



*Last Modified: 4/23/2009 Location: FL, PR, USVI Business: Part B*

## Medicare Part B local coverage determination (LCD) comment summary

### LCD Number

95805

### Contractor Name

First Coast Service Options, Inc.

### Contractor Number

09102 - Florida

09202 - Puerto Rico

09302 - U.S. Virgin Islands

### Contractor Type

MAC Part B

### LCD Title

Polysomnography and Sleep Testing

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### Start Date of Comment Period:

02/20/2009

### End Date of Comment Period:

04/06/2009

### Comments received:

**Comment #1:** A comment was received stating the local coverage determination (LCD) should not limit the ordering of a home sleep test (HST) to sleep disorders clinics, and unattended HST should not require the assistance of a sleep technician. There is no credible evidence on which to conclude that achieving reliable and accurate HST should be conditioned on the intervention of a sleep disorders clinic for either ordering or furnishing instructions to patients. The above draft LCD language conflicts with four diagnostic medical equipment (DME) MACs for positive airway pressure (PAP) devices for the treatment of obstructive sleep apnea (OSA). They state the instruction must be provided by the entity furnishing the sleep study and not by a DME supplier. Under this definition, a home sleep study supplier that is not a sleep disorders clinic may provide the instruction. They state the instruction may be either (1) a face-to-face demonstration, or (2) video or telephonic instruction, provided that there are qualified individuals available to answer questions. The above language conflicts with the DME MAC.

Based on the above, it was suggested the statement under the "Indications of Coverage" which states:

"If HST is used, they may be tested in the home environment after application of the sensors and receiving education regarding a monitoring device from the technical, professional, or appropriately trained staff of the sleep center or laboratory."

Be changed to read as follows:

"If HST is used, patients may be tested in the home environment either (1) after receiving instructions on the use of a monitoring device and positioning of sensors, or (2) by using a validated HST device that has proven it can be self applied without technical assistance and incorporates automated patient prompts for correction of signal quality problems."

**Contractor response:** The NCD for CPAP therapy for OSA (section 240.4) states “The sleep test must have been previously ordered by the beneficiary’s treating physician and furnished under appropriate physician supervision.” and the CIGNA Government Services DME MAC states “The test must be ordered by the beneficiary’s treating physician and conducted by an entity that qualifies as a Medicare provider of sleep tests and is in compliance with all applicable state regulatory requirements.”

The verbiage in the above section of the LCD does not limit the ordering of a HST to sleep disorders clinics.

The NCD for continuous positive airway pressure (CPAP) coverage does not identify or exclude a mechanism for HST application. Rather, the specifics of HST application were left to the discretion of the MAC contractors.

In the CMS Decision Memo for Sleep Testing for OSA (CAG-00405N) under “Evidenced based Guidelines,” the Portable Monitoring (PM) Task Force of the American Academy of Sleep Medicine (AASM) “recommended, “PM testing be performed under the auspices of an AASM-accredited comprehensive sleep medicine program with written policies and procedures. An experienced sleep technologist/ technician must apply the sensors or directly educate patients in sensor application.”

Given the technological and clinical expertise needed to set up, score, and interpret PM tests, it seems reasonable to require that only those experienced and qualified to uphold the highest standards in the field should be allowed to perform testing. FCSO MAC draft LCD for Polysomnography and Sleep Testing requires qualified personnel to apply the sensors or directly educate patients in sensor application.

**Comment #2:** A comment was received regarding when a psychiatrist has a patient who presents with a combination of depression, obesity, hypertension, excess daytime sleepiness, and snoring, an Rx for polysomnography to rule out OSA is given. Some sleep labs allow a direct referral while others require the patient to first be evaluated by a sleep specialist, pulmonologist, or neurologist.

It is not standard of care for office-based psychiatrists to perform a physical examination that documents body mass index (BMI), neck circumference, and a focused cardiopulmonary and upper airway evaluation. Nor is it standard of care for a psychiatrist to administer the Epworth Sleepiness Scale. Requiring these would essentially preclude psychiatrists from ordering sleep studies and force the patient to see another physician to have the study ordered, thus increasing costs to the Medicare program. Request the LCD be modified to eliminate the above requirements.

**Contractor response:** Based on the national coverage determination (NCD) section 240.4, a positive diagnosis of obstructive sleep apnea (OSA) for the coverage of CPAP must include a clinical evaluation and a positive polysomnography or home sleep test. Current literature supports the risk for OSA correlates on a continuum with obesity (BMI greater than or equal to 30), large neck circumference (42cm), specific abnormalities that could lead to upper airway obstruction, hypertension, CVA and CAD. Combinations of these factors increase risk for OSA in a non-linear manner. The Epworth Sleepiness Scale (ESS) uses a simple questionnaire to measure excessive daytime sleepiness (EDS) during various activities. Since OSA can cause excessive daytime sleepiness in the majority of patients, the ESS is a beneficial tool in helping to diagnose OSA.

Since the physician evaluation would determine whether a polysomnography or sleep test is needed, and the BMI, neck circumference, cardiopulmonary and upper airway evaluation are part of that determination, these requirements are necessary and should remain as part of the criteria for the clinical evaluation. The LCD does not restrict to certain physician specialties or non-physician practitioners as long as they are trained and perform evaluation and management criteria outlined in the LCD and their scope of practice.

**Comment #3:** A comment and literature were received requesting that language in the LCD includes American Osteopathic Association (AOA) certification for polysomnography and sleep testing since the AOA has developed through conjoint boards a certification process that is still in the implementation process.

**Contractor response:** Currently, the way the LCD is written, an AOA credentialed individual can interpret sleep testing as long as they are on staff with a sleep center accredited by either the AASM or the Joint Commission. Since the AOA certification for sleep medicine is still in the implementation process, adding credentialing for this organization may be something that can be reviewed after it is credentialed. At this time, the CIGNA Government Services DME MAC LCD does not include certification from the AOA in their credentialing requirements for interpreting PAP devices.

**Comment #4:** A comment was received stating the information from FCSO’s MAC LCD should mirror Medicare’s national coverage determination for CPAP Type IV device. The description in the LCD for Type IV devices mentions effort, airflow and saturation. Since saturation also consists of heart rate, this level IV is now really a Level III and is confusing. The LCD should state a level IV device must include at least three channels - oximetry, heart rate, and airflow.

**Contractor response:** The LCD description of type IV devices will be changed to reflect verbiage in the NCD.

**Comment #5:** A comment was received stating support for the coverage of polysomnography and sleep testing in the LCD.

**Contractor response:** FCSO MAC appreciates the support of the LCD.

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