change to the current LCD is discussed below under the Severe COPD section. Insisting upon a prolonged demonstration period of 2 hours desaturation puts patients at undue risk as also discussed below.

### **Severe COPD**

Current LCD policy covers an E0470 device if certain criteria are met. Additionally, an E0471 device is covered in either of two situations depending on the testing performed to demonstrate medical need. Based on our comments below, we recommend covering both E0470 and E0471 if the following criteria are met and removing the criterion related to sleep oximetry demonstrating specific oxygen saturation rates. The revised section should read as follows:

An E0470 or E0471 device is covered if criteria A-C are met.

*Patients with COPD must have GOLD Stage 3 or 4 airway obstruction and*

- A. An arterial blood gas PaCO<sub>2</sub> done while awake *is greater than or equal to 52 mm Hg.*
- B. Prior to initiating therapy, obstructive sleep apnea (OSA) and treatment with a continuous positive airway pressure device (CPAP) has been considered and ruled out *as the predominant reason for the hypercapnia in the opinion of the treating physician.* (Note: Formal sleep testing is not required if there is sufficient information in the medical record to demonstrate that the beneficiary does not suffer from some form of sleep apnea (Obstructive Sleep Apnea (OSA), CSA and/or CompSA) as the predominant cause of awake hypercapnia or nocturnal arterial oxygen desaturation).

If the above criteria for beneficiaries with *severe* COPD are met, either an E0470 or E0471 device (*based upon the judgment of the treating physician*) will be covered for the first three months of therapy.

If the above criteria are not met, E0470 or E0471 and related accessories will be denied as not reasonable and necessary.

**Rationale:** Recent level I evidence, especially from the Kohnlein<sup>21</sup> study described in detail below, supports the hypercapnia requirement. Chronic CO<sub>2</sub> retainers appear to be the group most likely to benefit. There should be a requirement that patients have severe COPD, so

similar to the Struik<sup>23</sup> et al study, we also recommend a requirement that patients should have GOLD Stage 3 or 4 airway obstruction. There should be no stipulation about the FIO<sub>2</sub> with the ABG as the issue at hand is about ventilation and not oxygenation. **We believe a more extensive review of the data here is crucial to support our major priority request to remove the backup rate criteria.**

### **Background**

COPD is the third leading cause of death in the U.S. and claimed 133,965 U.S. lives in 2009.<sup>24</sup> Chronic obstructive pulmonary disease (COPD) is a very common disease, affecting an estimated 12.7 to 24 million U.S. adults as of 2011.<sup>25,26</sup> COPD is also costly, with projected US costs of approximately \$49.9 billion in 2010.<sup>27</sup> It is also one of the diseases identified by CMS as having an excessively high rate of 30-day hospital readmissions. As COPD progresses, acute and chronic respiratory failure become more prevalent and contribute importantly to patient morbidity, especially due to exacerbations, with the accompanying need for hospitalization and risk of mortality.

The success of noninvasive positive pressure ventilation (NPPV) in treating hospitalized COPD patients with acute respiratory failure is well established. However, the nocturnal home use of NPPV to treat chronic respiratory failure in COPD is not as well established despite multiple studies over the past 2 decades. These studies have yielded variable and often conflicting results. More recently, scientific knowledge, clinical experience and technological innovations have substantially advanced our understanding of the role of NIV in the management of COPD for patients with chronic respiratory failure.

To implement a DME reimbursement structure for NPPV, CMS conceived the nomenclature of Respiratory Assist Device (RAD), which refers to bi-level ventilators used to provide intermittent and relatively short-term ventilatory assistance via a nasal or oronasal mask in a patient who is not harmed by short-term interruption of the device. Current Medicare coverage policy for use

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<sup>23</sup> Struik FM, Lacasse Y, Goldstein R, Kerstjens HA, Wijkstra PJ. Nocturnal non-invasive positive pressure ventilation for stable chronic obstructive pulmonary disease. *Cochrane Database of Systematic Reviews* 2013, Issue 6. Art. No.: CD002878.

<sup>24</sup> Mannino DM, Homa DM, Alkinbami LJ, Ford ES, Redd SC. Chronic obstructive pulmonary disease surveillance --- United States, 1971-2002; 51:1-16 [12198919].

<sup>25</sup> Chapter 4. Disease statistics in: In: National Institutes of Health National Heart, Lung, and Blood Institute Fact Book, Fiscal Year 2002. Bethesda, MD. NIH. 2003; 35-53.

<sup>26</sup> Global Initiative for Chronic Obstructive Lung Disease (GOLD) Guidelines. Global Strategy for the Diagnosis, Management, and Prevention of Chronic Obstructive Lung Disease: NHLBI/WHO Workshop Report. Halpin DM. Health economics of chronic obstructive pulmonary disease. *Proc Am Thorac Soc.* 2006 May; 3(3):227-33.

<sup>27</sup> Sin DD, Stafinski T, NG YC, Bell NR, and Jacobs P. The impact of chronic obstructive pulmonary disease on work loss in the United States. *Am J Respir Crit Care Med.* 2002; 165(5):704-707.

of RADs to treat chronic respiratory failure in COPD is based, in part, upon a 1998 NAMDRRC consensus conference and a CMS analysis of the use of RADs in COPD. Our aim is to re-examine the current CMS coverage policy considering that 16 years have elapsed since this was formulated, and more recent evidence is available.

The new evidence, which we summarize below, indicates that NPPV improves outcomes, including survival in COPD patients with chronic respiratory failure and may decrease hospitalization readmissions. These data also provide important information regarding 1) the level of resting hypercapnia in patients likely to benefit, 2) the use of higher inspiratory pressure settings during NPPV than have been used in previous studies 3) the importance of a backup respiratory rate, 4) lack of need to perform a sleep study or nocturnal 5-minute oxygen desaturation challenge to select COPD patients who demonstrate improvements in survival, and 5) reduced need for hospital readmission with the use of chronic intermittent nocturnal non-invasive positive pressure ventilation (NPPV).

We strongly believe the clinical evidence discussed below provides sufficient rationale to support changes to the current RAD policy in the context of our recommendations that follow.

### **Review of Recent Data**

For several decades, investigators have posited that nocturnal ventilator assistance would be helpful in patients with severe COPD to improve ventilator muscle function, nocturnal and consequently daytime gas exchange, and sleep quality and duration. However, due to the conflicting results of the many studies that have been done, clear recommendations on NPPV use in this situation have been difficult to make. As recently as 2013, a report from the Cochrane collaboration concluded that NPPV has “no clinically or statistically significant effect on gas exchange, exercise tolerance, quality of life, lung function, respiratory muscle strength or sleep efficiency [and] should only be used in the context of a clinical trial”.<sup>28</sup>

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<sup>28</sup> Struik FM, Lacasse Y, Goldstein R, Kerstjens HA, Wijkstra PJ. Nocturnal non-invasive positive pressure ventilation for stable chronic obstructive pulmonary disease. *Cochrane Database of Systematic Reviews* 2013, Issue 6. Art. No. CD002878.

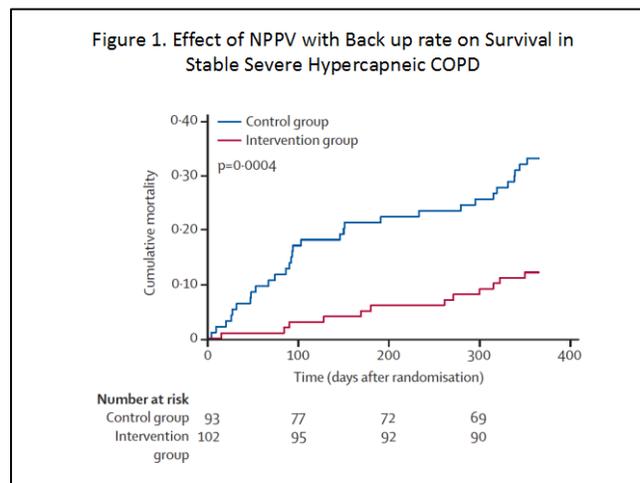
Recently, Kohnlein et al<sup>29</sup> published the results of a sentinel prospective multicentered randomized control trial of NPPV in patients with chronic stable hypercapnic COPD compared to optimized standard therapy. Patients had stage IV COPD with resting PaCO<sub>2</sub> of 51.9 mmHg or higher and pH > 7.35. Patients were comparable between the NPPV and control groups (Table 1).

**Table 1. Baseline Data**

	Control group (n=93)	Non-invasive positive pressure ventilation group (n=102)
Age, years	64.4 (8.0)	62.2 (8.6)
Male, n (%)	56 (60%)	65 (64%)
Body-mass index, kg/m <sup>2</sup>	24.5 (5.8)	24.8 (5.8)
FVC, % predicted	53.3% (13.8)	50.4% (13.3)
FEV <sub>1</sub> , % predicted	27.5% (8.9)	26% (11.0)
FEV <sub>1</sub> /FVC, %	41.2% (11.4)	40.4% (11.5)
Residual volume/total lung capacity, %	72.7% (8.9)	73.0% (8.5)
pH	7.39 (0.05)	7.39 (0.04)
PaCO <sub>2</sub> , kPa	7.7 (0.7)	7.8 (0.8)
PaO <sub>2</sub> , kPa*	8.7 (1.9)	8.6 (2.1)
SaO <sub>2</sub> , %*	90.8% (5.9)	90.3% (6.2)
HCO <sub>3</sub> <sup>-</sup> , mmol/L	33.9 (4.1)	34.3 (4.0)
Base excess, mmol/L	8.0 (3.9)	7.8 (3.8)
6-min walk distance, m	249.6 (145.3)	226.7 (121.2)
Long-term oxygen treatment, n (%)	60 (65%)	67 (66%)

Data are mean (SD), unless otherwise stated. FVC=forced vital capacity. FEV<sub>1</sub>=forced expiratory volume in 1 s. PaCO<sub>2</sub>=arterial carbon dioxide pressure. PaO<sub>2</sub>=arterial oxygen pressure. SaO<sub>2</sub>=arterial oxygen saturation. HCO<sub>3</sub><sup>-</sup>=bicarbonate. \*In patients with long-term oxygen treatment, oxygen was applied via nasal cannula at the previously prescribed flow rate.

NPPV was targeted to reduce baseline PaCO<sub>2</sub> by at least 20% or more, or to achieve PaCO<sub>2</sub> values lower than 48.1 mmHg. A preset pressure mode was used with a high back up rate (18-22 breath per minute). The mean inspiratory pressure was 21.6 cm H<sub>2</sub>O, the mean expiratory pressure was 4.8 cm H<sub>2</sub>O and the mean back up rate was 16.1 bpm (range 2-24). 70 patients (69%) had backup rates of 14.1 bpm or greater.



Mean NPPV usage was 5.6 Hours per day.

The primary outcome, 1-year all-cause mortality, was 12% in the NPPV group and 33% in the control group (Figure 1).

Secondary improvements were also seen in FEV<sub>1</sub>, PaCO<sub>2</sub> and pH in the NPPV compared to control group. No intervention-related complications were reported except for facial skin rash in 14% of patients.

These data show a much greater favorable effect of NPPV on overall survival in patients with chronic hypercapnic stable COPD than

has previously been reported. This benefit was stable over one year and continued to show a durable effect. This study differed from prior studies in chronic stable hypercapnic COPD by using a different treatment method to apply NPPV. NPPV settings were adjusted to reduce PaCO<sub>2</sub> by 20% or greater or to achieve a PaCO<sub>2</sub> lower than 48 mm Hg by using both higher

<sup>29</sup> Kohnlein T, Windisch W, Kohler D, Drabik A, Geiseler J, Hartl S, Karg O, Laier-Gorenveld G, Nava S, Shonhofer B, Schucher B, Wegscheider K, Criece C and Welte T. Non-invasive positive pressure ventilation for the treatment of severe stable chronic obstructive pulmonary disease: a prospective, mulitcentre, randomized, controlled clinical trial. *Lancet Resp Med* 2014; 2:698-705.

inflation pressures combined with a set backup rate. This approach likely explains the favorable outcome.

Another approach to initiating NPPV in severe COPD patients is to intervene after an admission for acute respiratory failure. This has garnered additional interest because of concerns about high hospital readmission rates in COPD patients. Two studies published within the past year have examined the role of NPPV in reducing hospital readmissions and improving other outcomes in severe COPD patients after a hospitalization for acute respiratory failure. Galli et al<sup>30</sup> conducted a retrospective, single-center, chart review on patients hospitalized in 2011 with a diagnosis of acute exacerbation of COPD (AECOPD), hypercapnia, and used NPPV during hospitalization at a single large urban academic medical center. A total of 166 patients were included and were divided into patients who used NPPV post discharge and patients who did not. Patients who used NPPV post discharge were comparable to those who did not in terms of severity of airflow obstruction, comorbid conditions and discharge medications. Patients who were discharged with NIV had a higher prevalence of obstructive sleep apnea and obesity hypoventilation than those who were not (Table 2).

**Table 2. Baseline Characteristics & Index Admission Data**

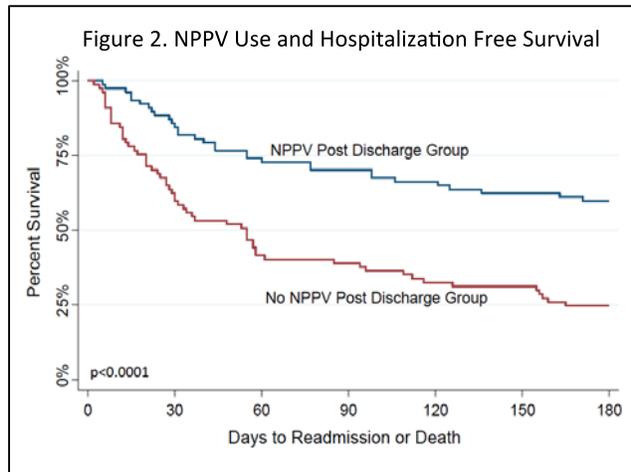
Baseline Characteristic	Used NPPV post discharge (N=78)	No NPPV post discharge (N=88)	P value
Age (years)	61.6±10.2	64.9±10.8	0.04
Body Mass Index (kg/m <sup>2</sup> )	33.7±12.0	30.6±13.0	0.11
Current Smoker – no. (%)	15 (19.2%)	24 (27.3%)	0.27
Race – no. (%):			
Caucasian	30 (38.5%)	27 (30.7%)	0.33
Black	40 (51.3%)	45 (51.2%)	1.00
Hispanic	8 (10.2%)	15 (17.0%)	0.26
Other	0 (0%)	1 (1.1%)	1.00
Male sex – no. (%)	33 (42.3%)	29 (33.0%)	0.26

<sup>30</sup> Galli, J.A., Krahnke, J.S., Mamary, J., Shenoy, K., Zhao, H. and Criner, G.J. Home noninvasive ventilation use following acute hypercapnic respiratory failure in COPD. *Resp Med* 2014; 108: 722-728.

Past Medical History – no. (%):			
OSA/OHS	37 (47.4%)	23 (26.1%)	0.006
Pulmonary HTN	20 (25.6%)	21 (23.9%)	0.86
CHF (EF<40%)	7 (9.0%)	11 (12.5%)	0.62
Diastolic Dysfunction	37 (47.4%)	35 (49.8%)	0.43
CAD	19 (24.4%)	16 (18.2%)	0.35
CVA	3 (3.9%)	7 (8.0%)	0.34
DM	37 (47.4%)	30 (34.1%)	0.08
HTN	64 (82.1%)	73 (83.0%)	1.00
Lung cancer (active)	2 (2.6%)	5 (5.7%)	0.45
Other cancer (active)	1 (1.3%)	4 (4.6%)	0.37
<b>Spirometry</b>			
FEV <sub>1</sub> (% predicted)	34.5±16.3 (n=57)	40±16.3 (n=47)	0.09
FVC (% predicted)	59±19.8 (n=57)	68.7±18.9 (n=47)	0.01
FEV <sub>1</sub> /FVC ratio	0.47±0.2 (n=57)	0.47±0.2 (n=47)	0.90
RV (% predicted)	154.6±65.7 (n=43)	152.6±65.8 (n=34)	0.89
TLC (% predicted)	92.9±28.4 (n=43)	98.9±27.9 (n=34)	0.36
RV/TLC ratio	58.2±11.8 (n=43)	56.7± 13.4 (n=34)	0.60

**Abbreviations:** OSA, obstructive sleep apnea; OHS, obesity hypoventilation syndrome; HTN, hypertension; CHF, congestive heart failure; CAD, coronary artery disease; CVA, cerebrovascular accident; DM, diabetes mellitus; FEV<sub>1</sub>, forced expiratory volume in 1s; FVC, forced vital capacity; RV, residual volume; TLC, total lung capacity; ICU, intensive care unit; PaCO<sub>2</sub>, arterial carbon dioxide tension; LABA, long acting beta agonist; SABA, short acting beta agonist; ICS, inhaled corticosteroid.

Patients in the NPPV post discharge group demonstrated superior event-free survival compared to the no-NPPV post discharge group ( $\chi^2 = 23.8$ ,  $p < 0.0001$ ) (Figure 2). The NPPV post discharge group had a statistically significant reduction in hospital readmissions (40% versus 75%,  $p < 0.0001$ ) through 180 days from the index admission.



A multivariate analysis was performed using a Cox regression model to identify baseline characteristics associated with reduced event-free survival. No NPPV at discharge, home O<sub>2</sub> use, LABA use, and pulmonary HTN were variables associated with reduced event free survival. The two study groups were subsequently matched with the use of propensity scores. Propensity scores for group matching were calculated using the variables of age, BMI, FEV<sub>1</sub>, OSA/OHS, PaCO<sub>2</sub>

at discharge, home O<sub>2</sub>, and admission date. The matching process resulted in 74 patients from the NPPV post discharge group being statistically matched with 74 patients from the no NPPV post discharge group. After matching with propensity scores, the characteristics of OSA/OHS and PaCO<sub>2</sub> at discharge still varied between groups. Subjects who did not use NPPV post discharge had inferior event free survival through 180 days after statistical matching when compared to patients who used NPPV post discharge (HR 3.33, 95% CI 2.07-5.34,  $p < 0.0001$ ).

These data demonstrate that following an admission for acute exacerbation complicated by acute hypercapnic respiratory failure, patients who used bi-level NPPV post discharge at home on a daily basis had lower readmission rates, reduced readmissions requiring a stay in the intensive care unit, and improved event-free survival. Compared to patients without NPPV post discharge, the NPPV group also tended to have more severe obstruction, and yet outcomes were improved. Although the data are retrospective, the investigation reflects the current “real world” clinical use of NPPV in patients with severe COPD exacerbation who are hospitalized and treated with NPPV during the hospitalization. These data suggest the importance of continuing with NPPV therapy as an outpatient post discharge and on a continuing nocturnal basis although the retrospective design precludes drawing firm conclusions.

Another study by Struik et al<sup>31</sup> examined outcomes of severe COPD patients discharged after an admission for hypercapnic respiratory failure (all required NPPV except 12-13% who were intubated). This yearlong randomized controlled trial from the Netherlands allocated 101 patients to continue NPPV after discharge and 100 patients to standard therapy including long-term O<sub>2</sub> supplementation as indicated. At baseline, patients had GOLD Stage 3 or 4 airway obstruction; average age was approximately 64 years; BMI 25 kg/m<sup>2</sup>; FEV<sub>1</sub> % 26 and PaCO<sub>2</sub> 55 to 60 with no significant differences between the NPPV group and controls. The authors did

<sup>31</sup> Struik FM, Lacasse Y, Goldstein R, Kerstjens H, Wijkstra PJ. Nocturnal non-invasive positive pressure ventilation for stable chronic obstructive pulmonary disease. *Thorax* 2014; 69: 826-834.

not assess the prevalence of OSA. NPPV patients were treated for a year with average IPAP 21 cm H<sub>2</sub>O, EPAP 5 cm H<sub>2</sub>O and backup rate 16, and average NPPV utilization among the 54 completers was 6.9 hours nightly. There were no significant differences in readmissions, mortality (22 in each group) or blood gases, and there was a trend for better quality of life using the Severe Respiratory Insufficiency questionnaire. The authors concluded that NPPV was not helpful in their study to reduce readmission or mortality rates for a year following admission of COPD patients for acute respiratory failure, but that the trend toward better health-related quality of life questionnaire deserved further study.

The conflicting data of these two recent studies preclude making firm recommendations, but a major difference between the studies may be the prevalence of OSA/OHS that was substantially higher in the NPPV group of the Galli study. The combination of OSA and COPD, referred to as the “overlap syndrome”, may be particularly likely to benefit from NPPV as discussed in a nicely organized comprehensive review by Pronzato.<sup>32</sup>

The new studies described above provide important information to warrant review and change of the current coverage guidelines for approval of bi-level devices in the treatment of patients with hypercapneic COPD. In aggregate, they indicate subgroups that show benefit: 1) patients with baseline PaCO<sub>2</sub>  $\geq$  52 mmHg, 2) a possible role in hypercapneic COPD patients treated in the hospital with acute on chronic respiratory failure, 3) COPD patients with comorbid COPD and obesity-hypoventilation, and 4) the application of a new treatment method to increase efficacy of chronic nocturnal ventilation using the combination of higher inflation pressures and the routine use of sufficient backup rates.

As stated above, we also support an NCD that would delete the oxygen desaturation requirement in the current LCDs for purposes of simplification and making the qualifications more consistent with the recent evidence. It is not consistent with the physiologic principles under discussion. Finally, a prolonged nocturnal monitoring period (2 hours) to document potential hypoxemia places patients at undue risk.

We recognize that this recommendation to eliminate the oximetry criterion for severe COPD is at odds with the one we are making for restrictive thoracic disorders, but there is very good rationale. In restrictive disorders, nocturnal desaturations herald the onset of nocturnal hypoventilation in patients who have not yet begun retaining CO<sub>2</sub> during the daytime. Ward et al<sup>33</sup> have shown better outcomes in patients with restrictive thoracic disorders and daytime

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<sup>32</sup> Pronzato C. Chronic obstructive pulmonary disease and obstructive sleep apnea. Association, consequences and treatment. *Monaldi Arch Chest Dis.* 2010; 73(4):155-61

<sup>33</sup> Ward S, Chatwin M, Heather S, Simonds AK. Randomised controlled trial of non-invasive ventilation (NIV) for nocturnal hypoventilation in neuromuscular and chest wall disease patients with daytime normocapnia. *Thorax* 2005; 60:1019-24.

hypercapnia when NPPV is started at the onset of nocturnal desaturations rather than awaiting the onset of daytime hypoventilation. Thus, it is important to retain this qualification in that category.

As discussed above, the combination of severe COPD and OSA (overlap syndrome) may be a particularly favorable one for responsiveness to NPPV. Whether or not CPAP is as efficacious as NPPV in such patients has not been examined. In fact, the Kohnlein study did not consider whether patients had sleep apnea at all; yet they showed very impressive favorable results. The current LCDs cover a bi-level device without backup if certain criteria are met during the first three months of therapy. A bi-level device with backup will not be covered for a patient with COPD during the first three months because it assumes therapy with a bi-level device without backup with proper adjustments of the device's settings and patient accommodation to its use will usually result in sufficient improvement without requiring a backup rate.

Once again, there is no rationale for proceeding with the current limitations in existing LCDs. There is no evidence to support the contention that patients with severe COPD usually have "sufficient improvement without the need of a backup rate".

#### **Central Sleep Apnea or Complex Sleep Apnea**

Currently, an E0470 or E0471 device is covered if certain criteria are documented. Based on our comments below, an E0601 device should also be covered. The revised section should read as follows:

An E0601, E0470 or E0471 device is covered when, prior to initiating therapy, a complete facility-based attended PSG is performed documenting the following (A and B):

- A. The diagnosis of central sleep apnea (CSA) or complex sleep apnea (CompSA); and
- B. Significant improvement of the sleep-associated hypoventilation with the use of an *E0601*, E0470 or E0471 device on the settings that will be prescribed for *initial use at home*.

If all of the above criteria are met, either an *E0601*, E0470 or an E0471 device (based upon the judgment of the treating physician) will be covered for beneficiaries with documented CSA or CompSA for the first three months of therapy.

If all of the above criteria are not met, then *E0601*, E0470 or E0471 and related accessories will be denied as reasonable and necessary.

**Rationale:** In the recent SERVE-HF trial<sup>34</sup> patients with symptomatic CHF with reduced LV function treated with the previously preferred E071 device adaptive servo-ventilator unexpectedly had a higher mortality. The manufacturer recommended that the device not be used in such patients. This limits alternative therapy for central apnea in these patients based on current American Academy of Sleep Medicine guidelines<sup>35</sup> to oxygen and CPAP (E0601) which is not permitted under current LCD policies. If this recommendation is not adopted, an E0470 device will be ordered at a higher cost to CMS and simply set in a CPAP mode. Once again for criteria B, it should not force oxygen therapy on the patient as it has nothing to do with assessing central apnea.

### **Hypoventilation Syndrome**

Currently an E0470 device is covered if certain criteria are met. As discussed throughout this document we believe the policy should also apply to E0471 based on our suggested revisions below. With these changes it is no longer necessary to set separate criteria E0471. The revised section should read as follows:

An E0470 or E0471 device is covered if both criteria A and B and either C or D are met.

- A. An initial arterial blood gas PaCO<sub>2</sub> done *while awake is greater than or equal to 45 mm Hg.*
- B. Spirometry shows an FEV1/FVC greater than or equal to 70%. (Refer to SEVERE COPD (above) for information about device coverage for beneficiaries with FEV1/FVC less than 70%). *This also includes patients with parenchymal lung disease leading to restriction AND hypercapnia that do not meet the criteria for the first category, Restrictive Thoracic Disease.*
- C. An arterial blood gas PaCO<sub>2</sub> done during sleep or *immediately upon awakening shows the beneficiary's PaCO<sub>2</sub> worsened greater than or equal to 7 mm HG compared to the original result in criterion AA (above).*
- D. A facility-based PSG or home sleep test (HST) demonstrates oxygen saturation  $\leq 88\%$  for  $\geq 5$  minutes of nocturnal recording time (*minimum recording time of 30 minutes*) that is not caused by *persistent untreated sleep disordered breathing events – i.e., AHI is shown to be less than 10. If there are persistent sleep disordered breathing events or oxygen saturation  $\leq 88\%$  for  $\geq 5$  minutes of nocturnal recording time (minimum recording time of 30 minutes), they are occurring with CPAP already at 16 cmH<sub>2</sub>O or the highest patient tolerated level.*

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<sup>34</sup> Cowie MR, Woehrle H, Wegscheider K, Angermann C, Pia d'Ortho M, Erdmann E, Levy P, Simonds AK, Somers VK, Zannad F, and Teschler H. Adaptive Servo-Ventilation for Central Sleep Apnea in Systolic Heart Failure. N Engl J Med 2015; 373:1095-105.

<sup>35</sup> Aurora RN, Chowdhuri S, Ramar K, Bista SR, Casey KR, Lamm CI, Kristo DA, Mallea JM, Rowley JA, Zak RS, Tracy SL. The treatment of central sleep apnea syndromes in adults: practice parameters with an evidence-based literature review and meta-analyses. SLEEP. 2012; 35(1):17-40.

(Refer to the Positive Airway Pressure Devices LCD for information about E0470 or E0471 coverage for obstructive sleep apnea.)

If the above criteria are not met, E0470 or E0471 and related accessories will be denied as not reasonable and necessary.

**Rationale:** As with the COPD discussion above, criteria should not force oxygen therapy on the patient when assessing hypercapnia.

This category also should allow patients with parenchymal lung disease leading to restriction AND hypercapnia to be treated with an E0470 or E0471 device. There was never a means to treat a small array of complex interstitial lung disease patients with restrictive parenchymal lung disease that did not fit in the first category, Restrictive Thoracic Disorders. This is especially crucial for many patients waiting for or after lung transplantation, for example interstitial pulmonary fibrosis. As with the COPD discussion above, criteria should not force oxygen therapy on the patient when assessing hypercapnia

The predominant patient profile in this category will be patients with obesity hypoventilation but a smaller number of less studied other diseases will also fulfill the need as stated in the suggested changes for item B in this category above. Two studies both in the obesity hypoventilation patient population provide the best evidence for the change in item D.<sup>36, 37</sup><sup>14,15</sup> These studies were randomized clinical trials both demonstrating the clear benefit of this therapy with improved oxygenation by oximetry and further reduction of the sleep disordered breathing events by polysomnography. As opposed to the COPD category explained above, the evidence does support the use of oximetry and polysomnography in the demonstration of benefit over CPAP (E0601 device) for a BPAP with or without a backup rate (E0470, 471) in this hypoventilation syndromes category (See studies by Masa et al and Contal et al as referenced below).

We further recommend elimination of the requirement for “An arterial blood gas PaCO<sub>2</sub>, done during sleep or immediately upon awakening, and breathing the beneficiary’s prescribed FIO<sub>2</sub>, shows the beneficiary’s PaCO<sub>2</sub> worsened greater than or equal to 7 mm HG compared to the

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<sup>36</sup> Carrillo A, Ferrer M, Gonzalez-Diaz G, et al. Noninvasive ventilation in acute hypercapnic respiratory failure caused by obesity hypoventilation syndrome and chronic obstructive pulmonary disease. *Am J Respir Crit Care Med* 2012; 186:1279-85.

<sup>37</sup> Masa JF, Corral J, Alonso ML, Ordax E, Tronconso MF, Gonzalez M, Lopez-Martinez S, Marin JM, Marti S, Diaz-Cambriles T, Chiner E, Aizpuru F, and Egea C, on behalf of the Spanish Sleep Network. Efficacy of Different Treatment Alternatives for Obesity Hypoventilation Syndrome. Pickwick Study. *Am J Respir Crit Care Med* 2015; 192: 86-95.

original result in criterion A.” This existing criterion in the current LCDs was arbitrarily placed by the DME MAC directors to presumptively help distinguish hypoventilation patients from OSA patients. This criterion exists nowhere else in the literature and under our recommendations the patients in this hypoventilation category are already distinguished by the recommendation that persistent hypoxemia “is not caused by persistent untreated sleep disordered breathing events.”

### **Conclusion Addressing Bi-Level Devices**

As with the HMV recommendations described above, the bi-level recommendations should also not be difficult to implement and in fact vastly simplifies existing coverage criteria. Using existing technology imbedded in the devices, usage is easily determined. By adopting the HMV and bi-level clinical parameters suggested above, in tandem with documented usage, would add clarity and important guidance to physicians and suppliers. Again we emphasize that if all are adopted, these suggestions should enable appropriate use of capped rental equipment and the more sophisticated frequent and substantially serviced devices for recipients who stand to benefit from it and not arbitrarily deny it to the noninvasively ventilated group who are clearly in just as much need for more sophisticated equipment as the invasively ventilated patients.