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SENT VIA EMAIL: OAOSARecon@noridian.com;

PAPLCDComments@cgsadmin.com; RADRecon@noridian.com

Re: Proposed Revisions to Local Coverage Determinations

Dear DME MAC Directors,

As the leading voice in the sleep field, the AASM sets standards and promotes excellence in sleep medicine health care, education, and research. The AASM has a combined membership of 11,000 accredited member sleep centers and individual members, including physicians, scientists, and other health care professionals.

The AASM appreciates the opportunity to provide comments on the proposed Local Coverage Determinations (LCDs) released for comment - Oral Appliances for Obstructive Sleep Apnea (DL33611), Positive Airway Pressure (PAP) Devices for the Treatment of Obstructive Sleep Apnea (DL33718), and Respiratory Assist Devices (DL33800).

The AASM has concerns about the removal of the Home Sleep Apnea Test (HSAT) information from the current LCDs, in deference to National Coverage Determination 240.4.1. While the National Coverage Determination (NCD) includes information about the types of HSAT devices, it does not include the more detailed information regarding HSATs, which if removed, will impact the quality of care provided to patients with obstructive sleep apnea.

Patient Education

The requirement to provide patient education regarding proper application of the portable sleep devices is extremely important but is not included in NCD 240.4.1. The current LCDs include specific information regarding how to



provide patient education, via face-to-face demonstration of administration and use OR video or telephonic instruction with 24-hour availability of qualified personnel for questions and/or troubleshooting. The AASM feels strongly that the removal of this criteria may lead to improper use of portable sleep devices, increased technical failure rates, missed diagnoses, and increased multiple night studies, which can negatively impact outcomes and lead to higher costs, due to repeat testing.

Training and Credentialing

Training and credentialing requirements for who can interpret sleep tests are also not included in the NCD but are being proposed for deletion in the LCDs. AASM emphasizes the importance of having the raw data from HSAT devices reviewed and interpreted by a properly trained and credentialed clinician to ensure accurate diagnosis and effective treatment of OSA. Properly trained and credentialed clinicians are able to assess the technical adequacy of the test, review potential artifacts of the study, and take into consideration the patient's comorbidities when reviewing results.

The AASM recommends keeping the following training and credentialing requirements for cliniciansⁱ:

- Board-certified in sleep medicine
- Board eligible (completed training and is eligible to sit for the sleep medicine board examination)
- Overseen by a board-certified sleep medicine physician
- An active staff member of a sleep center or laboratory accredited (i.e., by AASM, Accreditation Commission for Health Care or The Joint Commission)

Accreditation

Lastly, the AASM is extremely concerned with the proposed elimination of any mention of sleep center or laboratory accreditation since this also does not appear in the NCD. Accreditation is the standard by which the medical community and public can evaluate sleep medicine facilities. It demonstrates a provider's commitment to high quality, patient-centered care through adherence to standards. Data within the medical literature demonstrate that accreditation-certification status of sleep centers and physicians is associated with better treatment adherence, patient education, patient satisfaction and greater timeliness, in patients with OSA. i,ii.

The AASM understands the desire to simplify and streamline policies, however, this should not come at the expense of providing safe, high quality, patient-centered care. The AASM strongly recommends that the HSAT language about patient education, training and credentialing of clinicians, and accreditation in the current LCDs remain or that the more specific information be added to NCD 240.4.1, simultaneously with its removal from the current LCDs.

If you have any questions regarding this communication or would like to reach out for further discussion, please contact AASM Director of Health Policy, Diedra Gray, at (630) 737-9700 or dgray@aasm.org.

Sincerely,

Kannan Ramar, MD *AASM President*



ⁱ Kapur VK, Auckley DH, Chowdhuri S, Kuhlmann DC, Mehra R, Ramar K, Harrod CG. Clinical practice guideline for diagnostic testing for adult obstructive sleep apnea: an American Academy of Sleep Medicine clinical practice guideline. *J Clin Sleep Med.* 2017;13(3):479–504.

ⁱⁱ Parthasarathy S; Subramanian S; Quan SF. A multicenter prospective comparative effectiveness study of the effect of physician certification and center accreditation on patient-centered outcomes in obstructive sleep apnea. J Clin Sleep Med 2014;10(3):243-249.