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Executive Director

June 5, 2020

VIA EMAIL

Demetrios Kouzoukas
Principal Deputy Administrator and Director
Center for Medicare
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244
Demetrios.Kouzoukas@cms.hhs.gov

Dear Principal Deputy Administrator Kouzoukas:

On behalf of the American Academy of Sleep Medicine (AASM), I am writing today to encourage CMS to take steps to ensure innovative technology in the sleep medicine field is made available to Medicare beneficiaries. The AASM is the leading voice in the sleep field, as the only professional society dedicated exclusively to the medical subspecialty of sleep medicine. The AASM has a combined membership of 10,000 accredited member sleep centers and individual members, including physicians, scientists, and other health care professionals. The AASM is committed to our mission: Advancing sleep care and enhancing sleep health to improve lives.

In 2019, the AASM supported an effort at CMS to create a new billing code that would recognize a novel type of treatment device for patients being treated for “positional OSA”—defined as a person having more apneic events when in the supine position (sleeping on their back) than the non-supine position. While OSA is most commonly treated today with continuous positive airway pressure (CPAP) machines, the AASM recognized in our [2009 Clinical Guideline for Evaluation, Management and Long-term Care of Obstructive Sleep Apnea in Adults](#)ⁱ that positional therapy, consisting of a method that keeps the patient in a non-supine position, can be an effective therapy for patients who have positional OSA. A number of published studies have demonstrated that new, electronic positional therapy devices have been effective in treating positional OSA.ⁱⁱ

We were encouraged in November 2019 when CMS, through the HCPCS code process, agreed to establish a new code to describe electronic positional OSA treatment devices (K1001: electronic positional obstructive sleep apnea treatment, with sensor, includes all components and accessories, any type). We understand that by determining a new code should be established, CMS

also confirmed that these devices meet the core requirements of the durable medical equipment (DME) benefit under the Medicare program: that they are primarily used for a medical purpose, are durable, and are appropriate for home use.

Since this coding decision, however, we have seen no further action to establish the coverage criteria and fee schedule amount necessary for our members, their patients, and medical device suppliers to access this new treatment option. We understand the Medicare contractors responsible for developing these policies received a formal request to do so. The contractors will not take the first step in that process without input from CMS to confirm that electronic positional therapy devices—which CMS already evaluated through the year-long HCPCS process—qualify in the same DME benefit category as CPAP and other sleep therapy devices.

To resolve this unnecessary barrier to patient access, we request that CMS authorize the DME contractors to proceed with the very task the contractors have always been authorized to perform: evaluate the published evidence submitted with the coverage request and establish appropriate coverage criteria for this technology.

Thank you for your consideration of our input on this matter. If you have questions or would like additional information, please contact Steve Van Hout, AASM Executive Director, at svanhout@aasm.org.

Sincerely,

Kelly A. Carden, MD, MBA

AASM President

ⁱ Epstein LJ; Kristo D; Strollo PJ; Friedman N; Malhotra A; Patil SP; Ramar K; Rogers R; Schwab RJ; Weaver EM; Weinstein MD. Clinical guideline for the evaluation, management and long-term care of obstructive sleep apnea in adults. *J Clin Sleep Med* 2009;5(3):263-276.

ⁱⁱ See, e.g., Ravesloot MJ, White D, Heinzer R, Oksenberg A, Pépin JL. Efficacy of the new generation of devices for positional therapy for patients with positional obstructive sleep apnea: a systematic review of the literature and meta-analysis. *J Clin Sleep Med*.2017;13(6):813–824.