

Date: 4/5/2007
TO: Centers for Medicare & Medicaid Services
FROM: Amanda L. Barney, RN
RE: Public Comment re: Obstructive Sleep Apnea home testing (Ref: CAG-00093R2)

I am writing in my capacity as a Registered Nurse to urge you to positively consider changing your coverage determination for obstructive sleep apnea home-based testing.

I have encountered multiple instances where patients with suspected OSA are declining to get tested in an overnight facility. Most patients have very justifiable reasons as to why they are unable to stay elsewhere overnight. Many of my aging patients have degenerative eye diseases and are unable to drive after dark and as you are aware they are required to report later in the evening. Others have a spouse at home who is in failing health and require supervision due to dementia or other ailments that weaken them. My Medicaid population are generally single parents who are not able to leave children alone unattended in order that they stay overnight for the studies.

For decades, sleep laboratories have served a critical need in accurately diagnosing sleep apnea. But, just as our world has changed dramatically in other areas of technology, so has the field of sleep apnea research and diagnosis. Now, a proven wrist-worn device alternative versus the need for overnight clinic stays makes a strong case for updating CMS policies. It utilizes peripheral arterial tonometry (PAT), which has been approved by the FDA specifically for diagnosing sleep apnea in an unattended setting.

Peer reviewed research studies shows home testing is now as accurate and reliable as sleep clinics. Because of its efficacy and reliability PAT has been an accepted industry practice for some time; one where patients with the ability to pay cover the entire cost. But, many more patients suffering with OSA could be helped if insurance coverage was available.

Given these facts, I urge the CMS to change its coverage determination and to allow coverage for obstructive sleep apnea home testing.

Thank you,

Amanda L. Barney, RN
622 N. Logan Ave.
Danville, Illinois 61832
217.477.5712

TO WHOM IT MAY CONCERN:

“Patients with dangerous sleep disorders would be ill-served by approval of in-home sleep testing for coverage by the Centers for Medicare & Medicaid Services (CMS). It is difficult to appropriately diagnose these conditions in a well-supplied and organized sleep lab; approval of home testing would open the floodgates to poorly-trained providers whose primary concern is the sale and rental of CPAP equipment, not patient care. ”

As a Registered Polysomnographer I have worked in three states and have witness the results of in-home testing in all three states. At best, The result are questionable and more often than not, lead to in-house studies to clear up the poor quality work demonstrated by the in-home studies. They also result in more cost to the patient and the institution as a result of the poor quality signals and lack of attention to troubleshooting in the home setting.

Please think twice about providing insurance coverage for thses "services".

Thank you.

Andrea Engelmann BS RRT RPSGT

Date: 4/4/2007

TO: Centers for Medicare & Medicaid Services

FROM: Alex Mendez, RRT, CPFT

RE: Public Comment re: Obstructive Sleep Apnea home testing (Ref: CAG-00093R2)

I am writing in my capacity as a Registered Respiratory Therapist, a Pulmonary Function Technologist and owner of a Durable Medical Equipment company to urge you to positively consider changing your coverage determination for obstructive sleep apnea home-based testing.

For decades, sleep laboratories have served a critical need in accurately diagnosing sleep apnea. But, just as our world has changed dramatically in other areas of technology, so has the field of sleep apnea research and diagnosis. Now, a proven wrist-worn device alternative versus the need for overnight clinic stays makes a strong case for updating CMS policies. It utilizes peripheral arterial tonometry (PAT), which has been approved by the FDA specifically for diagnosing sleep apnea in an unattended setting.

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Given these facts, I urge the CMS to change its coverage determination and to allow coverage for obstructive sleep apnea home testing.

Thank you,

Alex Mendez, RRT, CPFT
Mendez Medical
116 E. Main, Cordell, OK 73632
580-832-2488

Sent: Tuesday, April 10, 2007 8:41 AM
To: CMS CAGInquiries
Subject: CAG-00093R2

April 10, 2007

TO: Centers for Medicare and Medicaid Services

From: Bill Kellenberger

Re: Public comment re:Obstructive Sleep Apnea Home Testing

I am the owner of a medical supply company. It is our task to manage the utilization of the sleep apnea patient on cpap. In this capacity, we talk to many patient before and after their sleep study. I talk to the patients, their spouses and their children. I have heard endless stories of how the patient is unwilling to go to the sleep lab or they were unable to sleep in the sterile environment, under the watch of a camera at the lab.

These patients are normally talking to me because they need answers to solving a problem. They, their spouse or their parent is sick or severely tired and they believe it is due to sleep apnea. I can screen them and confirm they are at high risk for OSA, but until they have the sleep lab test, I am unable to help them.

The introduction of the ambulatory sleep device marketed as the WatchPat 100 has been the savior of many patients whose insurance company will pay benefits based on these results. These patients overcome the inability to sleep in the lab with this in-home test. It is FDA approved and appears to be very accurate in determining the severity of OSA in the patients we have tested.

Evo has a mountain of information which I am sure they sent to you. I would encourage you to allow the ambulatory sleep test as a preventative measure to improve the health of the patient and their long term productivity.

Sincerely

William M Kellenberger

Subject: CAG-00093R2

Date: 4/10/2007

TO: Centers for Medicare & Medicaid Services

FROM: William Stadnik, MPA, RRT

RE: Public Comment re: Obstructive Sleep Apnea home testing
(Ref:
CAG-00093R2)

I am writing in my capacity as a Respiratory Therapist to urge you to positively consider changing your coverage determination for Obstructive Sleep Apnea (OSA) home-based testing.

I believe the percentage of individuals with undiagnosed OSA is huge. One reason for this is the reluctance of patients to undergo overnight sleep testing in an accredited sleep lab...and to assume the financial responsibility of the co-pay amount for this expensive testing procedure.

As a result they refuse testing and therefore diagnosis & treatment and place themselves and the public at risk. As you know, many people have

heart attacks in the middle of the night as a result of obstruction and de-saturation that results in insults to the cardiac system. Others, such as truck drivers, threaten our highways with their daytime and evening sleepiness.

Technology is now available to perform inexpensive OSA testing in the home, however it requires your support to make home based testing a reality.

I urge the CMS to change its coverage determination and to allow coverage for obstructive sleep apnea home testing.

Respectfully,

William Stadnik, MPA, RRT
Registered Respiratory Therapist
8901 Peterborough Drive
Louisville, KY 40222

Date: 4/8/2007

TO: Centers for Medicare & Medicaid Services

FROM: Brenda M. Gibson

RE: Public Comment re: Obstructive Sleep Apnea home testing (Ref: CAG-00093R2)

I am writing in my capacity as a professional in the field of Respiratory Care to urge you to positively consider changing your coverage determination for obstructive sleep apnea home-based testing.

For decades, sleep laboratories have served a critical need in accurately diagnosing sleep apnea. But, just as our world has changed dramatically in other areas of technology, so has the field of sleep apnea research and diagnosis. Now, a proven wrist-worn device alternative versus the need for overnight clinic stays makes a strong case for updating CMS policies. It utilizes peripheral arterial tonometry (PAT), which has been approved by the FDA specifically for diagnosing sleep apnea in an unattended setting.

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Given these facts, I urge the CMS to change its coverage determination and to allow coverage for obstructive sleep apnea home testing.

Thank you,

Brenda M. Gibson, RCP

TO: Centers for Medicare & Medicaid Services

FROM: Brian Parker, M.P.H., RRT-NPS, CPFT, AE-C

RE: Public Comment re: Obstructive Sleep Apnea home testing (Ref: CAG-00093R2)

I am writing in my capacity as Chair, Respiratory Care Major at Baptist College of Health Sciences to urge you not to consider changing your coverage determination for obstructive sleep apnea home-based testing.

My basis for this consideration is the propensity for off-site OSA testing providers (home care companies) to employ ill-prepared individuals to administer and manage the equipment. Unless there are strict guidelines for well qualified individuals (RRT, RPSGT, or MD) overseeing the in-home testing, I cannot support this rules change.

For decades, sleep laboratories have served a critical need in accurately diagnosing sleep apnea. Although a wrist-worn device alternative is available, the device is not a replacement for qualified oversight of the patient during testing.

Given these facts, I absolutely CANNOT urge the CMS to change its coverage determination and to allow coverage for obstructive sleep apnea home testing.

Thank you,

Brian Parker, M.P.H., RRT-NPS, CPFT, AE-C

Carilion Sleep Center – Position on Portable Unattended Home Sleep Studies 3/2007

There are varying degrees of opinion from professional societies, physicians and manufacturers on portable unattended home sleep studies and devices. There are companies, both locally and nationally, who would promote the use of portable sleep studies for diagnosing, then applying treatment, and management of OSA patients. There is a rising tide for such companies who claim they can diagnose, treat, and follow obstructive sleep apnea patients, citing several reasons for why they can and should do these things: Faster (quicker access to the study – claiming most sleep centers have prolonged wait times), easier (patient can be in the comfort of their own home with simple application and instructions), cost (usually claim to be able to do for about 1/3 to ¼ of the cost of traditional sleep centers).

After careful and thoughtful investigation, review of literature, benchmarking, and discussions among the professionals on our staff, our position is as follows: Agree with AASM statement paper issued Journal of Clinical Sleep Medicine, Vol.2, No.3, 2006 on Portable Monitoring in the Diagnosis of Obstructive Sleep Apnea

- Role of portables remain controversial and insufficient evidence to recommend portable monitoring as an alternative to attended polysomnography, except in a few selected circumstances.
- Disturbed by the uncontrolled use of this technology, especially by non-physicians and physicians not trained in Clinical Sleep Medicine.
- Task Force from AASM appointed to examine under what circumstances and how procedures should be performed. Until then physicians who choose to use portable monitoring should follow these recommendations:
 1. When used, portable monitoring must be combined with a clinical assessment, and must be interpreted by a comprehensive evaluation of the patient.
 2. Studies using these portable devices should be performed, read and interpreted only in AASM accredited sleep centers or by board certified Sleep Specialists.
 3. Decisions on therapy should be based on both the results of the studies as well as knowledge of the individual's sleep symptoms.

Also, agree with:

- CMS Medicare Coverage Decision Summary Jan. 7, 2005
- Technology Assessment done by Agency for Healthcare Research and Quality on "Effectiveness of Portable Monitoring Devices for Diagnosing Obstructive Sleep Apnea: Update of a Systematic Review" Sept. 1, 2004

- American Academy of Sleep Medicine “Practice Parameters for the Use of Portable Monitoring Devices in the Investigation of Suspected Obstructive Sleep Apnea in Adults (Sleep, Vol.26, No.7, 2003)
- Multiple other commercial insurers who also have outlined coverage of portable unattended home studies who agree with above, that conclude there is insufficient evidence for their widespread use.

The Medicare Review guidelines state that unattended portable recording studies for patients with a high pretest probability of obstructive sleep apnea/hypopnea syndrome as an acceptable alternative to standard polysomnography in certain situations:

1. patients with severe clinical symptoms that are indicative of a diagnosis of obstructive sleep apnea and when initiation of treatment is urgent and standard polysomnography is not readily available
2. patients unable to be studied in the sleep laboratory (*access/mobility/inpatients, etc*)
3. Follow-up studies when diagnosis has been established by standard polysomnography and therapy has been initiated.

We would agree with portable in home studies for adults on the limited basis on above (1 - 3).

Also, agree that per The American Academy of Pediatrics Clinical Practice Guideline: Diagnosis and Management of Childhood Obstructive Sleep Apnea Syndrome” – Polysomnography is the “gold standard” (PEDIATRICS Vol. 109 No. 4 April 2002)

Carilion Sleep Center considerations on portable unattended home studies:

-Careful equipment selection (ARES, Braebon, Embletta?, - need review process to determine) which devices have been most proven and published acceptance rate. Also, can perform functions necessary for the limited information a portable device can produce in the most simple, unattended fashion.

Parameters needed:

- Airflow/Snoring
- Respiratory Effort
- ECG
- O2 Saturation
- Body Position
- Actigraphy or some type of movement detection device

-Raw Data would need to be able to be analyzed and interpreted by one of our own boarded sleep professionals.

Even after considering the most acceptable portable device available, we feel strongly that the patient with a sleep disorder should have at least some oversight by the sleep specialist. The data from portables, even at best, must be

viewed in light of careful patient selection, history, and assessment to get a clear picture for proper diagnosis, treatment and follow up. We feel this is best done by the sleep professionals. Carilion Sleep Center has added beds to bring down wait time (3 weeks) and added providers (total of 4) to increase capacity to see patients.

A patient who might have a portable unattended home study needs careful considerations:

- Proper patient selection (Proper utilization vs.: improper cases for portable vs. in lab setting)
- Careful patient evaluation for review of comorbid conditions and co-sleep conditions
- Careful screening questionnaire tool for proper assessment
- The need for sleep specialist to interpret the data along with the history and clinical picture of the patient. Other sleep disorders may coexist, i.e., RLS, ECG dysrhythmias, Narcolepsy, Insomnias, and Parasomnias are not detectable by portable recordings.
- The need for minimum of at least one follow up which may include clinic visit or additional polysomnography study
- Clearly defined pathways for the use of portables, interpretation, and decision making would need to be developed

The challenge for portables:

- OSA often associated with other medical conditions including hypertension, nocturnal cardiac arrhythmias, CVAs and MIs.
- Portable unattended home studies, Type II, III, are still generally not reimbursed. Charges for them generally run from \$450-\$650

Need to define comorbid conditions

- COPD
- Severe or uncontrolled hypertension (160/100 not controlled by 2 or more antihypertensives)
- CHF or other known cardiac disease
- Severe Obesity (BMI>35)
- Neuromuscular Disease
- Suspected Central Sleep Apnea

Portables are considered Type III or II, depending on what they can monitor. (Type IV was not even considered in the major studies). The “simpler” they are to be applied for patients to use at home, generally the fewer channels of information they have. Limitations include not being able to visualize the patient in conjunction with events, intervene to apply therapy such as a split night or if devices become displaced, can’t see EEG to determine sleep staging, wakefulness, or arousals from events, would not be able to identify UARs, can’t see ECG, many don’t have body position sensors to see in what position the patient is sleeping. Also, without the opportunity to question the patient, don’t know if this was a normal night of sleep, or if they drank alcohol or had sedatives.

Conclusions:

Widespread use of portable unattended studies has not been accepted as a standard in the industry. There are numerous types of portable devices that provide varying types of information, creating a standardization challenge. Besides the more limited data available from an unattended portable home studies, patient outcomes from an accepted scientific study has not been done to insure this method is as good or better than Nocturnal Polysomnography attended in the accredited sleep center.

When deciding if portable unattended home sleep studies should be done, the more important issue becomes careful patient selection, assessment, and inclusion with relevant medical and sleep history. Also, thoughtful and knowledgeable treatment application and follow up with trained, credentialed, and experienced sleep professionals to insure maximum outcomes.

Carilion Sleep Center could therefore only endorse a product or algorithm which incorporated the above considerations.

The use of home portable studies is a high priority under review currently with a grant study initiated by the American Academy of Sleep Medicine, and conducted by the American Sleep Medicine Foundation.

Additionally, the American Academy of Otolaryngology recently requested and was granted another review of portable studies, by CMS, with a 30-day public comment period (which runs through April 13) for reconsideration of this issue. The proposed decision memo due date is September 14, 2007.

We look forward to additional studies with comparison and outcomes which will likely lead to solid pathways and guidelines for the use portable sleep studies, endorsement by the AASM, Medicare, and other private insurers, as well as reimbursement.

Teresa A. Carroll, Manager
Carilion Sleep Center
1030 Jefferson Street Suite G100
Roanoke, VA 24016
phone 540-985-8161

TO: Centers for Medicare & Medicaid Services

FROM: Paul Desmarais, RCP

RE: Public Comment re: Obstructive Sleep Apnea home testing (Ref: CAG-00093R2)

I am writing in my capacity as a home care provider, therapist, and former sleep technician to urge you to positively consider changing your coverage determination for obstructive sleep apnea home-based testing.

It is my belief that the patient is at time better served in their own bed and surroundings, and lower costs.

For decades, sleep laboratories have served a critical need in accurately diagnosing sleep apnea. But, just as our world has changed dramatically in other areas of technology, so has the field of sleep apnea research and diagnosis. Now, a proven wrist-worn device alternative versus the need for overnight clinic stays makes a strong case for updating CMS policies. It utilizes peripheral arterial tonometry (PAT), which has been approved by the FDA specifically for diagnosing sleep apnea in an unattended setting.

Peer reviewed research studies shows home testing is now as accurate and reliable as sleep clinics. Because of its efficacy and reliability PAT has been an accepted industry practice for some time; one where patients with the ability to pay cover the entire cost. But, many more patients suffering with OSA could be helped if insurance coverage was available.

Given these facts, I urge the CMS to change its coverage determination and to allow coverage for obstructive sleep apnea home testing.

Thank you,

Paul Desmarais, RCP
14 Woodruff Avenue
Narragansett, Rhode Island 02882

TO: Centers for Medicare & Medicaid Services

FROM: Jason Jones

RE: Public Comment re: Obstructive Sleep Apnea home testing (Ref: CAG-00093R2)

I am writing in my capacity as a home medical equipment provider for patients with sleep apnea to urge you to positively consider changing your coverage determination for obstructive sleep apnea home-based testing.

For decades, sleep laboratories have served a critical need in accurately diagnosing sleep apnea. But, just as our world has changed dramatically in other areas of technology, so has the field of sleep apnea research and diagnosis. Now, a proven wrist-worn device alternative versus the need for overnight clinic stays makes a strong case for updating CMS policies. It utilizes peripheral arterial tonometry (PAT), which has been approved by the FDA specifically for diagnosing sleep apnea in an unattended setting.

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Given these facts, I urge the CMS to change its coverage determination and to allow coverage for obstructive sleep apnea home testing.

Thank you,

Jason Jones
Owner
Jones Medical Supply
519-A S. Brundidge St.
Troy, AL 36081

TO: Centers for Medicare & Medicaid Services

FROM: Douglas Crana, President

RE: Public Comment re: Obstructive Sleep Apnea home testing (Ref: CAG-00093R2)

I am writing in my capacity as Respiratory / DME provider for over 30 years. My professional experience has seen many Medicare changes through out the year. The discovery of OSA has proved to be invaluable to healthcare today. I have seen first hand how patients can now manage their lives for the first time. In addition, OSA has been a helpful tool to further diagnosis other conditions. There are countless times that I have see patients that could benefit from in home OSA testing. Many labs are back logged. More importantly many patients do not want to go to a hospital for an over night study. Most would prefer to have it performed in the home. The Respiratory/DME industry has the ability and the experience to provide this service in the home. If CMS would take a close look at in home OSA testing, they also realize the huge benefits and saving. It is my professional opinion that if CMS approves in home OSA testing, it will greatly improve the quality of many lives in the US.

I urge you to positively consider changing your coverage determination for obstructive sleep apnea home-based testing.

For decades, sleep laboratories have served a critical need in accurately diagnosing sleep apnea. But, just as our world has changed dramatically in other areas of technology, so has the field of sleep apnea research and diagnosis. Now, a proven wrist-worn device alternative versus the need for overnight clinic stays makes a strong case for updating CMS policies. It utilizes peripheral arterial tonometry (PAT), which has been approved by the FDA specifically for diagnosing sleep apnea in an unattended setting.

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Given these facts, I urge the CMS to change its coverage determination and to allow coverage for obstructive sleep apnea home testing.

Thank you,

Douglas Crana
President
Consolidated Medical Inc.

I oppose in-home OSA testing. I am a HME company, Air-Care & Medical Equipment. We specialize in PAP. It is likely true I would make more money with in-home testing, yet I still oppose in-home testing. I have observed results of bad in-home testing, improper diagnosis, poor treatment plans and little or absolutely no follow up of patients.

Below is a copy of a fax I received today asking for support in-home OSA testing. I am unable to support their request.

The fax states:

- Patients will have better access to treatment
- Insurers could save millions
- HME industry would benefit from an expanded line of business.
- The American Academy of Otolaryngology – Head and Neck Surgery asked CMS to review the policy
- The HME industry has an important stake in the outcome of this issue.

The Voice of Support is a front for evo Medical Solutions, a HME company that sells PAP supplies.

Patients will have MORE not BETTER access to treatment. In the past there were many unscrupulous home study providers ripping off the public and government and insurance companies.

Insurers could save millions in the short term, but without proper medical diagnosis and follow up, in the long term it will cost more money and lives and quality of life,

DO NOT change a tried and true position just because “HME industry would benefit from an expanded line of business.”

It is true the HME industry has an important stake in the outcome. They, and I, will make millions at the expense of the insurance companies if you allow in-home testing. The position appears to be self serving.

Roger K. Wolff, President
Air-Care & Medical Equipment, LLC
315 S. Main Street
Spindale, NC

828.447.1312

Date: 04/04/2007

TO: Centers for Medicare & Medicaid Services

FROM: Brenda L. Foster, RRT

RE: Public Comment re: Obstructive Sleep Apnea home testing (Ref: CAG-00093R2)

I am writing in my capacity as a respiratory therapist who treats patients with sleep apnea to urge you to consider changing your coverage determination for obstructive sleep apnea home-based testing.

Many of my patients report negative experiences in sleep labs, and those experiences reflect on the outcome of the sleep study. Some patients who have severe sleep apnea cannot sleep on the night of the test due to the uncomfortable laboratory environment, so their test may reflect a "score" that is too high to qualify for therapy. A home test with the appropriate equipment would, in this case, provide a more realistic score for the medical professional to make the correct diagnosis.

For decades, sleep laboratories have served a critical need in accurately diagnosing sleep apnea. But, just as our world has changed dramatically in other areas of technology, so has the field of sleep apnea research and diagnosis. Now, a proven wrist-worn device alternative versus the need for overnight clinic stays makes a strong case for updating CMS policies. It utilizes peripheral arterial tonometry (PAT), which has been approved by the FDA specifically for diagnosing sleep apnea in an unattended setting.

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Given these facts, I urge the CMS to change its coverage determination and to allow coverage for obstructive sleep apnea home testing.

Thank you,

Brenda L. Foster, RRT
Sonora Regional Medical Center
1009 Mono Way
Sonora, CA 95370

Date: 04/04/2007

TO: Centers for Medicare & Medicaid Services

RE: Public Comment re: Obstructive Sleep Apnea home testing (Ref: CAG-00093R2)

I am writing in my capacity as a Registered Respiratory Therapist who has work with the sleep community since 1990 to urge you to positively consider changing your coverage determination for obstructive sleep apnea home-based testing.

I am very much in favor of 4-channel, ambulatory sleep studies for the "run of the mill OSA patient for these reasons:

1. The wait time for the labs is too long.
2. Many people with suspected OSA will not go to a lab to be studied.
3. There are approximately 80 M people with suspected sleep disordered breathing problems and the labs are only able to sleep 1.5M/year. How are we ever going to get a handle on the rest of the suspected population without doing ambulatory studies?
5. The labs should be sleeping people with complex sleep apnea and other sleep disorders – not your garden variety OSA person.
6. The technology is here. I have personally used the Watch_PAT 100 and it has been proven to be as good as a full poly over and over again.

For decades, sleep laboratories have served a critical need in accurately diagnosing sleep apnea. But, just as our world has changed dramatically in other areas of technology, so has the field of sleep apnea research and diagnosis. Now, a proven wrist-worn device alternative versus the need for overnight clinic stays makes a strong case for updating CMS policies. It utilizes peripheral arterial tonometry (PAT), which has been approved by the FDA specifically for diagnosing sleep apnea in an unattended setting.

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Given these facts, I urge the CMS to change its coverage determination and to allow coverage for obstructive sleep apnea home testing.

Thank you,

Helen A. Kent, BS, RRT
Owner

TO: Centers for Medicare & Medicaid Services

RE: Public Comment re: Obstructive Sleep Apnea home testing (Ref: CAG-00093R2)

I am writing in my capacity as a family member of a person with sleep apnea and an employee working with many people diagnosed with sleep apnea. I would like to urge you to positively consider changing your coverage determination for obstructive sleep apnea home-based testing.

Many people are unable to have this testing completed at sleep centers due to the lack of transportation and/or other illnesses that prevent them from leaving their homes.

For decades, sleep laboratories have served a critical need in accurately diagnosing sleep apnea. But, just as our world has changed dramatically in other areas of technology, so has the field of sleep apnea research and diagnosis. Now, there are proven in-home alternatives to overnight clinic stays that make a strong case for updating CMS policies. These alternatives utilize peripheral arterial tonometry (PAT), which has been approved by the FDA specifically for diagnosing sleep apnea in an unattended setting.

Peer reviewed research studies shows home testing is now as accurate and reliable as sleep clinics. Because of its efficacy and reliability PAT has been an accepted industry practice for some time; one where patients with the ability to pay cover the entire cost. But, many more patients suffering with OSA could be helped if insurance coverage was available.

Given these facts, I URGE the CMS to change its coverage determination and to allow coverage for obstructive sleep apnea home testing.

Thank you,

Pat Lott
Billing Clerk
Life Line Home Care Services

To Whom It May Concern:

This letter is in response to the CMS Public Comment Period for in home sleep testing. As an owner of 4 AASM accredited sleep disorder centers, I am very concerned about home sleep testing. Following are issues that need to be addressed:

1. Payment will be made when accuracy of testing can not be guaranteed with unattended studies. An integral part of a sleep study is artifact free, accurate data.
2. What guarantees that the subject being tested is the actual subject needing tested? Attended in home sleep studies pose many risks. One example is safety of the technician and patient.
3. To obtain accurate sleep disorder testing, multiple channels need to be reviewed. This includes EEG, EMG, EOG, EKG, SAO2, AIRFLOW, THORACIC AND ABDOMINAL MOVEMENT, ETC. An in home study can not provide the needed channels. Although, in home testing is being considered for Sleep Disordered Breathing, sleep testing can diagnose other disorders at the same time diagnosing OSA. This may lead to payment of multiple sleep tests in order to evaluate and treat multiple sleep disorder.
4. In home testing does not include one of the most critical elements of Sleep Disorder Testing, which is patient education. Sleep Technicians and Accredited Sleep Disorder Centers are the first line of defense when it comes to patient education which leads to patient compliance with home sleep equipment, medication usage, proper sleep hygiene (behaviors).
5. Please consider the driving force behind the pursuit of in home testing. They are manufacturers or suppliers of equipment. They are not health care providers or physicians. As health care providers, patient care, patient education, patient safety are our biggest concerns. But our primary concern is to provide the best service to our patients without increasing the costs to the healthcare system.

Thank you for time and consideration regarding this very important issue.

Teresa A. Adler
LifeLine Partner Sleep Disorder Centers
Youngstown, Ohio

Date: 4/5/2007
TO: Centers for Medicare & Medicaid Services
FROM: John Dycus
RE: Public Comment re: Obstructive Sleep Apnea home testing (Ref: CAG-00093R2)

I am writing in my capacity as DME that does full line respiratory to urge you to positively consider changing your coverage determination for obstructive sleep apnea home-based testing.

For decades, sleep laboratories have served a critical need in accurately diagnosing sleep apnea. But, just as our world has changed dramatically in other areas of technology, so has the field of sleep apnea research and diagnosis. Now, a proven wrist-worn device alternative versus the need for overnight clinic stays makes a strong case for updating CMS policies. It utilizes peripheral arterial tonometry (PAT), which has been approved by the FDA specifically for diagnosing sleep apnea in an unattended setting.

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Given these facts, I urge the CMS to change its coverage determination and to allow coverage for obstructive sleep apnea home testing.

Thank you,

John Dycus
C.E.O.
American Home Medical
106 Knox Rd
Knoxville TN 37918

Date: 04/05/2007

TO: Centers for Medicare & Medicaid Services

FROM: Pulmonary Home Care - Debbie Kidd, RRT

RE: Public Comment re: Obstructive Sleep Apnea home testing (Ref: CAG-00093R2)

I am writing in my capacity as a Durable Medical Equipment Supplier to urge you to positively consider changing your coverage determination for obstructive sleep apnea home-based testing.

For example Sleep Labs have a waiting period of six weeks or more. The entire process could take several weeks before a patient can be treated. This could be life threatening.

For decades, sleep laboratories have served a critical need in accurately diagnosing sleep apnea. But, just as our world has changed dramatically in other areas of technology, so has the field of sleep apnea research and diagnosis. Now, a proven wrist-worn device alternative versus the need for overnight clinic stays makes a strong case for updating CMS policies. It utilizes peripheral arterial tonometry (PAT), which has been approved by the FDA specifically for diagnosing sleep apnea in an unattended setting.

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Given these facts, I urge the CMS to change its coverage determination and to allow coverage for obstructive sleep apnea home testing.

Thank you,

Debbie Kidd, RRT
Pulmonary Home Care

Date: 04/05/2007
TO: Centers for Medicare & Medicaid Services
FROM: Vicky Lynn Anderson, CRT
RE: Public Comment re: Obstructive Sleep Apnea home testing (Ref: CAG-00093R2)

I am writing in my capacity as a Respiratory Therapist to urge you to positively consider changing your coverage determination for obstructive sleep apnea home-based testing.

I have been in the Respiratory field for 30 years. Home care is my specialty. I worked many years performing in home sleep testing. It is a convenient, practical and cost effective way to determine if a patient has sleep apnea. A patient is in their home environment and not in a strange bed that may cause restless sleep anyway. The test itself is much less invasive and restricting. There are only 4 leads to contend with, compared to 16 in a sleep lab. It is not necessary to stage sleep and monitor limb movement to determine if someone has sleep apnea. Simply monitoring the heart rate, oxygen saturation, airflow and chestwall movement will determine sleep apnea. Treatment is the same no matter how many leads the actual test monitored. I have people now that refuse to go to a sleep lab for this test. It's too uncomfortable and too expensive. They would much prefer an in home sleep study. Therefore, there are untreated sleep apnea patients who continue to have increased health problems directly related to their untreated sleep apnea. There are studies that confirm the association of increased risk of stroke, hypertension, diabetes, cardiac problems, depression, sexual dysfunction, etc..... Not to mention that these people are in the work force and are accidents waiting to happen. To themselves, or to innocent people who happen to be in their path. How much is this costing society? Medicare, Medicaid, insurance companies, employers, family, friends, etc.... All because we can't reach everyone who needs reaching with sleep lab testing. Routinely, I am asked by patients and medical professionals, for in home testing. I must reply that it is no longer covered and therefore, we can no longer provide this service. Call a sleep lab and find out the waiting period for an appointment. Weeks or maybe even months before an opening. I would greatly welcome the approval to once again perform in home sleep study testing.

For decades, sleep laboratories have served a critical need in accurately diagnosing sleep apnea. But, just as our world has changed dramatically in other areas of technology, so has the field of sleep apnea research and diagnosis. Now, there are proven in-home alternatives to the need for overnight clinic stays that make a strong case for updating CMS policies. These alternatives utilize peripheral arterial tonometry (PAT), which has been approved by the FDA specifically for diagnosing sleep apnea in an unattended setting.

Peer reviewed research studies shows home testing is now as accurate and reliable as sleep clinics. Because of its efficacy and reliability PAT has been an accepted industry practice for some time; one where patients with the ability to pay cover the entire cost. But, many more patients suffering with OSA could be helped if insurance coverage was available.

Given these facts, I urge the CMS to change its coverage determination and to allow coverage for obstructive sleep apnea home testing.

Thank you,

Vicky Lynn Anderson, CRT
85211 Blackmon Road
Yulee, FL 32097

Date: 4/5/2007

TO: Centers for Medicare & Medicaid Services

FROM: Jenny Cauthen

RE: Public Comment re: Obstructive Sleep Apnea home testing (Ref: CAG-00093R2)

I am writing in my capacity as a Director of HME to urge you to positively consider changing your coverage determination for obstructive sleep apnea home-based testing.

For decades, sleep laboratories have served a critical need in accurately diagnosing sleep apnea. But, just as our world has changed dramatically in other areas of technology, so has the field of sleep apnea research and diagnosis. Now, a proven wrist-worn device alternative versus the need for overnight clinic stays makes a strong case for updating CMS policies. It utilizes peripheral arterial tonometry (PAT), which has been approved by the FDA specifically for diagnosing sleep apnea in an unattended setting.

Peer reviewed research studies shows home testing is now as accurate and reliable as sleep clinics. Because of its efficacy and reliability PAT has been an accepted industry practice for some time; one where patients with the ability to pay cover the entire cost. But, many more patients suffering with OSA could be helped if insurance coverage was available.

Given these facts, I urge the CMS to change its coverage determination and to allow coverage for obstructive sleep apnea home testing.

Thank you,

Jenny Cauthen
Director of HME
Alacare Home Health & Hospice
2400 John Hawkins Parkway
Birmingham, AL 35244
205-981-8649
205-981-8118 fax
jcauthen@alacare.com

I am writing to urge you to consider changing your coverage determination for obstructive sleep apnea home-based testing. I know of several patients who need to have a sleep study done, but do not have any mode of transportation to get to a sleep lab. Our hospital and clinic in Cresco, IA does not have a sleep lab, and the closest sleep lab is 20 miles away. If they could have access to in-home sleep testing, we could find and help more people with sleep disordered breathing. Technology is changing in other areas of health care and the field of sleep apnea research and diagnosis should change, too. So, please consider changing the coverage determination and allow coverage for obstructive sleep apnea home testing.

Thank you,

Janine Mayer, CRT

Regional Health Services of Howard County

Home Medical Equipment

327 8th Avenue West

Cresco, IA 52136

(563)547-5573

(563)547-4223 (fax)

In Home Sleep Testing

I have been a therapist, manager and now director of Respiratory Therapy departments for 23+ years and have been involved in sleep medicine during this time. I have performed and scored unsupervised bed side testing and have managed accredited sleep laboratories. Based on this experience, I can say that In-Home studies will work for some patients, but at the same time, I feel it is far from the ideal method for obtaining good quality diagnostic sleep data. There is a lot of good diagnostic data that is obtained from observation of the patient. Also, real time intervention (leads coming off, poor signal quality, clinical assistance...) negates the need for patients to be retested for multiple nights until a good clinical data collection is acquired. I also believe that the higher quality level of the equipment from a full lab is quite significant when comparing the two methods of testing.

Overall I understand why CMS would be looking at In-Home studies, but I feel it would be the WRONG decision. Instead CMS should look at utilizing only Sleep Centers / Labs that are accredited and can guarantee quality testing.

Mark Rau

Director Diagnostic Services

Community Regional Medical Center

Lorain, Ohio

I would like voice my opposition to unattended home sleep studies. My experience with Ambulatory EEG's tells me that incomplete and artifactual studies are all to common when sending patients home with recording equipment.

Any potential cost savings are lost when multiple studies are needed. Laboratory sleep testing can many times accomplish dx and tx in one night; home studies of any quality will always require a minimum of two nights.

I can only speak of our 4 state area, but there are no delays for patients seeking sleep evaluations in an accredited laboratory.

The notion that care is delayed by the lack of facilities is not supported by any objective measure.

I have seen many technological developments in my 25 years in the medical field. But to date, the quality of home studies is not to the level that patient's expect.

David Wortley
Neurodiagnostic Services (Neurodx, IOM, Sleep)

In regards to in-home polysomnographic testing, there are several observations that should be forwarded to the reviewers at CMS. The first is the misperception that appropriate testing is not readily available to patients. In the Mid-South market, ours and several other accredited laboratories have empty beds **every** night which could accommodate additional patients. In addition, we attempt to perform a split night study (diagnostic followed by CPAP titration) if warranted. The second is that home testing will be a wonderful convenience for patients at a much reduced cost and with good clinical data. Our laboratory performed a number of in-home sleep studies through several DME companies using Poly-G devices in the mid 1990s. About one third of these studies were regarded as suboptimal for clinical interpretation because various probes became disconnected through the night. There was significant push-back by the DME companies to have an interpretation so that they did not have to repeat the testing and could bill for the service. If in-home testing is approved, there will definitely need to be quality controls in place.

Opinions expressed above are not necessarily those of BMHCC.

Dr. Schriener - Collierville Sleep Lab

Office (901) 861-9003

Fax (901) 861-9007

With the Auto set CPAP units on the market today, many patients could be places on these units and be treated much quicker and just as effectively with a MAJOR cost saving to the insurance companies. If they meet certain guidelines this should be made an acceptable mode of diagnostics and treatment.

A little common sense would go a long way on this subject

Daryl H. Bender CRT, RCP

I VOTE NO

I believe introducing coverage for home testing for OSA is dangerous and will lead to significant misdiagnosis and mistreatment for patients.

This will only lead to opportunists who will redirect specialty care. There is no significant wait for getting patients evaluated and treated in accredited sleep centers.

Thank you,

**Jim Curlee DO, FCCP
Diplomate, American Board of Sleep Medicine**

I am writing in my capacity as a Respiratory Homecare Specialist to urge you to positively consider changing your coverage determination for obstructive sleep apnea home-based testing.

For decades, sleep laboratories have served a critical need in accurately diagnosing sleep apnea. But, just as our world has changed dramatically in other areas of technology, so has the field of sleep apnea research and diagnosis. Now, a proven wrist-worn device alternative versus the need for overnight clinic stays makes a strong case for updating CMS policies. It utilizes peripheral arterial tonometry (PAT), which has been approved by the FDA specifically for diagnosing sleep apnea in an unattended setting.

Peer reviewed research studies shows home testing is now as accurate and reliable as sleep clinics. Because of its efficacy and reliability PAT has been an accepted industry practice for some time; one where patients with the ability to pay cover the entire cost. But, many more patients suffering with OSA could be helped if insurance coverage was available.

Given these facts, I urge the CMS to change its coverage determination and to allow coverage for obstructive sleep apnea home testing.

Thank you,
Gabriele Bailey Colvin
Community Home Care Services

I'm in support of cms covering in home sleep testing
Vince Roberts

Regarding In-Home Sleep Studies

It is my opinion that studies should not be forced into the home because there has been inadequate research to prove it is equal in quality to an attended sleep study in a lab. You will see such a proliferation of in-home devices and CPAP machines, the cost will no doubt exceed what the government is now paying for sleep studies. Every HME provider in country will jump on the band wagon and utilization will shoot through the roof. They will have no way of controlling and monitoring the usage of CPAP, in fact, most DME companies don't do it now because they say it is too much trouble.

Please leave the testing in the labs where it can be professionally administered and sleep testing companies can teach, monitor, and improve CPAP usage. If quality of care is the ultimate goal, please don't settle for less.

Thank you!

Sharon L. Tolliver

I am a Registered Respiratory Therapist that has been working in my field for 32 years. During that time I have worked with alot of OSA patients. I have heard many complaints about there experience in the sleep lab. Most have a hard time sleeping , so how accurate are these studies? Why would insurance companies want to pay for this very expensive hotel stay ? My patients have voiced to me that they would do much better if they could stay in there own bed and in there home. Please supprt CAG-00093R2 Sincerely,
Cathy Muller RRT.,RCP

Date: 4/5/2007

TO: Centers for Medicare & Medicaid Services

FROM: James B. Young

RE: Public Comment re: Obstructive Sleep Apnea home testing
(Ref:
CAG-00093R2)

I am writing in my capacity as a owner of an HME company to urge you to positively consider changing your coverage determination for obstructive sleep apnea home-based testing

For decades, sleep laboratories have served a critical need in accurately diagnosing sleep apnea. But, just as our world has changed dramatically in other areas of technology, so has the field of sleep apnea research and diagnosis. Now, a proven wrist-worn device alternative versus the need for overnight clinic stays makes a strong case for updating CMS policies. It utilizes peripheral arterial tonometry (PAT), which has been approved by the FDA specifically for diagnosing sleep apnea in an unattended setting.

Peer reviewed research studies shows home testing is now as accurate and reliable as sleep clinics. Because of its efficacy and reliability PAT has been an accepted industry practice for some time; one where patients with the ability to pay cover the entire cost. But, many more patients suffering with OSA could be helped if insurance coverage was available.

Given these facts, I urge the CMS to change its coverage determination and to allow coverage for obstructive sleep apnea home testing.

Thank you,

James B. Young
Owner of Homedical

Dear CMS,

I am a practicing sleep and pulmonary specialist for nearly 20 years and wish to register my objection to the coverage of in-home sleep diagnostics. I have performed in-home full polysomnography in the past using portable computers and video equipment operated by a sleep technologist that spent the night in the patient's home. The test was at best very difficult to administer (often there was a bed partner who took issue with the sleep study intruding into their sleep period) and technicians found it difficult to correct electrode loss or other technical problems during the study since they were often tripping around the house to get into the bedroom and had to turn on lighting, etc. – this could obviously lead to substantial disturbance of the entire household. Even placing redundant EEG electrodes and using a Kerlex to hold the leads in place, but the study data was often poor quality and incomplete.

In addition, I had several instances where techs refused to perform an in-home attended study due to their sense of personal discomfort and concern for their wellbeing in the patient's home. I stopped performing these over 13 years ago and do not see where there has been significant technological advances to overcome these problems (not to mention the tech safety issue). Moreover, they are inefficient to perform since it requires 1 tech per patient, thus making them more expensive.

I subsequently tried unattended limited polysomnography studies (no EEG) and also found them to be unsatisfactory due to frequent artifacts and signal loss making interpretation challenging and poor clinical decision making confidence with the results. Due to these critical problems, my practice no longer offers these type of studies. I recommend that these studies also not be approved for reimbursement by CMS due to the limited confidence in the data AS PERFORMED on a COMMUNITY LEVEL (not as in a carefully controlled research study).

I do recommend that you continue to reimburse overnight oximetry studies with computerized analysis since these HAVE proved quite useful and beneficial for patient care. They are well supported by a great number of non-industry supported studies, too. The oximetrys are also very inexpensive and can be performed by both specialists and non-specialists (primary care physicians commonly use these in my area of Georgia).

Thank you for your consideration of my comments,

James A. Daly, MD, FCCP
Diplomate, American Board of Sleep Medicine
Southeast Lung and Critical Care Specialists, PC
Savannah, GA

Date: 4/5/2007
TO: Centers for Medicare & Medicaid Services
FROM: Forrest Lewis
RE: Public Comment re: Obstructive Sleep Apnea home testing (Ref: CAG-00093R2)

I am writing in my capacity as a Respiratory Therapist and Registered Nurse to urge you to positively consider changing your coverage determination for obstructive sleep apnea home-based testing.

For decades, sleep laboratories have served a critical need in accurately diagnosing sleep apnea. But, just as our world has changed dramatically in other areas of technology, so has the field of sleep apnea research and diagnosis. Now, a proven wrist-worn device alternative versus the need for overnight clinic stays makes a strong case for updating CMS policies. It utilizes peripheral arterial tonometry (PAT), which has been approved by the FDA specifically for diagnosing sleep apnea in an unattended setting.

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Given these facts, I urge the CMS to change its coverage determination and to allow coverage for obstructive sleep apnea home testing.

Thank you,

Forrest Lewis, RN, RT

I am writing to urge you to approve coverage for in-home testing of obstructive sleep apnea. Such approval would allow many people who cannot travel to certain testing centers to get access to treatment. It is actually prejudicial that in-home coverage has been denied such people.

Lee Cali
2102 Elk Circle
Cottonwood AZ 86326

Dear Sir or Madam,

I respectfully request that you investigate thoroughly the need for home-based sleep apnea testing. I believe that it is a technology whose time has come.

I have been a technician working in sleep medicine for the past 7 years. One of the most frequent patient complaints is that they prefer to sleep in their own bed. They do have a point. Home-based testing would allow us to peek at our patients in their native environment (so to speak) and have a glimpse of how they really sleep on a nightly basis.

Previous home testing equipment was woefully inadequate to provide the information needed. It had too few recording channels and was quite bulky. The current (and future) equipment offers enough channels to record brain waves (to monitor sleep stages), position sensors (to tell how the patient is moving in bed), built-in oximeters (to monitor oxygen levels) and enough recording channels to monitor EKG, respiration effort, leg movements, eye movements, airflow, chin muscle tension and still has recording channels to spare! All of this technology is wrapped in a package that is small enough to manage to go to sleep with. Most Holter monitors are bulkier than this recording equipment!

It is also much more cost effective.

There is also the issue of a waiting list for testing currently in sleep labs. I believe that use of these recording systems would help to reduce this waiting time. That translates into being able to obtain treatment faster. And that is the bottom line after all, isn't it? Healthcare!

I also wish to impress upon you the fact that there will always be a need for sleep lab-based testing as well - but these patients would necessarily have complications such as known heart disease or a respiratory condition such as COPD. These are the patients who benefit the most from the intensive monitoring and the expertise of qualified technologists who know how to respond to their needs - especially in a hospital-based setting. There is also the whole gamut of sleep disorders and parasomnias that should really be investigated in a sleep laboratory, ie. narcolepsy.

Just as there are varying degrees of monitoring for cardiac arrhythmias ranging from a simple EKG to a 12 lead EKG to Holter monitoring to telemetry, there needs to be a range of services to treat sleep disorders that begins with simple home-based testing and goes all the way to more comprehensive sleep lab-based examinations.

Thank you for your consideration.

Sincerely,

Ann Ayala, R EEG/EP T, RPSGT

Supervisor

Parkridge East Hospital

Sleep Well Center

ph: (423) 499-2088

fax: (423) 499-2086

Email: Ann.Ayala@HCAhealthcare.com

Dear Sir/Madm:

I believe that In-Home, Unattended, 4 to 6 channels need to be covered for the following reasons:

They have some diagnostic value within the general OSA population as a general screening tool in conjunction with a history and physical exam.

They are probably about \$1,000.00 less expensive than a full 14 to 16 channel study.

I personally have done and been doing ,4 channel studies on prisoners, up until about a month ago when reimbursement issues became a primary concern, and the studies were stopped until there is definitive clarification re the issues of reimbursement. As you can reasonably appreciate and understand, prison medical teams will err in favor of over ordering of dx test vs being subjected to charges by prisoners and their lawyers, that they were being denied medical treatment. Therefore, the 4 to 6 channel sleep studies were being ordered for prisoners who alleged to be suffering from OSA. Are we really going to send a prisoner, with not less than two armed corrections officers and their cruiser and the escort cruiser, (another two armed men) to an independent sleep lab and engage in a \$1200 to \$1800 full 16 channel PSG when a simple 4 to 6 channel screening sleep study would probably do the job? Not to mention that most sleep study labs do 2 to 4 sleep studies a night. And what effect will two or four armed correction officers have on the quality of the sleep study on the other patients. And how many sleep techs will even agree to work with prisoners that need to be accompanied by armed guards?

In short, I believe that there is a place for the 4 to 6 channel unattended sleep study.

Thank you for your time

Sincerely

Dennis Otis

Date: 04/06/2007
TO: Centers for Medicare & Medicaid Services
FROM: Chuck Taylor, RRT RCP
RE: Public Comment re: Obstructive Sleep Apnea home testing (Ref: CAG-00093R2)

I am writing in my capacity as a Respiratory Therapist involved in home care to urge you to positively consider changing your coverage determination for obstructive sleep apnea home-based testing.

For decades, sleep laboratories have served a critical need in accurately diagnosing sleep apnea. But, just as our world has changed dramatically in other areas of technology, so has the field of sleep apnea research and diagnosis. Now, a proven wrist-worn device alternative versus the need for overnight clinic stays makes a strong case for updating CMS policies. It utilizes peripheral arterial tonometry (PAT), which has been approved by the FDA specifically for diagnosing sleep apnea in an unattended setting.

Peer reviewed research studies shows home testing is now as accurate and reliable as sleep clinics. Because of its efficacy and reliability PAT has been an accepted industry practice for some time; one where patients with the ability to pay cover the entire cost. But, many more patients suffering with OSA could be helped if insurance coverage was available.

Given these facts, I urge the CMS to change its coverage determination and to allow coverage for obstructive sleep apnea home testing.

Thank you,

Chuck Taylor, RRT RCP
311 10th Street
Gothenburg, NE 69138

Dear Sir or Madam

I am writing to urge you not to allow the CPAP manufacturers to bamboozle you into thinking home testing for sleep apnea will lead to better treatment for sleep apnea patients. This is an attempt to allow anyone with a physician's license to become a de facto "sleep expert" and put anyone with a complaint about their sleep on CPAP, to the benefit of the manufacturers of these CPAP devices. The argument that conventional sleep centers act as a "bottleneck" to the treatment of sleep apnea patients only holds water if you define "bottleneck" as waiting a week or two to be evaluated by an expert in the field of sleep medicine. Rather than providing CPAP to patients who truly need it and giving those patients expert instruction in the use of the device, home testing will undoubtedly lead to over-prescription of these devices (driving up costs to insurance companies) and will replace instruction on the use of CPAP by trained sleep professionals with instruction by DME delivery drivers or instruction by mail for DMEs that simply mail out medical equipment. In the end, patient compliance with CPAP will suffer due to lack of effective instruction and follow-up, and medical costs associated with sleep apnea will actually go up. The current system of in-lab testing under controlled conditions allows patients access to experts in the field for diagnosis, instruction in therapy, and follow-up care. I ask you to see through this attempt by the CPAP manufacturers to enrich themselves in the short term at the expense of the long term health of patients with sleep apnea.

Sincerely,

Rustin A. Glessner, RPSGT, CRT
Chief Sleep Technologist
Riddle Memorial Hospital

Date: 04/06/2007
TO: Centers for Medicare & Medicaid Services
FROM: Carol Jerauld @ Lacey Drugs
RE: Public Comment re: Obstructive Sleep Apnea home testing (Ref: CAG-00093R2)

I am writing in my capacity as a medical equipment provider to urge you to positively consider changing your coverage determination for obstructive sleep apnea home-based testing.

I have spoken with many customers whose doctor believes they have sleep apnea, but the customer, can't or won't, have the study done in a sleep lab. Having the option to have a home study done would ultimately lower costs associated with sleep apnea.

For decades, sleep laboratories have served a critical need in accurately diagnosing sleep apnea. But, just as our world has changed dramatically in other areas of technology, so has the field of sleep apnea research and diagnosis. Now, a proven wrist-worn device alternative versus the need for overnight clinic stays makes a strong case for updating CMS policies. It utilizes peripheral arterial tonometry (PAT), which has been approved by the FDA specifically for diagnosing sleep apnea in an unattended setting.

Peer reviewed research studies shows home testing is now as accurate and reliable as sleep clinics. Because of its efficacy and reliability PAT has been an accepted industry practice for some time; one where patients with the ability to pay cover the entire cost. But, many more patients suffering with OSA could be helped if insurance coverage was available.

Given these facts, I urge the CMS to change its coverage determination and to allow coverage for obstructive sleep apnea home testing.

Thank you,

Carol Jerauld
DME Manager
Lacey Drug Company

Date: 4/6/2007

TO: Centers for Medicare & Medicaid Services

FROM: Tim Carroll, O2 Solutions

RE: Public Comment re: Obstructive Sleep Apnea home testing (Ref: CAG-00093R2)

I am writing in my capacity as an employee of O₂ Solutions, a clinical respiratory service provider that offers home medical equipment supplies, including oxygen therapy and sleep medicine products, to people in upstate New York, to urge you to positively consider changing your coverage determination for obstructive sleep apnea home-based testing.

For decades, sleep laboratories have served a critical need in accurately diagnosing sleep apnea. But, just as our world has changed dramatically in other areas of technology, so has the field of sleep apnea research and diagnosis. Now, a proven wrist-worn device alternative versus the need for overnight clinic stays makes a strong case for updating CMS policies. It utilizes peripheral arterial tonometry (PAT), which has been approved by the FDA specifically for diagnosing sleep apnea in an unattended setting.

Peer reviewed research studies shows home testing is now as accurate and reliable as sleep clinics. Because of its efficacy and reliability PAT has been an accepted industry practice for some time; one where patients with the ability to pay cover the entire cost. But, many more patients suffering with OSA could be helped if insurance coverage was available.

Given these facts, I urge the CMS to change its coverage determination and to allow coverage for obstructive sleep apnea home testing.

Thank you,

Tim Carroll
Reimbursement Specialist
O2 Solutions
One West Ave Suite 125
Saratoga Springs, NY 12866
(518)226-6037 Phone (518) 226-4897 Fax
tim@myo2solutions.com

To whom it may concern:

I do not believe in home testing will be in the best interests of the patients. The lack of oversight and quality assurance opens the door to abuses of the healthcare system and the patients being served.

Jeff Scobee

Dear Sirs:

I am a pulmonologist who has had a busy sleep practice for almost 20 years. I have extensive experience with both home and in-lab attended sleep studies in well over 10,000 cases. While OSA may be successfully diagnosed in a home study with a 20-30% false negative rate and 25% inadequate study rate, ALL of the other coexistent sleep conditions which occur in over 70% of cases whose concurrent treatment is required for successful treatment are routinely missed. In addition, the most important element of an in-lab attended sleep study is an enlightened CPAP titration requiring frequent mask changes and adjustment, adjustment of pressure based on tolerance (which an auto machine cannot do), and looking for "deep sleep rebound" to confirm optimal CPAP pressure, mask, leak control, etc. which an auto machine cannot do.

You're probably thinking I'm writing this for financial reasons. Please note the following: In the 1990's, Group Health in Seattle, WA used home sleep studies exclusively in a large portion of their patients, Their Pulmonologists, who were not certified in sleep at the time and had virtually never used in-lab sleep studies, felt that their population was well-served and published their results. At that time, I helped with both sleep patients and utilization in the region north of Seattle. In our in-lab sleep patients, they had an average of about 1.05 sleep studies/5-10 year period (almost all split-night studies costing the same as a CPAP titration) and a one year "full compliance" rate approaching 89% in my group of patients. Part of the reason for success was sleep MD consultation pre-study to prepare them carefully for the study, and careful MD and DME RT sleep tech f/u to optimize all the little details that bring success.

In the general Group Health patient group, the average patient had a minimum of three home studies and often 4-5 over the first year, and estimated one-year compliance was less than 50% by the director of RT in Seattle. Patients who don't have a good experience in the 1st "Golden Month" of CPAP initiation often go on to have often ineffective surgeries, have multiple repeat studies, or even worse, go untreated even after \$1000's have been spent.

Our lab also published a direct head-to-head comparison of the Resmed Autoset CPAP machine vs conventional split-night study and found it did not work well in a third of cases. Another quarter required multiple pressure adjustments over the subsequent years.

Thus I believe that optimal, excellent sleep disorder evaluation benefits from expert consultative guidance and expert, attended in-lab sleep study and is FAR MORE COST EFFECTIVE, RELIABLE, QUALITY CONSCIOUS, and SAFER than in-home studies, especially when the latter is supervised by non-experts who are often not even aware that their study was inaccurate, or their patient has another disorder such as narcolepsy.

I therefore would continue to recommend that in-lab attended sleep studies supervised by knowledgeable experts who are performing in a cost-effective and patient-oriented manner remain the standard of care for original diagnosis and initial treatment. In-home autotitration studies are a helpful adjunct for patients requiring more titration or changes.

I don't think the decision to allow in-home studies to be used for initial diagnosis should be promoted by companies profiting from the sale of such equipment or by therapists who are not experts in this field and may be more interested in profits than in obtaining the best level of care for these often difficult patients.

Rolf Holle MD FCCP Diplomate ABSM

Date: 4/6/2007

TO: Centers for Medicare & Medicaid Services

FROM: Jann Sherin, RRT, RCP

RE: Public Comment re: Obstructive Sleep Apnea home testing
(Ref:
CAG-00093R2)

I am writing in my capacity as a homecare Respiratory Therapist to urge you to positively consider changing your coverage determination for obstructive sleep apnea home-based testing.

As a homecare therapist, I get to see the patients as they really are in their environment. We can save big money by testing people at home for basic OSA. The testing devices available today are reliable for OSA, and will give rise for further testing if, in fact, there are other underlying problems that require more advanced testing measures.

For decades, sleep laboratories have served a critical need in accurately diagnosing sleep apnea. But, just as our world has changed dramatically in other areas of technology, so has the field of sleep apnea research and diagnosis. Now, a proven wrist-worn device alternative versus the need for overnight clinic stays makes a strong case for updating CMS policies. It utilizes peripheral arterial tonometry (PAT), which has been approved by the FDA specifically for diagnosing sleep apnea in an unattended setting.

Peer reviewed research studies shows home testing is now as accurate and reliable as sleep clinics. Because of its efficacy and reliability PAT has been an accepted industry practice for some time; one where patients with the ability to pay cover the entire cost. But, many more patients suffering with OSA could be helped if insurance coverage was available.

Given these facts, I urge the CMS to change its coverage determination and to allow coverage for obstructive sleep apnea home testing.

Thank you,

Jann Sherin, RRT, RCP
Clinical Director
NBN Infusion and Respiratory
2 Pin Oak Ln. Suite 250
Cherry Hill, NJ 08003

Date: 4/6/2007

TO: Centers for Medicare & Medicaid Services

FROM: Ron Daniel, Pharm.D.

RE: Public Comment: Obstructive Sleep Apnea Home Testing (Ref: CAG-00093R2)

I am responding to the opportunity to make comments regarding coverage determination for obstructive sleep apnea [OSA] in-home testing, for Medicare recipients.

Traditionally, sleep laboratories have provided the necessary testing to diagnose OSA. However, there have been dramatic improvements in the technology of in-home equipment used to diagnose sleep disorders, such as OSA. Additionally, in-home testing for OSA more closely simulates a normal night's sleep, since patients sleep in their own beds, in a familiar environment.

The cost associated with in-home testing is substantially less than that of testing in a laboratory. Although costs vary from one laboratory to another, there can be as much as a three to four fold reduction in the cost of testing for OSA when using in-home sleep testing for OSA, as opposed to tests performed in a sleep laboratory. Studies demonstrate that in-home testing for OSA is just as accurate and reliable as sleep studies performed in sleep laboratories.

In consideration of these facts, I believe that it is imperative for CMS to evaluate in-home sleep testing for OSA, and to include this type of diagnostic testing as part of its covered services for Medicare recipients

Sincerely,

Ron Daniel, Pharm.D.
1610 Madison Ave.
Tifton, Ga. 31794

To whom it may concern,

I have been a registered respiratory therapist for almost twenty five years now and in that time, I have noticed a dramatic increase in the number of people suffering from obstructive sleep apnea. There are a few reasons for this increase. Lack of physical activity and increased food consumption are leading causes of obesity and this problem has led to an increase in OSA. Throughout my career, I have spoken with many patients regarding in-house sleep studies. Many are receptive. Once the test is completed and a proper diagnosis is rendered, these patients are often times prescribed a CPAP unit in order to alleviate their symptoms. Quite often, their condition becomes controlled. However, many times patients are reluctant to have an in-house study performed. This is where an in-home study could be extremely valuable. By allowing reimbursement for in-home sleep studies, many reluctant patients will receive the studies they require and receive the diagnosis necessary to receive a CPAP machine. By receiving the CPAP machine, these previously undiagnosed problems can be treated effectively. This may lead to an increase in the patients overall health and by becoming more healthy, these patients will pose a decreased burden on an already overburdened American health care system.

Sincerely,
John David McGrath, RRT

I am writing this letter due to the fact that CMS is in process of review of the sleep study in home testing policy. Having been involved with the field of sleep medicine for tens of years I must say that in home sleep testing would be a mistake. I was actually involved in home testing for quite some time and there is no way to validate the information gathered. I do not think sleep can effectively be measured or validated without EEG monitoring and staging of sleep. With the given technology that is out there at this time I don't feel that there is a means of validating the data that is gathered in the unattended session. I also feel that if this is permitted that every durable medical company will be in the sleep testing business and that will create a huge area for companies to create business for themselves. In turn by doing this we will create a huge area that is unmonitored by anyone and will in turn create a huge black pit where everyone who is tested will be positive.

One of the key issues in the home testing argument has always been the wait to get into a sleep lab. With new labs opening at a furious pace I don't see this as a problem anymore. I agree we do need more screening devices and there are some good ones out there but they should only be used for screening. I have used those and they are a good tool for that but you cannot validate the information gathered and it only gives you a good starting point.

I would therefore ask you to carefully consider that sleep centers be kept as the gold standard in sleep testing.

H. Kevin Gregory, RRT, RPFT, RPSGT

Date: 4/6/2007

TO: Centers for Medicare & Medicaid Services

FROM: Ellen Ayers, CRT/RPSGT

RE: Public Comment re: Obstructive Sleep Apnea home testing (Ref: CAG-00093R2)

My concerns are too many poorly run, non-educated clientele will perform home studies without Board certified MD's interpreting the studies. It has been my experience that the technicians stay busy t/o the night helping the pt.'s, educating them and getting histories not obtained from the physician. We also run into PLM's (periodic leg movements), RLS (restless leg syndrome), parasomnias as well as cardiac arrhythmias that would not be picked up by home sleep studies. I think more advancement needs to be made as I feel that it will be evitable to perform home studies but the technology is not quite in place.

Thank you,

Ellen Ayers, CRT/RPSGT
Branch Manager
SomniTech, Inc.
Sioux Falls/Omaha

Date: 04/06/2007
TO: Centers for Medicare & Medicaid Services
FROM: Stephen Newman
RE: Public Comment re: Obstructive Sleep Apnea home testing (Ref: CAG-00093R2)

I am writing in my capacity as (describe your involvement with sleep apnea; i.e., sufferer, family member, physician, technician, etc.) to urge you to positively consider changing your coverage determination for obstructive sleep apnea home-based testing.

(Insert personal experiences)

For decades, sleep laboratories have served a critical need in accurately diagnosing sleep apnea. But, just as our world has changed dramatically in other areas of technology, so has the field of sleep apnea research and diagnosis. Now, a proven wrist-worn device alternative versus the need for overnight clinic stays makes a strong case for updating CMS policies. It utilizes peripheral arterial tonometry (PAT), which has been approved by the FDA specifically for diagnosing sleep apnea in an unattended setting.

Peer reviewed research studies shows home testing is now as accurate and reliable as sleep clinics. Because of its efficacy and reliability PAT has been an accepted industry practice for some time; one where patients with the ability to pay cover the entire cost. But, many more patients suffering with OSA could be helped if insurance coverage was available.

Given these facts, I urge the CMS to change its coverage determination and to allow coverage for obstructive sleep apnea home testing.

Thank you,

Stephen R. Newman RRT, RCP
205 Palmer Lane
Bryan, Ohio 43506

Date: 4/6/2007

TO: Centers for Medicare & Medicaid Services

FROM: Jan Horton, RRT

RE: Public Comment re: Obstructive Sleep Apnea home testing (Ref: CAG-00093R2)

I am a practicing Respiratory Therapist and a Director of the Pulmonary Services Department in a large urban hospital. I'm writing to urge you to carefully consider any proposed change to your coverage determination for obstructive sleep apnea home-based testing.

A company called "evo Medical Solutions" has launched a write-in campaign to support their product which they say allows for a sleep study to be performed at home. While I believe this product might serve as an effective *screening* device to determine if a full-blown sleep study is indicated, it should by no means be considered a substitute for obtaining the complex differential diagnosis that only a polysomnogram, performed in a certified sleep lab by qualified personnel, can provide.

While I believe that home testing might eliminate the need for more complex testing for up to 20% of patients with suspected obstructive sleep apnea, the assertion that a wrist device can replace the multi-parameter testing performed in a sleep lab (as evo Medical Solutions suggests) is absurd.

In the interest of economy *and* diagnostic adequacy, I suggest allowing home testing to determine if there is a need for an overnight polysomnogram *for patients with borderline symptomology* provided you do not discontinue coverage of the latter.

Thank you for your time.

Jan Horton, RRT, Director, Pulmonary Services
Research Medical Center
2316 E. Meyer Boulevard
Kansas City, MO 64132-1199
ph 816-276-4080
fax 816-276-4528

Date: 04/06/2007
TO: Centers for Medicare & Medicaid Services
FROM: Kay Martin, RRT-NPS
RE: Public Comment re: Obstructive Sleep Apnea home testing (Ref: CAG-00093R2)

I am writing in my capacity as a Respiratory Therapy Practitioner and a Respiratory Clinical Educator to urge you to positively consider changing your coverage determination for obstructive sleep apnea home-based testing.

For decades, sleep laboratories have served a critical need in accurately diagnosing sleep apnea. But, just as our world has changed dramatically in other areas of technology, so has the field of sleep apnea research and diagnosis. Now, a proven wrist-worn device alternative versus the need for overnight clinic stays makes a strong case for updating CMS policies. It utilizes peripheral arterial tonometry (PAT), which has been approved by the FDA specifically for diagnosing sleep apnea in an unattended setting.

Peer reviewed research studies shows home testing is now as accurate and reliable as sleep clinics. Because of its efficacy and reliability PAT has been an accepted industry practice for some time; one where patients with the ability to pay cover the entire cost. But, many more patients suffering with OSA could be helped if insurance coverage was available.

Given these facts, I urge the CMS to change its coverage determination and to allow coverage for obstructive sleep apnea home testing.

Thank you,

Kay Martin, RRT-NPS
Clinical Educator
Respiratory Care Services
Children's Medical Center
1935 Motor Center
Dallas, TX 75235

I absolutely do *not* support in-home testing for the diagnosis of sleep apnea. I am the medical director of an accredited sleep center, and we "score" in-home portable sleep studies used in research. These studies are very difficult to evaluate accurately. As a result, I have decided not to pursue such testing, even though I was initially enthusiastic and intended to add this service.

Thank you for the opportunity to have input on this issue.

Donald Zedalis, MD

Date: 4/4/2007

TO: Centers for Medicare & Medicaid Services

FROM: Myra J. Thomas, RRT

RE: Public Comment re: Obstructive Sleep Apnea home testing (Ref: CAG-00093R2)

I am writing in my capacity as the Respiratory Care Coordinator for Gateway Home Care in Martinsburg, WV to urge you to positively consider changing your coverage determination for obstructive sleep apnea home-based testing.

As a healthcare provider I have 17 years of experience in respiratory therapy. The last seven years I have been in the home care setting with CPAP patients as one of my primary areas of care. I have seen the cost of laboratory sleep studies increase to an exorbitant cost for many patients. I have also been involved in the development of a program to offer home sleep studies for patients as an alternative to laboratory sleep studies. In comparing the accuracy of the home-based sleep studies vs. laboratory sleep studies, I have seen little difference in the level of and quality of information that is obtain in a home study when compared to that of laboratory studies. In fact, I have had many patients report that they felt that they had a better study with the home sleep study option than with the lab study because they were able to sleep in their own bed and maintain their normal sleep habit while at home. Without question, the same cannot be said of a laboratory study. Not only can the data be as accurate as in the sleep lab, but the cost of the home study is merely a fraction of the cost of a traditional sleep lab study.

For decades, sleep laboratories have served a critical need in accurately diagnosing sleep apnea. But, just as our world has changed dramatically in other areas of technology, so has the field of sleep apnea research and diagnosis. Now, a proven wrist-worn device alternative versus the need for overnight clinic stays makes a strong case for updating CMS policies. It utilizes peripheral arterial tonometry (PAT), which has been approved by the FDA specifically for diagnosing sleep apnea in an unattended setting.

Peer reviewed research studies shows home testing is now as accurate and reliable as sleep clinics. Because of its efficacy and reliability PAT has been an accepted industry practice for some time; one where patients with the ability to pay cover the entire cost. But, many more patients suffering with OSA could be helped if insurance coverage was available.

Given these facts, I urge the CMS to change its coverage determination and to allow coverage for obstructive sleep apnea home testing.

Thank you,
Myra J. Thomas, RRT
Gateway Home Care
Martinsburg, WV 25404

Vincent A. Viscomi, M.D., F.C.C.P

2525 deSales Avenue

Chattanooga, TN 37404

April 13, 2007

CMS

Inquiry Number: CAG-00093R2

Dear Sir or Madame:

I would like to voice my concern regarding CMS consideration of in-home sleep testing. This was considered several years ago and little has changed in the intervening years. There are several reasons for concern and I would like to outline them briefly.

There are a multitude of "ambulatory" sleep studies that are in the market. There are literally dozens of different companies and testing modalities that vary greatly in design and available information. The validation studies are typically small and performed in ideal situations. Marketing tactics of these companies is less than scrupulous as they are typically oriented to physicians or dentist in attempt to diagnosis sleep apnea and treat patients with alternative modalities.

A frequently stated reason for the need of these devices is that access to testing is limited. While this may have been the case in the past, it is certainly no longer true. The period of time for testing which had been as much as three to six months five or six years ago, is now typically within a week. The demand for sleep studies has certainly increased and with it there has also been an increase in the number of testing locations and available beds. It is of concern that the oversight of this testing has been limited. I can only imagine what the advent of ambulatory testing would bring with regard to the explosion in the number of the potential testing locations and individual and enterprises that would be performing these frequently marginal studies.

Sleep studies are sometimes required in a variety of occupations. Ambulatory testing would certainly provide an opportunity for fraudulent information. Monitored studies require identification and it is clear on whom the test is being performed. With ambulatory testing, DOT and FAA studies could be easily compromised, and fraudulent information could easily be given by individuals concerned with employment.

A multitude of ambulatory testing options that have been proposed to date have limited validation data. These studies are typically performed on a small number of patients under ideal circumstances. Some of these studies such as "Apnea Link" claim to have sensitivity values of 100%. This is simply not reasonable as their claims of sensitivity exceed that of overnight polysomnography and monitored testing. How such a limited study could provide more reliable data is simply not plausible and calls into question the small number of patients used to obtain this sort of data.

Ambulatory testing certainly will have limited information relating only to possible cooperation with sleep disorder breathing. Sleep architecture, movement disorder, electrocardiographic abnormalities, all have significant clinical usefulness involving patients daytime complaints regarding excessive daytime sleepiness and correlation with cardiac comorbidities. The explanations for excessive daytime sleepiness are often identified with abnormalities in the onset of REM sleep, movement disorders and alterations in sleep architecture. Lacking this data, the clinician's approach to treatment will be significantly hindered and poorer treatment result.

It is also of great concern that this sort of testing would be made available to physicians with absolutely no training in sleep disorders. The patients would be at the mercy of physicians or dentists who are unaware or unable to treat sleep apnea with appropriate means. The present requirements for monitored testing generally involve a referral to a sleep center or at least an evaluation by an individual who has training in sleep disorders. With ambulatory testing no such referral would be required and I suspect the marketing of this device to physicians treating the patient with the use of "alternative" treatment modalities would be of great concern. I also believe that this would be marketed to general practitioners and the number of tests would increase dramatically. The need for CPAP testing is not addressed by ambulatory testing modalities and expertise in providing this needed treatment would be left to individuals with little or no sleep training.

In summary, I believe that opening up sleep testing to the in-home environment would result in an explosion in this sort of testing typically marketed to individuals with little or no training. The validation of this testing often involves small studies in optimal at home situations. Reliable additional information regarding the patient's disease process will often be omitted and as a result the patient will be inadequately treated. Patient safety issues and the appropriateness of care and I would greatly be compromised and I would ask that you deny the College of Otolaryngology request for in-home sleep testing coverage.

Sincerely,

Vincent A Viscomi, M.D. F.C.C.P

Date: 4/8/2007

TO: Centers for Medicare & Medicaid Services

FROM: Katherine D. Yearwood

RE: Public Comment re: Obstructive Sleep Apnea home testing (Ref: CAG-00093R2)

I am writing in my capacity as a Registered Respiratory Therapist to urge you to positively consider changing your coverage determination for obstructive sleep apnea home-based testing.

For decades, sleep laboratories have served a critical need in accurately diagnosing sleep apnea. But, just as our world has changed dramatically in other areas of technology, so has the field of sleep apnea research and diagnosis. Now, a proven wrist-worn device alternative versus the need for overnight clinic stays makes a strong case for updating CMS policies. It utilizes peripheral arterial tonometry (PAT), which has been approved by the FDA specifically for diagnosing sleep apnea in an unattended setting.

Peer reviewed research studies shows home testing is now as accurate and reliable as sleep clinics. Because of its efficacy and reliability PAT has been an accepted industry practice for some time; one where patients with the ability to pay cover the entire cost. But, many more patients suffering with OSA could be helped if insurance coverage was available.

Given these facts, I urge the CMS to change its coverage determination and to allow coverage for obstructive sleep apnea home testing.

Thank you,

Katherine D. Yearwood, RRT

Date: 04/09/2007

TO: Centers for Medicare & Medicaid Services

FROM: Terry Minadeo

RE:Public Comment re: Obstructive Sleep Apnea home testing (Ref: CAG-00093R2)

I am writing in my capacity as sales rep. in the home care industry to urge you to positively consider changing your coverage determination for obstructive sleep apnea home-based testing. Many people have trouble sleeping in sleep centers & would prefer home testing. Home testing would save a lot of money spent in sleep centers.

For decades, sleep laboratories have served a critical need in accurately diagnosing sleep apnea. But, just as our world has changed dramatically in other areas of technology, so has the field of sleep apnea research and diagnosis. Now, a proven wrist-worn device alternative versus the need for overnight clinic stays makes a strong case for updating CMS policies. It utilizes peripheral arterial tonometry (PAT), which has been approved by the FDA specifically for diagnosing sleep apnea in an unattended setting.

Peer reviewed research studies shows home testing is now as accurate and reliable as sleep clinics. Because of its efficacy and reliability PAT has been an accepted industry practice for some time; one where patients with the ability to pay cover the entire cost. But, many more patients suffering with OSA could be helped if insurance coverage was available.

Given these facts, I urge the CMS to change its coverage determination and to allow coverage for obstructive sleep apnea home testing.

Thank you,

Terry Minadeo, Sales Rep.
Health Aid of Ohio
4467 Industrial Parkway
Cleveland, Ohio 44135

DATE: 04/09/2007
TO: Centers for Medicare & Medicaid Services
FROM: Craig A. Coleman, MBA, RRT
RE: Public Comment re: Obstructive Sleep Apnea home testing (Ref: CAG-00093R2)

I am writing in my capacity as Registered Respiratory Therapist to urge you to positively consider changing your coverage determination for obstructive sleep apnea home-based testing.

Working as a respiratory therapist in the home care setting for nearly 11 years, I believe if CMS would cover this new technology, it would provide an additional option for OSA diagnosis. Likewise, this allowance by CMS would benefit the entire sleep therapy industry and improve the quality of life for many patients currently suffering from OSA. It would allow the respiratory therapists to be more directly involved with their OSA patients, it would allow the sleep labs and sleep doctors to pre-screen and connect with those patients not willing or geographically able to come to a lab and it would allow the elderly Medicare patient to perform the study in the comfort of their own home. My personal experience has shown that many patients, although highly recommended by their doctor, refuse to be evaluated for OSA because they do not feel comfortable having a study in a foreign environment such as a sleep lab.

For decades, sleep laboratories have served a critical need in accurately diagnosing sleep apnea. But, just as our world has changed dramatically in other areas of technology, so has the field of sleep apnea research and diagnosis. Now, a proven wrist-worn device alternative versus the need for overnight clinic stays makes a strong case for updating CMS policies. It utilizes peripheral arterial tonometry (PAT), which has been approved by the FDA specifically for diagnosing sleep apnea in an unattended setting.

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Given these facts, I urge the CMS to change its coverage determination and to allow coverage for obstructive sleep apnea home testing.

Thank you,

Craig A. Coleman, MBA, RRT
Vice President of Operations

Date: 04/09/2007
TO: Centers for Medicare & Medicaid Services
FROM: Timothy R. Bialowas RRT,RCP
RE: Public Comment re: Obstructive Sleep Apnea home testing (Ref: CAG-00093R2)

I am writing in my capacity as Respiratory Home Care provider to urge you to positively consider changing your coverage determination for obstructive sleep apnea home-based testing.

I have worked in Home Care for 13 years and I have experienced first hand how difficult it can be for many patients to sleep in facility based labs! It has also become very difficult to get into these labs in a timely manner. I know of several labs that have a 3-6 month back log right now! I don't feel that it is fair for patients to have to wait that long.

For decades, sleep laboratories have served a critical need in accurately diagnosing sleep apnea. But, just as our world has changed dramatically in other areas of technology, so has the field of sleep apnea research and diagnosis. Now, a proven wrist-worn device alternative versus the need for overnight clinic stays makes a strong case for updating CMS policies. It utilizes peripheral arterial tonometry (PAT), which has been approved by the FDA specifically for diagnosing sleep apnea in an unattended setting.

Peer reviewed research studies shows home testing is now as accurate and reliable as sleep clinics. Because of its efficacy and reliability PAT has been an accepted industry practice for some time; one where patients with the ability to pay cover the entire cost. But, many more patients suffering with OSA could be helped if insurance coverage was available.

Given these facts, I urge the CMS to change its coverage determination and to allow coverage for obstructive sleep apnea home testing.

Thank you,

Timothy R. Bialowas RRT,RCP
Director of Respiratory Operations
Health Aid of Ohio Inc.
4467 Industrial Parkway
Cleveland, OH 44135

I think it is a very bad idea to allow at home testing to be paid for by Medicare. There are many draw backs and limitations with this sort of testing and patients who are already compromised will surely slip through the cracks with a minimal amount of their needs being met.

Many patients are simply too severe to be seen in this manner and in many cases would need to be titrated in a laboratory anyway. With these sorts of tests, they would inevitably need to be re-qualified and that would only add time and cost to the matter.

There is no standardized information coming from all systems available and that would mean that some "studies" would provide very limited information while others might provide more.

Bottom line is that we cannot sacrifice our patients for a perceived problem of not having enough beds or a lack of qualified personnel. There are still way too many patients who (especially in the CMS age group) that have a number of complications that would arise by doing at home testing is surely not worth the risk.

I sincerely encourage you to deny coverage for at home testing.

Shelli Cutting, President
Odyssey Sleep Works, Inc.

Date: 04/09/2007
TO: Centers for Medicare & Medicaid Services
FROM: Eric McNulty
RE: Public Comment re: Obstructive Sleep Apnea home testing (Ref: CAG-00093R2)

I am writing in my capacity as Co-Owner and Operations Director of Home Sleep Therapy, LLC to urge you to positively consider changing your coverage determination for obstructive sleep apnea home-based testing.

In the past, we used our Embletta equipment for Home Testing for Private Insurances. We had success in proving OSA to the carriers and they saved money themselves. Much to our lament, they discontinued their coding because they decided to follow Medicare rules. We were ahead of the times when we performed this service and we are extremely excited that you are considering adding this back into the fee schedule. For people with OSA, and OSA only, there is no better and more cost efficient way to diagnose them.

For decades, sleep laboratories have served a critical need in accurately diagnosing sleep apnea. But, just as our world has changed dramatically in other areas of technology, so has the field of sleep apnea research and diagnosis. Now, there are many proven alternative devices that extinguish the need for overnight clinic stays. This makes a strong case for updating CMS policies.

Peer reviewed research studies shows home testing is now as accurate and reliable as sleep clinics. Because of its efficacy and reliability PAT has been an accepted industry practice for some time; one where patients with the ability to pay cover the entire cost. But, many more patients suffering with OSA could be helped if insurance coverage was available.

Given these facts, I urge the CMS to change its coverage determination and to allow coverage for unattended obstructive sleep apnea home testing.

Thank you,

Eric McNulty, Co-Owner and Operations Director
Home Sleep Therapy, LLC
33 Lenape Trail
Lock Haven, PA 17745

I think OSA should be covered under medicare/medicaid , especially medicaid.

Megan Ludwig

I believe that the test should be covered at the patient's home. Have you ever seen a sleep test run on a patient. If you could go to a sleep center and watch the testing process you would agree. The patient's are in a unfamiliar place, unfamiliar and most of the time uncomfortable bed surrounded by all these crazy people with wires all over their head and legs. Talking about uncomfortable and embarrassing it is awful for these people. The patient's usually complain about the experience and do not get a decent night of sleep to properly diagnose them anyway. I say it again please go to a facility and then make a decision.

Thanks

Sonya McMahan CRT/PSGT

Sirs:

As a Registered Respiratory Therapist and a Registered Sleep Technologist with over 15 years of experience in sleep medicine, I write to discourage the use of in home testing. Particularly unattended studies. It has been my experience that too many things can happen that influence the quality of the test in settings where the environment and the patient cannot be carefully monitored and controlled. Additionally, as the Director of a Sleep Lab I am concerned about the safety of such testing. Both on behalf of the patient and the technician who would perform the study.

I have kept my comments pity out of respect of your time. Please feel free to contact me if any questions should arise.

Joseph Goode RRT, RPSgT
Director of Sleep Services
Semmes-Murphey Neurologic & Spine Institute
Jackson, TN
731-343-4114

I am a Registered Respiratory Therapist who has worked in the field of Sleep Medicine and am familiar with the technology available for in-home diagnostics. I encourage you to work toward establishing fair reimbursement for this service. I believe that in-home testing can be done reliably and at less cost per test than at a traditional sleep lab. This would provide opportunities for patients to access care for a debilitating problem, and avoid additional healthcare costs.

Thank you

Dale E Willrich RRT, RCP
Douglasville GA

To Whom It May Concern:

We have been selling an in home sleep diagnostic tool for over a year and have helped many grateful people who know they have OSA but do not have insurance or very high deductibles who can not afford a full blown sleep study. We have responded to pleas of help from wives who know their husbands need help, but refuse to go for the sleep study just because

I believe it should strongly be considered as a reimbursable equipment/procedure – it is saving lives and it will save Medicare and insurance companies a lot of money by not paying for the traditional sleep study.

Regards,

Roberta Baron

President

CPAP SUPPLIES PLUS/DIRECT

WWW.CPAPPLUS.COM

PH: 708-403-2776

FAX: 708-364-0166

To Whom It May Concern:

Patients should be evaluated in an accredited sleep disorders center.

Home recordings are not adequate to fully evaluate the patient for sleep disorders.

Cheryl L. Spinweber, Ph.D.
Diplomate, American Board of Sleep Medicine
Clinical Director
Scripps Mercy Sleep Disorders Center
San Diego, CA

To Whom It May Concern:

As the respiratory therapist for a home care company and the store manager, I have had a considerable experience with all aspects of CPAP and BiPAP. I set up numerous PAP patients every week. I have the opportunity to hear both positive and negative comments from our patients. One of the most common problems that is expressed is how hard it is to take time off of work to attend the sleep lab. Not only do patients have to attend once, but most all of them have to attend a second time for the titration study. This is inconvenient for these patients considering the majority of our patients are of working age group. One other problem that I hear is that it is very difficult to fall asleep in strange place. Most of the patients find it very difficult to sleep there normal pattern in a hospital like environment.

In home PAP trials would greatly improve the accessibility of a sleep study. It would allow those people who cannot attend normal studies, due to there work, the ability to have a study conducted in there own home at there convenience. It would also allow them to do this when it was convenient for them, such as a weekend night, etc. that was more applicable to there schedule, instead of working around the labs schedule. This also opens up opportunity for more people to be tested, and hopefully to improve more patients sleep habits. Considering that it has been proven that PAP therapy improves many other symptoms, other than just being sleepy, it is a positive for the insurance companies. It has been proven to decrease hypertension which in itself is a huge savings over time.

The ability to take the study in the home would have to improve the accuracy of the results obtained. When we are in our normal environment we function much better and are under less stress. When the patient can take the home study, they are in there own bed, and are in a more comfortable setting. There is no way that the patient cannot have an improved sleep study and therefore more accurate results.

Under no circumstances do I feel that these studies should completely eliminate the sleep lab. There are many instances that people will need to attend the sleep lab. With the home study equipment there is a good chance that the results can give the doctors all the information needed to diagnose the patient properly. This study is much more convenient to the patient and the results that are given could be more accurate considering the environment that the test was taken. The equipment is easily used, and very patient friendly. If a complete sleep study has to be ordered by a lab, then you have information to compare it to. I feel that it is unfair to the patient to have this technology and not be able to use it. As a therapist we need to be patient focused and do what is best for the patient. This technology definitely opens new doors for the working OSA patient and should be available to the public.

Thank You,

Kenny Cornelius BS, CRT
Bluegrass Home Oxygen
112 Hardin Lane
Somerset, KY 42503
1-866-577-0202

DATE: 04/10/2007
TO: Centers for Medicare & Medicaid Services
FROM: Nathan Fowler, CRT
RE: Public Comment re: Obstructive Sleep Apnea home testing (Ref: CAG-00093R2)

I am writing in my capacity as Certified Respiratory Therapist to urge you to positively consider changing your coverage determination for obstructive sleep apnea home-based testing.

Working as a respiratory therapist in the home care setting for nearly 4 months, I believe if CMS would cover this new technology, it would provide an additional option for OSA diagnosis. Likewise, this allowance by CMS would benefit the entire sleep therapy industry and improve the quality of life for many patients currently suffering from OSA. It would allow the respiratory therapists to be more directly involved with their OSA patients, it would allow the sleep labs and sleep doctors to pre-screen and connect with those patients not willing or geographically able to come to a lab and it would allow the elderly Medicare patient to perform the study in the comfort of their own home. My personal experience has shown that many patients, although highly recommended by their doctor, refuse to be evaluated for OSA because they do not feel comfortable having a study in a foreign environment such as a sleep lab.

For decades, sleep laboratories have served a critical need in accurately diagnosing sleep apnea. But, just as our world has changed dramatically in other areas of technology, so has the field of sleep apnea research and diagnosis. Now, a proven wrist-worn device alternative versus the need for overnight clinic stays makes a strong case for updating CMS policies. It utilizes peripheral arterial tonometry (PAT), which has been approved by the FDA specifically for diagnosing sleep apnea in an unattended setting.

Peer reviewed research studies shows home testing is now as accurate and reliable as sleep clinics. Because of its efficacy and reliability PAT has been an accepted industry practice for some time; one where patients with the ability to pay cover the entire cost. But, many more patients suffering with OSA could be helped if insurance coverage was available.

Given these facts, I urge the CMS to change its coverage determination and to allow coverage for obstructive sleep apnea home testing.

Thank you,

Nathan Fowler, CRT

DATE: 04/10/2007
TO: Centers for Medicare & Medicaid Services
FROM: Stacy Neece, CRT
RE: Public Comment re: Obstructive Sleep Apnea home testing (Ref: CAG-00093R2)

I am writing in my capacity as Certified Respiratory Therapist to urge you to positively consider changing your coverage determination for obstructive sleep apnea home-based testing.

Working as a respiratory therapist in the home care setting for nearly 7 years, I believe if CMS would cover this new technology, it would provide an additional option for OSA diagnosis. Likewise, this allowance by CMS would benefit the entire sleep therapy industry and improve the quality of life for many patients currently suffering from OSA. It would allow the respiratory therapists to be more directly involved with their OSA patients, it would allow the sleep labs and sleep doctors to pre-screen and connect with those patients not willing or geographically able to come to a lab and it would allow the elderly Medicare patient to perform the study in the comfort of their own home. My personal experience has shown that many patients, although highly recommended by their doctor, refuse to be evaluated for OSA because they do not feel comfortable having a study in a foreign environment such as a sleep lab.

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Given these facts, I urge the CMS to change its coverage determination and to allow coverage for obstructive sleep apnea home testing.

Thank you,

Stacy Neece, CRT

DATE: 04/10/2007
TO: Centers for Medicare & Medicaid Services
FROM: Shawn Yates, CRT
RE: Public Comment re: Obstructive Sleep Apnea home testing (Ref: CAG-00093R2)

I am writing in my capacity as Certified Respiratory Therapist to urge you to positively consider changing your coverage determination for obstructive sleep apnea home-based testing.

Working as a respiratory therapist in the home care setting for nearly 8 years, I believe if CMS would cover this new technology, it would provide an additional option for OSA diagnosis. Likewise, this allowance by CMS would benefit the entire sleep therapy industry and improve the quality of life for many patients currently suffering from OSA. It would allow the respiratory therapists to be more directly involved with their OSA patients, it would allow the sleep labs and sleep doctors to pre-screen and connect with those patients not willing or geographically able to come to a lab and it would allow the elderly Medicare patient to perform the study in the comfort of their own home. My personal experience has shown that many patients, although highly recommended by their doctor, refuse to be evaluated for OSA because they do not feel comfortable having a study in a foreign environment such as a sleep lab.

For decades, sleep laboratories have served a critical need in accurately diagnosing sleep apnea. But, just as our world has changed dramatically in other areas of technology, so has the field of sleep apnea research and diagnosis. Now, a proven wrist-worn device alternative versus the need for overnight clinic stays makes a strong case for updating CMS policies. It utilizes peripheral arterial tonometry (PAT), which has been approved by the FDA specifically for diagnosing sleep apnea in an unattended setting.

Peer reviewed research studies shows home testing is now as accurate and reliable as sleep clinics. Because of its efficacy and reliability PAT has been an accepted industry practice for some time; one where patients with the ability to pay cover the entire cost. But, many more patients suffering with OSA could be helped if insurance coverage was available.

Given these facts, I urge the CMS to change its coverage determination and to allow coverage for obstructive sleep apnea home testing.

Thank you,

Shawn Yates, CRT

RE: Public comment on Obstructive Sleep Apnea home testing (Ref: CAG-00093R2)

I am writing in my capacity as an educator in the field of respiratory care as well as the president of an industrial medical testing facility (Sentry Medical Corporation) to urge you to positively consider changing your coverage determination for obstructive sleep apnea home-based testing.

Nine years ago, I owned and ran three sleep labs and was an enrolled Medicare provider. The Balanced Budget Act necessitated closing of my sites because the new guidelines required testing to be done in hospitals under the direct supervision of a physician. I was using the same state-of-the-art equipment and licensed personnel as the hospital-based sleep lab and my medical director was a board-certified pulmonologist. My cost was 30% less than the hospital for a full polysomnography and less than 50% for a screening test. This decision essentially cost me a business and simultaneously increased Medicare payments across the nation for sleep diagnostics.

The technology for performing obstructive sleep apnea screening through pulse-oximetry and peripheral arterial tonometry has advanced greatly in the last nine years. It **MUST** be possible to establish a reimbursement structure for sleep diagnostics performed accurately, conveniently, less expensively, and faster, in the home environment than in a hospital setting. Nelcor and Respironics have published studies attesting to the clinical application of overnight desaturation testing. ProFox has software capable of downloading these devices and identifying significant changes in heart rate and oxygen saturations that correlate perfectly with periods of apnea.

You have a tremendous opportunity here to save millions of dollars by establishing a payment structure to include screening for obstructive sleep apnea through recorded pulse-oximetry, peripheral arterial tonometry, and peripheral recorded devices such as thermistors, snore recorders, and pneumo-belts. I not only urge you to consider this important change in coverage determination, but also would like to offer myself as a technical resource if needed.

Michael Samp, CPFT, RRT, RCP
Director of Clinical Education
Odessa College
201 W. University Blvd., CT 234
Odessa, Texas 79764
432-335-6457

To whom it may concern-

I do not feel like in home OSA testing should be covered by insurance.

The only way to ensure an artifact free recording and reliable diagnostic information is by having the test monitored by a live Polysomnographic Technician or Technologist.

Troubleshooting and maintaining the electrodes, monitoring belts/thermistors and computer equipment is vital to acquiring good data and must be performed by a qualified individual.

Having monitored testing performed in the home is not feasible and a safety risk. Having unmonitored testing used to diagnose potentially life-threatening diseases/disorders is unacceptable.

Rebecca Wagner RRT/RPSGT
Sleep Services Coordinator
Cass Medical Center
(816) 380-3474 ext. 418

To my fellow colleagues,

In response to the current CMS consideration to allow for patients to qualify for CPAP devices with anything less than a fully attended sleep study, I must voice both my personal and professional opposition. In a time where healthcare is at a critical crossroad, it is important to enter this debate and improve the systems we have in place and look for alternatives to improve overall. By allowing 'portable' or 'unattended' sleep studies to qualify for CPAP is a huge disservice to the population as well as the profession they serve. Using these formats as a 'screening tool' are fine but they can never replace or substitute the skills and qualifications needed to treat and diagnose OSA and a variety of other sleep disorders that will be missed or go undiagnosed! I can't tell you how many studies I have personally run or scored where patients had near fatal heart arrhythmias and needed to seek urgent medical treatment immediately.

The answer to treating this growing sleep disorder is to get to the patient population and educate them as to the need and seriousness of the disorder by utilizing trained professionals to acquire and tend to the patient during the study. There are no 'at home' radiological exams or unattended cardiac stress tests in the medicine and this matter can set a huge precedent and ultimately cause more harm than good to the profession and, more importantly, the patient.

Having been in the field of respiratory care and sleep medicine for over 20 years, it is my professional stance that allowing portable or at home studies will allow a lower standard of care by having unqualified people conduct these set ups and studies. In a time where we are trying to raise the standards of care in these allied health fields, it appears that this move would cause the patient to be diagnosed by the traveling road show that rolls into town and sets up shop as a cheap fix or alternative to the quality health care system that we have established and grown accustomed to in this great country of ours.

I urge you to remove this matter from consideration and focus on making the current process more efficient to all involved and not substitute it with a lower quality and potentially harmful substitute. Thank you for your time and attention in reading my letter.

Professionally,

Stephen Tarnoczy BS, RRT, RPSGT
Clinical Education Specialist/ SLEEPTECH Professor/QUINNIPIAC
UNIVERSITY Education Committee/AAST

This sounds absolutely wonderful especially for or resident in the rural area's. This makes such good sense.

Thank-you,
Debi

Debi Kloberdanz
Home Medical Director
Regional Health Service's
327 8th Avenue West
Cresco, Iowa 52136
Ph: 563-547-5573
Fax: 563-547-4223

It is of my opinion that home sleep studies are not a good idea. As the coordinator of a 6 bed lab I see a lot of patients that could never benefit from this type of test. To ensure a quality test the patients must be continuously monitored. A sleep technician is able to ensure a quality test every time. I think that home testing would allow many sleeping disorders to go undiagnosed and untreated. Would a radiologist allow a pt to perform his own x-ray? The sleep field is a specialty for a reason. Allowing home testing is an insult to the profession. I encourage you to study the inter workings of the sleep lab before you make a decision that could affect millions of people.
Sincerely, Krystal Ticen

Krystal Ticen LPN RPSGT
Sleep Lab Coordinator
Kokomo Sleep Center
krystal.ticen@md-sleep.com
765-513-5208

Patients with dangerous sleep disorders would be ill-served by approval of in-home sleep testing for coverage by the Centers for Medicare & Medicaid Services (CMS). It is difficult to appropriately diagnose these conditions in a well-supplied and organized sleep lab; approval of home testing would open the floodgates to poorly-trained providers whose primary concern is the sale and rental of CPAP equipment, not patient care.

Milton Erman, MD
President, Pacific Sleep Medicine

CAG-00093R2. In home testing is a bad way to go. It opens the doors to poorly trained providers to make a quick buck. Patient care would be dangerously inadequate with diagnosis of conditions being decided by a software program instead of an experienced physician with a professional staff.

PERIKSON@PACIFICSLEEPMEDICINE.COM

It has come to my attention that certain medical device manufacturers and Home Medical Equipment providers are soliciting support of the proposal to change CMS policy on allowing home testing for Obstructive Sleep Apnea. In my opinion as a physician specializing in pulmonary medicine and sleep disorders, the proposed change serves the interest of Home Medical Equipment (HME) and CPAP device manufacturers and is inconsiderate of the actual patients whom we serve.

Eliminating the current requirement for an attended facility based polysomnogram will provide insufficient data leaving no basis to compare pre treatment vs. post treatment changes in sleep. To my knowledge, there are currently no peer reviewed studies of long term outcomes of patients not undergoing attended polysomnography with manual CPAP titration. I fear that patient compliance will be quite poor when based on home studies with auto titration of CPAP.

In addition, facility based attended polysomnography provides the necessary data to properly investigate sleep complaints that often include comorbid sleep disorders beyond Obstructive Sleep Apnea. Central Sleep Apnea, sleep related Cheyne Stokes respirations, and nocturnal central hypoventilation can initially present as Obstructive Sleep Apnea but can not be adequately and accurately assessed by the limited parameters involved with home testing. In addition, unattended home testing does not properly aid in identifying any of the other 70+ classified sleep disorders such as Periodic Limb Movement Disorder (PLMD), and the various Parasomnias, as well as other intrinsic sleep disorders.

Home testing is likely to drive up the cost to CMS and private insurers, generated by self promoting HME companies and device manufacturers and dramatically decrease the quality of patient care.

As a physician concerned with quality patient care and treatment, I ask that CMS not change its coverage determination to allow coverage for Obstructive Sleep Apnea home testing.

Respectfully,

Joan M.K. Fox, MD, DABSM
Minnesota Lung Center / Minnesota Sleep Institute 920 East 28th Street,
Suite 700 Minneapolis, MN 55407

Date: 04/10/2007

TO: Centers for Medicare & Medicaid Services

FROM: Kim Croucher, RRT

RE: Public Comment re: Obstructive Sleep Apnea home testing (Ref: CAG-00093R2)

I am writing in my capacity as Registered Respiratory Therapist to urge you to positively consider changing your coverage determination for obstructive sleep apnea home-based testing.

Working in home health for 7 years as a respiratory therapist, I believe this new technology would be very beneficial to several patients. It would benefit those patients who do not have easy access to sleep labs in surrounding areas. The elderly patients that are not able to get out and do not have the transportation available to have a sleep study. So many times I hear patients complain about their experience at the sleep lab. The testing in home would give the patient a more naturally environment to have their study, and possible be more accurate in their diagnosis.

For decades, sleep laboratories have served a critical need in accurately diagnosing sleep apnea. But, just as our world has changed dramatically in other areas of technology, so has the field of sleep apnea research and diagnosis. Now, a proven wrist-worn device alternative versus the need for overnight clinic stays makes a strong case for updating CMS policies. It utilizes peripheral arterial tonometry (PAT), which has been approved by the FDA specifically for diagnosing sleep apnea in an unattended setting.

Peer reviewed research studies shows home testing is now as accurate and reliable as sleep clinics. Because of its efficacy and reliability PAT has been an accepted industry practice for some time; one where patients with the ability to pay cover the entire cost. But, many more patients suffering with OSA could be helped if insurance coverage was available.

Given these facts, I urge the CMS to change its coverage determination and to allow coverage for obstructive sleep apnea home testing.

Thank you,

Kim Croucher, RRT

I am writing this letter in regards to In Home sleep testing. I have 15 years experience in the home medical equipment/sleep industry, including owning a sleep lab. There is a large segment of the population that are unable to leave their homes for a sleep study. For whatever the reasons, these individuals are lost in a process that does not take their circumstances into consideration. For years we have had reliable in home testing equipment at our disposal, but were unable to use it due to reimbursement reasons. By not diagnosing and treating these patients, we are only increasing our healthcare costs. I strongly agree with in home testing and feel that it should be reimbursable.

Respectfully,

Robert Beymer, CRT/RCP
Respiratory Therapist
Option Care of SW Florida
Phone: 239-561-3456
Email: rbeymer@optioncare.net
OPTIONcare

I am a sleep specialist with extensive experience in use of in-lab polysomnography as well as in-home testing. Over many years of trying portable testing it became clear that appropriate diagnosis and treatment utilizing home testing is fraught with huge technical difficulties. And this is in our hands of specialized training, technologists and close clinical follow up. In hands of poorly or untrained providers with primary focus on profit from selling CPAP units without systems to follow compliance and treatment effectiveness I simply see a huge and expensive mess that will be created. Our local HMO tried portable testing and treatment approach. After encountering close to 80% technical failure rate they gave up. Sub specialized care in hands of entrepreneurs is dangerous and will ill-serve patients with life threatening sleep disorders such as sleep apnea and multitude of concomitant conditions that would be milled on portable test.

Yury Furman, MD
Los Angeles, CA

I support CMS covering in-home testing as long as the reimbursement allows them to do it with a reasonable profit margin. The benefit to the patients are innumerable and I believe includes a more accurate test in their normal sleep environment rather than the artificial lab setting. Nobody sleeps better in a hotel room. Also the device being used must be simple and accurate and NOT a screening tool but a diagnostic tool.

Geoff

Geoff Hill
TENDON

Case ref. number CAG-00093R2 (In opposition to CMS covering in-home testing.)

“Patients with dangerous sleep disorders would be ill-served by approval of in-home sleep testing for coverage by the Centers for Medicare & Medicaid Services (CMS). It is difficult to appropriately diagnose these conditions in a well-supplied and organized sleep lab; approval of home testing would open the floodgates to poorly-trained providers whose primary concern is the sale and rental of CPAP equipment, not patient care. “

Core Statement of the Physicians of Pacific Sleep Medicine Services

I am a Sleep Specialist in Rural Oregon. I was a Family Practice doctor for 11 years. I work with a dedicated group of individuals that stand at the forefront of sleep medicine clinical practice. We are from various areas of medicine, but we share a common goal of treating sleep disorders with the highest standards of patient care.

The proposed changes to the CMS guild lines are not in keeping with our current clinical practice. They are up for evaluation, again, by the same profiteers and unrealistic academic types that put forward the same question two years ago. They argue that technological advances warrant re-evaluation of these devices, but they refuse to look at the broader clinical picture.

We treat individual patients, not statistical percentages. The hallmark of current primary care medicine, especially in rural areas is the quality of the care, not how to distribute it to the greatest number at a lower quality. I do not support the current proposed changes on those grounds.

Thank you for taking time to hear my opinion.

**James W. Winde MD
Family Medicine
Pacific Sleep Medicine Services
La Grande, Oregon**

Date: 4/12/2007
TO: Centers for Medicare & Medicaid Services
FROM: Steven Weiner
RE: Public Comment re: Obstructive Sleep Apnea home testing (Ref: CAG-00093R2)

I am writing in my capacity as a pharmacist and provider of home medical equipment, including CPAP, to urge you to positively consider changing your coverage determination for obstructive sleep apnea home-based testing.

I have had potential customers who meet screening guidelines (snoring, cessation of breathing, etc.) for sleep apnea remain untreated because they refuse to spend one or two nights in a sleep lab.

For decades, sleep laboratories have served a critical need in accurately diagnosing sleep apnea. But, just as our world has changed dramatically in other areas of technology, so has the field of sleep apnea research and diagnosis. Now, a proven wrist-worn device alternative versus the need for overnight clinic stays makes a strong case for updating CMS policies. It utilizes peripheral arterial tonometry (PAT), which has been approved by the FDA specifically for diagnosing sleep apnea in an unattended setting.

Peer reviewed research studies shows home testing is now as accurate and reliable as sleep clinics. Because of its efficacy and reliability PAT has been an accepted industry practice for some time; one where patients with the ability to pay cover the entire cost. But, many more patients suffering with OSA could be helped if insurance coverage was available.

Given these facts, I urge the CMS to change its coverage determination and to allow coverage for obstructive sleep apnea home testing.

Thank you,

Steven Weiner, R.Ph
Wheelock Drug Store
700 East Church St.
Adrian, MI 49221

I don't support it wont work! All studies need to be attended.
THE SLEEP DISORDER CENTER

Cambridge Medical Center
Sleep Services
701 South Dellwood
Cambridge, MN 55008
763-689-7999
Fax 763-689-7819



April 12, 2007

Francina C. Spencer
Lead Analyst
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, Maryland 21244-1850

Re: Continuous Positive Airway Pressure (CPAP) Therapy for Obstructive Sleep Apnea (OSA). CAG – 00093R2

Dear Ms. Spencer,

We are writing in response to the request by the American Academy of Otolaryngology – Head and Neck Surgery (AAO-HNS) for inclusion of home sleep testing as an alternative to facility-based polysomnography (PSG) in the evaluation of OSA. We have serious concerns about how this decision would affect patient care.

We agree with the assumptions set forth by the AAO-HNS that OSA is as a prevalent, progressive illness with adverse affects on the physical, emotional, financial, and social aspects of those afflicted. This is well documented. However, we would like the opportunity to rebut the other assumptions that form the basis of their request.

First, the assertion that “current resources are inadequate to meet the demand for PSG, resulting in a long wait for patients to access care” is a generalization which does not apply to all areas of the country. Currently, we are able to perform testing on our patients within 1-2 weeks and through the use of protocols and coordination with a local Durable Medical Equipment company, offer optimal treatment immediately upon the conclusion of testing. How would the use of home testing improve our patient’s access to care?

Second, the assumption that a trial of CPAP “may help to diagnose OSA, to identify patients who benefit from CPAP, and to reduce the need for PSG” is not supported by our research. The AAO-HNS asserts that patients compliant with therapy during a 2 week trial of CPAP could be assumed to be positive for a diagnosis of OSA. We utilize Auto-CPAP or Auto-BiPAP as a desensitization device for some of our patients. This is accomplished by setting up Auto-PAP for a short period of time following an initial, diagnostic PSG, but prior to a titration PSG where optimal therapeutic pressures are determined. Over the past seven months we have accumulated data on 34 patients with some interesting results. One trend that is apparent concerns patients with mild OSA (AHI 5-20) who are less likely to be compliant with Auto-PAP, compared to those with moderate OSA (AHI

20-40). Average compliance (defined as percentage of nights with >4 hours of use) was 48.4% for mild OSA patients versus 63.3% for those with a diagnosis of moderate OSA. We fear that utilizing a CPAP trial to diagnose and identify patients may result in misdiagnosis of our mild OSA patients.

Furthermore, we have found that the education provided by sleep lab technicians can enhance patient compliance. This is supported by a study published in *Sleep & Breathing* (CPAP compliance in sleep apnea patients with and without laboratory CPAP titration; 8(1): 7-14, 2004 Mar.) which concluded that the support and education provided by sleep technologists are important factors in facilitating CPAP compliance. What will we gain by testing more patients if they do not receive the necessary support to become compliant with therapy?

Our sleep lab focuses on improving patient compliance to CPAP therapy. We feel it is our duty to not only diagnose, but provide follow-up care in an effort to assist our patients through the adjustment period on CPAP therapy. The National Sleep Foundation recently called for an increased focus on the long-term management of OSA (NSF Alert 4/3/07). We contend that the trained professionals staffing our nation's sleep labs are in the best position to provide this support, and the PSG experience itself provides many opportunities for an improved long-term experience on CPAP through proper education, mask selection, and determination of optimal therapy.

Finally, the assumption put forth by the AAO-HNS that "arbitrary pressure" or Auto-CPAP may be used to provide optimal treatment for OSA could result in treatment ranging from adequate to dangerous. The data obtained from our Auto-PAP study points to inconsistent treatment outcomes compared to lab titration. The data from 28 patients who utilized Auto-CPAP and returned for lab titration indicated that the optimal treatment pressure recommended by Auto-CPAP would have left over half of our patients (n=15) with an AHI >5 and almost a quarter of them (n=6) with an index >20. Lab titration performed on these 28 patients resulted in therapy with an average AHI of 4.9 while the pressures recommended by Auto-CPAP would have resulted in an average AHI of 16.23.

These results confirm the current Practice Parameters by the American Academy of Sleep Medicine which state that initial CPAP pressures should not be determined through the use of Auto-CPAP (*Sleep*, Vol. 25, No. 2, 2002). If we cannot be reasonably certain that Auto-CPAP will provide treatment that reduces AHI to normal levels, this method should not be relied upon for long-term treatment. If we are able to test a greater number of patients through the use of home studies, but treat them sub-optimally, are we really improving patient care?

We hope that the experience and data gathered by our lab will assist CMS in its review of this important request. Facility-based PSG's with proper PAP titration are a proven method of treatment for OSA. Until ambulatory methods are proven to provide comparable diagnostic and treatment results for our patients, it is our hope that CMS will not embrace their use.

We appreciate the opportunity to provide input on this important decision, and appreciate your time and attention.

Thank You,

Dr. Michelle Haroldson
Sleep Services Medical Director

Dr. Margret Lenarz
Sleep Services Physician

Laura Niemela BS, RRCP, RPSGT
Sleep Services Coordinator

To Whom It May Concern:

This letter is in reference to the impending review of the National Coverage Determination (NCD) regarding the diagnosis of patients with obstructive sleep apnea syndrome (OSAS) requiring CPAP therapy. The current Center for Medicare/Medicaid services (CMS) guidelines specify that only polysomnography done in a facility-based sleep disorders center or a sleep laboratory can be used to identify patients with obstructive sleep apnea syndrome requiring CPAP. The American Academy of Otolaryngology has requested modification of this guideline to include the use of portable multi-channel home sleep testing devices as an alternative to facility-based polysomnography in the evaluation of OSA.

The physicians of Wellstar Sleep Disorders Center (all board certified in sleep medicine) have strong reservation regarding the unrestricted use of portable multi-channel home sleep testing devices for the diagnosis of OSAS requiring CPAP. There is evidence that portable monitoring devices can be useful and cost effective in the diagnosis of OSAS. There is also strong evidence that testing outcomes from portable monitoring devices frequently differ significantly from results obtained at facility-based polysomnography, with both over estimation and under estimation of disease severity. This has clear ramifications for patient care, with significant potential for over treatment or under treatment of disease. Additionally, direct cost could increase due to repeat testing and indirect cost would increase due to mis-diagnosis.

The American Academy of Sleep Medicine (AASM), American Thoracic Society (ATS), and the American College of Chest Physicians (ACCP) jointly reviewed this issue in 2003. A summary of the consensus opinion was as follows:

- a. Portable monitoring is not recommended for general population screening in the absence of pretest probability of obstructive sleep apnea syndrome.
- b. If portable monitoring is used, raw data must be reviewed during interpretation by physicians familiar with the use and limitations of the portable monitoring equipment.

The AASM has reconvened a task force to re-evaluate under what circumstance portable monitoring devices should be employed, and how the monitoring should be performed. Specifically, the task force is considering types of portable monitoring data acquisition, analysis and interpretation, and application of results. The task force results are expected to be available within the next several months.

We strongly recommend that any decision on portable multi-channel home sleep testing devices be postponed until the results of the AASM task force become available. If a decision is made in the meantime to approve the use of portable devices for apnea testing, we would recommend that use be restricted as follows:

- a. When used, portable monitoring must be combined with clinical assessment, and must be interpreted along with a comprehensive evaluation of the patient by a physician boarded in sleep medicine..
- b. Studies using the device should be performed, reviewed, and interpreted only in AASM accredited sleep centers/laboratories, by physicians boarded in sleep medicine.
- c. Treatment plans should be developed by boarded sleep physicians who have correlated recommendations with the patient's symptoms.
- d. Negative portable studies in the setting of strong clinical suspicion for OSAS should be followed by formal facility-based polysomnography.

In summary, we strongly request CMS delay decisions regarding portable testing until the American Academy of Sleep Medicine has developed practice parameters for their appropriate use. Until then, we uphold the recommendation that formal facility based polysomnography (preferably in an AASM accredited center) is the gold standard for a definitive diagnosis of obstructive sleep apnea.

Thank you for your time and consideration.

Sincerely,

William T. Dowdell, M.D, D, ABSM
David Lesch, M.D., D, ABSM
Aris Iatridis, M.D., D, ABSM
Paul Zolty, M.D., D, ABSM
Hitendra Patel, M.D., ABSM
Susan Keller, RPSGT
Michael Poore, Administrator, WellStar Douglas Hospital

No in home studies. They are often faulty due to poor technical qualities and are fraught with opportunities for fraud and poor quality. Who wants a strange person in their home why they need to go to sleep. The clinical setting is still effective 99% of the time.
MARTIN OLIVARES

Date: 4/3/2007

TO: Centers for Medicare & Medicaid Services

FROM: Rick Simon

RE: Public Comment re: Obstructive Sleep Apnea home testing (Ref: CAG-00093R2)

I am writing in my capacity as a Respiratory Therapist to urge you to positively consider changing your coverage determination for obstructive sleep apnea home-based testing.

I have seen Hundreds of people have their quality of life Improved with C-pap and Bi-pap

For decades, sleep laboratories have served a critical need in accurately diagnosing sleep apnea. But, just as our world has changed dramatically in other areas of technology, so has the field of sleep apnea research and diagnosis. Now, a proven wrist-worn device alternative versus the need for overnight clinic stays makes a strong case for updating CMS policies. It utilizes peripheral arterial tonometry (PAT), which has been approved by the FDA specifically for diagnosing sleep apnea in an unattended setting.

Peer reviewed research studies shows home testing is now as accurate and reliable as sleep clinics. Because of its efficacy and reliability PAT has been an accepted industry practice for some time; one where patients with the ability to pay cover the entire cost. But, many more patients suffering with OSA could be helped if insurance coverage was available.

Given these facts, I urge the CMS to change its coverage determination and to allow coverage for obstructive sleep apnea home testing.

Thank you,

Rick A. Simon CRT 07586 Old US 31 No. Charlevoix, Mi. 49720

April 12, 2007

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
Room 445-G, Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

Re: **National Coverage Analysis for Continuous Positive Airway Pressure (CPAP) Therapy for Obstructive Sleep Apnea (OSA) (CAG – 00093R2)**

Dear Ms. Norwalk:

Air Products Healthcare appreciates the opportunity to submit comments on the National Coverage Analysis for Continuous Positive Airway Pressure (CPAP) Therapy for Obstructive Sleep Apnea (OSA). Air Products Healthcare is a full service provider of durable medical equipment (DME) services, respiratory and home infusion therapies, and rehab equipment and supplies to patients in their homes. Air Products Healthcare is a U. S. subsidiary of Air Products and Chemicals Inc., (Air Products), a company headquartered in Pennsylvania and a leader in the industrial and medical gases, energy, technology, and healthcare markets worldwide. Founded in 1940, Air Products has annual revenues of \$9 billion, operations in over 30 countries, and over 20,000 employees around the globe. The company is recognized for its innovative culture, operational excellence, and commitment to safety and the environment.

Worldwide, Air Products services over 400,000 homecare patients with operations in the United States, Europe, Mexico, and South America. In the United Kingdom, Spain, and Portugal, Air Products has been awarded long-term contracts to provide respiratory therapy on behalf of the national healthcare services in those countries. Air Products is also a major supplier of respiratory services in other European countries, including Portugal, Germany, France, and Italy. In the U. S., Air Products Healthcare has over 90 operating branches in 17 states and services over 100,000 patients.

Air Products Healthcare facilities are accredited by the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) as a provider of homecare services which include: clinical respiratory services, medical equipment services, and rehabilitation technology services. Our facilities employ a significant number of clinicians, including respiratory therapists, pharmacists, and nurses. The Air Products Healthcare Vice President of Regulatory and Clinical Affairs oversees the company's clinical staff in the U.S. We recognize that healthcare is a highly personal service and that a provider's commitment to its community is paramount in driving clinical excellence. We strive to deliver clinical excellence to every patient we serve. With the above background in mind, we feel that our experience and commitment as part of the healthcare team give us a unique perspective to comment on these guidelines.

Considerations:

The national coverage analysis identifies three specific areas of consideration by CMS:

1. Allow the use of portable, multi-channel sleep testing in the home
2. Revise the criteria for determining the Apnea-Hypopnea Index (AHI) to be equal to the average number of episodes of apnea and hypopnea per hour and be based on a minimum of 2 hours of sleep or less, if the actual number of AHI episodes recorded is 30 or more in less than 2 hours, recorded by polysomnography using actual recorded hours of sleep.
3. Develop a policy for the use and coverage of positive airway pressure therapy for a select group of patients who are severely compromised, but who have not yet been evaluated through formal sleep testing.

Portable, multi-channel sleep testing in the home

While there are still conflicting opinions on the use of this multi-channel sleep technology in the home, there is growing acceptance of its use by healthcare practitioners as referenced in the formal request from the *American Academy of Otolaryngology-Head and Neck Surgery*. This acceptance is not limited to the United States. In September 2005, a National Consensus on Sleep Apnea was held in Spain addressed home testing; in 2003, the Scottish Intercollegiate Guidelines Network published national clinical guidelines including home testing and in November 2004, the German Ministry of Health published a modification of directives for diagnosis and treatment of sleep disorders, which identifies the use of home-based technology for sleep testing. The complexity of the test required and personnel circumstances play a factor in determining the appropriateness of the site.

Home-based studies are considered a cost effective diagnostic alternative to facility based polysomnography for the evaluation of patients with likely OSA. Early identification and treatment of sleep disorders is essential for the safe and effective care and management of these patients. In the past, there were concerns voiced regarding the accuracy of the technology used for home-based studies. There have been significant technological improvements in ambulatory sleep diagnostic devices, along with substantial clinical data validating the use of these devices in both the patient's home and in mobile facilities. Requiring only facility-based sleep testing does not consider viable alternatives that impose additional financial and logistical burdens for individuals eligible for Medicare coverage. We are seeing private health plans now routinely covering in-home sleep testing and the subsequent prescribed PAP therapy. When adopting new diagnostic and treatment models, we urge CMS to employ clear standards and regulations based on the best available evidence. There is also a need to assure that adequate coding and payment policies are available to allow patient access to quality sleep diagnostic and therapy services.

Revise the criteria for determining the Apnea-Hypopnea Index (AHI)

We support the recommendation to change the criteria for determining the AHI in very severe patients to 2 hours of sleep or less, if the actual number of AHI episodes recorded is 30 or more in less than 2 hours, recorded by polysomnography using actual recorded hours of sleep. There is a subset of patients with severe OSA who, as a result of their condition, meet this threshold without having 2 hours of recorded sleep time. Many labs complete a split night study on these patients and begin the therapy as soon as possible. Due to current guidelines, some patients do not qualify for coverage under Medicare simply because the diagnostic test was stopped and the titration test begun before the patients measure sleep time was a full 2 hours. The clinician is making a therapeutic decision based on fact to begin the titration study. This change in the AHI criteria brings the Medicare rule in line with the current standard of practice and will ensure this subset of beneficiaries with the most severe OSA can be appropriately and expeditiously diagnosed and treated.

Develop a policy for the use and coverage of positive airway pressure therapy for a select group of severe patients not yet evaluated through formal sleep testing

Timely access to sleep facilities prevents the immediate testing and treatment of patients with OSA. While it is recognized that polysomnography is still the “gold standard” for the diagnosis of sleep disorders, there are additional objective and subjective measures being used by physicians to screen and diagnosis patients with OSA as part of a complete evaluation, which includes polysomnography. Patients determined to have a high probability of OSA can be quickly screened and, in some cases, initiate PAP [Positive Airway Pressure] treatment, a practice now commonly employed by many private insurance plans.¹

There is a growing body of evidence supporting the use of objective and subjective clinical and biochemical data collected as part of a comprehensive physical exam of obese patients with suspected OSA. Using a mix of data, including an objective sleepiness scale, body mass index (BMI), neck circumference, fasting insulin, waist-hip ratio, gender and overnight pulse oximetry, various researchers have been able to accurately predict AHI consistent with that obtained from a complete polysomnogram.^{2,3,4} The ability to effectively initiate treatment in the most severe OSA patients while awaiting more comprehensive evaluation is consistent with the standard of practice, but is not considered by the current NCD.

¹ Senn O, Brack T, Russi EW, Bloch KE. A CPAP Trial as a Novel Approach to the Diagnosis of Obstructive Sleep Apnea Syndrome. *Chest* 2006;129(1): 67-75

² Sharma SK, Kurian S, Mohan A, et al. A Stepped Approach for Prediction of OSA in Overtly Asymptomatic Obese Subjects: A Hospital Based Study *Sleep* 2004;5(4): 352-357

³ Dixon JB, Schachter LM, O'Brien PE. Predicting Sleep Apnea and Excessive Sleepiness in the Severely Obese. *Chest* 2003;123: 1134-1141

⁴ Netzer NC, Stoohs RA, Netzer CM, et al. Using the Berlin Questionnaire to Identify Patients at Risk for the Sleep Apnea Syndrome. *Sleep* 2000;23: 929-938

Advances in PAP technology, in particular the auto-PAP (APAP) devices, which use sophisticated sensor systems and logic-based feedback algorithms to automatically adjust the device pressure have opened the door to highly effective initial therapy for this subset of patients. APAP offers both a novel and readily accessible treatment modality for cases when the need for treatment is essential for the safe and appropriate management of a patient with OSA. APAP has been shown to be useful and effective as a titration tool to obtain fixed CPAP pressures,⁵ and has been associated with successful therapeutic outcomes on CPAP following an initial APAP for patients evaluated by their physician through objective/subjective measures as noted above.^{6,7}

We support the development of a policy that allows the physician to make diagnostic and therapeutic decisions for the use and coverage of PAP therapy devices and accessories for a select group of severely compromised, high-risk patients who have been evaluated and are awaiting a formal sleep diagnostic evaluation. This expanded use and coverage of PAP devices, in particular APAP devices, should be accompanied by appropriate HCPCS coding and payment. In short, we believe that Medicare policy should not limit the diagnostic options available to physicians for those individuals who can clearly benefit from its application.

CONCLUSION

Over 160 of Air Products Healthcare's clinical staff members interact daily with patients, physicians, allied health professionals and caregivers regarding the treatment and care of patients with OSA. Faster, more comprehensive care is needed to prevent the development of costly co-morbid diagnoses associated with OSA. CMS's consideration and adoption of policies to address the changes to the NCD will assist in the early diagnoses and treatment of OSA. Often considered a life altering intervention, the appropriate diagnosis and treatment of sleep disorders is critical to the American public's health and safety.

Thank you again for the opportunity to submit comments. Should you have any questions regarding the information in this document you may contact Mindy Eberhart, VP of Clinical and Regulatory affairs at eberhamj@airproductshc.com, or myself. .

Sincerely,
Laraine M.Forry
VP Compliance and Government Relations
Air Products Healthcare

⁵ Mulgrew AT, Fox N, Ayas NT, Ryan CF. Diagnosis and Initial Management of OSA without Polysomnography: a Randomized Validation Study. *Ann Intern Med* 2007;146(3): 157-166

⁶ [Senn O, Brack T, Russi EW, Bloch KE](#). A continuous positive airway pressure trial as a novel approach to the diagnosis of the obstructive sleep apnea syndrome. *Chest*. 2006;129(1):67-75

⁷ [Masa JF, Jimenez A, Duran J, et al](#). Alternative methods of titrating continuous positive airway pressure: a large multicenter study. *Am J Respir Crit Care Med*. 2004;170(11):1218-1224

Public Comment re: Obstructive Sleep Apnea In-home testing (Ref: CAG-00093R2)

As a respiratory care practitioner significantly involved in the treatment of OSA and indirectly involved with multiple sleep labs I encourage you to consider changing your coverage determination regarding home-based testing.

The considerable cost savings aside, often patients requiring overnight polysomnography will have a difficult time initiating and maintaining sleep. This is primarily due to the unfamiliar laboratory environment; they are not in their own bed where they are the most comfortable and use to recognizable surroundings. When the patients sleep time is compromised in this way many times the study must be repeated.

The need for independent sleep testing facilities have been established years ago. And, there will always be a need for these labs to continue testing not only OSA but other sleep disorders people suffer with. However, many patient's present classic symptoms of OSA where it is evident the airway is compromised during sleep. These patients may not requiring anything more than a thorough titration study.

As technology changes, more and more manufacturers are developing newer, improved and more cost effective equipment. This is certainly evident with sleep diagnostics. The newly FDA approved wrist-worn diagnostic device can provide a cost effective alternative and allow the patient to sleep in a familiar environment. Without the need for multiple electrodes, there is no need to provide an attended study which further reduces the cost.

Peer reviewed research studies demonstrates home testing is now as accurate and reliable as sleep clinics. Because of this, efficacy and reliability has been an accepted industry practice. Many more patients suffering with OSA could be helped when insurance coverage is not available.

Given these facts, I urge the CMS to change its coverage determination and to allow coverage for obstructive sleep apnea home testing.

Thank you,

Rock Kendrick, LRCP
Northlake Medical Supply
Covington, LA

April 12, 2007

Steve Phurrough, MD
Director of Coverage and Analysis Group
Centers for Medicare and Medicaid Services
7500 Security Boulevard
Baltimore, MD 21224-1850

Dear Dr. Phurrough,

The American Academy of Neurology (AAN), a medical specialty society of over 20,000 neurologists and neuroscience professionals, appreciates the opportunity to comment on the CMS review of its national coverage decision (NCD) on CPAP therapy for obstructive sleep apnea (OSA). CMS proposes to change its coverage guidelines to allow non-monitored sleep studies outside of certified sleep laboratories. The AAN supports the position of the American Academy of Sleep Medicine (AASM) that asks CMS not to alter its current NCD on CPAP therapy for OSA based on the five considerations that follow:

The number of accredited sleep centers in the United States continues to grow. There is no evidence to indicate that increasing demand will not be met by appropriate increased supply of labs.

The AAN agrees with the AASM review of available literature on portable monitoring for the diagnosis of OSA and believes that the recent results do not necessitate a change in the CMS national coverage determination.

Portable monitoring may not be more cost-effective than laboratory polysomnography (PSG). This is especially true when taking into account technical failures and false negative or false positive results from portable monitoring. If screening tests were to be widely used in a population with a small likelihood of having sleep apnea, the large number of false positive results would lead to expensive and unnecessary further testing and treatment. Similarly, if the wrong type of test is chosen as a screening test for patients who are likely to have sleep apnea, the large number of false negative results would lead to delayed treatment, and thus to unnecessary and expensive morbidity.

The American Academy of Sleep Medicine is sponsoring a large, multi-center trial of portable monitoring followed by auto-titrating CPAP, compared to the now-standard protocol of attended, in-laboratory PSG and fixed pressure CPAP titration. This study will be performed as soon as is practicable, and the results should be analyzed carefully before CMS makes a new decision regarding portable monitoring. Breathing in sleep varies for many patients according to the sleep state they achieve, their body position, and other factors that may not be monitored in most portable diagnostic protocols, but which factors may be directly monitored in the laboratory. There is inadequate scientific information for the medical community to know which patients may undergo portable diagnostic testing accurately, or to know which type of test is best for which patients.

Because there is not a scientific basis, there are no adequate standards of care for using portable diagnostic testing in patients with possible sleep apnea.

The AAN believes that portable monitoring that would be used in the future for diagnosis of OSA should be restricted to studies performed in accredited sleep facilities or by sleep specialists board certified in sleep medicine. It is essential that sleep studies be read and interpreted by specialists trained and experienced in their use and this is especially true for portable monitoring studies. This is the only sure way to be certain that patients receive the most comprehensive, appropriate, and cost-effective care.

Thank you for your thoughtful consideration of our comments. The AAN would be pleased to provide any clarification that would be helpful to CMS. In the event that you request anything further, please contact Katie Kuechenmeister, AAN staff, at 651-695-2783 or kkuechenmeister@aan.com.

Sincerely,

Thomas R. Swift, MD, FAAN
President, American Academy of Neurology

Date: 04/13/2007

TO: Centers for Medicare & Medicaid Services

FROM: Cindy Page, CRT

RE: Public Comment re: Obstructive Sleep Apnea home testing (Ref: CAG-00093R2)

I am writing in my capacity as a Certified Respiratory Therapist to urge you to positively consider changing your coverage determination for obstructive sleep apnea home-based testing.

In my personal experience in dealing with various patients there are sometimes limitations as far as transportation, debilitating health issues, special family circumstances, etc. that would cause them not to be able to participate in sleep lab studies.

For decades, sleep laboratories have served a critical need in accurately diagnosing sleep apnea. But, just as our world has changed dramatically in other areas of technology, so has the field of sleep apnea research and diagnosis. Now, a proven wrist-worn device alternative versus the need for overnight clinic stays makes a strong case for updating CMS policies. It utilizes peripheral arterial tonometry (PAT), which has been approved by the FDA specifically for diagnosing sleep apnea in an unattended setting.

Peer reviewed research studies shows home testing is now as accurate and reliable as sleep clinics. Because of its efficacy and reliability PAT has been an accepted industry practice for some time; one where patients with the ability to pay cover the entire cost. But, many more patients suffering with OSA could be helped if insurance coverage was available.

Given these facts, I urge the CMS to change its coverage determination and to allow coverage for obstructive sleep apnea home testing.

Thank you,

Cindy Page, CRT

April 13, 2007

RE: CAG 00093R2

NAMDRC, the National Association for Medical Direction of Respiratory Care, welcomes the opportunity to comment on the current NCD for CPAP therapy for obstructive sleep apnea (**CAG-00093R2**). NAMDRC's members serve as medical directors of respiratory therapy departments, critical care units, pulmonary rehabilitation services, and sleep laboratories, both free standing as well as facility based, in close to 2000 hospitals nationwide.

Obstructive sleep apnea (OSA) is a common disorder that is associated with serious complications such as excessive daytime sleepiness and cardiovascular disease.ⁱ Patients with OSA have a higher incidence of automobile crashes than patients without OSA and this disease has been found frequently in commercial truck drivers, and is associated with an increase in the number of vehicle accidents and deaths.^{ii, iii} Untreated OSA is associated with an increased prevalence of hypertension and cardiovascular disease including stroke and the incidence of OSA is increasing in the population due to the gradual aging of the population and the epidemic of obesity.^{iv} Treatment options include continuous positive airway pressure (CPAP), dental devices, and a limited number of surgical procedures. Treatment with CPAP reduces the adverse consequences of OSA, and is associated with reduced vehicle crashes, and has been shown to be associated with reduced morbidity due to cardiovascular disease.^v

The American Academy of Otolaryngology – Head and Neck Surgery (AAO-HNS) recently (1/2/07) submitted a letter to CMS primarily requesting reconsideration for coverage of portable monitoring (PM) when used for the initial diagnosis of sleep apnea. A similar request was turned down in 2003, largely relying on the evidence review by a multi-society specialty panel and resulting editorials which concluded that PM devices for the initial diagnosis of sleep apnea were 'not ready for prime time.'^{vi, vii} The subsequent posting of a new national coverage analysis (NCA) by CMS regarding the PM use for this purpose also included language requesting comment directed at the problematic requirement of 2 hours of recorded sleep time and also the role for 'direct to auto-CPAP or APAP titration.' NAMDRC wishes to comment on these and other related questions provoked by the NCA including:

Is there a role for a PM sleep study in the initial diagnosis of patients with suspected sleep disordered breathing and what patient scenario(s) might be most appropriate for such study particularly with the focus being OSA?

- a. What parameters might be needed for the type of recording equipment utilized in a given situation?***
 - b. What type of caregiver should most appropriately govern the PM data management and treatment recommendations?***
- 2. Should CMS also promote the incorporation of a chronic disease management concept into the diagnostic initiative and enable some necessary coupling with***

compliance data management which therefore mandates additional coverage for the follow-up process?

3. *Would it be in the best interest of patients to readdress the so-called ‘2 hour sleep recording time rule’ and revise this to require only 2 hours of recording time?*
4. *What are the roles of APAP devices in the outpatient setting:*
 - a. *Following PM study for initial CPAP titration?*
 - b. *For direct to CPAP treatment route after thorough sleep disorder consultation by a specialist?*
5. *Should CMS restrict direct access of OSA patients to surgical treatment and insist that patients at least first be exposed to CPAP and managed by a sleep specialist?*

Whatever coverage determinations are made by CMS for the diagnosis of OSA such determinations, where possible, should be evidence-based and favor devices that are highly accurate and accessible to patients. Diagnostic studies should be read and interpreted by individuals with training and experience in the field of sleep medicine. While OSA is the most common sleep-related breathing disorder, it is not the only one. Central sleep apnea (CSA), or Cheyne-Stokes respirations (CSR), is observed frequently in patients with congestive heart failure, and is associated with similar adverse outcomes as OSA.^{viii} Treatment options are different with CSA/CSR. CSA/CSR may improve with CPAP, but often worsens with CPAP. Supplemental oxygen, bi-level positive airway pressure therapy (BPAP), or more advanced forms of respiratory pressure support such as “adapt-servo-ventilation” may be the best option for treating CSA or CSR. In addition, the entity of “Complex sleep apnea” has been recognized as the combination of OSA and CSA, which appears primarily when CPAP therapy is initiated and may comprise more than 10% of patients presenting with what otherwise appears as common OSA syndrome.^{ix, x} The main point is that the diagnosis of “sleep apnea” can be complicated and requires the recognition of variants which may be treated differently.

In 2003, the American Academy of Sleep Medicine, American Thoracic Society, American College of Physicians, and NAMDRRC participated in a comprehensive, evidence based review of the literature regarding the diagnosis of OSA with portable monitoring devices.^{xi} This study concluded that the literature did not support the widespread use of portable monitoring in the diagnosis of OSA. There has not been a significant change in the literature since that time. However, many experienced clinicians believe that certain types of PM studies can be effective in correctly identifying and diagnosing patients with a high probability of having OSA. In all likelihood these high probability patients could benefit from rapid diagnosis and treatment utilizing a variety of portable or home monitoring devices.

Based on the above considerations, NAMDRRC makes the following comments and recommendations to CMS:

1. ***Is there a role for a PM sleep study in the initial diagnosis of patients with suspected sleep disordered breathing and what patient scenario(s) might be most appropriate for such study particularly with the focus being OSA?***
 - a. ***What parameters might be needed for the type of recording equipment utilized in a given situation?***
 - b. ***What type of caregiver should most appropriately govern the PM data management and treatment recommendations?***

A major issue in defining which patient would benefit from the use of portable monitoring in the diagnosis of OSA is in recognizing what characteristics constitute a 'high probability' classification. The most commonly used clinical tools include an Epworth sleepiness scale (ESS) and the Flemons criteria used to predict an AHI of 15-20 or greater.^{xii} These parameters were required in a recent request for grant application by the American Academy of Sleep Foundation, and in studies that proposed direct to APAP titration (see #4 below).

The Apnea-Hypopnea Index (AHI) is the current reference standard used by CMS for coverage and sleep specialists for the diagnosis of sleep-disordered breathing. Sole use of the AHI for portable sleep diagnostic testing is a concern because only the type 2 PM (see ref. #VI for description of types of monitors) is capable of recording sleep staging as it includes electro-encephalography (EEG), electromyography (EMG), and electro-oculography (EOG). While the type 2 PM may have some utility such as with hospitalized patients, it is much more complex for home use.

CMS acknowledges cardio-respiratory devices that study "presumptive sleep" without recording EEG, EMG or EOG in the new CPT codes for 2008. This new coding paradigm in essence acknowledges the respiratory disturbance index (RDI) which was used successfully in many studies reported in the Flemons 2003 evidence review. NAMDRRC believes that Type 3 monitors can be used effectively when the qualified prescribing physician determines that a Type 3 monitor will provide valuable clinical information to guide appropriate diagnostic decision making. Devices which measure only one or two parameters, that is type 4 monitors, may have some utility for follow-up but are not likely to be sensitive or specific enough to provide adequate information to handle the majority of patients coming in for an initial assessment of presumed sleep-disordered breathing.

Because the diagnostic algorithm of sleep apnea needs to include the accurate identification of OSA, CSA, CSR and complex sleep apnea, portable monitoring devices should be capable of measuring nasal airflow or pressure, oximetry, and chest and abdominal movement in order to distinguish obstructive from central apneas. A recent survey of chest specialists closely mimics this and adds high preference for a 10% or less failure rate, and an ability to do automated monitoring.^{xiii}

Nevertheless, an experienced sleep specialist should have the choice of PM or facility based PSG depending on clinical indications. The specialist ordering and interpreting sleep studies should be aware of the patient's entire medical condition and have access to all methods of diagnosis, and be able to refer patients for either PM or facility-based study depending on physician judgment and the needs of the patient. The specialist may not be able to rely solely on one type of technology for diagnosing or ruling out the diagnosis of sleep disordered breathing, but must be able to refer the patient for the most appropriate study for the given patient. Portable studies which yield a negative result in a patient with a high probability of having sleep disordered breathing or who remains very symptomatic from a presumed sleep disorder should be followed up by referral to a facility based study.

Patients with congestive heart failure have a high incidence of CSA/CSR which needs to be accurately identified.^{xiv} Patients with chronic obstructive pulmonary disease (COPD) frequently have oxygen desaturations due to hypoventilation from their disease which needs to be identified and properly treated. Patients with neuromuscular disease often require assisted ventilation with bilevel PAP. The use of PM devices has not been adequately studied in these patient groups. Therefore, we recommend that PM not be utilized in patients with CHF, COPD, or neuromuscular disease. Other patient groups with co-morbidities need to be identified in whom a home portable monitoring device would not be appropriate

We have strong disagreement with respect to the claim in the letter by AAO-HNS that since home-based diagnosis and subsequent titration/treatment are easier than with polysomnography, these could subsequently be performed by a greater number of practitioners. There are certainly no data to support their claim and in fact one could easily challenge that these more limited studies and expectedly higher failure rate would challenge even some sleep specialists. It has long been argued that the basics of sleep are not well taught in medical schools such that general practitioners are as likely to let sleep disorders go unrecognized as to misunderstand the basics of treatment. In a comparative study of primary-care practitioners to sleep-specialists, patient awareness of the disease process was greater and the evaluation was timelier than in patients treated by their less experienced primary care practitioners.^{xv}

We believe that sleep disordered breathing especially, but also sleep medicine in general, is a more complex endeavor than simply identifying OSA. We believe it is important that these studies, whether they are home portable studies or facility based, require that the interpretation is performed by an experienced sleep medicine specialist to provide the highest quality of care. Other specialists such as surgeons, general internists, or primary care physicians do not have the training and experience to guide management of the unique and variable manifestations of sleep disordered breathing.

2. *Should CMS also promote the incorporation of a chronic disease management concept into any diagnostic initiative for OSA and enable some necessary coupling with compliance data management which therefore mandates reconstruction of coverage for the follow-up process?*

We also believe that new emphasis should be placed upon the total management of the patient, not just the diagnostic modality. The current reimbursement system is weighted toward the diagnosis of sleep disordered breathing, but does not provide an incentive for the ongoing management and care of these patients with sleep disordered breathing. New emphasis should be placed on the care of the patient and not just solely on the diagnostic method and technology. OSA needs to be recognized and treated as a chronic disease under the supervision of trained physicians who can guide patients through the diagnosis and advise and monitor whichever form of treatment is most effective for the patient. The recently published practice parameters provide ample evidence that attention to aggressive follow-up, treatment of related complications, and education programs greatly enhance treatment and patient satisfaction.^{xvi}

3. *Would it be in the best interest of patients for CMS to readdress the so-called ‘2 hour sleep recording time rule’ and revise this to read only 2 hours of recording time?*

From a Coverage and Payment Rules section dated 04/01/2002 there was an update to reflect the newer National Coverage Decision to cover CPAP based on an apnea-hypopnea index definition offered by the American Academy of Sleep Medicine. This definition led to the decree that the facility-based polysomnogram must be done on the basis of **2 hours of recorded sleep** if done within a split night diagnostic and CPAP titration study. Several concerned sleep specialists pointed out to the DMERC medical directors that the ‘2 hour recorded sleep time’ can be problematic especially for those with severe sleep apnea and very disrupted sleep. As a result of this ruling, many needy patients were being forced into additional night titration studies that were added expense to the taxpayer, a burden to the patient, and an impediment to optimal care. Furthermore, many CMS carriers do not even allow coverage for a second night study, mandating a

split night sleep study protocol for all. An enlightened local medical review policy (LMRP) bulletin effective 1/1/2004 promulgated by the DMERCs revised the definition of AHI to require a minimum of **2 hours of recording time** without the use of the CPAP device rather than **2 hours of recorded sleep**:

The apnea-hypopnea index (AHI) is defined as the average number of episodes of apneas and hypopneas per hour and must be based on a minimum of **two hours of recording time** without the use of a positive airway pressure device, reported by polysomnogram. The AHI may not be extrapolated or projected.

This revision however was rescinded and reverted back to the original “**2 hours of recorded sleep time**” because the policy in the National Coverage Decision to cover CPAP was not simultaneously revised and trumped the LMRP decision noted above. Although there are no data available in the peer-reviewed literature, virtually all sleep specialists have encountered the situation of a difficult patient that could not sleep well or for 2 hours at all and was subsequently forced to return to the lab for an additional night study. This proposal is not intended to denigrate the value of the more complete recording of sleep time where possible but by altering the 2 hour sleep time mandate for selected situations provides a treatment plan alternative for these demanding patients. NAMDRC respectfully requests amending the NCD to reflect the policy cited above and incorporated into the LMRP/LCD prior to CMS Central Office rescission.

- 4. What are the roles of APAP devices in the outpatient setting:**
- a. following PM study for initial CPAP titration?**
 - b. direct to CPAP route after thorough sleep disorder consultation by a specialist?**

The APAP device has utility both for diagnostic and therapeutic purposes. The device has long been used therapeutically as an adjunct or alternative therapy to CPAP especially for patients who have a large pressure differential need for back vs. side body

position or for patients that struggle with compliance to CPAP and simply find an APAP device more comfortable as supported by several studies.^{xvii} It has been difficult to track the use of the APAP device because CMS has frequently argued that it is equivalent therapy to CPAP and has repeatedly refused to designate a separate HCPCS code for APAP. The studies noted above consistently show congruent resolution of the OSA events at slightly lower mean airway pressures with equivalent if not slightly better hours of use per night compared to CPAP. The use of an APAP device as a diagnostic tool to use either free-standing for initial diagnosis of OSA or to investigate the adequacy of previous titrations has also been recognized by clinicians and supported by studies noted in the same practice parameter paper for APAP as above although it has not been as well validated as a stand alone diagnostic device or as a titrating device.

It is difficult to avoid the discussion of overall benefit and even cost-effectiveness of PM studies without commenting on the subsequent pathway to CPAP titration. If one still assumes that a 2 night sleep lab-based study to include one for diagnosis and one for treatment is still the standard of care, then there would be a cost saving on the basis of eliminating the in-lab diagnostic study with the PM. However, if one assumes that even up to 70% of initial OSA patients could be diagnosed by PM, there is unlikely to be much cost-saving both due to the expected increased access with resultant large volume increase of PM studies and added expense associated with the need for patients to return to the sleep lab for CPAP titration. On the other hand, if one supports the broad use of a single in-lab split-night protocol study (as sanctioned for some patients by the practice parameter paper by Kushida et al noted above) then there would be very limited advantage of an initial outpatient PM diagnostic study followed by an in lab titration.

Cost-benefit analyses and discussion were notably limited in the evidence review paper for PM by Flemons et al due to the distinct lack of comparative studies with the split-night protocol.

Even fewer studies have investigated the direct to APAP route using a combined diagnostic and therapeutic approach for patients at high risk but a recent study by Mulgrew et al illustrates the issues well.^{xviii} The authors combined standard clinical assessment scales and overnight home oximetry to ensure a high pretest probability of OSA $\geq 90\%$ at AHI > 15 . When sleepy patients (mean Epworth scale = 14) were randomly assigned to usual care with full in-lab polysomnography before CPAP use vs. a management protocol going direct to APAP, they showed no differences in outcome at 3 months in the primary outcome, AHI on CPAP or in the secondary outcome variables of sleepiness (Epworth scale), Sleep Apnea Quality of Life Index, and CPAP pressure. There was a very small but significantly better adherence to CPAP therapy in the ambulatory group than in the PSG group (median, 5.4 vs. 6.0 hours per night). The authors concluded that PSG confers no advantage over the ambulatory approach in terms of diagnosis and CPAP titration and where access to PSG is inadequate, the ambulatory direct approach can be used to expedite management of patients with expectedly severe disease. Critics noted that this was a highly selected population with a careful study done by experienced clinicians and investigators and may not be easily generalizable. Furthermore, one could argue that by using sleep specialist governed 'screening tools, including oximetry, these patients did in fact have modified PM study before treatment. Many of the direct to APAP patients required further adjustments of the CPAP pressure and repeated oximetry.

Given the above issues, NAMDRRC would support the use of APAP titration following the use of a PM after thorough evaluation by a sleep specialist in high-risk patients with limited access to split-night in-lab studies. At this time, it is difficult to support a direct to APAP titration even for high-risk patients until further data that are more generalizable becomes available and its reliability as a stand alone diagnostic device is better supported by further studies. Regardless, CMS must reconsider a distinct HCPCS code for the APAP device at least when used as a diagnostic or titrating pressure device.

5. *Should CMS restrict direct access of OSA patients to surgical treatment and insist that patients at least first be exposed to CPAP and managed by a sleep specialist?*

Uvulopalatopharyngoplasty (UPPP) and different laser techniques have been used to treat snoring and sleep apnea, but there are few controlled studies with preferred randomized or well-controlled methodology. Janson et al studied the long term effects of UPPP in 34 patients with OSA and response to treatment was defined as a 50% or greater reduction in AHI and a postoperative AHI of 10 or less.^{xix} Only 64% were labeled as responders at 6 months and 4 to 8 years after surgery, 48% were responders with none of the seven patients with an initial AHI >40 being responders. In a meta-analysis study, Sher et al reported only a 39% success rate of UPPP in correcting OSA.^{xx} UPPP has seldom been credited with curing moderate or severe OSAS. Although there can be an improvement in sleep disordered breathing following UPPP, the degree of improvement is frequently insufficient compared to CPAP and hence the need to redefine the ‘surgical success’ of OSA treatment with inferior endpoints. It is not surprising that the practice parameter paper from the Standards of Practice Committee of the American Sleep

Disorders Association recommended thorough evaluation regarding the presence and severity of obstructive sleep apnea before initiating surgical therapy and that the ultimate treatment outcomes include resolution of OSA symptoms and normalization of the AHI, not just a partial improvement.^{xxi} They could condone a stepwise approach to surgical management plan if the patient is advised at the outset regarding the likelihood of the success of each procedure and that multiple operations may be necessary.

Given the above comments, NAMDRC believes safeguards must be established to prevent unnecessary routing of patients to surgical treatment for OSA, especially following the initial diagnosis. Certainly for patients with suspected more severe disease as might be studied with a PM, CPAP titration and subsequent treatment failure must be well documented before even considering surgical interventions.

NAMDRC again appreciates an opportunity to offer comment to the aforementioned NCA and, in summary, we support the use of a PM device for initial diagnosis of OSA in patients with high likelihood of disease. Furthermore, we urge strict governance of the interpretation of the data and preferably subsequent treatment management by an experienced sleep specialist who is familiar with all of the patient's issues. Following the diagnosis by a PM study, the subsequent CPAP titration could be reasonably carried out as an outpatient in selected patients using an APAP device provided there is an active management plan and follow-up to insure the success of treatment. Patients with OSA should be regarded as needing comprehensive chronic disease management planning. This may require new HCPCS codes and service coverage to optimize patient care and outcomes. Lastly, alternative treatment considerations to CPAP such as surgery should be

done in conjunction with a sleep specialist who has thoroughly evaluated the patient's severity of OSA and response to CPAP.

NAMDRC, as always, offers its resources and would be glad to assist CMS in whatever ways the Agency deems appropriate. Our Executive Office phone number is 703-752-4359 and we can be reached at ExecOffice@namdrc.org.

Respectfully,

A handwritten signature in black ink that reads "Peter C. Gay". The signature is written in a cursive style with a large, sweeping "P" and a long, trailing "y".

Peter C. Gay, MD

President

I am writing to voice my great concern if CMS elects to cover in-home testing CAG-00093R2 for sleep disorders. I am a board certified internist and pulmonologist. I have been actively in the field of diagnosing and treating patients with a variety of sleep disorders for over 25 years. I want to mention that I am very close to retirement so your decision will not impact me financially in any way.

HOWEVER, it will affect thousands of patients with complex and dangerous sleep disorders. They will be subjected to poorly trained providers whose primary objective is the sale or rental of DME equipment (CPAP) and not the accurate and effective outcome for these patients.

Anyone who claims that diagnosing and effectively treating most of these patients is an easy task requiring simplified home equipment, computer generated results with minimal, or in many cases, no physician oversight, does not appreciate the complexity of these patients.

I have seen the results of these limited home testing in my practice and frequently they have led to both extra expense of repeat testing and, more importantly, delay to proper patient treatment.

Stuart J. Menn, MD

stuartmenn@cs.com

760-285-2211

Date: 04/13/2007
TO: Centers for Medicare & Medicaid Services
FROM: Joseph Holmbo
RE: Public Comment re: Obstructive Sleep Apnea home testing (Ref: CAG-00093R2)

I am writing in my capacity as a CPAP Provider to urge you to positively consider changing your coverage determination for obstructive sleep apnea home-based testing.

For decades, sleep laboratories have served a critical need in accurately diagnosing sleep apnea. But, just as our world has changed dramatically in other areas of technology, so has the field of sleep apnea research and diagnosis. Now, a proven wrist-worn device alternative versus the need for overnight clinic stays makes a strong case for updating CMS policies. It utilizes peripheral arterial tonometry (PAT), which has been approved by the FDA specifically for diagnosing sleep apnea in an unattended setting.

Peer reviewed research studies shows home testing is now as accurate and reliable as sleep clinics. Because of its efficacy and reliability PAT has been an accepted industry practice for some time; one where patients with the ability to pay cover the entire cost. But, many more patients suffering with OSA could be helped if insurance coverage was available.

Given these facts, I urge the CMS to change its coverage determination and to allow coverage for obstructive sleep apnea home testing.

Thank you,

Joseph A. Holmbo
Kelly's Medical Equipment and Supply
931 13th Ave N
Clinton, IA 53732

12 April 2007

Leslie V. Norwalk
Acting Administrator
Center for Medicare and Medicaid Services
U.S. Department of Health and Human Services
Hubert H. Humphrey Bldg. – Room 445-G
200 Independence Avenue, SW
Washington, DC 20201

**Re: NCA for Continuous Positive Airway Pressure (CPAP) Therapy for
Obstructive Sleep Apnea (OSA) (CAG-00093R2)**

Dear Ms. Norwalk:

On behalf of the California Healthcare Institute (CHI), whose 270 members include our state's leading biomedical companies and academic research institutions, I am writing to comment on the national coverage analysis by CMS regarding the diagnostic pathway for CPAP coverage for OSA. For reasons explained below, CHI strongly supports expanding coverage to include home testing.

In 1988, Congress established the National Commission on Sleep Disorders Research, which, after five years of study, reported that OSA was a serious public health crisis, afflicting millions of Americans. Considering the scale of the problem, in 1993 the *New England Journal of Medicine* concluded, "it is time for the nation to wake up to the staggering impact of sleep disturbances on the health and welfare of our society, an impact that rivals that of smoking."⁸ Everything science has learned since not only confirms this conclusion, but indicates that the effects of OSA are far more pervasive and more serious than the Commission imagined.

CPAP is standard treatment for OSA. In 1986, CMS (then known as the Health Care Financing Administration) requested the Office of Health Technology Assessment (OHTA) to evaluate the safety, clinical effectiveness and use of CPAP. OHTA reported that "the consensus of clinical opinion from the available information appears to be that CPAP can in the majority of cases prevent OSA and provide substantial clinical improvement with minimal associated morbidity." OHTA recommended that "the use of CPAP be covered under Medicare when used in adult patients with moderate and severe OSA." The diagnosis of OSA required at least 30 episodes of apnea, each lasting a minimum of 10 seconds, during 6-7 hours of sleep. These specifications were based on expert opinions at the time.⁹

⁸ National Commission on Sleep Disorders Research (1993) *Wake up America: a national sleep alert*; Phillipson EA, Sleep apnea – a major public health problem. *N Engl J Med* (1993) 29:328(17):1271-1273

⁹ Decision memo for continuous positive airway pressure (CPAP) therapy for obstructive sleep apnea (OSA) (October 30, 2001) (CAG-00093N)

While CPAP is highly effective in treating OSA, only a small fraction of people suffering from OSA are diagnosed and properly treated. In a February 2007 interview, Dr. William C. Dement, Professor of Psychiatry and Behavioral Sciences at the Stanford University School of Medicine, and the Division Chief of the Stanford University Division of Sleep Medicine, observed that at least 85 percent of people with OSA are undiagnosed, and that the actual percentage is probably much higher. A major barrier to diagnosis and treatment, Dr. Dement noted, is the current diagnostic model.¹⁰

Today, CMS only covers CPAP for patients who have undergone polysomnography (PSG) in a facility-based sleep study laboratory and been diagnosed with OSA. In January 2007, the American Academy of Otolaryngology requested that CMS reassess the National Coverage Determination (NCD) for diagnosis and treatment of OSA. More specifically, the Academy recommended expanding diagnosis “to include home sleep testing as an alternative to polysomnography by physicians licensed to practice medicine.” The Academy’s rationale, which CHI supports, is that restricting diagnosis of OSA and sleep disordered breathing (SDB) to tests performed over one or more nights in sleep labs poses obstacles – chiefly high cost and inconvenience -- that discourage many patients. Lowering the barriers to diagnosis and treatment would yield substantial improvements in public health.

Indeed, as the Academy and many other critics point out, the present diagnosis-treatment paradigm is upside down. As a result of CMS and private payers requiring PSG and reimbursing sleep labs at high rates, diagnosis consumes about 60 percent of total U.S. health care spending on OSA and SDB. Even so, though, in many parts of the U.S. sleep labs and PSG require patients to travel to remote locations for testing. And the backlog in many urban center sleep labs forces patients to wait a minimum of four weeks for an appointment. For patients with serious disease, long lead times themselves increase health risks. Meanwhile, recent advances in monitoring technology have produced a variety of devices that can produce accurate diagnostic data in ambulatory settings. These technologies are much less expensive than sleep lab PSG. As for accuracy, a February 2007 study in the *Annals of Internal Medicine* concluded that PSG “confers no advantage over the ambulatory approach in terms of diagnosis and CPAP titration.” The authors also found that patients preferred an ambulatory approach and that it resulted in improved compliance.¹¹

Opposition to a NCD in favor of ambulatory testing is based on the argument that it is less accurate than PSG and will result in misdiagnoses. The American Academy of Otolaryngology letter of January 2, 2007, provides a thorough comparison of PSG to home sleep studies, including an extensive survey of peer-reviewed medical literature. The overwhelming conclusion of these papers is that several home testing technologies provide accurate data to diagnose OSA. This is a conclusion already adopted by a

¹⁰ Dement WC, (February 27, 2007) www.sleepreviewmag.com/podcast

¹¹ Mulgrew A, Fox N, (2007) diagnosis and initial management of obstructive sleep apnea without polysomnography: a randomized validation study. *Ann Intern Med* 146: 157-166.

number of private insurance companies, including Kaiser Permanente. In fact, CMS itself accepts multi-channel home testing in regions where PSG is unavailable.

From CHI's perspective, CMS coverage and reimbursement policy should encourage state-of-the-art science to maximize public health. Home testing can (a) dramatically reduce the cost of diagnosis; (b) rapidly expand access to diagnosis and treatment; (c) greatly increase the number and types of physicians sensitive to SDB in their patients and who are essential to patients appropriately managing their disease. Because CPAP is extremely safe, and is rarely tolerated by patients who do not suffer from SDB, the risks of misdiagnosis are slight.

The truly serious risk is leaving patients undiagnosed and untreated. With respect to cardiovascular disease, for example, Dr. Virend Somers, professor of hypertension and cardiology at the Mayo Clinic, has described the strong links between OSA and hypertension, heart failure, stroke and ischemic heart disease. Research has shown that OSA patients with normal blood pressure run a risk of developing high blood pressure within four years. Hypertension, of course, is a major risk factor in the development of heart disease and stroke. Somers and his colleagues have studied OSA patients who had no other illnesses, to rule out any confounding factors. They found that apnea patients have higher levels of sympathetic nervous system (SNS) activity during both wake and sleep than a matched set of control patients without OSA. Involuntary functions such as heart rate and blood vessel constriction are controlled by the sympathetic nervous system. In persons without apnea, there is usually a decrease in SNS activity and blood pressure falls when sleeping. During apnea events, however, elevated SNS activity constricts the blood vessels, while the heart rate increases, pushing blood into tight vessels. Blood pressure spikes of up to 250/150 have been seen during apneas. Sleep apnea patients also have faster heart rates than non-apnea patients, even when awake, but have less variability in their heart rates. This combination of a less variable heart rate and greater variability in blood pressure is an indicator of potential cardiovascular problems. Apnea patients also produce higher levels of endothelin and lower levels of nitric oxide. This results in more constriction and less relaxation of blood vessels. Dr. Somers said that after only four hours of sleep, an untreated apnea patient's levels of endothelin could rise up to 50 percent. When treated with CPAP, endothelin levels typically return to normal.¹²

In the area of endocrinology, a growing body of evidence suggests strong connections between diabetes and SDB. In a 2005 study published in the *Archives of Internal Medicine*, researchers evaluated the effects of OSA treatment with CPAP on blood sugar levels in a group of 25 people with type 2 diabetes. Patients received the treatment for at least four hours a night for three months. The results: CPAP prompted a significant reduction in blood sugar levels. For example the average blood glucose levels after

¹² Gami AS, Witt BJ, Howard DE, Erwin PJ, Gami LA, Somers VK, Montori VM. Metabolic syndrome and risk of incident cardiovascular events and death - A systematic review and meta-analysis of longitudinal studies. *J Am Coll Cardiol* 2007 Jan 30; 49(4): 403-14; Caples SM, Wolk R, Somers VK. Influence of cardiac function and failure on sleep-disordered breathing: evidence for a causative role. *J Appl Physiol* 2005 Dec; 99(6): 2433-9; Caples SM, Kara T, Somers VK. Cardiopulmonary consequences of obstructive sleep apnea. *Semin Respir Crit Care Med* 2005 Feb; 26(1):25-32.

breakfast were reduced from 191 mg/dL to 130 mg/gL, and similar reductions were observed after other meals. Considering prevalence of sleep apnea and obesity in people with diabetes, these results suggest that the treatment of OSA can have important health benefits. The researchers believe that CPAP may improve blood sugar levels by lowering insulin resistance. Restless sleep causes an increase in hormones that work against insulin's action. By improving sleep, CPAP may improve hormone levels.¹³

The science of SDB, the understanding of its relationship to serious, widespread comorbidities, the rapid advances in technology for diagnosis and treatment (including increasingly sophisticated sensors and algorithms that can automatically adjust to changes in patients' breathing) – all these developments call for CMS to develop a NCD based on 21st century medicine and suited to the needs of 21st century patients.

Thank you for the opportunity to comment on this important topic. Please contact me if there are any aspects of this you would like to discuss further.

Sincerely,

David L. Gollaher, Ph.D.
President and CEO
CHI – California Healthcare Institute

¹³ Babu AR, Herdegen J, Type 2 diabetes, glycemic control, and continuous positive airway pressure in obstructive sleep apnea. Arch Intern Med. (2005);165:447-452.

April 13, 2007

RE: CAG 00093R2

The Sleep Manufacturers Alliance (SMA), a group of 8 manufacturers that develop and market products related to the diagnosis and treatment of sleep disorder breathing, including sleep apnea, welcome the opportunity to comment on the open National Coverage Determination (NCD) [CAG 00093R2] and make recommendations for improving access to and quality of care for Medicare beneficiaries.

Our comments focus on several critical questions related to possible expansion of the coverage of sleep diagnostics to home monitoring, a shift that would, in our collective view, improve access and the quality of therapeutic treatment to Medicare beneficiaries who suffer from obstructive sleep apnea. Our comments do address matters beyond the specific questions raised by CMS as we know that this NCD process opens for discussion all component coverage aspects of CPAP for OSA.

1. Does the technology exist to diagnose patients in the home?
2. Does the health care system have a workable infrastructure to support such home diagnosis?
3. What is the extent of clinical evidence to support the efficaciousness of home monitoring?
4. What issues arise if CMS determines that under certain circumstances home monitoring is a viable option for diagnosis of sleep apnea?

Technology for Home Monitoring

While the standard approach to diagnosing obstructive sleep apnea (OSA) is in-laboratory, technician-attended polysomnography, a variety of portable monitoring technologies have been developed which may be appropriate alternatives in the diagnostic assessment of patients with suspected OSA.

A portable monitoring classification system was developed by the American Academy of Sleep Medicine (AASM) and includes the following types of portable monitoring devices (Type 1 monitoring devices are those used for laboratory-based, technician-attended overnight polysomnography).¹⁴

Type of Portable Monitoring Device	Parameters Measured
Type 2 Comprehensive Portable	Polysomnography minimum of 7 channels, including electroencephalogram,

¹⁴ Chesson, AL, Berry, RB and A Pack (2003). Practice parameters for the use of portable monitoring devices in the investigation of suspected obstructive sleep apnea in adults. Sleep 26(7):907-913.

	electrooculogram, chin electromyogram, electrocardiogram or heart rate, airflow, respiratory effort, and oxygen saturation
Type 3 Modified Portable Sleep Apnea Testing	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
Type 4 Continuous Single or Dual Bioparameters	One or 2 channels

The common measurement of sleep apnea is the Apnea-Hypopnea Index (AHI), which CMS currently utilizes for the diagnosis of obstructive sleep apnea. The AHI is arguably an imperfect measurement, but it is the reference standard that is most commonly used and the metric of sleep apnea severity for which there is the most published data relating to morbidity (e.g., neurocognitive dysfunction, hypertension, and quality of life). For these reasons, it formed the basis for a 2003 systematic review of home diagnosis of sleep apnea that was conducted by the American Thoracic Society, the American Academy of Sleep Medicine, and the American College of Chest Physicians.¹⁵ The AHI represents the combined number of apneas and hypopneas that occur per hour of sleep.

Use of the AHI as the reference standard for sleep diagnostic testing is important because the denominator for the measurement is hours of sleep. One of the concerns with some portable sleep testing monitors is the limited ability to monitor sleep staging, or whether the patient is actually sleeping, since electroencephalography (EEG) and electromyography (EMG) are the metrics used to determine sleep staging.^{16,17} While we recognize that these specific metrics are only defined by Type 2 portable monitors, SMA members recognize that the issue of device selection for home monitoring must not be based on the device's characteristics alone. Accessibility, cost and the technical acumen of patients in their homes should be integral to decisionmaking regarding appropriate device selection.

Type 3 diagnostic devices and Type 4 screening devices are cost-effective and the Type 3 devices may be useful tools for diagnosing and titrating for sleep disorders. In fact, new CPT codes for 2008 acknowledge a cardio/respiratory study with the concept of "presumptive sleep" where no EEG, EMG or EOG is recorded. That new coding

¹⁵ Flemons, WW et al. (2003). Home diagnosis of sleep apnea: a systematic review of the literature : an evidence review cosponsored by the American Academy of Sleep Medicine, the American College of Chest Physicians, and the American Thoracic Society. *CHEST* 124(4):1543-1579

¹⁶ Collop, NA. (2004). Portable monitoring for diagnosing obstructive sleep apnea. *CHEST* 125:809-811.

¹⁷ Flemons et al, 2003.

paradigm, we believe, mirrors Type 3 devices. Therefore, SMA does believe that Type 3 monitors can be used effectively when the prescribing physician determines that a Type 3 monitor will provide valuable clinical information to assist the physician in appropriate diagnosis.

Health Care Infrastructure

The simple presence of the technology that can serve as a viable complement to facility based diagnosis does not, by definition, signal that the health care system ought to adopt this technology. Legitimate questions arise regarding a viable infrastructure to support home diagnostics. As we examine that issue, we are convinced that the infrastructure does exist. We know that managed care organizations, commercial payers and the Veterans Administration have embraced home diagnostics as a reasonable, clinically sound approach to the diagnosis of sleep apnea and, to the best of our knowledge, problems have not arisen regarding the efficacy of the technology OR the inability of the payer to ensure that the clinical information generated by the home study is useful to the prescribing physician. Conversely, if the health care infrastructure could not accommodate this technology, we believe that the clinical literature would reflect such structural problems.

The issue of professionals involved in sleep diagnosis and therapy should be addressed and clarified by CMS. While we recognize and support the need for trained sleep specialists to be involved in virtually all phases of the continuum of care, it would be helpful for CMS to state succinctly what professional training it believes is necessary to support facility based as well as the home monitoring environments.

Clinical Evidence to Support CPAP as Treatment for OSA and Related Matters, including Home Monitoring

SMA members readily acknowledge that there is ongoing debate within the medical community regarding the level of evidence supporting the viability of home monitoring and its role in the diagnosis of obstructive sleep apnea. We also acknowledge that there can be levels of interpretation of clinical studies, abstracts, etc, that either support or criticize home monitoring. We strongly urge CMS to consider the following peer reviewed articles as it considers any change in the current NCD. We acknowledge that these articles address the broad scope of the NCD and their focus goes beyond the narrow question of home monitoring.

Flemons WW, Littner MR, Rowley JA, et al. Home diagnosis of sleep apnea: a systematic review of the literature. An evidence review cosponsored by the American Academy of Sleep Medicine, the American College of Chest Physicians, and the American Thoracic Society.[see comment]. Chest 2003; 124:1543-1579

Nancy A Collop. Portable Monitoring for Diagnosing Obstructive Sleep Apnea- Not Yet Ready for Primetime. Chest. 2004;125:809-811

- Eckert DJ, Jordan AS, Merchia P, et al. Central sleep apnea: Pathophysiology and treatment. *Chest* 2007; 131:595-607
- Morgenthaler TI, Kagramanov V, Hanak V, et al. Complex sleep apnea syndrome: is it a unique clinical syndrome? *Sleep* 2006; 29:1203-1209
- Pusalavidyasagar SS, Olson EJ, Gay PC, et al. Treatment of complex sleep apnea syndrome: a retrospective comparative review. *Sleep Medicine* 2006; 7:474-479
- Flemons WW, McNicholas WT. Clinical prediction of the sleep apnea syndrome. *Sleep Med Rev* 1997;1:19-32.
- Philip R Westbrook. Survey Regarding Limited Diagnostic Systems for Sleep Apnea, JCSM, accepted October 2006- online publication:
<http://www.aasmnet.org/jcsm/AcceptedPapers/LimitedDiagnosticSystemsSA.pdf>
- Scharf SM et al, Comparison of primary-care practitioners and sleep specialists in the treatment of obstructive sleep apnea *Sleep Breath*. 2004 Sep;8(3):111-24
- Kushida CA et al, Practice parameters for the use of continuous and bilevel positive airway pressure devices to treat adult patients with sleep-related breathing disorders. *Sleep*. 2006 Mar 1;29(3):375-80
- Littner M et al. Practice Parameters for the Use of Auto-Titrating Continuous Positive Airway Pressure Devices for Titrating Pressures and Treating Adult Patients with Obstructive Sleep Apnea Syndrome. *SLEEP, Vol. 25, No. 2, 2002*
- Mulgrew AT et al, Diagnosis and Initial Management of Obstructive Sleep Apnea without Polysomnography- A Randomized Validation Study. *Ann Intern Med*. 2007;146:157-166.
- Senn O et al (2006) A Continuous Positive Airway Pressure Trial as a Novel Approach to the Diagnosis of the Obstructive Sleep Apnea Syndrome *CHEST* 2006; 129:67-75
- Hiestand DM et al (2006) Prevalence of Symptoms and Risk of Sleep Apnea in the US Population *CHEST* 2006; 130:780-786
- Masa JF et al (2004) Alternative Methods of titrating Continuous Positive Airway Pressure *Am J Respir Crit Care Med* Vol 170. pp 1218-1224
- Chervin, RD et al (1999) Cost Utility of Three Approaches to the Diagnosis of Sleep Apnea: Polysomnography, Home Testing, and Empirical Therapy *Ann Intern ed*. 1999;130:496-505

Issues Directly Correlated to Home Monitoring

SMA members believe that any discussion of home monitoring must include the broader discussion of the continuum of care for sleep apnea patients. Therefore, it is vitally important to emphasize that appropriate diagnosis is more than facility based or home monitoring – titration of the patient to determine appropriate therapeutic settings on CPAP must be an integral part of any comprehensive diagnostic pathway.

Again, technology plays an integral role through auto titration systems. The literature examining auto titration systems supports the use of these devices, not for all sleep disorder breathing patients, but its applicability for certain patients, when used by a sleep specialist, is evident. Auto titrating positive airway pressure (APAP) can be prescribed by a physician for a patient as a trial to determine efficacy of PAP therapy, mean and median pressures, number of nights used at what pressures (determines adherence objectively) and as a means of determining future treatment options should the patient not comply with PAP in an unattended trial scenario. From a technological perspective, knowing that APAP provides a varying form of positive airway pressure and can treat OSA, it is **not** recommended for treating complex or mixed sleep apnea. Nor is it suited for patients suffering from severe and consistent hypopneas - or hypoventilation syndromes. Based on the reports generated from the devices, many of these issues will be recognized by a sleep specialist and the more difficult patients should be sent for attended overnight PSG studies. A great majority of patients however suffer from basic OSA and it is anticipated that over 70% of the OSA population could be successfully diagnosed and titrated using simpler pathways and the tools currently exist for these models as shown in the attached studies.

The SMA would be glad to offer its resources to CMS in any capacity the Agency believes is appropriate, and would be willing to clarify or amplify any of these comments if requested. We can be reached at 703-752-4353 or ExecOffice@sleepalliance.org.

April 13, 2007

To: CMS
Case # CAG-00093R2

RE: Concern about in home sleep apnea testing:

I am a sleep disorders physician treating patients for the last 16 years.

My concerns about in home testing are that at best, results may be difficult to interpret, and at worst, potentially dangerous outcomes can result.

On the diagnostic front, home studies (most of the screening devices) do not reliably demonstrate sleep from wake. The significance of respiratory oscillations becomes apparent when one can see whether there are associated arousals and/ or oxygen desaturations. Often, findings can be subtle, and therefore the context of arousals and desaturations becomes critical to interpretation of results.

Although CPAP is usually a very safe therapy, I have seen respiratory reflex disturbances induced by CPAP (essentially prolonged respiratory cessations). These have resulted in severe oxygen desaturations. My concern is that in the home setting, an unsuspecting patient could come to a bad outcome.

Lastly, primary physicians have not had the opportunity to be educated about diagnosis and management of sleep disorders. Home studies may enable an unsophisticated approach to diagnosis and management, without appreciation of limitations. This lack of education is an unfortunate result of difficulty getting Sleep Medicine into med school curricula. Hopefully this will change in the future, now that Sleep Medicine has been accepted as a recognized field within the American Board of Medical Specialties.

Not all sleep disorders are respiratory in nature, and many problems would be missed with sleep apnea screens. While there is likely a good use of screening in some cases as a first step, lab study should be required to confirm and treat the different varieties of sleep breathing problems. Thank you for your consideration.

Mindy Cetel MD
Diplomate, American Bd. Of Sleep Medicine
Pacific Sleep Medicine Services
10052 Mesa Ridge Ct 101
San Diego CA 92121
858-657-0550

Date: 04/13/2007
TO: Centers for Medicare & Medicaid Services
FROM: Danny Andrus – Regional Medical Rental & Sales
RE: Public Comment re: Obstructive Sleep Apnea home testing (Ref: CAG-00093R2)

I am writing in my capacity as general manager of a multi-location home medical equipment company, to urge you to positively consider changing your coverage determination for obstructive sleep apnea home-based testing.

Living in a rural area I find most small hospitals reluctant to invest in a sleep lab for polysomnographic studies which means the patient is referred to a sleep lab or large hospital some distance from the patient's home. This not only involves the patient taking off work for at least one day and possibly two, in order to have the study which is always very costly requiring significant out-of-pocket expenses for the patient. In-home diagnostic testing can be done for 1/4th the cost which will not only save the Medicare system money, it will save the patient lost wages, out of pocket expenses and travel costs.

For decades, sleep laboratories have served a critical need in accurately diagnosing sleep apnea. But, just as our world has changed dramatically in other areas of technology, so has the field of sleep apnea research and diagnosis. Now, a proven wrist-worn device alternative versus the need for overnight clinic stays makes a strong case for updating CMS policies. It utilizes peripheral arterial tonometry (PAT), which has been approved by the FDA specifically for diagnosing sleep apnea in an unattended setting.

Peer reviewed research studies shows home testing is now as accurate and reliable as sleep clinics. Because of its efficacy and reliability PAT has been an accepted industry practice for some time; one where patients with the ability to pay cover the entire cost. But, many more patients suffering with OSA could be helped if insurance coverage was available.

Given these facts, I urge the CMS to change its coverage determination and to allow coverage for obstructive sleep apnea home testing.

Thank you,

Danny Andrus
Regional Medical Rental & Sales
700 Poinciana Ave.
Mamou, La. 70554

April 13, 2007

Steve Phurrough, MD
Director of Coverage and Analysis Group
Centers for Medicare and Medicaid Services
7500 Security Boulevard
Baltimore, Maryland 21244-1850

Re: National Coverage Determination for Obstructive Sleep Apnea

Dear Dr. Phurrough:

We wish to thank CMS for considering a review of its policy, especially in light of the recent evidence in favor of portable monitoring. This letter is intended to highlight several of the points made by the American Academy of Sleep Medicine (AASM) in their letter dated April 12, 2007.

First, we agree with the AASM in commending CMS for adhering to scientific evidence for determining national coverage decisions. We are disappointed that the AASM submitted a conclusion to CMS that "Recent studies provide some support for portable monitoring in selected populations managed in academic centers" without referencing the largest multi-site, U.S. non-academically based comparison study between portable monitoring and PSG [1]. This study funded by the National Institute of Health, referenced by the Institute of Medicine and published in the journal *Chest* seems to have been overlooked. In this study participants completed both PSG and in-home studies. The study included a significant portion of healthy controls (20% of the 187 subjects) with no pretest probability of OSA. Using only written instructions, the failure rate was less than 3% because the technology was designed to be easy to use and it provided feedback to the patient when there was a problem, similar to what a technician does during an attended study.

This study was followed up with an 89-subject independent validation study again that included 20% healthy controls. The design of this study was intended to comply with the request of the Institute of Medicine for greater validation of portable monitoring. Again the failure rate was less than 3% and the results concluded that the portable device was equivalent to PSG when the specific goal was to obtain the AHI in both low and high levels of obstructive sleep apnea. An abstract of this study has been presented and published [2] at the 2006 annual meeting of the AASM and the manuscript is currently undergoing review for publication.

The presently accepted purpose of measuring the AHI in obstructive sleep apnea is to provide a numerical measure of the severity of the physiological disorder of breathing. No matter how the AHI is obtained there is conflicting evidence as to what level of

physiological abnormality results in proven sequelae. While it is now accepted that severe obstructive apnea merits treatment because of its proven health consequences, the definition of “true positive” disease has been undergoing refinement and much research remains to be done because limited outcomes data exist on the utility of treating borderline AHI. However studies to address these issues are underway, and it is notable that in its recent requests for proposals the NIH has mandated that many of the epidemiological studies being undertaken be conducted only with ambulatory monitors.

In the currently used clinical diagnostic algorithm, the AHI is combined with expert analysis of the clinical history and other factors to arrive at either:

1. The diagnosis of obstructive sleep apnea (if the AHI is sufficiently high)
- or
2. The exclusion of obstructive sleep apnea (if the AHI is sufficiently low).

The arguments invoked against the use of ambulatory unattended monitoring should be viewed differently in the two situations. In the case where one wishes to establish that the disease is sufficiently high, the present CMS standard is that the AHI be greater than 15 events per hour during 2 hours of EEG documented sleep. The AASM itself argues that if the disease is sufficiently severe (they suggest an AHI > 30 events per hour of recording time), then because the sleep may be so disrupted that it is impossible to obtain even 2 hours of sleep. This argument, that severe disease is immediately evident (to which we subscribe), is based on the fact that if the obstructive events are very frequent (i.e., the numerator of the AHI), then the denominator of recorded time (always greater than sleep time) can only cause us to underestimate severity. The AASM argues that in this situation the disease can be expeditiously diagnosed if only two hours of recording (not sleep) is obtained and shows severe disease to be present. We contend that this very argument applies equally to the use of ambulatory monitoring. If a high severity of AHI is required to justify diagnosis (and the need for treatment) when non-EEG recording is used, there is little gained by also requiring that the test be done in an attended setting. The only requirement of the testing method should be that it records a valid measure of breathing (which ambulatory monitoring does as well as PSG if the signals are of good quality) and that the recording be reviewed by an expert.

On the other extreme, when one wishes to exclude significant obstructive sleep apnea, the key argument used against ambulatory monitoring is that the insensitivity of the test will result in significant under-detection of the respiratory disease whereas PSG will adequately rule it out. Although we believe published data does not support this contention, it may be legitimate for CMS to require more testing of this aspect of the validity of unattended monitoring before allowing it to be considered fully equivalent to PSG. This does not however invalidate doing the test for the purpose of diagnosing severe disease as above. Therefore the test itself should be reimbursed and the results allowable if sufficiently severe.

The above arguments are particularly important in patient populations where it is difficult or impossible to obtain a PSG. While the wait time for PSG has dropped from 22.5 to 12 days for those coming to sleep laboratories, this does not count the many patients who

have little or no access to care because facilities are limited or reimbursement does not exist commensurate with the cost of a PSG. One such group is the Medicaid and underinsured population. In NYC there is essentially no facility able to do a PSG for these patients given current reimbursement without incurring a loss. Thus, even in public hospitals, severe obstructive sleep apnea goes untreated in many patients as few laboratories can afford to do their PSGs. For these patients, alternatives to PSG to obtain the very elevated AHI, including limited and ambulatory testing, have routinely been used for years. Furthermore, the Veterans Administration has been implementing a diagnostic algorithm including this option for many of its centers and endorses the use of ambulatory monitoring in severe disease when no other options exist. In some parts of the United States (i.e., Southern California), many insurers will simply not reimburse for a patient consultation and/or follow up with a sleep medicine professional. The sleep lab performs the PSG and a board certified physician interprets the recording, but the primary care physician must serve the role that the AASM argues should be filled by a trained specialist. We agree with AASM that in an ideal world the management of patients with sleep apnea would be done by sleep medicine specialists. By adopting the use of portable monitoring, the medical delivery system could free up resources that could then be allocated toward the management of this life-long disease under the direction of a sleep medicine expert. As a result of this reallocation, the quality of care would increase and the health care saving expected from the treatment of OSA would more likely be achieved because of improved disease management.

The AASM has worked very hard to establish a sub-specialty for sleep medicine. It is time that it begins to trust its board certified members to utilize all tools that provide rational alternatives to the PSG, especially the inexpensive ones. We urge the CMS to revise its policies to include reimbursement for ambulatory monitoring with the following provisos:

1. Meeting the interim guidelines proposed by the AASM for portable monitoring (e.g., all studies, both PSG and portable, need to be read by individuals certified in Sleep Disorders Medicine by the American Board of Sleep Medicine), and;
2. A different, more stringent criterion may be needed for the diagnosis of significant disease (e.g., an AHI > 20-30) when limited (non-EEG) methods are used to justify prescribing reimbursed CPAP or other therapy.

The above approach will best serve the public until more information is gathered, as by the planned AASM multi-center study of diagnostic strategies including ambulatory monitoring, rather than preventing the development of the field by refusing to admit the obvious: severe obstructive sleep apnea is easily diagnosed or confirmed by even the most rudimentary monitoring. The coverage decision for severe disease should not be about what device to use, but rather the level of expertise required to select an appropriate device and to interpret the findings.

We respectfully submit these comments as members in good standing in the AASM and wish to provide an alternative perspective to that in the AASM letter which we believe represents the views of a significant portion of its membership.

Respectfully;

David Rapoport, M.D.
Medical Director, NYU Sleep Disorders Center, New York, NY

Michael Coppola, M.D.
Associate Clinical Professor of Medicine, Tufts University School of Medicine,
Springfield, MA

Dennis Nicholson, M.D., ABSM, FCCP
Medical Director, Pomona Valley Hospital Sleep Disorders Center, Pomona, CA

Delmer Henninger, M.D., ABSM, FCCP
Director, Complete Sleep Solutions, Murrieta CA

Philip R. Westbrook, M.D., ABSM, FCCP
Chief Medical Officer, Advanced Brain Monitoring, Carlsbad, CA, Past-President
AASM

References:

- [1] Westbrook, P., Levendowski, DJ., Cvetinovic, M., Zavora, T., Velimirovic, V., Henninger, D., Nicholson, D. Description and Validation of the Apnea Risk Evaluation System: A Novel Method to Diagnose Sleep Apnea-Hypopnea in the Home, *Chest* 128: 2166-2175, 2005.
- [2] Ayappa, I., D. Rapoport, P. Westbrook, D. Levendowski, T. Zavora, and R. Norman, Validation of a Self-Applied Unattended Monitor for Sleep Disordered Breathing (SDB). *Sleep*, 2006. 29(Abstract Supplement 29): p. A343.

Date: 04/14/2007
TO: Centers for Medicare & Medicaid Services
FROM: John B. Velekkakan
RE: Public Comment re: Obstructive Sleep Apnea home testing (Ref: CAG-00093R2)

I am writing in my capacity as (describe your involvement with sleep apnea; i.e., sufferer, family member, physician, technician, etc.) to urge you to positively consider changing your coverage determination for obstructive sleep apnea home-based testing.

It is my belief and opinion home testing for OSA is an economical and very practical tool. This will enable patients to be comfort of their home and avoid 1st night effect that associated sleep lab testing. We have patients who are afraid to go to sleep lab for sleep studies and unable to get treated several disease that associated with sleep disorders.

For decades, sleep laboratories have served a critical need in accurately diagnosing sleep apnea. But, just as our world has changed dramatically in other areas of technology, so has the field of sleep apnea research and diagnosis. Now, a proven wrist-worn device alternative versus the need for overnight clinic stays makes a strong case for updating CMS policies. It utilizes peripheral arterial tonometry (PAT), which has been approved by the FDA specifically for diagnosing sleep apnea in an unattended setting.

Peer reviewed research studies shows home testing is now as accurate and reliable as sleep clinics. Because of its efficacy and reliability PAT has been an accepted industry practice for some time; one where patients with the ability to pay cover the entire cost. But, many more patients suffering with OSA could be helped if insurance coverage was available.

Given these facts, I urge the CMS to change its coverage determination and to allow coverage for obstructive sleep apnea home testing.

Thank you,

John B. Velekkakan, President & CEO
American Home Respiratory Care Inc
Monroe Sleep Solutions Inc.

My name is Ron Kolakowski and I am the President & CEO of Advanced Medical Solutions in Jackson, TN and I fully support the change to acceptance of in-home testing by CMS.

Thanks

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I

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<http://www.aasmnet.org/jcsm/AcceptedPapers/LimitedDiagnosticSystemsSA.pdf>

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Itamar Medical Inc.

160 Speen Street
Framingham, MA 01701
Tel: 1-888-748-2627

April 12, 2007

Steve Phurrough, MD, MHA
Director
Coverage and Analysis Group
Centers for Medicare and Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244-1850

Francina Spencer
Lead Analyst
Coverage and Analysis Group
Centers for Medicare and Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244-1850

RE: NCD Reconsideration – CPAP for Obstructive Sleep Apnea CAG – 00093RS

Dear Dr. Phurrough and Ms. Spencer:

On behalf of Itamar Medical, Inc. (“Itamar”), I thank you for the opportunity to submit these comments in support of the request from the American Academy of Otolaryngology – Head and Neck Surgery for the Centers for Medicare and Medicaid Services (CMS) to modify its current National Coverage Determination for CPAP Therapy for obstructive sleep apnea (OSA) (hereinafter referred to as the “CPAP NCD”) to recognize unattended, portable multi-channel home sleep testing as a reasonable and necessary method of diagnosing and documenting OSA in Medicare beneficiaries. Itamar is the developer and manufacturer of the Watch-PAT 100 a unique technology for the home diagnosis and treatment assessment of sleep-related breathing disorders. The Watch-PAT 100 is a self-contained device that is worn on the wrist and uses a non-invasive finger mounted pneu-optical probe to measure the peripheral arterial tone (PAT) signal. The recorded signals are stored in a removable memory card in the device to be downloaded to a computer for automatic analysis utilizing proprietary algorithms. In addition to the PAT Signal, the Watch-PAT 100 records oxygen saturation and actigraphy. A fourth channel, pulse rate, is derived from the PAT Signal.

Home sleep testing with technology that identifies apnea events and monitors sleep/wake phases will improve net health outcomes for Medicare patients by ensuring that these patients have access to effective OSA testing in a timelier manner and in a less daunting environment. Adoption of a coverage policy that includes home study of OSA in addition to polysomnography

will make Medicare policy consistent with other large healthcare networks, such as the Veteran Administration system and the Kaiser Permanente health system, as well as other large commercial insurers covering such studies.

I. Patient Access Supports Expanding Medicare Coverage to Home Sleep Studies

The negative consequence of disordered or inadequate sleep on the overall health and well-being of an individual has been well known for some time. However, the serious impact of this health problem on the public health at large was the subject of a 2006 report by the Institute of Medicine, National Academy of Sciences (IOM) -- "Sleep Disorders and Sleep Deprivation: An Unmet Public Health Problem." According to the IOM, sleep disorders and the related sequelae has reached a public health crisis.

Studies continue to point to the large number of patients that suffer from OSA that go undiagnosed and untreated. The risk of not diagnosing a patient is significant, especially in individuals already suffering from a higher incidence of additional morbidities, such as cardiovascular diseases, diabetics and obesity.

The growing attention to sleep apnea is leading to the recognition of larger numbers of patients for whom OSA should be part of the differential diagnosis for the symptoms for which they present for health care. Thus, one of the challenges to the health care system is ensuring access to effective testing that also is cost-efficient. To date, Medicare coverage for OSA has been limited to Level I, polysomnography (PSG) testing performed in a sleep laboratory. This policy, however, creates a significant barrier to treatment for some patients. Some patients simply do not have access to a sleep laboratory because there is no laboratory in their community, and traveling to a distant facility is not possible. Other patients must wait months for an appointment such that it would be hard to suggest that these patients have real access to a timely diagnosis and treatment. Finally, there are some patients who simply are anxious in the laboratory environment and elect not to obtain the necessary diagnosis they need.

The Minnesota-based Institute for Clinical Systems Improvement (ICSI)¹ has recognized the importance of offering more flexibility to physicians managing sleep disorders, stating that *"employment of portable monitoring as a second-best option is not likely to result in harm to patients with a high pretest probability of OSAHS, and may result in less risk than leaving the condition undiagnosed"* ("Diagnosis and Treatment of Obstructive Sleep Apnea", Institute for Clinical Systems Improvement, March 2006).

II. Clinical Evidence Supports Expanding Medicare Coverage to Home Sleep Studies

In the April 4, 2005 Decision Memorandum corresponding to the first reconsideration of the CPAP NCD, the Coverage and Analysis Group explained that the decision not to expand coverage to home sleep studies was based on a number of conclusions. The reason included: (1) a conclusion that there was insufficient evidence to conclude that home-based testing is as specific and sensitive as in-laboratory PSG, (2) a concern whether CMS could be confident in the

¹ The Institute for Clinical Systems Improvement (ICSI) is an independent non-profit organization which facilitates collaboration on health care quality improvement by medical groups, hospitals and health plans that provide health care services in the state of Minnesota and surrounding states. <http://www.icsi.org/home/>.

integrity of the data captured in home testing, (3) a concern that the sample sizes of the studies relied upon were too small, and (4) a question as to whether the study results could be extrapolated to the Medicare beneficiary population. Consequently, CMS decided that without this information it could not conclude that the net health outcomes for Medicare beneficiaries would be improved by access to home sleep studies.

1. Conclusions One and Two

Numerous studies have reported that diagnosing sleep apnea at patients' homes, using certain multi-channel testing devices (categorized by the American Academy of Sleep Medicine as "Level III Sleep Study"), are feasible, safe and efficacious. While it is clear that Level III studies are not identical to PSG, the evidence unequivocally supports a conclusion that for a significant number of patients, Level III studies are a reasonable clinical alternative to in-laboratory testing.

We recognize that a number of earlier studies stated that a sleep study conducted without a technician in attendance could compromise the integrity of the recorded data. Yet, a growing number of studies published in recent years, especially those reporting on the efficacy of newer devices approved by the FDA specifically for the diagnosis of sleep apnea in an unattended setting, have demonstrated the procedures to be highly reliable and well-tolerated by patients. In most of these studies, the clinical results used in patient management decisions were comparable to those achieved with polysomnography. These results are particularly significant for patients with high pre-test probability of sleep apnea. Specific references for many of these studies were included in the recent request for reconsideration submitted by the AAO-HNS. For the sake of brevity, we will not repeat the information provided by AAO-HNS, but note that we agree with AAO-HNS discussion of the clinical evidence supporting the clinical utility of home sleep studies.

In addition, we note that the ICSI concluded in its 2006 consensus guidelines that:

"In patients with a high pretest probability of OSA, unattended portable recording for the assessment of obstructive sleep apnea is an acceptable alternative to standard polysomnogram in the following situations: (1) patients with severe clinical symptoms that are indicative of a diagnosis of obstructive sleep apnea and when limitation of treatment is urgent and standard polysomnography is not available, (2) for patients unable to be studied in the sleep laboratory, and (3) for follow-up studies when diagnosis has been established by standard polysomnography and therapy has been initiated."

"Polysomnography is not available in some rural areas. Some patients decline to undergo a study in a sleep laboratory. For those and other reasons, some physicians are interested in expanding the use of in-home, unattended portable recording beyond the three situations listed above. At present the evidence supporting this expansion is limited and at times conflicting, but employment of portable monitoring as a second-best option is not likely to result in harm to patients with a high pretest probability of OSA, and may result in less risk than leaving the condition undiagnosed. Portable monitors should not be used in an unattended setting in patients with "Atypical or Complicating Symptoms". In a patient with suspected OSA, a negative study must be followed by a polysomnography test. The patient and physician must discuss fully the limitations of portable monitoring before employing this strategy" (emphasis added).

In light of the growing data showing that a Level III sleep study is an acceptable alternative to PSG for many patients, as well as the results of a comprehensive review by a credible body such as ICSI, we believe that any question articulated by CMS two years ago regarding the ability of certain home sleep studies to be reasonable and reliable tools to diagnosis OSA, in at least a subset of patients, and to assess ongoing treatment should be answered.

2. Conclusion Three

CMS noted in its 2005 Decision Memorandum that the study populations in the studies presented in support of coverage were too small. However, CMS never explained how and why it reached this conclusion. For example, the agency never suggested that the studies were not adequately powered, nor for that matter, did CMS suggest what sample would be sufficient. Provided the studies were well-designed and statistically significant we are unclear as to CMS's concern. We further believe that many of the published studies presented similar populations to those included in other studies of sleep medicine practices accepted by CMS.

3. Conclusion Four

Lastly, CMS stated that it was reluctant to extend coverage to home studies because there was insufficient data as to whether the study results were equally applicable to Medicare beneficiaries. Again, the Decision Memorandum did not elaborate why CMS felt this to be significant and offered no data or scientific rationale as why it would suspect or expect that there would be a difference in how a Medicare beneficiary experiences OSA as compared to an individual less than 65 years of age. Without such an explanation it is impossible to respond to these concerns. We also noted that most practices associated with the management of sleep apnea currently covered by CMS are not based on studies specifically conducted on Medicare beneficiaries.

III. If Coverage is Expanded to Home Sleep Studies, Peripheral Arterial Tonometry Should Be Among the Technologies Covered

The review by CMS referred specifically to the four types of sleep study devices, as classified by the ASDA in 1994. This classification is based on the number of channels monitored and the need for attendance by a technologist during the data collection period. The 2005 Decision Memorandum (the "Memorandum") cited deficiencies associated with the use of both Type II and Type III devices. Specific concerns were raised about covering Type III devices because these devices measure only cardiorespiratory parameters and do not permit the determination of sleep and wakefulness, and thus, abnormal breathing events are calculated as 'events per hour bed' instead of 'events per hour of sleep'. In addition to the lack of actual sleep measure, additional concerns raised in the memorandum included the findings that (1) 13%-18% of unattended studies had missing data, and (2) that in general, there was no sufficient information reporting on the use and performance of portable monitoring devices in an unattended settings in the patients' homes.

The CMS review addressed a number of Type II and Type III technologies, among them devices that have been developed over ten years ago. The review failed to properly address at least one new technology, the Watch-PAT, in spite of the significant body of peer-reviewed evidence and the large number of detailed comments that referred specifically to the Watch-PAT technology that were submitted to CMS during the May 2004 and July 2004 review periods, and

subsequently, in testimony before the Medicare Coverage Advisory Committee. We believe that this oversight may have been in part related to the misclassification of the Watch-PAT technology by AHRQ (RTI Project No. 8452.001.005) which provided much of the basis for the MCAC recommendations. AHRQ inappropriately classified in its report the Watch-PAT as a Type IV device (which includes the measurement of only 1-2 channels). Yet, the Watch-PAT technology actually provides more clinical data than a Level III device, since in addition to information summarizing nocturnal breathing disturbances, the Watch-PAT also provides clinically important information regarding sleep time and quality.

1. Peripheral Arterial Tonometry

The peripheral arterial tonometry (PAT) signal provides a reliable measurement of peripheral arterial responsiveness, and through this measurement considerable information about many medical conditions.² When a person is in a stressful situation, the autonomic nervous system responds with a series of physiological changes which include a rerouting and redistribution of blood to vital organs. Itamar Medical's research discovered that one of these events is a signal to constrict the peripheral vasculature, which affects peripheral arterial tone. The PAT signal measures circulatory responses based on the magnitude and time course of changes in arterial pulsatile blood flow in the fingertip. Consequently, the PAT signal may be used to identify breathing disturbances by directly monitoring reaction of the autonomous nerve system to apneic events by recording changes to peripheral arterial blood volume, in addition to heart rate and blood oxygen levels, the measurements generally used in other apnea diagnostic devices.

Plethysmographic devices have been used for over 100 years and have contributed important medical progress. However, prior to Itamar's technology the only methods available for measuring autonomic nervous system function were either painful, invasive procedures that carry with them certain risks, or methods that have been shown to be of limited accuracy and reliability. Because of these factors, as well as the associated costs, regular, or even periodic screening of autonomic nervous system indicators has not been a viable clinical option.

The fingertip and the palmar surface of the fingers are ideal sites for measuring the scope of peripheral vascular responsiveness because of their high density of arteriovenous anastomoses and corresponding high density of essentially exclusive alpha-adrenergic innervation. In contrast, the vascular beds at other sites are less densely innervated and are regulated by a variable mixture of autonomic regulators which can actively cause vasodilation or vasoconstriction. In the finger, the regulation of the blood vessels is accomplished by a single type of autonomic receptor (alpha-adrenergic) which clearly facilitates the unambiguous interpretation of the autonomic changes. The PAT signal reflects the overall level of the autonomic activity which is the summation of the tone resulting from the activated alpha receptors on the finger's arteries and arteriolar smooth muscles.

This new signal represents the vasoactivity of the arterial vasculature, without confounding artifacts, via the measurement of the amplitude of the pulse wave (i.e. pulsatile finger blood flow patterns). PAT technology is applied to non-invasively measure pulsatile finger blood flow patterns as indicators of changes in the autonomic nervous system in a wide range of medical conditions related to the cardiovascular and central nervous systems, including myocardial ischemia, obstructive sleep apnea, congestive heart failure, endothelial dysfunction, stress and

² The peripheral arterial tone has been described in leading scientific journals, including *Nature Medicine*, *SLEEP*, *Sleep Medicine*, *Am J Respir Crit Care Med*, and *Chest*. See enclosed "List of Publications", items 1-10.

others.

2. PAT for OSA Diagnosis

The Watch-PAT is a multi-channel monitoring device cleared by the FDA specifically for the purpose of diagnosing OSA. While standard Level III devices consist of 4 channels, including ventilation or airflow, heart rate and oxygen saturation, the Watch-PAT records heart rate and oxygen saturation, and instead of monitoring changes in airflow or ventilation as a precursor to apnea events, it identifies apneas by monitoring minute changes in the peripheral circulation caused by a reaction of the autonomous nervous system to temporary disturbances of airflow.

The Watch-PAT provides the same clinical information available in all other Level III devices plus it also incorporates a sophisticated actigraph³ that together with the PAT signal enables it to identify sleep, wake and REM phases. Thus, it provides for sleep information previously available only in Level I and Level II devices, but without using EEG sensors. Since the classification of sleep monitoring devices predates the introduction of new technologies, some devices, such as the Watch-PAT, do not fit the precise definition of any of the now out-dated categories. The Watch-PAT represents a new category for OSA diagnosis that is similar to other multi-channel devices on one hand, but yet, provides for some of the clinical utility available in Level I devices.

The performance of the PAT-based sleep study has been validated and extensively published in peer-review journals and presented in numerous scientific forums (literature list is attached). A number of the most important papers are included with this letter, including:

- “Evaluation of a portable device based on peripheral arterial tone for unattended home sleep studies”, Bar et al., CHEST 2003 2003; 123:695-703.
- “Using a Wrist Worn Device Based on Peripheral Arterial Tonometry to Diagnose Obstructive Sleep Apnea: In-Laboratory and Ambulatory Validation”, Pittman et al. SLEEP 27.5 (2004):923-933.
- “Assessment of a Wrist-Worn Device in the Detection of Obstructive Sleep Apnea”, Ayas et al. SLEEP MEDICINE 4 (2003): 435-442.
- “Validation a Portable Monitoring Device for Sleep Apnea Diagnosis in a Population Based Cohort Using Synchronized Home Polysomnography”, Zou et al. SLEEP 29.3 (2006): 367-374.
- “A Novel adaptive wrist actigraphy algorithm for Sleep-Wake assessment in sleep apnea patients”, Hedner et al. SLEEP 2004, 27(8):1560-6.
- "Detecting REM Sleep from the Finer: Automatic REM Sleep Algorithm based on Peripheral Arterial Tone (PAT) and Actigraphy", Herscovici et al. PHYSIOL MEAS 2006: 27, 1-12
- “Follow-Up Assessment of CPAP Efficacy in Patients with Obstructive Sleep Apnea using an Ambulatory Device Based on Peripheral Arterial Tonometry”, Pittman et al. SLEEP AND BREATHING, 2006 Sep: 10(3), 123-131.
- “Assessing Efficacy, Outcomes, and Cost Savings for Patients with Obstructive Sleep Apnea Using Two Diagnostic and Treatment Strategies”, Townsend et al. SLEEP DIAGNOSTIC AND THERAPY, 2007 Jan 1(7).

The paper by Townsend et al. reported on the results of 103 patients study, randomly assigned to

³ An actigraph is a well-established technology used by sleep specialists to obtain provides information about an individual’s sleep/wake patterns.

testing by polysomnography and PAT. The study reported both groups have demonstrated significant improvements in most variables assessed after 8-week and 6-month follow-up points, respectively. At 8-weeks, hours of CPAP use were higher for participants in the PSG group (PSG 5.1, PAT 4.0 hours), however at 6-months this difference was not significant (PSG 5.5, PAT 5.4 hours). The PAT group demonstrated higher Epworth Scale at 8-week but not 6-months. Cost of assessment using PAT was significantly less than PSG. The study concluded that using PAT to assess OSA can be a clinically and financially effective approach when used for select patients by a sleep specialist. Patient adherence to PAP and quality of life measures improved in both groups and were similar at 6-month. Cost savings are significant when using portable monitoring.

The clinical literature also addresses CMS' concerns regarding technology failure of home OSA diagnostic studies. The average failure rate of studies using the Watch-PAT, as reported in a number of publications was less than 3%. This rate is not only better than most of the data presented in the 2005 Memorandum, but is also consistent with test yields realized when using Level I devices, especially in split-night studies.⁴ Reported failure rate of all studies conducted by the largest user of the Watch-PAT in the US was Itamar Medical's largest user was 1.2% (N=7,730 studies in 2006).⁵ An audit by the company of data from larger number of accounts using the Watch-PAT reported total failure rate of home studies of 0.96% (N=39,710 studies).⁵

The Watch-PAT has been tested extensively, undergoing side-by-side comparisons with Level I devices, as well as thorough evaluations of its performance in unattended studies at patients' homes. Cumulatively, over 470 adult patients have been included in the peer-reviewed studies of the Watch-PAT. Specifically, the Pittman validation study⁶ reported that respiratory events identified during sleep studies using the Watch-PAT had 0.88 correlation with events recorded in an in-lab PSG. This study concluded that "[i]n a population of patients suspected of having obstructive sleep apnea, the Watch-PAT can quantify an Oxygen Desaturation Index (ODI) that compares very well with Medicare criteria for defining respiratory events and an Respiratory Disturbance Index (RDI) that compares favorably with Chicago criteria for defining respiratory events. The device can be used with a low failure rate for single use in the lab and home for self-administered testing". This is in agreement with the conclusion reached by Bar et al (2003)⁷ that "[t]he Watch-PAT may offer an accurate, robust and reliable ambulatory method for the detection of OSAS, with minimal patient discomfort."

In addition to the validation of the efficiency of the Watch-PAT in diagnosing OSA it has also been shown that it is accurate in differentiating between sleep and wake states over a wide range of age groups and severity of the disease (Hedner et al, 2004).⁸ This study concluded that the Watch PAT actigraphy algorithm "provides a reasonably accurate estimation of sleep and wakefulness in normal subjects and patients with obstructive sleep apnea on an epoch-by-epoch basis. This simple method for assessment of total sleep time may provide a useful tool for the

⁴ Rodway GW, Sanders MH. The Efficacy of Split-Night Sleep Studies. *Sleep Med Rev.* 2003 Oct;7(5):391-401.

⁵ Company data, unpublished.

⁶ Pittman et al. Using a Wrist Worn Device Based on Peripheral Arterial Tonometry to Diagnose Obstructive Sleep Apnea: In-Laboratory and Ambulatory Validation. *SLEEP* 2004 27(5):923-933

⁷ Bar A, Pillar G, Dvir I, Sheffy J, Schnall RP, Lavie P. Evaluation of a Portable Device Based on Arterial Peripheral Tonometry (PAT) For Unattended Home Sleep Studies. *Chest*, March 2003, 123(3):695-703.

⁸ Hedner J, Pillar G, Pittman DS, Zou D, Grote L, White D. A Noval Adaptive Wrist actigraphy Algorithm for Sleep-Wake Assessment in Sleep Apnea Patients. *Sleep*, 2004, 27(8):1560-6.

accurate quantification of obstructive sleep apnea in the home environment.”

Itamar shares CMS’ view expressed in the 2005 Memorandum that “given the absence of a true ‘gold standard’ reference, the clinical application of terms such as sensitivity and specificity is not straightforward”. The ongoing changes in the practice of diagnosing OSA clearly reflect the fact that in lack of an absolute test to confirm the severity of OSA, the decision to treat a patient requires a clinical judgment in addition to the results of any of the available sleep tests. While CMS identified the inherent limitations in comparing various types of sleep testing devices, the AHRQ report upon which CMS relied in 2005 failed to recognize that the primary mode of conducting sleep studies today is vastly different than the standard PSG studies referred to in most of the cited publications. The acceptance of the split-night protocol, in which the diagnostic study has been reduced to 2-3 hours, as the primary testing modality for OSA in today’s clinical practice, invalidates the primary premise of the AHRQ review, which compared the use of alternative tests to a standard PSG study lasting a minimum of 6 hours. In effect, there is much more evidence supporting the use of Level III studies than data supporting the use of the split-night protocol.

IV. Summary

In summary, we believe that there is sufficient data for CMS to determine that home OSA testing is reasonable and necessary. We recognize that the changes that took place in recent years in the standard practice of diagnosing OSA, including the wide use of split-night studies practically repudiates prior comparisons between Level I and Level II / Level III devices presented to the MCAC. Considering all the data available and the well-established and cumulative clinical experience using home studies, Medicare patients will realize improved net health outcomes when multi-channel sleep studies are added to PSG and to other options available for the physicians managing OSA. We recommend that final NCD incorporates the following points:

1. Cover the use of sleep studies that utilize the Watch-PAT or other technologies that identify apnea events and monitor sleep time and sleep quality to diagnose OSA.
2. Adopt coverage guidelines similar to those accepted by the Institute for Clinical Systems Improvement.

We would be pleased to provide additional information and to meet with the members of CMS to further explain our comments.

Respectfully submitted,



Peretz Lavie PhD
Andre Ballard Professor of Biological Psychiatry
Director, Itamar Medical Inc.
Head, Technion Sleep Medicine Center

Watch-PAT List of Publications

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14. Tauman R, O'Brien ML, Mast TB, Holbrook CH, Gozal D. Peripheral Arterial Tonometry Events and EEG Arousals In Children. *Sleep* 2004, Vol.27 (3), 502-506.
15. Pittman DS, Ayas NT, MacDonald MM, Malhotra A, Fogel RB, White D. Using a Wrist-Worn Device Based on Peripheral Arterial Tonometry to Diagnose Obstructive Sleep Apnea: In-Laboratory and Ambulatory Validation. *Sleep* 2004, Vol.27 (5), 923-933.
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AMERICAN ASSOCIATION FOR RESPIRATORY CARE

9425 North MacArthur Blvd., Suite 100, Irving, TX 75063, (972) 243-2272, Fax (972) 484-2720
<http://www.aarc.org>, E-mail: info@aarc.org

April 10, 2007

Ms. Francina Spencer
Centers for Medicare and Medicaid Services
Room C1-12-13 Central Building
Mail Stop: C1 -09-06
7500 Security Blvd.
Baltimore, MD 21244-1850

RE: NCA Tracking Sheet for Continuous Positive Airway Pressure (CPAP) Therapy for Obstructive Sleep Apnea (OSA) (CAG-00093R2).

Dear Ms. Spencer:

On behalf of the American Association for Respiratory Care (AARC), a professional association representing 43,000 respiratory therapists, I am pleased to submit comments on the Centers for Medicare and Medicaid Services' (CMS) National Coverage Determination (240.4) regarding the diagnosis of patients with Obstructive Sleep Apnea (OSA) requiring Continuous Positive Airway Pressure (CPAP) therapy.

Sleep diagnostics and therapeutics have been an integral component of the respiratory therapy scope of practice for decades. Our patients with sleep-disordered breathing, in particular OSA, often are afflicted with additional co-morbidities such as hypertension, diabetes, obesity, and heart failure. The acuity levels of these patients can vary widely, and this is especially true for the Medicare patient.

As licensed health professionals, a critical part of the respiratory therapist's role in assessing patients with sleep disorders is to evaluate their overall physical condition and specifically their responses to diagnostic services, tests, and therapies. Therefore, based on our background and level of expertise, we believe it is critical that CMS ensure that facilities and personnel meet certain standards and criteria in order to ensure the highest level of care for Medicare beneficiaries diagnosed and treated with this debilitating and progressive illness. Our comments focus on two aspects of the NCD:

- The current policy that polysomnography be done in a facility-based sleep study laboratory; and

- The request to modify existing policy to include the use of portable multi-channel home sleep testing devices as an alternative to facility-based polysomnography in the evaluation of OSA.

National Coverage Determination (NCD) 240.4

CMS notes in its tracking sheet (CAG-00093R2) that the scope of its reconsideration regarding the diagnosis of patients with OSA requiring CPAP includes all aspects of the NCD. One of AARC's concerns with current policy is the requirement that "The polysomnography must be performed in a facility-based sleep study laboratory..."

Comment: The current NCD (240.4) does not stipulate that facility-based polysomnography be performed in an "accredited" facility.

The AARC recommends that the CMS revise its coverage policy to require sleep testing be performed in *accredited* facilities with accreditation to be determined by CMS.

Prior to the year 2000, facilities providing polysomnograms were able to meet the demand of scheduling patients to receive sleep diagnostic services. At that time, sleep disorder testing was viewed as an additional health care service provided by hospitals. Sleep laboratories, centers and facilities were based in or affiliated with hospitals or other acute care facilities.

The presumption was that a hospital, as part of its own accreditation process and requirements, would assure that a sleep facility would meet standards for having equipment and supplies that met manufacturers specifications. Moreover, a sleep lab affiliated with a hospital provided a level of assurance that if a patient encountered a medical problem, immediate access to physicians and other qualified health personnel would be available. Finally, many hospital-based sleep facilities did obtain the voluntary accreditation status as an accredited facility, a further quality indicator.

Therefore, because of the close affiliation to accredited hospitals and the fact that many of these sleep facilities were separately accredited, there was no need for Medicare to require specific sleep facility or lab accreditation.

In the last seven years, however, there has been an unprecedented increase in the number of business entities entering into the sleep disorder arena. We believe the current structure of payment and reimbursement for diagnostic sleep testing has spurred this tremendous growth.

There is nothing to prevent these sleep businesses from billing themselves as a "sleep laboratory" or "sleep facility" or "sleep center". A June 22, 2005, Wall Street Journal article by Peter Sanders featured the growing trend of having sleep studies performed in hotel rooms. This article highlighted the use of La Quinta Inns and Suites in Southern California for such practices and also noted the following:

“Similar scenarios are played out nightly...hotels in Surprise, Ariz.; Salt Lake City; Houston and suburban Portland, Ore. The fledgling Encino, Calif., venture is carving a niche in the booming sleep test industry by finding hotels with low occupancies and renting blocks of rooms at discounts...”

The current Medicare policy of not requiring sleep facilities to be accredited permits any type of sleep entity to enter the marketplace without having to meet minimum standards of operation. The incentive to market sleep services to the public intensifies. Costly and unnecessary over utilization of services results.

Without the need for facilities to be accredited, there is no assurance that the testing is being properly performed, that the proper equipment is available and calibrated correctly, and that the personnel performing the services have verifiable competency. We believe this is a patient safety and quality of care issue. Accreditation means that there are standards that must be met. If there are no standards to be met, there is no assurance to Medicare that the sleep services are being performed accurately and appropriately.

Recommendation:

The AARC recommends that CMS revise the language in its current policy in the NCD to mandate that the “polysomnography must be performed in “**an accredited** facility-based sleep study laboratory.”

Comment: Current Medicare policy requires that the use of CPAP devices be ordered and prescribed by the licensed treating physician. The policy is silent, however, on the types of qualified personnel who would be expected to carry out the testing.

As stated above, the rapid expansion of the sleep disorder business has spurred unprecedented growth in the industry. Physicians who have no certification or specialization in sleep disorders are opening sleep disorder centers. Personnel must be hired to staff these sleep facilities and perform the testing on patients. Unfortunately, the demand for employees in these centers does not meet the supply of competency-tested health care professionals who are qualified to prepare the patient, set up the testing equipment, and run the polysomnogram while monitoring the patient’s clinical status. The result is that “on-the-job” trainees are hired with no prior training and no competency testing to provide these clinical services.

Untrained and untested personnel simply do not have the skills required to assure that the test is being performed correctly and the patient is responding appropriately. Inaccurate or poorly executed testing can result in false positives or false negatives or inconclusive testing results which require further costly testing.

Those who are qualified, the registered polysomnographic technologist, the licensed and credentialed respiratory therapist, and the specially trained nurse, and other licensed

qualified professionals do have the training, education and competency to provide sleep diagnostic services.

We believe it is important for Medicare to set a high standard in terms of personnel qualifications to help assure a high quality of services provided to the Medicare beneficiary.

Recommendation:

The AARC recommends that CMS specify in NDC 240.4 the types of qualified personnel needed to conduct sleep disorder testing in an accredited facility. Based on our comments above, we recommend that the Indications and Limitations section of NCD 240.4 be revised to include the following paragraph. :

Polysomnography must be performed by qualified personnel, such as registered polysomnographic technologists, licensed and certified respiratory therapists, specially-trained nurses or other health professionals who have been competency tested by nationally recognized accreditation entities and under the supervision and oversight of a board certified physician holding a sleep specialty credential.”

NCA Tracking Sheet for (CAG-00093R2)

CMS has requested comments on whether the Medicare program should modify its current coverage policy 240.4 and permit portable multi-channel home sleep testing devices as an alternative to facility-based polysomnography in the evaluation of OSA.

Comment: Standards for the proper use of new technologies in the home setting need to be established prior to widespread use.

The AARC fully supports the introduction and use of new scientifically proven technologies. These new technologies should, of course, be reviewed and analyzed and compared to those technologies that are currently proven to determine if they should be used and will not compromise quality, diagnosis or outcome. Innovative technologies improperly used can and will result in undesirable outcomes and misdiagnosis.

Recommendation:

If CMS determines that current policy should be revised to include multi-channel home sleep testing devices as an alternative to polysomnography, the AARC recommends that any new device introduced into the home for sleep testing should meet minimum testing criteria. For example, central apnea vs. obstructive apnea requires more physiologic data than pulse oximetry and flow. Without the appropriate data a misdiagnosis may result.

Comment: It is critical that the health care personnel who will be preparing the patient, instructing the patient, and setting up the testing in the patient's home be properly trained and competency-tested.

As noted earlier, the AARC believes Medicare policy should clearly set requirements and criteria for trained and competent personnel to ensure patient safety and quality of care for its Medicare beneficiaries.

Without specific personnel standards established by CMS, there a strong potential and risk that unqualified employees, such as truck drivers, delivery persons or on-the-job trainees who have been hired by sleep facilities with no competency testing will be substituted for licensed or credentialed health care personnel.

Sleep testing in the home raises unique issues that must be considered. The sleep set-up will most likely be performed at night in the patient's home. For patient safety reasons, the personnel, regardless of credential or licensing, must be required to have a background check performed.

CMS should consider the need for an algorithmic approach with a licensed or credentialed practitioner overseeing the algorithm. Any device that has reduced number of electrodes may misdiagnose a patient's co-morbidities. Proper triage would lessen this concern. In the hands of untrained personnel this could be a significant liability for the patient and healthcare entity providing the service.

As we stated in the above comments regarding current policy, improperly preparing the patient or misplacement of the equipment will result in inconclusive results or inaccurate readings. Patients could then require additional costly testing. Moreover, based on potentially inaccurate test results the Medicare beneficiary may not receive the appropriate therapy, or in the reverse situation, may receive unnecessary services.

Recommendation:

If CMS revises its policy to include home testing, it is critical for the individuals who would be setting up the testing equipment and instructing the patient to be competent to do so. It is not adequate to stipulate simply that the home services must be performed by "qualified personnel." This type of reference leaves it up to the sleep entities to come to their own conclusions as to what constitutes "qualified," and that can lead to the use of personnel with no training or competency testing in sleep disorder services.

The AARC strongly recommends that CMS specify the types of personnel qualified to provide home testing by adding a new paragraph under the Indications and Limitations Section to read as follows:

Personnel Qualified to Conduct Home Sleep Testing

Equipment set up and patient preparation and instruction for portable multi-channel home sleep testing devices as an alternative to facility-based polysomnography in the evaluation of OSA must be performed by qualified personnel such as physicians, registered polysomnographic technologists, licensed and credentialed respiratory therapists, specially trained nurses, electroneurodiagnostic technologists or other health professionals who have been competency tested by nationally recognized accreditation entities.

We appreciate the opportunity to provide comments to CMS on the subject NCD and proposed revisions and appreciate your consideration of our recommendations.

Sincerely,

A handwritten signature in black ink, appearing to read "Toni Rodriguez". The signature is written in a cursive style with a large, looping "y" at the end.

Toni Rodriguez, Ed.D, RRT

President



Landauer Metropolitan, Inc.

One Bradford Road
Mount Vernon, NY 10553
Tel. 914-665-9050

Comments on the CMS reconsideration of the NCD on CPAP for OSA (CAG-00093R2)

Background

Landauer Metropolitan, Inc. (LMI) is a diversified provider of home care products and services in the New York metropolitan area. Our key service lines are durable medical equipment, home infusion, and clinical support services for hospitals and physician groups, including a sleep division which provides contracted services for traditional facility based sleep centers.

With the patient home as our primary site of care, LMI, like most home care companies, is uniquely positioned to provide all in-home diagnostic and treatment modalities critical to successful patient outcomes and related cost savings to medicare beneficiaries, and will remain an essential link to OSA treatment outcomes regardless of the final details of this NCD review.

LMI strongly supports the use of all clinically validated OSA assessment, diagnostic, and treatment modalities under the direct supervision of qualified physicians. Expanding the use of more readily available, less expensive procedures is the only solution to addressing the current OSA healthcare crisis in an efficient, cost-effective manner while ensuring successful treatment outcomes. The 70%-80% of undiagnosed OSA patients will eventually require care, both for OSA and related conditions exacerbated by OSA, and the current service structure for diagnosis and treatment of OSA simply cannot provide the capacity to handle these patients without major added costs to an already financially strained healthcare system.

Home Diagnosis and Therapy

There has been significant controversy regarding what kinds of tools should be used to assess and diagnose patients for OSA. Clinically validated diagnostic algorithms can be used to establish high pre-test probabilities of OSA, setting the stage for simpler, less expensive diagnostic studies and more rapid deployment of effective therapy. Comparisons between ambulatory diagnostic technologies and traditional, in lab polysomnography seem to ignore the real issue, which is successful therapy and long term treatment of OSA. CMS seems to agree by stating in its latest Decision Memo for CAG-00093R, "There is insufficient clinical evidence available to assess the validity of laboratory based polysomnography in the diagnosis of OSA in adults."¹ In 2006, the Institutes of Medicine released an influential report on sleep disorders, which stated sleep

centers should not make diagnostic testing their focus, but rather emphasize their treatment and long term care.²

The ability to perform in-home attenuated parameter tests for OSA has been shown to be feasible in many studies with numerous devices, with results comparable to laboratory polysomnography. These comparisons have received significant criticism, including poor study design and variances caused by night-to-night variability in the severity of sleep disordered breathing, which are issues that affect and might also call into question the accuracy of laboratory polysomnography to which home studies are regularly compared.³ Full polysomnography can also be performed in the home, with accurate data acquisitions and low rates of sensor loss.^{4,5,6} Home polysomnography should experience the least amount of resistance for CMS coverage approval relative to other home diagnostic studies from a clinical perspective, especially when the same diagnostic equipment, analysis software, and acquisition montages can be used in both the laboratory and home setting, as was done in the Sleep Heart Health Study for 6,802 study participants.⁵

Autotitrating CPAP offers both a diagnostic and treatment modality, and has been shown to be useful as a titration study tool to obtain fixed CPAP pressures.⁷ With the use of simple assessment and diagnostic tools to identify high-probability OSA patients, successful therapeutic outcomes on CPAP following autotitration at home has been demonstrated by several recently published studies.^{8,9,10,11}

With the current opening of this NCD, LMI requests CMS provide practical coverage for services related to treatment and management of OSA patients at home. This coverage should include a general home visit for polysomnography and sleep studies, home oximetry, home visit for respiratory therapy care for an apnea evaluation, and CPAP initiation and management. If these services are not covered for home evaluations, patient beneficiaries may need to carry the cost burden and inconvenience of traveling to and from study application sites, both for hook ups and equipment return. These patients will likely prefer the more expensive overnight polysomnograms, defeating the purpose of cost savings relative to providing less expensive in-home ambulatory sleep studies and subsequent therapy. These home services are also necessary if outcomes are to match the procedures and the results obtained from studies showing that home autotitration without polysomnography is a viable alternative to traditional polysomnography. Another benefit is that with trained technicians applying sensors and calibrating acquisition systems, patient failures common to self applied systems should be reduced; this was a concern expressed by CMS in the most recent Decision Memo on CPAP (CAG-00093R).

LMI is concerned that if CMS does not provide the required attention and detailed coverage review of services necessary for successful ambulatory sleep testing and therapy, the commercial viability of delivering cost-saving services will not exist, and if this NCD is changed, providers willing to offer cost-saving services will not materialize and the only option for beneficiaries would be more expensive, traditional diagnostic testing.

In addition to well defined service coverage guidelines in-line with existing billing practices, LMI requests CMS consider continuity of care and the simple practicality of a single provider performing diagnostic tests, placement of therapy, and follow up care, all under the direction of a qualified physician. Strict definitions for coverage of testing, data scoring and analysis, and therapy qualification will also help avoid inappropriate testing or therapy placement, and any related potential of fraud and abuse or over-utilization by providers.

LMI supports coverage for all clinically validated sleep tests and support services that can be performed in the home under the direction of a qualified physician, by all classifications including the American Academy of Sleep Medicine designated device Types I, II, III or IV, or by service classification by American Medical Association Current Procedural Terminology (CPT) codes, including CPT 94762, 95806, 95807, 95808, 95810, 95811, 94660, 99503, and 99508, with sleep diagnostic code related definitions of “attended by a technician” appropriately defined as being attended patient set-ups and data calibrations with remote monitoring during data acquisition, unless other validated technology is available.

CPAP Qualification Coverage (2 hr rule)

LMI supports the standing of the American Association for Homecare on the two hour rule issue found in its response to this NCD.¹⁴

CONCLUSION

In summary, LMI agrees with the formal request to CMS from the *American Academy of Otolaryngology-Head and Neck Surgery* to remove the requirement for facility-based polysomnography,¹² and with responses to this NCD forwarded by the *National Sleep Foundation*¹³ and the *American Association for Homecare*.¹⁴

Approved and Submitted for your review by:

Alan Landauer
Chairman, Board of Directors
Landauer Metropolitan, Inc.

Louis Rocco
President and Chief Executive Officer
Landauer Metropolitan, Inc.

Tom Saulys
Director, Business Development
Landauer Metropolitan, Inc.
LMI Sleep Diagnostics Division

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April 12, 2007

James Rollins, MD, MHSA, Ph.D.
Centers for Medicare and Medicaid Services
Office of Clinical Standards and Quality
Coverage and Analysis Group
Attn: Public Comments,
7500 Security Blvd.
Baltimore, MD 21244-1850

Dear Dr. Rollins:

The American College of Chest Physicians (ACCP) appreciates the opportunity to comment on the national coverage analysis (NCA) proposed by CMS to review its National Coverage Determination (NCD) regarding the diagnosis of patients with obstructive sleep apnea (OSA) (CAG-00093R2) with a public comment deadline of April 13, 2007. We would like to take full advantage of the opportunity by providing our opinions and analyses about the current state of sleep apnea diagnostics.

The ACCP comprises over 16,500 physicians and allied health professionals, whose everyday practice involves diseases of the chest in the specialties of pulmonology, cardiology, thoracic and cardiovascular surgery, critical care medicine, sleep medicine and anesthesiology. These health care professionals practice in virtually every hospital in this country, and many of the physicians head major departments in these hospitals. As a multidisciplinary society, the ACCP offers broad viewpoints on matters of public health and clinical policy in cardiopulmonary medicine and surgery.

The unique multidisciplinary nature of the ACCP enables examination of this topic from a perspective encompassing an extraordinary wealth of diverse specialty knowledge of sleep-disordered breathing. ACCP includes a Sleep Medicine NetWork comprised of over 2000 members, and the ACCP Sleep Institute – a center of excellence within the ACCP.

The current state of clinical science forming the prompting of the NCA points to a concern: the growing acceptance that the diagnosis of OSA is needlessly complex for some, and perhaps many, patients. Indeed, the Institute of Medicine (IOM) highlighted this in their report last year on sleep deprivation and sleep disorders. As their only recommendation in this comprehensive report, they identified the development of new tools to be used in the diagnosis of patients with sleep disorders as an urgent priority. These “new tools” would make diagnosis easier and more broadly available than laboratory-based polysomnography (PSG).

The ENT Academy requested the NCA based on a series of arguments. The ACCP has concluded that the arguments presented in the ENT Academy request are seriously flawed. The brief literature review is superficial, highly selective, and therefore one-sided and misleading.

We agree with the ENT Academy description of obstructive sleep apnea as a prevalent condition, with serious health consequences for both those affected and for public health in general. It is also certainly true that OSA is seriously underdiagnosed. However, it is not clear, at least in the United States, that “current resources are inadequate to meet the demand for polysomnography resulting in a long wait for patients to access care” as stated in the ENT Academy letter. A survey of more than 1,000 sleep centers in the United States found that the average wait time for polysomnography was only 22 days (Collop NA, *Chest* 2006; 129:7). This number is expected to continue diminishing as additional new facilities are opened.

The ENT Academy claim that the current reimbursement paradigm is based on high reimbursement for PSG and low reimbursement for treatment is misleading. Continuous positive airway pressure treatment (CPAP) is the preferred therapy for the overwhelming majority of adults with OSA, and its initial reimbursement is generally satisfactory at the present time. The most important factor contributing to successful treatment of patients with OSA is an established system for patient education, support of patients adjusting to CPAP therapy, and continuity of care. This system for education supporting continuity of care is, however, not reimbursed satisfactorily, if at all. As a chronic disease, OSA requires the continued skills of physicians to ensure proper treatment and long-term compliance. Inadequate provisions currently exist to reimburse healthcare providers for this aftercare.

Growing numbers of clinical trials are examining different aspects of this field. Unfortunately, few studies of adequate quality allow clinicians to know precisely those patients with suspected OSA for whom non-facility based sleep apnea diagnostic testing works best, or not at all. This is especially true of the age group of most Medicare beneficiaries: a paucity of data exists for patient populations exceeding 65 years of age. Current clinical trials addressing these deficiencies in this field are underway, with additional studies being considered.

The document put forth by the ENT Academy focuses upon diagnostic testing performed outside the sleep laboratory. Diagnostic testing is important, but too narrow a focus. The ACCP Sleep Institute has been trying to shift the “discussions about sleep apnea management from a focus on the test to a renewed emphasis on the patient.” The ACCP Sleep Institute Continuity of Care Conference last fall placed the patient with OSA at the center of a sorely needed, better coordinated long-term management program. This fresh but immature approach remains difficult to place into practical policies that CMS can endorse and reimburse; nonetheless, we believe this is where the field should be heading.

Notably absent in the ENT Academy letter is any reference to the extensive evidence-based review of home diagnosis of sleep apnea, which was cosponsored by the American Academy of Sleep Medicine, the American College of Chest Physicians, and the American Thoracic Society. By far the most comprehensive analysis of the evidence for non-facility-based diagnostic testing performed to date (Flemons WW, et al. *Chest* 2003; 124:1543-1579), an executive summary of the findings of this review was published in the *ATS journal* (*Am Rev Respir Crit Care Med* 2003; 169:1160-1163) and practice parameters for the use of portable monitoring devices were published in the *AASM journal* (Chesson AL Jr, et al. *Sleep* 2003; 26:907-913).

We conclude that additional research addressing important clinical outcomes in a variety of age and ethnic populations that reflect our society are required. One example is

the recent article by Mulgrew et.al.), titled “Diagnosis and Initial Management of Obstructive Sleep Apnea without Polysomnography: A Randomized Validation Study” (Annals of Internal Medicine, Feb 6, 2007. We encourage CMS to support this type of research to answer the questions posed by CMS at the last Medical Advisory Board meeting in 2003. Perhaps a formal demonstration project study in partnership with NIH or AHRQ could allow payment during a formal investigation fashioned as in the landmark National Emphysema Treatment Trial. Such a study would of course include assessment of long-term outcomes and costs.

Legitimate situations exist where patients may not have access to diagnostic PSGs. In those unusual circumstances, CMS should cover portable sleep apnea diagnostic monitoring. However, acknowledge the challenge of operationalizing this recommendation fairly might be challenging. We also recommend that qualified physicians oversee all decision-making before and after any diagnostic testing.

We also encourage CMS to consider reimbursement of home care companies and physicians to encourage universal CPAP adherence monitoring. Establishing payment for this key component of the long-term management of sleep apnea, like existing reimbursement mechanisms for home health care plan oversight, will shift the focus favorably from the diagnostic test to optimizing therapy for the patient.

ACCP also recommends that CMS change the “2 hour rule”, which says that a patient must have 2 hours of sleep time prior to initiating CPAP therapy in a “split-night” sleep study. For difficult sleep apnea patients, this rule hinders starting CPAP therapy promptly. Some patients simply cannot stay asleep for 2 hours in a night and still have time for a CPAP titration. The current rule delays good and timely care. We recommend changing the rule to require the patient have a minimum of 2 hours of *recording time* before CPAP therapy can be started.

The ACCP agrees that portable monitoring may ultimately have a place in the diagnostic armamentarium of physicians evaluating and treating patients with sleep apnea. However, this approach has not yet been validated well, its limits clarified, nor the costs and benefits assessed beyond the unsupported assumption that it must be less expensive than polysomnography. Portable monitoring will require judicious application to avoid errors in diagnosis, and carefully designed investigations are underway. Until the results of these studies are available for critical review, modification of the CMS National Coverage Determination to include at-home unattended portable monitoring is premature and not in the best interests of patients with obstructive sleep apnea or other sleep disorders.

The ACCP appreciates the opportunity to respond to your coverage request for comments. I am available to discuss these issues at any time, or please contact our coding and reimbursement staff consultant, Diane Krier-Morrow at 847-677-9464 or dkriermorr@aol.com.

Sincerely



Mark J. Rosen, MD, FCCP
President



Via Electronic Submission

April 13, 2007

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
Room 445-G, Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

Re: **National Coverage Analysis for Continuous Positive Airway Pressure (CPAP) Therapy for Obstructive Sleep Apnea (OSA) (CAG – 00093R2)**

Dear Ms. Norwalk:

The American Association for Homecare (AAHomecare) is pleased to have the opportunity to submit the following comments on the Centers for Medicare and Medicaid Services' (CMS') national coverage determination (NCD) for continuous positive airway pressure (CPAP) therapy for obstructive sleep apnea (OSA).

Currently, the NCD states that only polysomnography performed in a facility-based sleep study laboratory may be used to identify patients with OSA who require CPAP. In response to a formal request from the *American Academy of Otolaryngology-Head and Neck Surgery* to remove the requirement for facility-based polysomnography, CMS has reopened the NCD on CPAP therapy for OSA for reconsideration. CMS has indicated that it is reconsidering all aspects of the NCD but is specifically requesting comments on clinical studies and other pertinent scientific information related to the technology under review.

AAHomecare is the largest national professional trade association representing the homecare community. AAHomecare represents health care providers and manufacturers that serve the medical needs of Americans who require sleep therapy technologies, oxygen equipment and therapy, mobility assistive technologies, medical supplies, inhalation drug therapy, home infusion, and other home medical equipment, therapies, services, and supplies in their homes. Our membership reflects a broad cross-section of the homecare community including national, regional, and local providers operating approximately 3,000 locations in all 50 states. AAHomecare and its members are committed to advancing the value and practice of quality health care services at home.

I. RECOMMENDATIONS

Early identification and treatment of sleep disorders is essential for the safe and effective care and management of Medicare beneficiaries. The clinical and economic benefits of logical, practical, and clinically sound sleep testing and treatment will become evident as the Medicare program continues to evolve. The long-term value of such a practical and clinically important benefit cannot be understated. Therefore, the AAHomecare supports a revision to the current NCD that will:

- A. Permit the use of portable, multi-channel sleep testing in the home as a diagnostic alternative to facility-based polysomnography for the evaluation of patients with likely OSA.
- B. Revise the criteria for determining the Apnea-Hypopnea Index (AHI) to be equal to the average number of episodes of apnea and hypopnea per hour and be based on a minimum of 2 hours of sleep or less, if the actual number of AHI episodes recorded is 30 or more in less than 2 hours, recorded by polysomnography using actual recorded hours of sleep.
- C. Develop a policy for the use and coverage of positive airway pressure therapy for a select group of severe patients not yet evaluated through formal sleep testing.

II. BACKGROUND

Sleep apnea is a disorder characterized by periods of apneas and hypopneas (breathing cessation and reduced breathing respectively). Obstructive sleep apnea (OSA) is the most common form of sleep apnea and is characterized by the partial or complete collapse of the upper airway during sleep. Symptoms of OSA include daytime sleepiness, fatigue, headaches, and cognitive impairment. OSA can lead to serious health risks for the individual, including but not limited to: hypertension, increased risk of stroke, and increased risk of being involved in a motor vehicle accident.

OSA was clinically recognized more than 30 years ago and is considered today to be a major public health problem in the United States.^{1,2} OSA prevalence in North America is estimated to be as high as 1 in 5 adults for mild sleep apnea (defined by AHI ≥ 5) and 1 in 15 for moderate sleep apnea (defined by AHI ≥ 15).³ Despite the high incidence of the disorder, the vast majority of patients with OSA are not diagnosed and receiving treatment.

While there are a number of treatment options for OSA, including surgery, the most prevalent, cost-effective, and preferred form of therapy involves the non-invasive application of positive airway pressure (PAP) to the upper airway.⁴ Types of PAP treatment include continuous positive airway pressure (CPAP), bilevel PAP, and automatically adjusting PAP (APAP). The

¹ Guilleminault C, Tilkian A, Dement WC. The Sleep Apnea Syndromes. *Annu Rev Med* 1976;27: 465-484

² Institute of Medicine of the National Academies. Sleep Disorders and Sleep Deprivation: An Unmet Public Health Problem. Washington DC; National Academies Press 2006

³ Young T, Peppard PE, Gottlieb DJ. Epidemiology of Obstructive Sleep Apnea. *Am J Respir Crit Care Med* 2002;165: 1217-1239

⁴ Gay P, Weaver T, Loube D, Iber C. Evaluation of Positive Airway Pressure Treatment of Sleep Related Breathing Disorders in Adults. *Sleep* 2006;29(3): 381-401

PAP device delivers a flow of air at a prescribed pressure through the upper airways using a non-invasive nasal or oral interface. The air, flowing under pressure, produces a splint-like effect that keeps the airway open during both inhalation and exhalation. Since 1987, CMS has covered the use of PAP devices for patients with “moderate or severe OSA for whom surgery is a likely alternative.” The NCD CMS issued in 1987 was consistent with the consensus opinion on the diagnostic criteria for OSA at that time.

In 2001, CMS revised the NCD for the use of CPAP and other PAP devices for the treatment of OSA to reflect current diagnostic criteria for OSA. Medicare will cover and pay for PAP for the treatment of adults with OSA who meet the following diagnostic criteria:

- AHI \geq 15 events per hour, or
- AHI \geq 5 and \leq 14 events per hour with documented symptoms of excessive daytime sleepiness, impaired cognition, mood disorders or insomnia, or documented hypertension, ischemic heart disease or history of stroke.

OSA is most often diagnosed via a laboratory-based, attended comprehensive multi-channel sleep study (polysomnography) that measures at the least, sleep time through sleep staging and respiration. The current Medicare NCD specifically states that the polysomnography used to diagnose OSA must be performed in a “facility-based sleep study laboratory, and not in a home or mobile facility.” In 2004, CMS opened this portion of the NCD to reconsider whether to allow the use of portable multi-channel sleep testing in the home site of service as an alternative to facility-based polysomnography. In 2005, CMS determined that unattended portable multi-channel sleep study testing would remain a non-covered service, noting at the time that there was not sufficient evidence to conclude this testing was reasonable and necessary in diagnosing OSA. CMS has now re-opened the NCD for reconsideration.

III. COMMENTS

A. **Permit the use of portable, multi-channel sleep testing in the home as a cost effective diagnostic alternative to facility based polysomnography for the evaluation of patients with likely OSA**

We believe the combination of the large and growing body of favorable scientific evidence, as presented in the letter from the *American Academy of Otolaryngology-Head and Neck Surgery*⁵, along with the obvious practicality of in-home or mobile sleep testing strongly support the need to permit the use of portable, multi-channel sleep testing in the home as a diagnostic alternative to facility-based polysomnography for the evaluation of patients with likely OSA.

Both anecdotal and peer-reviewed published data have confirmed the myriad problems and difficulties patients encounter when seeking traditional, facility-based diagnosis and treatment for OSA. Numerous scientific publications refer to the high cost, access, and backlog issues

⁵ Nielsen DR. Letter to the Centers for Medicare and Medicaid Services Regarding the National Coverage Determination for Obstructive Sleep Apnea. *American Academy of Otolaryngology-Head and Neck Surgery* January 2, 2007

associated with the coordination and provision of facility-based diagnostic studies.⁶ One study notes the average time from patient referral to a sleep lab until initial testing can range from a few weeks to up to *one year*; with the longest wait times in university, state, and federal government facilities.⁷ Delaying treatment for sleep disorders imposes a significant burden on patients and the health care system, with estimates suggesting untreated sleep apnea may cause \$3.4 billion in additional medical costs in the United States.⁸ These issues are clearly compounded for the elderly seeking treatment for sleep disorders.

There have been significant technological improvements in ambulatory sleep diagnostic devices, along with substantial clinical data validating the use of these devices in both the patient's home and mobile facilities. Requiring only facility-based sleep testing is a rigid policy that imposes additional financial and logistical burdens for individuals eligible for Medicare coverage. Our experience suggests that many private health plans now routinely cover in-home sleep testing and the subsequently prescribed PAP therapy. In adopting new diagnostic and treatment models, we urge CMS to employ appropriate standards and regulations based on the best available evidence, in conjunction with adequate coding and payment to ensure patients maintain access to quality sleep diagnostic and therapy services in the home.

We urge CMS to carefully consider the evidence and benefits supporting this clinically sound, economically beneficial and high quality alternative to facility-based polysomnography and develop policy for the use of portable, multi-channel sleep testing in the home and mobile facilities as a diagnostic alternative to facility based polysomnography for the evaluation of patients with likely OSA.

B. Revise the criteria for determining the Apnea-Hypopnea Index (AHI) to be equal to the average number of episodes of apnea and hypopnea per hour and be based on a minimum of 2 hours of sleep or less, if the actual number of AHI episodes recorded is 30 or more in less than 2 hours, recorded by polysomnography using actual recorded hours of sleep

We support the recommendation to change the criteria for determining the AHI in very severe patients to a minimum of 2 hours of sleep or less, if the actual number of AHI episodes recorded is 30 or more in less than 2 hours, recorded by polysomnography using actual recorded hours of sleep. There are a subset of patients with obvious and severe OSA who, as a result of their impairment, are simply unable to tolerate a prolonged sleep study and cannot achieve 2 complete hours of sleep during the polysomnogram. Additionally, in current practice, an individual undergoing a polysomnogram may reach the AHI episode threshold prior to meeting the 2 hour rule. Using a split-study method, this patient is then moved into the PAP titration phase of the sleep study. Under the current NCD, the patient does not satisfy the 2 hour rule and therefore

⁶ Mulgrew AT, Fox N, et al. Diagnosis and Initial Management of Obstructive Sleep Apnea Without Polysomnography: a Randomized Validation Study. *Ann Intern Med* 2007;146(3): 157-166

⁷ Flemons WW, Douglas NJ, Kuna ST, et al Access to Diagnosis and Treatment of Patients with Suspected Sleep Apnea. *Am J Respir Crit Care Med* 2004;169: 668-672

⁸ Kapur V, Blough DK, Sandlom RE, et al. The Medical Cost of Undiagnosed Sleep Apnea. *Sleep* 1999;22(6): 749-755

does not meet the Medicare coverage criteria. Patients meeting these criteria clearly have severe OSA and meet the spirit of the 2 hour rule. Therefore, we strongly support a change in the AHI criteria that will bring the Medicare rules in line with the current standard of practice and ensure this subset of beneficiaries with the most severe OSA can be appropriately and expeditiously diagnosed and treated.

C. Develop a policy for the use and coverage of positive airway pressure therapy for a select group of severe patients not yet evaluated through formal sleep testing

As noted previously, there is strong evidence of the difficulty in scheduling and completing facility-based polysomnography due to the limited number of sleep labs and the ensuing backlogs. While it is recognized that polysomnography is still the “gold standard” for the diagnosis of sleep disorders, there are additional objective and subjective measures being used by physicians to screen and diagnose patients with OSA as part of a complete evaluation. Individuals determined to have a high probability of OSA can be quickly screened and, in some cases, initiate PAP treatment, a practice now commonly employed by many private insurance plans.⁹

There is a growing body of evidence supporting the use of objective and subjective clinical and biochemical data collected as part of a comprehensive physical exam of obese patients with suspected OSA. Using a mix of data, including an objective sleepiness scale, body mass index (BMI), neck circumference, fasting insulin, waist-hip ratio, gender, and overnight pulse oximetry, various researchers have been able to accurately predict AHI consistent with that obtained from a complete polysomnogram.^{10,11,12} The ability to initiate treatment in the most severe OSA patients while awaiting more comprehensive evaluation is consistent with the standard of practice but is unfortunately discouraged by the current NCD.

Advances in PAP technology, in particular the auto-PAP (APAP) devices, which use sophisticated sensor systems and logic-based feedback algorithms to automatically adjust the device pressure, have opened the door to highly effective initial therapy for this subset of patients. APAP offers both an effective and readily accessible diagnostic and treatment modality for cases when the need for immediate treatment is essential for the safe and appropriate management of a patient with OSA. APAP has been shown to be useful and effective as a titration tool to obtain fixed CPAP pressures¹³ and has been associated with successful

⁹ Senn O, Brack T, Russi EW, Bloch KE. A CPAP Trial as a Novel Approach to the Diagnosis of Obstructive Sleep Apnea Syndrome. *Chest* 2006;129(1): 67-75

¹⁰ Sharma SK, Kurian S, Mohan A, et al. A Stepped Approach for Prediction of OSA in Overtly Asymptomatic Obese Subjects: A Hospital Based Study *Sleep* 2004;5(4): 352-357

¹¹ Dixon JB, Schachter LM, O'Brien PE. Predicting Sleep Apnea and Excessive Sleepiness in the Severely Obese. *Chest* 2003;123: 1134-1141

¹² Netzer NC, Stoohs RA, Netzer CM, et al. Using the Berlin Questionnaire to Identify Patients at Risk for the Sleep Apnea Syndrome. *Sleep* 2000;23: 929-938

¹³ Mulgrew AT, Fox N, Ayas NT, Ryan CF. Diagnosis and Initial Management of OSA without Polysomnography: a Randomized Validation Study. *Ann Intern Med* 2007;146(3): 157-166

therapeutic outcomes on CPAP following an initial APAP for patients evaluated by their physician through objective/subjective measures as noted above.^{14,15}

AAHomecare supports the development of a policy for the use and coverage of PAP therapy devices and accessories for a select group of severe, high-risk patients that have been evaluated and prescribed PAP therapy by their physician while awaiting a formal sleep diagnostic evaluation. This expanded use and coverage of PAP devices, in particular APAP devices, should be accompanied by appropriate HCPCS coding and payment. In short, we believe that Medicare policy should not limit the treatment options available to physicians for those individuals who can clearly benefit from its application.

IV. CONCLUSION

Each day AAHomecare members serve the sleep therapy and technology needs of tens of thousands of patients diagnosed with OSA. We are the front line providers that witness first-hand the importance and benefits of the early diagnosis and treatment of patients with OSA. Often considered a life altering intervention, the appropriate diagnosis and treatment of sleep disorders is critical to the American public's health and safety. Early identification and appropriate treatment of sleep disorders can prevent progression of the disease and dramatically improve the health and quality of life for the individual while concurrently reducing or preventing the development of dangerous and costly co-morbidities.

We appreciate this opportunity to share our views on this matter and are available to discuss them further with you at your convenience. Please do not hesitate to call me if you have any questions.

Sincerely,

A handwritten signature in black ink that reads "Tyler J. Wilson". The signature is written in a cursive, flowing style.

Tyler Wilson
President
American Association for Homecare

¹⁴ Senn O, Brack T, Russi EW, Bloch KE. A continuous positive airway pressure trial as a novel approach to the diagnosis of the obstructive sleep apnea syndrome. *Chest*. 2006;129(1):67-75

¹⁵ Masa JF, Jimenez A, Duran J, et al. Alternative methods of titrating continuous positive airway pressure: a large multicenter study. *Am J Respir Crit Care Med*. 2004;170(11):1218-1224

Submitted via electronic message

April 12, 2007



Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
U.S. Department of Health and Human Services
Room 445-G, Hubert H. Humphrey Building
200 Independence Ave, SW
Washington, DC 20201

RE: National Coverage Analysis for Continuous Positive Airway Pressure (CPAP) Therapy for Obstructive Sleep Apnea (OSA) (CAG-00093R2)

Dear Ms Norwalk:

Thank you for providing us with the opportunity to make comments on the NCA for Continuous Positive Airway Pressure Therapy for Obstructive Sleep Apnea NCD 240.4.

Nationwide Respiratory, a division of The VGM Group, is a member service organization that represents more than 4000 locations related to home medical equipment and sleep diagnostic providers in all 50 states. We believe that our membership represents the stakeholders that would be most responsible for utilizing the therapy and diagnostic components outlined in the tracking sheet issued by the Centers for Medicare and Medicaid Services.

The current NCD dictates that polysomnography must be performed in a facility-based sleep study laboratory, and not in the home or in a mobile facility. The NCD further dictates that Apnea-Hypopnea Index (AHI) must be equal to the average number of episodes of apnea and hypopnea per hour and must be based on a minimum of 2 hours of sleep recorded by polysomnography using actual recorded hours of sleep (i.e., the AHI may not be extrapolated or projected). The current NCD was reviewed and decision was made on April 4, 2005, that polysomnography would continue to be approved if performed in a facility-based sleep study laboratory, and not in the home or in a mobile facility. At the request of the American Academy of otolaryngology- Head and Neck Surgery, CMS issued a NCA Tracking Sheet seeking comments on the use of portable multi-channel home sleep testing devices as an alternative to facility-based polysomnography in the evaluation of OSA. Additionally, at the request of a Medicare beneficiary and numerous informal requests from stakeholders, and

interest from Medicare contractors concerning the criteria for determining the AHI. Lastly, the opportunity was presented to comment on the use of CPAP based on published research suggesting benefit for the use of CPAP without prior sleep testing in selected populations (trial of CPAP).

A. Background

More than 20 million Americans are affected by some sort of sleep disorder related to obstructive sleep apnea (OSA). It is important that persons at risk for OSA have access to early identification and continued treatment for their sleep disorder. Obstructive Sleep Apnea has proven to be fatal. There are many patients who have other types of illnesses that would benefit from the use of CPAP therapy to improve quality of life and slow disease progression. There are many economic benefits available to CMS if changes to the NCD are allowed. In addition, there would be a greater opportunity for the improvement of the quality of life for Medicare beneficiaries.

B. Recommendations and Comments

Nationwide Respiratory offers the following:

- A. Nationwide Respiratory supports the use of portable multi-channel sleep testing in the home. Since the previous decision to change this NCD was provided, there have been many improvements to the types of equipment that exists today and there have been many papers published that have compared multi-channel portable sleep testing devices to those of facility-based sleep testing equipment. Most of the studies that have been published have been favorable.
 - a. One of the main issues that was utilized in the denial of utilization of portable multi-channel sleep testing equipment in the decision memo of April 4, 2005, was the various parameters of sleep and cardio-respiratory function.
 - i. There are a number of devices today that are utilized in the home that would provide additional information that was required, in addition to many devices today have added some or all of the functions discussed in the April 4, 2005 decision memo.
 - ii. There should be criteria developed that would dictate which patient type would be able to participate in utilizing a portable multi-channel sleep testing device in the home and who would be required to utilize a sleep diagnostic testing facility for diagnosis.
 - b. There are many beneficiaries at risk for OSA who are unable to receive a sleep diagnostic test in a timely manner due to a shortage

of available sleep testing beds in the areas in which they reside. Additionally, there is a greater rural population that is unable to receive a test in a facility-based sleep laboratory due to time and distance to travel.

- i. The current policy is too restrictive and doesn't allow the entire beneficiary population to receive the proper testing. The utilization of multi-channel portable sleep testing devices would ensure all beneficiaries could receive the proper diagnosis and treatment regardless of where they reside.
 - ii. The VA Health System in many areas relies on portable multi-channel sleep testing equipment for the diagnosis of its patients.
- B. Nationwide Respiratory supports revising the criteria for determining the Apnea-Hypopnea Index.
- a. There is an obvious population that is unable to maintain sleep for greater than 2 hours due to a number of influences. It appears that a person that has an AHI of 30 or greater in a period less than 2 hours would certainly benefit from the use of CPAP therapy.
 - b. Current standards of practice support the change in determining the AHI.
- C. Nationwide Respiratory supports the use of CPAP by a select group of beneficiaries who meet a certain criteria. The development of proper coverage criteria, proper coding and proper payment for devices to be utilized within the scope of this particular segment would need to be created.
- a. The utilization of a CPAP device prior to receiving a sleep diagnostic test would benefit those patients who have shown a high risk and probability of OSA.
 - b. The utilization of Automatic Adjusting Positive Airway Pressure devices is further recommended with this population. The utilization of an auto-adjusting device has proven to be effective in ensuring the proper pressure is being delivered to the patient at the right time.
 - c. Patients who are at risk and have a long waiting period because of limited access to diagnostic testing would also benefit.

C. Summary

Nationwide Respiratory supports the changes to the NCD. We believe that this will eliminate the barrier to care that Medicare beneficiaries seek for their overall well-being and quality of life. Additionally, numerous studies have been published that support the use of CPAP therapy as a way to greatly reduce health-care costs. There have been recent studies that suggest the early diagnosis and treatment of OSA will also lessen the monetary impact by preventing or reducing the development of other costly types of illnesses.

We are grateful for the opportunity to have offered our comments on this very important health issue. We are encouraged by the opportunities that exist in the diagnosis and treatment of OSA for all Medicare beneficiaries. We also welcome the opportunity to work with the Centers for Medicare and Medicaid Services in the creation of any criteria related to OSA. Please do not hesitate to contact me if I can be of further assistance.

Sincerely,

A handwritten signature in black ink, appearing to read "Tom Pontzius", with a long horizontal flourish extending to the right.

Tom Pontzius
President
Nationwide Respiratory

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April 13, 2007

VIA ELECTRONIC MAIL AND OVERNIGHT MAIL

Steve E. Phurrough, M.D.
Director, Coverage Analysis Group
Centers for Medicare & Medicaid Services
Office of Clinical Standards & Quality
7500 Security Boulevard
Mail Stop C1-09-06
Baltimore, MD 21224-1850

Re: Comments Reconsideration of NCD on Continuous Positive Airway Pressure (CPAP) Therapy for Obstructive Sleep Apnea (OSA) (CAG-00093R2)

Dear Dr. Phurrough:

We are writing on behalf of our client, Sleep Solutions, Inc. (“**Sleep Solutions**”), to comment on the reconsideration by the Centers for Medicare and Medicaid Services’ Coverage Analysis Group (“**CAG**”) of National Coverage Determination 24.4 (“**Continuous Positive Airway Pressure (CPAP) Therapy for Obstructive Sleep Apnea (OSA)**”) (the “**NCD**”). Sleep Solutions appreciates this opportunity to present its comments to the CAG.

The use of home sleep testing as an inexpensive, safe and valid alternative diagnostic modality to expensive laboratory-based polysomnography (“**PSG**”) has been well established and accepted by the medical community, vastly improving patient access to testing for life-threatening sleep-disordered breathing conditions (“**SDB**”). In its January 2, 2007 letter requesting the CAG to modify the NCD to include home sleep testing as a cost-effective alternative diagnostic modality to PSG, the American Academy of Otolaryngology (“**AAO**”) explained that SDB is grossly under-diagnosed, in large part due to a limited number of sleep diagnostic facilities. The AAO thus stressed the urgency for improved capability of physicians to diagnose SDB so as to reduce early and untimely death due to these conditions. In support of its arguments, the AAO cited 19 studies of nearly 1200 patients involving 10 different home sleep testing models that demonstrated excellent correlation between home testing and PSG.

The AAO further explained that PSG has never been established as a gold standard in the diagnosis of SDB and that home sleep testing and PSG use the same equipment to measure respiration. The difference between the two modalities is that home testing modalities do not involve the sleep stage electroencephalogram (“**EEG**”). The AAO explained that these additional EEG measures make no contribution to the diagnosis or treatment of SDB. In other

words, in-home sleep testing provides the critical measures needed to diagnose OSA.

The vast body of available scientific literature demonstrates that continued lack of coverage for CPAP solely because the diagnosis is made through home testing devices seriously hinders access of Medicare beneficiaries to life-saving diagnosis and treatment for OSA. Sleep Solutions thus urges CMS to permit coverage of CPAP for patients diagnosed with cost-saving, safe and scientifically valid home testing devices.

After providing the CAG with a brief overview of Sleep Solutions, the company would like to bring to the CAG's attention some recently published studies that support this position but that were not included in AAO's January 2 request letter.

About Sleep Solutions

Sleep Solutions is both a manufacturer and service provider of in-home diagnostic sleep study technology and has been providing physicians and patients with state-of-the-art equipment and service for over five years. Sleep Solutions' NovaSom[®] QSG[®] system is an extensively validated¹ Level III+² cardiorespiratory in-home sleep testing device that collects real time raw data and allows patients to self correct when sensors detect the loss of any one signal.

Sleep Solutions has gained vast experience and expertise in testing patients of all ages and at all stages of diagnosis with OSA. The company's patients have completed over 12,000 studies to date with an overall success rate of > 95% completed testing. Because Sleep Solution's technology and services are an integral part of the Veterans Health Administration's sleep apnea diagnostic and treatment program, the company has had the unique experience of testing a population very similar to the Medicare population. Approximately 25% of Sleep Solutions' patients are of Medicare age and have successfully completed testing.

Sleep Solutions believes that its technology, which has been validated by scientific sleep research, sets a new standard for in-home OSA diagnosis. Based on the prevalence of OSA in the United States, the current in-lab capacity of PSG cannot meet the need for diagnosis of OSA.³ Even when PSG can be performed, it has several significant drawbacks, including high cost, high interpreter variability of EEG information and testing of the patient in an unfamiliar

¹ Reichert, JA, *et al.*, "Comparison of the NovaSom QSG, a new sleep apnea home-diagnostic system, and polysomnography," *Sleep Medicine*, 4 (2003) 213-218, 214; Claman D, *et al.*, "Clinical validation of the Bedbug in detection of OSA," *Otolaryngology – Head and Neck Surgery*, 125 (2001) 227-230.

² In-home portable devices may record a single channel such as oximetry (Level IV devices); two or more channels that measure only cardiorespiratory variables (Level III devices) or multiple channels that allow for sleep staging as well as measurement of cardiorespiratory variables (Level II devices). Tice, JA, *et al.*, "Portable Devices for Home Testing for Obstructive Sleep Apnea," *California Technology Assessment Forum*, Jun 15, 2005. Sleep Solutions considers the NovaSom QSG to be a Level III+ device because it is not only a multi-channel device that measures cardiorespiratory variables, but it is also a patient friendly, electronically attended device that allows patients to correct cardiorespiratory signal loss in real time and thus collects higher quality data than other devices.

³ Kapur, V. *et al.*, "Underdiagnosis of sleep apnea syndrome in U.S. communities," *Sleep & Breathing*, 6 (2002) 2:49-54.

setting. Sleep Solutions technology eliminates these drawbacks, and the company is working diligently to make its technology more available to physicians and their patients so as to reduce the numbers of undiagnosed cases of OSA. Because Medicare beneficiaries represent a significant portion of patients at risk for OSA and other sleep disorders, Sleep Solutions urges the CAG to carefully consider revising the NCD so as to include home sleep testing as an alternative to PSG for the diagnosis of OSA.

Additional Research

In addition to the scientific studies cited by AAO in its January 2, 2007 letter, Sleep Solutions brings to the CAG's attention the following recent studies that support the use of in-home OSA testing. (We have attached copies of these studies to this letter for your convenience.)

1. **Mulgrew.** Just this year, Mulgrew et al. concluded that, in the initial management of patients with a high probability of obstructive sleep apnea, PSG confers no advantage over the ambulatory approach in terms of diagnosis and CPAP titration and that the ambulatory approach may improve adherence to treatment.⁴ The Mulgrew study was a randomized, controlled, open-label trial that compared standard PSG with ambulatory CPAP titration in 68 high-risk patients identified by a diagnostic algorithm in a tertiary referral sleep disorders program. The patients all had a high pretest probability of moderate to severe obstructive sleep apnea with an apnea-hypopnea index ("AHI") > 15. The patients were randomly assigned to PSG or ambulatory titration by using a combination of auto-CPAP and overnight oximetry and were observed for 3 months.

The PSG and ambulatory groups had similar median body mass index (38 kg/m²), age (55 years), ESS score (14 points), and respiratory disturbance index (31 episodes of respiratory disturbance/hour). After 3 months, there were no differences in the primary outcome, AHI on CPAP (median, 3.2 vs. 2.5; difference, 0.8/h [95% CI, -0.9 to 2.3]) ($P=0.31$), between the PSG and ambulatory groups, or in the secondary outcomes, ESS score, Sleep Apnea Quality of Life Index, and CPAP. The ambulatory group demonstrated better adherence to CPAP therapy than the PSG group (median, 5.4 vs. 6.0; difference, -1.12 h/night [CI, -2.0 to 0.2]) ($P=0.021$).

This study supports the conclusion that, when access to PSG is inadequate, the ambulatory approach can be used to expedite management of patients most in need of treatment. The outcomes for both groups were essentially the same, but the ambulatory group had improved CPAP adherence.

2. **Rice.** Rice et al. evaluated an algorithm for managing patients with suspected OSA.⁵ Patients with a moderate to high degree of suspicion for OSA were offered portable study or PSG. Among the 106 patients who chose portable study, those with positive results

⁴ Mulgrew, AT, et. al, "Diagnosis and initial management of obstructive sleep apnea polysomnography," *Annals of Internal Medicine*, 3 (2007) 146:157-166.

⁵ Rice K, et al., "Unattended cardiopulmonary sleep studies to diagnose obstructive sleep apnea," *Federal Practitioner*, (2006) 23:17-31.

LATHAM & WATKINS^{LLP}

were placed on auto-titrating CPAP. Those with negative results were tested with PSG. Follow-up analysis of those with positive portable studies (90% of portable study patients) revealed a high rate of improvement in OSA symptoms that were similar to published reports of patients who had undergone conventional PSG. For those patients who tested negative by portable study (10% of portable study patients), there was only one clear false positive based on subsequent PSG. Other patients declined PSG or had borderline studies.

These studies, as well as the 19 studies cited in the AAO letter, demonstrate the validity of home testing and strongly support coverage for CPAP based on a diagnosis made by home testing devices, so as to improve access of Medicare beneficiaries to life-saving diagnosis and treatment for OSA. Sleep Solutions thus urges CMS to permit coverage of CPAP for patients diagnosed with cost-saving, safe and scientifically valid home testing devices.

On a final note, Sleep Solutions recognizes that other parties intend to request a delay in coverage pending the publication of additional studies. As explained in this letter, there already is overwhelming support of the validity of home sleep testing as an alternative to costly PSG. This clinical evidence and the need for better access to medically necessary CPAP devices supports coverage at this time. Further, Sleep Solutions urges CMS to carefully review the design of any proposed studies. We understand that one or more professional societies may seek to conduct some studies. With respect to any study designed to compare the diagnostic validity of home testing and PSG, we urge CMS to assess whether the study design is symmetrical with respect to the in-home modality and PSG by ensuring that patients who test negative for OSA (e.g., AHI < 15) by either the home-testing modality or PSA modality under study (not just one or the other) are retested by a third, independent laboratory. All such study designs should also include controls for night-to-night and scorer-to-scorer variability.

Thank you for your attention to our comments. We welcome any questions that this letter may raise regarding the CAG's reconsideration of the NCD to include coverage for CPAP in patients diagnosed by home-testing devices, and we look forward to speaking with you in the near future about this. In the interim, should you have any questions or comments, please feel free to contact me at 202-637-2200.

Truly yours,



Stuart S. Kurlander
of LATHAM & WATKINS LLP

Enclosures

cc: Sleep Solutions, Inc.
Esther Scherb, Latham & Watkins LLP
R. Gregory Cochran, M.D., J.D., Latham & Watkins LLP

Fred Oehler, RCP
6056 State Route 132
Goshen, OH 45122

Ms. Francina Spencer
Centers for Medicare and Medicaid Services
Room C1-12-13 Central Building
Mail Stop: C1 -09-06
7500 Security Blvd.
Baltimore, MD. 21244-1850

5/11/07

Ms. Spencer,

I am the Clinical Director of a Home Oxygen and Durable Medical Equipment Company in Southern Ohio servicing areas of Ohio, Kentucky and Indiana and a member of the AARC

I agree with the AARC's request to modify the existing NCD 240.4 policy to include the use of portable multi-channel home sleep testing devices as an alternative to facility based polysomnography in the evaluation of OSA.

We set up and instruct patients needing CPAP therapy for numerous Sleep Centers in the Tri-State area. Many times the patients state that they did not sleep at the facility to the same degree they would have in their own house and bed. I believe this has a negative effect on the outcome of the test results and resulting sleep therapy prescription.

The second phase of the sleep testing process is the CPAP titration. Patients are routinely placed on a Positive Airway Pressure device and have the pressure adjusted up and down until their "desired level" is attained. I believe that basing the prescribed pressure on one night of titration does not give the proper pressure setting because people's sleep patterns vary greatly due to numerous outside forces such as stress, alcohol consumption, prescription medications, exercise, etc. A pressure set on a Monday may not be the proper pressure for the week-end. There are auto-titrating CPAP machines that when placed on a patient, in their home for a period of time, self adjust and track the pressure needed to correct the OSA. These machines are currently used infrequently due to inadequate reimbursement but should be considered in the future.

Medicare would save hundreds of millions of dollars and provide better sleep therapy by incorporating in-home sleep testing at a reduced amount of facility based testing and increasing the reimbursement for the auto-titrating machines.

Additional benefits of in-home testing and auto-titrating machines include:

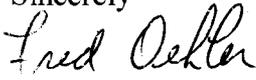
- Quicker access to testing (most centers have a six week back log)
- Beneficiaries will obtain therapy sooner leading to less Medicare expenses for treating OSA complications such as Hypertension, Stroke, Heart Attack, and automobile and work related accidents due to excessive daytime sleepiness
- More accurate test results
- Correct pressure settings resulting in increased compliance
- Elimination of titration sleep studies

I also support the AARC's belief that it is important for Medicare to set a high standard in terms of personnel qualifications to help assure high quality of services provided to the Medicare beneficiary.

The AARC recommendation that polysomnography must be performed by qualified personnel, such as registered polysomnographic technologists, licensed and certified respiratory therapists, specially trained nurses or other health professionals who have been competency tested by nationally recognized accreditation entities and under the supervision and oversight of a board certified physician holding a sleep specialty credential is also of utmost importance. It is now time to mandate the aforementioned professionals be background checked yearly, at a minimum, to substantiate their licensure and moral character in order to protect the Medicare beneficiary being treated in their home.

I appreciate the opportunity to provide comments to CMS on the subject NCD and proposed revisions and appreciate your considerations of the AARC's recommendations.

Sincerely



Fred Oheler, RCP,

✓

Steve Phurrough, MD
Director of Coverage and Analysis Group
Centers for Medicaid and Medicare Services
7500 Security Boulevard
Baltimore, MD 21224-1850

Dear Dr. Phurrough;

I am writing this letter as an individual practitioner and not as a member of the American Academy of Sleep Medicine (AASM), any other society involved in representing the science of Sleep Medicine, or my institution.

I have read the beautifully written letter by Dr. Michael Silber, the current President of the AASM, on the subject of portable monitoring in the diagnosis of sleep apnea (letter to CMS regarding its national coverage decision on CPAP therapy for obstructive sleep apnea) and directed at you. While in agreement with his recommendations of who should diagnose and treat patients with sleep apnea and the modification of the 2-hour rule, I find little more to agree with.

I have been a clinician/teacher most of my professional life. I am 71 years old and I plan to retire within the next year or two. My primary interest in the last twenty five years or so has been Sleep Medicine and the teaching of excellence in the practice of Medicine. While I am not a researcher, I have kept up very carefully with the developments in this specialty, including the issue of portable monitoring for sleep apnea and its treatment with automatic positive pressure machines. I fully understand that "extensive clinical experience" does not count much in scientific affairs, but that is the best I have to offer.

It is my opinion that our representatives (AASM, ACCP, ATS) must stop hiding behind questionable statistics and face the reality that portable monitoring works, and that its accuracy parallels that of conventional polysomnography in the hands of the expert. This is true as long as physicians trained in Sleep Medicine respect the obvious exclusions for portable monitoring, including the obesity hypoventilation syndrome, low left ventricular ejection fraction, severe COPD, patients on large doses of narcotic medications, limited understanding of instructions for the application of the sensors, significant psychiatric disease, unreliability, known excessive alcohol consumption, and others.

The medical societies already mentioned and CMS must accept that since the 2003 dictum on portable monitoring, the portable monitors have added advances like peripheral arterial tonometry, semi-quantitative chest/abdominal plethysmography, and nasal pressures among others, and that oximeters have become outstanding (capable of discarding artifacts, greater stability, etc). In spite of these advances, investigators continue to compare portable monitors to conventional polysomnography, yet there is a paucity of studies that compare one portable monitor to another. It is clear that when utilizing a portable monitor that measures nasal pressures, plethysmography, position, pulse rate and oximetry there is little chance of misdiagnosing sleepy snorers particularly with an apnea/hypopnea threshold above 5 (or ten or fifteen, I admit that this remains a bit controversial). In fact the trained

eye can also identify central apneas and the pattern of Cheyne-Stokes respiration with portable studies utilizing nasal pressures and plethysmography with the same accuracy as with conventional polysomnography. Sleep recording and staging is of limited use in the laboratory diagnosis of obstructive sleep apnea as, among other things, “awake obstructive events” do not occur (but the denominator, total sleep time, will alter the absolute value for apnea/hypopnea index, and irregularities in breathing during the wake state with the patient moving may result in the scoring of events that are not significant). With the addition of actigraphy, a very approximate scoring of sleep/wake (and even REM sleep) can be accomplished. It must also be considered that the gold standard (conventional polysomnography) is less than perfect, and that false negative studies occur. It is also probable that peripheral arterial tonometry identifies central nervous system arousals more accurately than the eye can identify electroencephalographic arousals. In summary, it is time to recognize the utility and the accuracy of portable monitors as long as this is performed by a trained physician in the context of good clinical data. The physician must realize that “not all monitors are created equally” and that selection is therefore important.

Laboratory polysomnography is widely available in the United States: The data cited by Dr. Silber neither proves or disproves the assertion that access is a problem for patients with sleep apnea. Waiting time for evaluation or studies in accredited laboratories may not reflect the reality in the general community. In our accredited Center, and in spite of the use of portable polysomnography selectively, our waiting time is nearly eight weeks in spite of strong competition from many other laboratories in the area.

Previous analyses have not recommended the use of unassisted portable monitors for the diagnosis of sleep apnea: I have addressed this statement partially above. Conflict of interest must be considered as there will be a significant economic impact on sleep laboratories if portable monitoring is approved by CMS and other insurance. I have great respect for those who participated in the 2003 review, but it must be noticed that a respected figure like Flemmons (as one of the participants) wrote about the clinical usefulness of home oximetry compared with polysomnography for the assessment of sleep apnea and concluded “that the ability of physicians to predict the outcome of CPAP in individual patients is not significantly better with polysomnography than with home oximeter-based monitoring” (American Journal of Respiratory and Critical Care Medicine; Jan 15, 2005; 171:188-193). In addition, it is my understanding that respected clinician/scientists in the Veterans Administration system have utilized portable polysomnography and automatic CPAP titrations rather successfully to shorten the waiting list in their sleep laboratories. Our experience, while unpublished and therefore not submitted to scientific inquiry, is that the use of portable monitoring utilized by experts is extremely helpful in “decompressing” the sleep laboratory.

While recent studies provide some support for portable monitoring in selected population managed in academic centers, they do not warrant a current change in CMS policy: Dr. Silber cites four different articles to make his point. He excludes most of the positive conclusions from these articles. For example, in the study of Senn there were 31 true negatives and 9 false negatives (none of the latter agreed to use CPAP after the study, and the trial ruled them out as potential users). Dr. Silber cited the high degree of clinical

(subjective) selectivity in that study. I will add that if we want to add an objective measure of selectivity, even oximetry alone utilizing an accurate oximeter will do. More extensive monitoring will be even better, and may be as easy to perform as oximetry alone with the current portable monitors. He does not mention that Hukins published an article in 2004 where he used automatic CPAP, rather than arbitrary pressure CPAP. Treatment with conventional CPAP and automatic CPAP were identical in that study. Neither does he mention the repeated articles on the equivalence of fixed pressure CPAP machines and automatic ones. Silber states that Mulgrew's selection criteria included a high pretest probability of moderate to severe OSA, and that exclusions included patients on sedatives or with major cardiorespiratory or psychiatric diseases. This should not concern us, we should rather learn for it. Silber wants more studies to confirm what we already know. He fails to cite several abstracts that have addressed portable monitoring (SLEEP, volume 28, abstract supplement, 2005, Abstracts number 483, 484, 558, 565, 588, and 956 among others, with only one concluding that the use of an Embletta apparatus was not useful). He also excluded articles published in refereed journals (for example: "Using a Wrist-Worn Device Based on Peripheral Arterial Tonometry to Diagnose Obstructive Sleep Apnea: In Laboratory and Ambulatory Validation; SLEEP 2004;27(5):923-33) While I welcome new studies on this and everything we think we know, we have to at some time "go with what we have" and alter it as we learn more about it.

Sleep apnea should be diagnosed and managed by sleep specialists in accredited facilities: indiscriminate use of portable monitoring will result in increased cost and decrease patient benefit: I addressed this partially in my opening statement. CMS has not limited payment for conventional polysomnography to exclusively sleep specialists in accredited facilities perhaps to avoid worsening the problem with access, and I assume for political reasons. The criteria mandated by CMS for the diagnosis of OSAS in the laboratory have been realistic and reasonable, although it has excluded some patients who could have benefited from treatment. CMS can mandate similar criteria for the diagnosis with portable monitoring just as well. There is enough data in the literature regarding thresholds and exclusions. I must agree that a "free-for-all" must be avoided, and that the criteria should give the clinician enough latitude to deal with symptomatic patients with serious comorbidities that do not tightly fit the rules, something that incidentally should also apply to conventional polysomnography (which strengthens the recommendation for diagnosis and management by experts, and exclusion by non payment of those who are not committed to excellence in the practice of sleep medicine).

Will it result in increased cost? Not if used appropriately, but clearly so if used indiscriminately. If used "strategically" to document the clinical impression of OSA it has the potential to save the government and other third party payers a large amount of money. It will however not be easy to convince some academicians and many clinicians of the equivalence between conventional polysomnography and portable polysomnography (because of financial considerations, lack of training and experience, or insecurity, among others). Education will be needed, but politics may win in the long run. In many instances conventional polysomnography utilizing a split night study will be more economical than portable polysomnography (distance and age are particular considerations, and under these circumstances a split night study will be more efficient and economical). This is a fertile area

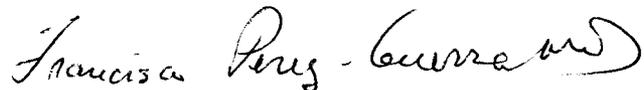
for discussion and study, and in this sense the study sponsored by the AASM (see below) may provide an answer. Regardless, the controversy will continue for a long period of time (money talks, it has been said many times).

Is it necessary to wait for the completion of sponsored multi-center study of portable monitoring sponsored by the AASM? It is my opinion that such study will not improve upon common sense practice by those who are well trained, although I encourage its performance. To answer the question posed, no, I do not believe that we have to wait for this study to be completed, even if rules and regulations have to be altered with time and experience.

I also hope that the new practice parameters to be published by the AASM on portable monitoring reflect reality and not bias, and I look forward to their publication.

In summary, I agree with those that have asked CMS to reassess and change its stance on portable monitoring for sleep apnea. Ground rules and restrictions will be necessary to avoid a “free-for-all” and improper utilization. The prescription of CPAP machines (and incidentally, dental appliances) based on the diagnosis of obstructive sleep apnea with portable monitors should be permitted by CMS and other third-party payers. Access and affordability are only two of many potential benefits to society.

Respectfully;

A handwritten signature in black ink that reads "Francisco Perez-Guerra". The signature is written in a cursive style with a large, sweeping flourish at the end.

Francisco Perez-Guerra MD, FCCP
Diplomate in Sleep Medicine
Professor of Medicine, Texas A and M Health Science Center
Medical Director, Scott and White Sleep Disorders Center

This is in response to the request from the Am. Acad. Otolaryngology-Head and Neck Surgery to bypass attended, in-lab polysomnography in the diagnosis of sleep apnea, in favor of home studies. I have been director of an accredited sleep disorders center (accredited by the American Academy of Sleep Medicine) for 17 years and seen thousands of sleep apnea patients. This proposal is reckless and simply bad medicine. A reader will note that the American Academy of Sleep Medicine, that sets national standards for the entire field of sleep medicine and is responsible for accrediting sleep disorders centers and sleep physicians, is not mentioned anywhere in the proposal. It's as though this national body does not exist or is superfluous to their proposal. Does this mean that accreditation of physicians and sleep disorders centers is not necessary along with controlled in-lab studies?

This proposal is fraught with fallacies, implied or stated. Some examples are:

1. The idea that OSA can be diagnosed by simply applying CPAP and seeing who likes it is absurd to anyone who has worked with the widely varied OSA population. Required CPAP pressures vary from 4 cm H₂O to as high as 30 cm H₂O, and some apneics require various bilevel devices to achieve optimal treatment. Furthermore, excessive levels of CPAP, as would occur if not determined by an in-laboratory study, would result in the occurrence of recurrent central sleep apnea in many patients, as is well known. There is also the recent concern of a newly identified form of OSA patients that look just like commonplace OSA during a diagnostic study, but once CPAP is applied they exhibit central apnea that responds selectively and beautifully to adaptive servo positive-pressure ventilation, but not CPAP. These are nuances of OSA evaluation and treatment not addressed in the proposal.

2. Home sleep studies are inherently fraught with problems, especially those that do not record sleep stages and arousals, as put forth in the proposal. Technicians have to intervene many times during a diagnostic sleep study to address technical and patient concerns. The home environment is fraught with unforeseen interferences, either electrical or from family members, creating a totally un-controlled study that often has to be repeated again in-laboratory to derive reliable data. The idea that sleep staging is unnecessary is totally wrong...REM sleep is notoriously the stage where OSA is worst, and many patients have OSA only in REM. If you can't determine sleep stage, you do not know if you have an adequate sample of REM sleep to make an accurate assessment.

Similarly, the idea that recording EEG arousals is unnecessary is totally false since the apnea or hypopnea is terminated by arousal - arousal is intrinsic to making a valid assessment of a breathing event. Consider also that periodic leg movement disorders in sleep can masquerade as mild hypopnea if a complete polysomnogram, including sleep staging and EEG arousals, is not in place. Furthermore, patients are notorious for misjudging their sleep. They could tell you they slept 8 hrs and really slept 1 hr, or the reverse could also be true. Without EEG monitoring, how would you know how much sleep (if any) was recorded? There would be no way to derive an accurate apnea/hypopnea index.

3. The proposal points out that the VA system and Kaiser both get by using home studies. They both use home studies because their wait times for in-lab studies can be a full year or more. That is an internal problem to these two providers and does not generalize to Medicare. Accredited sleep centers do not allow for such waits.

I think that the ability to use portable sleep test devices is a wonderful idea. I just had a lady in the other day that has a neighbor that needs a sleep study because she is showing symptoms of severe sleep apnea but this lady is bed bound and she would require the use of an ambulance to get her to the sleep lab so as a result she has not gone.

robin.rotz@aerocareusa.com

I have a comment regarding coverage of home polysomnography. There is absolutely no reason that CMS should not cover this service. The home testing is a simple, effective tool that is useful for definitive diagnosis and far less expensive than inpatient testing. I have been baffled as to the reason that only inpatient testing is covered. Inpatient polysomnography still has an important role for those patients who require monitoring of more parameters, but many patients could be diagnosed and treated in a more efficient manner with home testing. Appropriate reimbursement should be provided to the physicians who interpret home sleep testing results.

Thank you,
Jeffrey A. Livingston MD
Vero Beach, FL
jaliving@aol.com
772-567-1164

I oppose home sleep testing.

Luke Pluto, MD
Diplomat, American Board of Sleep Medicine

sycahill@aol.com

Home sleep studies are no less labor intensive, require interpretation by both technologists and physicians as do polysomnograms in a lab setting. Quality control becomes an issue when the environment is less controlled in the home setting, thus the data is more reliable in a sleep laboratory setting. It seems obvious we should continue to utilize the laboratory setting.

jmholm@madronamedical.com

OSA In-Home Testing

From approximately 1987 thru 1994 we performed In-Home OSA Testing on hundreds of patients.

The results were remarkable in tracking OSA/Hypopnic episodes in the home setting.

The number of a Central Sleep candidates was so small I cannot remember any in all those years of testing.

An article appeared in the AARC magazine about our In-Home testing.

Our company was called Escland Medical Altamonte Florida.

We only discontinued performing them in the home because of the reimbursement issue.

100% of the patients and 100% of the Doctors were excited with the performance in the home, the convenience of being at home.

In 2007 compliance would be easy to attain with a positive In-Home sleep study and a Auto PAP tracing which was not available in 1987

Hospital based and Physician Office based sleep labs are the same in the following respect:

1. Often the patient has to be tested twice
2. In some cases a nap study is performed as well
3. The patient "NEVER" is given the mask they were tested with so a new mask has to be delivered and adjusted.
4. Many patients have difficulty adjusting to the new mask although it is the same mask "size and manufacturer"

I am absolutely for In-Home OSA testing

Rich Escobar RCP, President
Pulmonary Services Consultants
411 SE 82nd Place
Ocala, FL 34480

resco71148@mfi.net

I am writing to discourage CMS from paying for in home sleep studies. Sleep studies will proliferate and all the amateurs will be doing them. Many of them will have to be repeated in accredited sleep labs and this will cost CMS a lot of money for a lot of low quality studies. Think about it if every doctor starts doing in home sleep studies, CMS will be broke sooner than expected even. The tragedy will be that all these studies would be of inferior quality, and have to be repeated costing even more money. The average waiting time to get in a sleep lab for a study nationally is about 2 weeks. So there is no need for in home studies. Also with no technical persons to observe the study and intervene, when necessary, many of these home studies will have technical glitches that will make restudy necessary. The home sleep equipment is not that user friendly. In addition a lot of unqualified practitioners will be "interpreting" these studies and that will lead to many inaccurate diagnoses with many persons being placed on CPAP who do not need it medically speaking.

drsleeper@surfsouth.com

The Kentucky Sleep Society is an organization of medical professionals practicing in the state of Kentucky and adjacent states, who are committed to educating healthcare professionals and community leaders in the practice of sleep medicine and related disorders. Organized in 1998 by health professionals who realized the potential in forming a network for the specific purposes of education, promotion of wellness, diagnosis, treatment and research in sleep medicine, the Kentucky Sleep Society promotes patient advocacy and evidence based quality in the practice of sleep medicine.

We recommend the following guidelines be entered into comment with CMS, who is requesting review to include the use of portable multi-channel home sleep testing devices as an alternative to facility-based polysomnography in the evaluation of OSA:

1. Only sleep facilities accredited by the American Academy of Sleep Medicine or Joint Commission on Accreditation of Hospitals receive reimbursement for full diagnostic study done in the home comparable to what is performed in a sleep lab. For sleep programs, who are not accredited, we recommend that reimbursement be made to developing centers in retrospect if accreditation is achieved. It is anticipated that these studies will be performed in circumstances where an in facility study cannot be performed, for example a disability that prevents the patient from easily getting to the Sleep Center, geographical barriers, and significant delays in performing in Center studies.

If the home study is done for screening using a multi-channel home monitor only measuring ECG, respiratory effort, pulse oximetry and airflow, the Independent Testing facility and hospital based sleep facility with a credentialed sleep technologist or respiratory care practitioner should be capable of performing the screening study for reimbursement.

If the home study is done for screening using a multi-channel home monitor only measuring at a minimum ECG, respiratory effort, pulse oximetry and airflow, the DME companies with a credentialed respiratory care practitioner or credentialed sleep technologist should be capable of performing the screening study for reimbursement. If the screening test demonstrates a significant likelihood of Obstructive Sleep Apnea, then confirmation with a formal polysomnogram is recommended. In certain clinical circumstances (e.g. insomnia associated with disruptive snoring) falsely negative in home monitoring might be anticipated, and a formal polysomnogram may also be required.

A complete history and physical is required for review by a physician board certified in sleep medicine, who will be responsible for ordering, interpreting, and determination of treatment recommendations based on the results of the screening or full diagnostic studies done in the ambulatory setting.

The referring physician will be responsible for follow-up with the patient to implement treatment recommendations and monitor compliance with treatment and health improvement.

2. Only equipment that has the capability to review the raw data for interpretation of the results should be approved for performing home studies.

3. Clinical interpretations of home monitoring or ambulatory monitoring be completed by a Board certified sleep specialist with an active medical license in the state in which the study is performed.

4. The technologist or therapist performing a full diagnostic study done in an ambulatory setting be competent in sleep medicine through demonstrated certification by the BRPT or demonstrated evidence of satisfactory completion of the A-STEP program or another CAAHEP educational program in sleep medicine.

5. Quality indicators for sleep medicine should be developed so that insurers can track the excellence of the study, therefore pay for performance.

6. Durable Medical Equipment providers should not have the option to order or interpret in home studies.

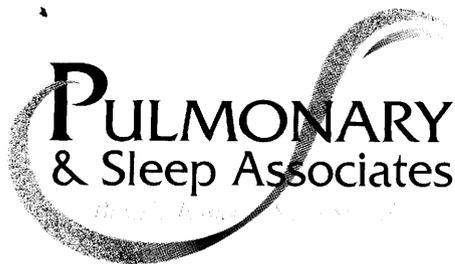
We request to participate in the determination of the guidelines for determination of appropriate guidelines to perform home monitoring and ambulatory monitoring. For questions please do not hesitate to contact me.

Michael J. Zachek, MD

President

Kentucky Sleep Society

www.kyss.com



The Sleep Center

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Steve Phurrough, MD
Director of Coverage and Analysis
Centers for Medicare and Medicaid
7500 Security Boulevard
Baltimore, Maryland 21244-1850

20 March 2007

Dear Dr. Phurrough;

I am writing to state our opposition to coverage by CMS, of portable unattended home studies for the diagnosis of sleep apnea at this time.

It is our feeling that studies supporting unattended testing that have been performed to date have been promising but have lacked adequate numbers of subjects to fully support the use of unattended home studies. We are concerned by possible testing error variables that could arise, if uncontrolled, unregulated, unattended testing is encouraged by reimbursement at this time.

At this time there are proposals for study of larger population groups, by the American Sleep Medicine Foundation, to help in establishing the appropriate roll of portable unattended testing in the diagnosis and management of sleep apnea. The results of this study will also help in evaluating clinical limitations and cost effectiveness of diagnosis and treatment of OSA using unattended home testing.

There is no question that the technology exists to provide reasonably accurate screening for obstructive sleep apnea in severe cases. There are currently several devices on the market, provided by manufactures of diagnostic and or therapeutic devices. Current multi channel devices use differing combinations of parameters and techniques to produce results. There are questions of differential diagnosis that have still not been fully answered and remain somewhat speculative.

We feel that it would be in the best interest of the patient to reserve action on this question until the American Academy of Sleep Medicine has developed a set of clinical practice parameters for the use of this technology.

Sincerely,

Henry L. Johns, BS, RPSGT, CRT, CPFT
Sleep Center Director

✓ ~~USA~~ 195

Spencer, Francina C. (CMS/OCSQ)

From: Jim Spector, RRT, RPSGT [jimspector@earthlink.net]
Sent: Thursday, March 15, 2007 5:40 PM
To: Spencer, Francina C. (CMS/OCSQ)
Subject: Reconsideration of coverage of CPAP with portable sleep studies

Against in home
sleep tests

To whom it may concern,

I believe it would be a serious mistake to rely on data from portable studies for CPAP coverage. Data from home studies can be accurate; however an unattended study cannot be 100% reliable due to obvious considerations. These include fraud, disconnections, lack of practice parameters and lack of accurate titration protocols. Automatic titrating CPAP has not been adequately evaluated and true titrations will be eliminated.

CPAP dealers could purposely forge or influence results easily; and without witnessed, recorded studies that are reviewed and scored by Sleep Technologists and Sleep Physicians, there will be gross overuse and over-prescription of CPAP. If this is considered and passed, the cost of unnecessary therapy will be astounding. If you would like further examples and data, I will be happy to elaborate.



*Jim Spector, RRT, RPSGT
Adjunct Faculty, Texas State University
Cell: 512-750-2080
Fax: 512-280-4112
Email: jimspector@earthlink.net*

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April 13, 2007

VIA EMAIL AND OVERNIGHT MAIL

Steve Phurrough, MD
Director, Coverage and Analysis Group
Office of Clinical Standards and Quality
Centers for Medicare & Medicaid Services
Mail Stop: C1-09-06
7500 Security Boulevard
Baltimore, MD 21244

Re: National Coverage Determination for Obstructive Sleep Apnea

Dear Dr. Phurrough:

Thank you for this opportunity to comment on the proposed revisions to the Center for Medicare & Medicaid Services' (CMS') National Coverage Decision for Continuous Positive Airway Pressure (CPAP) Therapy for Obstructive Sleep Apnea (OSA). Aspire Medical is a California based company that is developing minimally invasive surgical treatments for OSA. Our Advance System, which is currently under clinical investigation, involves a device that is surgically implanted in the tongue and lower jaw. The purpose of this implant is to prevent obstruction of the upper airway and improve breathing during sleep. Once implanted, adjustments can be made on the day of the surgery or during subsequent physician visits to advance the tongue in order to maintain an open airway during sleep. This adjustment is performed without causing swallowing problems.

I am writing to support the American Academy of Otolaryngology – Head and Neck Surgery's proposal to modify the existing NCD for OSA to include home sleep testing as an alternative to in-lab polysomnography. As you know, there is a shortage of sleep diagnostic facilities and thousands of Americans with OSA remain undiagnosed. Home sleep testing is a safe and effective way of diagnosing OSA while simultaneously reducing costs and improving access to this vital diagnostic tool. As explained in Academy's January 2, 2007 letter, home sleep testing uses the same respiratory, oximetry, chest, abdominal, and position equipment as polysomnography. It produces reliable results that allow physicians to diagnose and plan proper treatment for their patients.

Aspire Medical shares CMS' goal of ensuring access to high quality for all Medicare beneficiaries. For this reason, we urge CMS and the Coverage and Analysis Group to accept the Academy's recommendations and expand the Obstructive Sleep Apnea NCD to include home sleep testing.

Very truly yours,

Michael T Dineen
VP Marketing and Business Development

cc: Francina C. Spencer
David Nielson, MD, FACS
Linda Ayers, MHCM

✓ 113

PETER A. FOTINAKES, M.D.

*Diplomate of the American Academy of Neurology
Diplomate of the American Board of Sleep Medicine
Fellow of the American Academy of Sleep Medicine*

April 10, 2007

Steve Phurrough, MD
Director of Coverage and Analysis Group
Centers for Medicare and Medicaid Services
7500 Security Boulevard
Baltimore, Maryland 21244-1850

RE: National Coverage Determination for Obstructive Sleep Apnea

Dear Dr. Phurrough:

David R. Nielsen, M.D., executive vice president and CEO of the American Academy of Otolaryngology-Head and Neck Surgery, recently submitted a request to reassess the National Coverage Determination for diagnosis and treatment of obstructive sleep apnea (OSA) to include home sleep testing as an alternative to attended facility-based polysomnography (PSG) by physicians licensed to practice medicine. In my opinion, Dr. Nielsen's request incorrectly characterizes the assessment and treatment of OSA and is misleading in regards to the utility of home sleep testing and its purported cost savings.

Although Dr. Nielsen plans to forward his letter to the American Academy of Cardiology and the American Society of Anesthesiologists, he chose not to notify or consult with the American Academy of Sleep Medicine (AASM). The AASM was established in 1975 as the Association of Sleep Disorders Centers and remains the only professional society dedicated exclusively to the specialty of sleep medicine. The AASM sets practice parameters, promotes excellence in healthcare, research, and education. Dr. Nielsen failed to acknowledge the AASM's formal assessment of home sleep testing devices and practice parameter recommendations (SLEEP 2003:26(7):907-13) in his letter. The AASM's practice parameter recommendations provide a more comprehensive and scientific evaluation of home sleep testing than Dr. Nielsen's personal assessment of 19 different studies examining 10 different home sleep testing devices. Dr. Nielsen's letter and request is analogous to the AASM providing an assessment and making

recommendations for the surgical correction of nasopharyngeal cancer without either consulting or acknowledging the American Academy of Otolaryngology-Head and Neck Surgery. This is not a complaint but an observation that Dr. Nielsen's assessments and recommendations lacks input from the very specialists involved in the diagnosis and treatment of OSA.

OSA is a highly prevalent condition with significant morbidity and the potential of increased mortality through secondary pulmonary and cardiac complications. The cardinal symptoms of OSA consist of pervasive snoring, broken by hesitations, gasps, and snorts, poor sleep quality and excessive daytime somnolence, all of which are easily identified during history and physical examination. The most prevalent morbidity associated with OSA consists of excessive daytime somnolence resulting from repetitive sleep disruption. OSA also increases the long-term (over 5 to 8 year) risk of developing hypertension, pulmonary hypertension, myocardial infarction, and stroke (Ann Intern Med 1994:(120):382, Chest 1988(94):9, Chest 1988(94):1200). The OSA patient at risk for sudden death from ventricular arrhythmia are the most severe; those who have significant hypoxia associated with their apnea (Chest 1985(88):335-340).

The current treatment guideline is to provide treatment for patients with an Apnea/Hypopnea Index (AHI) greater than 15 per hour or to treat if the AHI is greater than 5 and less than 15 per hour and the patient has a co-morbidity of excessive daytime sleepiness sufficient to interfere with daily activities, impaired cognition, mood disorder, insomnia, hypertension, ischemic heart disease, or history of stroke. The goal of treatment is to reduce the morbidity and mortality associated with OSA. The initial treatment of choice is nasal CPAP treatment, which is a highly effective, non-invasive treatment, but has a compliance rate between 50 to 80% (Chest 1986:90:330-33 & Eur Respir J1988;1:436-38). Upper airway surgery, such as uvulopalatopharyngoplasty has a success rate below 50% and is an invasive treatment (Chest 1985:(88):385, Otolaryngol Head Neck Surg 1984(92):375). More severe sleep apnea patients are less likely to respond to upper airway surgery and carry a higher risk of complication. Patients who snore, but do not have treatable sleep apnea as defined above, commonly seek surgical treatment for snoring. Since primary snoring does not carry the same risks of morbidity and mortality as OSA, its treatment is considered cosmetic and is not reimbursed under CMS guidelines or through most private insurance. Dr. Nielsen's proposal is not concerned with the

diagnosis and treatment of sleep apnea; its primary focus is screening patients for sleep apnea who are considering surgical correction of snoring.

Dr. Nielsen cites 19 studies, including 1,173 patients undergoing 10 different home sleep tests to substantiate the validity of home sleep testing. All 1,173 patients were not tested by a single home sleep testing method, using a single array of test parameters. Furthermore, he implies that all of the home sleep studies listed use the same monitoring parameters as facility-based PSG with the exception of the EEG channels. Four studies used AutoSet to examine a total of 242 patients. AutoSet is a CPAP that counts OSA by detecting snoring and throat vibrations without examining any other testing parameters. Four studies examined 330 patients using WatchPAT 100, which uses peripheral arterial tone variations, oximetry and heart rate to detect apnea. Two citations concerning LifeShirt and Embletta were not peer review studies, they were discussions or poster presentations at meeting. The presentation of these disparate studies is hardly sufficient validation of a single testing method, let alone sufficient scientific evidence to change the national guidelines of the diagnostic and treatment parameters for a medical condition carrying significant morbidity and mortality.

Most diagnostic testing methods cited by Dr. Nielsen have a sensitivity of around 85% in patients with an AHI over 15/hour, but their sensitivity decreases as AHI decreases. Studies of the NovaSom device indicate that there would have been better sensitivity if NovaSom results are paired with a history and physical examination. Twenty-nine of 61 patients tested with Embletta required further testing to validate their diagnosis, which means it was a redundant test in these cases, increasing costs and delaying treatment. The conclusions of several studies, such as Autoset CPAP, WatchPAT 100, and MicroMESAM were that they are reasonable SCREENING devices for OSA in the general population. Attended facility-based split-night PSG not only confirms the diagnosis of OSA, it assesses OSA severity, and allows CPAP titration during the same study night.

As mentioned above, OSA symptoms are obvious and increase as the AHI increases. In such a disease process the factors governing test and treatment selection is clinical suspicion, not a screening test capable of missing 15% of all patients. If the clinical symptoms are significant,

but the screening test is negative the situation compels the practitioner to order a more sensitive test (PSG), making the screening test redundant and increasing the overall cost of evaluation. If the symptoms are obvious, the diagnosis made clinically and the screening test is not required. Performing an attended facility-based split-night PSG confirms the diagnosis by the 'gold standard, thereby reducing test repetition AND allows CPAP titration during the same study night, which reduces costs and prevents delays to treatment. By contrast, a CPAP titration must still be scheduled after the performance of the home sleep screening tests, adding an additional test and delaying time to treatment. A facility-based split-night PSG may initially be slightly more expensive than home sleep testing, but it there are substantial cost and time savings getting patient to the ultimate goal of effective sleep apnea treatment.

Dr. Nielsen advocates empirical trials of CPAP using arbitrary pressures to diagnose sleep apnea. The studies Dr. Nielsen cites to substantiate this recommendation do not use final AHI (elimination of OSA health risk) as the outcome measure, they use quality of life measures, objective compliance and subjective attitudes. One study considered use of CPAP greater than two hours per night as success, but this method missed about 50% of OSA patients. These studies therefore do not prove effective CPAP compliance was achieved. The primary goal of reducing OSA morbidity and mortality associated with effective treatment was not a measured outcome in these studies.

Determining appropriate CPAP treatment parameters is a complicated process that cannot be performed during unattended home sleep testing. CPAP is a simple device, but many practical problems may occur at the beginning of treatment. CPAP pressures range from 4 to 20 cm water. There is CFLEX, BiLevel, BiLevel with ST mode, and now Adapt SV VPAP. There are nasal pillow masks, full-face masks, chamber-style nasal masks, chinstraps, and humidifiers. Insufficient CPAP pressure allows break-through obstructive apnea; excessive CPAP pressure produces central apnea. Furthermore, even though CPAP efficacy is more than 90%, studies have shown that CPAP compliance ranges from 50 to 80% in patients with documented sleep apnea and whose CPAP treatment pressure has been determined by testing (Chest 1986:90:330-33 & Eur Respir J1988;1:436-38). Using Dr. Nielsen's recommended empirical CPAP screening potentially misses 50% of all sleep apnea patients and probably much more when merely

guessing the treatment pressure. Getting patients through the initial adjustment period of CPAP treatment is hard enough when starting with accurately determined CPAP parameters; guessing treatment pressures promotes failure and cannot be used as an accurate means of screening for significant sleep apnea patients.

Dr. Nielsen states that attended facility-based PSG has never been established as the gold standard. PSG have been the primary test used to diagnose OSA for more than 30 years and all other testing procedures developed afterwards are measured against PSG and few approach its sensitivity or specificity. ..which is as close to definition of a “gold standard” as one can get.

Dr. Nielsen states that the current practice of attended facility-based split night diagnostic/CPAP PSG has not been validated. Dr. Nielsen’s glaring omission when comparing facility-based PSG and home sleep testing is that a facility-based PSG is ATTENDED by a sleep technologist. A trained, preferably certified, sleep technologist is capable of performing an ongoing assessment and altering the test parameters throughout the test night. If a patient does not obviously have OSA sufficient to require treatment in the first two to three hours the testing parameters are switched to a full-night diagnostic PSG; providing a more sensitive measure, saving time, and reducing overall costs. By comparison, home sleep testing would simply collect data that is interpreted later. If the test results were negative, but the patient has a high clinical suspicion of OSA, a facility-based PSG will be needed to establish the diagnosis, thereby increasing cost and delaying treatment. If the home sleep test results were positive, the patient must still be scheduled for a CPAP pressure titration, again, delaying treatment and increasing overall costs. An attended facility-based PSG is adaptable, allows fewer tests, and reduces time to treatment. Time to treatment is the imperative, not time to diagnosis.

During a facility-based CPAP titration, the attending technologist makes numerous interventions not only to document the treatment pressure, but also to determine the requirement for humidification, chin straps, CFLEX, BiLevel, and a change in mask. AutoCPAP devices are only capable of determining treatment pressure and accurately do so for only about 80-85% of the cases (SLEEP 2002 25(2):148-73). AutoCPAP does not detect OSA in patients who have undergone palate surgery and is contraindicated. Trying to determine effective CPAP pressure

through arbitrary pressure prescription requires multiple follow-up visits and adjustments until the physician makes the final guess in treatment pressure. These follow-up visits delay treatment and increase costs. Subjective measures of sleep are notoriously erroneous because the patients are sleeping when they have their symptoms, leading to treatment failure, and unused CPAP machines.

Attended facility-based PSG also determines EEG arousals to diagnose the more subtle OSA patients that home sleep testing does not detect, as related by Dr. Nielsen's cited studies. EEG also documents REM sleep, which is the most provocative time for OSA and when the most significant apnea occurs. Some OSA patients only manifest their apnea during REM sleep, which may be suppressed or short-lived in severe apnea. These patients are at the highest risk of ventricular arrhythmia and sudden death, because the worst hypoxia occurs during REM sleep. Furthermore, of the home sleep tests cited by Dr. Nielsen do not utilize body position analysis. Sleeping supine is also a provocation of OSA and some patients only manifest their OSA when in this body position. Without confirmation of REM sleep and body position the most subtle and most severe OSA patients may go undetected.

Nasal CPAP treatment is not as simple as writing a prescription for a CPAP pressure and sending the patient on their way. The highest cost of OSA treatment does not arise from facility-based PSGs; it comes from treatment failure. The cost of an unused CPAP machine sitting in a patient's closet is much higher than any testing and does not reduce the morbidity and mortality of OSA. As noted above, CPAP compliance may range from 50% to 80% in patients diagnosed and titrated by PSG. Guessing at CPAP pressures, determining poor CPAP treatment parameters, and treatment by physicians with little experience will cause CPAP treatment compliance to plunge. CPAP compliance is best assured by accurately determining CPAP treatment parameters (not just pressure) and through follow-up in a sleep center by an experienced sleep medicine specialist.

Dr. Nielsen accurately states that there are many more sleep apnea patients than there are sleep centers to assess and treat their conditions and there are waiting lists to get treatment, even in areas where there are many sleep centers. Dr. Nielsen's allusion of patients dying of sudden

death while awaiting their sleep apnea evaluation and treatment is a gross exaggeration. Only the most severe sleep apnea patients are at risk of immediate complications of sleep apnea, and these patients are easily identified by history and physical examination, making a home sleep test that only performs detection redundant and expensive. At reputable sleep disorders centers, a sleep medicine specialist can easily identify patient with severe OSA during the history and physical and their diagnosis and treatment is then expedited. LONG-TERM cardiopulmonary health risks are the primary problem in most sleep apnea patients presenting to sleep disorders centers. These long-term health risks are elevated if sleep apnea is left untreated over five to ten years, so a brief waiting time will not significantly impact health risk in most sleep apnea patients. Improper diagnosis and establishing ineffective treatment parameters in the hands of inexperienced practitioners using inadequate methods WILL place patients in harm's way, however, because it sets up treatment failure.

Dr. Nielsen states that the controversy comes down to a single issue: is an attended facility-based PSG the most diagnostic paradigm and are home sleep testing sufficiently accurate to diagnose routine OSA patients. Dr. Nielsen is incorrect in his assessment; the most important single issue is an accurate and economical paradigm to effective OSA treatment. As determined by the numerous studies cited by Dr. Nielsen, home sleep tests only screen for OSA in the general population. We do not require screening tests in a disease process with obvious clinical symptoms and signs, because history and physical are sufficient screening tests. To date, nasal CPAP remains the most effective treatment of OSA. CPAP treatment may have a low compliance rate if the appropriate CPAP parameters are not accurately determined. The highest cost of testing and treatment of OSA comes from unused CPAP equipment. Untreated OSA patient continue to have increased mortality and morbidity. Attended facility-based split-night PSG reduces test repetition, provides greater adaptability, and determines more accurate treatment parameters faster. Attended facility-based split-night PSG lowers overall cost of attaining the goal of effective OSA treatment.

Currently, there are independent physicians and technologists that provide home sleep testing services in Southern California. Kick-back schemes arise when these practitioners solicit referrals from pulmonologists, ENT surgeons, and general practitioners in exchange for

providing a computer generated interpretations that these practitioner then charge for. Some facilities offer home sleep testing at a much-reduced price in exchange for receiving the referral to provide the CPAP equipment. ENT surgeons seek a simple screening test for OSA during the preoperative evaluation of patients seeking treatment for snoring, a cosmetic procedure. To insure cost effective evaluation and treatment of OSA patients, regardless of whether they are facility or home tests, these practices must be controlled by only reimbursing for interpretation of sleep testing through an accredited facility independent of the physicians performing surgery or the organization providing CPAP equipment.

If CMS desires the most economical method to get sleep apnea patients to the goal of EFFECTIVE treatment they should consider the following:

- Reimbursement should only be allowed for sleep studies performed through a sleep disorders center accredited by the American Academy of Sleep Medicine and read by a physician certified by the American Board of Sleep Medicine.
- A technologist supervised split-night CPAP polysomnogram should be the preferred testing protocol, because it is the most cost effective means of establishing treatment parameters. Diagnostic PSG is only necessary if the diagnosis of clinically significant OSA cannot be determined during the first two to three hours of a split-night PSG.
- Close follow-up of sleep apnea patients by sleep medicine specialist after initiation of CPAP treatment should be a mandatory requirement of facilities prescribing CPAP.
- Reimbursement for upper airway surgery treatment of sleep apnea should be allowed only after an INDEPENDENT practitioner, preferably by a sleep medicine specialist, establishes an accurate diagnosis and documents treatment failure with nasal CPAP.
- Only board certified sleep medicine specialist should be reimbursed for interpretation of sleep testing regardless as to whether they are home or facility based. This practice eliminates the kick-back interpretation schemes now prevalent between non-accredited sleep labs and general practitioners, ENT surgeons, pulmonologists, and neurologists.
- Reimbursement for CPAP equipment should be independent of the physician prescribing CPAP treatment, again to prevent kick-back schemes.

Thank you for your time and consideration.

Very Truly Yours,

A handwritten signature in black ink that reads "Peter A. Fotinakes" followed by a stylized flourish.

Peter A. Fotinakes, M.D.

Diplomat, American Board of Sleep Medicine

Fellow, American Association of Sleep Medicine

Medical Director, St. Joseph Hospital Sleep Center

Associate Professor of Neurology, UC Irvine (ret.)



STANFORD
SCHOOL OF MEDICINE

Stanford University Medical Center

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Thomas J. Fogarty, M.D.
Clinical Professor of Surgery

Office: (650) 723-2031
Clinic: (650) 725-5227
Fax: (650) 498-6044

April 4, 2007

Steve Phurrough, MD
Director, Coverage and Analysis Group
Center for Medicare and Medicaid Services
7500 Security Boulevard
Baltimore, Maryland 21244-1850

RE: Comment Period
National Coverage Decision (NCD) on portable sleep studies for the diagnosis of obstructive sleep apnea(OSA)

Disclosure: It should be considered in the evaluation of this letter that Dr. Fogarty has a financial interest in companies intending to reduce healthcare cost by moving expensive hospital based procedures, technologies, monitoring and diagnostic devices into less expensive environments.

Dear Dr Phurrough:

I urge CMS to allow for coverage of FDA approved portable devices that have had validation studies and whose results are interpreted by a physician qualified in sleep medicine.

- 1) **Undiagnosed OSA is a significant and acute issue for Medicare, its beneficiaries, and the country as a whole.**
- 2) **PSG (Polysomnography) is not perfect and there are inherent advantages to portable testing.**
- 3) **The medical literature has evolved quickly with more comparative studies of portable devices and PSG.**
- 4) **New paradigms of care have been documented in the medical literature including outcome studies involving patients diagnosed without PSG. A substantial literature documents effective use of auto titrating CPAP in lieu of in lab titration.**
- 5) **Integrated health systems such as Kaiser Permanente and the Veterans Administration are using portable sleep studies effectively.**

These important considerations should lead CMS to make a positive decision this time around.

1) Undiagnosed OSA is a significant and acute issue for Medicare, its beneficiaries, and the country as a whole. In the time that has elapsed since the previous CMS analysis of this issue it has become increasingly clear that unrecognized and untreated OSA is a significant issue for the individual and an economic burden on society. Undiagnosed OSA patients have a markedly increased risk of hypertension, stroke, heart failure, sudden death, depression and accidents. The problem has become so severe that in April 2006 The Institute of Medicine issued a report, *Sleep Disorders and Sleep Deprivation: An Unmet Public Health Problem*, that included a recommendation for improved diagnosis and treatment of OSA.

2) PSG (Polysomnography) is not perfect and there are inherent advantages to portable testing. As discussed in the previous NCD:

“There is no anatomic or physiologic “gold standard” for the diagnosis of obstructive sleep apnea, in contrast to conditions such as cancer where a tissue biopsy result is the definitive standard reference.”

Thus the literature comparing portable studies to PSG must be appreciated in this context. Moreover there are problems with PSGs including:

- **Access-** Sleep labs do not have the capacity to meet the needs of testing in many communities. Most patients, whom their physicians suspect as having OSA, remain undiagnosed.
- **First night effect-** it has been observed that given the artificial environment present in sleep labs, a single night study is not always sufficient to establish an accurate diagnosis. Indeed, it has been demonstrated that up to 25% of PSG's are inaccurate due to the first night effect¹ and that patients may need to be studied on multiple nights to achieve an accurate assessment². It has also been observed that one night is not sufficient to diagnose OSA in approximately 1 in 10 cases and that there is little nightly change in sleep disordered breathing in the home environment³. Portable studies are conducted in the patients own bed and many can provide multiple nights testing. The NovaSom QSG™ routinely provides three nights of data thus enhancing its clinical usefulness.
- **Accuracy and Reproducibility-** it is well known that the quality of sleep labs vary and that inter and intra scorer variability compound the inaccuracies of the first night effect.⁴
- **Cost** PSGs are expensive. Portable studies typically cost less than a third of what Medicare pays for a PSG.

It should also be recognized that PSG and portable studies are measuring the same parameters for the diagnosis of OSA. This is not like assessing a new biomarker. Portables merely provide a more efficient way to record these in the patients actual sleep environment. EEG and other PSG parameters not found on portables are important for the diagnosis of Narcolepsy and other sleep disorders; however they are not needed or used for the diagnosis of OSA.

Sleep studies performed outside of a sleep lab have potential problems as well. Level 2 studies have been known to be problematic because when unattended, patient movement can dislodge leads and important data is lost. Portable studies have the potential for similar problems. Thus a key aspect when considering portable studies is the ability of the device to detect difficulty with lead placement and prevent data loss. This can be demonstrated in the devices' basic characteristics as well as their track records in providing interpretable studies. Current generation portable devices are much improved with better sensors and safeguards to prevent data loss. The NovaSom QSG™ has a voice prompt that notifies the patient in real time if a monitoring wire comes loose or a sensor dislodges.

3) The medical literature has evolved quickly with more comparative studies of portable devices and PSG.

Given multiple devices an assessment of this literature can be difficult. We urge CMS not to over rely on assessments by others such as AHRQ. When AHRQ last performed an analysis in 2004 there were several problems. The AHRQ analysis was subcontracted and appeared both biased and out of date. The analysis appeared to be largely based on an earlier AASM review. Moreover the 2004 AHRQ report combined data from a variety of portable diagnostic devices including older devices to draw conclusions regarding all devices. This approach makes it extremely difficult (impossible?) for reliable devices to pass muster as they are pulled down by the older weakest links in the chain. I hope that if AHRQ is involved this time they provide a fresh approach and the CMS look closely at the clinical usefulness of specific devices.

It is very important that portable devices for the diagnosis of OSA should also be evaluated in light of realistic parameters. PSG machines do not have 100% correlation with other PSG machines due to data acquisition, averaging, and presentation; therefore it should not be expected that portable devices will have 100% correlation with PSG's! It should also be recognized that using cutoffs like AHI >5, >10 or >15 are arbitrary and that PSG's are likely to give problems in this range as well. Indeed, upper airway resistance syndrome is one manifestation of where the PSG fails to detect illness treatable by CPAP. Thus, portable devices, which have been shown in rigorous clinical studies to have sensitivities and specificities above 90% for number of events (such as an AHI > 15), should be given serious consideration for medical technology assessment approval. This is a degree of performance that will provide useful clinical information for the treating physician in the context of the patient's clinical findings. This is, after all, what the expectation is for a good diagnostic test.

Validation studies of portable devices were nicely summarized in Dr. Nielsen's letter to CMS. (January 2, 2007 American Academy of Otolaryngology-Head and Neck Surgery). Validation studies of the NovaSom QSG™ were included in that review: Claman et al⁵ compared the "Bed Bug" (NovaSom's original name) to polysomnography (PSG) at the UCSF Sleep Lab. The positive predictive value of the Bedbug at an AHI of 15 was 94%. Reichert et al⁶ looked at the NovaSom QSG™, both in the sleep lab and the home in comparison with PSG. In home NovaSom had a sensitivity of 91% and specificity of 83%. If an AHI cutoff of 18 were utilized the specificity would have been 100%. As a reminder, a single night PSG has a false negative rate ranging from 15% to 25% when compared to a two or three night PSG.

4) New paradigms of care have been documented in the medical literature including outcome studies involving patients diagnosed without PSG. Several more recent studies are worth noting. Whitelaw et al⁷ compared the outcomes achieved utilizing PSG and home oximetry monitoring in patients with suspected OSA without significant co-morbidities. It was observed that PSG and home oximetry were equal predictors of improvement with CPAP. Mulgrew et al⁸ performed a randomized controlled trial in which patients with a high probability of OSA based on their Epworth Scores were tested with a portable device and then randomized to PSG /CPAP titration vs auto titrating CPAP-an "ambulatory group". Outcomes were essentially the same except that the ambulatory group had improved CPAP adherence. This study also proposed a clinical algorithm for management of patients with a high probability of obstructive sleep apnea (OSA). Rice et al⁹ evaluated an algorithm for managing patients with suspected OSA. If patients had a moderate to high degree of suspicion for OSA they were offered portable study or PSG. For those who had portable studies if positive they went on auto-titrating CPAP and if negative they had a PSG. Follow-up analysis of those with positive portable studies (90% of patients) revealed a high rate of improvement in OSA symptoms similar to published reports of patients who had undergone conventional PSG. For those patients that tested negative by portable study (10%) there was only one clear false positive based on subsequent PSG. Other patients declined PSG or had borderline studies.

A substantial literature documents effective use of auto titrating CPAP in lieu of in lab titration. Patients who have been diagnosed with OSA via a PSG must come back to the sleep lab for another night of CPAP titration. Alternatively, a so-called split night study is often performed during the initial PSG. This involves making a diagnosis of OSA early in the night and beginning CPAP titration at the conclusion of the truncated diagnostic test. This practice has not been standardized and validation in the literature is limited. Some critics of portable studies have argued that, given the need for CPAP titration, those patients who are positive on portables will end up coming to a sleep lab anyway for titration. However, this is a spurious argument because of contemporary self-adjusting CPAP machines which utilize technology that allows for the CPAP pressure to vary with the patient's airway resistance, even as this varies during any given night or from night to night. CPAP titration can be done in the patient's own

home and ongoing use of auto-titrating CPAP automatically adjusts pressure as the patient's circumstances change. The clinical usefulness of this approach is well validated in many peer-reviewed studies including but not limited to these referenced studies.^{10 11 12 13 14 15}

Thus the use of auto-titrating CPAP allows patients with OSA diagnosed using a reliable portable study to move on to CPAP therapy using auto-titrating CPAP without an in-lab study for CPAP titration. This is logical, clinically sound, and an efficient use of health care resources. The use and validation of auto-titrating CPAP is pertinent when considering the issue of portable sleep studies because it provides a framework for considering how portable studies can be used in clinical practice.

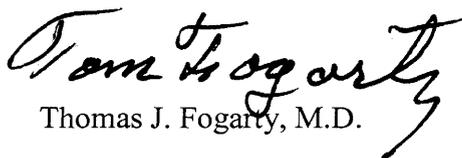
6) Integrated health systems such as Kaiser Permanente and the Veterans Administration are using portable sleep studies effectively. This real life experience is pertinent as these systems are at risk for the cost of OSA treatments, the costs of undiagnosed OSA as well as the cost of diagnostic testing. Over 15,000 NovaSom® QSG® studies have been performed at VA Medical Centers over the last 5 years. Peer reviewed published studies have reported a success rate between 93% and 94%. Only 1% of these tests were un-interpretable and required repeating or PSGs.

Although its been only three years since CMS began its last NCD on this issue, much has changed. There is more evidence regarding the reliability of portables and positive outcomes in patients managed without PSGs. Meanwhile the need for more efficient diagnosis of patients with suspected OSA has become more acute. Of note even the AASM who have been critics of portable studies in the past have stated "...physicians who choose to use portable monitoring should follow these recommendations:

1. When used, portable monitoring must be combined with a clinical assessment, and must be interpreted within a comprehensive evaluation of the patient.
2. Studies using these devices should be performed, read and interpreted only in AASM accredited sleep laboratories or centers, or by board certified Sleep Specialists.
3. Decisions on therapy should be based on both the results of the studies as well as knowledge of the individual patient's symptoms"

Clearly the potential benefits to the Medicare program of allowing of coverage of portable studies outweigh the potential harms. Indeed are there potential harms?

Sincerely,



Thomas J. Fogarty, M.D.

¹ Le Bon , O et al Mild to Moderate Respiratory Events* One Negative Night May Not Be Enough *Chest* 2000 118. 353-359

² Hutter DA, Holland BK, et al Occult Sleep Apnea: the dilemma of negative polysomnography in symptomatic patients. *Sleep Medicine* 5 2004 501-506

³ Stepnowski CJ, Orr WC, and Davidson TM. Nightly variability of sleep disordered breathing measured over 3 nights. *Otolaryngol Head Neck Surg* 2004; 131:837-43

⁴ Collop NA Scoring variability between polysomnography technologists in different sleep laboratories. *Sleep Medicine* 3 2002 43-47

⁵ Claman D, et al Clinical Validation of the Bedbug in detection of obstructive sleep apnea *Otolaryngology-Head and Neck Surgery* September 2001 125 227-230

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- ⁶ Riechert et al Comparison of the NovaSom QSG, a new sleep apnea home-diagnostic system, and polysomnography *Sleep Medicine* 4 2003 213-218
- ⁷ Whitelaw WA, Brant RF, and Flemons W. Clinical Usefulness of Home Oximetry Compared with Polysomnography for Assessment of Sleep Apnea *American Journal of Crit Care Med* 2005 Vol 171. 188-193.
- ⁸ Mulgrew AT, Fox N, Ayas N, and Ryan F Diagnosis and Initial Management of Obstructive Sleep Apnea without Polysomnography. *Ann Intern Med* 2007;146:157-166.
- ⁹ Rice K, Nelson, K Rubins J, Arjes S Unattended Cardiopulmonary Sleep Studies to Diagnose Obstructive Sleep Apnea. *Federal Practitioner* May 2006 17-31
- ¹⁰ Massie, C, NcArdle, N. Comparison between Automatic and Fixed Positive Airway Pressure Therapy in the Home. *Am J Respir Crit Care Med* 2003;167:20-23
- ¹¹ Series, F Accuracy of Unattended Home CPAP Titration in the Treatment of OSA *Am J Respir Crit Care Med* 2000 ; 162 94-97
- ¹² Masa A , Jiminez J et al Alternative Methods of Titrating Continuous Positive Airway Pressure *Am J Respir Crit Care Med* 2004 170;1218-1223.
- ¹³ Hukins, C A comparative study of autotitrating and fixed CPAP in the home. A randomized single blind crossover trial. *Sleep* 2004 27(8) 1512-1514.
- ¹⁴ Planes C, D'Otho M, Efficacy and Cost of Home Initiated auto CPAP vs Conventional N CPAP *Sleep* 2003 (2) 156-160.
- ¹⁵ Woodson B, Saurejan A Non attended home automated continuous positive airway pressure titration : comparison with polysomnography *Otol Head and Neck Surgery* 2003 128 353-7

From: Asif Muhammed
Sent: Saturday, April 07, 2007 10:03 AM
Subject:

In home sleep studies are not the standard of care and will result in unnecessary use of cpap in patients based on artifactual data. Just like a lot of patients not in need of oxygen get home O2 based on home overnight monitoring.

AM, Diplomat ABSM

From: bbeine@pacificsleepmedicine.com

Sent: Friday, April 13, 2007 4:55 PM

To: CMS CAGInquiries

Subject: case reference number CAG-00093R2

I have been in sleep medicine for ~7 years. I regularly interact with a variety of sleep medicine centers, labs, mobile sleep clinics, insurance companies, referring physicians, DME providers, etc. My many experiences lead me to believe that the floodgates of poorly-trained providers who are unable to provide good patient care have been open over the past 5 years. Poor training and lack of true patient interest daily leads to mistreated patients, repeated sleep studies, wasted money, and simply dangerous situations.

Sent: Thursday, April 05, 2007 6:56 PM

To: CMS CAGInquiries

Subject: CAG-00093R2

I do not believe that Medicare should provide for reimbursement of portable in-home sleep studies at this time. This was recently reviewed and turned down for very valid reasons, and does not need to be reassessed at this time. Specific studies regarding the effectiveness of in-home sleep testing is currently underway and needs time to be completed. Too many devices, too many questions regarding ulterior motives of industry. An example is Itamar, which uses PAT technology, essentially a two-channel recorder, there is no way to differentiate central from obstructive sleep apnea with this device. The recent push by ENT surgeons is somewhat disturbing, given the less than 30% success rate for surgical procedures for sleep apnea, what is their need for portable testing? The Cardiologists also, may not realize, that many of their patients would be complex and may end up in the sleep disorders center anyway. Certainly portable testing in a controlled format is the future, however, sleep centers are taking care of more serious patients, devices for home use need to be evaluated, and adequate channels need to be available to record the information needed to separate one sleep disorder from another.

Sincerely,

Bernie W. Miller, RRT/RPSGT

Mayo Clinic Hospital Sleep Disorders Center

Mayo Clinic Arizona

Sent: Saturday, April 07, 2007 12:12 AM

To: CMS CAGInquiries

Subject: OSA regulations

Home studies for patients with OSA, can be performed at home in most cases.

As a respiratory professional I know the most normal sleep is in their own home and environment.

Thank You,

Bert Guzman, RRT

bguzman@pima.gov

Sent: Wednesday, April 04, 2007 9:08 AM

To: CMS CAGInquiries

Subject: CAG-00093R2

To Whom It May Concern:

I believe the home testing of sleep disorders has merit. I believe the real benefit is derived from the patient not undergoing more testing than is reasonable. While I believe there may be cost savings achieved by allowing home testing, I also believe home tests can provide practitioners with the information they will need to better serve the patient and their condition. If additional tests (through authorized sleep labs) are necessary or whether the home test proves to be sufficient for prescribing treatment for the patient, the "time factor" can greatly be lessened from diagnosis to treatment. Cost savings alone will not be the only benefit if providers are allowed to provide home sleep tests.

Bill Bishop Owner Advantage Home Medical Co.

Sent: Thursday, April 05, 2007 8:33 AM

To: CMS CAGInquiries

Subject: CAG-00093R2

Clearly the efficacy and economic efficiencies of in home OSA testing are a benefit to everyone. With the budget concerns of today CMS should take a close look at a sure source of saving millions of dollars, improving service to the patients, and stimulating new technology. With existing home testing systems and with the use of "auto" titrating CPAP units we can realize the benefits of a new system almost immediately.

Bob Mayer, President Harbor Oxygen

Sent: Saturday, April 07, 2007 12:23 PM

To: CMS CAGInquiries

Subject: CAG-00093R2

Dear Sir Our accredited sleep lab has been operating for over 10 years. During this time we have had the opportunity to compare PAT....peripheral artery tonometry sleep studies done in the home to our standardized results. In over 30 cases there was agreement in a little over half the cases. The rest had not correlation whatsoever. Usually the severity of sleep apnea has very little night to night variability. I am not sure why the studies were so far off. The ENT doctors who were interpreting these studies have abandoned them for most part possible because of economic or liability concerns. Home testing for

sleep apnea at some point will be the diagnostic study of choice, but at this time the technology is not reliable.....as noted in your consensus statement a few years back. Thank you

Bruce R Tammelin MD

Diplomate American Board of Sleep Medicine

Sent: Friday, April 06, 2007 10:23 AM

To: CMS CAGInquiries

Subject: Home sleep studies

Regarding: CAG-00093R2

To Whom It May Concern: I am supportive of home sleep studies as a covered procedure by CMS. Updated technology makes for accurate diagnosis for sleep apnea. As a cardiac and pulmonary rehab nurse, I see a large population of patients with suspect sleep apnea. Many cannot afford or are very uncomfortable with in-patient sleep studies. Heart failure is the result of untreated sleep apnea, an expensive and life-limiting, but preventable disease. I hope you will consider supporting CMS adding home sleep studies to covered treatment codes.

Sincerely, Carla Bahr RN

Director, Graham Wellness Center

We have been helping Docs with home sleep studies for 8 months and have had no negative feed back. The Doctors are wondering why they can't bill a Cpap from the results as the test gives everthing but the titration and this could be accomplished with an auto-pap. This could save in the hundreds of thousands of dollars for all Insurance companies. Some Blue Cross states are accepting the test today.

Thanks

Jim jernigan President Jernigan Healthcare

To Whom It May Concern:

I am both a Registered Nurse, and a Registered Respiratory Therapist with over 25 years experience with diagnosing and treating people with Obstructive Sleep Apnea.

The technology to perform home sleep studies has been around for over 20 years. The ability to confirm the diagnosis of obstructive sleep apnea can easily and inexpensively performed in a persons home. CPAP titration can also be performed like wise in the person's home. It would be logical to expect that insurance companies, as well as Medicare, would recognize this and assign HCPCS & CPT codes for it. In my opinion, sleep centers and labs have become cash cows. In many instances, timely diagnosis and treatment of obstructive sleep apnea does not occur. Allowing for home testing would be a solution to this.

Sincerely,

Paul Morgan RN, RRT 2213 Old Jeanerette Rd. New Iberia, LA 70563

paul@gomorgan.us

To whom it may concern,

My name is Polina Fooks. I am a Registered Respiratory Therapist with twelve years of experience in a hospital, and in a homecare. I do believe OSA testing should be covered by insurance companies for serious reasons.

My first reason is that a lot of my patients complain that they don't feel comfortable to fall asleep someplace other than their own bed. The families of the patients do not feel comfortable with this situation either.

The second reason I believe the OSA should be covered by insurance companies is because with the new technology, test can be performed in the patient's own home with great quality results. The test can be much more affordable for the patients as well as the insurance company when it is performed at home. The reason is, if the tests are performed in the patients house the company doesn't have to worry about the rent, the utility costs, and extra technicians. The result from the tests would be automatically sent to the doctors.

The last reason is, in many places patients have to wait for months for their appointment. This problem would be automatically eliminated if the HME industry would receive the right to perform this test at patient home.

Please send me your feedback.

Thank you very much for your attention to this issue.

Sincerely,

Polina Fooks

President/CEO RRT

I do not support in-home OSA testing because I am concerned that many important health issues that are picked up in a formal lab setting will be missed in the in-home testing. Obviously, OSA is not the only sleep disorder. Does this in-home testing diagnose PLMD or RLS, insomnia, narcolepsy, REM behavior disorders, etc? If not, a patient may think that they do not have a sleep disorder if OSA is not the diagnosis; and therefore, not seek help for the other potentially dangerous disorders.

Also, I am concerned about the total accuracy of the test due to the patient's inability to follow the instructions; and therefore, inappropriate treatment.

If in-home testing becomes covered by insurance, I trust that the controls will be tight as far as connections between the testing company and the DME companies that will be providing the equipment. It seems that this could potentially become a huge fraud issue with the patient being the one to suffer.

Sue Miles

I am writing in my capacity as a Respiratory Therapist that has been involved with sleep medicine for twenty years. I have performed many home based sleep studies, and worked with hospital based sleep labs, both accredited and non-accredited. Without a doubt, home based studies fall far short of retrieving the diagnostic information needed to make an accurate diagnosis. As a simple example, they cannot determine if a person is sleeping, much less determine what stage of sleep they are in. Without this information, accurate treatment is a guess. After performing countless home sleep studies, I found that (in most cases) the treatments prescribed were incorrect, and the patient had to be followed further by a sleep MD, or Sleep Lab. Don't be fooled by 'advances in technology' that claim equal or better diagnostic results to a sleep lab. There is no way that they can compare to a hospital based lab, with a Pulmonologist or Sleep Doc. following them. If home sleep studies are approved, CMS will simply

pay a bigger bill in the end when these patients are admitted because their OSA was incorrectly managed. Phil Carter CRT, RCP
PHIL CARTER

TO WHOM IT MAY CONCERN:

In-Home Sleep Testing should be covered by all insurance methods. Most current formal Sleep Laboratories are booked months in advance and In-Home Sleep Testing would allow individuals with severe sleep disorders to have improved access to diagnosis and treatment. Respiratory Therapists are the health care experts with regard to airway management and approval for insurance reimbursement would allow physicians to order In-Home Testing and Respiratory Therapists to perform this testing. Once a confirmed diagnosis can be made, the attending physician will be able to consult with the Respiratory Therapist and prescribe appropriate therapy. Approval of such reimbursement will greatly improve the patient outcomes and reduce future health care costs.

Dave Robbins

David W. Robbins, DC, RRT, Director, Respiratory Therapy Program ATI College of Health 1395 N. W. 167th Street Miami, FL 33169 305-628-1000, Ext. 2844 - Cell: 305-807-2760 (Always At Your Service)

As a long time owner of a DME Business and Chairwoman of the Board of Pharmacy in NC that regulates our industry, I wholeheartedly support in home OSA testing.

Marcia L. Ladd

Triangle Aftercare 105 West NC Hwy 54 Ste 267 Durham, NC 27713 919-544-1336

www.triangleaftercare.com

I received an email requesting that I contact you in support of coverage for in-home sleep testing. As a Registered Polysomnography Technologist (Sleep Tech), I am opposed to this action. When a patient/Client is tested in the sleep lab, the neurological component is one of the many important aspects that we review. By doing studies in the home with a device on the wrist, you are unable to fully analyze what is going on with your patient.

This could cause misdiagnosis & long-term effects for the patient. Please consider this in making your decision on coverage of in-home testing.

Marcia Mullikin, RRT, RPSGT Director, Respiratory Care & Sleep Lab Regional Hospital of Jackson 367 Hospital Blvd. Jackson, TN 38305

731-661-2162 Fax: 731-661-2483

marcia_mullikin@chs.net

Please BAN this notion, sleep apnea is a serious condition that should remain in a hospital based or independent lab facility. The technology is not at a point to replace that of human knowledge and ready access to the patient should difficulties occur. For the safety of patients, please disregard the use of in home sleep studies.

dcpepsi42@aol.com

I am a respiratory care professional and would like to comment on CAG00093R2. I believe that there are a large number of sleep disorder patients that could be adequately tested in the home for obstructive sleep apnea. Many of these patients present with obvious symptoms of OSA. If Medicare would allow home testing, the costs for studies would drop, the waiting lists at sleep labs would decrease and private insurances would follow Medicare's lead resulting in further cost savings. As we look at the costs of health care continuing to grow this is a low risk way of reducing those costs. Thanks,
Ron Drees

Dear Sirs,

I am in support of allowing in-home portable testing in the diagnosis of OSA. This should allow a significant cost savings in diagnosing OSA, and in turn leave more funds available for the treatment and follow-up care for patients with OSA. I believe that should be the focus of our limited monies and resources.

Sincerely, Kristi Kirkeby, RPSGT, CRCP 2700 12th Ave. S Fargo, ND 58103

I not only object to this, it is entirely a farce to think that a machine can determine the variables needed to accurately do a sleep study on a human being. Are any two humans the same? Is any one situation the same? How many DME companies are pushing this as hard as possible so they can make a quick buck by cutting out a necessary and needed in lab human attended sleep study? There are just too many things that can happen during a person's sleep affecting results, that can NOT be recorded by a machine alone. You show me a statistic that says these "auto" diagnoses are accurate and I will show you statistic's that prove it wrong.

Scott Powers, RPSGT 828-654-6000 50 Hospital Dr. Ste. 1C Hendersonville, N.C. 28792

I have been in the sleep field since 1981 and have done research and written extensively on home monitoring versus in laboratory monitoring. The problem is that home monitoring for sleep apnea is not for everybody. If a patient with a low clinical pretest suspicion for sleep apnea has a negative test for sleep apnea using a LEVEL 3 device at home does this mean the person does not have sleep apnea or does it mean that the monitoring equipment is insensitive to detect sleep apnea? Our current NIH sponsored research studies do use home monitoring to detect and track sleep apnea, but we are not using a Level 3 device because we feel it is inadequate to detect mild sleep apnea. We are doing full polysomnography in the home and we include a nasal pressure transducer to detect subtle increase in upper airway resistance. I would not approve generalized home testing since it opens the door to home testing with inadequate equipment. In addition, I do not feel that full polysomnography in the home is justified since it is labor intensive and will probably not decrease health costs.

Richard P. Millman, MD

Director, Sleep Disorders Center of Lifespan Hospitals

Professor of Medicine

The Warren Alpert Medical School of Brown University
P 401-444-2670 F 401-444-8447

The attached pdf file shows that setting CPAP pressures with Auto-titrating CPAP can be dangerously inadequate. It also demonstrates that the algorithms used in Auto CPAP devices don't always work. This is unpublished data, but it is very real and is seen more than rarely. A picture is worth a thousand words...Please see the attached pdf.

These are my comments only and do not necessarily reflect the opinions of my employer.

Jeff Pray, RRT, RPFT - Respiratory Care Services Coordinator Allina Hospitals and Clinics - Cambridge Medical Center 701 South Dellwood Cambridge, MN 55008

As a Respiratory Therapist and a HME owner I believe patients should be able to be tested in the home. I believe it to be cost effective and the outcome much better. I believe the patient along with their Dr. should be able to determine if a home sleep test is appropriate for them. Many of the Medicare patients I see with OSA have found it to be a hard ship on them to go to a lab to complete the testing. Thank You for your consideration.

R. Marteney CRT.

To decrease insurance costs, and make management of this disease more accessible to everyone, please support case reference # CAG-00093R2.

Making health care more cost-effective, and providing a comfortable home setting to educate & more likely resolve this wide-spread medical condition, will be a large step to improve cardiac health in America.

Because recent cuts in oxygen re-imburement have also further limited all licensed health-care professionals to patients with complex respiratory education and care, please give serious thought to this growing problem.

Thank you, Rick Steenback-Home Care Respiratory Therapist

I totally disagree with home testing.

-

It has been well proven that the accuracy is poor and unreliable, at least too much so for something as risky as OSA.

-

THIS WOULD OPEN THE DOOR FOR EVEN MORE OF THE ILLEGITIMATE MONEY SEEKERS THAT ARE OVERPOWERING THE INDUSTRY AT THIS TIME. AT PRESENT, A COMPLETELY UNTRAINED WHEELCHAIR SALESMAN (SUCH AS A DME COMPANY) CAN LEGALLY OPEN A SLEEP LAB AND COLLECT THE SAME REIMBURSEMENT AS AFULLY ACCREDITED SLEEP CENTER.

PLEASE DO NOT APPROVE HOME TESTING.

RONALD D CATES, MD, DABSM

To whom it may concern: I am writing in opposition to the push to perform sleep studies via home testing devices. As a sleep professional I do not think this is in the best interest of patient care. First, there is much room for fraud. From my understanding, there is no way of validating the data you have received is truly from the patient. I have tested many truck drivers in my career. The department of Transportation has very strict guidelines regarding sleep apnea and the majority of the drivers are not happy at the thought of being diagnosed with apnea and possibly losing their DOT license. If home testing is permitted, what is will keep the truck driver from putting the sleep testing equipment on his wife for the night??? The study is read as normal and the driver falls asleep and runs over someone. What then? How have we protected the patient or the community by allowing medical testing to be done in an uncontrolled environment? I am not aware of any medical test that is performed in an uncontrolled, unmonitored setting. It is a mistake to start now.

Pam Dalton, RPSGT Clinical Coordinator Regional Sleep Center Memorial Health Care System 423-495-5297

“Patients with dangerous sleep disorders would be ill-served by approval of in-home sleep testing for coverage by the Centers for Medicare & Medicaid Services (CMS). It is difficult to appropriately diagnose these conditions in a well-supplied and organized sleep lab; approval of home testing would open the floodgates to poorly-trained providers whose primary concern is the sale and rental of CPAP equipment, not patient care.”

These are not my words, but I agree completely with the above statement. With home testing covered there would be not only a decrease in quality patient care, but also a potential to increase health risk in some patients who have not been accurately treated in a sleep disorders laboratory. There is evidence that an inappropriately treated patient on CPAP, there can be an actual increase in blood pressure, which in turn can lead to other more serious cardiac problems. Home testing devices have not proven that they can titrate to effective CPAP pressure as accurately as a trained professional in the sleep disorders facility can. Home testing in my opinion is harmful to the patients, which I think you would agree is the complete opposite of what we as health professionals are trying to achieve.

David Parenteau

Registered Polysomnographic Technologist (RPSGT)

Dear Sirs,

I believe technology has come a long way for home testing, but there are still to many unanswered questions to warrant this testing.

-Who will follow up with these patients once testing is completed. If the door is open to all physicians, then patients will slip through the cracks.

-There are many different styles of equipment, and many will not be as reliable.

-If a sensor or more falls off during acquisition, then the test wont be reliable.

-There are many hospital/and stand alone sleep labs now, and the wait time is no longer an issue with getting patients in to the sleep lab in a timely manner.

-Often in the sleep lab, a patient will exhibit life threatening arrhythmia that can be

addressed right away when a technician is viewing the test in real time.

Thank you,

Paul

Paul Bietz RRT-NPS, RPSGT

Cardiopulmonary Clinical Supervisor

Sleep Disorders, Pulmonary Rehab, EEG - Parkview Hospital

Cardiopulmonary Diagnostics - Parkview North

260-373-4365

I've just heard about the home studies and I think this is a horrible idea .Patient care will be severely compromised.

Thank you for your attention.

Sekpsms@cs.com

I strongly suspect that the proposal to circumvent in-lab studies is a means to create business for Head and Neck surgeons who are doing less surgery for OSA in recent decades since upper airway surgery has proven to be only 50% effective overall in treating OSA. CPAP, the main alternative, is 90%+ effective in the hands of experienced sleep practitioners. CPAP is also reversible, which surgery is not, and allows for patients to lose weight & hopefully improve their underlying sleep apnea. By circumventing an in-lab study, patients will not learn that CPAP is the state-of-the-art treatment and will be talked into surgery without a proper diagnosis or well-conducted trial of CPAP that most often negates the need for very expensive and painful surgery (that has a poor statistical treatment outcome). Respectfully, Sarah S. Mosko, Ph.D. Diplomate, American Board of Sleep Medicine St. Joseph Hospital Sleep Disorders Center Orange, Calif.

smhanhs5@cox.net

At home sleep studies are just ways for dme co to make it easier to bilk the system.

sleep1065@epix.net