

---

**Subject: Home Sleep Studies for  
Obstructive Sleep Apnea  
Number: 0061**

**Effective Date: 4/15/2006**

---

## **INSTRUCTIONS FOR USE**

*This Medical Necessity Guideline outlines the factors CareAllies considers in determining medical necessity for this indication. Please note, the terms of a participant's particular benefit plan document or summary plan description (SPD) may differ significantly from the standard upon which this Medical Necessity Guideline is based. For example, a participant's benefit plan document or SPD may contain a specific exclusion related to the topic addressed. In the event of a conflict, a participant's benefit plan document or SPD always supercedes the information in this Medical Necessity Guideline. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document or SPD. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable group benefit plan document or SPD in effect on the date of service; 2) any applicable laws/regulations, and; 3) the specific facts of the particular situation. Medical Necessity Guidelines are not recommendations for treatment and should never be used as treatment guidelines. ©2006 Intracorp/CareAllies*

---

**Portable home sleep studies are considered medically necessary for the diagnosis of obstructive sleep apnea (OSA) when ALL of the following criteria are met:**

- The individual has findings suggestive of OSA (e.g., loud snoring, excessive daytime sleepiness, or observed cessation of breathing during sleep).
- A level III device is used that at a minimum has **ALL** of the following features:
  - ability to record ventilation (at least two channels of respiratory movement, or respiratory movement and airflow)
  - ECG or heart rate
  - oxygen saturation
- Standard PSG (polysomnography) is not readily available, the patient is unable to be studied in a sleep laboratory, or a home study is being used to evaluate the treatment rendered after the diagnosis of OSA has been established by previous PSG or home sleep study.

**Portable home sleep studies are considered experimental, investigational or unproven and thus not medically necessary for ALL of the following because these indications (this list may not be all-inclusive):**

- chronic obstructive pulmonary disease (COPD)
- central apnea
- periodic leg movement
- narcolepsy
- patients who decline to undergo study in a sleep laboratory based on personal preference

**The following portable home sleep study diagnostic aid devices are considered experimental, investigational or unproven and thus not medically necessary (this list may not be all-inclusive):**

- SleepStrip (R)<sup>™</sup>
  - Watch PAT<sup>™</sup> 100S
- 

## **General Background**

Obstructive sleep apnea (OSA) occurs at any age and in both sexes. The typical patient is a male, aged 30-60, although it is more prevalent in women than previously thought. The OSA patient characteristically presents with a history of snoring, excessive daytime sleepiness, nocturnal choking or gasping, witnessed apneas during sleep, moderate obesity and, often, mild to moderate hypertension. Sleep disorders span a spectrum of specific disorders; there is no single type of diagnostic approach that is appropriate for all situations.

The following signs and symptoms may suggest significant risk for OSA:

- reported apneas by a sleep partner
- awakening with choking
- intense snoring
- severe daytime sleepiness, especially with impairment of driving
- male gender
- obesity (BMI  $\geq 30$ )
- large neck circumference  $\geq 16.5$  inches in men)
- hypertension

After evaluation of all the clinical data and test results, the physician determines the appropriate therapeutic strategies. The accepted standard diagnostic test for the investigation of suspected OSA is polysomnography (PSG), a detailed overnight sleep study that includes recording of the following:

- electroencephalogram (EEG), electrooculogram (EOG) and electromyogram (EMG)
- ventilatory variables that permit the identification of apneas and their classification as central or obstructive
- arterial O<sub>2</sub> saturation by ear or finger oximetry
- heart rate

The apnea/hypopnea index (AHI) is commonly defined as the total number of apneas plus total hypopneas that occur during total time asleep, divided by the number of hours asleep. According to the American Academy of Sleep Medicine (2001) it is currently standard in clinical practice to assess the severity of sleep disordered breathing by combining the number of apneas and hypopneas per hour of sleep in an index called the apnea hypopnea index (AHI) or the respiratory disturbance index (RDI). The RDI has been defined variously as the AHI, or as the AHI plus oxygen desaturation events unrelated to apneas or hypopneas. Authors have also described the use of AHI during the more formalized PSG testing and the RDI used in home portable monitors as a measure of the number of breathing disturbances during an hour of monitoring. For the purposes of this policy the diagnosis of OSA will be based on AHI.

A diagnosis of OSA is confirmed when testing shows that the AHI is ONE of the following:

- AHI  $\geq 15$
- AHI  $\geq 5$  when accompanied by symptoms of OSA, impaired cognition, mood disorders or insomnia, or documented hypertension, ischemic heart disease, or history of stroke.

Because PSG is a time consuming and expensive test, and because some patients may be unable or decline to undergo study in a sleep laboratory there is considerable interest in the role of a simplified, unattended, ambulatory sleep monitoring device for the investigation of OSA that would allow the patient to be studied at home, rather than in the sleep laboratory (Chesson, 1997).

Studies suggest that a number of different portable devices are able to detect OSA with relatively high accuracy, using the standard sleep-laboratory PSG as the reference standard. There is a wide variety in the capabilities of the different devices used for home sleep studies. Those that provide only blood oxygen saturation measurement are less accurate in diagnosing OSA than those that measure a number of other parameters (Chesson, 1997).

## **U.S. Food and Drug Administration (FDA)**

There are varied portable OSA diagnostic devices on the market. Some are not FDA-approved for use in the United States. Those level III devices with current FDA 510(k) approval include:

- Stardust II® (Respironics, Inc, Murrysville, PA) approved in 1996 (upgraded 2004, 2005) as a class II recording device. The Stardust II is a multi-function recording device intended to be used to collect and store physiological signals related to sleep disorders and to aid in the diagnosis of related respiratory sleep disorders. The Stardust II is only to be used under the direction and supervision of a physician, technologist or clinician.
- NovaSom QSG™ (formerly named Bedbug™, Silent Night V™) (Sleep Solutions, Palo Alto, CA) approved in 2000 as a class II device. The indicated use is the diagnostic evaluation of adults with possible sleep apnea and can score obstructive and mixed apneas. NovaSom QSG is a level III home tested device. The device consists of a bedside unit with a cable that runs to a patient module which is positioned on the patients arm. The sensors are positioned on the patient's body and connect into the patient module. The current device has been expanded from previous models to include blood oxygen saturation level, pulse rate, and respiratory effort monitoring.
- Somte' Patient Recording System (Compumedics, Abbotsford, Victoria, Australia) approved in 2003 as a class II device. The indicated use is to collect and store signals related to sleep disorders, including respiratory, ECG, and limb movement signals to aid in the diagnosis of respiratory and/or cardiac related sleep disorders which are then used as an aid in the diagnosis of cardiac and/or respiratory related sleep disorders by qualified physicians. The Somte' System is only to be used under the direction and supervision of a physician, technologist or clinician.

The FDA has approved level IV PM, class II devices through the 510(k) process. Neither of the following devices is designed to fully diagnose OSA nor do they meet the device criteria for home sleep study for the diagnosis of OSA.

- SleepStrip™ (Influent Ltd., Herzliya, Israel), was granted 510(k) (2000). SleepStrip is intended for use in screening patients for OSA by scoring respiratory air flow that correlates with AHI in adult users in overnight sleep.
- Watch PAT™ 100S (Respironics, Murrysville, PA), was FDA-approved through the 510(k) (2003). Watch PAT 100S is worn on the finger to record peripheral arterial tone intended to diagnose OSA.

### **Literature Review**

Claman (2001) reported a comparison study of 42 patients in a simultaneous home sleep monitoring Bedbug device (renamed Silent Night V and, ultimately, NovaSom OSG) to 53 patients in formal PSG showing a correlation coefficient between PSG and Bedbug of  $r=0.96$ . The authors report that the sensitivity of Bedbug for detecting AHI  $\geq 15$  was 85.7%, the specificity 95.2%.

Golpe et al. (2002) studied 55 patients in a prospective case study. The first study was performed unattended in the home with a five-channel recording device (Apnoescreen-1, CNS-Jaeger, Hochberg, Germany), and one month later PSG was performed in the sleep laboratory. Analysts were blinded to the source of the records. The diagnoses obtained from the home sleep recording service and PSG agreed in 75% of the cases. The authors concluded that home sleep studies are a viable form of diagnosing sleep apnea/hypopnea syndrome.

Reichert et al. (2002) conducted a clinical trial ( $n=51$ ) comparing the NovaSom QSG™, a five-channel home diagnostic system, to PSG both in the laboratory and in the home. Using an AHI  $\geq 15$ , the sensitivity and specificity of the in-lab NovaSom QSG versus PSG were 95% and 91%, respectively. For home NovaSom QSG versus in-lab PSG, the sensitivity was 91% and specificity was 83%. The intra-class correlation coefficient for the agreement between three separate nights of NovaSom QSG home data was  $r=0.88$ . The authors report that in the patient population suspected of having OSA NovaSom QSG was believed to have demonstrated acceptable sensitivity and specificity when compared to PSG both in the lab and self-administered in the home.

Iber et al. (2004) reported a multicenter, randomized clinical trial to compare PSG recordings obtained in the home and laboratory setting. Sleep Heart Health Study (SHHS) standardized PSG recording and scoring techniques were used for both settings. Sixty-four (of 76) nonSHHS participants recruited from seven SHHS field sites had both a laboratory and home PSG of acceptable quality. Median sleep duration was greater in the home than in the laboratory (375 vs 318 minutes, respectively,  $p < .0001$ ) as was sleep efficiency (86% vs 82%, respectively,  $p < .0024$ ). Very small, but significant increases in percentage of rapid eye movement sleep and decreases in stage 1 sleep were noted in the laboratory. The median RDI was similar in both settings (e.g., RDI with 3% desaturation: home 12.4; laboratory 9.5,  $p = .41$ ). Quartile analysis of laboratory RDI showed moderate agreement with home RDI measurements. Based on the mean of laboratory and home RDI and using a cutpoint of 20, there was a biphasic distribution, with the RDI 3% above 20 being more common in the recordings performed in the laboratory than in the home and below 20 being more common in the recordings performed in the home than in the laboratory. These differences could not be attributed to quality of recording, age, sex, or body mass index. The authors concluded that using SHHS methodology, median RDI was similar in the unattended home and attended laboratory setting with differences of small magnitude in some sleep parameters. Differences in RDI between settings resulted in a rate of disease misclassification that is similar to repeated studies in the same setting.

Whitelaw et al. (2006) reported a clinical randomized controlled trial to predict which patients have symptoms of OSA that will improve on treatment. The accuracy with which clinicians make this prediction using PSG compared to oximeter-based home monitoring was measured. Patients referred to a sleep center with suspicion of symptomatic OSA were randomized to have PSG or home monitoring. Patients with comorbidity or physiologic consequences of sleep apnea were excluded. Sleep specialists estimated the likelihood of success of treatment as greater than 50% (predicted success) or less than 50% (predicted failure) on the basis of clinical data and test results. All patients were treated for four weeks with autoadjusting continuous positive airway pressure. Success was defined as an increase greater than 1.0 in Sleep Apnea Quality of Life Index. Correct prediction rates were compared. Two hundred eighty-eight patients were enrolled. Initial patient characteristics, compliance, and improvement in quality of life at four weeks were not different in the two groups. The correct prediction rate was 0.61 with PSG and 0.64 with home monitoring (not significant). The authors conclude that the ability of physicians to predict the outcome of continuous positive airway treatment in individual patients is not significantly better with PSG than with home oximeter-based monitoring.

Yin et al. (2006) conducted a prospective study to evaluate the reliability of level III portable monitor (PM) in a home setting. The level III device (Stardust II) was evaluated in comparison to PSG among patients with OSA. Stardust II recorded longer time in bed (TIB) than total sleep time (TST) and detected more events. As a total result,  $AHI_{PM}$  is higher than  $AHI_{PSG}$  but without significant difference if considering body mass index (BMI), record, or sleep time as covariance factors. Supine and nonsupine AHI were also higher in PM than in PSG, but a significant difference was only suggested in nonsupine AHI. This may be because nonsupine consists of different positions such as lateral and prone position, and the AHI of each position obviously varies. A good correlation between PM and PSG was suggested. The agreement limits turned narrow in severe cases, and  $AHI_{PM}$  was more reliable. The agreement limits turned wider with severity in auto analyzed data.  $AHI_{PM}$  had a high sensitivity to rule in OSA. Yet a low specificity was suggested in mild to moderate OSA. If cases with  $AHI > 50/h$ , sensitivity would reach 90.0% with a specificity of 97.1%. The authors report that the correlation and discrepancy between PM and PSG suggested the usefulness of PM and its limitation should be improved in future. The authors believe that as a screening method for diagnosis at the first step PM is useful.

The American Thoracic Society (ATS) (2003) completed a systematic review of the levels of the various devices and made the following recommendations:

- **Level I:** Standard PSG is currently the standard of care.
- **Level II:** Portable monitors (PMs): comprehensive portable PSG monitors are not recommended for clinical use to evaluate patients with sleep apnea.
- **Level III:** Modified portable sleep apnea testing in the attended setting appears capable of being used to decrease/increase the probability that the patient has an AHI (apnea-hypopnea index)  $\leq$  or

≥15. There appears to be some evidence suggesting that the use of Level III PMs may be acceptable in an in-laboratory setting to rule in and to rule out OSA. Level III PMs are not recommended for use to decrease/increase the probability that the patient has an AHI ≤15 or ≥15 or to rule out OSA in the unattended setting.

- **Level IV:** PMs continuous single or dual bioparameter recording in the attended or unattended setting are not recommended for the routine use to increase or decrease the probability that a patient has an AHI ≤ or ≥15 or in diagnosis OSA.

The Institute of Clinical Systems Improvement (ICSI) (2005) conducted a systematic review of the evidence and reported that in patients with a high pretest probability of OSA; unattended portable recording for the assessment of OSA is an acceptable alternative to standard PSG in the following situations:

- patients with severe clinical symptoms that are indicative of a diagnosis of OSA and when initiation of treatment is urgent and standard PSG is not available
- for patients unable to be studied in the sleep laboratory
- For follow-up studies when diagnosis has been established by standard PSG and therapy has been initiated. The intent most often is to evaluate the response to therapy.

The main limitations of unattended sleep tests arise because of the absence of a trained technologist who, when present, is able to correct or make equipment adjustments. Additional limitations include:

- the lack of ability to enlist patient cooperation
- make continuous patient observations
- intervention for the medically unstable patient
- Provision of therapeutic interventions such as CPAP, O<sub>2</sub>, supine positioning and resuscitation.

At present the evidence supporting the expansion of sleep testing to the home 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 (ICSI, 2005).

### **Professional Societies/Organizations**

The American Academy of Sleep Medicine (AASM) classifies four levels of complexity of recording technology used for the diagnosis of sleep related breathing disorders. The sleep-disorder studies are placed in a four-category classification system where they are ranked according to their intensity:

- **Level I: Standard PSG:** Minimal requirements include recording of EEG, EOG, chin EMG, ECG, airflow, respiratory effort and oxygen saturation. Body position must be documented or objectively measured. Trained personnel must be in constant attendance and able to intervene. Leg movement recording (EMG or motion sensor) is desirable but optional.
- **Level II: Complex Home Monitoring:** This type of monitoring is defined as any system designed for use in the home that records at least four channels of physiological data (White, 1996). Comprehensive, portable PSG is the same as level I, except heart rate instead of ECG is acceptable and having trained personnel present to intervene is not required for all studies.
- **Level III: Modified, Portable Sleep Apnea Testing:** Minimum requirements include recording of ventilation (at least two channels of respiratory movement, or respiratory movement and airflow); ECG or heart rate; and oxygen saturation. Personnel are needed for preparation, but the ability to intervene is not required for all studies.
- **Level IV: Continuous (Single or Dual) Bioparameter Recording:** Only one or two physiological variables need to be recorded. The ability to intervene is not required.

## Summary

There is some evidence that portable recording devices with the capability of recording several parameters can provide measurements that correlate with standard polysomnography (PSG). However, many of the portable devices did not provide information that could be used to diagnose other sleep disorders, such as restless leg syndrome, periodic leg movement, or narcolepsy. There is insufficient information that the sensitivity and specificity of portable home sleep testing is equivalent to in-laboratory PSG. There are varied ambulatory sleep devices on the market: Some are not U.S. Food and Drug Administration (FDA)-approved for use in the United States; others have level II or level IV capabilities. NovaSom QSG by Sleep Solutions (Palo Alto, CA) is a level III device with FDA approval and has been tested in the home (Reichert, et al., 2002). Polysomnography is not available in some rural areas. Some patients decline to undergo study in a sleep laboratory. Home sleep studies are not indicated for individuals who are unable to use or connect to the monitoring device unassisted and are not considered appropriate for patients with chronic obstructive pulmonary disease (COPD) or for those suspected of having other sleep complications, such as central apnea, periodic leg movements, or narcolepsy.

---

## Coding/Billing Information

**Note: This list of codes may not be all-inclusive.**

**When medically necessary:**

CPT <sup>®</sup> * Codes	Description
95806	Sleep study, simultaneous recording of ventilation, respiratory effort, ECG or heart rate, and oxygen saturation, unattended by a technologist

HCPCS Codes	Description
	No specific code

ICD-9-CM Diagnosis Codes	Description
327.23	Obstructive sleep apnea (adult) (pediatric)

**Experimental/Investigational/Unproven/Not medically necessary:**

CPT* Codes	Description
0089T	Actigraphy testing, recording, analysis and interpretation (minimum of three-day recording)

HCPCS Codes	Description
	No specific code

ICD-9-CM Diagnosis Codes	Description
327.27	Central sleep apnea in conditions classified elsewhere
347.00	Narcolepsy, without cataplexy
496	Chronic airway obstruction, not elsewhere classified
	Multiple/varied

**\*Current Procedural Terminology (CPT<sup>®</sup>) © 2005 American Medical Association: Chicago, IL.**

---

## References

1. Agency for Health Care Policy and Research (AHRQ). Systematic review of the literature regarding the diagnosis of sleep apnea. Health technology assessment. AHCPR pub. no. 99-E0021998. Update 2005 Accessed Apr 26, 2004; Feb 23, 2005, Feb 23, 2006. Available at URL address: <http://www.ahrq.gov/clinic/epcsums/apneasum.htm>
2. Thorpy M, Chesson A, Kader G, Millman R, Potolicchio S Jr., Reite M, et al. (Standards of Practice Committee of the American Sleep Disorders Association [ASDA]). Indications for the clinical use of unattended portable recording for the diagnosis of sleep-related breathing disorders. Accessed April 26, 2004, Feb 23, 2005, Feb 23, 2006. Available at URL address: <http://www.aasmnet.org/PDF/UsePSGParameter.pdf>
3. American Sleep Disorders Association (ASDA). Practice parameters for the indications for polysomnography and related procedures. *Sleep Update* 2005. 1997;20(60):406-22.
4. ATS/ACCP/AASM Taskforce Steering Committee. Executive summary on the systematic review and practice parameters for portable monitoring in the investigation of suspected sleep apnea in adults.. *Am J Respir Crit Care Med*. 2004;169:1160-3.
5. Bar A, Pillar G, Dvir I, Sheffy J, Schnall R, Peretz L. Evaluation of a portable device based on peripheral arterial tone for unattended home sleep studies. *Chest*. 2003 Mar;123(3):695-703.
6. Chervin R, Murman D, Malow B, Totten V. Cost-utility of three approaches to the diagnosis of sleep apnea: polysomnography, home testing, and empirical. *Ann Intern Med*. 1999 Mar;130(6):496-550.
7. Chesson A, Ferber R, Fry J, Grigg-Damberger M, Hartse K, Hurwitz T, et al. The indications for polysomnography and related procedures [report]. American Sleep Disorder Association (ASDA). *Sleep*. 1997;20:406-22.
8. Chesson A, Berry R, Pack A. Practice parameters for the use of portable monitoring devices in the investigation of suspected obstructive sleep apnea in adults. *Sleep*. 2003;26(7):907-13.
9. Claman D, Murr A, Trotter K. Clinical validation of the Bedbug<sup>™</sup> in the detection of obstructive sleep apnea. *Otolaryngol Head Neck Surg*. 2001;125:227-30.
10. Dingli K, Coleman M, Vennelle M, Finch P, Wraith P, Mackay T, et al. Evaluation of a portable device for diagnosing the sleep apnea/hypopnea syndrome. *Eur Respir J*. 2003;21:253-9.
11. Fitzpatrick M, Alloway C, Wakeford T, MacLean A, Munt P, Day A. Can patients with obstructive sleep apnea titrate their own continuous positive airway pressure? *Am J Respir Crit Care Med*. 2003;167:716-22.
12. Flemons W, Littner M. Measuring agreement between diagnostic devices. *Chest*. 2003 Oct;124(4):1535-42.
13. Flemons W. Obstructive sleep apnea. *N Engl J Med*. 2002 Aug;347(7):498-504.
14. Fry J, DiPhillipo M, Curran K. Full polysomnography in the home. *Sleep*. 1998;21(6):635-42.
15. Gagnadoux F, Pelletier-Fleury N, Philippe C, Rakotonanahary D, Fleury B. Home unattended vs hospital telemonitored polysomnography in suspected obstructive sleep apnea. *Chest*. 2002;121(3):753-8.

16. Golpe R, Jiminez A, Carpizo R. Home sleep studies in the assessment of sleep apnea/hypopnea syndrome. *Chest*. 2002;122(4):1-14.
17. HAYES Medical Technology Directory™ Home Sleep Studies for Diagnosis of Obstructive Sleep Apnea in Adults. Lansdale, PA: HAYES Inc.; ©2003 Winifred S. Hayes, Inc. 2003 Apr. Updated 2004 Apr. 2005 Feb.
18. Iber C, Redline S, Kaplan Gilpin AM, Quan SF, Zhang L, Gottlieb DJ, Rapoport D, Resnick HE, Sanders M, Smith P Polysomnography performed in the unattended home versus the attended laboratory setting--Sleep Heart Health Study methodology. *Sleep*. 2004 May 1;27(3):536-40.
19. Institute for Clinical System Improvement (ICSI). Diagnosis and treatment of obstructive sleep apnea. Updated May 2005. Accessed Feb 24, 2005, Feb 23, 2006. Available at URL address: <http://www.icsi.org/knowledge/detail.asp?catID=29&itemID=891>
20. Li C, Flemons W. State of home sleep studies. *Clin Chest Med*. 2003;124(4):1543-79.
21. Nieto F, Young T, Lind B, Sharar E, Samet J, Redline S, et al. Association of sleep-disordered breathing, sleep apnea, and hypertension in a large community-based study. *JAMA*. 2000;283(14):1829-36.
22. Phillipson E. Obstructive sleep apnea. In: Braunwald E, Fauci AS, Isselbacher KJ, Kasper DL, Hauser SL, Longo DL, Jameson JL, editors. *Harrison's principles of internal medicine*. 15<sup>th</sup> ed. Philadelphia, PA: McGraw-Hill Companies, Inc.; 2001. Chapter 264: sleep apnea.
23. Portier F, Portmann A, Czernichow P, Vascaut L, Devin E, Benhamou D, et al. Evaluation of home versus laboratory polysomnography in the diagnosis of sleep apnea syndrome. *Am J Respir Crit Care Med*. 2000;162:814-8.
24. Reichert J, Bloch D, Cundiff E, Votteri B. Comparison of the NovaSom QSG™, a new sleep apnea home-diagnostic system, and polysomnography. *Sleep Med*. 2003;213-8.
25. Shochat T, Hadas N, Kerkhofs M, Herchuelz T, Penzel T, Peter J, Lavie P. The SleepStrip™: an apnea screen for the early detection of sleep apnea syndrome. *Eur Respir J*. 2002;19:121-6
26. Yin M, Miyazaki S, Ishikawa K. Evaluation of type 3 portable monitoring in unattended home setting for suspected sleep apnea: factors that may affect its accuracy. *Otolaryngol Head Neck Surg*. 2006 Feb;134(2):204-9
27. Whitelaw W, Brant R, Flemons W. Clinical Usefulness of Home Oximetry Compared with Polysomnography for Assessment of Sleep Apnea. *Am J Respir Crit Care Med* 2005;171:188-93.