Medical Management of Obstructive Sleep Apnea Syndrome

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Applies to all products administered or underwritten by Blue Cross and Blue Shield of Louisiana and its subsidiary, HMO Louisiana, Inc. (collectively referred to as the “Company”), unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.

Note: Surgical Treatment of Snoring and Obstructive Sleep Apnea Syndrome is addressed separately in medical policy 00329.

Note: Actigraphy is addressed separately in medical policy 00330.

When Services May Be Eligible for Coverage
Coverage for eligible medical treatments or procedures, drugs, devices or biological products may be provided only if:

- Benefits are available in the member’s contract/certificate, and
- Medical necessity criteria and guidelines are met.

Based on review of available data, the Company may consider continuous positive airway pressure (CPAP), auto-adjusting continuous positive airway pressure (APAP), bilevel positive airway pressure (BIPAP) or Intraoral Appliances in adult or pediatric patients with clinically significant obstructive sleep apnea (OSA) to be eligible for coverage.

Patient Selection Criteria for adult patients
OSA Coverage eligibility will be met under the following conditions:

- An apnea/hypopnea index (AHI) of at least 15 per hour, or
- An AHI of at least 5 per hour in a patient with excessive daytime sleepiness, unexplained hypertension, history of stroke, or ischemic heart disease.

Patient Selection Criteria for pediatric patients
OSA Coverage eligibility will be met under the following conditions:

- In pediatric patients, an AHI greater than 1.5 per hour is considered abnormal, and an AHI of at least 10 per hour is considered severe.

Based on review of available data, the Company may consider auto-adjusting continuous positive airway pressure (APAP) during a 4-week trial or a Facility Based Titration Study to initiate and titrate continuous positive airway pressure (CPAP) in patients with clinically significant obstructive sleep apnea (OSA) to be eligible for coverage.

Patient Selection Criteria
APAP Titration and/or Facility Based Titration Study coverage eligibility will be met under the following conditions:
Facility Based Titration-
- Pediatric patients (< 18 years of age) with AHI > 1.5
- Adult patients with severe OSA with documented AHI 30 or greater
- Patients with OSA complicated by comorbid diseases such as super-obesity with BMI 50 or greater, congestive heart failure, chronic obstructive pulmonary disease, central sleep apnea syndromes, and hypoventilation syndromes associated with obesity, chronic opioid use, and neuromuscular disease affecting respiration are not appropriate for APAP and may have a CPAP titration study in an attended sleep laboratory if a split night study was not previously performed.

APAP Titration-
- Uncomplicated OSA patients not meeting criteria for facility based titration study will be required to utilize an APAP trial.

Based on review of available data, the Company may consider bilevel positive airway pressure (BiPAP) or auto-adjusting PAP in patients with clinically significant obstructive sleep apnea (OSA) and who have failed a prior trial of continuous positive airway pressure (CPAP) or for whom BiPAP is found to be more effective in the sleep lab to be **eligible for coverage**.

Based on review of available data, the Company may consider intraoral appliances (tongue-retaining devices or mandibular advancing/positioning devices) in adult patients with clinically significant obstructive sleep apnea (OSA) to be **eligible for coverage**.

**Patient Selection Criteria**
Coverage eligibility will be met under the following conditions:
- OSA, defined by an AHI of at least 15 per hour or an AHI of at least 5 events per hour in a patient with excessive daytime sleepiness, unexplained hypertension, history of stroke, or ischemic heart disease, AND
- A trial with CPAP has failed or is contraindicated, AND
- The device is prescribed by a treating physician, AND
- The device is custom-fitted by qualified dental personnel, AND
- There is absence of temporomandibular dysfunction or periodontal disease.

*Note: CPAP has been shown to have greater effectiveness than oral appliances in general. This difference in efficacy is more pronounced for patients with severe OSA, as oral appliances have been shown to be less efficacious in patients with severe OSA than they are in patients with mild-moderate OSA. Therefore, it is particularly important that patients with severe OSA should have an initial trial of CPAP and that all reasonable attempts are made to continue treatment with CPAP, prior to the decision to switch to an oral appliance.*
When Services Are Considered Investigational

Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.

Based on review of available data, the Company considers the use of an abbreviated daytime sleep study (PAP-NAP) as a supplement to standard sleep studies to be investigational.*

Based on review of available data, the Company considers nasal expiratory positive airway pressure and oral pressure therapy devices to be investigational.*

Based on review of available data, the use of bilevel positive airway pressure (BiPAP) or auto-adjusting PAP in patients with clinically significant obstructive sleep apnea (OSA) when patient selection criteria are not met is considered to be investigational.*

Based on review of available data, the Company considers facility based titration studies for patients diagnosed with uncomplicated obstructive sleep apnea (OSA) and when patient selection criteria are not met to be investigational.*

Based on review of available data, the use of intraoral appliances (tongue-retaining devices or mandibular advancing/positioning devices) in adult patients with clinically significant obstructive sleep apnea (OSA) when patient selection criteria are not met is considered to be investigational.*

Based on review of available data, the Company considers continuous positive airway pressure (CPAP) in adult or pediatric patients when patient selection criteria are not met to be investigational.*

Based on review of available data, the Company considers palate and mandible expansion devices for the treatment of obstructive sleep apnea (OSA) to be investigational.*

Policy Guidelines

RISK FACTORS FOR OBSSTRUCTIVE SLEEP APNEA

Although not an exclusive list, patients with all of the following symptoms are considered to be at high risk for OSA:

- Habitual snoring;
- Observed apneas;
- Excessive daytime sleepiness;
- A body mass index (BMI) greater than 35 kg/m².

If no bed partner is available to report snoring or observed apneas, other signs and symptoms suggestive of OSA (eg, age of the patient, male gender, thick neck, craniofacial or upper airway soft tissue abnormalities,
unexplained hypertension) may be considered. Objective clinical prediction rules are being developed; at present, risk assessment is based primarily on clinical judgment.

The STOP-BANG questionnaire, a method developed for nonsleep specialists, assesses the signs and symptoms of OSA (Snore, Tired, Observed apnea, blood Pressure, BMI, Age, Neck, Gender), has been shown to have 97% sensitivity and 96% negative predictive value (specificity, 33%) for the identification of patients with severe OSA (Apnea/Hypopnea Index [AHI] >30 events per hour). Overnight oximetry has been used by some sleep specialists as a component of the risk assessment but is inadequate 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 BMI 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 events per hour is considered abnormal (an AHI ≥10 events per hour 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.

MULTIPLE SLEEP LATENCY TEST
The multiple sleep latency test (MSLT) is an objective measure of the tendency to fall asleep in the absence of alerting factors, while the maintenance of wakefulness test is an objective measure of the ability to stay awake under soporific conditions (used to assess occupational safety). The MSLT and maintenance of wakefulness test are not routinely indicated in the evaluation and diagnosis of OSA or in the assessment of change following treatment with CPAP. The MSLT may be indicated in the evaluation of patients with suspected narcolepsy to confirm the diagnosis (often characterized by cataplexy, sleep paralysis, and hypnagogic/hypnopompic hallucinations) or to differentiate between suspected idiopathic hypersomnia and narcolepsy. Narcolepsy and OSA can co-occur. Because it is not possible to differentiate between the excessive sleepiness caused by OSA and by narcolepsy, OSA should be treated before confirming a diagnosis of narcolepsy with the MSLT.
SPECIALIST TRAINING
Medical professionals who interpret a polysomnogram or home sleep study should be trained in sleep medicine and should review the raw data from PSG and home sleep studies to detect artifacts and data loss. In addition, the treatment of patients diagnosed with OSA should be initiated and monitored by a professional trained in sleep medicine. It is important to monitor symptoms and adherence to positive airway pressure treatment (eg, review of symptoms and device utilization between 30 and 90 days).

SPLIT-NIGHT STUDIES
American Academy of Sleep Medicine practice parameters (2005) indicate that a split-night study (initial diagnostic PSG followed by CPAP titration during PSG on the same night) is an alternative to 1 full night of diagnostic PSG followed by a second night of titration if the following 4 criteria are met:

a. An AHI of at least events per hour 40 is documented during a minimum of 2 hours of diagnostic PSG. Split-night studies may sometimes be considered at an AHI between 20 and 40 events per hour, based on clinical judgment (eg, if there are also repetitive long obstructions and major desaturations). However, at AHI values below 40, determination of CPAP-level requirements, based on split-night studies, may be less accurate than in full-night calibrations.

b. CPAP titration is carried out for more than 3 hours (because respiratory events can worsen as the night progresses).

c. PSG documents that CPAP eliminates or nearly eliminates the respiratory events during rapid eye movement (REM) and non-REM sleep, including REM sleep with the patient in the supine position.

d. A second full night of PSG for CPAP titration is performed if the diagnosis of a sleep-related breathing disorder is confirmed, but criteria b and c are not met.

CATEGORIZATION OF PSG AND PORTABLE MONITORING
There is not full correspondence between the CPT codes and the most current categorization scheme for the different types of studies. The 2005 practice parameters from the American Academy of Sleep Medicine list 4 types of monitoring procedures: type 1, standard attended in-lab comprehensive PSG; type 2, comprehensive portable PSG; type 3, modified portable sleep apnea testing (also referred to as cardiorespiratory sleep studies), consisting of 4 or more channels of monitoring; and type 4, continuous single or dual bioparameters, consisting of 1 or 2 channels, typically oxygen saturation, or airflow. Types 1 and 2 would be considered polysomnographic studies, and types 3 and 4 would be considered polygraphic sleep studies. The terms sleep studies and PSG are often used interchangeably. CPT coding makes a distinction between sleep studies that do not include electroencephalographic (EEG) monitoring, and PSG, which includes EEG monitoring. PSG is usually conducted in a sleep laboratory and attended by a technologist, but may also be conducted with type 2 portable monitoring. The type of study is further characterized as attended (supervised) or unattended by a technologist. Home or portable monitoring implies unattended sleep studies, typically conducted in the patient's home. There are no specific codes for remotely monitored home sleep studies. They would likely be reported with the CPT code for the sleep study with the GT modifier ("via interactive audio and video telecommunications systems") appended. There is no CPT code for "unattended" PSG.
Cardiorespiratory sleep studies without EEG may be called polygraphic studies and can be attended or unattended by a technologist. The CPT codes 95807 and 95806 distinguish polygraphic sleep studies that are attended or unattended, but there are no codes that distinguish between type 3 and type 4 sleep studies. A wide variety of portable monitors and proprietary automated scoring systems are being tested and marketed, but the optimum combination of sensors and scoring algorithms is currently unknown. Current recommendations are that the portable monitoring device have 4 channels (oxygen saturation, respiratory effort, respiratory airflow, heart rate) and permit review of the raw data. Type 4 monitors with fewer than 3 channels are not recommended due to reduced diagnostic accuracy and higher failure rates. As with attended PSG, it is important that the raw data from home sleep studies be reviewed by a professional trained in sleep medicine in order to detect artifacts and data loss.

**Background/Overview**

**Description of Disease**

Obstructive sleep apnea syndrome is characterized by repetitive episodes of upper airway obstruction due to the collapse of the upper airway during sleep. This 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 (ESS), 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 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, ie, cars, trucks, or heavy equipment, while OSA in children may result in neurocognitive impairment and behavioral problems.

Obstructive sleep apnea can also affect the cardiovascular and pulmonary systems. For example, apnea leads to periods of hypoxemia, alveolar hypoventilation, hypercapnia, and acidosis. This in turn can cause systemic hypertension, cardiac arrhythmias, pulmonary hypertension, and cor pulmonale. Systemic hypertension is common in patients with OSA. Severe OSA is also associated with decreased survival, presumably related to severe hypoxemia, hypertension, or an increase in automobile accidents related to daytime 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.

**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, BiPAP, or APAP) during sleep.

Continuous positive airway pressure 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. Bilevel positive airway pressure is similar to CPAP, but these devices are capable of generating 2 adjustable pressure levels. Auto-adjusting PAP 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 both 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. Oral pressure therapy 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.

**FDA or Other Governmental Regulatory Approval**

U.S. Food and Drug Administration (FDA)

A variety of oral appliances have received marketing clearance through the U.S. FDA 510(k) pathway for the treatment of snoring and mild to moderate sleep apnea, including the Narval CC™‡, Lamberg SleepWell-Smartrusion, 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. FDA product code: LQZ

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In 2014, the mRNA Appliance® (BioModeling Solutions, Beaverton, OH) was cleared for marketing by FDA through the 510(k) process (K130067) for the treatment of snoring and mild-to-moderate OSA. FDA product code: LRK.

Various continuous positive airway pressure devices have been cleared by FDA through the 510(k) process since 1977. Bilevel positive airway pressure devices were first cleared for marketing in 1996. FDA product codes: BZD, MNT.

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

Centers for Medicare and Medicaid Services (CMS)
Effective for claims with dates of service on and after March 13, 2008, CMS determines that CPAP therapy when used in adult patients with OSA is considered reasonable and necessary under the following situations:

1. The use of CPAP is covered under Medicare when used in adult patients with OSA. Coverage of CPAP is initially limited to a 12-week period to identify beneficiaries diagnosed with OSA as subsequently described who benefit from CPAP. CPAP is subsequently covered only for those beneficiaries diagnosed with OSA who benefit from CPAP during this 12-week period.

2. The provider of CPAP must conduct education of the beneficiary prior to the use of the CPAP device to ensure that the beneficiary has been educated in the proper use of the device. A caregiver, for example a family member, may be compensatory, if consistently available in the beneficiary's home and willing and able to safely operate the CPAP device.

3. A positive diagnosis of OSA for the coverage of CPAP must include a clinical evaluation and a positive:
   a. Attended PSG performed in a sleep laboratory; or
   b. Unattended home sleep test with a type II home sleep monitoring device; or
   c. Unattended home sleep test with a type III home sleep monitoring device; or
   d. Unattended home sleep test with a type IV home sleep monitoring device that measures at least 3 channels.

4. The sleep test must have been previously ordered by the beneficiary's treating physician and furnished under appropriate physician supervision.

5. An initial 12-week period of CPAP is covered in adult patients with OSA if either of the following criteria using the AHI or RDI are met:
   a. AHI or RDI greater than or equal to 15 events per hour, or
   b. AHI or RDI greater than or equal to 5 events and less than or equal to 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.
6. The AHI or RDI is calculated on the average number of events of per hour. If the AHI or RDI is calculated based on less than 2 hours of continuous recorded sleep, the total number of recorded events to calculate the AHI or RDI during sleep testing must be at minimum the number of events that would have been required in a 2-hour period.

7. Apnea is defined as a cessation of airflow for at least 10 seconds. Hypopnea is defined as an abnormal respiratory event lasting at least 10 seconds with at least a 30% reduction in thoracoabdominal movement or airflow as compared to baseline, and with at least a 4% oxygen desaturation.

8. Coverage with Evidence Development: Medicare provides the following limited coverage for CPAP in adult beneficiaries who do not qualify for CPAP coverage based on criteria 1–7 cited here. A clinical study seeking Medicare payment for CPAP provided to a beneficiary who is an enrolled subject in that study must address one or more of the following questions:
   a. In Medicare-aged subjects with clinically identified risk factors for OSA, how does the diagnostic accuracy of a clinical trial of CPAP compare with PSG and types II, III, and IV home sleep test in identifying subjects with OSA who will respond to CPAP?
   b. In Medicare-aged subjects with clinically identified risk factors for OSA who have not undergone confirmatory testing with PSG or types II, III, and IV home sleep test, does CPAP cause clinically meaningful harm?

In March 2009, CMS issued the following national coverage decision (CAG-00405N) for the types of sleep testing devices that would be approved for coverage.

CMS finds that the evidence is sufficient to determine that the results of the sleep tests identified below can be used by a beneficiary's treating physician to diagnose OSA:
   1. Type I PSG is covered when used to aid the diagnosis of OSA in beneficiaries who have clinical signs and symptoms indicative of OSA if performed attended in a sleep lab facility.
   2. A type II or type III sleep testing device is covered when used to aid the diagnosis of OSA in beneficiaries who have clinical signs and symptoms indicative of OSA if performed unattended in or out of a sleep lab facility, or attended in a sleep lab facility.
   3. A type IV sleep testing device measuring 3 or more channels, one of which is airflow, is covered when used to aid the diagnosis of OSA in beneficiaries who have signs and symptoms indicative of OSA if performed unattended in or out of a sleep lab facility, or attended in a sleep lab facility.
   4. A sleep testing device measuring 3 or more channels that include actigraphy, oximetry, and peripheral arterial tone is covered when used to aid the diagnosis of OSA in beneficiaries who have signs and symptoms indicative of OSA if performed unattended in or out of a sleep lab facility, or attended in a sleep lab facility.

Rationale/Source
Positive Airway Pressure Devices
The 2011 AHRQ CER concluded that the strength of evidence for CPAP for OSA was moderate based on the large magnitude of effect on the intermediate outcomes of the AHI, 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 bilevel 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 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, 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. Study limitations 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 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 AHI, 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 (AHI <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 AHI) 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 AHI was assessed in a home sleep study without the oral appliance. AHI 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 AHI 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.

PAP-NAP
In 2008, Krakow et al reported use of a daytime abbreviated sleep study to acclimate patients with complex insomnia to PAP. Patients had been referred by psychiatrists or primary care physicians for unspecified insomnia conditions, insomnia due to a mental disorder, or hypnotic dependence. Nearly all patients had anxiety, fear, and/or resistance regarding PAP therapy or the diagnosis of OSA. Thirty-nine patients who would not complete a titration protocol (full-night or split-night) were offered a daytime procedure positive airway pressure nap (PAP-NAP) prior to night-time titration. The PAP-NAP protocol had 5 components: pretest instructions to maximize chances for daytime napping; introduction of PAP therapy addressing barriers to use; type 3 monitoring hookup (10 channels without electroencephalography leads); PAP therapy during 1 to 2 hours in bed in which the patient had the opportunity to fall asleep with the mask in
place; and posttest follow-up. Thirty-five of 39 nap-tested patients subsequently scheduled and completed an overnight titration or split-night study with full PSG. The effect of the PAP-NAP intervention on compliance was compared to historical controls (n=38) with insomnia, mental health conditions, and OSA with resistance to CPAP who completed titration. A prescription for PAP therapy was filled by 85% of the PAP-NAP group compared with 35% of controls. Regular use during a 30-day period was recorded by the PAP device in 67% of the intervention group than in 23% of controls. Adherence, defined as at least 5 days a week with an average of at least 4 hours a day, was 56% in the PAP-NAP group and 17% in controls.

Nasal Expiratory Positive Airway Pressure

Evidence includes a moderately sized RCT and a systematic review on the Provent device. In 2011, Berry et al on reported an industry-sponsored multicenter, double-blind, randomized sham-controlled trial of nasal expiratory positive airway pressure (EPAP). Two hundred fifty patients with OSA and an AHI of 10 or more events per hour were randomized to nasal EPAP (n=127) or to 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 3 months of treatment (78% follow-up). EPAP reduced median AHI from 13.8 to 5.0 events per hour (-52.7%) at week 1 and from 14.4 to 5.6 events per hour (-42.7%) at 3 months. This reduction in AHI in the treatment group was a significantly greater than in the sham group (-7.3% at week 1, -10.1% at 3 months). Over 3 months, the decrease in ESS score 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 1-point difference in ESS score is unclear. Treatment success and oxygenation data were presented only for the 58% of per-protocol patients who had an AHI of 5 or more events per hour on the device-off PSG night. The oxygenation results 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 reduction to less than 10 events per hour (if device-off AHI was ≥10 events per hour), was greater in the EPAP group at 1 week (62% vs 27.2%) and at 3 months (50.7% vs 22.4%). Device-related adverse events were reported by 45% of patients in the EPAP group and by 34% of patients in the sham group, with 7% of patients in the EPAP group discontinuing due to adverse events. Overall, the validity of these results was 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 evaluated 12-month safety and durability of the treatment response in patients who had an initially favorable response to EPAP. Included were 41 (32%) of the 127 patients in the EPAP arm of the study who used the device for an average of at least 4 hours per night on at least 5 nights a week during months 1 and 2 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 (40%) of 127 eligible patients, 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 score 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, most frequently difficulty exhaling, nasal discomfort, dry mouth, headache, and
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Insomnia. This open-label extension study was limited by its inclusion only of responders and by the potential for a placebo effect on the ESS score. However, the data suggested that some patients may have responded 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 25% of 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 this 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 on a small (N=14) double-blind, pilot, crossover RCT of 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 varied (3 did not improve, 2 worsened). No other measures were statistically significant in this trial. For responders who used the devices at home for 30 days, adherence was 83% of nights. ESS scores improved from 11 to 7 (p=0.031) and Obstructive Sleep Apnea–18 questionnaire scores 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 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. 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 bilevel 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 (eg, 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 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.

References

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06/28/2012 Medical Policy Committee review
07/27/2012 Medical Policy Implementation Committee approval. Split our current policy into three separate policies to track BCBSA. Auto-adjusting CPAP to initiate and titrate CPAP in adult patients with clinically significant OSA was changed from a 2 week trial to a 4 week trial.

01/23/2013 Coding updated
06/27/2013 Medical Policy Committee review
07/17/2013 Medical Policy Implementation Committee approval. Clarification of a single night for a home sleep study. PAP-NAP studies considered investigational. Oral pressure therapy added as investigational.
03/19/2014 Medical Policy Implementation Committee approval. Not medically necessary statement reworded to state “Based on review of available data, the Company considers multiple sleep latency testing in the diagnosis of obstructive sleep apnea (OSA), except to exclude or confirm narcolepsy or other hypersomnia syndromes, in the diagnostic workup of obstructive sleep apnea (OSA) syndrome to be not medically necessary.**

08/06/2015 Medical Policy Committee review

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08/19/2015 Medical Policy Implementation Committee approval. Added bariatric surgery eligibility statement. Added parasomnias and to initiate and titrate CPAP in children to eligibility statement. Updated rationale and references.
09/23/2015 Medical Policy Implementation Committee approval. Added criteria for supervised polysomnography (PSG) performed in a sleep laboratory in patients with a moderate/high pretest probability of OSA.
03/03/2016 Medical Policy Committee review
03/16/2016 Medical Policy Implementation Committee approval. Deleted the Diagnosis section from the policy and title.
04/07/2016 Medical Policy Committee review
04/20/2016 Medical Policy Implementation Committee approval. Clarified facility based titration versus APAP titration.
"Based on review of available data, the Company considers facility based titration studies for patients diagnosed with uncomplicated obstructive sleep apnea (OSA)" was added as investigational.
01/01/2017 Coding Update: Removing ICD-9 Diagnosis Codes
03/02/2017 Medical Policy Committee review
03/15/2017 Medical Policy Implementation Committee approval. Criteria revised.
10/05/2017 Medical Policy Committee review
10/18/2017 Medical Policy Implementation Committee approval. AHl clarified for pediatric patients. Added "Based on review of available data, the Company considers palate and mandible expansion devices for the treatment of OSA to be investigational."

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Next Scheduled Review Date: 01/2019

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*Investigational – A medical treatment, procedure, drug, device, or biological product is Investigational if the effectiveness has not been clearly tested and it has not been incorporated into standard medical practice. Any determination we make that a medical treatment, procedure, drug, device, or biological product is Investigational will be based on a consideration of the following:

A. Whether the medical treatment, procedure, drug, device, or biological product can be lawfully marketed without approval of the U.S. FDA and whether such approval has been granted at the time the medical treatment, procedure, drug, device, or biological product is sought to be furnished; or

B. Whether the medical treatment, procedure, drug, device, or biological product requires further studies or clinical trials to determine its maximum tolerated dose, toxicity, safety, effectiveness, or effectiveness as compared with the standard means of treatment or diagnosis, must improve health outcomes, according to the consensus of opinion among experts as shown by reliable evidence, including:

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2. Credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community; or
3. Reference to federal regulations.

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A. In accordance with nationally accepted standards of medical practice;

B. Clinically appropriate, in terms of type, frequency, extent, level of care, site and duration, and considered effective for the patient's illness, injury or disease; and

C. Not primarily for the personal comfort or convenience of the patient, physician or other health care provider, and 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.

For these purposes, “nationally accepted standards of medical practice” means standards that are based on credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community, Physician Specialty Society recommendations and the views of Physicians practicing in relevant clinical areas and any other relevant factors.

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