



# CMS CONSIDERS APPROVAL OF HOME DIAGNOSTICS FOR CPAP

*Vernon Pertelle RRT MBA*

Just in time for the New Year, the Centers for Medicare & Medicaid Services (CMS) reconsiders approving reimbursement for home sleep diagnostics for Medicare beneficiaries suspected of having obstructive sleep apnea (OSA). This comes at a time when the home care/home medical equipment (HME) industry is retrenching to combat additional cuts by CMS in reimbursement for durable medical equipment (DME). Past efforts to gain approval by CMS fell short because of contentions between the Academy of Sleep Medicine (AASM), other physician organizations and the home care/HME industry. In addition there were concerns by CMS regarding quality, lack of evidence and control over home diagnostics. However those disagreements and concerns seem to have been resolved as the latest proposed rule by CMS appears to have a consensus agreement of all interested stakeholders. Home diagnostics has been in place for years yet has not been accepted by the AASM and CMS. Unlike previous efforts by the industry to obtain approval for

**Home diagnostics can provide another opportunity for home care/HME providers to partner with sleep centers to provide essential services**

home testing this latest effort is supported by a collaborative group including the AASM, American College of Chest Physicians (ACCP) and the Home Care industry. CMS has embraced the approach to mitigate the expense associated with expensive in lab testing as home testing will definitely reduce the overall expense for diagnosing Medicare beneficiaries. I recall over 15 years ago establishing a program at a medical group (Graybill Medical Group, North San Diego County, CA) responsible for managing the care of 60,000 members in which all patients for whom we were at risk for providing DME received home diagnostics. We saved significant dollars from this approach and most importantly our patients experienced positive health outcomes and better adherence to CPAP. The organization continues this program exclusively for patients suspected of having OSA. In addition during my time as DME benefit administrator for Kaiser Permanente, the nation's largest integrated health maintenance organization (HMO) we developed a system to meet the needs of 6 million covered lives in which sleep labs were tertiary centers for patients difficult to diagnose; while home diagnostics was routinely used

for patients who presented with high Epworth Sleepiness Scale (ESS) scores and symptoms suggestive of OSA. This approach allowed us to quickly diagnose patients followed by treatment with continuous positive airway pressure (CPAP). We realized a savings of 1.6 million dollars the first year following implementation of home diagnostics and the process remains in place today. The most important benefit of using home diagnostics is patients are treated sooner, which helps mitigate the long-term negative affects due to backlogs at accredited sleep labs. There is more evidence available to support home diagnostics and this is yet another significant opportunity for home care/HME providers to partner with accredited sleep centers to provide the essential services. While the proposed rule represents an opportunity for home care/HME providers; owners of sleep labs now face challenges with reimbursement for more expensive fully attended polysomnography (PSG) should CMS determine that home sleep testing is a covered benefit for Medicare beneficiaries.

### ***Proven approach that does not compromise quality***

During my time at Kaiser Permanente we established clinics to provide group education, instruction on the operation of the in-home diagnostic equipment for unattended studies and partnered with Apria Healthcare (my previous employer) to set up CPAP and auto-CPAP to establish the appropriate pressures. Access to diagnostics at accredited sleep labs has been an issue for years, so adding home testing to the armamentarium of available diagnostic tools will quickly eliminate this issue. However there will be a resultant increase in utilization of CPAP so the savings potentially are neutral. Yet the long-term benefits will be significant as early diagnosis and treatment will reduce the incidence of co-morbid conditions that ultimately create greater expense for the Medicare program. The additional concern by many "purist" in sleep diagnostics is the potential for compromise in quality by not using the "gold" standard of PSG. Quite the opposite occurred at Kaiser Permanente as patients had greater levels of satisfaction, better health outcomes and adherence to therapy and more importantly quicker treatment that facilitated a better quality of life. The types of devices that were used at Kaiser Permanente ranged from oximetry with auto-CPAP, Type II, III and IV devices. The current proposed coverage calls for expansion

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using a combination of a clinical assessment [including ESS] followed by unattended home sleep monitoring using a Type II, III or IV device in addition to required monitoring for 12-weeks. This is the same approach we used at Kaiser Permanente in 1999 in which patients were evaluated at 7-days following set-up, 14 days, 30 days and 90 days to assess compliance with the treatment plan, mask fit as well as need for humidification to improve adherence to treatment.

### **Coverage Determination on the Horizon**

Home care/HME providers are poised for success in providing home testing as they possess the infrastructure as well as clinicians (RTs) to effectively execute the process thus the only need would be to establish policies & procedures, medical oversight by a board certified sleep physician, accreditation and obtain the equipment necessary for diagnostics. A final coverage determination must be issued by CMS although the AASM has already recommended home sleep diagnostics as a method of diagnosing OSA; however requires the patient be followed by an AASM-accredited sleep disorders center. This will most certainly be included in the final rule by CMS thus home care/HME providers desirous of providing the service must either establish an accredited sleep center or partner with a center. It appears that CMS is beginning to apply practical solutions to help reduce the rate of increase in expenditures and this is good news for home care/HME providers.

The proposed changes can be reviewed at the CMS website at [www.CMS.gov](http://www.CMS.gov) however the following is an overview:

1. We are proposing that, due to the evidence demonstrating that no combination of diagnostic procedures adequately identifies all of those beneficiaries who will benefit from CPAP, the coverage of CPAP is initially limited to a twelve week period to identify beneficiaries diagnosed with OSA as subsequently described who benefit from CPAP. CPAP is subsequently covered for those beneficiaries diagnosed with OSA who benefit from CPAP during this twelve week period.

2. We are proposing that the use of CPAP will be covered when diagnosed using a clinical evaluation and PSG performed in a sleep laboratory. In addition, we are proposing to expand coverage of CPAP to include those beneficiaries with a diagnosis of CPAP made using a combination of a clinical evaluation and unattended home sleep monitoring using a Type II, III, or IV device.

3. We are proposing to modify the criteria for a positive sleep study to remove the requirement for a minimum two hours of continuous recorded sleep and instead recognize shorter periods of continuous recorded sleep if the total number of recorded events during that shorter period is at least the number of events that would have been required in a two hour period.

4. We are proposing to delete the current distinct requirements that an individual have moderate to severe OSA and that surgery is a likely alternative because these terms are not sufficiently precise.

5. Due to a lack of sufficient evidence that clinical diagnosis alone or clinical diagnosis in combination with devices other than Type I, II, III, or IV adequately identify beneficiaries with OSA that will benefit from CPAP, we are proposing to expand Medicare coverage for CPAP in these instances only when provided in the context of a clinical study when that study meets the following standards:

A clinical study seeking Medicare payment for CPAP provided to the beneficiary pursuant to Coverage with Evidence Development (CED) must address one or more of the following questions:

1. In Medicare aged subjects with clinically identified risk factors for OSA, how does the diagnostic accuracy of a clinical trial of CPAP compare with PSG and Type II, III & IV HST in identifying subjects with OSA who will respond to CPAP?

2. In Medicare aged subjects with clinically identified risk factors for OSA who have not undergone confirmatory testing with PSG or Type II, III & IV HST, does CPAP cause clinically meaningful harm?

3. In Medicare aged subjects with clinically identified risk factors for OSA, how does the diagnostic accuracy of tests other than PSG or Type II, III & IV HST, such as oximetry, peripheral arterial tone and actigraphy, alone or in combination, compare with PSG and Type II, III & IV HST in confirming a diagnosis of CPAP-responsive OSA?

As home care/HME providers look for mainstream acceptance as an essential component in the continuum of care it is important that providers take full advantage of the opportunity to participate in home diagnostics for OSA while we continue to combat the challenges with reimbursement cuts and recognition by policymakers as "true" providers of healthcare.

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