

May 15, 2008

RE: Highmark LCD Draft Policy for Sleep Disorder Testing (J12-D44)

ACCP, ATS, and NAMDRRC appreciate the opportunity to submit comments on this draft LCD.

The American College of Chest Physicians is a professional society of 17,000 pulmonary, critical care and sleep medicine physicians, cardiothoracic surgeons, cardiologists and allied health professionals whose goal is to support education and patient focused care in our areas of expertise, including sleep medicine. The ACCP's Sleep NetWork and Sleep Institute are driving forces in sleep medicine with an interest in fostering excellent patient care and rigorous standards of excellence in the diagnosis and provision of health care to those with sleep disorders.

The American Thoracic Society represents over 18,000 physicians, researchers, and allied health professionals, who are actively engaged in the diagnosis, treatment and research of respiratory disease, critical care and sleep medicine.

NAMDRRC is a national organization of physicians whose members serve as medical directors of respiratory care departments, blood gas labs, sleep labs and pulmonary rehabilitation programs in 2000 hospitals nationwide. NAMDRRC's mission is to educate its members and address regulatory, legislative and payment issues that relate to the delivery of healthcare to patients with respiratory disorders. The diagnosis and treatment of sleep disorders is one area of importance to NAMDRRC members.

- Because this DRAFT was promulgated prior to the release by CMS of G codes, the issue of billing process needs to be addressed. Upon review of those codes, there is confusion in trying to understand the purpose of G0399 vs. use of existing CPT code 95806. Here are the descriptors:

G0399 – Home sleep test with type 3 portable monitor, unattended; minimum of 4 channels: 2 respiratory movement/airflow, 1 ECG heart rate and 1 oxygen saturation  
CPT 95806 – Sleep study, simultaneous recording of ventilation, respiratory effort, ECG or heart rate, and oxygen saturation, unattended by a technologist.

Importantly, here is the American Academy of Sleep Medicine (AASM) definition of Type 3 device – Minimum of 4 channels monitored, including ventilation or airflow (at least 2 channels of respiratory movement or respiratory movement and airflow), heart rate or electrocardiogram and oxygen saturation.

We also understand that there is a proposed code related to sleep studies pending before the CPT editorial panel and, with societies support, is likely to be approved at the June meeting. Given these seemingly less than coordinated variables, and the fact that two Medicare contractors, one in a proposed LCD and the other in a revised LCD, make references to the 95806 descriptor, we would hope that a more coordinated, more consistent process for processing claims for Type 3 devices might be established.

Recommendation #1: The creation of G code 0399 is not necessary as existing CPT code 95806 already addresses an unattended sleep study using Type 3 device.

Related to this, the test name and test code should reflect the test being done. We recommend using the more precise term, "Home Sleep Apnea Testing" (HSAT) to reflect the purpose of the "alternative" technology and its limited application in clinical decision making. Calling it "home sleep testing" permits discussion about whether the technology is diagnostic for all sleep disorders (which it is not). This is a clinical test for a purpose with a need for pre-test probability, especially for direct referrals.

- The DRAFT LCD has areas of inconsistency which can easily be misinterpreted. For example, on p. 3 of the document, it states that reasonable and necessary diagnostic tests are covered when the services are provided in a facility/sleep center. Yet, on p. 5 the policy does recognize the use of home sleep tests. Compliance officers could interpret the section on p. 3 as definitive that HSATs are not covered.

Recommendation #2: The policy should be very clear that both facility based and home sleep studies are covered when medical necessity exists and the prescribing physician has determined that the diagnostic test of choice is clinically indicated. We recommend that the LCD include guidelines as to when in-laboratory testing should be performed and reimbursed when a portable monitor study in a symptomatic patient is negative or non-diagnostic. We believe that there are times when it is essential to perform a complete polysomnographic study when portable monitoring is not adequate and that these studies should be reimbursed. Similarly, we believe that providers using a home unattended sleep study to diagnose a patient with sleep apnea may want to perform a home unattended autoCPAP titration study, rather than an in-laboratory polysomnogram, to determine the optimal pressure setting for CPAP treatment. We recommend that a unique HCPCS code be developed for the home autoCPAP titration study. Without the development of such a code, it is likely that patients with newly diagnosed sleep apnea who need CPAP treatment will be scheduled for an in-laboratory CPAP titration polysomnogram, obviating the ability

of portable monitor testing to serve as a complete disease management pathway alternative to in-laboratory testing.

- The policy states that PSG is the test of choice (p. 4). While that may very well be true in many cases, there are certainly situations, particularly related to geography, which may indicate that the HSAT is the preferred diagnostic tool of choice.

Recommendation #3: We believe the definitive statement that PSG is the test of choice should be clarified to address the entire spectrum of appropriate clinical decision making. Specifically, the physician, based on the patient's clinical status, should decide which type of testing is most appropriate. The type of test should not be regulated but should be based on what is best for the patient.

- The policy states on p. 4 that the “provider of CPAP must conduct education of the beneficiary prior to the use of the CPAP device...” Medicare statutory and regulatory language is very specific that companies involved with the provision of DME are **not providers** who provide hands on care; rather, they are suppliers of equipment and must follow dramatically different rules for participation in the Medicare program. This, we assume, is an inadvertent comment but it should be addressed.

Recommendation #4: The draft policy should clarify use of the term “provider” and instead use the term “supplier.”

- The policy does attempt to address the question of multiple sleep tests (HSAT followed by PSG, or other potentially ‘duplicative’ scenarios) when it states on p. 7, *“diagnostic testing that is duplicative of previous sleep testing, to the extent the results are still pertinent, is not covered if there have been no significant clinical changes in medical history since the previous study.”*

Recommendation #5: There is scientific evidence to support an expected failure rate in excess of 10% using HSAT as well as false positive and negative results. If HSAT results conflict with the clinical findings, then repeat testing of the treating physician's choice should not be considered duplicative regardless of any clinical changes in the medical history. Flexibility for providers in ordering an appropriate second study, whether it is another home sleep apnea test or a full polysomnogram, should be left to the discretion of the clinician, with appropriate regulatory oversight and justification from the clinician if necessary. No one is in favor of wasteful Sleep studies in any setting, however, clinicians need to be free to order the best test for that particular patient and be reimbursed for these studies.

- The policy does address the concept of “training and experience” on p. 8 for the technicians or physicians performing the specific study.

Recommendation #6: There are 2 issues here as the ordering/prescribing physician and interpreting physician may often be different persons. One could promote the

concept that the physician ordering the test should have direct contact with the patient and have determined a reasonable likelihood that the patient has a straight-forward OSA condition and is likely to benefit from CPAP. The sleep study interpreting physician should be obligated to look at the raw data and be board-eligible or board certified in sleep medicine. Furthermore, physicians ordering and interpreting portable sleep apnea tests should be affiliated with, and have access to, a facility-based sleep laboratory, so that patients have access to the best study for their clinical needs. The CPAP prescribing physician should have direct contact with the patient and either delegate or take direct responsibility for determining the benefit of treatment. Therefore the treating and ordering physician may be different persons and may conflict with the statement on p. 5: "The sleep test must have been previously ordered by the beneficiary's treating physician and furnished under appropriate physician supervision."

- We welcome the decision to initially limit coverage of CPAP to a twelve week period to identify beneficiaries diagnosed with OSA who will benefit from CPAP. This decision will have important beneficial consequences by focusing on comprehensive disease management and treatment outcome on CPAP rather than the overemphasized diagnosis of OSA.

Recommendation # 7:

Successful implementation of this decision will require determination of the specific measure(s) used to assess treatment benefit. To identify individuals who benefit from CPAP at the end of this trial period, we recommend:

- 1) Determination of treatment benefit should include documentation of adequate CPAP use based on an objective adherence measurement (either power on time or mask on time). We propose that adequate CPAP use be defined as an average use of at least 4 hours per day.
  - 2) In those patients whose objective daily CPAP adherence falls below the specified threshold, there should be a process for determination of continued coverage based on clinical judgment, thereby providing additional time for continued clinical management to improve adherence to this therapy.
  - 3) Determination of treatment benefit should not require symptomatic or quality of life improvement as relatively asymptomatic patients with sleep apnea can derive clinical benefit with CPAP by the prevention of respiratory-related arousals and/or intermittent oxygen desaturation during sleep, intermediate markers of cardiovascular risk.
- Multiple Sleep Latency Test (MSLT)-The LCD uses the parameter of 5 minutes or less to indicate excessive sleepiness.

Recommendation # 8:

In accordance with the American Academy of Sleep Medicine's recently revised guidelines for Multiple Sleep Latency Testing, we recommend that the mean sleep

latency on the MSLT indicating excessive daytime sleepiness should be 8 minutes or less.

If you have questions or require further information, please contact Karen Lui or Phillip Porte at NAMDRC headquarters, 703-752-4359, or [karen@NAMDRC.org](mailto:karen@NAMDRC.org).

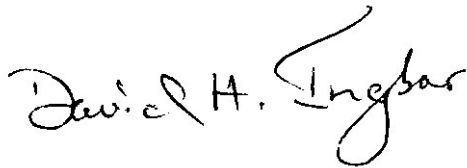
Respectfully submitted,



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