

## **Corporate Medical Policy**

### **Obstructive Sleep Apnea**

#### **Description of Service**

There are multiple methods of testing available to diagnose obstructive sleep apnea (OSA). The method used is influenced by symptom severity, comorbid condition status and other patient-centric factors.

#### **Background**

Obstructive sleep apnea is a disorder that is characterized by obstructive apneas and hypopneas caused by repetitive collapse of the upper airway during sleep. Risk Factors for OSA include patients with all 4 of the following symptoms and are considered to be at high risk for OSA: habitual snoring; observed apneas; excessive daytime sleepiness; and a body mass index (BMI) > 35. If there is no sleep partner to determine witnessed apneas, then factors such as age, neck size, and gender can be considered.

Excessive daytime sleepiness and other factors suggestive of sleep apnea may be subjective and are assessed by questionnaires such as the Epworth Sleepiness Scale (ESS). The sleep fragmentation associated with repeated sleep disruption can lead to impairment of daytime activity. Adult patients with OSA associated daytime somnolence are thought to be at higher risk for vehicular accidents while OSA in children may result in neurocognitive impairment and behavioral problems.

OSA can also affect the cardiovascular and pulmonary systems. OSA can lead to episodic hypoxemia, alveolar hypoventilation, hypercapnia, and acidosis. This is associated with hypertension, cardiac arrhythmias, pulmonary hypertension, and systolic hypertension.

#### **Policy Statement**

GEHA will provide coverage for the diagnosis and medical management of obstructive sleep apnea in members with symptoms suggestive of OSA when it is determined to be medically necessary because the medical criteria and guidelines as documented below have been demonstrated.

#### **When Testing for Obstructive Sleep Apnea (OSA) is Covered**

**A: Unattended home sleep testing (HST): 95800, 95801, 95806**

A single unattended (unsupervised) home sleep test (95800, 95801, 95806) may be considered medically necessary in adult patients who are at moderately high risk for obstructive sleep apnea (OSA) and have no evidence by history or physical examination of a health condition that might alter ventilation or

require alternative treatment, including central sleep apnea, heart failure, chronic pulmonary disease, alveolar hypoventilation syndrome, narcolepsy, injurious or potentially injurious parasomnias, underlying neuromuscular disease. When the exceptions above are not present, Randomized clinical trials have reported that home sleep testing is non-inferior to testing in the sleep lab. Sleep studies using devices that do not provide a measurement of apnea-hypopnea index (AHI) and oxygen saturation are considered not medically necessary because they do not provide sufficient information to prescribe treatment.

B: Attended sleep study (polysomnography) exams: 95805, 95807, 95808, 95810, 95811

Attended sleep study exams include 95807, 95808, 95810 and 95811. Multiple sleep latency sleep latency (MSLT), 95805, may also be an attended study if clinically indicated. All of these exams may be attended when indicated and will be performed in a facility considered medically necessary in the presence of the following conditions that inhibit the accuracy of an HST:

1. Underlying neuromuscular disease such as myasthenia gravis, amyotrophic lateral sclerosis, muscular dystrophy, or CVA with residual respiratory impairment
2. Severe pulmonary disease such as COPD or asthma demonstrated by an FEV1 < 39 and P02 < 60 on room air or a PCO2 > 45
3. Severe congestive heart failure manifested by a LVEF < 39% or moderately severe diastolic failure on echocardiogram
4. Normal prior HST in patients at high risk for OSA
5. Periodic limb movements (PLM) associated with injurious events to the patient
6. Central apneas previously diagnosed and documented on prior sleep study demonstrating 50% of total respiratory events are central in nature.
7. Documentation/indication that the patient is mentally or physically impaired to an extent that they, nor their capable aide/caregiver, are capable of operating the HST equipment.
8. The patient is < 18 years old

C: Unattended Auto-adjusting continuous positive airway pressure (APAP): E0601

APAP (E0601) may be considered medically necessary for the titration of pressure in adult patients with clinically significant OSA defined as those patients who have:

1. An apnea/hypopnea index (AHI) or respiratory disturbance index (RDI) of  $\geq 15$  per hour, or
2. An AHI or RDI of  $\geq 5$  per hour in a patient with excessive daytime sleepiness or unexplained hypertension.

D: Split-night study: 95811

American Academy for Sleep Medicine (AASM) Practice Parameters indicates that a split-night study (95811) is appropriate if the following 3 criteria are met:

1. An AHI of  $\geq 15$  is documented during a  $\geq 2$  hours of diagnostic sleep study. Split-night studies may sometimes be considered at an AHI of  $\geq 15$  to  $\leq 40$ , based on clinical judgment if there are also repetitive long obstructions and major

desaturations.

2. CPAP titration will be carried out for  $\geq 3$  hours
3. Criteria is met for an in-lab study

Of note, sleep study documents that CPAP eliminates or nearly eliminates the respiratory events during Rapid Eye Movement (REM) and non-REM (NREM) sleep, including REM sleep with the patient in the supine position.

#### E: Attended sleep study continuous positive airway pressure (CPAP) with titration:

Attended CPAP titration in which an additional night PSG is used to titrate continuous positive airway pressure (95811) is performed in a facility may be considered medically necessary for patients who met the requirements for an attended PSG and where a split-night was not feasible, as determined by:

1. Respiratory events could not be suppressed during the time remaining in a Split Night study or
2. Patients with OSA who have persistent significant symptoms despite documented  $AHI < 5$  or  $> 15$  on CPAP with documented compliance with CPAP (CPAP used for 70 percent of nights for  $\geq 4$  hours per night, for  $\geq 2$  months)

#### **When Treatment for Obstructive Sleep Apnea (OSA) is Not Covered**

Diagnostic or Therapeutic Procedures considered experimental and investigational because clinical effectiveness has not been established include:

1. Portable sleep apnea devices inconsistent with the descriptions outlined within sections A and B of this policy (eg, WatchPat, etc.)
2. PAP-NAP
3. Sleep Strip
4. Sonography
5. Diagnostic audio recording
6. MSLT and MWT for OSA not meeting criteria for narcolepsy
7. Provent Sleep Apnea Therapy
8. Positional Devices (eg, Zzoma, SlumberBumper, etc.)
9. Nasal Dilators
10. Apnea-Triggered Muscle Stimulation
11. Winx Therapy System/Oral Pressure Therapy
12. Hypoglossal Nerve Neurostimulation
13. Somnoplasty and Coblation
14. Repose (AIRvance Tongue Suspension) System and the Encore Tongue Base Suspension
15. Adult Lingual or Pharyngeal Tonsillectomy
16. Injection Snoreplasty Cautey-Assisted Palatal Stiffening
17. Pillar™ Palatal Implant System

18. Flexible Positive Airway Pressure
19. Transpalatal Advancement Pharyngoplasty
20. Nasal Surgery
21. The Advance System
22. Tongue Base Reduction Surgery
23. Partial Glossectomy

**CPT or HCPCS Codes Covered if Criteria are Met:**

95800 - Sleep study, unattended, simultaneous recording; heart rate, oxygen saturation, respiratory analysis (eg, by airflow or peripheral arterial tone), and sleep time

95801 - Sleep study, unattended, simultaneous recording; minimum of heart rate, oxygen saturation, and respiratory analysis (eg, by airflow or peripheral arterial tone)

95806 - Sleep study, unattended, simultaneous recording of, heart rate, oxygen saturation, respiratory airflow, and respiratory effort (eg, thoracoabdominal movement)

E0601 - Continuous positive airway pressure (CPAP) device

95805 - Multiple sleep latency or maintenance of wakefulness testing, recording, analysis and interpretation of physiological measurements of sleep during multiple trials to assess sleepiness

95807 - Sleep study, simultaneous recording of ventilation, respiratory effort, ECG or heart rate, and oxygen saturation, attended by a technologist

95808 - Polysomnography; any age, sleep staging with 1-3 additional parameters of sleep, attended by a technologist

95810 - Polysomnography; age 6 years or older, sleep staging with 4 or more additional parameters of sleep, attended by a technologist

95811 - Polysomnography; age 6 years or older, sleep staging with 4 or more additional parameters of sleep, with initiation of continuous positive airway pressure therapy or bi-level ventilation, attended by a technologist

**Acronym Legend:**

AASM – American Academy of Sleep Medicine

AHI – Apnea/Hypopnea Index

APAP – Automatic Positive Air Pressure

BMI – Body Mass Index

CPAP – Continuous Positive Air Pressure

CSA – Central Sleep Apnea

ECG – Electro Cardio Gram  
ESS – Epworth Sleepiness Scale  
HST – Home Sleep Test  
MSLT – Multiple Sleep Latency Test  
MWT – Maintenance of Wakefulness Test  
NREM – Non Rapid Eye Movement  
OSA – Obstructive Sleep Apnea  
PAP-NAP – Positive Air Pressure - NAP  
PLM – Periodic Limb Movement  
PSG – Polysomnography (Sleep exam)  
RCT – Randomized Clinical Trials  
RDI – Respiratory Disturbance Index  
REI – Respiratory Event Index  
REM – Rapid Eye Movement  
RERA – Respiratory Effort-Related Arousal

**STOP-BANG - Snoring, Tired, Observed, Pressure, Body Mass Index, Age, Neck Size, Gender**

**Policy Rationale**

Clinical guidelines on the use of unattended home monitoring devices for the diagnosis of obstructive sleep apnea in adults from the American Academy of Sleep Medicine (Collop, et al., 2007) state that unattended sleep studies are not appropriate for the diagnosis of OSA in patients with significant comorbid medical conditions that may degrade the accuracy of unattended sleep studies, including moderate to severe pulmonary disease, neuromuscular disease, or congestive heart failure. The guidelines note that unattended sleep studies are not appropriate for the diagnostic evaluation of OSA in patients suspected of having other sleep disorders. They also suggest that unattended sleep studies may be indicated for the diagnosis of OSA in patients for whom in-laboratory NPSG is not possible by virtue of immobility, safety, or critical illness. Unattended sleep studies may be indicated to monitor the response to non-continuous positive airway pressure (CPAP) treatments for obstructive sleep apnea, including oral appliances, upper airway surgery, and weight loss (typically considered at least 10% loss or gain). The guidelines note that in laboratory NPSG may be indicated in cases where unattended sleep studies are technically inadequate or fail to establish the diagnosis of OSA in patients with a high pretest probability.

According to the American Sleep Disorders Association (ASDA) (1997), split-night study NPSG is indicated for patients with an AHI greater than 40 events/hour during the first 2 hours of a diagnostic NPSG. Split-night studies may also be considered for patients with an AHI of 20 to 40 events/hour, based on clinical observations, such as the occurrence of obstructive respiratory events with a prolonged duration or in

association with severe oxygen desaturation. Split-night studies require the recording and analysis of the same parameters as a standard diagnostic NPSG. Accepted guidelines provide that the diagnostic portion of a split-night study should be at least 2 hours duration. A minimum of 3 hours sleep is preferred to adequately titrate CPAP after this treatment is initiated.

Following a standard diagnostic NPSG, the available literature indicates that OSA patients should receive CPAP titration to specify the lowest CPAP level, which abolishes obstructive apneas, hypopneas, and snoring in all sleep positions and sleep stages. On occasion, an additional full-night CPAP titration NPSG may also be required following split-night study if the split-night NPSG did not allow for the abolishment of the vast majority of obstructive respiratory events or prescribed CPAP treatment does not control clinical symptoms. Alternatively, persons diagnosed with portable monitoring may be prescribed an auto-titrating positive airway pressure device (APAP) that does not require attended titration.

According to guidelines from the American Academy of Sleep Medicine (Chesson et al, 1997), polysomnography with video recording and additional EEG channels in an extended bilateral montage may be indicated to assist with the diagnosis of paroxysmal arousals or other sleep disruptions that are thought to be seizure related when the initial clinical evaluation and results of a standard EEG are inconclusive.

Accepted guidelines indicate that nocturnal pulse oximetry alone is not appropriately used as a case finding or screening method to rule out OSA. Pulse oximetry, when used alone, has not been shown to have an adequate negative predictive value to rule out OSA i.e., all patients with symptoms suggestive of OSA would require polysomnography regardless of whether the pulse oximetry was positive or negative.

In 2012 Rosen et al published results from the Home PAP study, reported that a home-based strategy for diagnosis and treatment of OSA was non-inferior to in-laboratory PSG. Home PAP was an independently funded multicenter trial of 373 patients with a high pretest probability of moderate severe OSA. Patients were randomized to diagnosis with limited channel portable sleep studies (airflow, respiratory effort, oxygen saturation, electrocardiogram, and body position) and titration with APAP, or to laboratory-based PSG with CPAP titration. Repeat in-lab PSG was required in 11.1% of patients while the technical failure rate in the home arm, requiring in-lab PSG, was 21.4%. The 2 strategies were similar for acceptance of CPAP therapy, titration pressures, effective titrations, time to treatment, and improvement in ESS scores. Kuna et al conducted a non-inferiority trial that compared home testing with a type 3 portable monitor followed by at least 3 nights of APAP versus in-laboratory titration and testing in 296 patients. Patients with an AHI of 15 or more on home monitoring were scheduled for 4- to 5-day APAP titration, while patients with an AHI of less than 15 per hour on home monitoring underwent in-laboratory PSG. Improvement in ESS, Center for Epidemiologic Studies Depression Scale, Mental Component Summary of the 12-Item Short-Form Health (SF-12), and Functional Outcomes of Sleep Questionnaire (FOSQ) was similar for home-based and hospital based treatment, meeting non-inferiority parameters. Bruyneel and Skomro have also found outcomes to be similar between home diagnosis and treatment in comparison with hospital-based diagnosis (HST) and treatment titration when both strategies are supervised by a sleep medicine specialist. In addition, use of unattended home PSG has also been reported as an alternative to in-lab PSG for patients with comorbidities.

Stepnowsky et al. (2004) examined the nightly variability of AHI in a retrospective comparison of 3 sequential nights of testing performed in the home in 1091 patients who were referred for diagnostic testing of sleep-disordered breathing (SDB). Based on night 1, approximately 90% of patients were

classified consistently with "AHI-high" (the highest AHI measured across the 3 nights) using an AHI threshold of 5. However, 10% were misclassified on night 1 relative to the highest AHI level. The authors concluded that there is little, if any, significant nightly change in SDB in the home environment.

The results of these clinical studies demonstrate, that night-to-night variability in home sleep testing is comparable to laboratory-based PSG and that a single night testing can correctly diagnose OSA in the majority of patients with a high pretest-probability of OSA.

Recent comparative effectiveness research studies have shown that clinical outcomes of patients with a high pretest probability for obstructive sleep apnea who receive ambulatory management using portable-monitor testing have similar functional outcomes and adherence to CPAP treatment, compared to patients managed with in-laboratory PSG (Kuna, 2010).

Mulgrew et al. (2007) randomly assigned 68 high-risk patients identified by a diagnostic algorithm to PSG or ambulatory titration by using a combination of auto-CPAP and overnight oximetry. After 3 months, there were no differences in AHI on CPAP between the PSG and ambulatory groups, or in the ESS score, or quality of life. Adherence to CPAP therapy was better in the ambulatory group than in the PSG group. Results of another randomized controlled multicenter non inferiority study by Antic et al. (2009) that compared nurse-led home diagnosis and CPAP therapy with physician-led current best practice in OSA management in 195 patients complement and extend the findings of Mulgrew et al. There were no differences between both groups in ESS score and CPAP adherence at 3 months. Within-trial costs were significantly less in the simplified home model. Cost-effectiveness of home APAP titration compared to manual laboratory titration was also confirmed by McArdle et al. (2011). In this randomized controlled study involving 249 patients with moderate to severe OSA without serious comorbidities, outcomes at one month indicated that average nightly CPAP use, subjective sleepiness, quality of life, cognitive function and polysomnographic outcomes were similar among the per-protocol groups.

Berry et al. (2008) compared a clinical pathway using portable monitoring (PM) for diagnosis and unattended APAP for selecting an effective CPAP with another pathway using PSG for diagnosis and treatment of OSA in a randomized parallel group study involving 106 patients with a high likelihood of having OSA. After 6 weeks of treatment 40 patients in the PM-APAP group and 39 in the PSG arm were using CPAP treatment. The mean nightly adherence, decrease in ESS score, improvement in functional score and CPAP satisfaction did not differ between the groups.

In a randomized controlled study involving 102 patients with suspected OSA, Skomro et al. (2010) compared a home-based diagnostic and therapeutic strategy for OSA with in-laboratory PSG and CPAP titration (using mostly split-night protocol). Subjects in the home monitoring arm underwent 1 night of level three testing followed by 1 week of auto-CPAP therapy (Auto-Set) and 3 weeks of fixed-pressure CPAP based on the 95% pressure derived from the auto-CPAP device. After 4 weeks of CPAP therapy, there were no significant differences in daytime sleepiness (ESS), sleep quality, quality of life, blood pressure and CPAP adherence.

In another randomized controlled non-inferiority study Kuna et al. (2011) compared functional outcome and treatment adherence in veterans with suspected OSA who received ambulatory versus in-laboratory testing for OSA. Home testing consisted of a type 3 portable monitor recording followed by at least three nights using an APAP device. In-laboratory testing was performed as a split-night PSG if clinically indicated. Of the 296 subjects enrolled, 260 (88%) were diagnosed with OSA, and 213 (75%) were

initiated on CPAP. At 3 months of CPAP treatment the functional outcome score improved  $1.74 \pm 2.81$  in the home group and  $1.85 \pm 2.46$  in the in-laboratory group. CPAP adherence was  $3.5 \pm 2.5$  hours/day in the home group and  $2.9 \pm 2.3$  hours/day in the in-laboratory group ( $P = 0.08$ ).

Lettieri et al. (2011) conducted an observational cohort study including 210 patients with OSA that were grouped into one of three pathways based on the type and location of their diagnostic and titration. Group 1 underwent unattended, type III home diagnostic (Stardust II) and unattended home APAP titrations; group 2 underwent in-laboratory, type I diagnostic and CPAP titration studies; group 3 underwent type I diagnostic and APAP titration studies. Group 1 was primarily managed and educated in a primary care clinic, whereas groups 2 and 3 received extensive education in an academic sleep medicine center. The authors found that type of study and location of care did not affect PAP adherence. Patients in all three pathways demonstrated equivalent use of PAP despite differences in polysomnographic procedures, clinical education and follow-up.

A single-blind randomized controlled trial with 200 CPAP-naive patients found home-based APAP to be as effective as automatic in-laboratory titrations in initiating treatment for OSA at 3-month follow-up with no significant difference in CPAP use, ESS score, OSLEP, Functional Outcomes of Sleep Questionnaire or SF-36 between the groups (Cross et al., 2006).

Another multicenter randomized controlled prospective study involving 35 patients with newly diagnosed severe obstructive OSA concluded that OSA can be effectively and reliably treated with APAP at home, with reduced time from diagnosis to treatment and at a lower cost compared with in-laboratory titration (Planes et al., 2003).

Prescribed split-night studies with those in full-night patients, matched 1:2 using an AHI of  $\pm 15\%$  and Epworth score of  $\pm 3$  units. There were no differences between the groups in long-term CPAP use, median nightly CPAP use, post-treatment Epworth scores and frequency of nursing interventions/clinic visits required. The median time from referral to treatment was less for the split-night patients than for full-night patients.

Khawaja et al. (2010) reviewed 114 consecutive full-night PSGs (FN-PSG) on subjects with OSA and compared the AHI from the first 2 hours (2 hr-AHI) and 3 hours (3 hr-AHI) of sleep with the "gold standard" AHI from FN-PSG (FN-AHI), considering OSA present if FN-AHI  $\geq 5$ . The authors found that the AHI derived from the first 2 or 3 hours of sleep is of sufficient diagnostic accuracy to rule-in OSA at an AHI threshold of 5 in patients suspected of having OSA. This study

Attended Polysomnography for Evaluation of Sleep Disorders: Medical Policy (Effective 04/01/2016) suggests that the current recommended threshold for split-night studies (AHI  $\geq 20$  to 40) may be revised to a lower number, allowing for more efficient use of resources.

Collen et al. (2010) evaluated 400 consecutive patients presenting for follow-up 4-6 weeks after initiating CPAP therapy. Among the patients, 267 and 133 underwent split- and dual-night studies, respectively. The mean number of days between diagnosis and titration in the dual-night group was 80.5 days. There was no difference in therapeutic adherence between groups as measured by percentage of nights used (78.7% vs 77.5%;  $p = 0.42$ ), hours per night used (3.9 vs 3.9;  $p = 0.95$ ), or percentage of patients using CPAP for  $>4$  hours per night for  $>70\%$  of nights (52.9% vs 51.8%;  $p = 0.81$ ). There was no difference in use after adjusting for severity of disease. The authors concluded that split-night PSG does not adversely affect short-term CPAP adherence in patients with OSA.



CMS finds that the evidence is sufficient to determine that the results of the sleep tests identified below can be used by a beneficiary's treating physician to diagnose OSA:

1. Type I PSG is covered when used to aid the diagnosis of OSA in beneficiaries who have clinical signs and symptoms indicative of OSA if performed attended in a sleep lab facility.
2. A type II or type III sleep testing device is covered when used to aid the diagnosis of OSA in beneficiaries who have clinical signs and symptoms indicative of OSA if performed unattended in or out of a sleep lab facility, or attended in a sleep lab facility.
3. A type IV sleep testing device measuring 3 or more channels, one of which is airflow, is covered when used to aid the diagnosis of OSA in beneficiaries who have signs and symptoms indicative of OSA if performed unattended in or out of a sleep lab facility, or attended in a sleep lab facility.

The American Academy of Pediatrics (AAP) published a 2012 guideline on the diagnosis and management of uncomplicated childhood OSA associated with adenotonsillar hypertrophy and/or obesity in an otherwise healthy child treated in the primary care setting, which updates AAP's 2002 guidelines. (51,52) AAP recommends that all children/adolescents should be screened for snoring, and PSG should be performed in children/adolescents with snoring and symptoms/signs of OSA as listed in the guideline. If PSG is not available, an alternative diagnostic test or referral to a specialist may be considered. The estimated prevalence rates of OSA in children/adolescents range from 1.2% to 5.7%. High-risk patients should be reevaluated with an objective test or referred to a sleep specialist. CPAP is recommended if adenotonsillectomy is not performed or if OSA persists postoperatively. Weight loss is recommended in addition to other therapy in patients who are overweight or obese, and intranasal corticosteroids are an option for children with mild OSA in whom adenotonsillectomy is contraindicated or for mild postoperative OSA.

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