



# Louisiana

## Medical Management of Obstructive Sleep Apnea Syndrome

**Policy #** 00328

Original Effective Date: 07/27/2012

Current Effective Date: 09/01/2018

*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)  $\geq 15$ , OR
- An AHI, RDI, or REI  $\geq 5$  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  $\geq 5$  OR
- An AHI or RDI  $\geq 1.5$  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**.

©2018 Blue Cross and Blue Shield of Louisiana

Blue Cross and Blue Shield of Louisiana is an independent licensee of the Blue Cross and Blue Shield Association and incorporated as Louisiana Health Service & Indemnity Company.

No part of this publication may be reproduced, stored in a retrieval system, or transmitted, in any form or by any means, electronic, mechanical, photocopying, or otherwise, without permission from Blue Cross and Blue Shield of Louisiana.



# Louisiana

## Medical Management of Obstructive Sleep Apnea Syndrome

Policy # 00328

Original Effective Date: 07/27/2012

Current Effective Date: 09/01/2018

### 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, 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
- 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*

©2018 Blue Cross and Blue Shield of Louisiana

Blue Cross and Blue Shield of Louisiana is an independent licensee of the Blue Cross and Blue Shield Association and incorporated as Louisiana Health Service & Indemnity Company.

No part of this publication may be reproduced, stored in a retrieval system, or transmitted, in any form or by any means, electronic, mechanical, photocopying, or otherwise, without permission from Blue Cross and Blue Shield of Louisiana.



# Louisiana

## Medical Management of Obstructive Sleep Apnea Syndrome

Policy # 00328

Original Effective Date: 07/27/2012

Current Effective Date: 09/01/2018

*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 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;

©2018 Blue Cross and Blue Shield of Louisiana

Blue Cross and Blue Shield of Louisiana is an independent licensee of the Blue Cross and Blue Shield Association and incorporated as Louisiana Health Service & Indemnity Company.

No part of this publication may be reproduced, stored in a retrieval system, or transmitted, in any form or by any means, electronic, mechanical, photocopying, or otherwise, without permission from Blue Cross and Blue Shield of Louisiana.



# Louisiana

## Medical Management of Obstructive Sleep Apnea Syndrome

Policy # 00328

Original Effective Date: 07/27/2012

Current Effective Date: 09/01/2018

- A body mass index (BMI) greater than 35 kg/m<sup>2</sup>.

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  $\geq$ 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.

### **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

©2018 Blue Cross and Blue Shield of Louisiana

Blue Cross and Blue Shield of Louisiana is an independent licensee of the Blue Cross and Blue Shield Association and incorporated as Louisiana Health Service & Indemnity Company.

No part of this publication may be reproduced, stored in a retrieval system, or transmitted, in any form or by any means, electronic, mechanical, photocopying, or otherwise, without permission from Blue Cross and Blue Shield of Louisiana.



# Louisiana

## Medical Management of Obstructive Sleep Apnea Syndrome

Policy # 00328

Original Effective Date: 07/27/2012

Current Effective Date: 09/01/2018

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

©2018 Blue Cross and Blue Shield of Louisiana

Blue Cross and Blue Shield of Louisiana is an independent licensee of the Blue Cross and Blue Shield Association and incorporated as Louisiana Health Service & Indemnity Company.

No part of this publication may be reproduced, stored in a retrieval system, or transmitted, in any form or by any means, electronic, mechanical, photocopying, or otherwise, without permission from Blue Cross and Blue Shield of Louisiana.





# Louisiana

## Medical Management of Obstructive Sleep Apnea Syndrome

Policy # 00328

Original Effective Date: 07/27/2012

Current Effective Date: 09/01/2018

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

©2018 Blue Cross and Blue Shield of Louisiana

Blue Cross and Blue Shield of Louisiana is an independent licensee of the Blue Cross and Blue Shield Association and incorporated as Louisiana Health Service & Indemnity Company.

No part of this publication may be reproduced, stored in a retrieval system, or transmitted, in any form or by any means, electronic, mechanical, photocopying, or otherwise, without permission from Blue Cross and Blue Shield of Louisiana.



# Louisiana

## Medical Management of Obstructive Sleep Apnea Syndrome

Policy # 00328

Original Effective Date: 07/27/2012

Current Effective Date: 09/01/2018

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 (ie, 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<sup>™‡</sup>. 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

©2018 Blue Cross and Blue Shield of Louisiana

Blue Cross and Blue Shield of Louisiana is an independent licensee of the Blue Cross and Blue Shield Association and incorporated as Louisiana Health Service & Indemnity Company.

No part of this publication may be reproduced, stored in a retrieval system, or transmitted, in any form or by any means, electronic, mechanical, photocopying, or otherwise, without permission from Blue Cross and Blue Shield of Louisiana.



# Louisiana

## Medical Management of Obstructive Sleep Apnea Syndrome

Policy # 00328

Original Effective Date: 07/27/2012

Current Effective Date: 09/01/2018

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.

**Table 1. Definitions of Terms for OSA**

Terms	Definition
<b>Respiratory event</b>	
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 an 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 increasing respiratory effort, terminating in an arousal but not otherwise meeting criteria for apnea or hypopnea
<b>Respiratory event reporting</b>	
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	<ul style="list-style-type: none"> <li>In adults: AHI or RDI of 5 to &lt;15</li> <li>In children: AHI <math>\geq</math>1.5 is abnormal</li> </ul>
Moderate OSA	AHI or RDI of 15 to < 30
Severe OSA	<ul style="list-style-type: none"> <li>Adults: AHI or RDI <math>\geq</math>30</li> <li>Children: AHI of <math>\geq</math>10</li> </ul>
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.
<b>Positive airway pressure</b>	
APAP	Auto-adjusting positive airway pressure may be used either to provide treatment or to determine the most effective pressure for CPAP
CPAP	Positive airway pressure (PAP) may be continuous (CPAP) or auto-adjusting (APAP) or bi-level (bi-PAP). CPAP is a more familiar abbreviation and will refer to the 3 types of devices for delivery of positive airway pressure.
CPAP failure	Usually defined as an AHI >20 events per hour while using CPAP
CPAP intolerance	CPAP use for <4 hours per night for $\geq$ 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; CPAP: continuous positive airway pressure; EEG: electroencephalogram; OSA: obstructive sleep apnea; RDI: Respiratory Disturbance Index; REI: Respiratory Event Index; RERA: respiratory event-related arousal; UARS: upper airway resistance syndrome.

### **FDA or Other Governmental Regulatory Approval**

U.S. Food and Drug Administration (FDA)

©2018 Blue Cross and Blue Shield of Louisiana

Blue Cross and Blue Shield of Louisiana is an independent licensee of the Blue Cross and Blue Shield Association and incorporated as Louisiana Health Service & Indemnity Company.

No part of this publication may be reproduced, stored in a retrieval system, or transmitted, in any form or by any means, electronic, mechanical, photocopying, or otherwise, without permission from Blue Cross and Blue Shield of Louisiana.





# Louisiana

## Medical Management of Obstructive Sleep Apnea Syndrome

Policy # 00328

Original Effective Date: 07/27/2012

Current Effective Date: 09/01/2018

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<sup>™‡</sup>, Lamberg SleepWell-Smarttrusion, 1st Snoring Appliance, Full Breath Sleep Appliance, PM Positioner, Snorenti, Snorex, Osap, Desra, Elastomeric Sleep Appliance, Snoremaster Snore Remedy, Snore-no-More, Napa, Snoar<sup>™‡</sup> Open Airway Appliance, and The Equalizer Airway Device. FDA product code: LQZ

In 2014, the mRNA Appliance<sup>®‡</sup> (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<sup>®‡</sup>, 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:

©2018 Blue Cross and Blue Shield of Louisiana

Blue Cross and Blue Shield of Louisiana is an independent licensee of the Blue Cross and Blue Shield Association and incorporated as Louisiana Health Service & Indemnity Company.

No part of this publication may be reproduced, stored in a retrieval system, or transmitted, in any form or by any means, electronic, mechanical, photocopying, or otherwise, without permission from Blue Cross and Blue Shield of Louisiana.



# Louisiana

## Medical Management of Obstructive Sleep Apnea Syndrome

Policy # 00328

Original Effective Date: 07/27/2012

Current Effective Date: 09/01/2018

- 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.

©2018 Blue Cross and Blue Shield of Louisiana

Blue Cross and Blue Shield of Louisiana is an independent licensee of the Blue Cross and Blue Shield Association and incorporated as Louisiana Health Service & Indemnity Company.

No part of this publication may be reproduced, stored in a retrieval system, or transmitted, in any form or by any means, electronic, mechanical, photocopying, or otherwise, without permission from Blue Cross and Blue Shield of Louisiana.



# Louisiana

## Medical Management of Obstructive Sleep Apnea Syndrome

Policy # 00328

Original Effective Date: 07/27/2012

Current Effective Date: 09/01/2018

### **Rationale/Source**

Evidence reviews assess the clinical evidence to determine whether the use of a technology improves the net health outcome. Broadly defined, health outcomes are length of life, quality of life, and ability to function—including benefits and harms. Every clinical condition has specific outcomes that are important to patients and to managing the course of that condition. Validated outcome measures are necessary to ascertain whether a condition improves or worsens; and whether the magnitude of that change is clinically significant. The net health outcome is a balance of benefits and harms.

To assess whether the evidence is sufficient to draw conclusions about the net health outcome of a technology, 2 domains are examined: the relevance and the quality and credibility. To be relevant, studies must represent one or more intended clinical use of the technology in the intended population and compare an effective and appropriate alternative at a comparable intensity. For some conditions, the alternative will be supportive care or surveillance. The quality and credibility of the evidence depend on study design and conduct, minimizing bias and confounding that can generate incorrect findings. The randomized controlled trial (RCT) is preferred to assess efficacy; however, in some circumstances, nonrandomized studies may be adequate. RCTs are rarely large enough or long enough to capture less common adverse events and long-term effects. Other types of studies can be used for these purposes and to assess generalizability to broader clinical populations and settings of clinical practice.

**Table 2. Health Outcome Measures Relevant to OSA**

Outcome	Measure	Description	Clinically Meaningful Difference (If Known)
Change in AHI	AHI	Mean change in AHI from baseline to posttreatment	Change from severe-to-moderate or mild OSA
AHI success	Percentage of patients achieving success	Studies may use different definitions of success, but the most common for AHI success is the Sher criteria	<ul style="list-style-type: none"> <li>• Sher criteria include a decrease in AHI of <math>\geq 50\%</math> and an AHI <math>&lt; 20</math> events per hour</li> <li>• Alternative measures of success may be AHI <math>&lt; 15</math>, <math>&lt; 10</math>, or <math>&lt; 5</math> events per hour</li> </ul>
ODI	Oxygen levels in blood during sleep	The number of times per hour of sleep that the blood oxygen level drops by $\geq 4$ percentage points	More than 5 events per hour
ESS	Scale ranges from 0 to 24	The ESS is a short self-administered questionnaire that asks patients how likely they are to fall asleep in 8 different situations (eg, watching TV, sitting quietly in a car, or sitting and talking to someone)	An ESS of $\geq 10$ is considered excessively sleepy
FOSQ	30 questions	Disease-specific quality of life questionnaire that evaluates functional status related to excessive sleepiness	A score of $\geq 18$ is the threshold for normal sleep-related functioning, and a change of $\geq 2$ points is considered a clinically meaningful improvement

AHI: Apnea/Hypopnea Index; ESS: Epworth Sleepiness Score; FOSQ: Functional Outcomes of Sleep Questionnaire; ODI: Oxygen Desaturation Index; OSA: obstructive sleep apnea.

©2018 Blue Cross and Blue Shield of Louisiana

Blue Cross and Blue Shield of Louisiana is an independent licensee of the Blue Cross and Blue Shield Association and incorporated as Louisiana Health Service & Indemnity Company.

No part of this publication may be reproduced, stored in a retrieval system, or transmitted, in any form or by any means, electronic, mechanical, photocopying, or otherwise, without permission from Blue Cross and Blue Shield of Louisiana.



# Louisiana

## Medical Management of Obstructive Sleep Apnea Syndrome

Policy # 00328

Original Effective Date: 07/27/2012

Current Effective Date: 09/01/2018

### **Clinical Context and Therapy Purpose**

The purpose of medical management in patients who have OSA is to provide a treatment option that is an alternative to or an improvement on existing therapies.

The question addressed in this evidence review is: Does management with PAP, oral appliances, or novel OSA treatments improve the net health outcome?

The following PICOTS were used to select literature to inform this review.

### **Patients**

The relevant population of interest is patients with OSA.

### **Interventions**

The therapy being considered is the medical management of OSA in adults, which may include the use of various types of positive airway pressure therapy (ie, fixed CPAP, bilevel positive airway pressure, or APAP) during sleep.

CPAP involves the administration of air, usually through the nose, by an external device at a fixed-pressure to maintain the patency of the upper airway. Bilevel positive airway pressure is similar to CPAP, but these devices are capable of generating 2 adjustable pressure levels. APAP adjusts the level of pressure based on the level of resistance and thus administers a lower mean level of positive pressure during the night. It has been hypothesized that both bilevel positive airway pressure 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 or positioning devices or tongue-retaining devices. Oral appliances can either be “off the shelf” or customized for the patient by a dental laboratory or similar provider.

The Daytime-Nighttime Appliance (DNA Appliance) and the mandibular Repositioning Nighttime Appliance (mRNA Appliance) 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 being marketed for the treatment of OSA are 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. 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.

©2018 Blue Cross and Blue Shield of Louisiana

Blue Cross and Blue Shield of Louisiana is an independent licensee of the Blue Cross and Blue Shield Association and incorporated as Louisiana Health Service & Indemnity Company.

No part of this publication may be reproduced, stored in a retrieval system, or transmitted, in any form or by any means, electronic, mechanical, photocopying, or otherwise, without permission from Blue Cross and Blue Shield of Louisiana.



# Louisiana

## Medical Management of Obstructive Sleep Apnea Syndrome

Policy # 00328

Original Effective Date: 07/27/2012

Current Effective Date: 09/01/2018

### **Comparators**

The following therapy is currently being used to make decisions about the treatment of OSA. The criterion standard treatment is CPAP or its variants. The major limitation of CPAP is poor patient compliance due to the need to wear a face or nasal mask.

### **Outcomes**

The outcomes of interest are a decrease in AHI and Oxygen Saturation Index on PSG and improvement in a measure of sleepiness such as the ESS or FOSQ (see Table 2).

### **Timing**

The effect of medical treatment on OSA should be observed on follow-up PSG, typically conducted within weeks or months.

### **Setting**

Treatment would be given by a primary care physician or sleep specialist following a laboratory PSG or home sleep study.

### **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 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

©2018 Blue Cross and Blue Shield of Louisiana

Blue Cross and Blue Shield of Louisiana is an independent licensee of the Blue Cross and Blue Shield Association and incorporated as Louisiana Health Service & Indemnity Company.

No part of this publication may be reproduced, stored in a retrieval system, or transmitted, in any form or by any means, electronic, mechanical, photocopying, or otherwise, without permission from Blue Cross and Blue Shield of Louisiana.





# Louisiana

## Medical Management of Obstructive Sleep Apnea Syndrome

Policy # 00328

Original Effective Date: 07/27/2012

Current Effective Date: 09/01/2018

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

©2018 Blue Cross and Blue Shield of Louisiana

Blue Cross and Blue Shield of Louisiana is an independent licensee of the Blue Cross and Blue Shield Association and incorporated as Louisiana Health Service & Indemnity Company.

No part of this publication may be reproduced, stored in a retrieval system, or transmitted, in any form or by any means, electronic, mechanical, photocopying, or otherwise, without permission from Blue Cross and Blue Shield of Louisiana.



# Louisiana

## Medical Management of Obstructive Sleep Apnea Syndrome

Policy # 00328

Original Effective Date: 07/27/2012

Current Effective Date: 09/01/2018

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 (oxygenation desaturation index and percent of total sleep time with oxygen saturation  $< 90\%$ ) showed small but statistically significant decreases at 1 week and 3 months. Treatment success, defined as a 50% or

©2018 Blue Cross and Blue Shield of Louisiana

Blue Cross and Blue Shield of Louisiana is an independent licensee of the Blue Cross and Blue Shield Association and incorporated as Louisiana Health Service & Indemnity Company.

No part of this publication may be reproduced, stored in a retrieval system, or transmitted, in any form or by any means, electronic, mechanical, photocopying, or otherwise, without permission from Blue Cross and Blue Shield of Louisiana.



# Louisiana

## Medical Management of Obstructive Sleep Apnea Syndrome

Policy # 00328

Original Effective Date: 07/27/2012

Current Effective Date: 09/01/2018

greater reduction in the AHI or an AHI reduction to less than 10 events per hour (if device-off AHI was  $\geq 10$  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 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.

©2018 Blue Cross and Blue Shield of Louisiana

Blue Cross and Blue Shield of Louisiana is an independent licensee of the Blue Cross and Blue Shield Association and incorporated as Louisiana Health Service & Indemnity Company.

No part of this publication may be reproduced, stored in a retrieval system, or transmitted, in any form or by any means, electronic, mechanical, photocopying, or otherwise, without permission from Blue Cross and Blue Shield of Louisiana.



# Louisiana

## Medical Management of Obstructive Sleep Apnea Syndrome

Policy # 00328

Original Effective Date: 07/27/2012

Current Effective Date: 09/01/2018

### 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.

### PRACTICE GUIDELINES AND POSITION STATEMENTS

AASM (2017) published a position statement on the clinical use of a home sleep apnea test. AASM indicated that a home sleep apnea test should be ordered by a physician after “a face-to-face examination” to diagnose OSA or evaluate treatment efficacy and should not be used for general screening of asymptomatic populations. AASM supported the review of “raw data” and interpretation by a “physician board-certified in sleep medicine”, stating that automatically scored data “could lead to sub-optimal care that jeopardizes patient health and safety”.

### 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

©2018 Blue Cross and Blue Shield of Louisiana

Blue Cross and Blue Shield of Louisiana is an independent licensee of the Blue Cross and Blue Shield Association and incorporated as Louisiana Health Service & Indemnity Company.

No part of this publication may be reproduced, stored in a retrieval system, or transmitted, in any form or by any means, electronic, mechanical, photocopying, or otherwise, without permission from Blue Cross and Blue Shield of Louisiana.



# Louisiana

## Medical Management of Obstructive Sleep Apnea Syndrome

Policy # 00328

Original Effective Date: 07/27/2012

Current Effective Date: 09/01/2018

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

1. Blue Cross and Blue Shield Association, Medical Policy Reference Manual, "Diagnosis and Medical Management of Obstructive Sleep Apnea", Policy #2.01.18, 06:2018.
2. Kushida CA, Littner MR, Morgenthaler T, et al. Practice parameters for the indications for polysomnography and related procedures: an update for 2005. *Sleep*. Apr 1 2005;28(4):499-521. PMID 16171294
3. Somers VK, White DP, Amin R, et al. Sleep apnea and cardiovascular disease: an American Heart Association/American College Of Cardiology Foundation Scientific Statement from the American Heart Association Council for High Blood Pressure Research Professional Education Committee, Council on Clinical Cardiology, Stroke Council, and Council On Cardiovascular Nursing. In collaboration with the National Heart, Lung, and Blood Institute National Center on Sleep Disorders Research (National Institutes of Health). *Circulation*. Sep 2 2008;118(10):1080-1111. PMID 18725495
4. Boynton G, Vahabzadeh A, Hammoud S, et al. Validation of the STOP-BANG Questionnaire among Patients Referred for Suspected Obstructive Sleep Apnea. *J Sleep Disord Treat Care*. Sep 23 2013;2(4). PMID 24800262
5. Littner MR, Kushida C, Wise M, et al. Practice parameters for clinical use of the multiple sleep latency test and the maintenance of wakefulness test. *Sleep*. Jan 1 2005;28(1):113-121. PMID 15700727
6. Ahmed I, Thorpy M. Clinical features, diagnosis and treatment of narcolepsy. *Clin Chest Med*. Jun 2010;31(2):371-381. PMID 20488294
7. Berry RB, Budhiraja R, Gottlieb DJ, et al. Rules for scoring respiratory events in sleep: update of the 2007 AASM Manual for the Scoring of Sleep and Associated Events. Deliberations of the Sleep Apnea Definitions Task Force of the American Academy of Sleep Medicine. *J Clin Sleep Med*. Oct 15 2012;8(5):597-619. PMID 23066376
8. Giles TL, Lasserson TJ, Smith BH, et al. Continuous positive airways pressure for obstructive sleep apnoea in adults. *Cochrane Database Syst Rev*. 2006;3:CD001106. PMID 16855960
9. Lim J, Lasserson TJ, Fleetham J, et al. Oral appliances for obstructive sleep apnoea. *Cochrane Database Syst Rev*. 2006(1):CD004435. PMID 16437488
10. Balk EM, Moorthy D, Obadan NO, et al. Diagnosis and Treatment of Obstructive Sleep Apnea in Adults. Comparative Effectiveness Review No. 32 (Prepared by Tufts Evidence-based Practice Center under Contract No. 290-2007-100551) AHRQ Publication No. 11-EHC052-EF. Rockville MD: Agency for Healthcare Research and Quality Jul 2011.
11. Mutter TC, Chateau D, Moffatt M, et al. A matched cohort study of postoperative outcomes in obstructive sleep apnea: could preoperative diagnosis and treatment prevent complications? *Anesthesiology*. Oct 2014;121(4):707-718. PMID 25247853
12. Rosen CL, Auckley D, Benca R, et al. A multisite randomized trial of portable sleep studies and positive airway pressure autotitration versus laboratory-based polysomnography for the diagnosis and treatment of obstructive sleep apnea: the HomePAP study. *Sleep*. Jun 2012;35(6):757-767. PMID 22654195
13. Kuna ST, Gurubhagavatula I, Maislin G, et al. Noninferiority of functional outcome in ambulatory management of obstructive sleep apnea. *Am J Respir Crit Care Med*. May 1 2011;183(9):1238-1244. PMID 21471093
14. Skomro RP, Gjevre J, Reid J, et al. Outcomes of home-based diagnosis and treatment of obstructive sleep apnea. *Chest*. Aug 2010;138(2):257-263. PMID 20173052
15. Andreu AL, Chiner E, Sancho-Chust JN, et al. Effect of an ambulatory diagnostic and treatment programme in patients with sleep apnoea. *Eur Respir J*. Feb 2012;39(2):305-312. PMID 21719490

©2018 Blue Cross and Blue Shield of Louisiana

Blue Cross and Blue Shield of Louisiana is an independent licensee of the Blue Cross and Blue Shield Association and incorporated as Louisiana Health Service & Indemnity Company.

No part of this publication may be reproduced, stored in a retrieval system, or transmitted, in any form or by any means, electronic, mechanical, photocopying, or otherwise, without permission from Blue Cross and Blue Shield of Louisiana.





# Louisiana

## Medical Management of Obstructive Sleep Apnea Syndrome

Policy # 00328

Original Effective Date: 07/27/2012

Current Effective Date: 09/01/2018

16. Bruyneel M, Ninane V. Unattended home-based polysomnography for sleep disordered breathing: current concepts and perspectives. *Sleep Med Rev.* Aug 2014;18(4):341-347. PMID 24388970
17. Thurnheer R. Obstructive sleep apnea and cardiovascular disease - time to act! *Swiss Med Wkly.* Apr 21 2007;137(15-16):217-222. PMID 17525876
18. Mulgrew AT, Fox N, Ayas NT, et al. Diagnosis and initial management of obstructive sleep apnea without polysomnography: a randomized validation study. *Ann Intern Med.* Feb 6 2007;146(3):157-166. PMID 17283346
19. Senn O, Brack T, Russi EW, et al. A continuous positive airway pressure trial as a novel approach to the diagnosis of the obstructive sleep apnea syndrome. *Chest.* Jan 2006;129(1):67-75. PMID 16424414
20. Chai-Coetzer CL, Antic NA, Rowland LS, et al. Primary care vs specialist sleep center management of obstructive sleep apnea and daytime sleepiness and quality of life: a randomized trial. *JAMA.* Mar 13 2013;309(10):997-1004. PMID 23483174
21. Centers for Medicare and Medicaid Services (CMS). Coverage Decision Memorandum for Sleep Testing for Obstructive Sleep Apnea (OSA) 100-3, Change request 6543. 2009; <http://www.cms.gov/transmittals/downloads/R103NCD.pdf>. Accessed August, 2014.
22. Pepin JL, Tamisier R, Borel JC, et al. A critical review of peripheral arterial tone and pulse transit time as indirect diagnostic methods for detecting sleep disordered breathing and characterizing sleep structure. *Curr Opin Pulm Med.* Aug 29 2009;15(6):550-558. PMID 19724229
23. Berry RB, Hill G, Thompson L, et al. Portable monitoring and autotitration versus polysomnography for the diagnosis and treatment of sleep apnea. *Sleep.* Oct 1 2008;31(10):1423-1431. PMID 18853940
24. Pittman SD, Pillar G, Berry RB, et al. Follow-up assessment of CPAP efficacy in patients with obstructive sleep apnea using an ambulatory device based on peripheral arterial tonometry. *Sleep Breath.* Sep 2006;10(3):123-131. PMID 16586136
25. Pang KP, Gourin CG, Terris DJ. A comparison of polysomnography and the WatchPAT in the diagnosis of obstructive sleep apnea. *Otolaryngol Head Neck Surg.* Oct 2007;137(4):665-668. PMID 17903588
26. Penzel T, Kesper K, Pinnow I, et al. Peripheral arterial tonometry, oximetry and actigraphy for ambulatory recording of sleep apnea. *Physiol Meas.* Aug 2004;25(4):1025-1036. PMID 15382839
27. Pittman SD, Ayas NT, MacDonald MM, et al. Using a wrist-worn device based on peripheral arterial tonometry to diagnose obstructive sleep apnea: in-laboratory and ambulatory validation. *Sleep.* Aug 1 2004;27(5):923-933. PMID 15453551
28. Collop NA, Anderson WM, Boehlecke B, et al. Clinical guidelines for the use of unattended portable monitors in the diagnosis of obstructive sleep apnea in adult patients. Portable Monitoring Task Force of the American Academy of Sleep Medicine. *J Clin Sleep Med.* Dec 15 2007;3(7):737-747. PMID 18198809
29. Kayyali HA, Weimer S, Frederick C, et al. Remotely attended home monitoring of sleep disorders. *Telemed J E Health.* May 2008;14(4):371-374. PMID 18570567
30. Pelletier-Fleury N, Lanoe JL, Philippe C, et al. Economic studies and 'technical' evaluation of telemedicine: the case of telemonitored polysomnography. *Health Policy.* Nov 1999;49(3):179-194. PMID 10827296
31. Fox N, Hirsch-Allen AJ, Goodfellow E, et al. The impact of a telemedicine monitoring system on positive airway pressure adherence in patients with obstructive sleep apnea: a randomized controlled trial. *Sleep.* Apr 2012;35(4):477-481. PMID 22467985
32. Reeves-Hoche MK, Hudgel DW, Meck R, et al. Continuous versus bilevel positive airway pressure for obstructive sleep apnea. *Am J Respir Crit Care Med.* Feb 1995;151(2 Pt 1):443-449. PMID 7842204
33. Marcus CL, Rosen G, Ward SL, et al. Adherence to and effectiveness of positive airway pressure therapy in children with obstructive sleep apnea. *Pediatrics.* Mar 2006;117(3):e442-451. PMID 16510622
34. Marcus CL, Beck SE, Traylor J, et al. Randomized, double-blind clinical trial of two different modes of positive airway pressure therapy on adherence and efficacy in children. *J Clin Sleep Med.* Feb 15 2012;8(1):37-42. PMID 22334807
35. Berry RB, Parish JM, Hartse KM. The use of auto-titrating continuous positive airway pressure for treatment of adult obstructive sleep apnea. *An American Academy of Sleep Medicine review.* *Sleep.* Mar 15 2002;25(2):148-173. PMID 11902425
36. Littner M, Hirshkowitz M, Davila D, et al. Practice parameters for the use of auto-titrating continuous positive airway pressure devices for titrating pressures and treating adult patients with obstructive sleep apnea syndrome. *An American Academy of Sleep Medicine report.* *Sleep.* Mar 15 2002;25(2):143-147. PMID 11902424
37. Kushida CA, Morgenthaler TI, Littner MR, et al. Practice parameters for the treatment of snoring and Obstructive Sleep Apnea with oral appliances: an update for 2005. *Sleep.* Feb 1 2006;29(2):240-243. PMID 16494092

©2018 Blue Cross and Blue Shield of Louisiana

Blue Cross and Blue Shield of Louisiana is an independent licensee of the Blue Cross and Blue Shield Association and incorporated as Louisiana Health Service & Indemnity Company.

No part of this publication may be reproduced, stored in a retrieval system, or transmitted, in any form or by any means, electronic, mechanical, photocopying, or otherwise, without permission from Blue Cross and Blue Shield of Louisiana.



# Louisiana

## Medical Management of Obstructive Sleep Apnea Syndrome

Policy # 00328

Original Effective Date: 07/27/2012

Current Effective Date: 09/01/2018

38. Morgenthaler TI, Aurora RN, Brown T, et al. Practice parameters for the use of autotitrating continuous positive airway pressure devices for titrating pressures and treating adult patients with obstructive sleep apnea syndrome: an update for 2007. An American Academy of Sleep Medicine report. *Sleep*. Jan 1 2008;31(1):141-147. PMID 18220088
39. Hussain SF, Love L, Burt H, et al. A randomized trial of auto-titrating CPAP and fixed CPAP in the treatment of obstructive sleep apnea-hypopnea. *Respir Med*. Apr 2004;98(4):330-333. PMID 15072173
40. Marrone O, Resta O, Salvaggio A, et al. Preference for fixed or automatic CPAP in patients with obstructive sleep apnea syndrome. *Sleep Med*. May 2004;5(3):247-251. PMID 15165530
41. Stammnitz A, Jerrentrup A, Penzel T, et al. Automatic CPAP titration with different self-setting devices in patients with obstructive sleep apnoea. *Eur Respir J*. Aug 2004;24(2):273-278. PMID 15332397
42. Krakow B, Ulibarri V, Melendrez D, et al. A daytime, abbreviated cardio-respiratory sleep study (CPT 95807-52) to acclimate insomnia patients with sleep disordered breathing to positive airway pressure (PAP-NAP). *J Clin Sleep Med*. Jun 15 2008;4(3):212-222. PMID 18595433
43. Phillips CL, Grunstein RR, Darendeliler MA, et al. Health Outcomes of CPAP versus Oral Appliance Treatment for Obstructive Sleep Apnea: A Randomised Controlled Trial. *Am J Respir Crit Care Med*. Feb 14 2013. PMID 23413266
44. Berry RB, Kryger MH, Massie CA. A novel nasal expiratory positive airway pressure (EPAP) device for the treatment of obstructive sleep apnea: a randomized controlled trial. *Sleep*. Apr 2011;34(4):479-485. PMID 21461326
45. Kryger MH, Berry RB, Massie CA. Long-term use of a nasal expiratory positive airway pressure (EPAP) device as a treatment for obstructive sleep apnea (OSA). *J Clin Sleep Med*. Oct 15 2011;7(5):449-453B. PMID 22003339
46. Polysomnography Task Force - American Sleep Disorders Association Standards of Practice Committee. Practice parameters for the indications for polysomnography and related procedures *Sleep*. Jun 1997;20(6):406-422. PMID 9302725
47. Chesson AL, Jr., Berry RB, Pack A. Practice parameters for the use of portable monitoring devices in the investigation of suspected obstructive sleep apnea in adults. *Sleep*. Nov 1 2003;26(7):907-913. PMID 14655928
48. Flemons WW, Littner MR, Rowley JA, et al. Home diagnosis of sleep apnea: a systematic review of the literature. An evidence review cosponsored by the American Academy of Sleep Medicine, the American College of Chest Physicians, and the American Thoracic Society. *Chest*. Oct 2003;124(4):1543-1579. PMID 14555592
49. Kushida CA, Littner MR, Hirshkowitz M, et al. Practice parameters for the use of continuous and bilevel positive airway pressure devices to treat adult patients with sleep-related breathing disorders. *Sleep*. Mar 1 2006;29(3):375-380. PMID 16553024
50. Aurora RN, Zak RS, Karipoot A, et al. Practice parameters for the respiratory indications for polysomnography in children. *Sleep*. Mar 2011;34(3):379-388. PMID 21359087
51. Section on Pediatric Pulmonology - Subcommittee on Obstructive Sleep Apnea Syndrome. Clinical practice guideline: diagnosis and management of childhood obstructive sleep apnea syndrome. *Pediatrics*. Apr 2002;109(4):704-712. PMID 11927718
52. Marcus CL, Brooks LJ, Draper KA, et al. Diagnosis and management of childhood obstructive sleep apnea syndrome. *Pediatrics*. Sep 2012;130(3):576-584. PMID 22926173
53. Qaseem A, Dallas P, Owens DK, et al. Diagnosis of obstructive sleep apnea in adults: a clinical practice guideline from the American College of Physicians. *Ann Intern Med*. Aug 2014; 161(3):210-20 <http://annals.org/article.aspx?articleid=1892620&resultClick=1>. Accessed November 14, 2014.
54. Qaseem A, Holty JE, Owens DK, et al. Management of Obstructive Sleep Apnea in Adults: A Clinical Practice Guideline From the American College of Physicians. *Ann Intern Med*. Sept 2013; 159(7):471-83. <http://annals.org/article.aspx?articleid=1742606>. Accessed November 14, 2014.
55. Spencer J, Patel M, Mehta N, et al. Special consideration regarding the assessment and management of patients being treated with mandibular advancement oral appliance therapy for snoring and obstructive sleep apnea. *Cranio*. Jan 2013;31(1):10-13. PMID 23461257
56. American Society of Anesthesiologists Task Force on Perioperative Management of Patients with Obstructive Sleep Apnea. Practice guidelines for the perioperative management of patients with obstructive sleep apnea. *Anesthesiology*. 2014;120(2):1-19. <https://www.asahq.org/For-Members/Practice-Management/-/media/For%20Members/Practice%20Management/PracticeParameters/2014/Practice%20Guidelines%20for%20Perioperative%20Management%20of%20Patients%20With%20OSA.pdf>
57. American Society for Metabolic and Bariatric Surgery Clinical Issues Committee. Peri-operative Management of Obstructive Sleep Apnea. *Surg Obes Relat Dis*. 2012 May-Jun;8(3):e27-32. <http://asmbs.org/2012/03/peri-operative-management-of-obstructive-sleep-apnea/>. Accessed June, 2014.

©2018 Blue Cross and Blue Shield of Louisiana

Blue Cross and Blue Shield of Louisiana is an independent licensee of the Blue Cross and Blue Shield Association and incorporated as Louisiana Health Service & Indemnity Company.

No part of this publication may be reproduced, stored in a retrieval system, or transmitted, in any form or by any means, electronic, mechanical, photocopying, or otherwise, without permission from Blue Cross and Blue Shield of Louisiana.



# Louisiana

## Medical Management of Obstructive Sleep Apnea Syndrome

Policy # 00328

Original Effective Date: 07/27/2012

Current Effective Date: 09/01/2018

58. Roland PS, Rosenfeld RM, Brooks LJ, et al. Clinical practice guideline: Polysomnography for sleep-disordered breathing prior to tonsillectomy in children. *Otolaryngol Head Neck Surg.* Jul 2011;145(1 Suppl):S1-15. PMID 21676944
59. Strohl KP, Brown DB, Collop N, et al. An official American Thoracic Society Clinical Practice Guideline: sleep apnea, sleepiness, and driving risk in noncommercial drivers. An update of a 1994 Statement. *Am J Respir Crit Care Med.* Jun 1 2013;187(11):1259-1266. PMID 23725615
60. National Institute for Health and Clinical Excellence. NICE technology appraisal guidance 139. Continuous positive airway pressure for the treatment of obstructive sleep apnoea/hypopnoea syndrome. 2010; <http://www.nice.org.uk/nicemedia/pdf/TA139Guidance.pdf> Accessed August, 2014.
61. Centers for Medicare and Medicaid Services (CMS). Pub 100-03 Medicare National Coverage Determinations, Change request 6048. 2008; <http://www.cms.hhs.gov/Transmittals/Downloads/R96NCD.pdf>. Accessed August, 2014.
62. Centers for Medicare and Medicaid Services (CMS). National coverage determination for continuous positive airway pressure (CPAP) therapy for obstructive sleep apnea (OSA); 240.4. [http://www.cms.hhs.gov/manuals/downloads/ncd103c1\\_Part4.pdf](http://www.cms.hhs.gov/manuals/downloads/ncd103c1_Part4.pdf). Accessed August, 2014
63. Corral J, Sanchez-Quiroga MA, Carmona-Bernal C, et al. Conventional Polysomnography Is Not Necessary for the Management of Most Patients with Suspected Obstructive Sleep Apnea. Noninferiority, Randomized Controlled Trial. *Am J Respir Crit Care Med.* Nov 1 2017;196(9):1181-1190. PMID 28636405
64. Yu J, Zhou Z, McEvoy RD, et al. Association of Positive Airway Pressure With Cardiovascular Events and Death in Adults With Sleep Apnea: A Systematic Review and Meta-analysis. *JAMA.* Jul 11 2017;318(2):156-166. PMID 28697252
65. Rosen IM, Kirsch DB, Chervin RD, et al. Clinical Use of a Home Sleep Apnea Test: An American Academy of Sleep Medicine Position Statement. *J Clin Sleep Med.* Oct 15 2017;13(10):1205-1207. PMID 28942762

### Policy History

Original Effective Date: 07/27/2012

Current Effective Date: 09/01/2018

- |            |  |
|------------|--|
| 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  |

©2018 Blue Cross and Blue Shield of Louisiana

Blue Cross and Blue Shield of Louisiana is an independent licensee of the Blue Cross and Blue Shield Association and incorporated as Louisiana Health Service & Indemnity Company.

No part of this publication may be reproduced, stored in a retrieval system, or transmitted, in any form or by any means, electronic, mechanical, photocopying, or otherwise, without permission from Blue Cross and Blue Shield of Louisiana.



# Louisiana

## Medical Management of Obstructive Sleep Apnea Syndrome

Policy # 00328

Original Effective Date: 07/27/2012

Current Effective Date: 09/01/2018

- 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
  - 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.
- Next Scheduled Review Date: 08/2019

### 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)<sup>®</sup>†, copyright 2017 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.*

*The responsibility for the content of Blue Cross Blue Shield of Louisiana Medical Policy Coverage Guidelines is with Blue Cross and Blue Shield of Louisiana and no endorsement by the AMA is intended or should be implied. The AMA disclaims responsibility for any consequences or liability attributable or related to any use, nonuse or interpretation of information contained in Blue Cross Blue Shield of Louisiana Medical Policy Coverage Guidelines. Fee schedules, relative value units, conversion factors and/or related components are not assigned by the AMA, are not part of CPT, and the AMA is not recommending their use. The AMA does not directly or indirectly practice medicine or dispense medical services. The AMA assumes no liability for data contained or not contained herein. Any use of CPT outside of Blue Cross Blue Shield of Louisiana Medical Policy Coverage Guidelines should refer to the most current Current Procedural Terminology which contains the complete and most current listing of CPT codes and descriptive terms. Applicable FARS/DFARS apply.*

*CPT is a registered trademark of the American Medical Association.*

©2018 Blue Cross and Blue Shield of Louisiana

Blue Cross and Blue Shield of Louisiana is an independent licensee of the Blue Cross and Blue Shield Association and incorporated as Louisiana Health Service & Indemnity Company.

No part of this publication may be reproduced, stored in a retrieval system, or transmitted, in any form or by any means, electronic, mechanical, photocopying, or otherwise, without permission from Blue Cross and Blue Shield of Louisiana.





# Louisiana

## Medical Management of Obstructive Sleep Apnea Syndrome

Policy # 00328

Original Effective Date: 07/27/2012

Current Effective Date: 09/01/2018

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

Code Type	Code
CPT	94660, 95782, 95783, 95805, 95807, 95808, 95810, 95811
HCPCS	E0470, E0471, E0485, E0486, E0561, E0562, E0601
ICD-10 Diagnosis	F51.04-F51.05      F51.13-F51.19      G47.01      G47.09-G47.39 G47.50-G47.59      G47.61-G47.69      G47.8      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. 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:** 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.

©2018 Blue Cross and Blue Shield of Louisiana

Blue Cross and Blue Shield of Louisiana is an independent licensee of the Blue Cross and Blue Shield Association and incorporated as Louisiana Health Service & Indemnity Company.

No part of this publication may be reproduced, stored in a retrieval system, or transmitted, in any form or by any means, electronic, mechanical, photocopying, or otherwise, without permission from Blue Cross and Blue Shield of Louisiana.