

<b>Obstructive Sleep Apnea - Diagnosis and Management</b>	
<b>Type:</b> Medical Necessity and Investigational / Experimental	<b>Policy Specific Section:</b> Medicine
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### **Description**

Obstructive sleep apnea (OSA) syndrome is characterized by repetitive episodes of upper airway obstruction due to the collapse of the upper airway during sleep. Obstructive sleep apnea is typically diagnosed by overnight monitoring with polysomnography (PSG) or a portable/home sleep study. Upper airway resistance syndrome (UARS) is a variant of OSA characterized by a partial collapse of the airway resulting in increased resistance to airflow. The increased respiratory effort required results in multiple sleep fragmentations as measured by very short alpha electroencephalographic (EEG) arousals on PSG.

Medical management of OSA or UARS includes weight loss, oral appliances, and use of continuous positive airway pressure during sleep. If these conservative procedures fail or are not tolerated, surgical therapy may be indicated.

This medical policy addresses:

- I. Diagnosis
- II. Medical Management
- III. Surgical Management
- IV. Obstructive Sleep Apnea in children (Rationale only)

### **Policy**

- I. **Diagnosis**

## Polysomnography in a Sleep Laboratory

Supervised polysomnography (PSG) in a sleep laboratory is considered **medically necessary** for any of the following indications:

- As a diagnostic study when **any** of the following are met:
  - Observed apneas of at least 10 seconds during sleep
  - Moderate or severe congestive heart failure, stroke/transient ischemic attack, coronary artery disease, or significant tachycardic or bradycardic arrhythmias in patients who have nocturnal symptoms suggestive of a sleep-related breathing disorder (i.e., frequent awakenings, gasping, choking) or otherwise are suspected of having sleep apnea
  - A combination of at least two of the following:
    - Excessive daytime sleepiness evidenced by an Epworth Sleepiness Scale greater than 10, inappropriate daytime napping (e.g., during driving, conversation, or eating), or sleepiness that interferes with daily activities and is not explained by other conditions
    - Habitual snoring, or gasping/choking episodes associated with awakenings
    - Unexplained hypertension
    - Obesity, defined as a body mass index greater than 35 kg/m in adults (18 years or older) or greater than the 90th percentile for the weight/height ratio in pediatric patients (under age 18)
    - Craniofacial or upper airway soft tissue abnormalities, including adenotonsillar hypertrophy, or neuromuscular disease
- To initiate and titrate continuous positive airway pressure (CPAP) in adult patients (18 years or older) for **one** of the following conditions:
  - Obstructive sleep apnea (one of the following criteria):
    - Apnea/Hypopnea Index (AHI) of at least 15 per hour
    - An AHI of at least 5 per hour with **any** of the following: excessive daytime sleepiness, impaired cognition, mood disorders, insomnia, hypertension, ischemic heart disease, or history of stroke
  - Upper airway resistance syndrome (one of the following criteria):
    - Greater than 10 electroencephalogram (EEG) arousals per hour of sleep associated with increased respiratory efforts (or reduced intrathoracic pressures)
    - Presence of increased negative intrathoracic pressures (i.e., more negative than 10 centimeters (cm) measured by an esophageal manometer
- To initiate and titrate CPAP in children (under age 18) with clinically significant OSA or UARS defined as an apnea index (AI) or AHI greater than or equal to 1.0
- Continuous positive airway pressure (CPAP) titration following an adult split-night PSG\* when the positive airway pressure titration portion of the original study was insufficient (i.e., less than three hours of titration or failure to effectively eliminate respiratory events)

- Failure of resolution of symptoms or recurrence of symptoms during treatment of OSA or UARS
- To assess the efficacy of surgery (including adenotonsillectomy) or oral appliances/devices
- To re-evaluate the diagnosis of OSA or UARS and the need for continued CPAP (e.g., if there is a significant change in weight or change in symptoms suggesting that CPAP should be re-titrated or possibly discontinued)

Note: In children (under age 18), symptoms may include habitual (nightly) snoring (often with intermittent pauses, snorts, or gasps), disturbed sleep, and daytime neurobehavioral problems (i.e., hyperactivity) rather than daytime sleepiness

A second full-night PSG to titrate CPAP is considered **not medically necessary** when all of following criteria for a split-night PSG study\* were met in the first full-night PSG:

- Apnea/Hypopnea index (AHI) of greater than or equal to 40 is documented during two hours of a diagnostic study or an AHI of 20 to 40 with symptoms of significant OSA (e.g., repetitive obstructions, major oxygen desaturation)
- CPAP titration was carried out for more than three hours (because respiratory events can worsen as the night progresses)
- PSG documented that CPAP eliminated or nearly eliminated respiratory events during rapid eye movement (REM) and non-REM (NREM) sleep

\*A split-night PSG study, in which sleep apnea is documented during the first portion of the PSG followed by CPAP titration on the same night, may eliminate the need for a second study to titrate CPAP.

### Home/Portable Sleep Studies

Unattended (unsupervised) home sleep studies are considered **medically necessary** in adult patients (18 years or older) when **all** of the following criteria are met:

- Requested, performed and evaluated by a medical professional with training in sleep medicine
- Device used has a minimum of four recording channels including at least two channels of respiratory movement, or respiratory movement and airflow, heart rate or electrocardiography, and oxygen saturation
- No evidence of a significant comorbid condition that might alter ventilation or require alternative treatment (e.g., congestive heart failure, chronic pulmonary disease, obesity hypoventilation syndrome, neuromuscular disease)
- No suspicion or evidence of another sleep disorder (e.g., central sleep apnea, narcolepsy, or periodic limb movements during sleep, restless leg syndrome)
- Patient meets **any** of the following circumstances:
  - o High pre-test probability of moderate to severe OSA with all four of the following symptoms\*:
    - Habitual snoring
    - Observed apneas

- Excessive daytime sleepiness
- A body mass index greater than 35
- Diagnosis of OSA has been established and treatment initiated, and assessment of the efficacy of surgery or oral appliances/devices is needed
- Re-evaluation of the diagnosis of OSA and need for continued CPAP (e.g., if there is a significant change in weight or change in symptoms suggesting that CPAP should be re-titrated or possibly discontinued)

\*If no bed partner is available to report snoring or observed apneas, other signs and symptoms suggestive of OSA (e.g., age of the patient, male gender, thick neck, or craniofacial or upper airway soft tissue abnormalities) may be considered.

Unattended (unsupervised) sleep studies are considered **investigational** in adult patients who do not have high pre-test probability of OSA.

Unattended (unsupervised) sleep studies are considered **investigational** in pediatric patients (under age 18).

### **Other Procedures**

Multiple sleep latency testing (MSLT) is considered **not medically necessary** in the diagnosis of OSA except to exclude or confirm narcolepsy or idiopathic hypersomnia in the diagnostic workup of OSA syndrome.

The following devices or procedures for the diagnostic evaluation or assessment of OSA are considered **not medically necessary** including, but not limited to:

- Watch Pat™
- Sleep Strip™
- Nap Studies
- Diagnostic Audio Recording
- Maintenance of Wakefulness Testing

Actigraphy is considered **investigational** in the diagnostic evaluation or assessment of OSA. (Refer to Blue Shield of California Medical Policy: Actigraphy)

## **II. Medical Management**

### **Positive Airway Pressure Devices**

Reimbursement for the following positive airway pressure (PAP) devices will initially be limited to a three month rental period when the service is determined to be **medically necessary** based on the criteria listed below.

Subsequent reimbursement will be provided when documentation substantiates patient compliance and clinical benefit from the device. (See continued coverage criteria beyond the first three months of therapy listed below).

Continuous positive airway pressure (CPAP), with or without a humidifier, is considered **medically necessary** in adult patients (18 years or older) with clinically significant OSA or

UARS defined as **one** of the following:

- Obstructive sleep apnea (one of the following criteria):
  - An AHI or respiratory disturbance index (RDI) of at least 15 events per hour
  - An AHI of at least 5 per hour with **any** of the following: excessive daytime sleepiness, impaired cognition, mood disorders, insomnia, hypertension, ischemic heart disease, or history of stroke
- Upper airway resistance syndrome (one of the following criteria):
  - Greater than 10 EEG arousals per hour of sleep associated with increased respiratory efforts (or reduced intrathoracic pressure)
  - Presence of increased negative intrathoracic pressures (i.e., more negative than 10 centimeters) measured by an esophageal manometer

Continuous positive airway pressure (CPAP), with or without a humidifier, is considered **medically necessary** for children (under age 18) when **both** of the following criteria are met:

- Documented diagnosis of OSA or UARS and PSG demonstrates an apnea index (AI), AHI or RDI greater than or equal to 1.0 event per hour
- **One** of the following:
  - Adenotonsillectomy is unsuccessful in relieving OSA
  - Child is not a candidate for surgery or adenotonsillectomy is contraindicated or delayed

Auto-adjusting CPAP (APAP), with or without a humidifier, is considered **medically necessary** in adult patients (18 years or older) with clinically significant OSA when **both** of the following are met:

- CPAP criteria (listed above)
- **One** of the following:
  - During a two-week trial to initiate and titrate CPAP
  - Failure of a prior trial of CPAP (described in policy guideline)

Auto-adjusting CPAP (APAP) is considered **not medically necessary** in patients who can tolerate a CPAP device.

Note: Refer to Bi-Level Positive Airway Pressure (BPAP/NPPV) for the medical necessity criteria for BPAP for OSA.

Continued coverage of a PAP device beyond the first three months of therapy is considered **medically necessary** if the following criteria are met:

- Documented patient compliance/tolerance to therapy defined as consistent home use of the device for an average of four hours per 24 hour period
- Documentation of therapeutic benefit from use of the device

### **Intraoral Appliances**

A prescription tongue-retaining device (TRD) or a mandibular advancing/ repositioning device

(MRD), also referred to as a mandibular advancement appliance (MAA), or mandibular advancement splint (MAS), is considered **medically necessary** when **all** of the following are met:

- CPAP criteria\*
- Prescribed and recommended by a sleep disorders specialist Medical Doctor (MD) or Doctor of Osteopathic (DO) Medicine
- Device has United States Food and Drug Administration 510(k) clearance
- Device is laboratory fabricated and custom made for jaw repositioning

\*An initial TRD/MRD/MAA/MAS requires a documented PSG or sleep study within the last five years. If a study was performed greater than five years ago, an updated study is required. A replacement device does not require a new PSG or sleep study but documentation should include when the initial device was placed and the reason for replacement.

Oral appliances/devices that can be fitted by the patient themselves are considered **not medically necessary**.

Over the counter oral appliances that can be obtained without a prescription are not covered benefits.

### III. Surgical Management

Tonsillectomy and/or adenoidectomy are considered **medically necessary** in children (under age 18) with OSA and hypertrophic tonsils.

Uvulopalatopharyngoplasty (UPPP) is considered **medically necessary** for the treatment of adult patients (18 years or older) with clinically significant OSA or UARS when **all** of the following are met:

- CPAP criteria (listed above)
- Documented positive airway pressure (CPAP/APAP/BPAP) intolerance or treatment failure (see Policy Guideline)

Hyoid myotomy and suspension, genioglossal (tongue) advancement, and/or maxillofacial surgery, including maxillomandibular osteotomy and advancement (MMO or MMA), is considered **medically necessary** for the treatment of appropriately selected adult patients (18 years or older) with clinically significant OSA or UARS when **all** of the following are met:

- CPAP criteria (listed above)
- Objective documentation of hypopharyngeal obstruction (e.g., fiberoptic endoscopy of cephalometric radiographs)
- Documented positive airway pressure (CPAP/APAP/or BPAP) intolerance or treatment failure (see Policy Guideline)

The following minimally-invasive surgical procedures or services for the treatment of OSA or UARS are considered **investigational**:

- Radiofrequency Volumetric Tissue Reduction (RFVTR) of the palatal tissues, uvula or tongue base (e.g., Somnoplasty® and Coblation®)

- Laser-Assisted Uvulopalatoplasty (LAUP)
- Palatal procedures including but not limited to palatal injections, palatal stiffening, and alternative palatal flaps (e.g., Cautery-Assisted Palatal Stiffening Operation (CAPSO), Pillar™ Palatal Implant System, Injection snoreplasty)
- Tongue procedures (tongue base suspension) including but not limited to, the Repose™ Bone Screw system
- Cardiac (Atrial) Pacing
- All other minimally-invasive surgical procedures not described above

### **Snoring**

Snoring, in the absence of documented OSA, is not considered a medical condition; therefore any surgical procedure, service or device for the treatment of snoring in the absence of documented OSA is considered **not medically necessary**.

### **Policy Guideline**

**Note:** Apnea hypopnea index (AHI) and respiratory disturbance index (RDI) may be used interchangeably for the purpose of this document. Respiratory effort-related arousals (RERAs) represent electroencephalographic (EEG) arousals which in some cases are included in the RDI value.

### **Polysomnography (PSG) and Sleep Studies**

#### *Classification*

- Type 1 - Full attended overnight PSG  $\geq$  seven channels including EEG in a laboratory, technician-attended
- Type 2 - Full unattended PSG ( $\geq$  seven channels)
- Type 3 - Limited channel devices with a minimum of four monitoring channels including airflow (two different channels), electrocardiogram, oxygen saturation
- Level 4 - One or two channels usually using oximetry as one of the parameters

#### *Coding Guideline*

The following CPT and HCPCS codes are considered medical necessary when the above criteria are met:

- Supervised PSG: 95808, 95810, 95811 (split-night PSG)
- Supervised sleep study CPT code: 95807
- Unattended sleep study CPT code 95806, and HCPCS code G0398, G0399

The following CPT and HCPCS codes **do not meet** the above medically necessary criteria:

- CPT codes: 95800, and 95801
- HCPCS code: G0400

### **Continuous Positive Airway Pressure (CPAP)**

**Note:** Blue Shield of California follows the Medicare Durable Medical Equipment Regional

Carrier (DMERC) rules with respect to the usual medically necessary quantity of supplies for PAP devices. (Refer to Table Section)

Examples of failed CPAP include but are not limited to:

- Claustrophobia
- Inability to breathe through the nose
- Patient intolerance
- Discomfort or pain
- Patients requiring high pressures of CPAP (>10 cm H2O) complaining of pressure discomfort

### **Replacement of a positive airway pressure (PAP) device**

Replacement of a PAP device (beyond the warranty period) requires documentation of the reason for replacement, use and benefit from the device; however, a repeat PSG, sleep study, or trial period is not required.

### **Intraoral Appliances**

Common laboratory fabricated mandibular repositioning devices with United States Food and Drug Administration (FDA) 510K clearances include but are not limited to:

- TAP I<sup>®</sup>, TAP II<sup>®</sup>, TAP Titanium<sup>®</sup> (Thornton Adjustable Positioner)
- OASYS<sup>™</sup>
- SommoMed MAS
- Adjustable PM Positioner<sup>™</sup>, APM Ultra
- Klearway Oral Appliance
- Full-Breath Solution (FBS)
- SUAD<sup>®</sup> (Modified Herbst appliance)

### **Internal Information**

There is an MD Determination Form for this Medical Policy. It can be found on the following Web page:

[http://myworkpath.com/healthcareservices/MedicalOperations/PSR\\_Determination\\_Pages.htm](http://myworkpath.com/healthcareservices/MedicalOperations/PSR_Determination_Pages.htm)

### **Rationale**

#### **I. Diagnosis**

Obstructive sleep apnea (OSA) syndrome is caused by repetitive obstruction of the upper airway during sleep, resulting in cessation of breathing (apnea) or a significant reduction in airflow (hypopnea). Obstructive sleep apnea occurs in persons of all ages and its incidence increases with age. It is estimated that about 7% of adults have moderate to severe OSA and 20% have at least mild OSA. The referral population of OSA patients represents only a small proportion of patients who have clinically significant and treatable disease (Somers et al, 2008).

Obstructive sleep apnea is associated with a heterogeneous group of anatomic variants producing obstruction. In patients with OSA, the normal pharyngeal narrowing is accentuated by anatomic factors, such as a short, large neck circumference (> 17 inches in men or 16 inches in women), an elongated palate and uvula, or large tonsillar pillars with redundant lateral pharyngeal wall mucosa and obesity. Furthermore, OSA may be associated with a wide variety of craniofacial abnormalities, including micrognathia, retrognathia, or maxillary hypoplasia.

The hallmark clinical symptom of OSA is excessive snoring. Snoring abruptly ceases during the apneic episodes and during the brief period of patient arousal and then resumes when the patient again falls asleep. Sleep fragmentation associated with repeated arousal during sleep can lead to impairment of daytime activity. In addition, “a number of studies have documented an increase in cardiovascular disease risk and a high prevalence of systemic hypertension in middle-aged and older individuals who have OSA” (Hayes, 2008). Severe OSA is also associated with decreased survival, presumably related to severe hypoxemia, hypertension, or an increase in automobile accidents related to daytime sleepiness.

Upper airway resistance syndrome (UARS) is a condition related to OSA described as a form of sleep-disordered breathing that may result in excessive daytime sleepiness. Upper airway resistance syndrome is defined by repetitive increases in airway resistance associated with multiple sleep fragmentations as measured by very brief electroencephalographic (EEG) arousals. Unlike OSA, the resistance to airflow is typically subtle and does not result in apneic or hypopneic events. Additionally, snoring or obesity may not be a feature of UARS. However, it does result in increasingly negative intrathoracic pressure during inspiration, which can be measured using an esophageal manometer as an adjunct to a polysomnogram (PSG). Therefore, this diagnosis rests on polysomnographic documentation. It has been proposed that UARS is a distinct syndrome from OSA that may be considered a disease of arousal. In the absence of intrathoracic pressure monitoring, a positive response to continuous positive airway pressure (CPAP) has been used to support the diagnosis.

#### *Epworth Sleepiness Scale, Multiple Sleep Latency Test, Maintenance of Wakefulness Test*

Excessive daytime sleepiness is the most common reason given by patients seeking treatment for OSA syndrome. Excessive daytime sleepiness while subjective, is assessed by questionnaires such as the Epworth Sleepiness Scale (ESS); a short self-administered questionnaire that asks patients their likelihood of falling asleep in eight situations ranked from 0 (would never doze) to 3 (high chance of dozing). The maximum score on the ESS is 24 and a score of 10 or below is considered normal.

Daytime sleepiness may also be measured objectively with tests such as the multiple sleep latency test (MSLT) or the maintenance of wakefulness test (MWT). The MSLT measures how quickly the patient falls asleep when instructed to relax in a quiet and dimly lit room, while the MWT measures sleep latency when the patient is instructed to attempt to remain awake in an unstimulating environment. These tests are not considered necessary to evaluate sleep apnea, but the MSLT may be used when symptoms, including excessive daytime sleepiness, suggest narcolepsy or hypersomnia (Littner et al., 2005).

#### **Diagnostic Tests**

Diagnostic tests for sleep-disordered breathing are generally classified into four types (Collop et al., 2007):

- Type 1 - Full attended overnight polysomnography ( $\geq 7$  channels) in a laboratory, technician-attended. Monitoring channels including electroencephalogram (measures electrical activity of the brain), electrocardiogram or EEG (measures electrical activity and heart rate), electrooculogram (measures movement of the eyes during sleep), chin electromyogram (measures muscle activity of the chin), airflow, respiratory effort and oxygen saturation.
- Type 2 - Full unattended polysomnography ( $\geq 7$  channels)
- Type 3 - Limited channel devices that have a minimum of four monitoring channels including airflow (two different channels), electrocardiogram, and oxygen saturation.
- Type 4 - One or two channels usually using oximetry as one of the parameters

The final diagnosis of OSA rests on a combination of clinical evaluation and objective criteria to identify those levels of obstruction that are considered to be clinically significant.

Obstruction anywhere along the upper airway can result in apnea. Apnea is defined as a complete cessation of airflow at the nose and mouth that lasts at least 10 seconds. Hypopnea is defined as a partial (30% to 50%) decrease in airflow that lasts at least 10 seconds and is often associated with a decrease in oxygen saturation of 4% or higher. The severity of OSA is typically quantified by the number of apneas and hypoapneas per hour of sleep, which is termed the apnea-hypopnea index (AHI). The AHI may also be referred to as the respiratory disturbance index (RDI). The RDI is similar to the AHI; however, it also includes respiratory events that do not technically meet the definitions of apneas or hypoapneas, but do disrupt sleep. The RDI is calculated based on the total recording time.

The severity of OSA is determined by the most severe ratings of three domains: sleepiness (defined as mild, moderate, and severe), respiratory disturbance (AHI), and gas exchange abnormalities. In adults, the respiratory disturbance is mild with an AHI of 5 to 15; moderate with an AHI of 16 to 30; and severe with an AHI greater than 30 episodes per hour of sleep (Kushida et al., 2006; Institute for Clinical Systems Improvement (ICSI), 2008). A diagnosis of OSA syndrome is accepted when an adult patient has an AHI greater than 5 and symptoms of excessive daytime sleepiness, impaired cognition, mood disorders or insomnia, or documented hypertension, ischemic heart disease, or history of stroke. Although there is poor correlation between AHI and OSA symptoms, an increase in mortality is associated with an AHI of greater than 15 in adults. Mortality has not been shown to be increased in adult patients with an AHI between 5 (considered normal) and 15.

In contrast to OSA, clinically significant UARS is identified by polysomnographic documentation of greater than 10 EEG arousals per hour of sleep correlated with episodes of reduced intrathoracic pressure.

#### *Supervised Polysomnography*

Supervised PSG in a sleep laboratory (Type 1 study) has been considered to be the gold standard in the definitive diagnosis of OSA (Kushida et al, 2007). Physiologic sensors are placed on the patient to record: brain electrical activity, eye and jaw muscle movement, leg muscle movement,

airflow, respiratory effort (chest and abdominal excursion, electrocardiography, blood pressure, and oxygen saturation during sleep). A Type 1 study always includes an EEG, submental electromyogram, and electroculogram for sleep staging. A sleep technician performs sleep staging by assessing arousals from sleep, and frequency of apneas and hypopneas and ensures monitors are attached appropriately to the patient through the night.

The American Academy of Sleep Medicine (AASM) published practice parameters for PSG and related procedures which suggested that patients had a 70% likelihood of having an AHI index of at least 10 if all of the following were present: habitual snoring, excessive daytime sleepiness, a body mass index greater than 35, and observed apneas (Kushida et al., 2005). Full-night PSG was recommended for the diagnosis of sleep-related breathing disorders and for PAP titration in patients with an RDI of at least 15 per hour, or with an RDI of at least 5 per hour in a patient with excessive daytime sleepiness.

The AASM Practice Parameter also advised that a split-night study was an alternative to one full night of diagnostic PSG followed by a second night of titration if the following four criteria are met:

1. An AHI of at least 40 is documented during a minimum of two hours of diagnostic PSG. Split-night studies may sometimes be considered for an AHI of 20 to 40, based on clinical judgment (e.g., if there are also repetitive long obstructions and major desaturations). However, for an AHI value below 40, determination of CPAP pressure requirements, based on split-night studies may be less accurate than in full night calibrations.
2. Continuous positive airway pressure titration is carried out for more than three hours (because respiratory events can worsen as the night progresses).
3. Polysomnography documents that CPAP eliminates or nearly eliminates the respiratory events during rapid eye movement (REM) and non-REM (NRE) sleep, including REM sleep with the patient in the supine position.
4. A second full night of PSG for CPAP titration is performed if the diagnosis of a Sleep Related Breathing Disorder (SRBD) is confirmed but criteria 2 and 3 are not met.

#### *Unattended Home Sleep Studies*

Due to the prevalence of OSA and the limited capacity of sleep-laboratories to perform Type 1 PSG studies, there has been ongoing interest in unattended home-based studies. Portable monitoring systems typically consist of a small recording device, sensors, belts and related accessories. The system is worn by patients while they sleep at home. The home recordings are then analyzed by a sleep specialist and scoring of apneas and hypopneas are performed. These devices are supplied through sleep centers located in a hospital or separate clinical setting. In the diagnosis of OSA or UARS, portable testing does not assess sleep staging, are rarely attended, and in some cases does not include an EEG.

A Type 2 study, or comprehensive portable PSG is similar to a Type 1 study (i.e., PSG), but ECG can be replaced by a heart rate monitor and a technician is not present. In a Type 3 study, referred to as a cardiopulmonary study or modified portable sleep apnea testing, at least four

parameters are measured. A Type 4 study, or continuous single or dual bioparameter recording, generally uses oximetry and may employ a second airflow assessment parameter.

The AASM Clinical Guidelines (Collop et al., 2007; Epstein, 2009; Collop, 2010) recommended the following indications for portable monitoring:

- Portable monitoring for the diagnosis of OSA should be integrated into a comprehensive program of patient evaluation and treatment under the direction of a sleep specialist board certified in sleep medicine
- Portable monitoring is an acceptable approach to the diagnostic evaluation of suspected OSA in patients with a high pre-test probability of having moderate to severe OSA and no comorbid medical or sleep disorders (e.g., moderate to severe pulmonary disease, neuromuscular disease, congestive heart failure)
- A portable monitor should record at a minimum airflow, respiratory effort, and blood oxygenation with biosensors conventionally used for in-laboratory PSG including an oronasal thermal sensor to detect apneas, a nasal pressure transducer to measure hypopneas, oximetry, and ideally, calibrated or uncalibrated inductance plethysmography for respiratory effort
- The diagnosis confirmation of OSA and severity should be determined using the same criteria as PSG defined as mild for a RDI  $\geq 5$  and less than 15, moderate for RDI  $\geq 15$  and  $\leq 30$  and severe for RDI  $> 30$ /hour
- The RDI in portable monitors is different than when used with PSG. The RDI in portable monitoring measures the number of apneas plus hypopneas/total recording time rather than total sleep time. Portable monitors are likely to underestimate the severity of events compared to AHI with PSG. In-laboratory PSG should be performed in cases where portable monitoring is technically inadequate or fails to establish the diagnosis of OSA in patients with high pretest probability

Additionally, portable monitoring can also be used to guide the titration of PAP therapy if the chosen mode of PAP is either CPAP or auto-titrating positive airway pressure (Mulgrew et al., 2007; Collop 2010).

Current recommendations suggest that the portable monitoring device have four channels (oxygen saturation, respiratory effort, respiratory airflow, and heart rate), and allow review of the raw data. Type 4 monitoring devices are defined differently by different organizations. The AASM guidelines (2007) define Type 4 monitors as devices that record one or two variables (e.g., oxyhemoglobin saturation and airflow). Type 4 monitors with fewer than three channels are not recommended due to reduced diagnostic accuracy and higher failure rates (Flemons et al., 2003; Chesson et al., 2003; Collop, 2010). There is insufficient evidence in the peer-reviewed literature that demonstrates the accuracy of Type 4 devices (e.g., pulse oximetry, actigraphy, Sleep Strip, Watch PAT) in the diagnosis of OSA (Berry et al., 2002; Ghegan et al., 2006; Pittman et al., 2006; Thurnheer et al., 2007; Collop et al., 2010). Additional studies are needed to determine the most reliable types of devices and combinations of sensors.

**II. Medical Management** Treatment decisions for OSA are based on condition severity, the presence of comorbidities and complicating factors, and the patient's tolerance and response to treatment. Medical management of OSA includes weight loss, oral appliances, and various types

of continuous positive airway pressure (CPAP) (i.e., fixed CPAP, bi-level positive airway pressure [BPAP], or auto-adjusting CPAP [APAP]).

### **Positive Airway Pressure (PAP) Devices**

#### *Continuous Positive Airway Pressure*

Continuous positive airway pressure (CPAP) is the most common treatment for sleep apnea in adults. Continuous positive airway pressure consists of a nasal or oro-nasal mask or modified nasal prongs (e.g., nasal pillows) held in position with elastic headgear that is connected by tubing to a flow generator. The flow generator is set to a specific pressure sufficient to maintain airway patency and overcome respiratory disturbances by forcing air through the nasal passages, and opening the back of the throat. In OSA, tissues in the upper airway, including the tongue, soft palate and nasal passages sag and block the airway. The pressurized air through CPAP forces the upper airway tissues out of the way, which allows for normal breathing to occur.

The Centers for Medicare and Medicaid Services (CMS, 2001) published a decision memorandum for CPAP that addressed the issue of how to define moderate to severe OSA. This review of the literature suggested there is a risk of hypertension with an AHI greater than 15, and thus treatment is warranted for these patients without any additional signs and symptoms. For patients with an AHI between 5 and 15 and associated symptoms, the CMS document concluded that the data from three randomized controlled trials demonstrated improved daytime somnolence and functioning in those treated with CPAP.

Currently, CMS allows an initial three month rental period of a CPAP device when ordered and prescribed by the licensed treating physician to be used in adults with OSA if either of the following criteria using the AHI or RDI are met:

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

The peer-reviewed literature supports the use of CPAP as first line treatment of adults with OSA (Giles et al., 2006; Gay et al., 2006; ICSI, 2008; National Institute for Health and Clinical Excellence (NICE), 2008) and UARS (Guilleminault et al., 2003; Kristo et al., 2005). The AASM Task Force conducted a systematic review of the literature evaluating PAP therapy and reported that resolution of sleepiness was accompanied by improved driving performance, and that the majority of studies revealed a positive benefit on psychometric or vigilance measures, as well as neurobehavioral and quality of life measures (Gay et al., 2006).

The biggest issue with CPAP therapy is non-compliance. Frequently, patients use the machine for only a few hours a night or a few days a week. Non-compliance may be the result of sneezing, nasal discharge and dryness but CPAP failure may also be caused by perceived discomfort, claustrophobia and panic attacks. Patients with more severe apnea and debilitating daytime sleepiness are often more compliant, as they are motivated by the prompt reversal of their symptoms. (Lyle, 1999; ICSI, 2008).

### *Auto-titrating CPAP*

Auto-titrating CPAP (APAP) adjusts the level of pressure based on the level of resistance, and thus administers a lower mean level of positive pressure during the night. Auto-titrating CPAP devices may aid in the pressure titration process, address possible changes in pressure requirements throughout a given night and from night to night, aid in treatment of OSA when attended CPAP titration has not or cannot be accomplished, or improve patient comfort.

Evidence-based guidelines from the AASM concluded that CPAP and APAP devices have similar outcomes in terms of AHI, oxygen saturation, and arousals (Berry et al., 2002; Littner et al., 2002; Kushida et al., 2006; Morgenthaler et al., 2008). However, most studies have not demonstrated increased compliance using APAP, nor have functional outcomes been superior to those seen in fixed CPAP (Stammnitz et al., 2004; Marrone et al., 2004; Hussain et al., 2004; Morgenthaler et al., 2008). Thus APAP may be considered medically necessary in patients who have failed a prior trial of CPAP.

According to the AASM evidence-based guideline on auto-titrating CPAP; APAP was not recommended to diagnose OSA, for split-night studies, or for patients with congestive heart failure, significant lung disease such as chronic obstructive pulmonary disease, patients expected to have nocturnal arterial oxyhemoglobin desaturation due to conditions other than OSA (e.g., obesity hypoventilation syndrome), patients who do not snore, and patients who have central sleep apnea syndromes (Morgenthaler et al., 2008). Unattended APAP in patients without significant comorbidities was considered an option (uncertain clinical use). The guidelines indicated patients being treated on the basis of APAP titration must have close clinical follow-up to determine treatment effectiveness and safety, especially during the first few weeks of PAP use, and a re-evaluation and, if necessary, a standard CPAP titration should be performed if symptoms do not resolve or if the APAP treatment otherwise appears to lack efficacy.

### *Bi-level Positive Airway Pressure*

For further information regarding bi-level positive airway pressure (BPAP) devices for the treatment of OSA refer to Blue Shield of California Medical Policy: Bi-level Positive Airway Pressure (BPAP/NPPV).

### *Intraoral Appliances*

Intraoral appliances can be broadly categorized as mandibular advancing/repositioning devices (MADs or MRDs) and tongue retaining devices (TRDs). Cephalometric radiographic studies have shown that MADs or MRDs, lower the tongue position, reduce the mandibular plane-to-hyphoid distance, and widen the upper oropharynx thus reducing or relieving upper airway obstruction. These appliances may be prefabricated and adapted to the patients dimensions, or custom-made based on dental impressions. The appliance is attached to the upper and lower dental arches allowing for additive advancement of the mandible. Some designs can be used in conjunction with a CPAP device (e.g., OPAP®).

Tongue retaining devices or appliances (TRAs) act by holding the tongue forward thereby affecting the genioglossus muscle activity. Tongue retaining devices may be custom made or fitted by the patient. These devices are helpful for patients with limited or loose natural dentition,

temporomandibular disorders and limited mouth opening. They are generally used in patients who have contraindications to the use of an MRA.

The AASM practice parameters for the use of oral appliances (Ferguson et al., 2006) advise the following:

- The presence or absence of OSA must be determined before initiating treatment with an oral appliance to identify patients at risk due to complications of sleep apnea and to provide a baseline to establish the effectiveness of subsequent treatment
- In patients with OSA, the desired outcome of treatment includes the resolution of the clinical signs and symptoms of OSA and the normalization of the AHI and oxyhemoglobin saturation
- Although not as efficacious as CPAP, oral appliances are indicated for use in patients with mild to moderate OSA who prefer oral appliances to CPAP, or who do not respond to CPAP, are not appropriate candidates for CPAP, or who fail treatment attempts with CPAP or behavioral measures such as weight loss or sleep position change
- Patients with severe OSA should have an initial trial of CPAP because greater effectiveness has been shown with this intervention than with the use of oral appliances. Upper airway surgery (including tonsillectomy and adenoidectomy, craniofacial operations and tracheostomy) may also supersede use of oral appliances in patients for whom these operations are predicted to be highly effective in treating the OSA
- To ensure satisfactory therapeutic benefit from oral appliances, patients with OSA should undergo PSG or attended cardiorespiratory (Type 3) sleep study with the oral appliance in place after adjustments of fit have been performed

A 2010 Hayes Medical Technology report evaluated a total of 16 randomized controlled or comparative studies and five systematic reviews/meta-analyses that compared MAD to a placebo device or an active control condition. The report concluded that there was “sufficient evidence from randomized trials to conclude that MAD therapy improves sleep-disordered breathing and daytime sleepiness in patients with mild to moderate OSA.” Further, MAD therapy is more effective than placebo MAD therapy but less effective than CPAP therapy for reducing sleep-disordered breathing.

In summary, the success of any PAP device or intraoral appliances in the treatment of OSA or UARS depends primarily on patient adherence, which can be enhanced by education, proper mask or interface fit, proper oral appliance fitting, and frequent follow-up by the durable medical equipment (DME) provider, sleep medicine specialty physician, dentist or orthodontist.

### **III. Surgical Management**

Patients with OSA who fail or are unable to comply with conservative medical management (i.e., CPAP failure) may also be candidates for surgical interventions. Surgical management of OSA includes a variety of upper airway reconstructive or bypass procedures, often site directed and/or staged (Epstein et al., 2009). Traditional surgeries for OSA include uvulopalatopharyngoplasty (UPPP) and adenotonsillectomy. Patients who fail UPPP may be candidates for additional more complex procedures including maxillofacial surgeries such as mandibular-maxillary advancement osteotomy (MMA or MMO), hyoid suspension, genioglossus advancement and

tracheostomy. The aim of surgical intervention is to alleviate symptoms of daytime sleepiness, improve quality of life, and reduce the signs of sleep apnea recorded by the upper airway. As with OSA, surgical procedures have been used with effective outcomes in UARS (Kristo et al., 2005).

The general approach to the management of OSA with surgical therapy was discussed in the AASM Clinical Guidelines on the long-term care of OSA in adults (Epstein et al., 2009). The guideline advised (excerpts specific to surgical treatment):

- Primary surgical treatment can be considered in patients with mild OSA who have severe obstructing anatomy that is surgically correctable (e.g., tonsillar hypertrophy obstructing the airway)
- Surgical procedures can be considered as secondary treatment for OSA when the outcome of PAP therapy is inadequate, such as when the patient is intolerant of PAP, or PAP therapy is unable to eliminate OSA
- Surgery may also be considered when there is inadequate treatment outcome with an oral appliance (OA), when the patient is intolerant of the OA, or the OA therapy provides unacceptable improvement of clinical outcomes of OSA
- Surgery may also be considered as an adjunct therapy when obstructive anatomy or functional deficiencies compromise other therapies or to improve tolerof other OSA treatments

Overall, the surgical success for OSA is often unpredictable and less effective than PAP (with the exception of tracheotomy) (Won et al., 2008). Surgical success is dependent on appropriate patient selection, the type of procedure performed, and the surgeon's experience.

#### *Tracheostomy*

Tracheotomy is the only operation shown to be consistently effective as a sole procedure in the treatment of OSA, but should only be considered when other options do not exist, have failed or are refused, or when deemed necessary due to clinical urgency (Epstein et al., 2009).

#### *Uvulopalatopharyngoplasty (UPPP)*

Uvulopalatopharyngoplasty involves surgical resection of the mucosa and submucosa of the soft palate, tonsillar fossa, and the lateral aspect of the uvula. Uvulopalatopharyngoplasty is useful in retropalatal and combination retropalatal and retrolingual obstruction. The UPPP procedure may be combined with tonsillectomy as well as performed sequentially with other procedures. The amount of tissue removed is individualized for each patient as determined by potential space and width of the tonsillar pillar mucosa between the two palatal arches. The UPPP enlarges the oropharynx but cannot correct obstructions of the hypopharynx. Thus, patients who fail UPPP may be candidates for additional procedures, depending on the site of obstruction.

The overall significant benefit and success rate of UPPP is variable (i.e., 50%); most positive results have been reported in patients whose obstruction is limited to the retropalatal airway (Sher, 1996; Sundaram et al., 2005). Some studies report that long-term follow-up of surgical patients is required to determine whether surgery is curative or whether the signs and symptoms of OSA tend to recur, requiring further treatment (Sundaram et al., 2005; Franklin et al., 2009).

The AASM Practice Parameters advised UPPP, with or without tonsillectomy, may be appropriate for patients with narrowing and collapse in the retropalatal region, and the procedure should only be performed when non-surgical treatment options, such as PAP, have been considered (Thorpy, 1999; Epstein et al., 2009).

#### *Mandibular Osteotomy with Genioglossus Advancement*

The purpose of the procedures is to pull the tongue base forward, resulting in a larger hypopharyngeal airway. The genoid tubercle of the mandible, which acts as the anterior attachment of the tongue, is advanced by a limited mandibular osteotomy. Modifications of the procedure include stabilization of the hyoid bone anteriorly and inferiorly by attachment to the thyroid cartilage (hyoid suspension). These procedures may be performed with or following a UPPP procedure. Fiberoptic endoscopy and/or cephalometric measurements have been used as methods to identify hypopharyngeal obstruction in these patients. The cure rate ranges from 35% to 60% depending on the severity of the disorder (Lewis and Ducic, 2003; Kezirian and Goldberg, 2006).

The procedure appears to be the most promising at enlarging the retrolingual region in the treatment of OSA. However, it is listed as an option by the AASM practice parameters because the success of the procedure is dependent on surgical skill and expertise, and centers that have experience with the procedure (Thorpy et al., 1999).

#### *Hyoid Myotomy and Suspension*

The hyoid complex aids in maintaining the upper airway space, and forward movement of the complex improves the airway space behind the tongue (Vilaseca et al., 2002; Verse et al., 2006). Currently, hyoid myotomy and suspension is not considered primary therapy, and is performed instead as adjunctive surgical therapy for tongue base obstruction (such as with genioglossus advancement with UPPP) (Bowden et al., 2005).

#### *Maxillomandibular Osteotomy and Advancement (MMO or MMA)*

This surgery specifically addresses hypopharyngeal or base-of-tongue obstruction. The maxilla and mandible are advanced simultaneously by means of LeFort I maxillary and sagittal-split mandibular osteotomies to enlarge the retrolingual and retropalatal airway. The MMO procedure is generally considered when UPPP and other surgical procedures have failed (Thorpy et al., 1999). Initial therapy with MMO may be considered as a first intervention for patients with mandibular skeletal deformities associated with a narrowed posterior airway space, tongue base obstruction, and severe OSA (Sher et al., 1996; Won et al., 2008). The MMO procedure is successful for patients with base of tongue obstruction, severe OSA, morbid obesity and failure of other treatments (Sher et al., 1996; Thorpy et al., 1999; ICSI 2008).

Vincini et al., (2010) compared MMO to conservative management with APAP. While no differences in outcome were found between the two groups; satisfaction with surgery was reported to be as high as 88% compared with 56% for APAP.

### **Minimally Invasive Procedures or Services**

#### *Laser-Assisted Uvuloplasty (LAUP)*

The LAUP procedure is an outpatient alternative to UPPP that is proposed as a treatment of

snoring with or without associated OSA. In this procedure, superficial palatal tissues and the uvula are sequentially reshaped using a carbon dioxide laser. The LAUP procedure differs from UPPP in that less palatal tissue is removed, the tonsils and pharyngeal pillars are not altered, and a laser is used rather than a scalpel. The procedure may require up to five treatments spaced four to eight weeks apart.

In 2001, the AASM published practice parameters for the use of LAUP and stated LAUP was not recommended for the treatment of OSA nor as a substitute for UPPP. This position was restated in AASM clinical guidelines for the evaluation, management and long-term care of OSA in adults, published in 2009. Ferguson and colleagues (2003) reported on a randomized trial of 45 subjects with mild sleep apnea who underwent either LAUP or no treatment. In the treatment group a total of 24% were considered treatment successes (an AHI of less than 10), and 76% were failures. The authors concluded that LAUP can be effective in some patients, but the reduction in AHI and the level of symptomatic improvement were minor overall.

A 2005 Hayes report evaluated evidence from a search of the peer reviewed literature (1980 to September 2005) regarding the surgical treatment (including LAUP) of OSA or sleep-disordered breathing. The report concluded that no randomized trials were identified that evaluated LAUP with sleep outcome measures other than snoring or the efficacy of the procedure relative to nasal CPAP, or the standard non-surgical treatments for sleep apnea. Therefore, an appraisal of the safety and efficacy of LAUP for OSA could not be made. Additionally, there is concern regarding the safety of performing LAUP in the outpatient setting because of possible early postoperative edema of the upper airway, as well as significant postoperative pain (Won et al., 2008).

#### *Radiofrequency Volumetric Tissue Reduction (RFVTR)*

Radiofrequency ablation (RFA) of the soft palate is similar in concept to LAUP, although a different energy source is used, and radiofrequency is used to produce thermal lesions within the tissues, rather than using a laser to ablate the tissue surface, which may be painful. For this reason, radiofrequency ablation appears to be growing in popularity as an alternative to LAUP. Two procedures Somnoplasty<sup>®</sup> and Coblation<sup>®</sup> have been described in the medical literature. In some situations, radiofrequency of the soft palate and base of tongue are performed together as a multilevel procedure. The mean number of treatments required for patient satisfaction ranged between three to seven (Steward et al., 2004; Farrar et al., 2008)

The 2000 Blue Cross Blue Shield Technology Evaluation Committee (TEC) Assessment on RFVTR (i.e., Somnoplasty<sup>®</sup>) included four primary studies on palatal radiofrequency ablation and one study on tongue base radiofrequency ablation. The assessment concluded that data were inadequate to make conclusions. Hayes (2007) reported the durability of improvements obtained with upper airway RFTVR has not been established, since none of the available controlled trials of this procedure involved long-term follow up.

In 2008, Farrar and colleagues published a meta-analysis of RFA for the treatment of OSA in patients with an RDI of 5 or more. The number of patients who were successfully treated (e.g., 50% reduction in RDI) was not reported. This meta-analysis is limited by the inclusion of poor quality uncontrolled studies. Van den Broek and colleagues (2008) assessed the incremental value of RFA of the tongue in combination with UPPP in a retrospective cohort study of 75

patients with both palatal and retroglottal obstruction, an RDI between 5 and 50, and no previous OSA surgery. Surgical success rate were defined as more than 50% reduction of the AHI and AHI below 20, the success rate was 42% with UPPP alone and 49% with RFA (not significantly different). The authors concluded that the addition of RFA to UPPP resulted in only limited improvement, but there was no major downside to it.

A single-blinded RCT of single-stage radiofrequency surgery of the soft palate was reported by Back and colleagues in 2009. Thirty two patients with mild OSA (AHI between 5 and 15), habitual snoring and excessive daytime sleepiness were randomized to a single session of RFA or sham ablation. There was no difference between the groups for baseline to post-treatment (four to six months) changes in the ESS, reports of snoring, AHI, or any other outcome measure. Results of this small RCT indicate that single stage RFA of the soft palate is not effective for the treatment of mild OSA.

Fernandez-Julian and colleagues (2009) compared the efficacy and side effects of two tongue-based procedures (RFA and tongue base suspension) when combined with UPPP in patients with moderate to severe sleep apnea (AHI  $\geq$  15). Although interpretation of the results is limited by the lack of control group treated with UPPP alone, success rates for combined procedures (defined as  $\geq$  50% reduction and final AHI  $<$  15) were 51% to 57%. Body mass index (BMI) was the main predictor of success, with success rates of only 10% to 12.5% in patients with a BMI between 30 and  $<$  35kg/m. The authors reported that neither technique should be used in obese patients who have moderate to severe OSA.

#### *Palatal Stiffening Procedures*

Palatal stiffening procedures include insertion of palatal implants, injection of a sclerosing agent (snoreplasty) or a cautery-assisted palatal stiffening operation (CAPSO). The CAPSO procedure uses cautery to induce a midline palatal scar designed to stiffen the soft palate to eliminate excessive snoring. The Pillar™ Palatal Implant System (Restore Medical, St Paul, MN) is an implantable device that has been cleared by the FDA 510(k) process. The labeled indication of the device is as follows: “The Pillar™ Palatal Implant System is intended for the reduction of the incidence of airway obstructions in patients suffering from mild to moderate OSA (obstructive sleep apnea).” The device is a cylindrical-shaped segment of braided polyester filaments that is permanently implanted submucosally in the soft palate.

There is limited evidence regarding CAPSO in patients with clinically significant OSA, most studies on CAPSO focus on patients with simple snoring (AHI  $<$  5) or mild sleep apnea (AHI  $<$  15) (Mair & Day, 2000; Pang & Terris, 2007). In 2000, Wassmuth and colleagues reported on the results of a case series of 25 patients with OSA who underwent CAPSO. Responders were defined as patients who had a reduction in AHI of at least 50%. Mean AHI improved from 25.1 $\pm$ 12.9 to 16.6 $\pm$ 15.0. The broad confidence intervals limit any scientific interpretation of these data.

The National Institute for Health and Clinical Excellence (NICE, United Kingdom) in 2007 advised that while there are no major safety concerns on soft palate implants for OSA; there is inadequate evidence that the procedure is efficacious in the treatment of this potentially serious condition for which other treatments exist. Therefore, soft palate implants should not be used for OSA.

A Hayes Health Technology Brief (2010) identified two RCTs, a randomized controlled study, and four uncontrolled studies evaluating the Pillar<sup>®</sup> Palatal Implant System for treatment of OSA (Friedman et al., 2006a & 2006b; Walker et al., 2006; Goessler et al., 2007; Norgard et al., 2007; Friedman et al., 2008; Steward et al., 2008). Hayes reported that the “results of these studies provided preliminary but somewhat inconsistent evidence that the procedure benefits patients who have mild-to-moderate OSA.” The largest RCT found that average OSA worsened in spite of treatment rather than with other minimally invasive procedures for OSA (Steward et al., 2008). The authors advised that the procedure had potential however a beneficial impact on health outcomes has not been proven. Additional studies are needed to determine the role of the Pillar<sup>™</sup> Implant System in the management of OSA.

A newer treatment method, injection snoreplasty, involves the injection of a hardening agent into the upper palate. Currently, there is insufficient evidence in the peer-reviewed published literature to establish the safety or efficacy of injection snoreplasty.

#### *Tongue Base Suspension*

In this procedure, the base of the tongue is suspended with a suture that is passed through the tongue and then fixated with a screw to the inner side of the mandible, below the tooth roots. The aim of the suspension is to make it less likely for the base of the tongue to prolapse during sleep. The Repose<sup>™</sup> Bone Screw System (Influence, San Francisco, CA) is used to perform anterior tongue base suspension by fixation of the soft tissue of the tongue base to the mandible bone using a bone screw with pre-threaded sutures. The Repose<sup>™</sup> Bone Screw System has been proposed as a sole treatment of OSA but has also been performed with UPPP and radiofrequency ablation.

The efficacy of tongue base suspension with the Repose System for OSA has not been established in the peer-reviewed literature. Permanent anatomical change in the posterior airway space, and cure rates of only 20%, require further research to define the role of the Repose system for the treatment of OSA (Miller et al., 2002; Kuhnei et al., 2005; Hayes, 2010).

#### *Atrial Pacing*

Because of the bradycardia that is noted during episodes of apnea, atrial pacing has been studied as a treatment for sleep apnea. A study by Simantirakis (2005) compared pacing to CPAP and a study by Krahn (2006) compared pacing to no treatment. In neither study was an effect seen on the AHI for those treated with pacing. Epstein and colleagues (2008) reported that although a small retrospective trial demonstrated a decrease in central or OSA without reducing the total sleep time, subsequent randomized trials have not validated a role for atrial pacing in OSA.

### **IV. Obstructive Sleep Apnea in Children**

Obstructive sleep-disordered breathing is common in children. From 3% to 12% of children snore, while OSA syndrome affects 1% to 10% of children (American Academy of Pediatrics (AAP), 2002). The majority of these children have mild symptoms, and many outgrow the condition. The most frequently reported symptoms by parents include mouth breathing, diaphoresis, paradoxical rib-cage movement, restlessness, frequent awakenings, and witnessed apneic episodes. Children (five years and older) more commonly exhibit enuresis, behavior problems, deficient attention span, and failure to thrive, in addition to snoring. Risk factors

include adenotonsillar hypertrophy, obesity, craniofacial anomalies, and neuromuscular disorders (Chan et al., 2004).

The AAP guidelines stated diagnostic evaluation is useful in discriminating between primary snoring and OSA; although the gold standard is overnight PSG. Other diagnostic tests such as PSG of daytime naps or home oximetry tend to only be useful if results are positive and have poor predictive value (AAP, 2002; Chan et al., 2004). Therefore, children with negative study results need to have a comprehensive PSG evaluation. The uses of techniques, other than an attended PSG, for the evaluation of OSA syndrome have not been evaluated (Chan et al., 2004).

Due to faster respiratory rates in children, pediatric scoring criteria define an apnea as two or more missed breaths, regardless of its duration in seconds. Hypopneas are scored by a 50% or greater drop in nasal pressure and either a 3% or greater decrease in oxygen saturation or an associated arousal. In pediatric patients, an AHI greater than 1.0 is considered abnormal and an AHI of 15 or more is considered severe (Hoban, 2007).

The most common etiology of OSA is adenotonsillar hypertrophy occurring most commonly in preschool aged children when the tonsils and adenoids are the largest, in relation to the airway size. For this reason, adenotonsillectomy (AT) is generally recognized as the most appropriate first-line treatment of choice for childhood OSA (AAP, 2002; Hoban, 2007; Won et al., 2008). Adenotonsillectomy is less likely to be successful in older and obese children and in children who have underlying chromosomal or craniofacial abnormalities. Follow-up PSG may be required to assess for residual OSA and to determine whether other interventions (e.g., CPAP) are needed (Cataletto et al., 2009).

Continuous positive airway pressure is the second most common treatment for OSA in children. For children whose OSA has failed to resolve following AT, or who have a condition not amenable to AT (e.g., craniofacial anomaly as the primary underlying cause of OSA), or where AT is contraindicated, CPAP has been shown to be effective therapy with success rates in the 74% to 97% range (Hoban, 2007). Continuous PAP is used most often, but in children in whom high pressure is required, BPAP may prove to be more comfortable. Positive airway pressure is used either until testing shows it is no longer needed or until further surgical or orthodontic interventions can be tried.

Adherence to CPAP therapy may be suboptimal in the pediatric age group. Continuous PAP is difficult for approximately 20% of children to tolerate. Because children grow rapidly, frequent follow-up visits are necessary, and the mask must be adjusted at least every six months (Marcus, 2006).

Other adjunctive measures in the treatment of childhood OSA have not been prospectively evaluated. Although dental appliances are used to treat mild to moderate OSA in adults, their use is not common in children because of the potential for alteration of the bite and for temporomandibular joint disease. Orthodontic interventions, such as maxillary expansion, have been shown to be very successful, both as a standalone procedure and in conjunction with adenotonsillectomy, in treating OSA in children. Surgical interventions, other than AT, are not commonly performed in children.

## Benefit Application

Benefit determinations should be based in all cases on the applicable contract language. To the extent there are any conflicts between these guidelines and the contract language, the contract language will control. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

Some state or federal mandates (e.g., Federal Employee Program (FEP)) prohibit Plans from denying Food and Drug Administration (FDA) - approved technologies as investigational. In these instances, plans may have to consider the coverage eligibility of FDA-approved technologies on the basis of medical necessity alone.

*This Policy relates only to the services or supplies described herein. Benefits may vary according to benefit design; therefore, contract language should be reviewed before applying the terms of the Policy. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement Policy*

Type	Number	Description
CPT	21198	Osteotomy, mandible, segmental;
	21199	Osteotomy, mandible, segmental; with genioglossus advancement
	21206	Osteotomy, maxilla, segmental (eg, Wassmund or Schuchard)
	21685	Hyoid myotomy and suspension
	41512	Tongue base suspension, permanent suture technique
	41530	Submucosal ablation of the tongue base, radiofrequency, 1 or more sites, per session
	42145	Palatopharyngoplasty (eg, uvulopalatopharyngoplasty, uvulopharyngoplasty)
	42299	Unlisted procedure, palate, uvula
	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)

Type	Number	Description
	95803	Actigraphy testing, recording, analysis, interpretation, and report (minimum of 72 hours to 14 consecutive days of recording)
	95805	Multiple sleep latency or maintenance of wakefulness testing, recording, analysis and interpretation of physiological measurements of sleep during multiple trials to assess sleepiness
	95806	Sleep study, unattended, simultaneous recording of, heart rate, oxygen saturation, respiratory airflow, and respiratory effort (eg, thoracoabdominal movement)
	95807	Sleep study, simultaneous recording of ventilation, respiratory effort, ECG or heart rate, and oxygen saturation, attended by a technologist
	95808	Polysomnography; sleep staging with 1-3 additional parameters of sleep, attended by a technologist
	95810	Polysomnography; sleep staging with 4 or more additional parameters of sleep, attended by a technologist
	95811	Polysomnography; sleep staging with 4 or more additional parameters of sleep, with initiation of continuous positive airway pressure therapy or bilevel ventilation, attended by a technologist
<b>HCPC</b>	C9727	Insertion of implants into the soft palate; minimum of 3 implants
	E0485	Oral device/appliance used to reduce upper airway collapsibility, adjustable or nonadjustable, prefabricated, includes fitting and adjustment
	E0486	Oral device/appliance used to reduce upper airway collapsibility, adjustable or nonadjustable, custom fabricated, includes fitting and adjustment
	E0561	Humidifier, nonheated, used with positive airway pressure device
	E0562	Humidifier, heated, used with positive airway pressure device
	E0601	Continuous airway pressure (CPAP) device

Type	Number	Description
	G0398	Home sleep study test (HST) with type II portable monitor, unattended; minimum of 7 channels: EEG, EOG, EMG, ECG/heart rate, airflow, respiratory effort and oxygen saturation
	G0399	Home sleep test (HST) with type III portable monitor, unattended; minimum of 4 channels: 2 respiratory movement/airflow, 1 ECG/heart rate and 1 oxygen saturation
	G0400	Home sleep test (HST) with type IV portable monitor, unattended; minimum of 3 channels
	S2080	Laser-assisted uvulopalatoplasty (LAUP)
	S8262	Mandibular orthopedic repositioning device, each
<b>ICD9 Procedure</b>		
	27.64	Insertion of palatal implant
	27.73	Repair of uvula
	29.4	Plastic operation on pharynx
	89.17	Polysomnogram
	89.18	Other sleep disorder function tests
	93.90	Non-invasive mechanical ventilation
<b>ICD9 Diagnosis</b>	327.23	Obstructive sleep apnea (adult) (pediatric)
	780.51	Insomnia with sleep apnea, unspecified
	780.53	Hypersomnia with sleep apnea, unspecified
	780.57	Unspecified sleep apnea
<b>Place of Service</b>	All Places of Service	

### Prior Authorization Requirements

This service (or procedure) is considered **medically necessary** in certain instances and **investigational** in others (refer to policy for details).

For instances when the indication is **medically necessary**, clinical evidence is required to determine **medical necessity**.

For instances when the indication is **investigational**, you may submit additional information to the Prior Authorization Department.

Within five days before the actual date of service, the Provider **MUST** confirm with Blue Shield that the member's health plan coverage is still in effect. Blue Shield reserves the right to revoke an authorization prior to services being rendered based on cancellation of the member's eligibility. Final determination of benefits will be made after review of the claim for limitations or exclusions.

Questions regarding the applicability of this policy should also be directed to the Prior Authorization Department. Please call 1-800-541-6652 or visit the Provider Portal [www.blueshieldca.com/provider](http://www.blueshieldca.com/provider).

#### Documentation Required for Clinical Review

- History and Physical, or Consultation notes, or Office Notes: including conservative treatment trials/results, current treatment plan, documented test results (if applicable)
- Polysomnography or Sleep study reports (if applicable)
- Sleep specialty physician recommendation and prescription for positive airway pressure device or intraoral appliance (if applicable)
- Copy of FDA 510 K clearance document for intraoral appliance (if applicable)
- Re-evaluation of a Continuous Positive Airway Pressure (CPAP) Device:
- Documentation of patient compliance/tolerance to therapy defined as consistent home use of the device for an average of four hours per 24 hour period on 70% of the nights (e.g., direct download from the device or Smart Card or other data card)
- Documentation of therapeutic benefit from use of the device

#### Post Service

- No records required
- Operative report (if applicable)

## Tables

### OSA table

The following table represents the maximum amount of accessories used with a positive airway pressure (PAP) device:

A4604	1 per 3 months
A7027	1 per 3 months

A7028	2 per 1 month
A7029	2 per 1 month
A7030	1 per 3 months
A7031	1 per 1 month
A7032	2 per 1 month
A7033	2 per 1 month
A7034	1 per 3 months
A7035	1 per 6 months
A7036	1 per 6 months
A7037	1 per 3 months
A7038	2 per 1 month
A7039	1 per 6 months
A7046	1 per 6 months

### **Index / Cross Reference of Related BSC Medical Policies**

The following Medical Policies share diagnoses and/or are equivalent BSC Medical Policies:

- Bi-level Positive Airway Pressure (BPAP) Devices (NPPV)
- Orthognathic Surgery

### **Definitions**

**Sleep Strip** - A disposable home screening electronic device with an integrated microprocessor that measures the number of times that you stop breathing while you sleep and then determines the presence and severity of sleep apnea.

**Watch-PAT™** - A type of portable monitoring device which records sympathetic changes in peripheral arterial tone, heart rate, oximetry, and actigraphy.

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### Key / Related Searchable Words

- BiPAP

### Policy History

This section provides a chronological history of the activities, updates and changes that have occurred with this Medical Policy.

Effective Date	Action	Reason
4/3/2009	Policy title change Policy revision with position change Policy combined: <ul style="list-style-type: none"> <li>• Diagnosis and Medical Management of Obstructive Sleep Apnea Syndrome</li> <li>• Obstructive Sleep Apnea Surgeries</li> </ul>	Medical Policy Committee
6/18/2009	Administrative Review	Administrative Review

Effective Date	Action	Reason
1/19/2010	Coding Update	Administrative Review
10/1/2010	Policy title change from Diagnosis and Treatment Services for Obstructive Sleep Apnea (OSA) and Upper Airway Resistance Syndrome (UARS)  Policy revision with position change	Medical Policy Committee
1/21/2011	Coding Update	Administrative Review
4/12/2011	Coding Update	Administrative Review

The materials provided to you are guidelines used by this plan to authorize, modify, or deny care for persons with similar illness or conditions. Specific care and treatment may vary depending on individual need and the benefits covered under your contract. These Policies are subject to change as new information becomes available.