April 22, 2015

Ms. Tamara Syrek Jensen
Director
Coverage and Analysis Group
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244:

Dear Ms. Syrek Jensen:

On behalf of the ALS Association, the American Association for Respiratory Care, the American College of Chest Physicians, the American Thoracic Society, the Cystic Fibrosis Foundation, the COPD Foundation, the International Ventilator Users Network, the National Association for Medical Direction of Respiratory Care, the Pulmonary Fibrosis Foundation, the Pulmonary Hypertension Association and the United Spinal Association, we are submitting this request for changes to "Decision Memo for Noninvasive Positive Pressure RADs for COPD" (CAG-00052N) dated June 29, 2001. This specific Decision Memo is cited as the medical rationale for subsequent policy changes cited in L11504 in December, 2014 and again in L33800, an LCD posted by all four DME MACs with an effective date of October 1st, 2015. While we fully recognize that this Decision Memo is not integral to any National Coverage Determination, this request for updating the Decision Memo should be addressed without the formal need to promulgate an NCD.

Individuals as well as societies have engaged the DME MACs in various discussions related to this matter, and the DME MACs continue to signal to us that they are bound by this Decision Memo and have virtually no flexibility as long as it remains "on the books." Therefore, we are asking for a revision of the 2001 Decision Memo to reflect the current science of chronic ventilator management which will provide important guidance to the DME MAC medical directors as they move forward to refine and improve existing policies related to home mechanical ventilation.

Since the publication of this Decision Memo there have been significant changes in the science and documented effectiveness of noninvasive mechanical ventilation that, in most clinical scenarios, is the preferred ventilator modality over mechanical ventilation that involves an artificial airway (tracheostomy or intubation). To require the establishment of an artificial airway for long term mechanical ventilation is contrary to current standards of care and we ask that you consider carefully the recommendations included in this request for review.

Background: The June 29th Decision Memo states that noninvasive mechanical 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." Revised LCD L33800, scheduled to take effect October 1, 2015 specifically cites the Decision Memo as the basis for device selection based on the severity of the beneficiary's condition. Given that

justification for what we interpret as extremely problematic policies if implemented, modifications in the Decision Memo are necessary. Perhaps as problematic is the reality that two HCPCS codes, E0461 and E0464 have similar descriptors that refer to noninvasive ventilation yet can be interpreted to be contrary to the 2001 Decision Memo.

We fully appreciate CMS and contractor policies that are formulated to ensure that appropriate mechanical ventilation devices are provided to reflect documented beneficiary need. Growth in utilization of one category of ventilator, billed under E0464, further validates the standard of care for mechanical ventilation without an artificial airway. The transition from noninvasive mechanical ventilation to invasive mechanical ventilation further can complicate this issue and is a challenge to physicians as well as suppliers.

Under current policies, it is notably easier for a prescribing physician to order an E0464 or similar home mechanical ventilator than it is to order devices that CMS calls "respiratory assist devices" or RADs. As you well know, that term is a creation of HCFA/CMS and is antithetical to not only FDA classifications but the term does not appear as accepted clinical terminology in the peer reviewed literature. Given the relative ease with which physicians can prescribe E0464 devices and the significant difficulty in prescribing less expensive RADs, often the more clinically appropriate devices, the problem of exponential growth is self-inflicted by CMS's own policies. We believe that adjustments to existing policies, as recommended in detail below, could be used by CMS and its contractors to improve access to certain mechanical ventilators (i.e. called respiratory assist devices by the Agency) as well as to ensure that beneficiaries who receive mechanical ventilation under the broad "frequent and substantial servicing (fss)" category retain access to those devices even though these beneficiaries are not intubated via endotracheal intubation or tracheostomy.

Mechanical ventilation in the home – 2015: Advances in noninvasive positive pressure ventilation (NPPV) have been dramatic in the past two decades. Intensive care units across the country now routinely use noninvasive ventilation in certain forms of acute respiratory failure because of the documented reduction in morbidity and mortality as well as time in the ICU and hospital. These techniques almost simultaneously have gravitated into various settings including the SNF and LTACH where mechanical ventilation is often a relatively common component of post-acute care. That shift to noninvasive ventilation is also pronounced in the home setting.

Under the interpretation of the DME MAC policies, the only legitimate access to ventilators that fit into the fss payment category is a clinical scenario that involves an artificial airway. Ironically, the DME MAC medical directors reached out to NAMDRC, one of the signatories of this request, in March 2014 to develop a "white paper" on Home Mechanical Ventilation. That effort was undertaken by eight nationally recognized experts in that specific field and submitted late last Fall. As best we can determine, the recommendations included in that document have been ignored in L33800 and the premises of CAG 00052N from 2001 remain intact in the newer document. That white paper is now being reformatted and will be submitted for peer review publication shortly.

In 2015, ventilators that fit into the E0464 and other fss payment categories are prescribed for beneficiaries who suffer from a range of diagnoses as described in further detail below. Importantly, the vast majority of these beneficiaries have no "secured artificial airway", as evidenced by a review of claims data that shows a very small number of replacement tracheostomy tubes covered under the program. We recognize, however, that one must not presume, therefore, that all beneficiaries in the fss payment category are appropriately placed in that category.

Recommendations for change in CAG00052N Decision Memo: As discussed above, the primary consideration for device selection for covered clinical indications should not be the presence of an artificial airway. Rather, it should be based, in part, on specific clinical need tied to the amount of time a physician determines that ventilatory support is necessary to effectively manage the beneficiary's condition(s). We would first like to propose a definition of a mechanical ventilator and the process of mechanical ventilation.

1. 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.

2. 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.
   We further propose the following 3 distinct categories of mechanically ventilated patients:

   1. <u>Use of a mechanical ventilator 16 hours/day or greater.</u>
   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 dependence from a permanent hospital setting to the home with their families. [i, ii, iii] These patients are a small segment of the broad mechanical ventilation population.

We suggest using hours of use because the concept of removal of these devices leading to death is problematic and needs to be clarified. The concern is that if "leading to death" is interpreted as immediate death, then many patients who are in appropriate need of sophisticated devices that require frequent and substantial servicing will not receive them. A patient who requires ventilator support more than 16 hours daily is not stable without ventilator support and is likely to die within days or weeks without interruption, 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 E0464 and similar ventilators for only patients "with a securely intubated airway" not only ignores the reality that many such patients today are receiving noninvasive ventilation at home, but also places them at undue risk in the event of ventilator interruption. An example is a patient of one of the authors (of the white paper) with muscular dystrophy who had received 24/7 noninvasive ventilation for 10 years and died 2 years ago when the RAD she was using became inadvertently disconnected from the power supply. The device, which her DME provided because they believed she only qualified for RAD devices, had no loss of power alarm and the problem wasn't detected until it was too late. Had this patient been provided an E0464 device with an internal backup battery and appropriate power alarms, it is likely that she would be alive today.

A policy that removes payment 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 E0464 devices were denied to them due to a failure to meet the "leading to death" criteria, the rule would assuredly lead to the deaths of some of these patients due to the circumstances in the patient scenario described above.

This recommendation is also in line with criteria used in France[iv] with its long-established and excellent home ventilator program. Patients on 16 or more hours of ventilator support are provided not only with sophisticated ventilators such as those in the E0464 category, 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.

2. **<u>Use of a mechanical ventilator greater than nocturnally alone or approximately > 8 hours, but<16 hrs/24 hrs.</u>**

These devices, labeled by FDA as ventilators but referred to by CMS as RADs, may involve a back-up rate that is warranted by clinical documentation in the medical record but the patient is not in need of the hours of ventilator support described above. They may have the same diagnoses as those listed in the first category above but their need for ventilator support isn't 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. Special consideration should be given to the broadly accepted clinical practice of using a ventilator capable of providing mouthpiece or sip ventilator support as is commonly used in patients with neuromuscular disease who suffer from severe daytime dyspnea and persistent hypercapnia.[V] The only ventilators that offer a specific mouthpiece ventilation mode fall into the EO464 category.

3. <u>Use of a mechanical ventilator (RAD) just nocturnally or up to 8 hours /24 hrs.</u>

These clinical and coverage criteria are already well described in the current proposed LCD 33800 and supporting clinical literature. We take special issue however with the inappropriate restriction on the use of a RAD with a backup rate as clarified in the argument below. For patients using mechanical ventilation in this fashion (and the vast majority are on noninvasive ventilation), RADs as defined by CMS are generally sufficient. There are two most concerning criteria applied to COPD patients which have been driving practitioners to prescribe E0464 devices. First is the criterion for an "S" mode device rather than one with a backup rate for the first 2 months. Recent evidence from Kohnlein et al[iv]hat demonstrates very impressive clinical improvements including survival when patients were treated with high inspiratory pressures and backup rates supports the idea that use of a backup rate may improve outcomes. Presently, to require withholding a backup rate for 2 months makes no physiologic sense, is not supported by evidence, and using a backup rate adds relatively minor if any additional reimbursement costs. The determination to use a backup rate should no longer be made by payers, but should rather be a clinical decision made by the patient's physician.

The second concern is the requirement for five consecutive minutes of desaturation to 88% or below during oximetry with the patient using the usual FIO2. Once again, this requirement **<u>is not evidence based</u>** nor does it have any defensible rationale. The use of supplementary O2 could mask significant hypoventilation that could have adverse effects on respiratory drive and cardiovascular function, yet never be detected via oximetry. These criteria have made it difficult to qualify COPD patients, encouraging the use of alternative means of acquiring ventilator support (i.e. the E0464 code). We strongly encourage CMS to remove these criteria, enabling practitioners to appropriately use RADs for severe COPD patients, and reverse the migration toward the E0464 code.

- **Failure to lower CO2 levels in hypoventilating patients despite appropriate use of a RAD**

There is an additional sub-category of patients who potentially also need access to a mechanical ventilator, namely those patients who experience persistent hypercapnia on a RAD device with or without a backup rate despite optimal use. Home mechanical ventilation devices are more akin to hospital ventilators in capabilities. The Kohnlein[V]

study published last year demonstrated the value of targeting a certain reduction in PaCO2 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 CO2 levels when using NIV have not shown the same improvements in physiological endpoints or survival.

The same adverse outcomes associated with failure to improve CO2 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 RAD devices. As such, we believe that patients in categories 2 and 3 should have initial access to a RAD with a backup rate. If, after a reasonable trial period (30 days) of a RAD device used for at least 4 hrs daily and at the highest pressures tolerated (minimum $\geq$12 cm H20), there is no improvement in hypercapnia, or before that period of time the patient's hypercapnia clinically deteriorates (rise of $\geq$5mmHg), then the patient should be eligible for a trial of a sophisticated ventilator under the E0464 code. These devices offer many more options than RADs that can provide more effective ventilator support and are more likely to improve or even normalize CO2 through the delivery of higher pressures, greater levels of pressure support, synchronized expiratory phasing and enhanced modes such as target tidal volume ventilation.

If, after a reasonable trial period (30 days) of a RAD device used for at least 4 hrs daily and at the highest pressures tolerated (minimum $\geq$12 cm H20), there is no improvement in hypercapnia, or before that period of time the patient's hypercapnia clinically deteriorates (rise of $\geq$5mmHg), then the patient should be eligible for a trial of a sophisticated ventilator under the E0464 code.

In conclusion, the recommendations above should not be difficult to implement. Hours of use/24 hours is easily determined using existing technology imbedded in the devices. This is a reasonable requirement for CMS and its contractors to consider. The 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 actual usage, would add clarity to a modified Decision Memo. 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. Therefore, a Decision Memo change that clarifies for the DME MAC contractors that reasonable criteria to afford access to the two less intensive categories noted above would ensure that less ill patients have access to more appropriate, less expensive, more easily portable devices and their providers will not be forced to seek alternative pathways due to the regulatory barriers, as has been the case recently.

One of the Associations involved with the development of this request, NAMDRC, is coordinating this response and we will be contacting you shortly to schedule a meeting in Baltimore to further discuss this important matter. You should certainly feel free to contact any of the organizations which are supporting this submission to you, and NAMDRC will be glad to coordinate any such dialogue with you and your colleagues.

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[i] King A. Long-Term Home Mechanical Ventilation in the United States Respir Care 2012; 57(6): 921–930.

[ii] 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.

[iii] W. Windisch* on behalf of the quality of life in home mechanical ventilation study group Eur Respir J 2008; 32: 1328–1336

[iv] The citation for the 16hr rule that the French use is this link: http://www.codage.ext.cnamts.fr/cgi/tips/cgi-fiche?p_code_tips=1163030&p_date_jo_arrete=%&p_menu=FICHE&p_site=ameli

[v] 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, Criee 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 Sept 2014; Vol 2 (9): 698–705