

National Imaging Associates, Inc.\*

2021

# Magellan Clinical Guidelines For Medical Necessity Review

## SLEEP STUDY GUIDELINES

*Effective January 1, 2021 – December 31, 2021*



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# Guidelines for Clinical Review Determination

## **Preamble**

Magellan is committed to the philosophy of supporting safe and effective treatment for patients. The medical necessity criteria that follow are guidelines for the provision of diagnostic imaging. These criteria are designed to guide both providers and reviewers to the most appropriate diagnostic tests based on a patient's unique circumstances. In all cases, clinical judgment consistent with the standards of good medical practice will be used when applying the guidelines. Determinations are made based on both the guideline and clinical information provided at the time of the request. It is expected that medical necessity decisions may change as new evidence-based information is provided or based on unique aspects of the patient's condition. The treating clinician has final authority and responsibility for treatment decisions regarding the care of the patient.

# Guideline Development Process

These medical necessity criteria were developed by Magellan Healthcare for the purpose of making clinical review determinations for requests for therapies and diagnostic procedures. The developers of the criteria sets included representatives from the disciplines of radiology, internal medicine, nursing, cardiology, and other specialty groups. Magellan's guidelines are reviewed yearly and modified when necessary following a literature search of pertinent and established clinical guidelines and accepted diagnostic imaging practices.

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## 94660 – Sleep Disorder Treatment Initiation and Management

### CPT Codes: 94660

#### **INDICATIONS FOR SLEEP DISORDER TREATMENT INITIATION AND MANAGEMENT:**

(ATS, 2010; Epstein, 2009; Kushida, 2006, 2008)

- The patient has been diagnosed with sleep disordered breathing that would benefit from treatment using a positive airway pressure (PAP) device, AND all of the following:
  - The chief purpose of the office visit with the physician is to initiate PAP device treatment or address issues related to the PAP device
  - The patient requires education or problem solution related to the PAP device
  - The visit does not include discussion of other health issues beyond initiation and management of a PAP device.

**NOTE:** This service should not occur for the same patient on the same date as an evaluation and management service.

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#### **BACKGROUND:**

Treatment of sleep disorders is often managed during standard evaluation and management services. The “Sleep Disorder Treatment Initiation and Management” service can be used when the only purpose for the office visit is for the implementation of, or issue resolution related to, a PAP device. Devices include Continuous Positive Airway Pressure (CPAP), Bi-Positive Airway Pressure (BiPAP), Auto-Adjusting Positive Airway Pressure (APAP), and Variable Positive Airway Pressure (VPAP).

Kapur, et al (2017) reported on an updated clinical practice guideline from the American Academy of Sleep Medicine. This updated guideline is based on a systematic review evaluated by a sleep medicine expert task force.

Based on expert consensus, implementation of the following is necessary for appropriate and effective management of patients with OSA treated with positive airway pressure: 1. Treatment of OSA with PAP therapy should be based on a diagnosis of OSA established using objective sleep apnea testing. 2. Adequate follow-up, including troubleshooting and monitoring of objective efficacy and usage data to ensure adequate treatment and adherence, should occur following PAP therapy initiation and during treatment of OSA. (Patil, 2019)

#### **POLICY HISTORY:**

**Review Date:** July 2019

**Review Summary:**

- Additional background information added

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**Review Date:** May 2020

**Review Summary:** No changes

**REFERENCES:**

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Kushida CA, Littner MR, Hirshkowitz M, 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*. March 2006; 29(3):375-380.

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## 95811 – Sleep Study, attended

### CPT Codes:

**95805, 95807, 95808, 95810, 95811**

### INDICATIONS FOR SLEEP STUDY, ATTENDED – ADULTS:

#### Suspected sleep-related breathing disorders

With a high pre-test probability of moderate to severe OSA (Collop, 2012, Ghuman, 2011; Kapur, 2017; Kundel, 2017):

#### Signs and symptoms including:

- Excessive daytime sleepiness; **AND**
- Any **TWO** of the following:
  - Habitual loud snoring
  - Witnessed apneas or gasping and choking
  - Diagnosed hypertension
  - BMI  $\geq$  30 or large neck circumference ( $\geq$  17 inches in men,  $\geq$  16 inches in women);
- **AND**
- There is a contraindication for an unattended sleep study (see below)

#### OR

- A member of a high-risk population, including: (Epstein, 2009)
  - Congestive heart failure
  - Atrial fibrillation
  - Chronic kidney disease
  - Treatment refractory hypertension
  - Type 2 diabetes
  - Nocturnal dysrhythmias
  - Stroke
  - Pulmonary hypertension
  - High-risk driving populations
  - Obesity (BMI  $\geq$  35)
  - Preoperative for bariatric surgery
  - Craniofacial or upper airway soft tissue abnormalities, including:
    - Adenotonsillar enlargement
    - Modified Mallampati score of 3 or 4
    - Retrognathia
    - Lateral peritonsillar narrowing
    - Elongated/enlarged uvula
    - High arched/narrow hard palate

- Nasal abnormalities (polyps, deviation, valve abnormalities, turbinate hypertrophy)
- **AND** any **TWO** of the following
  - Excessive daytime sleepiness (with Epworth Sleepiness Scale (ESS) score > 10) (Johns, 1991)
  - Habitual loud snoring
  - Witnessed apneas or gasping and choking
- **AND** there is a contraindication for an unattended sleep study (see below)
- **With documented clinical concern for central sleep (CSA) based on** (Muza, 2015):
  - Sleep symptoms (e.g., fragmented sleep, insomnia, apneas, daytime sleepiness); **AND**
  - Comorbid medical conditions (e.g., heart failure, opioid use, neurological disorders)

**CONTRAINDICATIONS FOR A HOME SLEEP STUDY, UNATTENDED - ADULTS**

<b>Comorbid Medical Conditions</b>
<ul style="list-style-type: none"> <li>• Moderate to severe pulmonary disease with: FEV1/FVC 0.7 and FEV1 less than 80% predicted, oxygen use, daytime hypercapnia or hypoxemia.</li> <li>• Obesity hypoventilation syndrome: BMI &gt; 35 plus arterial blood gas with PCO<sub>2</sub> &gt; 45, BMI &gt; 35 plus inability to lie flat in bed, or BMI ≥ 40</li> <li>• Chronic opiate medication use</li> <li>• Neuromuscular disease (e.g., Parkinson’s disease, ALS, myotonic dystrophy, spina bifida)</li> <li>• Congestive Heart Failure: NYHA class III or IV, or LVEF less than 45%</li> <li>• Stroke</li> </ul>
<b>Comorbid Sleep Disorders, known or suspected</b>
<ul style="list-style-type: none"> <li>• Periodic Limb Movement Disorder</li> <li>• Parasomnia</li> <li>• REM Behavior Disorder</li> <li>• Nocturnal seizures</li> <li>• Narcolepsy or idiopathic hypersomnia</li> <li>• Circadian Rhythm Disorder</li> <li>• Central sleep apnea or complex sleep apnea</li> <li>• Hypoventilation</li> <li>• Sleep-related hypoxemia</li> <li>• Severe insomnia</li> </ul>
<b>Technical Contraindications</b>
<ul style="list-style-type: none"> <li>• Inability to follow instructions or lack of mobility or dexterity to use portable equipment and the absence of a competent caregiver</li> <li>• Previous negative or technically inadequate home sleep study*</li> </ul>
<b>Other</b>
<ul style="list-style-type: none"> <li>• Low pre-test probability of sleep apnea**</li> <li>• Screening for asymptomatic individuals in high risk populations</li> </ul>

\* If a single home sleep study is inconclusive or technically inadequate or negative with continued clinical suspicion of OSA, an attended polysomnography (PSG) is recommended (Kapur, 2017).

\*\* If there is a low pre-test probability of sleep apnea, but well documented ongoing concern for a sleep disorder causing functional impairment (e.g., upper airway resistance syndrome or mild OSA), PSG may be indicated.

**Suspected narcolepsy/idiopathic hypersomnia** (Kapur, 2017)

- A multiple sleep latency test (MSLT) is indicated in the evaluation of hypersomnia including narcolepsy and idiopathic hypersomnia (Aurora, 2012; Littner, 2005)
- PSG must be done on the night preceding MSLT to rule out other sleep disorders and to document adequate nocturnal sleep time (6 hours).
- Narcolepsy is characterized by:
  - Excessive daytime sleepiness
  - Cataplexy
  - Hypnagogic hallucinations
  - Sleep paralysis
- Idiopathic hypersomnia is characterized by:
  - Excessive daytime sleepiness despite adequate sleep in the absence of another sleep disorder

\* All other indications for an MSLT are considered experimental and investigational since effectiveness for other indications has not been established.

**Suspected parasomnias and nocturnal seizure disorders** (Kapur, 2017; Kushida, 2005):

- Polysomnography with expanded bilateral montage and video recording is indicated for evaluation of patients with:
  - Suspected nocturnal seizures based on clinical history with abnormal or inconclusive EEG findings
  - Suspected REM sleep behavior disorder
  - Sleep behaviors suggestive of parasomnias (paroxysmal arousals and other sleep disruptions) that are unusual or atypical because of:
    - Patient's age at onset
    - Time, duration or frequency of occurrence
    - Behaviors that are violent or otherwise potentially injurious to the patient or others
      - Features of the motor patterns in question (e.g. stereotypical, repetitive, or focal)
      - Lack of response to conventional therapy

**Evaluation of suspected periodic limb movement disorder** (Kushida, 2005; Sateia, 2014):

- Polysomnography is indicated when patient or an observer report repetitive limb movements during sleep with any of the following
  - Frequent awakenings
  - Difficulty maintaining sleep
  - Excessive daytime sleepiness; **AND**
  - No known concurrent untreated sleep disorder

- PSG is not indicated in other sleep related movement disorders (restless leg syndrome, bruxism, sleep related leg cramps, rhythmic movement disorder or sleep related myoclonus) unless another underlying sleep disorder is suspected.

### **INDICATIONS FOR CPAP TITRATION STUDIES AND FOLLOW-UP STUDIES:**

#### **Split night sleep study** (Kawaja, 2010; Kushida, 2008):

In a split night study, the initial 2 or more hours of the PSG are used to diagnose OSA and the final portion is used to titrate continuous positive airway pressure (CPAP)

- A split-night study PSG is indicated when criteria for attended PSG is met AND
  - The Apnea Hypopnea Index (AHI) is  $\geq 15$  in first 2 hours
  - There are 3 hours available to perform the CPAP titration (Kapur, 2017)

#### **CPAP/BiPAP titration study:**

- Indicated after a diagnostic PSG if:
  - The AHI is  $\geq 15$ , and a split night study was not performed; **OR**
  - AHI is between 5 and 15, and there is significant daytime sleepiness, comorbid hypertension or impaired self-related quality of life (e.g., snoring, insomnia, morning headaches, nocturia, impaired daytime functions or fatigue) (Patil, 2009b).
- Indicated after a split night study if:
  - The diagnostic portion of the split does not demonstrate an AHI of  $\geq 15$ , but the overall study reaches this threshold due to events occurring later in the night; **OR**
  - During the titration portion of the split night the titration is not successful (there are residual apneas or hypopneas)

#### **Attended sleep study following a home sleep test (HST) is indicated if:**

- HST is technically inadequate (e.g., loss of signal through the night, bad recording due to patient device interface problem, etc.); **OR**
- A single HST is inconclusive or negative with continued clinical suspicion of OSA, (Kapur, 2017); **OR**
- HST is positive (AHI  $> 15$ ) and an attended sleep study is needed for CPAP/BiPAP titration; **OR**
- HST shows an AHI between 5 and 15, and there is significant daytime sleepiness, comorbid hypertension or impaired self-related quality of life (e.g., snoring, insomnia, morning headaches, nocturia, impaired daytime functions or fatigue) and an attended sleep study is needed for CPAP/BiPAP titration (Patil, 2009).
- HST shows prolonged hypoxemia or central apneas

#### **Repeat sleep studies in patients with diagnosed OSA:**

A repeat attended sleep study is indicated if there is a contraindication for an unattended (home) sleep study (above) or for PAP titration; otherwise, unattended (home) sleep studies should be performed

- Repeat sleep studies may be performed up to twice a year for:
  - Patients continuing to report symptoms (e.g., daytime sleepiness or snoring) despite adequate adherence (4 hours/night for 70% of nights over a 30-day period); **OR**

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- Patients requiring a change of device due to intolerance of current device; **OR**
- Determining if positive airway pressure treatment settings need to be changed; **OR**
- Determining if treatment with PAP treatment is still necessary after significant weight loss
- Determining if there is a need to reinstitute PAP after significant weight gain or recurrent symptoms; **OR**
- Assessing treatment response after upper airway surgical procedures, or initial treatment with oral appliances; **OR**
- Remote history of OSA not on PAP with a need to re-establish diagnosis and/or initiate CPAP

**INDICATIONS FOR SLEEP STUDY, ATTENDED – PEDIATRIC PATIENTS (< 18):**

(Aurora, 2011, 2012)

**Respiratory Indications**

- Habitual snoring with one or more below signs or symptoms of obstructive sleep apnea syndrome (OSAS) to differentiate from primary snoring

Symptoms	Signs
Frequent snoring (≥3 nights/week)	Underweight or overweight
Gasps/observed apneas/snorting noises	Tonsillar hypertrophy
Labored breathing during sleep	Adenoidal facies
Cyanosis	Micrognathia/retrognathia
Sleeping in a seated position or with an extended neck	High-arched palate
Cyanosis	Failure to thrive
Attention-deficit/hyperactivity disorder	Hypertension
Learning problems	
Daytime sleepiness	
Sleep enuresis (especially secondary enuresis)	

Adapted from Marcus, 2012

\* In children, OSAS is often associated with daytime neurobehavioral problems (e.g., inattention, hyperactivity, impulsivity, and irritability). Daytime sleepiness is less common than in adults

- Children being considered for adenotonsillectomy to treat OSAS
- Suspected congenital central alveolar hypoventilation syndrome
- Suspected sleep related hypoventilation due to chest wall deformities or neuromuscular disorders (e.g., Duchenne muscular dystrophy, Charcot-Marie-Tooth disease, myotonic dystrophy, congenital myopathies) (Tolaymat, 2017).
- In the following respiratory disorders only if there is a clinical suspicion for an accompanying sleep related breathing disorder:
  - Chronic asthma
  - Cystic fibrosis
  - Pulmonary hypertension
  - Bronchopulmonary dysplasia
  - Chest wall abnormality, such as kyphoscoliosis

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- Following an apparent life-threatening event (ALTE) where there is clinical evidence of sleep-related breathing disorder
- Neurological disorders (e.g., myelomeningocele, Chiari malformation, known brain lesion) (Leu, 2015; Patel, 2015; Tolaymat, 2017)
- Genetic disorders such as achondroplasia, Down syndrome, Prader-Willi syndrome, Ehler-Danlos syndrome Pierre Robin sequence, sickle cell disease and mucopolysaccharidosis (Zaffanello, 2018).

### **Non-Respiratory Indications**

- Suspected narcolepsy (PSG/MSLT) as suggested by the presence of:
    - Excessive daytime sleepiness
    - Cataplexy
    - Hypnagogic hallucinations
    - Sleep paralysis
  - Hypersomnia from suspected causes other than narcolepsy (PSG/MSLT)
  - Suspected parasomnia or seizure disorders:
    - Non-REM parasomnias, epilepsy, or nocturnal enuresis when there is a clinical suspicion for co-morbid sleep disorder such as sleep-disordered breathing or periodic limb movement disorder (PLMD).
    - To confirm the diagnosis of an atypical or potentially injurious parasomnia or differentiate a parasomnia from sleep-related epilepsy
  - Suspected restless leg syndrome or periodic limb movement disorder
    - When patient or an observer reports repetitive limb movements during sleep along with frequent awakenings, fragmented sleep, difficulty maintaining sleep, or excessive daytime sleepiness; **OR**
    - To document periodic limb movements when PLMD or RLS is suspected
- \* The following is **NOT** indicated:
- Home (unattended) sleep studies (Kirk, 2017)
  - Polysomnography for management of oxygen therapy
  - Nap (abbreviated) polysomnography
  - PSG for sleep-related bruxism

### **INDICATIONS FOR TITRATION AND FOLLOW-UP STUDIES – PEDIATRIC PATIENTS (< 18)** (Aurora, 2011; Marcus, 2010)

- Positive airway pressure (PAP) titration in children with obstructive sleep apnea syndrome
- Children with OSAS treated with an oral appliance, to assess response to treatment
- Following an adenotonsillectomy or other pharyngeal surgery for OSAS when **ANY** of the following is met (study should be delayed 6 to 8 weeks postoperatively):
  - Moderate to severe OSAS was present on preoperative PSG
  - Cardiac complications of OSAS (e.g., right ventricular hypertrophy)
  - Craniofacial anomalies
  - Neurological disorders (e.g., Down syndrome, Prader-Willi syndrome, and myelomeningocele)

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- Obesity
  - Presence of symptoms of OSAS persisting after treatment
  - After rapid maxillary expansion
  - Follow-up PSG in children on chronic PAP support to determine whether pressure requirements have changed due to:
    - The child's growth and development (weight or craniofacial)
    - Recurrent symptoms while on PAP
    - Or if additional or alternate treatment is instituted
  - Noninvasive positive pressure ventilation (NIPPV) titration in children with other sleep related breathing disorders
  - Children treated with mechanical ventilation to adjust ventilator settings
  - Children treated with tracheostomy for sleep related breathing disorders as part of the evaluation prior to decannulation
- 

### **BACKGROUND:**

Attended sleep studies or nocturnal polysomnography (PSG) are indicated to assess the following sleep related disorders:

- Sleep related breathing disorders (obstructive sleep apnea and central sleep apnea)
- Narcolepsy and idiopathic hypersomnia
- Parasomnias and seizure disorders
- Periodic limb movement disorder

Polysomnography requires a minimum of the following channels: Electroencephalogram (EEG), Electrooculogram (EOG), chin Electromyogram (EMG), air-flow, oxygen saturation, respiratory effort and heart rate, and are attended by a technologist (Kapur, 2017). They are used for initial, repeat diagnosis as well as follow-up of therapeutic interventions for these conditions in the adult pediatric patients.

**Types/Levels:** Sleep studies refer to the continuous and simultaneous recording of various physiological parameters of sleep followed by physician review and interpretation, performed in the diagnosis and management of sleep disorders. Sleep studies have been classified based on the number and type of physiologic variables recorded and whether or not the study is attended by a technologist or performed with portable equipment in the home or some other unattended setting

The types of sleep studies are as follows:

Type (Level)	Description
I	Standard polysomnography (PSG) with a minimum of 7 parameters measured, including EEG, EOG, chin EMG, and ECG, as well as monitors for airflow, respiratory effort, and oxygen saturation. A sleep technician is in constant attendance.

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<b>II</b>	Comprehensive portable PSG studies that measure the same channels as type I testing, except that a heart rate monitor can replace the ECG and a sleep technician is not necessarily in attendance.
<b>III</b>	Monitor and record a minimum of 4 channels and must record ventilation (at least two channels of respiratory movement, or respiratory movement and airflow), heart rate or ECG, and oxygen saturation. A sleep technician is not necessarily in constant attendance but is needed for preparation.
<b>IV</b>	Three or more channels, one of which is airflow. Other measurements include oximetry and at least 2 other parameters (e.g., body position, EOG, peripheral arterial tonometry (PAT) snoring, actigraphy, airflow). A sleep technician is not necessarily in attendance but is needed for preparation.

Type II, Type III and Type IV devices are used for unattended home sleep studies. Type III and Type IV devices do not include sleep EEG recording channels and do not measure sleep. Therefore, when Type III and Type IV devices are used, AHI is calculated by dividing the total number of apneas + hypopneas by the total recording time.

**Home sleep test (HST):** Unattended (home) sleep studies are considered medically necessary for patients with symptoms suggestive of OSA when the home sleep study is used as part of a comprehensive sleep evaluation, using a Type II, Type III, or Type IV device measuring airflow. Home sleep tests are considered inappropriate for testing people with co-morbid conditions, people who are suspected of having sleep disorders other than obstructive sleep apnea (OSA), and those who are not in the category of high risk for moderate to severe OSA. There may be some situations in which home sleep test may require follow-up with an attended test when the home test is negative or there are other factors that contribute to a technical failure. (See separate clinical guideline for “Sleep Study, Unattended” when that procedure requires authorization.)

**AHI/RDI:** After physician review and interpretation of the data recorded in sleep studies, the total number, type, and rate of occurrence of apneas (cessation of breathing for at least 10 seconds) and hypopneas (reduction, but not cessation of airflow with an associated fall in oxygen saturation of 3 to 4% or an arousal) are reported and the number of events per hour, the Apnea/Hypopnea Index (AHI) or respiratory disturbance index (RDI) is calculated to classify the severity of OSA:

<b>Severity of OSA in adults &gt; 18 years old</b>	
AHI= 5-15/hr	Mild OSA
AHI= 15-30/hr	Moderate OSA
AHI= > 30/hr	Severe OSA

**OSA:** Obstructive sleep apnea is characterized by recurrent episodes of upper airway obstruction and is linked with reductions in ventilation, resulting in repeated arousals and episodic oxyhemoglobin desaturations during sleep.

**Central Sleep Apnea (CSA):** The central sleep apnea syndrome is characterized by a lack of drive to breathe during sleep and there is a diminished or absent respiratory effort during cessation of airflow (Muza, 2015).

**Epworth sleepiness scale** (see: [Johns, 1991](#))

**Daytime nap polysomnography** (sometimes referred to as “PAP-nap”) is not considered medically necessary.

**Maintenance of wakefulness test** is considered investigational for members with symptoms suggestive of OSA because its effectiveness for this indication has not been established.

**Narcolepsy:** PSG must be done on the night preceding MSLT to rule out other sleep disorders and to document adequate nocturnal sleep time prior to daytime MSLT. The MSLT helps confirm diagnosis of narcolepsy and determine severity of daytime sleepiness

- Multiple Sleep Latency Testing (MSLT) includes minimum channels of EEG, EOG, chin EMG and ECG)
- The use of MSLT to support a diagnosis of narcolepsy is suspect if total sleep time on prior night sleep study is less than 6 hours
- MSLT should not be performed after a split night sleep study

**Parasomnias and seizure disorders:** Polysomnography for evaluation of parasomnias and seizure disorders includes minimum channels of EEG, EOG, chin EMG; (EEG using an expanded bilateral montage; and anterior tibialis or extensor digitorum EMG for body movements) and video with documented technologist observations.

- PSG is used to assist in the diagnosis of paroxysmal arousals or other sleep disruptions that are unusual or atypical.
- PSG is not routinely indicated in cases of typical, uncomplicated, non-injurious parasomnias when the diagnosis is clearly delineated.
- PSG is used to evaluate suspected nocturnal seizures based on clinical history with abnormal or inconclusive EEG findings
- PSG is used to evaluate suspected REM sleep behavior disorder (dream enactment behavior in sleep due to loss of muscle atonia during REM sleep, which is often seen with (or precede) neurodegenerative disease) (Zhang, 2020)
- For pediatric patients, studies have indicated that there is a significant prevalence of sleep disordered breathing, ranging from 58% to 100% on PSG in children with chronic NREM parasomnias.

**Periodic limb movement disorder:** Polysomnography for the evaluation of periodic limb movement disorder includes minimum channels of EEG, EOG, chin EMG, and left and right anterior tibialis EMG AND respiratory effort, airflow and oximetry.

**PAP titration (CPAP/BIPAP/APAP):** PAP titration should include sleep staging and the ability to identify arousals to appropriately titrate PAP with a goal of the elimination or near elimination of apneas, hypopneas and respiratory related arousals in REM and NREM sleep, including REM sleep with the patient in the supine position (Epstein, 2009). These pressure settings from the titration study will be programmed into the device that the patient uses at home. In-laboratory titration refers to both full-

night and split-night titration. A cardiorespiratory sleep study without EEG recording is not recommended for PAP titration (either CPAP, BIPAP or ASV). Most Automatically titrating positive airway pressure (APAP) supplies variable pressure in response to acute or chronic changes (body position, sleep stage or weight changes). When APAP is initiated in the home setting, therapy is started in the auto-adjusting mode after which it can be maintained or changed to a fixed, continuous pressure setting determined from PAP monitoring data. Most PAP machines record at a minimum usage, leak, pressure and AHI. This requires close patient follow-up and monitoring. The choice of PAP initiation (either in the home or lab) should be based on access, cost-effectiveness, patient preference, sleep clinician judgement, and other factors (Patil, 2019a).

**Split-night study:** A split-night study should be used unless criteria are met for a second night titration study (see above in “split night study” section). A split night study is expected for most attended PSGs in those who have a high suspicion of OSA. In a split night sleep study, the diagnosis of OSA is established in the first half of the night and the optimal CPAP pressure is determined during the second half of the night. In this type of study, the Apnea+ Hypopnea Index (AHI) needs to be > 15 in the first 2 hours of the diagnostic portion of the study and there needs to be at least 3 hours available to perform the titration portion.

**Treatment of OSA:** Once the diagnosis of OSA is made the patient and physician should decide on an appropriate treatment strategy. Depending on the severity of the OSA, symptoms and comorbidities this may include positive airway pressure devices (PAP), oral appliances, behavioral treatments, surgery, and/or adjunctive treatments (Epstein, 2009).

Positive airway pressure (PAP) devices provide a pneumatic splint to maintain upper airway patency during sleep. PAP devices can deliver continuous positive airway pressure (CPAP), bi-level positive airway pressure (BPAP), where there is a difference in inspiratory and expiratory positive pressure, or automatically titrating positive pressure (APAP). PAP therapy can be initiated using either APAP at home or in-laboratory titration in adults with OSA and no significant comorbidities (Patil, 2019a). Those with comorbidities can be considered for an in-lab PAP titration. CPAP or APAP if preferred over BIPAP except when there is higher pressure requirements required, or a failure of CPAP or APAP (Patil, 2019a). Adaptive Servo-Ventilation (ASV) may be useful in central and complex OSA particularly in specific CHF populations when other treatment option have failed (Aurora, 2012; Husseini, 2020).

An AHI of 15 or more, even in the absence of sleep related symptoms, warrants treatment due to a greater association of this level of sleep disordered breathing with consequences such as increased cardiovascular risk (Epstein, 2009). An AHI of 5-15 (mild OSA) per hour warrants treatment if there is excessive sleepiness, comorbid hypertension or impaired self-related quality of life (e.g., snoring, insomnia, morning headaches, nocturia, impaired daytime functions or fatigue). “There is insufficient and inconclusive evidence to recommend or withhold PAP treatment to treat non-sleepy adults as a means to reduce cardiovascular events or mortality” (Patil, 2009a). PAP treatment’s effect on neurocognitive function, mood disorders, metabolic syndrome, heart failure and all-cause mortality is currently unclear and more evidence is needed to determine the efficacy of PAP therapy to improve outcomes and symptoms associated with OSA outside of excessive sleepiness (Patil, 2009b).

**Consequences of OSA:** The most significant consequences of sleep apnea include neurocognitive and cardiovascular effects. Excessive daytime sleepiness, difficulties with concentration and memory, decreased libido, and irritability result from OSA and sleep fragmentation. Some studies have shown that motor vehicle accidents are more common among patients with sleep apnea compared with normal controls and some the degree of driving impairment is similar to what is seen in drivers who are impaired by alcohol consumption (Tragear, 2009). There has been evidence that patient with OSA are at increased risk for cardiovascular consequences including hypertension, coronary artery disease and heart failure, nocturnal cardiac arrhythmias, stroke, and death (Maeder, 2016; Shahar, 2001). Though recent metanalysis have not been able to show the effect that treatment of OSA has on improving outcomes and symptoms associated with OSA outside of excessive sleepiness (Patil, 2009b).

**New York Heart Association (NYHA) Functional Classes (Dolgin, 1994)**

<b>Class</b>	<b>Patient Symptoms</b>
Class I (Mild)	Cardiac disease, but no symptoms and no limitation in ordinary physical activity, e.g., shortness of breath when walking, climbing stairs, etc.
Class II (Mild)	Mild symptoms (mild shortness of breath and/or angina) and slight limitation during ordinary activity.
Class III (Moderate)	Marked limitation in activity due to symptoms, even during less-than-ordinary activity, e.g., walking short distances (20–100 m). Comfortable only at rest.
Class IV (Severe)	Severe limitations. Experiences symptoms even while <i>at rest</i> . Mostly bedbound patients.

**POLICY HISTORY:**

**Review Date:** July 12, 2019

**Review Summary:**

- Revised the criteria for sleep apnea to correspond to a high pre-test probability population
- Changes to contraindication table to assure accord between attended and unattended sleep study guidelines
- EEG being required before parasomnias removed
- REM sleep behavior disorder added as an indication
- Revised the criteria for attended sleep study following a home sleep study
- Pediatric indications added respiratory disorders with suspicion for sleep apnea, neurologic disorders such as Prader Willi
- Deleted section identifying experimental and investigational indications

**Review Date:** May 2020

**Review Summary:**

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- Updated references
- Updated and reordered background information where appropriate
- Clarified:
  - Reworded: With a high pre-test probability of moderate to severe OSA
  - BMI > or equal to 30, neck circumference > or equal to 17 inches in men, > or equal to 16 inches in women
  - Obesity (BMI > or equal to 35)
  - Changed: BMI > 45 to BMI  $\geq$  40 for class III obesity
  - Comorbid Sleep Disorders, known or suspected
- Added:
  - Remote history of OSA not on PAP with a need to re-evaluate the diagnosis and/or initiate PAP
- Categorized indications in the pediatric section
- Clarified:
  - Suspected parasomnias and nocturnal seizure disorders
  - Reformatted suspected periodic limb movement disorder section
  - Clarified need for repeat attended study vs home sleep study
  - Split into 2 indications: Determining if there is a need to reinstitute PAP after significant weight gain or recurrent symptoms. Determining if treatment with PAP treatment is still necessary after significant weight loss
  - Suspected sleep related hypoventilation due to chest wall deformities or neuromuscular disorders (e.g., Duchenne muscular dystrophy, Charcot-Marie-Tooth disease, myotonic dystrophy, congenital myopathies)
  - Neurological disorders (e.g., myelomeningocele, Chiari malformation, known brain lesion)
  - Suspected narcolepsy (PSG/MSLT)
  - Hypersomnia from suspected causes other than narcolepsy
- Added:
  - With documented clinical concern for central sleep (CSA) based on:
    - Sleep symptoms (e.g., fragmented sleep, insomnia, apneas, daytime sleepiness) AND
    - Comorbid medical conditions (e.g., heart failure, opioid use, neurological disorders)
  - In the CPAP/BiPAP titration and the Attended sleep study following a home sleep test (HST) sections
    - The AHI is >15, and a split night study was not performed OR
    - AHI is between 5 and 15, and there is significant daytime sleepiness, comorbid hypertension or impaired self-related quality of life (e.g., snoring, insomnia, morning headaches, nocturia, impaired daytime functions or fatigue)
  - In the pediatric section:
    - Genetic disorders such as achondroplasia, Down syndrome, Prader-Willi syndrome, Ehler-Danlos syndrome Pierre Robin sequence, sickle cell disease and mucopolysaccharidosis
    - Habitual snoring with one or more below signs or symptoms of obstructive sleep apnea syndrome (OSAS) to differentiate from primary snoring; added s/s chart

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- Deleted:
  - In the indications for follow up studies in pediatric patients < 18, following adenotonsillectomy:
    - Age younger than 3 years
    - Failure to thrive
    - Prematurity
    - Recent respiratory infection

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## 95806 – Sleep Study, Unattended

**CPT Codes: 95800, 95801, 95806, G0398, G0399, G0400**

### **INDICATIONS FOR HOME SLEEP STUDY, UNATTENDED - ADULTS** (Collop, 2007; Kapur, 2017)

Home sleep testing (HST) for obstructive sleep apnea (OSA) should be performed in conjunction with a comprehensive sleep evaluation and adequate follow-up. A comprehensive sleep evaluation should include a sleep history (snoring, apneas, daytime sleepiness), BMI, neck circumference, cardiopulmonary examination, and identification of comorbid sleep disorders and medical conditions.

### **Suspected Obstructive Sleep Apnea in adults >18 years old**

With a high pre-test probability of moderate to severe OSA (Collop, 2012; Ghuman, 2011; Kapur, 2017; Kundel, 2017):

#### **Signs and symptoms including:**

- Excessive daytime sleepiness; **AND**
- Any **TWO** of the following:
  - Habitual loud snoring
  - Witnessed apneas or gasping and choking
  - Diagnosed hypertension
  - BMI  $\geq 30$  or large neck circumference ( $\geq 17$  inches in men,  $\geq 16$  inches in women); **AND**
- There are no contraindications to a home sleep study (see below)

#### **OR**

- A member of a high-risk population, including (Epstein, 2009):
  - Congestive heart failure, Class I or II
  - Atrial fibrillation
  - Chronic kidney disease
  - Treatment refractory hypertension
  - Type 2 diabetes
  - Nocturnal dysrhythmias
  - Pulmonary hypertension
  - High-risk driving populations
  - Obesity (BMI  $\geq 35$ )
  - Preoperative for bariatric surgery
  - Craniofacial or upper airway soft tissue abnormalities, including:
    - Adenotonsillar enlargement
    - Modified Mallampati score of 3 or 4
    - Retrognathia
    - Lateral peritonsillar narrowing
    - Elongated/enlarged uvula

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- High arched/narrow hard palate
  - Nasal abnormalities (polyps, deviation, valve abnormalities, turbinate hypertrophy)
- **AND** any **TWO** of the following
  - Excessive daytime sleepiness (with Epworth Sleepiness Scale (ESS) score > 10) (Johns, 1991)
  - Habitual loud snoring
  - Witnessed apneas or gasping and choking
- **AND** there are no contraindications to a home sleep study (see below)

**CONTRAINDICATIONS FOR HOME SLEEP STUDY, UNATTENDED - ADULTS**

<b>Comorbid Medical Conditions</b>
<ul style="list-style-type: none"> <li>• Moderate to severe pulmonary disease with: FEV1/FVC 0.7 and FEV1 less than 80% predicted, oxygen use, daytime hypercapnia or hypoxemia</li> </ul>
<ul style="list-style-type: none"> <li>• Obesity hypoventilation syndrome: BMI <math>\geq</math> 35 plus arterial blood gas with PCO<sub>2</sub> &gt; 45, BMI <math>\geq</math> 35 plus inability to lie flat in bed, or BMI <math>\geq</math> 40</li> </ul>
<ul style="list-style-type: none"> <li>• Chronic opiate medication use</li> </ul>
<ul style="list-style-type: none"> <li>• Neuromuscular disease (e.g., Parkinson’s disease, ALS, myotonic dystrophy, spina bifida)</li> </ul>
<ul style="list-style-type: none"> <li>• Congestive Heart Failure: NYHA class III or IV, or LVEF less than 45% (see background)</li> </ul>
<ul style="list-style-type: none"> <li>• Stroke</li> </ul>
<b>Comorbid Sleep Disorders, known or suspected</b>
<ul style="list-style-type: none"> <li>• Periodic limb movement disorder</li> </ul>
<ul style="list-style-type: none"> <li>• Parasomnia</li> </ul>
<ul style="list-style-type: none"> <li>• REM behavior disorder</li> </ul>
<ul style="list-style-type: none"> <li>• Nocturnal seizures</li> </ul>
<ul style="list-style-type: none"> <li>• Narcolepsy or idiopathic hypersomnia</li> </ul>
<ul style="list-style-type: none"> <li>• Circadian rhythm disorder</li> </ul>
<ul style="list-style-type: none"> <li>• Central sleep apnea or complex sleep apnea</li> </ul>
<ul style="list-style-type: none"> <li>• Hypoventilation</li> </ul>
<ul style="list-style-type: none"> <li>• Sleep-related hypoxemia</li> </ul>
<ul style="list-style-type: none"> <li>• Severe insomnia</li> </ul>
<b>Technical Contraindications</b>
<ul style="list-style-type: none"> <li>• Inability to follow instructions or lack of mobility or dexterity to use portable equipment and the absence of a competent caregiver</li> </ul>
<ul style="list-style-type: none"> <li>• Previous negative or technically inadequate home sleep study*</li> </ul>
<b>Other</b>
<ul style="list-style-type: none"> <li>• Low pre-test probability of sleep apnea**</li> </ul>
<ul style="list-style-type: none"> <li>• Screening for asymptomatic individuals in high risk populations</li> </ul>

\* If a single home sleep study is inconclusive or technically inadequate or negative with continued clinical suspicion of OSA, an attended polysomnography (PSG) is recommended (Kapur, 2017)

\*\* If there is a low pre-test probability of sleep apnea, but well documented ongoing concern for a sleep disorder causing functional impairment (e.g., upper airway resistance syndrome or mild OSA), PSG may be indicated.

- HST may be indicated for the diagnosis of OSA in patients for whom in-laboratory PSG is not possible due to immobility, safety, or critical illness (Collop, 2007)

#### **INDICATIONS FOR REPEAT HOME SLEEP STUDY**

- Previously diagnosed OSA and a re-evaluation is required for the following:
    - Response to upper airway surgical procedures **OR**
    - Response after initial treatment with oral appliances **OR**
    - Re-evaluation of the diagnosis after a change in  $\geq 10\%$  of body weight
    - Remote history of OSA not on PAP with a need to re-evaluate the diagnosis and/or initiate PAP
- 

#### **BACKGROUND:**

OSA is a common disorder and is associated with significant morbidity and mortality. Recent epidemiologic data have demonstrated that the prevalence of moderate to severe sleep-disordered breathing is 10% among 30-49-year-old men, 17% among 50-70-year-old men, 3% among 30-49-year-old women, and 9% among 50-70 year old women. These percentages are substantially increased from previously reported studies (Franklin, 2015; Peppard, 2013; Young, 1993). OSA is caused by recurrent complete or partial upper airway obstruction during sleep, resulting in loud snoring or apnea frequently reported by a bed partner, episodes of gasping or choking, and associated frequent awakenings from sleep. The increase in prevalence of OSA is likely largely attributable to the rising rates of obesity in the United States, as obesity is often associated with a narrowed upper airway. There are several neurocognitive and cardiovascular effects of untreated sleep apnea.

The diagnosis of OSA is made by clinical evaluation and confirmed by sleep testing. Unattended home sleep studies are indicated to confirm the diagnosis of sleep apnea as part of a comprehensive sleep evaluation. This guideline above outlines the indications and contra-indications for unattended home sleep studies in adults with suspected OSA.

**Sleep Study Types/Levels:** Sleep studies refer to the continuous and simultaneous recording of various physiological parameters of sleep and breathing. Sleep studies have been classified based on the number and type of physiologic variables recorded and whether or not the study is attended by a technologist or performed using portable equipment in the home or some other unattended setting.

The types of sleep studies are as follows:

Type (Level)	Description
I	Standard PSG with a minimum of 7 parameters measured, including electroencephalogram (EEG), electroculogram (EOG), electromyogram (EMG), and electrocardiogram (ECG), as well as monitors for airflow, respiratory effort, and oxygen saturation. A sleep technician is in constant attendance.
II	Comprehensive portable PSG studies that measure the same channels as type I testing, except that a heart rate monitor can replace the ECG and a sleep technician is not necessarily in attendance.
III	Monitor and record a minimum of 4 channels and must record ventilation (at least two channels of respiratory movement, or respiratory movement and airflow), heart rate or ECG, and oxygen saturation. A sleep technician is not necessarily in constant attendance but is needed for preparation.
IV	Three or more channels, one of which is airflow. Other measurements include oximetry and at least 2 other parameters (e.g., body position, EOG, peripheral arterial tonometry (PAT) snoring, actigraphy, airflow). A sleep technician is not necessarily in attendance but is needed for preparation.

Type II, Type III, and Type IV devices are used for unattended home sleep studies. Type III and Type IV devices do not include sleep EEG recording channels and do not measure sleep. Therefore, when Type III and Type IV devices are used, AHI is calculated by dividing the total number of apneas + hypopneas by the total recording time.

A technically adequate home sleep apnea testing device incorporates a minimum of the following sensors: nasal pressure, chest and abdominal respiratory inductance plethysmography, and oximetry; or else PAT with oximetry and actigraphy.

A technically adequate diagnostic test includes a minimum of 4 hours of technically adequate oximetry and flow data obtained during a recording attempt that encompasses the habitual sleep period. A single home sleep study recording is conducted over at least one night (Kapur, 2017).

**Unattended Sleep Study - Home Sleep Test (HST) vs. Attended Sleep Study:** When a Sleep Study, Unattended (i.e., HST) is a covered benefit, the health plan may require use of the unattended study unless the patient has contraindications or co-morbidities that would require an attended sleep study. Home Sleep Tests are considered inappropriate for testing people with co-morbid conditions, people who are suspected of having sleep disorders other than OSA, and those who are not in the category of high risk for moderate to severe OSA. There may be some situations in which a home sleep test may require follow-up with an attended test when the home test is negative or there are other factors that contribute to a HST failure.

**AHI/RDI:** After physician review and interpretation of the data recorded in sleep studies, the total number, type, and rate of occurrence of apneas (cessation of breathing for at least 10 seconds) and hypopneas (reduction, but not cessation of airflow with an associated fall in oxygen saturation of 3 to

4% or an arousal) are reported and the number of events per hour, the Apnea/Hypopnea Index (AHI) or respiratory disturbance index (RDI) is calculated to classify the severity of OSA:

Severity of OSA in adults > 18 years old	
AHI= 5-15/hr	Mild OSA
AHI= 15-30/hr	Moderate OSA
AHI= >30/hr	Severe OSA

The terms RDI/AHI have been defined differently when used with Home Sleep Testing than when used with PSG. RDI/AHI is the number of apneas + hypopneas/total recording time, rather than the total sleep time since sleep parameters are not recorded with type III and IV devices. As a result, home sleep testing is more likely to underestimate the severity of events compared to the RDI/AHI by PSG. Due to this risk of false negative HST tests, in laboratory PSG should be performed in cases where HST is technically inadequate or fails to establish the diagnosis of OSA in patients with a high pre-test probability.

**Epworth sleepiness scale** (see: [Johns, 1991](#))

**Treatment of OSA:** Once the diagnosis of OSA is made the patient and physician should decide on an appropriate treatment strategy. Depending on the severity of the OSA, symptoms and comorbidities this may include positive airway pressure devices (PAP), oral appliances, behavioral treatments, surgery, and/or adjunctive treatments (Epstein, 2009).

Positive airway pressure (PAP) devices provide a pneumatic splint to maintain upper airway patency during sleep. PAP devices can deliver continuous positive airway pressure (CPAP), bi-level positive airway pressure (BPAP), where there is a difference in inspiratory and expiratory positive pressure, or automatically titrating positive pressure (APAP). PAP therapy can be initiated using either APAP at home or in-laboratory titration in adults with OSA and no significant comorbidities (Patil, 2019a). Those with comorbidities can be considered for an in-lab PAP titration. CPAP or APAP is preferred over BIPAP except when there is higher pressure requirements required, or a failure of CPAP or APAP (Patil, 2019a). Adaptive Servo-Ventilation (ASV) may be useful in central and complex OSA particularly in specific CHF populations when other treatment options have failed (Aurora, 2012; Huseini, 2020).

An AHI of 15 or more, even in the absence of sleep related symptoms, warrants treatment due to a greater association of this level of sleep disordered breathing with consequences such as increased cardiovascular risk (Epstein, 2009). An AHI of 5-15 (mild OSA) per hour warrants treatment if there is excessive sleepiness, comorbid hypertension or impaired self-related quality of life (e.g. snoring, insomnia, morning headaches, nocturia, impaired daytime functions or fatigue). “There is insufficient and inconclusive evidence to recommend or withhold PAP treatment to treat non-sleepy adults as a means to reduce cardiovascular events or mortality” (Patil, 2009a). PAP treatments’ effect on neurocognitive function, mood disorders, metabolic syndrome, heart failure and all-cause mortality is currently unclear and more evidence is needed to determine the efficacy of PAP therapy to improve outcomes and symptoms associated with OSA outside of excessive sleepiness (Patil, 2009b).

**Positive Airway Pressure (PAP) Titration:** PAP titration should include sleep staging and the ability to identify arousals to appropriately titrate PAP with a goal of the elimination or near elimination of apneas, hypopneas and respiratory related arousals in REM and NREM sleep, including REM sleep with the patient in the supine position (Epstein, 2009). These pressure settings from the titration study will be programmed into the device that the patient uses at home. In-laboratory titration refers to both full-night and split-night titration. A cardiorespiratory sleep study without EEG recording is not recommended for PAP titration (either CPAP, BIPAP or ASV).

When APAP is initiated in the home setting, therapy is started in the auto-adjusting mode after which it can be maintained or changed to a fixed, continuous pressure setting determined from PAP monitoring data. Most PAP machines record at a minimum usage, leak, pressure and AHI. This requires close patient follow-up and monitoring. The choice of PAP initiation (either in the home or lab) should be based on access, cost-effectiveness, patient preference, sleep clinician judgement, and other factors (Patil, 2019a).

**Consequences of OSA:** The most significant consequences of sleep apnea include neurocognitive and cardiovascular effects. Excessive daytime sleepiness, difficulties with concentration and memory, decreased libido, and irritability result from OSA and sleep fragmentation. Some studies have shown that motor vehicle accidents are more common among patients with sleep apnea compared with normal controls and some the degree of driving impairment is similar to what is seen in drivers who are impaired by alcohol consumption (Tragear, 2009). There has been evidence that patient with OSA are at increased risk for cardiovascular consequences including hypertension, coronary artery disease and heart failure, nocturnal cardiac arrhythmias, stroke, and death (Maeder, 2016; Shahar, 2001). Though recent metanalysis have not been able to show the effect that treatment of OSA has on improving outcomes and symptoms associated with OSA outside of excessive sleepiness (Patil, 2009b).

**New York Heart Association (NYHA) Functional Classes (Dolgin, 1994)**

Class	Patient Symptoms
Class I (Mild)	Cardiac disease, but no symptoms and no limitation in ordinary physical activity, e.g., shortness of breath when walking, climbing stairs, etc.
Class II (Mild)	Mild symptoms (mild shortness of breath and/or angina) and slight limitation during ordinary activity.
Class III (Moderate)	Marked limitation in activity due to symptoms, even during less-than-ordinary activity, e.g., walking short distances (20–100 m). Comfortable only at rest.
Class IV (Severe)	Severe limitations. Experiences symptoms even while <i>at rest</i> . Mostly bedbound patients.

**POLICY HISTORY:**

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**Review Date:** July 12, 2019

**Review Summary:**

- Revised the criteria for sleep apnea to correspond to a high pre-test probability population
- Changes to contraindication table to assure accord between attended and unattended sleep study guidelines]
- Clarified that HST should be performed in conjunction with a comprehensive sleep evaluation and adequate follow-up
- Revised the indications for a repeat HST to remove indication for pressure setting evaluation

**Review Date:** May 2020

**Review Summary:**

- Updated references
- Updated and reordered background information where appropriate
- Clarified:
  - Reworded: With a high pre-test probability of moderate to severe OSA
  - BMI > or equal to 30, neck circumference > or equal to 17 inches in men, > or equal to 16 inches in women
  - Obesity (BMI > or equal to 35)
  - Changed: BMI > 45 to BMI  $\geq$  40 for class III obesity
  - Comorbid Sleep Disorders, known or suspected
- Added:
  - Remote history of OSA not on PAP with a need to re-evaluate the diagnosis and/or initiate PAP
- Clarified:
  - Re-evaluation of the diagnosis after a change in > 10% of body weight

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