December 17, 2018

The Honorable Seema Verma
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: Public Comments on New Product Categories
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: Competitive Bidding Product Categories

Dear Administrator Verma:

The American Academy of Sleep Medicine (AASM) appreciates the opportunity to provide public comments on the competitive bidding product categories. The AASM is a membership organization representing over 10,000 sleep medicine practitioners and sleep centers. The AASM improves sleep health and fosters high-quality, patient-centered care through advocacy, education, strategic research and practice standards.

The competitive bidding process, in its current configuration has not been effective in controlling costs for sleep-disordered breathing outside of OSA. We are all keenly aware of the OIG report of 2016, which has highlighted the rapid escalation of costs for home based non-invasive ventilation using Life Support Mechanical Ventilation (LSMV) with a non-invasive interface (E0466). The AASM has several additional suggestions that may contribute to the Agency's efforts to control costs for sleep-disordered breathing including: 1) Review and potential revision of the Respiratory Assist Device (RAD) guidelines, in order to ensure that they are aligned with the medical literature and current standards of care 2) Continue providing ongoing in-home Respiratory Therapist (RT) support for the life of the device, 3) Prioritize the use of E0466 for those who are not appropriate for a bilevel positive airway pressure (BPAP) device and 4) Ensure that all bids include support for the basics: humidification, electronic monitoring and multiple interfaces.

The care of those with sleep-related breathing disorders other than OSA, were not previously adequately addressed. In 1998, the treatment of other sleep-disordered breathing disorders, such as central sleep apnea, hypoventilation syndromes, restrictive thoracic disorders (RTD), and severe chronic obstructive pulmonary disease (COPD), were addressed in the RAD guidelines developed in collaboration between physicians and CMS. A RAD would be best known by physicians as a BPAP device.

These RAD guidelines no longer meet the needs of the community, as they do not allow physicians to provide adequate therapy. The following are some examples of this:

1) Hypoventilation – Patients with severe hypercapnia due to obesity may require hospitalization for symptomatic, even life threatening, complaints. The need to discharge patients on PAP therapy is well documented, but the RAD guidelines unrealistically limit the ability to use a BPAP device. The guidelines require multiple hard-to-obtain tests for hospitalized patients include sleep studies, pulmonary function tests, overnight oximetry and arterial blood gas testing, off therapy. The guidelines have not kept pace with clinical needs, as a life-threatening hypercapnia patient cannot safely be taken off therapy to obtain these tests.

2) COPD – Frequent hospital re-admissions for acute exacerbation of COPD is well recognized by CMS, and to reduce these episodes there is a focus on providing home BPAP for use during sleep. Current data supports that the reduction in hypercapnia is the key to success, but the RAD guidelines do not reflect this. The guidelines require an overnight oximetry to prove ongoing hypoxemia. These tests are typically not available in hospitals, limiting access to care.

3) Respiratory failure – Those with persistent hypercapnia due to end stage lung disease require home-based nocturnal PAP therapy, but the RAD guidelines have no mechanism for these patients to obtain a device.

4) RTD – There are some neurological conditions that are known to cause hypercapnia but are not included in the RTD guidelines. Those with phrenic nerve disorders and/or those with brain disorders such as chiari malformations may commonly have severe limitations to effective ventilation. These patients may be hypercapnic and require BPAP therapy, but this is not included in the RAD guidelines.

The common response by physicians to these challenges is to prescribe an LSMV/E0466 as an alternative. The fact that there is no formal national coverage determination (NCD) means that the ability to obtain an E0466 is much easier than the documentation needed to obtain a RAD. This is one factor driving the exponential increase in costs to CMS for the use of these devices. The limited guidelines which are in place, instruct durable medicine equipment (DME) suppliers that what is needed to provide the LSMV/E0466 device, is documentation that the patient is hypercapnic and that the physician believes this is due to respiratory failure. As mentioned above, the first thing that needs to be done in order to fix the ventilator problem is to modernize the RAD guidelines. Allowing easier access to the less expensive BPAP device will instantly reduce costs and simultaneously, improve access to the therapeutic devices.

The next issue is one of access to respiratory care. The current “Frequent and Substantial Servicing” plan associated with the E0466 absolutely drives up costs, but it is the only mechanism available to provide home-based respiratory therapist (RT) care. Research, which has shown benefit of the devices in reducing readmissions etc., contains protocols providing patients with BOTH a device and aggressive in-home support from an RT. Additionally, support for RT should be provided in a mechanism common to other therapists such as physical or occupational therapists further improving access to RT services. Improving access to RT services would also significantly reduce the inappropriate dependence on E0466. At this time, physicians often choose an E0466 as it is the only way to ensure being able to provide the needed in-home care.

The E0466 does, however, have appropriate applications. The internal battery is needed for those who require daytime or portable use or who live in areas without reliable power. These devices are also needed for children because the RADs are not FDA-approved in children. Additionally, the low-pressure alarm capabilities of the E0466 are important for any patient who requires closer monitoring.

In summary, if LSMV (E0466) is added to the Competitive Bidding Program, this should also include continuing to provide ongoing in-home RT support for the life of the device, prioritizing the use of E0466 for those who are not appropriate for a BPAP device and including support for basics, such as humidification, electronic monitoring and multiple interfaces. Although NCDs are not a part of the Competitive Bidding Program, we also highly recommend a review and potential revision of the RAD guidelines, in order to ensure that they are aligned with the medical literature and current standards of care.

Thank you for your consideration of these comments. We encourage the Agency to adopt the suggestions outlined in this letter. Please feel free to contact Diedra Gray, AASM Director of Health Policy, at dgray@aasm.org or 630-737-9700, for additional information or clarifications.

Sincerely,

Douglas B. Kirsch, MD
AASM President

cc: Steve Van Hout, AASM Executive Director
Sherene Thomas
Diedra Gray