Name of Policy:
Medical Management of Obstructive Sleep Apnea Syndrome

Policy #: 065        Latest Review Date: July 2017
Category: Surgery/Medical/DME      Policy Grade: D

Background/Definitions:
As a general rule, benefits are payable under Blue Cross and Blue Shield of Alabama health plans only in cases of medical necessity and only if services or supplies are not investigational, provided the customer group contracts have such coverage.

The following Association Technology Evaluation Criteria must be met for a service/supply to be considered for coverage:

1. The technology must have final approval from the appropriate government regulatory bodies;
2. The scientific evidence must permit conclusions concerning the effect of the technology on health outcomes;
3. The technology must improve the net health outcome;
4. The technology must be as beneficial as any established alternatives;
5. The improvement must be attainable outside the investigational setting.

Medical Necessity means that health care services (e.g., procedures, treatments, supplies, devices, equipment, facilities or drugs) that a physician, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury or disease or its symptoms, and that are:

1. In accordance with generally accepted standards of medical practice; and
2. Clinically appropriate in terms of type, frequency, extent, site and duration and considered effective for the patient’s illness, injury or disease; and
3. Not primarily for the convenience of the patient, physician or other health care provider; and
4. Not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient’s illness, injury or disease.
Description of Procedure or Service:
Obstructive sleep apnea (OSA) syndrome is characterized by repetitive episodes of upper airway obstruction due to the collapse of the upper airway during sleep. The gold standard for diagnosing OSA is overnight monitoring with polysomnography (PSG) in a sleep lab. Medical management of OSA may include weight loss, avoidance of stimulants, body position adjustment, oral appliances, and use of continuous positive airway pressure (CPAP) during sleep.

Obstructive Sleep Apnea
Obstructive sleep apnea (OSA) causes a drop in blood oxygenation and a brief arousal, and can occur as frequently as every minute throughout the night. The most common signs and symptoms in adults are snoring, excessive daytime sleepiness, and hypertension. Excessive daytime sleepiness may be subjective, and is assessed by questionnaires such as the Epworth Sleepiness Scale, a short self-administered questionnaire that asks patients how likely they are to fall asleep in different scenarios such as watching TV, sitting quietly in a car, or sitting and talking to someone. Daytime sleepiness is uncommon in young children with OSA. Symptoms in children may include disturbed sleep and daytime neurobehavioral problems. In otherwise healthy children, OSA is usually associated with adenotonsillar hypertrophy and/or obesity.

A hallmark sign of OSA is snoring. The snoring abruptly ceases during the apneic episodes and during the brief period of patient arousal and then resumes when the patient again falls asleep. Upper airway resistance syndrome (UARS) is a variant of OSA that is characterized by a partial collapse of the airway, resulting in increased resistance to airflow. The increased respiratory effort is associated with multiple sleep fragmentations, as measured by very short alpha electroencephalographic (EEG) arousals (“respiratory event-related arousals” [RERAs]). The sleep fragmentation associated with repeated sleep disruption can lead to impairment of daytime activity. Adult patients with OSA-associated daytime somnolence are thought to be at higher risk for accidents involving motorized vehicles, i.e., cars, trucks, or heavy equipment, while OSA in children may result in neurocognitive impairment and behavioral problems.

OSA can also affect the cardiovascular and pulmonary systems. For example, apnea leads to periods of hypoxia, alveolar hypoventilation, hypercapnia, and acidosis. This in turn can cause systemic hypertension, cardiac arrhythmias, and cor pulmonale. Systemic hypertension is common in patients with OSA. Severe OSA is associated with decreased survival, presumably related to severe hypoxemia, hypertension, or an increase in automobile accidents related to overwhelming sleepiness. It is estimated that about 7% of adults have moderate or severe OSA, and 20% have at least mild OSA and that the referral population of OSA patients represents a small proportion of patients who have clinically significant and treatable disease.

Diagnosis
The criterion standard diagnostic test for sleep disorders is a polysomnogram performed in a sleep laboratory. A standard polysomnogram includes EEG, submental electromyogram (EMG) and electro-oculogram (to detect rapid eye movement [REM] sleep) for sleep staging. PSG also typically includes electrocardiography and monitoring of respiratory airflow, effort, snoring, oxygen desaturation, and sleep position. An attended study ensures that the electrodes and sensors are functioning adequately and do not become dislodged during the night. In addition, an attendant is able to identify severe OSA in the first part of the night and titrate CPAP in the
second part of the night, commonly known as a "split-night" study. If successful, this strategy can eliminate the need for an additional PSG for CPAP titration. Auto-adjusting positive airway pressure (APAP) may also be used to determine the most effective pressure.

Typically, the evaluation of OSA includes sleep staging to assess arousals from sleep and determination of the frequency of apneas and hypopneas. In adults, apnea is defined as a drop in the peak signal excursion (airflow) by 90% or more of pre-event baseline for at least 10 seconds. Hypopnea in adults is scored when the peak signal excursions drop by at least 30% of pre-event baseline for at least 10 seconds in association with either at least 3% arterial oxygen desaturation or an arousal. The Apnea/Hypopnea Index (AHI) may also be referred to as the Respiratory Disturbance Index (RDI). The AHI is defined as the total number of events per hour of sleep. RDI may be defined as the number of apneas, hypopneas, and RERAs per hour of sleep. When sleep onset and offset are unknown, e.g., in home sleep studies, the Respiratory Event Index may be calculated based on the number of apneas and hypopneas per hour of recording time. A diagnosis of OSA is accepted when an adult patient has an AHI greater than 5 and symptoms of excessive daytime sleepiness or unexplained hypertension. An AHI equal to or greater than 15 is typically considered moderate OSA, while an AHI greater than 30 is considered severe OSA.

Due to faster respiratory rates in children, pediatric scoring criteria define an apnea as 2 or more missed breaths, regardless of its duration in seconds. An apnea is scored when peak signal excursions (airflow) drop by at least 90% of pre-event baseline and the event meets duration and respiratory effort criteria for an obstructive, mixed, or central apnea. A hypopnea is scored in children when the peak signal excursions drop is at least 30% of pre-event baseline for at least the duration of 2 breaths in association with either a 3% or greater oxygen desaturation or an arousal. In pediatric patients, an AHI greater than 1.5 is considered abnormal, and an AHI of 10 or greater may be considered severe. 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.

A variety of devices have been developed specifically to evaluate OSA at home. These range from portable full PSG systems to single channel oximeters. Available devices evaluate different parameters, which may include oximetry, respiratory and cardiac monitoring, and sleep/wake activity, but the majority of portable monitors do not record EEG activity.

Medical Management
Medical management of OSA in adults may include weight loss, avoidance of stimulants, body position adjustment, oral appliances, and use of various types of positive airway pressure (PAP) therapy (i.e., fixed CPAP, bilevel PAP [BiPAP], or APAP) during sleep.

CPAP involves the administration of air, usually through the nose, by an external device at a fixed pressure to maintain the patency of the upper airway. BiPAP is similar to CPAP, but these devices are capable of generating 2 adjustable pressure levels. 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. It has been hypothesized that both BiPAP and APAP are more comfortable for the patient and thus might improve patient compliance or acceptance.
Oral appliances can be broadly categorized as mandibular advancing/positioning devices or tongue-retaining devices. Oral appliances can either be “off the shelf” or custom made for the patient by a dental laboratory or similar provider.

The Daytime Nighttime Appliance (DNA Appliance, Biomodeling Solutions) and the mandibular Repositioning Nighttime Appliance (mRNA Appliance, Biomodeling Solutions) are customized palate and mandible expanding devices. In addition to the upper-jaw device that is common to the DNA Appliance and the mRNA Appliance (worn both during the day and night), the mRNA Appliance moves the mandible forward and is worn during sleep. The DNA Appliance and mRNA Appliance systems use 3-dimensional axial springs which are proposed to expand the upper and lower jaw and airway gradually to treat and eliminate mild-to-moderate OSA eventually.

Other devices that are being marketed for the treatment of OSA are PROVENT and Winx™. PROVENT is a single use nasal expiratory resistance valve device containing valves that are inserted into the nostrils and secured with adhesive. The Winx™ system uses oral pressure therapy (OPT) for the treatment of OSA. OPT provides light negative pressure to the oral cavity by using a flexible mouthpiece connected to a bedside console that delivers negative pressure. This device is proposed to increase the size of the retropalatal airway by pulling the soft palate forward and stabilizing the base of the tongue.

Risk Factors for OSA
Although not an exclusive list, patients with all 4 of the following symptoms are considered to be at high risk for obstructive sleep apnea (OSA):
- habitual snoring;
- observed apneas;
- excessive daytime sleepiness;
- a body mass index (BMI) greater than 35kg/m²

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, craniofacial or upper airway soft tissue abnormalities, or unexplained hypertension) may be considered. Objective clinical prediction rules are being developed; however, at the present time, risk assessment is based primarily on clinical judgment.

The STOP-BANG questionnaire is a method developed for non-sleep specialists to assess the signs and symptoms of OSA (Snore, Tired, Observed apnea, blood Pressure, BMI, Age, Neck, Gender) and has been shown to have 97% sensitivity and a negative predictive value of 96% (specificity of 33%) for the identification of patients with severe OSA (Apnea/Hypopnea Index [AHI] score >30). Overnight oximetry has been used by some sleep specialists as a component of the risk assessment but is not adequate for the diagnosis of OSA. Therefore, a follow-up polysomnography (PSG) or home sleep study would still be required to confirm or exclude a diagnosis of OSA.
OSA in Children
The presentation of OSA in children may differ from that of adults. Children frequently exhibit behavioral problems or hyperactivity rather than daytime sleepiness. Obesity is defined as a body mass index greater than the 90th percentile for the weight/height ratio. Although the definition of severe OSA in children is not well established, an AHI greater than 1.5 is considered abnormal (an AHI score of ≥10 may be considered severe). In addition, the first-line treatment in children is usually adenotonsillectomy. CPAP is an option for children who are not candidates for surgery or who have an inadequate response to surgery.

Bariatric Surgery Patients
Screening for OSA should be performed routinely in patients scheduled for bariatric surgery, due to the high prevalence of OSA in this population. The optimal screening approach is not certain. An in-laboratory PSG or home sleep study is the most accurate screening method. Some experts recommend a symptom based screening instrument, followed by PSG in patients who exceed a certain threshold, as an alternative to performing PSG in all patients. It should be noted that there is a high prevalence of obesity hypoventilation syndrome in patients who are candidates for bariatric surgery. Therefore, obesity hypoventilation syndrome should be ruled out prior to home sleep testing in this population.

Note: The AHI (Apnea Hypopnea Index) is equal to the average number of episodes of apnea and hypopnea per hour of sleep and must be based on a minimum of 2 hours (unless an emergency protocol was activated) of sleep recorded by polysomnography using actual recorded hours of sleep, (i.e., the AHI may not be extrapolated or projected). The RDI (Respiratory Disturbance Index) may be defined as the number of apneas, hypopneas, and Respiratory event-related arousals (RERAs) per hour of sleep. Respiratory event-related arousals (RERAs) are scored if there is a sequence of breaths lasting at least 10 seconds characterized by increasing respiratory effort or flattening of the nasal pressure waveform leading to an arousal from sleep when the sequence of breaths does not meet criteria for an apnea or hypopnea. For purposes of this policy, apnea is defined as a cessation of airflow for at least 10 seconds. Hypopnea is defined using either the AASM recommended or alternative definitions.

Leg movement, snoring, and other sleep disturbances that may be included by some polysomnographic facilities are not considered to meet the AHI and/or RDI definition in this policy. Although AHI and RDI have been used interchangeably, some facilities use the term RDI to describe a calculation that includes these other sleep disturbances. Requests for the following pieces of DME will be considered not medically necessary if based upon an index that does not score apneas, hypopneas and RERAs separately from other sleep disturbance events. Only persons with an AHI and/or RDI, as defined in this policy that meets medical necessity criteria may qualify for coverage.

*Please refer to medical policy #305 for Polysomnography for Respiratory Sleep Disorders Testing.*
Policy:
Effective for dates of service on or after June 12, 2017:

Medical Management of OSA

CPAP for Obstructive Sleep Apnea (OSA)
Continuous positive airway pressure (CPAP) for the treatment of obstructive sleep apnea (OSA) in adults meets Blue Cross and Blue Shield of Alabama’s coverage criteria for patients who meet either of the following criteria on polysomnography:

1. Apnea Hypopnea Index (AHI) greater than or equal to 15 events per hour; **OR**
2. AHI greater than or equal to 5, and less than 15 events per hour with documentation demonstrating any of the following symptoms:
   - Excessive daytime sleepiness, as documented by either a cumulative or total score of ten or greater on the Epworth Sleepiness scale or inappropriate daytime napping, (e.g., during driving, conversation or eating) or sleepiness that interferes with daily activities; **OR**
   - Impaired cognition or mood disorders; **OR**
   - Hypertension; **OR**
   - Ischemic heart disease, congestive heart failure or history of stroke; **OR**
   - Cardiac arrhythmias; **OR**
   - Pulmonary hypertension; **OR**
   - Insomnia.

**Note:** Polysomnography should be performed per guidelines in medical policy #305.

CPAP for CHILDREN
CPAP for the treatment of obstructive sleep apnea (OSA) in children (17 years of age or younger) meets Blue Cross and Blue Shield of Alabama’s coverage criteria when the following criteria are met:

- There is a documented diagnosis of obstructive sleep apnea (OSA) and polysomnography demonstrates an apnea index (AI) or apnea-hypopnea index (AHI) equal to or greater than one (1); **AND**
- Adenotonsillectomy has been unsuccessful in relieving OSA; **OR**
- Adenotonsillar tissue is minimal; **OR**
- Adenotonsillectomy is inappropriate based on OSA being attributable to another underlying cause (e.g., septum deviations, facial abnormalities (craniofacial syndromes), obesity or when adenotonsillectomy is contraindicated.

BiPAP for the treatment of Obstructive Sleep Apnea meets Blue Cross and Blue Shield of Alabama’s medical criteria for coverage when used by patients diagnosed with Obstructive Sleep Apnea (OSA) when prior to initiating therapy, a complete (full or split night), approved facility based, attended polysomnography has been performed and the test results have confirmed the diagnosis of OSA and **ALL** of the following criteria are met:

CPAP would have met the medical criteria for coverage as defined in the previous policy statement and CPAP has been tried and proven ineffective.
Failed CPAP is defined as any of the following criteria documented in the medical record:

- Patient intolerance (claustrophobia, discomfort and/or pain due to pressure)
- Optimal PAP pressure has not been achieved, proven by evidence of respiratory events (apneas, hypopneas, etc) while on high pressures of CPAP (>10 cm H2O).

**Compliance Documentation**
Compliance documentation should be maintained in the supplier’s record. This documentation should include that the physician certifies the patient is compliant with the treatment and the sleep disorder has improved based on the treatment OR a recorded compliance document indicating proper usage. (≥ 4 hours per night on 70% of the nights during a 30 consecutive day period during the initial 90 days of usage) (Compliance documentation that extended beyond the 90 days will be reviewed on an individual basis i.e. Accidents, change in physical status, surgery, etc.)

**Replacement Devices**
Previously covered devices meet Blue Cross and Blue Shield of Alabama’s medical criteria for coverage to be replaced when the following criteria are met: (a repeat sleep study is not required)

- The equipment has suffered irreparable damage (cost more to repair than to replace) and has been in the home for three years or longer; OR
- The patient’s condition has changed and a different piece of equipment is determined to be medically necessary.

Replacement devices will not be covered for replacing functioning equipment with a newer more advanced model. (Compliance documentation is not required for replacement equipment.)

**Oral Devices for Obstructive Sleep Apnea (OSA)**
Oral Pressure Therapy (OPT) does not meet Blue Cross and Blue Shield of Alabama’s medical criteria for coverage and is considered investigational (an example of this therapy is Winx™, Sleep Therapy System by ApniCure).

Oral appliances for the treatment of obstructive sleep apnea meet Blue Cross and Blue Shield of Alabama’s medical criteria for coverage when all of the following criteria are met:

- Nocturnal polysomnogram has been performed in an approved facility or home sleep study and a diagnosis of obstructive sleep apnea has been made; AND
- Devices are used in patients who prefer oral appliances to CPAP, who do not respond to CPAP, OR have failed CPAP treatment; and ordered by the physician treating the patient for the diagnosed obstructive sleep apnea: AND
- The device must be fitted by qualified dental personnel (Over the counter devices or prefabricated, even if fitted by dental personnel are not covered).

Oral appliances for snoring do not meet Blue Cross and Blue Shield of Alabama’s medical criteria for coverage and are considered investigational.
Palate and mandible expansion devices (mRNA) do not meet Blue Cross and Blue Shield of Alabama’s medical criteria for coverage and are considered investigational for the treatment of OSA.

**EPAP**
Nasal Expiratory Airway Pressure (EPAP) also known as PROVENT does not meet Blue Cross and Blue Shield of Alabama’s coverage criteria and is considered investigational.

**Surgical management** of OSA (i.e., adenotonsillectomy, uvulopalatopharyngoplasty, orthognathic surgery, hypoglossal nerve stimulation) is discussed in medical policy #621-Surgical Treatment of Snoring and Obstructive Sleep Apnea Syndrome.

**Effective for dates of service from June 17, 2014 through June 11, 2017:**
**Medical Management of OSA**
**CPAP for Obstructive Sleep Apnea (OSA)**
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3. Apnea Hypopnea Index (AHI) greater than or equal to 15 events per hour; **OR**
4. AHI greater than or equal to 5, and less than 15 events per hour with documentation demonstrating any of the following symptoms:
   - Excessive daytime sleepiness, as documented by either a cumulative or total score of ten or greater on the Epworth Sleepiness scale or inappropriate daytime napping, (e.g., during driving, conversation or eating) or sleepiness that interferes with daily activities; **or**
   - Impaired cognition or mood disorders; **or**
   - Hypertension; **or**
   - Ischemic heart disease, congestive heart failure or history of stroke; **or**
   - Cardiac arrhythmias; **or**
   - Pulmonary hypertension; **or**
   - Insomnia.

**Note:** Polysomnography should be performed per guidelines in medical policy #305.

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CPAP for the treatment of obstructive sleep apnea (OSA) in children (17 years of age or younger) meets Blue Cross and Blue Shield of Alabama’s coverage criteria when the following criteria are met:

- There is a documented diagnosis of obstructive sleep apnea (OSA) and polysomnography demonstrates an apnea index (AI) or apnea-hypopnea index (AHI) equal to or greater than one (1); **AND**
- Adenotonsillectomy has been unsuccessful in relieving OSA; **OR**
- Adenotonsillar tissue is minimal; **OR**
• Adenotonsillectomy is inappropriate based on OSA being attributable to another underlying cause (e.g., septum deviations, facial abnormalities (craniofacial syndromes), obesity or when adenotonsillectomy is contraindicated.

**BiPAP for the treatment of Obstructive Sleep Apnea meets** Blue Cross and Blue Shield of Alabama’s medical criteria for coverage when used by patients diagnosed with Obstructive Sleep Apnea (OSA) when prior to initiating therapy, a complete (full or split night), approved facility based, attended polysomnography has been performed and the test results have confirmed the diagnosis of OSA and ALL of the following criteria are met:

CPAP would have met the medical criteria for coverage as defined in the previous policy statement and CPAP has been tried and proven ineffective.

Failed CPAP is defined as any of the following criteria documented in the medical record:

• Patient intolerance (claustrophobia, discomfort and/or pain due to pressure)
• Optimal PAP pressure has not been achieved, proven by evidence of respiratory events (apneas, hypopneas, etc) while on high pressures of CPAP (>10 cm H2O).

**Compliance Documentation**
Compliance documentation should be maintained in the supplier’s record. This documentation should include that the physician certifies the patient is compliant with the treatment and the sleep disorder has improved based on the treatment **OR** a recorded compliance document indicating proper usage. (≥ 4 hours per night on 70% of the nights during a 30 consecutive day period during the initial 90 days of usage) (Compliance documentation that extended beyond the 90 days will be reviewed on an individual basis i.e. Accidents, change in physical status, surgery, etc.)

**Replacement Devices**
*Previously covered* devices *meet* Blue Cross and Blue Shield of Alabama’s medical criteria for coverage to be replaced when the following criteria are met: (a repeat sleep study is not required)

• The equipment has suffered irreparable damage (cost more to repair than to replace) and has been in the home for three years or longer; **OR**
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Replacement devices will not be covered for replacing functioning equipment with a newer more advanced model. (Compliance documentation is not required for replacement equipment.)

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*Oral Pressure Therapy (OPT) does not meet* Blue Cross and Blue Shield of Alabama’s medical criteria for coverage and is considered investigational (an example of this therapy is Winx™, Sleep Therapy System by ApniCure).
Oral appliances for the treatment of obstructive sleep apnea meet Blue Cross and Blue Shield of Alabama’s medical criteria for coverage when all of the following criteria are met:

- Nocturnal polysomnogram has been performed in an approved facility or home sleep study and a diagnosis of obstructive sleep apnea has been made; AND
- Devices are used in patients who prefer oral appliances to CPAP, who do not respond to CPAP, OR have failed CPAP treatment; and ordered by the physician treating the patient for the diagnosed obstructive sleep apnea: AND
- The device must be fitted by qualified dental personnel (Over the counter devices or prefabricated, even if fitted by dental personnel are not covered).

Oral appliances for snoring do not meet Blue Cross and Blue Shield of Alabama’s medical criteria for coverage and are considered investigational.

EPAP
Nasal Expiratory Airway Pressure (EPAP) also known as PROVENT does not meet Blue Cross and Blue Shield of Alabama’s coverage criteria and is considered investigational.

Surgical management of OSA (i.e., adenotonsillectomy, uvulopalatopharyngoplasty, orthognathic surgery, hypoglossal nerve stimulation) is discussed in medical policy #621-Surgical treatment of Snoring and Obstructive Sleep Apnea Syndrome.

Blue Cross and Blue Shield of Alabama does not approve or deny procedures, services, testing, or equipment for our members. Our decisions concern coverage only. The decision of whether or not to have a certain test, treatment or procedure is one made between the physician and his/her patient. Blue Cross and Blue Shield of Alabama administers benefits based on the member’s contract and corporate medical policies. Physicians should always exercise their best medical judgment in providing the care they feel is most appropriate for their patients. Needed care should not be delayed or refused because of a coverage determination.

Key Points:
The most recent update and literature review was performed through April 25, 2017.

Primary Care versus Specialist Care
A 2013 randomized noninferiority trial by Chai-Coetz et al compared primary care versus specialist sleep center management of OSA. Prospective participants were screened for eligibility by 34 primary care physicians using a screening questionnaire (n=402) followed by overnight oximetry (n=301). Inclusion criteria were a score of 5 or more on the questionnaire, at least 16 events per hour of oxygen desaturation (≥3%), and an ESS of eight or higher or persistent hypertension. An ambulatory sleep study with the recommended number of channels was not performed. Enrolled subjects were then randomly allocated to management by a primary care physician and community-based nurse, both of whom received brief training in sleep medicine (n=81), or to a sleep medicine specialist (n=74). CPAP pressure was determined through either 3 days of APAP or PSG titration. At the 6-month follow-up, 63% of patients in the primary care group and 61% of patients in the specialist groups were using CPAP. ESS
scores improved to a similar extent in both groups, from a mean score of 12.8 to 7.0 in the primary care group and from 12.5 to 7.0 in the specialist group. There were similar improvements in secondary outcomes (FOSQ, Sleep Apnea Symptoms Questionnaire, SF-36) for the 2 groups.

**Diagnosed Obstructive Sleep Apnea**

**Positive Airway Pressure Devices**

The 2011 AHRQ CER concluded that the strength of evidence for continuous positive airway pressure (CPAP) for OSA was moderate based on the large magnitude of effect on the intermediate outcomes of the AHI, Epworth Sleepiness Scale (ESS), and arousal index, even though there was weak evidence demonstrating an effect of CPAP on clinical outcomes. In addition, the review found moderate evidence that APAP and fixed-pressure CPAP result in similar levels of compliance (hours used per night) and treatment effects for patients with OSA. There was moderate evidence that CPAP is superior to mandibular advancement devices in improving sleep study measures.

Evidence-based guidelines from AASM concluded that CPAP and APAP devices have similar outcomes in terms of AHI, oxygen saturation, and arousals. As indicated in the CER, increased compliance with APAP devices has not been well-documented in clinical trials. Thus, the issues associated with APAP are similar to those for bi-level positive airway pressure.

The 2016 SAVE randomized controlled trial (RCT) found no benefit of CPAP on the primary composite outcome of death or hospitalization for cardiovascular events in 2717 adults with moderate-to-severe OSA and cardiovascular disease. With a mean duration of adherence to CPAP therapy of 3.3 hours per night, CPAP significantly reduced daytime sleepiness (adjusted difference in ESS score, -2.5; 95% confidence interval [CI], -2.8 to -2.2; p<0.001) and improved health-related quality of life (HRQOL) and mood. An improvement in postoperative outcomes with CPAP was suggested in a 2014 matched comparison of patients with OSA who had been diagnosed prior to surgery (2640 surgeries), those not diagnosed until up to 5 years after surgery (1571 surgeries), and 16,277 surgeries for patients without a diagnosis of OSA out of 21 years of available data. In multivariate analysis, the risk of respiratory complications was increased for both diagnosed and undiagnosed OSA patients compared to controls (odds ratio [OR], 2.08; p<0.001). The risk of cardiovascular complications, primarily cardiac arrest and shock, was higher in OSA patients not diagnosed until after surgery (relative risk [RR], 2.20; 95% CI, 1.16 to 4.17; p=0.02), but not in those diagnosed prior to surgery (RR=0.75; 95% CI, 0.43 to 1.28; p=0.29); the difference between groups was significant (p=0.009). There was a significant trend toward a higher risk with increasing OSA severity. Limitations of the study included the inability to determine whether CPAP was used perioperatively, and because body mass index could not be determined, potential confounding from the close association between obesity and OSA.

A systematic review of the evidence on the treatment of OSA with oral appliance therapy was performed for a 2015 update of clinical practice guidelines by AASM and the American Academy of Dental Sleep Medicine. Meta-analysis showed that oral appliances reduced the AHI, arousal index, and oxygen desaturation index, and increase oxygen saturation. However, oral appliances had no significant effect on sleep architecture or sleep efficiency. Meta-analysis found CPAP to be more effective than oral appliances in reducing the AHI, arousal index, and
oxygen desaturation index, and in improving oxygen desaturation, supporting the use of CPAP as a first-line therapy for treating OSA.

Subsection Summary: Positive Airway Pressure Devices
Positive airway pressure devices are accepted therapies for OSA. Studies suggest that both CPAP and APAP are associated with improvements in sleep architecture.

Mandibular Advancement Device
In 2017, Johal et al reported on a randomized crossover trial of ready-made versus custom-made mandibular repositioning devices. Twenty-five patients with mild-to-moderate OSA (mean AH1, 13.3 events/h; range, 10.9-25 events/h) were randomized to a 3-month trial of a ready-made or to custom-made device, with a 2-week washout between treatments. An overnight home sleep study was performed at baseline and on the last night of the 3-month trial period. Patients used the custom-made device for more nights per week (7 vs 3, p=0.004) and hours per night (5 vs 3, p=0.006) than the ready-made device. Treatment response (AH1 <5 events/h) was obtained in 64% of patients during use of the custom-made device phase compared to a 24% response rate with the ready-made device (p<0.001). Treatment failure (<50% reduction in AH1) was more frequent with the ready-made device (36%) than with the custom device (4%), while an ESS score of at least 10 was more frequent during the ready-made phase (66%) compared to the custom made phase (33%). An improvement in quality of life was observed only during the custom-made device phase.

In the 2011 AHRQ CER on the diagnosis and treatment of OSA in adults, the strength of the evidence that mandibular advancement devices improve sleep apnea signs and symptoms was rated moderate.

Novel OSA Treatments
Palate and Mandible Expansion
In 2016, Singh et al reported on a series of 15 consecutive patients with severe sleep apnea who were treated with a DNA Appliance or mRNA Appliance. All patients had failed to comply with CPAP. Pre- and posttreatment AH1 was assessed in a home sleep study without the oral appliance. AH1 decreased from a mean 45.9 events per hour to 16.5 (p<0.01) after a mean 9.7 months of treatment. In a 2017 study, Singh and Cress reported on a series of 19 patients who had mild-to-moderate sleep apnea who were treated with a DNA or mRNA Appliance. Only patients who complied with oral appliance wear were included in the study. The mean AH1 was reduced from 12.85 to 6.2 events per hour (p<0.001) without the appliance while the oxygen saturation index improved from 6.3% to 2.6% (p<0.001). Limitations of these studies included the use of a home sleep study rather than the more accurate laboratory PSG, uncertain blinding of the physician evaluating the sleep study, the small number of patients studied, the lack of intention-to-treat analysis, and the lack of long-term follow-up.

Oral Pressure Therapy
No full-length, peer-reviewed studies on oral pressure therapy were identified in the published literature. Therefore, it is not possible to evaluate the efficacy of this treatment based on scientific evidence.
**Section Summary: Novel OSA Treatments**

The evidence on palate and mandible expansion devices includes a few small cohort studies. Further study with well-designed trials is needed to evaluate this treatment.

**Oral Appliance Therapy**

A systematic review of the evidence on the treatment of OSA with oral appliance therapy was performed for a 2015 update of clinical practice guidelines by the American Academy of Sleep Medicine (AASM) and the American Academy of Dental Sleep Medicine. Meta-analysis showed that oral appliances reduce AHI, arousal index, and oxygen desaturation index, and increase oxygen saturation. However, oral appliances had no significant effect on sleep architecture and sleep efficiency. Meta-analysis found CPAP to be more effective than oral appliances in reducing the AHI, arousal index, and oxygen desaturation index and improving oxygen desaturation, supporting the use of CPAP as a first line therapy for treating OSA.

One of the studies included in the systematic review was a 2013 randomized crossover trial by Phillips et al, who found similar health outcomes after one month of CPAP or oral appliance therapy (OAT) in 126 patients (82% with moderate to severe OSA, AHI ≥15). CPAP was more effective than mandibular advancement therapy in reducing AHI (CPAP AHI=4.5, OAT AHI=11.1), but patient-reported compliance was higher with OAT (6.5 vs 5.2 hours/night). Neither treatment improved the primary outcome of 24-hour ambulatory blood pressure, except in a subgroup of patients who were initially hypertensive. The two treatments resulted in similar improvements in sleepiness (improvement, 1.6-1.9), FOSQ (improvement, 1.0), some measures on driving simulator performance, and disease-specific quality of life. OAT was superior to CPAP in four domains on the SF-36.

**Nasal EPAP**

Evidence includes a moderately sized RCT and a systematic review on the Provent device. In 2011, Berry et al reported an industry-sponsored multicenter double-blind randomized sham-controlled trial of nasal EPAP. Two hundred fifty patients with OSA and an AHI of 10 or more per hour were randomized to nasal EPAP (n=127) or a sham device (n=123) for 3 months. PSG was performed on 2 nights (device-on, device off, in a random order) at week 1 (92% follow-up) and after three months of treatment (78% follow-up). EPAP reduced the AHI from a median of 13.8 to 5.0 (-52.7%) at week 1 and from 14.4 to 5.6 (-42.7%) at three months. This was a significantly greater reduction in AHI than the sham group (-7.3% at week 1, -10.1% at three months). Over three months, the decrease in ESS was statistically greater in the EPAP group (from 9.9 to 7.2) than in the sham group (from 9.6 to 8.3), although the clinical significance of a one point difference in the ESS is unclear. Treatment success and oxygenation data were presented only for the 58% of per-protocol patients who had an AHI of five or more per hour on the device-off PSG night. The oxygenation results (oxygenation desaturation index and % of total sleep time with SpO2 <90%) showed small but statistically significant decreases at 1 week and 3 months. Treatment success, defined as a 50% or greater reduction in the AHI or an AHI reduced to less than 10 (if device-off AHI was 10 or more), was greater in the EPAP group at 1 week (62% vs 27.2%) and three months (50.7% vs 22.4%). Device-related adverse events were reported by 45% of patients in the EPAP group and 34% of patients in the sham group, with 7% of patients in the EPAP group discontinuing the study due to adverse events. Overall, the validity...
of these results is limited by the high dropout rate, and the clinical significance of the results is uncertain.

An open-label extension of the 2011 randomized study by Berry et al evaluated 12-month safety and durability of the treatment response in patients who had an initial favorable response to EPAP. Included were 41 patients (32% of 127) in the EPAP arm of the study who used the device for an average of at least four hours per night on at least five nights per week during months one and two and had at least a 50% reduction in AHI, or reduction to less than 10 events per hour, compared to the device-off PSG. Of the 51 patients (40% of 127) eligible, 41 enrolled in the extension study, and 34 (27% of 127) were still using the EPAP device at the end of 12 months. Median AHI was reduced from 15.7 to 4.7 events per hour; the percentage of patients who met criteria for success was not reported. The arousal index was modestly decreased (from 23.9 to 19.0). Over 12 months of treatment, the ESS decreased from 11.1 to 6.0. The median percentage of reported nights used (entire night) was 89.3%. Device-related adverse events were reported by 42% of patients, and the most frequently reported adverse events were difficulty exhaling, nasal discomfort, dry mouth, headache, and insomnia. This open-label extension study is limited by the inclusion of responders only and by the potential for a placebo effect on the ESS. However, the data suggest that some patients may respond to this device, and the patient compliance data might indicate a positive effect on daytime sleepiness that leads to continued use of the device in about one in four patients. Additional controlled studies are needed to distinguish between these alternatives.

A 2015 systematic review identified 18 studies (total N=920 patients) that had data on pre- and postnasal EPAP. Study designs included 10 conference papers and 8 publications (case series, cohort studies, RCTs). Of patients included in the meta-analysis (n=345 patients) AHI decreased from 27.32 to 12.78 events per hour (p<0.001). For 359 patients, ESS score modestly improved from 9.9 to 7.4 (p<0.001). Data from the Berry RCT (described above) were not included in the meta-analysis because mean data were not reported. Response to nasal EPAP was variable and inconsistent, and there were no clear characteristics (demographic factors, medical history, and/or physical exam finding) that predicted a favorable response.

Kureshi et al (2014) reported a small (n=14) double-blind, pilot, crossover RCT on EPAP in children to evaluate efficacy and compliance with this new treatment. PSG with EPAP or a placebo device showed a significant mean improvement in obstructive apnea index with EPAP (index of 0.6 vs 4.2, p = 0.01), but responses were variable (three not improved and two worsening). No other measures were statistically significant in this small study. For the responders who utilized the devices at home for 30 days, adherence was 83% of nights. The Epworth Sleepiness scale improved from 11 to 7 (p=0.031) and the Obstructive Sleep Apnea -18 questionnaire improved from 50 to 39 (p = 0.028). Other outcome measures did not improve significantly.

Oral Pressure Therapy
No full-length, peer-reviewed studies on OPT have been identified in the published literature. Therefore, it is not possible to evaluate the efficacy of this treatment based on scientific evidence.
Section Summary: Treatment
The evidence on EPAP devices in patients with OSA has been reported in several prospective case series, 1 industry-sponsored RCT, and a systematic review that did not include the RCT. The main finding of the RCT was a decrease in AHI with a minor impact on oxygenation and ESS score.

One comparative trial with historical controls used a PAP-NAP study of patients with complex insomnia who are resistant to CPAP titration or use. This single study of PAP-NAP does not provide sufficient evidence to form conclusions on the efficacy of this approach in improving compliance with CPAP. The patient population was highly selected and the behavioral intervention may be dependent on the specific clinicians providing treatment. In addition, historical controls were used, and they were not well-matched to the study population. For these reasons, the internal validity and generalizability of the results are uncertain.

Summary of Evidence
For individuals who have OSA who receive positive airway pressure or mandibular advancement devices, the evidence includes RCTs and systematic reviews of RCTs. Relevant outcomes are symptoms, functional outcomes, and quality of life. Conventional medical management of OSA includes weight loss, avoidance of stimulants, body position adjustment, oral appliances, and use of CPAP during sleep. A diagnostic sleep study may be followed by a trial of auto-adjusting positive airway pressure to evaluate efficacy and adjust pressure. Auto-adjusting positive airway pressure or bi-level positive airway pressure may also be indicated if the patient is intolerant of CPAP. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

For individuals who have OSA who receive novel OSA treatments (e.g., expiratory positive airway pressure, oral pressure therapy, palate and mandible expansion), the evidence includes 1 RCT and a meta-analysis of case series. Relevant outcomes are symptoms, functional outcomes, and quality of life. The evidence on palate and mandible expansion devices includes a few small series. Further study with well-designed trials is needed to evaluate this treatment. The evidence on expiratory positive airway pressure devices in patients with OSA has been reported in prospective case series, 1 industry-sponsored RCT, and a systematic review that did not include the RCT. The main finding of the RCT was a decrease in the Apnea/Hypopnea Index, with minor impact on oxygenation, and a decrease in Epworth Sleepiness Scale score. One comparative trial with historical controls used a positive airway pressure nap (PAP-NAP) to study patients with complex insomnia resistant to CPAP titration or use. Additional study is needed to evaluate with greater certainty the efficacy of this intervention. No evidence was identified on use of the oral therapy device or palate and mandible expansion devices. The evidence is insufficient to determine the effects of the technology on health outcomes.

Refer to policy #621 – Surgical Management of Obstructive Sleep Apnea for information on surgical treatments.
Practice Guidelines and Position Statements
American Academy of Sleep Medicine

In 1997 the American Sleep Disorders Association (now the American Academy of Sleep Medicine [AASM]) published practice parameters for PSG and related procedures; these were most recently updated in 2005. The guidelines 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 35kg/m², and observed apneas.

In 2017, AASM published clinical practice guidelines on diagnostic testing for adult obstructive sleep apnea (OSA). AASM provided the following recommendations (see Table 1).

Table 1. Summary of Recommendations

<table>
<thead>
<tr>
<th>Recommendation Statement</th>
<th>SOR</th>
<th>QOE</th>
<th>Benefits vs Harms</th>
</tr>
</thead>
<tbody>
<tr>
<td>We recommend that clinical tools, questionnaires, and prediction algorithms not be used to diagnose OSA in adults, in the absence of PSG or HSAT</td>
<td>Strong</td>
<td>Moderate</td>
<td>High certainty that harms outweigh benefits</td>
</tr>
<tr>
<td>We recommend that PSG, or HSAT with a technically adequate device, be used for the diagnosis of OSA in uncomplicated adult patients presenting with signs and symptoms that indicate an increased risk of moderate to severe OSA.</td>
<td>Strong</td>
<td>Moderate</td>
<td>High certainty that benefits outweigh harms</td>
</tr>
<tr>
<td>We recommend that if a single HSAT is negative, inconclusive, or technically inadequate, PSG be performed for the diagnosis of OSA.</td>
<td>Strong</td>
<td>Low</td>
<td>High certainty that benefits outweigh harms</td>
</tr>
<tr>
<td>We recommend that PSG, rather than home sleep testing, be used for patients with significant cardiopulmonary disorder, potential respiratory muscle weakness, awake or suspected sleep hypoventilation, chronic opioid medication use, history of stroke or severe insomnia.</td>
<td>Strong</td>
<td>Very low</td>
<td>High certainty that benefits outweigh harms</td>
</tr>
<tr>
<td>We suggest that, if clinically appropriate, a split-night diagnostic protocol, rather than a full-night diagnostic protocol for PSG be used for the diagnosis of OSA.</td>
<td>Weak</td>
<td>Low</td>
<td>Low certainty that benefits outweigh harms</td>
</tr>
<tr>
<td>We suggest that when the initial PSG is negative, and there is still clinical suspicion for OSA, a second PSG be considered for the diagnosis of OSA.</td>
<td>Weak</td>
<td>Very low</td>
<td>Low certainty that benefits outweigh harms</td>
</tr>
</tbody>
</table>

HSAT: home sleep apnea testing; OSA: obstructive sleep apnea; PSG: polysomnography; QOE: quality of evidence; SOR: strength of recommendation.

AASM also issued guidelines in 2009 on the evaluation, management, and long-term care of adults with OSA. The levels of recommendation are “standard” (generally accepted patient-care strategy, with high degree of certainty; level 1 to 2 evidence), “guideline” (moderate degree of clinical certainty; Level 2 to 3 evidence), or “option” (uncertain clinical use; insufficient or inconclusive evidence).

Diagnosis

AASM recommended that patients who are obese, retrognathic, hypertensive, or who complain of snoring or daytime sleepiness should be assessed for presence or absence as well as severity of OSA using the following methods (standard):

- Sleep history assessment includes “witnessed apneas, gasping/choking at night, excessive sleepiness, total sleep amount, nocturia, morning headaches and decreased concentration and memory.”
• Physical assessment includes evaluation of “respiratory, cardiovascular, and neurologic system and signs of upper respiratory narrowing.”

• Objective testing, under an AASM-accredited program, and attended by trained technical personnel. The diagnosis of OSA is confirmed if the number of obstructive events (apneas, hypopneas plus respiratory event related to arousals) is greater than 15 events/hour or greater than 5 events/hour in a patient reporting any of the following: unintentional sleep episodes during wakefulness; daytime sleepiness, unrefreshing sleep; fatigue; insomnia; waking up breath holding, gasping, or choking; or a bed partner describing loud snoring, breathing interruptions, or both.

• In laboratory polysomnography (standard) records “electroencephalogram, electrooculogram, chin electromyogram, airflow, oxygen saturation, respiratory effort, and heart rate.”

• Home testing with portable monitors should “at minimum, record air flow, respiratory effort, and blood oxygenation.”

Treatment with Positive Airway Pressure

• Continuous positive airway pressure (CPAP) is indicated for patients with “moderate to severe OSA (Standard) and mild OSA.”

• Bi-level positive airway pressure can be considered in “CPAP-intolerant patients”.

• Auto titrating positive airway pressure (APAP) can be considered in “CPAP-intolerant patients”.

Treatment with oral appliances (OA) is indicated for “patients with mild to moderate OSA, who prefer OAs to CPAP, or who do not respond to CPAP, or are not appropriate candidates for CPAP, or who fail CPAP.

• Mandibular repositioning appliance covers the upper and lower teeth.

• Tongue retaining device holds the tongue in a forward position.

In 2015, AASM and the American Academy of Dental Sleep Medicine (AADSM) published a Clinical Practice Guideline on the treatment of OSA and snoring with oral appliance therapy. AASM and AADSM provided a recommendation of “standard” that sleep physicians consider prescription of oral appliances, rather than no treatment, for adult patient with OSA who are intolerant of CPAP therapy or prefer alternative therapy. The quality of evidence was rated as moderate. “Guideline” recommendations were provided for the use of custom, titratable appliance over non-custom oral devices, that qualified dentists provide oversight, that sleep physicians conduct follow-up sleep testing to improve or confirm treatment efficacy, and that patients return for periodic office visits with a qualified dentist and a sleep physician.

AASM published evidence-based guidelines for respiratory indications for PSG in children in 2011. “Standard” recommendations were made for the following: PSG in children should be performed and interpreted in accordance with the AASM Manual for the Scoring of Sleep and Associated Events; PSG is indicated when the clinical assessment suggests the diagnosis of OSA in children; children with mild OSA preoperatively should have clinical evaluation following adenotonsillectomy to assess for residual symptoms. If there are residual symptoms of OSA,
PSG should be performed; PSG is indicated following adenotonsillectomy to assess for residual OSA in children with preoperative evidence for moderate to severe OSA, obesity, craniofacial anomalies that obstruct the upper airway, and neurologic disorders; PSG is indicated for positive airway pressure titration in children with OSA.

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

American College of Physicians
The 2014 guidelines on the diagnosis of OSA in adults from the American College of Physicians (ACP) recommend that clinicians should target their assessment of OSA to individuals with unexplained daytime sleepiness. ACP recommends PSG for diagnostic testing in patients suspected of OSA, and portable sleep monitors in patients without serious comorbidities as an alternative to PSG when PSG is not available for diagnostic testing (weak recommendation, moderate-quality evidence). Inconclusive areas of evidence included preoperative screening for OSA, phased testing for the diagnosis of OSA, and the utility of portable monitors for diagnosis OSA in patients with comorbid conditions.

The 2013 guidelines on the management of OSA in adults from the ACP recommend that all overweight and obese patients diagnosed with OSA should be encouraged to lose weight (strong recommendation, low-quality evidence). ACP recommends CPAP as initial therapy for patients diagnosed with OSA (strong recommendation; moderate-quality evidence), and mandibular advancement devices as an alternative therapy to CPAP for patients diagnosed with OSA who prefer mandibular advancement devices or for those with adverse effects associated with CPAP (weak recommendation, low-quality evidence).

American Academy of Craniofacial Pain
The American Academy of Craniofacial Pain Task Force on Mandibular Advancement Oral Appliance Therapy for Snoring and Obstructive Sleep Apnea published a position paper in 2013. The position paper states that oral appliance therapy is recognized as an effective therapy for many with primary snoring and mild to moderate OSA, as well as those with more severe OSA who cannot tolerate PAP therapies, but that oral appliance therapy has the potential to cause
adverse effects including temporomandibular joint (TMJ) pain and dysfunction. The authors recommend that dentists engaged in, or who wish to engage in, the assessment and management of patients with snoring and OSA using mandibular advancement oral appliances should be properly trained and experienced in the assessment, diagnosis and management of TMJ and craniofacial pain.

American Society of Metabolic and Bariatric Surgery
The American Society of Metabolic and Bariatric Surgery (ASMBS) Clinical Issues Committee published guidelines on the perioperative management of obstructive sleep apnea in 2012. The guidelines were reviewed in October 2015 and no changes were recommended. The guidelines note that while some reports in the literature recommend routine screening for OSA prior to bariatric surgery, other reports suggest clinical screening only does not result in any increase in postoperative pulmonary complications after laparoscopic Roux-en-Y gastric bypass, and that most current surgical practices refer patients with clinical symptoms of OSA for polysomnography, but do not make this a routine preoperative test prior to bariatric surgery. ASMBS provided, based on the evidence in the literature to date, the following guidelines regarding OSA in the bariatric surgery patient and its perioperative management:

- OSA is highly prevalent in the bariatric patient population. The high prevalence demonstrated in some studies suggests that consideration be given to testing all patients, and especially those with any preoperative symptoms suggesting obstructive sleep apnea.
- Patients with moderate to severe OSA should bring their CPAP machines, or at least their masks, with them at the time of surgery and use them following bariatric surgery at the discretion of the surgeon.
- Routine pulse oximetry or capnography for postoperative monitoring of patients with OSA after bariatric surgery should be utilized, but the majority of these patients do not routinely require an ICU setting.
- No clear guidelines exist upon which to base recommendations for retesting for OSA following bariatric surgery. Strong consideration should be given to retesting patients who present years after bariatric surgery with regain of weight, a history of previous OSA, and who are being reevaluated for appropriate medical and potential reoperative surgical therapy.

American Academy of Otolaryngology–Head and Neck Surgery
The American Academy of Otolaryngology–Head and Neck Surgery published clinical practice guidelines on PSG for sleep-disordered breathing prior to tonsillectomy in children in 2011. The committee made the following recommendations:

- Before determining the need for tonsillectomy, the clinician should refer children with sleep-disordered breathing for PSG if they exhibit certain complex medical conditions such as obesity, Down syndrome, craniofacial abnormalities, neuromuscular disorders, sickle cell disease, or mucopolysaccharidoses.
- The clinician should advocate for PSG prior to tonsillectomy for sleep-disordered breathing in children without any of the comorbidities listed above for whom the need for surgery is uncertain or when there is discordance between tonsillar size of physical examination and the reported severity of sleep-disordered breathing.
• Clinicians should communicate PSG results to the anesthesiologist prior to the induction of anesthesia for tonsillectomy; clinicians should admit children with OSA documented on PSG for inpatient, overnight monitoring after tonsillectomy if they are younger than age 3 years or have severe OSA (AHI ≥10, oxygen saturation nadir <80%, or both)
• In children for whom PSG is indicated to assess sleep-disordered breathing prior to tonsillectomy, and obtain laboratory based PSG, when available.

American Thoracic Society
The American Thoracic Society (ATS) published 2013 Guidelines on sleep apnea and driving risk in noncommercial drivers. ATS gives a strong recommendation (based on moderate quality evidence) for treatment of confirmed OSA with CPAP to reduce driving risk. ATS defines a high-risk driver as one who has moderate to severe daytime sleepiness and a recent unintended motor vehicle crash or a near-miss attributable to sleepiness, fatigue, or inattention. Weak recommendations (based on very low-quality evidence) were made for expeditious diagnostic evaluation for patients in whom there is a high clinical suspicion of OSA and against the use of stimulant medications or empiric CPAP to reduce driving risk.

In 2016, ATS published a research statement on the long-term effects and treatment of mild OSA in adults. One research question in the statement was to determine if treatment of mild OSA improved daytime sleepiness, quality of life, and reduced neurocognitive consequences. ATS’s systematic review concluded:
• Daytime sleepiness: subjective improvement with CPAP; unclear effect with non-CPAP therapies
• Quality of life: small improvements seen in different domains in different studies
• Neurocognition: treatment effects inconsistent.

U.S. Preventive Services Task Force Recommendations
In 2017, the U.S. Preventive Services Task Force (USPSTF) reviewed the evidence on screening for OSA in adults and concluded that “the current evidence is insufficient to assess the balance and harms of screening for obstructive sleep apnea (OSA) in asymptomatic adults. Evidence on screening tools to accurately detect persons in asymptomatic populations who should receive further testing and treatment of subsequently diagnosed OSA to improve health outcomes is lacking, and the balance of benefits and harms cannot be determined.”

Key Words:
Continuous positive airway pressure, CPAP, Bi-level positive airway pressure, BiPAP, obstructive sleep apnea syndrome, OSA, OSAS, upper airway resistance syndrome, UARS, auto-titrate CPAP, auto-adjusting CPAP, APAP, oral appliances, OA, mandibular repositioning device, MRA, BiPAP BiFlex, Repose, C-Flex, A-Flex, Auto-CPAP, nasal expiratory positive airway pressure, Winx™ Sleep Therapy System, Oral Pressure Therapy (OPT), Hypoglossal Nerve Stimulator, DNA Appliance, mRNA Appliance, mandible expanding devices
Approved by Governing Bodies:
A variety of oral appliances have been cleared for marketing clearance by U.S. Food and Drug Administration (FDA) though the 510(k) process for the treatment of snoring and mild to moderate sleep apnea, including the Narval CCTM, Lamberg SleepWell Smarttrusion, 1st Snoring Appliance, Full Breath Sleep Appliance, PM Positioner, Snorenti, Snorex, Osap, Desra, Elastomeric Sleep Appliance, Snoremaster Snore Remedy, Snore-no-More, Napa, Snoar™ Open Airway Appliance, and The Equalizer Airway Device.

In 2014, the mRNA Appliance® was cleared for marketing by FDA through the 510 (k) process for the treatment of snoring and mild to moderate obstructive sleep apnea.

A number of various CPAP devices have received clearance through the 510(k) process since 1977. BiPAP devices were first cleared for marketing by FDA in 1996.

In 2010, a nasal expiratory resistance valve (PROVENT®, Ventus Medical) received clearance for marketing by FDA through the 510(k) process for the treatment of OSA. The Winx™ system received marketing clearance in 2012.

Benefit Application:
Coverage is subject to member’s specific benefits. Group specific policy will supersede this policy when applicable.
ITS: Home Policy provisions apply
FEP: Special benefit consideration may apply. Refer to member’s benefit plan. FEP does not consider investigational if FDA approved and will be reviewed for medical necessity.

Current Coding:

CPT 94660 Continuous positive airway pressure ventilation (CPAP), initiation and management

HCPCS Codes:

A7047 Oral interface used with respiratory suction pump, each

E0470 Respiratory assist device, bi-level pressure capability, without backup rate feature, used with non-invasive interface, e.g., nasal or facial mask (intermittent assist device with continuous positive airway pressure device)

E0471 Respiratory assist device, bi-level pressure capability, with back-up rate feature, used with noninvasive interface, e.g., nasal or facial mask (intermittent assist device with continuous positive airway pressure device)
E0472 Respiratory assist device, bi-level pressure capability, with backup rate feature, used with invasive interface, e.g., tracheostomy tube (intermittent assist device with continuous positive airway pressure device)

E0485 Oral device/appliance used to reduce upper airway collapsibility, adjustable or non-adjustable, prefabricated, includes fitting and adjustment.

E0486 Oral device/appliance used to reduce upper airway collapsibility, adjustable or on-adjustable, custom fabricated, includes fitting and adjustment

E0561 Humidifier, non-heated, used with positive airway pressure device

E0562 Humidifier, heated, used with positive airway pressure device

E0601 Continuous airway pressure (CPAP) device-(This code should also be used to bill the APAP devices.)

E1399 Unlisted code – This should be used to report the Winx™ system and all associated supplies

References:


Policy History:
Medical Policy Group, August 2002
Medical Policy Administration Committee, September 2002
Available for comment December 18, 2002-February 3, 2003
Medical Policy Group, October 2003 (1)
Medical Policy Group, October 2004
Medical Policy Group, February 2005 (3)
Medical Policy Administration Committee, July 2005
Available for comment August 6-September 19, 2005
Medical Policy Group, October 2005 (1)
Medical Policy Administration Committee, October 2005
Available for comment October 24-December 7, 2005
Medical Policy Group, July 2006 (1)
Medical Policy Administration Committee, August 2006
Available for comment August 4-September 18, 2006
Medical Policy Group, February 2007
Medical Policy Group, July 2007 (1)
Medical Policy Administration Committee, July 2007
Available for comment July 27-August 15, 2007
Medical Policy Group, August 2007 (1)
Medical Policy Administration Committee, August 2007
Available for comment August 16-September 29, 2007
Medical Policy Group, February 2009 (1)
Medical Policy Group, March 2010 (3): Policy update regarding Medical management, and clarification, References added, Key Points
Medical Policy Administration Committee April 2010
Available for comment March 24-May 7, 2010
Medical Policy Group, June 2010 (3)
Medical Policy Administration Committee, July 2010
Medical Policy Group, July 2010 (3)
Medical Policy Administration Committee, August 2010
Available for comment August 6-September 18, 2010
Medical Review Group, March 2011 (3)
Medical Policy Administration Committee, March 2011
Available for comment April 4 – May 18, 2011
Medical Policy Group, July 2011; Update to Benefit Application Section –Monsanto Grp
Medical Policy Group, April 2012 (3): Updated Policy to add oral devices (Provent), Key Points, Approved by Governing Bodies, & References
Medical Policy Administration Committee; May 2012
Available for comment May 10 through June 25, 2012
Medical Policy Group, May 2012 (3): Updated Key Points and References
Medical Policy Group, May 2012 (3): Added information regarding non-coverage of the Winx™ System, Oral Pressure Therapy (by ApniCure)
Available for comment June 14 through July 30, 2012
Medical Policy Panel, May 2013
Medical Policy Group, May 2013 (3): 2013 Updates – no new literature available for review through April 17, 2013; no changes in policy statement
Medical Policy Group, April 2014 (5): Updated Maximums for CPAP tubing; Policy section reworked and organized to include Medical and Surgical management of OSA under new effective date.
Medical Policy Administration Committee May 2014
Available for comment May 6 through June 19, 2014
Medical Policy Panel, May 2014
Medical Policy Group, June 2014(5): Updated Policy statement adding investigational statement for hypoglossal nerve stimulation; Key word, Key Points, Approved by Governing Bodies, & References updated with literature review through April 25, 2014.
Medical Policy Administration Committee June 2014
Available for comment June 19 through August 2, 2014
Medical Policy Group, July 2014(5): Updated policy statement to included RERA(respiratory event- related arousals) in the definition of RDI; Rearranged and added information under description and added reference July 2014.
Medical Policy Panel November 2014
Medical Policy Group, November 2014 (5): Updated key points and references per literature review; no change in policy statement.
Medical Policy Group, May 2015 (6): Updates to Description, Key Points, Approved by Governing Bodies, Key Words and References; no change to policy statement.
Medical Policy Group, October 2015 (6): Clarification to Policy section – Related Supply Coverage, A4604 and A7037 covered for a combined max of 1 per 120 days. Added new Key Word (hypoglossal nerve stimulation)
Medical Policy Panel, November 2015
Medical Policy Group, December 2015 (6): Updates to Description, Key Points and References; no change in policy statement.
Medical Policy Group, March 2016 (6): Updates to Description, Policy Statement, Key Points, Key Words, Approved by Governing Bodies, Coding and References to remove information on surgical treatment of OSA. Surgical Treatment is now covered in medical policy #621 – "Surgical Management of Obstructive Sleep Apnea." Policy statement regarding BiPAP coverage for OSA moved from MP#203 and added to this policy; no changes in policy intent.
Medical Policy Group, November 2016(6): Added clarification statement to policy statement: “Note: Nocturnal polysomnogram testing to determine coverage should be performed per guidelines in medical policy #305.”, included “or home sleep study” under policy statement for oral appliances.
Medical Policy Panel, November 2016
Medical Policy Group, December 2016 (6): Updates to Background, Key Points, Practice Guidelines, removed K codes from Coding section and References. No change to policy statement.

Medical Policy Panel, June 2017
Medical Policy Group, July 2017 (6): Updates to Policy statement, added “Palate and mandible expansion devices do not meet Blue Cross and Blue Shield of Alabama’s medical criteria for coverage and are considered investigational for the treatment of OSA.”, Key Points, Coding, Key Words, Preventive Services Task Force and References.

This medical policy is not an authorization, certification, explanation of benefits, or a contract. Eligibility and benefits are determined on a case-by-case basis according to the terms of the member’s plan in effect as of the date services are rendered. All medical policies are based on (i) research of current medical literature and (ii) review of common medical practices in the treatment and diagnosis of disease as of the date hereof. Physicians and other providers are solely responsible for all aspects of medical care and treatment, including the type, quality, and levels of care and treatment.

This policy is intended to be used for adjudication of claims (including pre-admission certification, pre-determinations, and pre-procedure review) in Blue Cross and Blue Shield’s administration of plan contracts.