Dear Dr. Chervin,

Thank you for your comments and request for reconsideration regarding LCD DL36745 for Home Sleep Testing. Please see responses 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.*

The title and content of LCD DL 36745 clearly limits the scope of this policy to home sleep testing only.  While there is an ongoing effort to draft an LCD for polysomnography and sleep conditions other than obstructive sleep apnea, this is not that LCD.  We appreciate your request for clarification on the matter.

***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 pre-test 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.*

The LCD criteria for establishing a clinically significant pre-test probability for moderate to severe OSA requires that AT LEAST two of the symptoms requirements.  Documentation to justify sleep testing must be persuasive in establishing medical necessity.  We believe this to be a guideline for physician documentation in communicating why an evaluation for OSA is necessary.  This section also communicates criteria where the evidence suggests that home sleep testing would not be appropriate. We require all sleep testing be performed in conjunction with a comprehensive sleep evaluation and define the appropriate qualifications of testing providers. We believe that this adequately addresses this concern.

***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.*

We agree.  The section of the policy titled “Medical Conditions for Which Testing is Covered” has been rewritten to better define the condition and criteria for diagnosis for OSA.  We have clarified the parameters to be monitored to more appropriately reflect home sleep testing technology.  Lastly, language not relevant to home sleep testing has been eliminated under the “Documentation Requirements” Section.

***In-Center Polysomnography***

*AASM practice guidelines note that due to the known rate of false negative HSAT studies, in-center 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.*

The LCD is to clarify when home sleep testing is covered as a Medicare benefit. We believe we have now adequately addressed the possibility of non-diagnostic testing and possibility of in-lab testing with new language added in the ‘Criteria for Coverage of Diagnostic Tests” section.

***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.*

We agree and believe that the present language of the LCD reflects this.

***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.*

We agree. The CPT codes 95800, 95801, and 95806 have been added to the approved codes list for home sleep apnea testing.

Thank you again for your comments.  The aforementioned changes will be published forthwith.

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