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Kimberley Brummett
Chair Region C Council
4001 Piedmont Pkwy.
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RE: LCD for Positive Airway Pressure (PAP) Devices for the Treatment of Obstructive Sleep Apnea - Response

Dear Ms. Brummett,

Thank you for your comments on behalf of the Jurisdiction C Council on the recently released PAP devices local coverage determination (LCD). I appreciate the time and efforts of the Council to contribute to the DME MAC policy development process. Based on comments submitted by your organization and others, we will be publishing a revised policy on September 18, 2008. I will respond to the Council's concerns in the order presented in your e-mail of Thursday, August 14, 2008.

1. The DME MACs did not follow the requirements for public comment.

Response: The DME MAC medical directors followed all requirements in the Program Integrity Manual Pub. 100-8, Chapter 13 for the development of the local coverage determination (LCD) on Positive Airway Pressure (PAP) Devices for the Treatment of Obstructive Sleep Apnea. AAH alleges that several provisions of the LCD were a restriction of the current LCD. On the contrary, the PAP LCD significantly expands the coverage of PAP devices for the treatment of obstructive sleep apnea by incorporating the national coverage determination coverage criteria for the use of home sleep tests.

2. The elements of the face-to-face examination outlined in the LCD are not standard of medical practice for treating physicians.

Response: The medical literature supports that home sleep testing is most accurate in patients who have a high pre-test likelihood of OSA. Moreover, the medical literature also supports that there are some patients in whom it is not appropriate to diagnose sleep disordered breathing based on a home sleep test. The policy requirements for the face-to-face evaluation reflect simple diagnostic indicators designed to help determine who should receive a home sleep test and who should have a more in-depth evaluation via facility-based, attended Polysomnography. The calculation of a body mass index or the measurement of neck circumference are easily within the capabilities of a family practice physician or internist and should be included in the evaluation of any patient in whom the treating physician suspects sleep disordered breathing.

The DME MAC medical directors attempted to provide general guidance on the history and physical examination for a patient in whom the physician is considering a diagnosis of sleep disordered breathing. We anticipate that physicians evaluating patients for sleep disordered breathing will be well-versed in the necessary diagnostic skills. Note that we have moved the specific evaluation information (history elements, Epworth, exam elements) to the Documentation Section of the LCD; however, we have kept intact the requirement for a face-to-face initial and re-evaluation.

3. Must Medicare pay for a sleep test, based upon the term “Medicare covered sleep test” in the LCD? What information does the DME supplier need to collect?

Response: In order to be eligible for reimbursement, the PAP device must be dispensed based on a sleep test that meets all the requirements for Medicare coverage. Local Part B contractors, Fiscal Intermediaries and A/B MAC contractors may have policies outlining additional requirements for the conduct of sleep tests. DME suppliers should obtain as much information as necessary to assure themselves that the coverage criteria have been met. This may include determining if the testing methodology is covered by another Medicare contractor.

4. If a sleep center or laboratory conducting facility-based studies is not accredited, are they precluded from interpreting sleep studies unless one of the criteria for the interpreting physicians is met?

Response: That is correct; however, the revised policy has extended the timeframe for accreditation of the sleep centers and certification of the interpreting physicians performing facility-based sleep tests until January 1, 2010.

5. IDTFs are only allowed an MD to interpret for 3 centers. Are there sufficient numbers of MDs to interpret studies?

Response: The LCD is structured in such a way that there are multiple avenues for an interpreting physician to meet the requirements in the policy. We are not aware of any issues with insufficient numbers of interpreting MDs.

6. Changing from an E0601 to E0470 after the 91st day requires a physician face-to-face evaluation.

Response: Changing devices from a CPAP to RAD in the first 90 days can occur without a repeat face-to-face evaluation. It is anticipated that the physician and/or DME supplier is actively engaged with the patient to ensure that they are adherent to therapy and that any factors impacting the successful improvement in their OSA symptoms are being addressed. However once past the initial 90 days, changing from CPAP to RAD is often necessitated by complicating factors and should be done in consultation with the treating physician.

7. Unreasonable requirement to mandate use of devices with downloadable data capabilities.

Response: The LCD has been revised to allow visual inspection of compliance information that may then be reported to the treating physician via written report for inclusion in the beneficiary's medical record.

8. The policy requires ICD-9 diagnosis code 327.23 for coverage of a PAP device. Previous policy allowed 780.53 to be used. Do new orders need to be obtained for patients currently being billed for PAP devices indicating the new diagnosis?

Response: A new order does not need to be obtained; however, Medicare policy requires that the ICD-9 diagnosis necessitating the piece of DMEPOS be listed on the claim. While the previous LCD did not require a specific ICD-9 code, suppliers are required to use a diagnosis code that is as specific as possible. Prior to the creation of ICD-9 327.23, code 780.53 was most applicable to an OSA diagnosis; however, code 327.23 was effective January 1, 2006 and is specific to the diagnosis of OSA. This code should already be in use if it accurately describes the patient's diagnosis.

9. Is a patient diagnosed with OSA under a managed care plan who then transitions to Medicare and needs supplies required to have a face-to-face evaluation and meet all of the other requirements for Medicare coverage of CPAP?

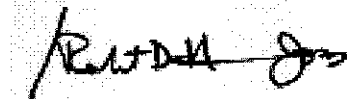
Response: The general Medicare rule for any item purchased prior to Medicare eligibility is that the beneficiary must meet Medicare coverage criteria in effect at the time they become Medicare eligible.

10. The LCD does not allow billing in the interim time if the patient misses the re-evaluation window of the 61st to 91st day but is re-evaluated at a later date.

Response: Correct. The NCD contains language requiring that, for continued coverage of a PAP device, the beneficiary must demonstrate improvement in the first 12 weeks (90 days). The NCD makes no provisions for "late" demonstration of improvement; therefore, the DME MACs do not have the authority to cover claims in the absence of a re-evaluation. The LCD maintains consistency with the NCD by allowing for reimbursement of a PAP device to resume only after the beneficiary obtains the re-evaluation.

I appreciate the opportunity to respond to your concerns. Should you have additional questions, please feel free to contact me.

Sincerely,



Robert D. Hoover, Jr., MD, MPH, FACP