Medical Management of Obstructive Sleep Apnea Syndrome

Policy #  00328
Original Effective Date:  07/27/2012
Current Effective Date:  03/15/2017

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

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

Note: Actigraphy is addressed separately in medical policy 00330.

When Services May Be Eligible for Coverage
Coverage for eligible medical treatments or procedures, drugs, devices or biological products may be provided only if:
- Benefits are available in the member’s contract/certificate, and
- Medical necessity criteria and guidelines are met.

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

Patient Selection Criteria for adult patients
OSA Coverage eligibility will be met under the following conditions:
- An apnea/hypopnea index (AHI) of at least 15 per hour, or
- An AHI of at least 5 per hour in a patient with excessive daytime sleepiness, unexplained hypertension, history of stroke, or ischemic heart disease.

Patient Selection Criteria for pediatric patients
OSA Coverage eligibility will be met under the following conditions:
- In pediatric patients, an AHI greater than 1.5 per hour is considered abnormal, and an AHI of 15 is considered severe.

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

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

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

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

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

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

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

When Services Are Considered Investigational
Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.

Based on review of available data, the Company considers 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.*

**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 electroencephalographic (EEG) arousals (“respiratory event-related arousals” [RERAs]). The sleep fragmentation associated with repeated sleep disruption can lead to impairment of daytime activity. Adult patients with OSA-associated daytime somnolence are thought to be at higher risk for accidents involving motorized vehicles, 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...
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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.

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

FDA or Other Governmental Regulatory Approval

U.S. Food and Drug Administration (FDA)
A variety of oral appliances have received marketing clearance through the U.S. FDA 510(k) pathway for
the treatment of snoring and mild to moderate sleep apnea, including the Narval CC™, Lamberg SleepWell-
Smartrusion, 1st Snoring Appliance, Full Breath Sleep Appliance, PM Positioner, Snorenti, Snorex, Osap,
Desra, Elastomeric Sleep Appliance, Snorenmaster Snore Remedy, Snore-no-More, Napa, Snoar™ Open
Airway Appliance, and The Equalizer Airway Device. FDA product code: LQZ

A number of various CPAP devices have received 510(k) clearance since 1977. BiPAP devices were first
cleared for marketing by FDA in 1996. FDA product codes: BZD, MNT

In 2010, a nasal expiratory resistance valve (PROVENT™, Ventus Medical) received marketing clearance
through the 510(k) process for the treatment of OSA. The Winx system received marketing clearance in
2012.
Centers for Medicare and Medicaid Services (CMS)

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

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

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

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

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

5. An initial 12-week period of CPAP is covered in adult patients with OSA if either of the following criteria using the AHI or RDI are met:
   a. AHI or RDI greater than or equal to 15 events per hour, or
   b. AHI or RDI greater than or equal to 5 events and less than or equal to 14 events per hour with documented symptoms of excessive daytime sleepiness, impaired cognition, mood disorders or insomnia, or documented hypertension, ischemic heart disease, or history of stroke.

6. The AHI or RDI is calculated on the average number of events of per hour. If the AHI or RDI is calculated based on less than 2 hours of continuous recorded sleep, the total number of recorded events to calculate the AHI or RDI during sleep testing must be at minimum the number of events that would have been required in a 2-hour period.

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

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

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

CMS finds that the evidence is sufficient to determine that the results of the sleep tests identified below can be used by a beneficiary’s treating physician to diagnose OSA:

1. Type I PSG is covered when used to aid the diagnosis of OSA in beneficiaries who have clinical signs and symptoms indicative of OSA if performed attended in a sleep lab facility.
2. A type II or type III sleep testing device is covered when used to aid the diagnosis of OSA in beneficiaries who have clinical signs and symptoms indicative of OSA if performed unattended in or out of a sleep lab facility, or attended in a sleep lab facility.
3. A type IV sleep testing device measuring 3 or more channels, one of which is airflow, is covered when used to aid the diagnosis of OSA in beneficiaries who have signs and symptoms indicative of OSA if performed unattended in or out of a sleep lab facility, or attended in a sleep lab facility.
4. A sleep testing device measuring 3 or more channels that include actigraphy, oximetry, and peripheral arterial tone is covered when used to aid the diagnosis of OSA in beneficiaries who have signs and symptoms indicative of OSA if performed unattended in or out of a sleep lab facility, or attended in a sleep lab facility.

Rationale/Source
This policy is updated periodically using the MEDLINE database. The most recent literature update was performed through May 29, 2014.

As described in Cochrane reviews from 2006, treatment of OSA with CPAP or oral appliances has been shown to improve objective and subjective symptoms in patients with OSA. This policy focuses, therefore, on patient selection criteria for PSG, or sleep study. In addition, the use of expiratory positive airway pressure (EPAP), oral pressure therapy (OPT), APAP or BiPAP in patients with OSA is reviewed.

Treatment

BiPAP and APAP
A 1995 study by Reeves-Hoche et al randomized adult patients with OSA to receive either CPAP or BiPAP. The authors found that patient complaints and effective use were similar in both groups but that the dropout rate was significantly higher in the CPAP group. This study suggests that BiPAP should be limited to those patients who have failed a prior trial of CPAP. However, two randomized trials comparing CPAP and BiPAP in children found no difference in adherence between the 2 devices. The 2011 AHRQ CER 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.

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 2011 AHRQ CER, increased compliance...
with APAP devices has not been well-documented in clinical trials. Thus, the issues associated with APAP are similar to BiPAP; ie, APAP may be considered medically necessary in patients who have failed a prior trial of CPAP.

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 of these patients had anxiety, fear, and/or resistance regarding PAP therapy or the diagnosis of OSA. Thirty-nine patients who could not be persuaded to complete a titration protocol (full-night or split-night) were offered a daytime procedure (PAP-NAP) prior to night-time titration. The PAP-NAP protocol consisted of 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 EEG leads); PAP therapy during 1 to 2 hours in bed in which the patient has the possibility of falling 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 compared with 23% of controls. Adherence, defined as at least 5 days per week with an average of at least 4 hours per day, was 56% in the PAP-NAP group and 17% in controls.

This single study of PAP-NAP is not 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.

Oral Appliance Therapy

A 2013 randomized crossover trial by Phillips et al found similar health outcomes after 1 month of CPAP or oral appliance therapy (OAT) in 126 patients (82% with moderate to severe OSA, AHI ≥15). CPAP was more effective than mandibular advancement therapy in reducing AHI (CPAP AHI=4.5, OAT AHI=11.1), but patient-reported compliance was higher with OAT (6.5 vs 5.2 hours/night). Neither treatment improved the primary outcome of 24-hour ambulatory blood pressure, except in a subgroup of patients who were initially hypertensive. The 2 treatments resulted in similar improvements in sleepiness (improvement, 1.6-1.9), FOSQ (improvement, 1.0), some measures on driving simulator performance, and disease-specific quality of life. OAT was superior to CPAP in 4 domains on the SF-36.

Nasal EPAP

One randomized controlled trial and several prospective case series have been published with the PROVENT device.
In 2011, Berry et al reported an industry-sponsored multicenter double-blind randomized sham-controlled trial of nasal EPAP. Two hundred fifty patients with OSA and an AHI of 10 or more per hour were randomized to nasal EPAP (n=127) or a sham device (n=123) for 3 months. Polysonmography 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 the AHI from a median of 13.8 to 5.0 (−52.7%) at week 1 and from 14.4 to 5.6 (−42.7%) at 3 months. This was a significantly greater reduction in AHI than the sham group (−7.3% at week 1, −10.1% at 3 months). Over 3 months, the decrease in ESS was statistically greater in the EPAP group (from 9.9 to 7.2) than in the sham group (from 9.6 to 8.3), although the clinical significance of a 1 point difference in the ESS is unclear. Treatment success and oxygenation data were presented only for the 58% of per-protocol patients who had an AHI of 5 or more per hour on the device-off PSG night. The oxygenation results (oxygenation desaturation index and % of total sleep time with SpO2 <90%) showed small but statistically significant decreases at 1 week and 3 months. Treatment success, defined as a 50% or greater reduction in the AHI or an AHI reduced to less than 10 (if device-off AHI was ≥10), was greater in the EPAP group at 1 week (62% vs 27.2%) and 3 months (50.7% vs 22.4%). Device-related adverse events were reported by 45% of patients in the EPAP group and 34% of patients in the sham group, with 7% of patients in the EPAP group discontinuing the study due to adverse events. Overall, the validity of these results is limited by the high dropout rate, and the clinical significance of the results is uncertain.

An open-label extension of the 2011 randomized study by Berry et al evaluated 12-month safety and durability of the treatment response in patients who had an initial favorable response to EPAP. Included were 41 patients (32% of 127) in the EPAP arm of the study who used the device for an average of at least 4 hours per night on at least 5 nights per 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 patients (40% of 127) eligible, 41 enrolled in the extension study, and 34 (27% of 127) were still using the EPAP device at the end of 12 months. Median AHI was reduced from 15.7 to 4.7 events per hour; the percentage of patients who met criteria for success was not reported. The arousal index was modestly decreased (from 23.9 to 19.0). Over 12 months of treatment, the ESS decreased from 11.1 to 6.0. The median percentage of reported nights used (entire night) was 89.3%. Device-related adverse events were reported by 42% of patients, and the most frequently reported adverse events were difficulty exhaling, nasal discomfort, dry mouth, headache, and insomnia. This open-label extension study is limited by the inclusion of responders only and by the potential for a placebo effect on the ESS. However, the data suggest that some patients may respond to this device, and the patient compliance data might indicate a positive effect on daytime sleepiness that leads to continued use of the device in about 1 in 4 patients. Additional controlled studies are needed to distinguish between these alternatives.

Oral Pressure Therapy
No full-length, peer-reviewed studies on OPT have been identified in the published literature. Therefore, it is not possible to evaluate the efficacy of this treatment based on scientific evidence.

Clinical Input Received From Physician Specialty Societies and Academic Medical Centers
While the various physician specialty societies and academic medical centers may collaborate with and make recommendations during this process, through the provision of appropriate reviewers, input received
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does not represent an endorsement or position statement by the physician specialty societies or academic medical centers, unless otherwise noted.

2009 Input
In response to requests, input was received from 5 physician specialty societies (6 reviewers) and 3 academic medical centers while this policy was under review in 2009. Professional society guidelines and position statements were also reviewed. In general, the input supported the use of PSG, portable sleep monitoring tests, multiple sleep latency test, and CPAP for adults as described in the policy. The March 2009 update includes the reviewer's recommendations for clarifications and modifications to the policy statements.

2010 Input
In response to requests, input was received from 1 physician specialty society and 6 academic medical centers (8 reviewers) for the 2010 policy update. The input focused on the sensors required for unattended home sleep studies and on diagnosis and treatment of OSA in children. In general, the reviewers supported the requirement that home monitors measure 4 parameters, including respiratory effort, airflow, and oxygen saturation, and that their use be restricted to adults. Some exceptions were noted for specific situations. The January 2010 policy update includes recommendations from reviewers regarding indications that are specific to pediatric patients.

2014 Input
In response to requests, input was received from 7 physician specialty societies (8 reviewers) and 4 academic medical centers (6 reviewers) while this policy was under review in 2014. The input focused on routine screening of patients scheduled to undergo bariatric surgery. There was consensus that routine screening is considered medically necessary in this population due to the high prevalence of OSA in patients with a body mass index greater than 40, combined with the increased rate of perioperative complications in patients with OSA. Input was mixed on whether the use of portable home sleep testing was appropriate for patients scheduled for bariatric surgery. Concerns were raised about the high prevalence of obesity hypoventilation syndrome in this population, which is a contraindication to home sleep testing. Other reviewers considered home sleep testing to be appropriate in patients scheduled for bariatric surgery, with the caveat that obesity hypoventilation syndrome should be ruled out prior to home sleep testing.

Summary of Evidence
Current literature indicates that evaluation of OSA should be by clinical evaluation and overnight monitoring, either by attended PSG or by portable unattended home monitoring under qualified supervision and that this may be followed by a trial of APAP to evaluate efficacy and adjust pressure.

- Portable monitoring may be conducted in adult patients with a high pretest probability of OSA and absence of comorbid conditions as determined by clinical evaluation.
- A positive portable monitoring study with at least 4 channels of recording, including arterial oxygen saturation, airflow and respiratory effort, has a high positive predictive value for OSA and can be used as the basis for a CPAP trial to determine efficacy of treatment.
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- A negative portable monitoring study cannot be used to rule out OSA. Patients who have a negative result from portable monitoring or have a positive study but do not respond to CPAP should undergo further evaluation.
- Due to the probability of artifacts or loss of data, raw data from the portable monitoring device should be interpreted by a sleep specialist. Follow-up and review of the APAP trial is also needed.

Although evidence indicates that portable monitoring can be a safe and effective method to evaluate OSA, the variety of portable monitoring devices available and the lack of standardization remains problematic. Additional study is needed to determine the most reliable types of devices and combinations of sensors. Questions also remain about the specific training of the medical personnel required to diagnose OSA without increasing risk of misdiagnosis. Based on the current evidence, use of portable monitoring may be considered medically necessary in adult patients considered to be at high risk for OSA, with clinical evaluation and follow-up conducted by a medical professional experienced in the diagnosis and treatment of sleep disorders.

Use of the novel EPAP device has been reported in several prospective case series and 1 industry-sponsored randomized controlled trial. The main finding of this study was a decrease in AHI with minor impact on oxygenation and the ESS. No evidence was identified on the oral therapy device. Evidence at this time is insufficient to permit conclusions regarding the effect of these technologies on health outcomes. One comparative trial with historical controls was identified on use of a PAP-NAP study for patients with complex insomnia who are resistant to CPAP titration or use. Additional study is needed to evaluate the efficacy of this intervention with greater certainty.

References


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Management/~/media/For%20Members/Practice%20Management/PracticeParameters/2014/Practice%20Guidelines%20for%20Perioperative%20Management%20of%20Patients%20With%20Obstructive%20Sleep%20Apnea.pdf


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

01/23/2013 Coding updated
06/27/2013 Medical Policy Committee review
07/17/2013 Medical Policy Implementation Committee approval. Clarification of a single night for a home sleep study. PAP-NAP studies considered investigational. Oral pressure therapy added as investigational.

03/19/2014 Medical Policy Implementation Committee approval. Not medically necessary statement reworded to state “Based on review of available data, the Company considers multiple sleep latency testing in the diagnosis of obstructive sleep apnea (OSA), except to exclude or confirm narcolepsy or other hypersomnia syndromes, in the diagnostic workup of obstructive sleep apnea (OSA) syndrome to be not medically necessary.”

08/06/2015 Medical Policy Committee review
08/19/2015 Medical Policy Implementation Committee approval. Added bariatric surgery eligibility statement. Added parasomnias and to initiate and titrate CPAP in children to eligibility statement. Updated rationale and references.

09/23/2015 Medical Policy Implementation Committee approval. Added criteria for supervised polysomnography (PSG) performed in a sleep laboratory in patients with a moderate/high pretest probability of OSA.

03/03/2016 Medical Policy Committee review
03/16/2016 Medical Policy Implementation Committee approval. Deleted the Diagnosis section from the policy and title.

04/07/2016 Medical Policy Committee review
04/20/2016 Medical Policy Implementation Committee approval. Clarified facility based titration versus APAP titration.
Based on review of available data, the Company considers facility based titration studies for patients diagnosed with uncomplicated obstructive sleep apnea (OSA) was added as investigational.

01/01/2017 Coding Update: Removing ICD-9 Diagnosis Codes
03/02/2017 Medical Policy Committee review
03/15/2017 Medical Policy Implementation Committee approval. Criteria revised.

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

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

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

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

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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.

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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.