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American Academy of Sleep Medicine

September 22, 2016

Anitra Graves, MD; Eddie Humpert, MD, MS; and Thom Mitchell, MD CAHABA Government Benefit Administrators PO Box 381896 Birmingham, AL 35238

Dear Directors Graves, Humpert and Mitchell:

I am contacting you on behalf of the American Academy of Sleep Medicine (AASM), the premiere membership organization for sleep professionals and centers. We recently became aware of the draft local coverage determination for home sleep apnea testing (HSAT) posted to the CAHABA website this summer. Unfortunately, we did not become aware of this policy until after the posted deadline for comment. Upon review of the LCD, we have a number of concerns. While we recognize that you are no longer accepting public comment on this LCD, we strongly encourage you to consider our comments below.

In Center Polysomnography

The draft LCD is specific to HSAT and does not address in-center polysomnography. CAHABA has not had an LCD for sleep testing in a number of years. We believe it will lead to significant confusion to have an LCD addressing only HSAT. It is very unclear as to whether polysomnography is considered a covered service, and for which patients it should be used. Additionally, it is unclear whether patients who meet the criteria for HSAT must receive that type of testing, or whether the testing mechanism is at the discretion of the physician. We recommend revising the draft LCD to address both polysomnography and HSAT, which is consistent with other LCDs nationwide. Additionally, we recommend that physicians have the discretion to choose the appropriate testing mechanism for their patients as is the case with other LCDs nationwide.

High Pre-Test Probability

According to AASM practice guidelines, HSAT is appropriate for patients with high pre-test probability of moderate to severe obstructive sleep apnea (OSA). This includes risk factors for OSA such as snoring, sleepiness, obesity and witnessed apneas. The symptoms outlined in this section of the LCD are appropriate and relevant to OSA. However, we disagree that patients meeting only two of these symptom requirements would be considered as having high pretest probability for moderate to severe OSA. In practice, this probability is assessed during a thorough clinic visit based on many additional historical and physical exam findings, and cannot be reduced to such a simple formula for all patients. We are concerned the definition of high pre-test probability outlined in the draft LCD is overly broad.

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Home Sleep Apnea Testing Terminology and Limitations

Many terms have been used to describe overnight testing for obstructive sleep apnea done outside the sleep center. It is important to note that although many different types of equipment are marketed to assess OSA from the home, the large majority of these machines do not include EEG, which is necessary for measuring sleep. The AASM is careful now to use the term home sleep apnea testing rather than home sleep testing so as not to give the impression that sleep is being monitored. We encourage CAHABA to adopt this more accurate language as well.¹

The AASM has also worked to clarify terminology for the determination of OSA severity. In the notes section of the LCD it is indicated that "respiratory disturbance index (RDI) may be used in place of apnea/hypopnea index (AHI) in unattended sleep studies." As sleep is not monitored or even estimated in most of the devices used for HSAT, the AASM has determined that Respiratory Event Index (REI) is the more appropriate term for the quantification of apneic events per hour of recording, as provided by most HSAT devices. We recommend CAHBA adopt this terminology as well.²

Furthermore, HSAT devices are designed specifically to detect obstructive sleep apnea. Under the section of the policy titled "Medical Conditions for Which Testing is Covered," both obstructive sleep apnea and general sleep apnea are noted. We recommend that the section on general sleep apnea be removed as it is not recommended to diagnose central sleep apnea with HSAT technology.

The "parameters to be monitored" section of "Documentation Requirements" includes a number of elements that are not relevant to HSAT. This section should be revised to include HSAT parameters or removed entirely. Specifically, total sleep time, sleep efficiency and number/duration of awakenings are not provided by the large majority of HSAT machines in use today. HSAT is not used for daytime testing (MSLT or MWT). Additionally, the respiratory patterns as described in this section are not typically derived in a validated manner from existing Type III or Type IV devices. Detailed behavioral observations are also not possible in HSAT testing because the patient is not being monitored in person. Additionally, EEG and EMG are not measured by HSAT and therefore abnormalities cannot be monitored or documented.

Finally, we recommend that patients with a negative HSAT or non-diagnostic HSAT receive a follow-up in-center polysomnogram.

In-Center Polysomnography

AASM practice guidelines note that due to the known rate of false negative HSAT studies, incenter polysomnography should be performed in cases where HSAT is technically inadequate or fails to establish the diagnosis of OSA in patients with high pre-test probability.³ The LCD should be revised to reflect that patients should have follow-up in-center testing in these instances.

In-Home Titrations

The draft LCD requires that patients tested with HSAT receive home titration of positive airway pressure. While this may be appropriate for a number of patients, home titration is not always the best option. We encourage CAHABA to consider allowing certain patients tested with

HSAT to receive an in-center PAP titration when necessary. Certain patients with psychiatric conditions may find acclimation to PAP therapy more difficult, requiring an in-center titration to encourage acceptance of therapy. In-center titration is also preferable in cases when the physician suspects that bi-level PAP may be necessary. While home titration is appropriate in many situations, it should be at the physician's discretion to determine the appropriate therapy titration mechanism.

HSAT Coding

The draft LCD includes three approved codes for HSAT: G0398, G0399 and G0400. While these codes are appropriate, there are other CPT codes for HSAT that are also appropriate. We encourage CAHABA to add the CPT codes for home sleep apnea testing - 95800, 95801 and 95806 - to the list of approved codes.

Thank you in advance for your consideration of the above comments. The AASM shares your goals to provide optimal health in a cost-effective manner. However, we are concerned that an LCD designed to reduce costs could significantly reduce targeted health benefits from OSA treatment if the LCD does not follow evidence-based methods and best practice for the Medicare population. If you have any questions about the information in this letter, please feel free to contact Carolyn Winter-Rosenberg, AASM Director of Coding and Compliance, at 630-737-9700 or cwinter-rosenberg@aasmnet.org.

Sincerely,

Ronald Chervin, MD, MS President

¹ American Academy of Sleep Medicine. AASM style guide for sleep medicine terminology. Updated November 2015. Darien, IL: American Academy of Sleep Medicine, 2016.

² Ibid.

³ Collop NA; Anderson WM; Boehlecke B; Claman D; Goldberg R; Gottlieb DJ; Hudgel D; Sateia M; Schwab R. Clinical guidelines for the use of unattended portable monitors in the diagnosis of obstructive sleep apnea in adult patients. *J Clin Sleep Med* 2007;3(7):737-747.