



WILL SLEEP TESTING FOR OSAHS AND CPAP GO OVER THE COUNTER?

by Steven Grenard RRT, RPSGT

A few days before I sat down to write this column, CMS released its deliberations and public hearings on whether it will cover payment for portable sleep testing. These deliberations were not particularly straight forward because they included consideration for a variety of procedures which depart substantially from traditional sleep testing, but which purport to confirm a diagnosis of OSAHS as justification for coverage for CPAP or BIPAP therapy. Clearly, government employees and various committees and consultants, in response to the demands of the pro-portable sleep testing lobby, attacked this issue with more

than the customary zeal and attention to detail seen in previous deliberations. The committee conducted hearings to receive public comments in person, in writing and by way of published studies. The huge amount of data generated by this effort will form the

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basis of their decision(s) on this matter which was promised for mid-December, 2007 or about 30 days from when this is being written. These wonderful folks should have everyone's gratitude and sympathy for what some may consider an onerous job that will definitely not satisfy everyone who worked so hard to advance their positions.

Irrespective of the decision made by CMS, it is interesting to speculate on the future of sleep testing and PAP use, basing predicted future developments on past ones and recent advances in the field. In fact there are gurus who get paid a great deal of money to predict future trends for big corporations who then start gearing up for them in anticipation of such developments being realized.

Let's look at what's happened so far: Equipment to administer PAP therapy in various modes is getting smaller, easier to use and less expensive. Competition in the market is responsible for this. Will there ever be a fifty dollar CPAP machine, so cheap people will pay out of pocket for them and hardly bat an eyelash? The answer is yes if the market includes a significant percentage of the population. The same is true for masks but is especially true if a two dollar nasal cannula can be made to do the job. It could be changed weekly.

Interfaces are becoming more innovative, more comfortable, easier to use, and less expensive. Yes, there is technology promised by one company that says it can deliver sufficient air flow to achieve adequate PAP pressures through what amounts to a regular sized nasal cannula. If this comes to market and is astutely managed it will make PAP therapy a whole lot more palatable to a vast majority of people who need it or maybe even just want it. After all, there are enough doctors who have gone on the record extolling the safety of PAP to make it attractive to even those with the mildest forms of sleep apnea. Or perhaps no apnea/hypopneas at all. Since PAP therapy tried in patients with cardiac arrhythmias tends to eliminate those arrhythmias, you may not even need a rip roaring case of OSAHS to benefit from the therapy. Ditto for recent findings relating potential cause and effect between obesity, metabolic syndrome, diabetes and sleep disordered breathing. So every obese person, child or adult, at risk of, or who has metabolic syndrome or Type 2 diabetes might someday be a candidate for PAP therapy.

CMS in previous deliberations agreed to qualify and pay for PAP therapy in patients with AHI's as low as 5 events per hour if they have symptoms such as EDS or other significant co-morbidities. So, it's not very difficult to qualify for PAP therapy under such guidelines and that's just a step above for any drug, if PAP were a drug, to be taken off prescription status and sold over the counter. If a drug is extremely safe, efficacious, and does not cause any serious or subtle side effects or drug interactions, it can become a candidate for OTC status.

The issue of what pressure level to use will be neatly dealt with by units employing algorithms designed to optimize pressure levels. So, unless one has a particularly difficult case to fine tune, most patients wouldn't need a trip to the lab for a titration study either. Sleep labs have plenty of other difficult problems to diagnose and help to treat so it is predicted they will reposition themselves to perform these tasks, many of which have been neglected in the past. This may even include getting into the portable studies business themselves.

So, the next question for the CMS deliberators, (assuming they approve portable testing) is how they will dictate the qualifications for who does portable testing on the technical level. Physicians, of course, will remain in the loop as interpreters of test results, explaining their findings to patients and making recommendations as well as writing orders (prescriptions?) for

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technology that those in need can have filled over the internet, in their local drug stores or perhaps even at the mall in a Sharper Image store. Will *anyone* be able to do portable sleep testing? I know, for example, that DMEs are very interested in doing this work. Not only for financial reasons, but for patient convenience. One stop shopping has certain advantages as those sleep labs which have gotten into the business of dispensing PAP machines and masks to their patients have proved. But, irrespective of what business entities are approved for this purpose, if any are, what would be the requirements for the personnel who apply the sensors, go into or send the patient home and then score the results of such testing?

Or will all this be accomplished as do-it-yourself plus robotic scoring? If you think you might need a sleep study, the big question is "who you gonna call?" Will every Tom, Dick, Harry or Jane be able to get into the portable testing business? That may not be a good thing. Not only because of competency issues but because of side issues like the potential for abuse or financial rip-offs.

The American Academy of sleep Medicine preempting CMS has already approved Portable Testing of OSA cases in a stunning announcement made on November 2nd, 2007:

"The role of portable monitoring devices (PM) as a diagnostic tool for obstructive sleep apnea (OSA) is a complex issue that has been widely discussed and debated in the sleep medicine field for a number of years.

In 2003 the American Academy of Sleep Medicine (AASM), American College of Chest Physicians (ACCP) and American Thoracic Society (ATS) jointly published "Practice Parameters for the Use of Portable Monitoring Devices in the Investigation of Suspected Obstructive Sleep Apnea in Adults." This systematic

review of available data found that Type 2 and Type 4 PM devices are not recommended for general-population screening in attended or unattended settings. Further, the parameters state Type 3 PM devices are appropriate for use in an attended setting in select patients with certain limitations, but not in an unattended setting. These parameters have served as the standard of practice for the field.

New research has advanced our knowledge and understanding of sleep disorders and relevant technology has had an impact on clinical practice. The confluence of the emergence of germane literature and the introduction of new therapies for patient care prompted the AASM, as the organization representing the professional interests of sleep medicine specialists, to develop a comprehensive initiative to address the use of PM in the diagnosis of OSA."

The AASM is also releasing "Clinical Guidelines for the Use of Unattended Portable Monitors in the Diagnosis of Obstructive Sleep Apnea in Adult Patients"



"A dinner and a movie sounds great, but how dow we pay for the gas?"