Medical Management of Obstructive Sleep Apnea Syndrome

Policy # 00328
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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
Clinically significant OSA in adults is:

- An Apnea/Hypopnea Index (AHI), Respiratory Disturbance Index (RDI), or Respiratory Event Index (REI) ≥15, OR
- An AHI, RDI, or REI ≥5 in a patient with excessive daytime sleepiness, unexplained hypertension, cardiovascular heart disease, or stroke.

Patient Selection Criteria for pediatric patients
Clinically significant OSA in pediatric patients is:

- An AHI or RDI ≥5 OR

- An AHI or RDI ≥1.5 in a patient with excessive daytime sleepiness, behavioral problems or hyperactivity.

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, or retitrate 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 abnormal AHI or RDI as noted above
- Adult patients with severe OSA with documented AHI, RDI, or REI 30 or greater
- Patients with OSA complicated by comorbid diseases such as super-obesity with BMI 50 or greater, heart failure, chronic obstructive pulmonary disease, central sleep apnea, hypoventilation syndromes associated with obesity, chronic opioid use, impaired dexterity or mobility, cognitive impairment, 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
- Patients with uncomplicated OSA not meeting criteria for facility based titration with a significant change in weight or change in symptoms suggesting that continuous positive airway pressure (CPAP) should be retitrated or possibly discontinued 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, RDI, or REI of at least 15 per hour or an AHI, RDI, or REI 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.***

Based on review of available data, the Company considers the use of daytime electrical stimulation of the tongue for the treatment of OSA to be **investigational.***

Based on review of available data, the Company considers the use of a sleep positioning trainer with vibration for the treatment of positional OSA to be **investigational.***

Policy Guidelines

RISK FACTORS FOR OBSTRUCTIVE 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/m^2.

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 apnea test 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 apnea test 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.

SIGNIFICANT WEIGHT CHANGE
There is no established threshold for significant change in weight. Studies have reported improvements in OSA with an average weight loss of 20 kg or 20% of body weight.

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 apnea test 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. A technically adequate Home Sleep Apnea Testing device incorporates a minimum of the following sensors: nasal pressure, chest and abdominal respiratory inductance plethysmography, and oximetry; or else Peripheral Arterial Tonometry signal with oximetry and actigraphy. 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.

For initial request of PAP device rental:

- Medical records will need to include sleep study report and clinical evaluation, e.g. history of present illness, past medical history, physical examination, etc.
- A minimum of 30 days initial renting of PAP device will be required to determine if PAP treatment is tolerated, if patient has been adhering to PAP therapy and is benefiting from its use.
- Initial PAP device rental will be allowed for up to 120 days.

For continued rental of PAP device beyond the initial 120 days, or for purchase of PAP device after initial renting:

- Medical records must document objective findings of compliance information (i.e., compliance chip, tele monitoring, computer software), confirming that the member has been adhering to PAP therapy and is benefiting from its use.
- Adherence to therapy is defined as use of PAP treatment greater than or equal to four (4) hours per night on at least 70% of nights during a consecutive thirty (30) day period, anytime during up to the three (3) months of usage.

Continued PAP device supplies should be provided by DME providers only when there is documented objective evidence of adherence to use of the PAP device, defined as use of PAP device for four (4) or more hours per night on 70% of nights during a consecutive 30-day period anytime during the three (3) months of use.

Background/Overview

Obstructive Sleep Apnea

OSA 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 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.

The hallmark 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. The sleep fragmentation associated with repeated sleep disruption can lead to impairment of daytime activity. Adults with OSA-associated daytime somnolence are thought to be at higher risk for collisions involving motorized vehicles (ie, cars, trucks, 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 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 collisions related to daytime sleepiness. It is estimated that about 7% of adults have moderate or severe OSA, 20% have mild OSA, and the referral population of OSA patients represents a small proportion of patients who have clinically significant and treatable disease.

Diagnosis

The criterion standard for a diagnosis of sleep disorders is a polysomnogram performed in a sleep laboratory. A standard polysomnogram includes electroencephalogram (EEG), submental electromyogram, and electrooculogram (to detect rapid eye movement sleep) for sleep staging. Polysomnography 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 dislodge 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 eliminates the need for additional polysomnography for CPAP titration.

Table 1. Definitions of Terms and Scoring Criteria for OSA

Terms	Definition
Respiratory event	
Apnea	The frequency of apneas and hypopneas is measured from channels assessing oxygen desaturation, respiratory airflow, and respiratory effort. In adults, apnea is defined as a drop in airflow by 90% or more of pre-event baseline for at least 10 seconds. 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.
Hypopnea	Hypopnea in adults is scored when the peak airflow drops by at least 30% of pre-event baseline for at least 10 seconds in association with either at least 4% arterial oxygen desaturation or an arousal. Hypopneas in children are scored by a 50% or greater drop in nasal pressure and either a 3% or more decrease in oxygen saturation or associated arousal.
RERA	Respiratory event-related arousal is defined as an event lasting at least 10 seconds associated with flattening of the nasal pressure waveform and/or evidence of increased respiratory effort, terminating in arousal but not otherwise meeting criteria for apnea or hypopnea
Respiratory event reporting	
AHI	The apnea/hypopnea index is the average number of apneas or hypopneas per hour of sleep
RDI	The respiratory disturbance index is the number of apneas, hypopneas, or respiratory event-related arousals per hour of sleep time. RDI is often used synonymously with the AHI.
REI	The respiratory event index is the number of events per hour of monitoring time. Used as an alternative to AHI or RDI in-home sleep studies when actual sleep time from EEG is not available.
OSA	Obstructive sleep apnea is repetitive episodes of upper airway obstruction due to the collapse and obstruction of the upper airway during sleep

Mild OSA	In adults: AHI or RDI of 5 to <15. In children: AHI ≥1.0 to <5
Moderate OSA	AHI or RDI of 15 to < 30; Children: AHI of ≥ 5 to <10
Severe OSA	Adults: AHI or RDI ≥30; Children: AHI of ≥10
UARS	Upper airway resistance syndrome is characterized by a partial collapse of the airway and results in increased resistance to airflow. The increased respiratory effort is associated with multiple sleep fragmentations, as measured by very short alpha EEG arousals.
Positive airway pressure	
APAP	Auto-adjusting positive airway pressure may be used either to provide treatment or to determine the most effective pressure for CPAP
PAP	Positive airway pressure (PAP) may be continuous (CPAP) or auto-adjusting (APAP) or bi-level (bi-PAP). CPAP is a more familiar abbreviation for delivery of positive airway pressure.
PAP failure	Usually defined as an AHI >20 events per hour while using CPAP
PAP intolerance	CPAP use for <4 hours per night for ≥5 nights per week, or refusal to use CPAP. CPAP intolerance may be observed in patients with mild, moderate, or severe OSA

AHI: Apnea/hypopnea Index; APAP: auto-adjusting positive airway pressure;EEG: electroencephalogram; OSA: obstructive sleep apnea; PAP: positive airway pressure; RDI: Respiratory Disturbance Index; REI: Respiratory Event Index; RERA: respiratory event-related arousal: UARS: upper airway resistance syndrome.

Due to faster respiratory rates in children, pediatric scoring criteria define an apnea as two or more missed breaths, regardless of its duration in seconds. In pediatric patients, an AHI greater than 1.5 events per hour is considered abnormal, and an AHI of 10 or more may be considered severe.

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

Treatment
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 therapy (ie, fixed CPAP, bilevel positive airway pressure, or auto-adjusting positive airway pressure) during sleep. This evidence review addresses established and novel devices including the Daytime-Nighttime Appliance (BioModeling Solutions), the mandibular Repositioning Nighttime Appliance (BioModeling Solutions), Provent and Winx. Provent is a single-use nasal expiratory resistance valve device containing valves inserted into the nostrils and secured with adhesive. The Winx system uses oral pressure therapy to treat OSA.

Surgical management of OSA (ie, adenotonsillectomy, uvulopalatopharyngoplasty, orthognathic surgery) is discussed in evidence review medical policy 00329 (surgical treatment of snoring and OSA syndrome).

FDA or Other Governmental Regulatory Approval

U.S. Food and Drug Administration (FDA)
A variety of oral appliances have been cleared for marketing by the U.S. FDA through the 510(k) process for treatment of snoring and mild-to-moderate OSA, including the Narval™‡ CC, Lamberg Sleep Well 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.

Various PAP devices have been cleared by the 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.

Novel devices for OSA diagnosis and treatment are described in Table 2.

Table 2. Novel Devices for OSA Diagnosis and Treatment

Device	Manufacturer	Description	FDA Marketing Clearance	FDA Product Code	Year
Diagnosis					
SleepImage System	MyCardio	Software as a medical device that provides automated analysis of sleep data from a single photoplethysmogram sensor to aid in the evaluation of sleep disorders.	K163696	MNR	2017
Treatment					
Provent®‡	Ventus Medical	Nasal expiratory resistance valve.		OHP	2010
Winx™‡		Nasal expiratory resistance valve.		OZR	2012
mRNA Appliance®‡	BioModeling Solutions	Expandable oral appliance for the treatment of snoring and mild-to-moderate OSA	K130067	LRK	2014
NightBalance Lunoa System	Philips	The positional sleep trainer is worn with an elasticized chest strap, and is intended to keep patients with positional obstructive sleep apnea from sleeping in the supine position.	K180608	MYB	2018
eXciteOSA®‡	Signifier Medical Technologies	The device delivers neuromuscular stimulation during the day to strengthen the	DEN200018	QNO	2021

		tongue in order to reduce snoring and mild sleep apnea. It is used for 20 minutes once a day for a period of 6-weeks, and once a week thereafter.			

FDA: Food and Drug Administration; OSA: obstructive sleep apnea

Rationale/Source

Description

OSA syndrome is characterized by repetitive episodes of upper airway obstruction due to the collapse of the upper airway during sleep. Polysomnography and portable sleep apnea testing (with sensors for respiratory effort, airflow, and oxygen saturation, or alternatively with peripheral arterial tone (PAT), actigraphy, and oxygen saturation are established methods for diagnosing OSA. Other proposed methods of diagnosing OSA include limited channel home sleep monitors. Conventional medical management of OSA includes weight loss, avoidance of stimulants, body position adjustment, oral appliances, and use of CPAP during sleep. Novel treatments include nasal expiratory positive airway pressure (EPAP) and oral pressure therapy.

Summary of Evidence

Diagnosis

For individuals who have suspected OSA who receive home sleep apnea testing with at least three recording channels, the evidence includes RCTs. Relevant outcomes are test accuracy, symptoms, functional outcomes, and resource utilization. RCTs have reported that home sleep apnea testing (with sensors for respiratory effort, airflow, and oxygen saturation, or alternatively with peripheral arterial tone, actigraphy and oxygen saturation) is noninferior to testing in the sleep lab for adults with a high pretest probability of OSA and absence of comorbid conditions as determined by clinical evaluation. A positive portable monitoring study with channels that include arterial oxygen saturation, airflow, and respiratory effort has a high positive predictive value for OSA and can be used as the basis for a CPAP trial to determine the efficacy of treatment. A negative portable monitoring study cannot be used to rule out OSA. Patients who have a negative result from portable monitoring or have a positive study but do not respond to CPAP should undergo further evaluation.

The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

For individuals who have suspected OSA who receive limited channel home sleep apnea testing, the evidence includes studies on diagnostic accuracy. Relevant outcomes are test accuracy, symptoms, functional outcomes, and resource utilization. The ability to detect clinically significant OSA without sensors for respiratory effort, airflow, and oxygen saturation, or alternatively without peripheral arterial tone, actigraphy and oxygen saturation, lacks support in the literature. The evidence is insufficient to determine the effects of the technology on health outcomes.

Treatment

For individuals who have OSA who receive PAP devices or oral appliances, the evidence includes RCTs and systematic reviews of RCTs. Relevant outcomes are symptoms, functional outcomes, and QOL. 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 APAP to evaluate the efficacy and adjust pressure. APAP or bilevel PAP 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, palate expansion, EPAP, oral pressure therapy), the evidence includes RCTs and a meta-analysis of case series. Relevant outcomes are symptoms, functional outcomes, and QOL. 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 nasal EPAP devices in patients with OSA has been reported in prospective case series, an industry-sponsored RCT, and a systematic review that did not include the RCT. The main finding of the RCT was a decrease in the AHI, with minor impact on oxygenation, and a decrease in ESS 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. One small RCT with 22 patients found no benefit of an oral EPAP therapy device when added to an oral appliance. The evidence is insufficient to determine the effects of the technology on health outcomes.

Single arm studies suggest that daytime tongue stimulation may improve snoring, but the effect on OSA is of uncertain. Several RCTs have been published with a sleep positioning device that vibrates

when the individual is in a supine position. Drop-out rates were high and long-term compliance is unknown. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Additional Information
The policy statements focus on criteria for the diagnosis and treatment of sleep apnea for procedures considered standard of care and are based in part on evidence-based practice guidelines. In addition, clinical input was obtained on several occasions to assess, among other items, the sensors required for portable monitors, diagnosis and treatment of OSA in children, and screening of patients scheduled to undergo bariatric surgery. Informed by clinical input and clinical practice guidelines, testing is indicated for patients who are suspected of OSA, prior to bariatric surgery, for certain pediatric patients, and with type 4 monitors under certain circumstances.

Supplemental Information

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.

Ongoing and Unpublished Clinical Trials
A search of ClinicalTrials.gov in May 2021 identified over 300 ongoing studies on diagnosis and medical management of OSA.

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Policy History

Original Effective Date: 07/27/2012
Current Effective Date: 10/11/2021

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
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. AHI 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.*"
01/04/2018	Medical Policy Committee review

Policy # 00328
Original Effective Date: 07/27/2012
Current Effective Date: 10/11/2021

01/17/2018	Medical Policy Implementation Committee approval. "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 was added to policy".
08/09/2018	Medical Policy Committee review
08/15/2018	Medical Policy Implementation Committee approval. Policy statements clarified that sleep studies may report the Respiratory Disturbance Index or Respiratory Event Index. Criteria for changes in weight or changes in symptoms were removed from the policy statement on in-laboratory polysomnography and added to the statement on auto-adjusting positive airway pressure. Clinically significant OSA was defined.
01/10/2019	Medical Policy Committee review
01/23/2019	Medical Policy Implementation Committee approval. Added a Not medically necessary statement.
10/03/2019	Medical Policy Committee review
10/09/2019	Medical Policy Implementation Committee approval. Added impaired dexterity or mobility and cognitive impairment to indications under APAP titration. Removed When Services are Considered Not Medically Necessary section.
12/10/2019	Coding update
08/25/2020	Coding update
10/01/2020	Medical Policy Committee review
10/07/2020	Medical Policy Implementation Committee approval. Coverage eligibility unchanged. Sentence in background clarified to reflect standard of care as noted in UpToDate and AASM guidelines.
09/02/2021	Medical Policy Committee review
09/08/2021	Medical Policy Implementation Committee approval. Added investigational statement. "Based on review of available data, the Company considers The use of daytime electrical stimulation of the tongue for the treatment of OSA to be investigational.*" and "Based on review of available data, the Company considers the use of a sleep positioning trainer with vibration for the treatment of positional OSA to be investigational.*" FDA updated.
09/30/2021	Coding update

Next Scheduled Review Date: 09/2022

Coding

The five character codes included in the Blue Cross Blue Shield of Louisiana Medical Policy Coverage Guidelines are obtained from Current Procedural Terminology (CPT®)‡, copyright 2020 by the American Medical Association (AMA). CPT is developed by the AMA as a listing of descriptive terms and five character identifying codes and modifiers for reporting medical services and procedures performed by physician.

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CPT is a registered trademark of the American Medical Association.

Codes used to identify services associated with this policy may include (but may not be limited to) the following:

Code Type	Code
CPT	21085, 94660, 95782, 95783, 95805, 95807, 95808, 95810, 95811
HCPCS	E0470, E0471, E0485, E0486, E0561, E0562, E0601, K1001 Add code eff 10/1/21: K1027
ICD-10 Diagnosis	F51.04-F51.05, F51.13-F51.19, G47.01-G47.9, R68.3

*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. Food and Drug Administration (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:
    1. Consultation with the Blue Cross and Blue Shield Association technology assessment program (TEC) or other nonaffiliated technology evaluation center(s);
    2. Credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community; or
    3. Reference to federal regulations.

**Medically Necessary (or "Medical Necessity") - Health care services, treatment, procedures, equipment, drugs, devices, items or supplies that a Provider, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury, disease or its symptoms, and that are:

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.

‡ Indicated trademarks are the registered trademarks of their respective owners.

NOTICE: If the Patient's health insurance contract contains language that differs from the BCBSLA Medical Policy definition noted above, the definition in the health insurance contract will be relied upon for specific coverage determinations.

NOTICE: Medical Policies are scientific based opinions, provided solely for coverage and informational purposes. Medical Policies should not be construed to suggest that the Company recommends, advocates, requires, encourages, or discourages any particular treatment, procedure, or service, or any particular course of treatment, procedure, or service.