



Name of Blue Advantage Policy:

Medical Management of Obstructive Sleep Apnea Syndrome

Policy #: 065

Latest Review Date: June 2020

Category: Surgery/Medical/DME

Policy Grade: D

BACKGROUND:

Blue Advantage medical policy does not conflict with Local Coverage Determinations (LCDs), Local Medical Review Policies (LMRPs) or National Coverage Determinations (NCDs) or with coverage provisions in Medicare manuals, instructions or operational policy letters. In order to be covered by Blue Advantage the service shall be reasonable and necessary under Title XVIII of the Social Security Act, Section 1862(a)(1)(A). The service is considered reasonable and necessary if it is determined that the service is:

1. *Safe and effective;*
2. *Not experimental or investigational*;*
3. *Appropriate, including duration and frequency that is considered appropriate for the service, in terms of whether it is:*
 - *Furnished in accordance with accepted standards of medical practice for the diagnosis or treatment of the patient's condition or to improve the function of a malformed body member;*
 - *Furnished in a setting appropriate to the patient's medical needs and condition;*
 - *Ordered and furnished by qualified personnel;*
 - *One that meets, but does not exceed, the patient's medical need; and*
 - *At least as beneficial as an existing and available medically appropriate alternative.*

Routine costs of qualifying clinical trial services with dates of service on or after September 19, 2000 which meet the requirements of the Clinical Trials NCD are considered reasonable and necessary by Medicare. Providers should bill **Original Medicare for covered services that are related to **clinical trials** that meet Medicare requirements (Refer to Medicare National Coverage Determinations Manual, Chapter 1, Section 310 and Medicare Claims Processing Manual Chapter 32, Sections 69.0-69.11).*

POLICY:

CPAP, APAP, Bi-PAP, and BiPap S/T are not addressed in this policy. Please refer to CIGNA LCD Positive Airway Pressure (PAP) Devices for the Treatment of Obstructive Sleep Apnea (L11518); CMS NCD for Continuous Positive Airway Pressure (CPAP) Therapy for Obstructive Sleep Apnea (OSA) (NCD 240.4).

Oral Appliances for Obstructive Sleep Apnea is not addressed in this policy. Please refer to CIGNA LCD Oral Appliances for Obstructive Sleep Apnea (L28620).

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

DESCRIPTION OF PROCEDURE OR SERVICE:

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

Obstructive Sleep Apnea

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

A hallmark sign of OSA is snoring. The snoring abruptly ceases during the apneic episodes and during the brief period of patient arousal and then resumes when the patient again falls asleep. Upper airway resistance syndrome (UARS) is a variant of OSA that is characterized by a partial collapse of the airway, resulting in increased resistance to airflow. The increased respiratory effort is associated with multiple sleep fragmentations, as measured by very short alpha

electroencephalographic (EEG) arousals (“respiratory event-related arousals” [RERAs]). The sleep fragmentation associated with repeated sleep disruption can lead to impairment of daytime activity. Adult patients with OSA-associated daytime somnolence are thought to be at higher risk for accidents involving motorized vehicles, i.e., cars, trucks, or heavy equipment, while OSA in children may result in neurocognitive impairment and behavioral problems.

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

Diagnosis

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

Table 1. Definitions of Terms for OSA

Terms	Definition
Respiratory Event	
Apnea	The frequency of apneas and hypopneas is measured from channels assessing oxygen desaturation, respiratory airflow, and respiratory effort. In adults, apnea is defined as a drop in airflow by 90% or more of pre-event baseline for at least 10 seconds. Due to faster respiratory rates in children, pediatric scoring criteria define an apnea as 2 or more missed breaths, regardless of its duration in seconds.
Hypopnea	Hypopnea in adults is scored when the peak airflow drops by at least 30% of pre-event baseline for at least 10 seconds in association with either at least 4% arterial oxygen desaturation or an arousal. Hypopneas in children are scored by a 50% or greater drop in nasal pressure and either a 3% or more decrease in oxygen saturation or 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
Respiratory event reporting	
AHI	The apnea/hypopnea index is the average number of apneas or hypopneas per hour of sleep
RDI	The respiratory disturbance index is the number of apneas, hypopneas, or respiratory event-related arousals per hour of sleep time. RDI is often used synonymously with the AHI.
REI	The respiratory event index is the number of events per hour of monitoring time. Used as an alternative to AHI or RDI in home sleep studies when actual sleep time from EEG is not available.
OSA	Obstructive sleep apnea is repetitive episodes of upper airway obstruction due to the collapse and obstruction of the upper airway during sleep
<ul style="list-style-type: none"> Mild OSA 	<ul style="list-style-type: none"> In adults: AHI or RDI of 5 to <15 In children: AHI ≥ 1.0 to < 5
<ul style="list-style-type: none"> Moderate OSA 	AHI or RDI of 15 to < 30. Children: AHI of ≥ 5 to <10
<ul style="list-style-type: none"> Severe OSA 	<ul style="list-style-type: none"> Adults: AHI or RDI ≥ 30 Children: AHI of ≥ 10
UARS	Upper airway resistance syndrome is characterized by a partial collapse of the airway and results in increased resistance to airflow. The increased respiratory effort is associated with multiple sleep fragmentations, as measured by very short alpha EEG arousals.
Positive airway pressure	
APAP	Auto-adjusting positive airway pressure may be used either to provide treatment or to determine the most effective pressure for CPAP
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.
<ul style="list-style-type: none"> CPAP failure 	Usually defined as an AHI >20 events per hour while using CPAP
<ul style="list-style-type: none"> CPAP intolerance 	CPAP use for <4 hours per night for ≥ 5 nights per week, or refusal to use CPAP. CPAP intolerance may be observed in patients with mild, moderate, or severe OSA

AHI: Apnea/hypopnea Index; APAP: auto-adjusting positive airway pressure; 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.

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. In pediatric patients, an AHI greater than 1.5 events per hour is considered abnormal, and an AHI of 10 or more may be considered severe.

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

Treatment

Medical management of OSA in adults may include weight loss, avoidance of stimulants, body position adjustment, oral appliances, and use of various types of positive airway pressure therapy (i.e., fixed CPAP, bilevel positive airway pressure, or auto-adjusting positive airway pressure) during sleep. This evidence review, addresses CPAP, oral appliances, and novel devices including the Daytime-Nighttime Appliance (BioModeling Solutions), the mandibular Repositioning Nighttime Appliance (BioModeling Solutions), Provent and Winx. Provent is a single-use nasal expiratory resistance valve device containing valves inserted into the nostrils and secured with adhesive. The Winx system uses oral pressure therapy to treat OSA.

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.

Risk Factors for OSA

Although not an exclusive list, patients with all 4 of the following symptoms are considered to be at high risk for obstructive sleep apnea (OSA):

- habitual snoring;
- observed apneas;
- excessive daytime sleepiness;
- a body mass index (BMI) greater than 35kg/m²

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

STOP-BANG Questionnaire

The STOP-BANG questionnaire is a method developed for non-sleep specialists to assess the signs and symptoms of OSA (Snore, Tired, Observed apnea, blood Pressure, BMI, Age, Neck, Gender) and has been shown to have 97% sensitivity and a negative predictive value of 96% (specificity of 33%) for the identification of patients with severe OSA (Apnea/Hypopnea Index [AHI] score >30). Overnight oximetry has been used by some sleep specialists as a component of the risk assessment but is not adequate for the diagnosis of OSA. Therefore, a follow-up polysomnography (PSG) or home sleep study would still be required to confirm or exclude a diagnosis of OSA.

OSA in Children

The presentation of OSA in children may differ from that of adults. Children frequently exhibit behavioral problems or hyperactivity rather than daytime sleepiness. Obesity is defined as a body mass index greater than the 90th percentile for the weight/height ratio. Although the definition of severe OSA in children is not well established, an AHI or RDI greater than 1.5 is considered abnormal (an AHI or RDI score of ≥ 10 may be considered severe). In addition, the first-line treatment in children is usually adenotonsillectomy. CPAP is an option for children who are not candidates for surgery or who have an inadequate response to surgery.

Bariatric Surgery Patients

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

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.

Please refer to medical policy #305 for Polysomnography for Respiratory Sleep Disorders Testing.

KEY POINTS:

The most recent update and literature review was performed through May 11, 2020

Summary of Evidence

For individuals who have OSA who receive PAP devices or oral appliances, the evidence includes RCTs and systematic reviews of RCTs. The relevant outcomes are symptoms, functional outcomes, and QOL. Conventional medical management of OSA includes weight loss, avoidance of stimulants, body position adjustment, oral appliances, and use of CPAP during sleep. A diagnostic sleep study may be followed by a trial of APAP to evaluate the efficacy and adjust pressure. APAP or bilevel PAP may also be indicated if the patient is intolerant of CPAP. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

For individuals who have OSA who receive novel OSA treatments (e.g., palate expansion, EPAP, oral pressure therapy), the evidence includes an RCT and a meta-analysis of case series. The relevant outcomes are symptoms, functional outcomes, and QOL. The evidence on palate and mandible expansion devices includes a few small series. Further study with well-designed trials is needed to evaluate this treatment. The evidence on EPAP devices in patients with OSA has been reported in prospective case series, an industry-sponsored RCT, and a systematic review that did not include the RCT. The main finding of the RCT was a decrease in the AHI, with minor impact on oxygenation, and a decrease in ESS score. One comparative trial with historical controls used a PAP-NAP to study patients with complex insomnia resistant to CPAP titration or use. Additional study is needed to evaluate with greater certainty the efficacy of this intervention. One small RCT with 22 patients found no benefit of an oral EPAP therapy device when added to an oral appliance. The evidence is insufficient to determine the effects of the technology on health outcomes.

Refer to policy #621 – Surgical Management of Obstructive Sleep Apnea for information on surgical treatments.

Practice Guidelines and Position Statements

American Academy of Sleep Medicine

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

Table 1. Summary of Recommendations

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

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

The AASM considers a technically adequate home sleep apnea test (HSAT) device to incorporate "a minimum of the following sensors: nasal pressure, chest and abdominal respiratory inductance plethysmography, and oximetry; or else PAT [peripheral arterial tone] with oximetry and actigraphy." The guidelines refer to the AASM Manual for the Scoring of Sleep and Associated Events for additional information regarding HSAT sensor requirements.

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

American Academy of Pediatrics

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

American College of Physicians

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

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

American Academy of Craniofacial Pain

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

American Society of Metabolic and Bariatric Surgery

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

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

American Thoracic Society

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

In 2016, ATS published a research statement on the long-term effects and treatment of mild OSA in adults. One research question in the statement was to determine if treatment of mild OSA improved daytime sleepiness, quality of life, and reduced neurocognitive consequences. ATS's systematic review concluded:

- Daytime sleepiness: subjective improvement with CPAP; unclear effect with non-CPAP therapies
- Quality of life: small improvements seen in different domains in different studies
- Neurocognition: treatment effects inconsistent.

U.S. Preventive Services Task Force Recommendations

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

KEY WORDS:

Continuous positive airway pressure, CPAP, Bi-level positive airway pressure, BiPAP, obstructive sleep apnea syndrome, OSA, OSAS, upper airway resistance syndrome, UARS, auto-titrate CPAP, auto-adjusting CPAP, APAP, oral appliances, OA, mandibular repositioning device, MRA, BiPAP BiFlex, Repose, C-Flex, A-Flex, Auto-CPAP, nasal expiratory positive airway pressure, Winx™ Sleep Therapy System, Oral Pressure Therapy (OPT), Hypoglossal Nerve Stimulator, DNA Appliance, mRNA Appliance, mandible expanding devices, Provent®

APPROVED BY GOVERNING BODIES:

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

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

Various PAP devices have received clearance through the 510(k) process since 1977. BiPAP devices were first cleared for marketing by FDA in 1996.

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

BENEFIT APPLICATION:

Coverage is subject to member’s specific benefits. Group specific policy will supersede this policy when applicable.

CURRENT CODING:

CPT:

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

A7027	Combination oral/nasal mask, used with continuous positive airway pressure device, each
A7028	Oral cushion for combination oral/nasal mask, replacement only, each
A7029	Nasal pillow for combination oral/nasal mask, replacement only, pair
A7034	Nasal interface (mask or cannula type) used with positive airway pressure device, with or without head strap
A7035	Headgear used with positive airway pressure device
A7036	Chin strap used with positive airway pressure device
A7037	Tubing used with positive airway pressure device
A7038	Filter, disposable, used with positive airway pressure device
A7039	Filter, nondisposable, used with positive airway pressure device
A7047	Oral interface used with respiratory suction pump, each
E0470	Respiratory assist device, bi-level pressure capability, without backup rate feature, used with non-invasive interface, e.g., nasal or facial mask (intermittent assist device with continuous positive airway pressure device)
E0471	Respiratory assist device, bi-level pressure capability, with back-up rate feature, used with noninvasive interface, e.g., nasal or facial mask (intermittent assist device with continuous positive airway pressure device)
E0472	Respiratory assist device, bi-level pressure capability, with backup rate feature, used with invasive interface, e.g., tracheostomy tube (intermittent assist device with continuous positive airway pressure device)
E0485	Oral device/appliance used to reduce upper airway collapsibility,
E0486	Oral device/appliance used to reduce upper airway collapsibility, adjustable or on-adjustable, prefabricated, includes fitting and adjustment. custom fabricated, includes fitting and adjustment
E0561	Humidifier, non-heated, used with positive airway pressure device
E0562	Humidifier, heated, used with positive airway pressure device
E0601	Continuous airway pressure (CPAP) device-(This code should also be used to bill the APAP devices.)
E1399	Unlisted code – This should be used to report the Winx™

REFERENCES:

1. American Academy of Pediatrics. AAP recommends pediatricians screen children for snoring, News Release, April 1, 2002, www.aap.org/advocacy/archives/aprsnoring.htm.
2. American Academy of Pediatrics. Clinical practice guideline: Diagnosis and management of childhood obstructive sleep apnea syndrome. *Pediatrics*, April 2002, Vol. 109, No. 4, pp. 704-712.
3. American Society of Anesthesiologists Task Force on Perioperative Management of patients with obstructive sleep a. Practice guidelines for the perioperative management of patients with obstructive sleep apnea: an updated report by the American Society of Anesthesiologists Task Force on Perioperative Management of patients with obstructive sleep apnea. *Anesthesiology*. Feb 2014; 120(2):268-286.
4. American Society for Metabolic & Bariatric Surgery. Peri-operative management of obstructive sleep apnea. 2012. asmb.org/2012/03/peri-operative-management-of-obstructive-sleep-apnea/.
5. 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.
6. Barthel, Steven W. and Strome, Marshall. Snoring, obstructive sleep apnea, and surgery. *Medical Clinics of North America*, January 1999, Vol. 83, No. 1.
7. 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* 2011; 34(4):479-485.
8. 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.
9. Chowdhuri S, Quan SF, Almeida F, et al. An official American Thoracic Society research statement: impact of mild obstructive sleep apnea in adults. *Am J Respir Crit Care Med*. May 1 2016; 193(9):e37-54.
10. Cummings: *Otolaryngology: Head & Neck Surgery*, 4th edition. Treatment.
11. Epstein LJ, Kristo d, Strollo PJ et al. Clinical Guideline for Evaluation, Management and Long-term Care of Obstructive Sleep Apnea in Adults. *J Clin Sleep Med* 2009; 5(3): 263-276.
12. Ferguson Kathleen A, et al. Oral appliances for snoring and obstructive sleep apnea: A review. *SLEEP* 2006, Vol. 29, No. 2.
13. Friedman M, Schalch P, Lin HC et al. Palatal implants for the treatment of snoring and obstructive sleep apnea/hypopnea syndrome. *Otolaryngol Head Neck Surg* 2008; 138(2):209-16.
14. Gay Peter, et al. Evaluation of positive airway pressure treatment for sleep related breathing disorders in adults. *SLEEP* 2006, Vol. 29, No. 3.
15. Health Technology Advisory Committee. Treatment of obstructive sleep apnea in adults: Executive summary, June 1999, www.health.state.mn.us/htac/apnea.htm.

16. 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.
17. Johal A, Haria P, Manek S, et al. Ready-made versus custom-made mandibular repositioning devices in sleep apnea: a randomized clinical trial. *J Clin Sleep Med.* Feb 15 2017; 13(2):175-182.
18. Jonas DE, Amick HR, Feltner C, et al. Screening for obstructive sleep apnea in adults: evidence report and systematic review for the US Preventive Services Task Force. *JAMA.* Jan 24 2017; 317(4):415-433.
19. Kapur VK, Auckley DH, Chowdhuri S, et al. Clinical practice guideline for diagnostic testing for adult obstructive sleep apnea: an American Academy of Sleep Medicine Clinical Practice Guideline. *J Clin Sleep Med.* Mar 15 2017; 13(3):479-504.
20. Krahn AD, Yee R, Erickson MK, et al. Physiologic pacing in patients with obstructive sleep apnea: A prospective, randomized crossover trial. *J Am Coll Cardiol.* January 2006; 47(2): 379-383.
21. 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* 2011; 7(5):449-453B.
22. Kuhle S, Urschitz MS, et al. Interventions for obstructive sleep apnea in children: A systematic review. *Sleep Med Rev.* April 2009; 13(2): 123-131.
23. Kureshi SA, Gallagher PR, McDonough JM, et al. Pilot study of nasal expiratory positive airway pressure devices for the treatment of childhood obstructive sleep apnea syndrome. *J Clin Sleep Med.* 2014; 10(6):663-669.
24. Kushida Clete A, et al. Practice parameters for the treatment of snoring and obstructive sleep apnea with oral appliances: An update for 2005. *SLEEP* 2006, Vol. 29, No. 2.
25. Kushida Clete A, 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* 2006, Vol. 29, No. 3.
26. Lai V, Tong BK, Tran C, et al. Combination therapy with mandibular advancement and expiratory positive airway pressure valves reduces obstructive sleep apnea severity. *Sleep.* Aug 01 2019; 42(8).
27. Lee NR. Current medical and surgical management of sleep related breathing disorders. *Oral and Maxillofacial Surgery Clinics of North America*, August 2002, Vol. 14, No. 3.
28. Lisan Q, Van Sloten T, Marques Vidal P, et al. Association of Positive Airway Pressure Prescription With Mortality in Patients With Obesity and Severe Obstructive Sleep Apnea: The Sleep Heart Health Study. *JAMA Otolaryngol Head Neck Surg.* Jun 01 2019; 145(6): 509-515.
29. 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.
30. Loubé Daniel I. Technologic advances in the treatment of obstructive sleep apnea syndrome. *Chest*, November 1999, Vol. 116, No. 5.
31. Marcus Carol J. Letters to the Editor: Clinical practice guideline: Diagnosis and management of childhood obstructive sleep apnea syndrome. *Pediatrics*, December 2002, Vol. 110, No. 6.

32. Marcus CL, Brooks LJ, Draper KA et al. Diagnosis and management of childhood obstructive sleep apnea syndrome. *Pediatrics* 2012 130(3):e714-55.
[//pediatrics.aappublications.org/content/130/3/576.full.pdf+html?sid=d61600bf-6989-4879-8d96-43f0421d186a](http://pediatrics.aappublications.org/content/130/3/576.full.pdf+html?sid=d61600bf-6989-4879-8d96-43f0421d186a).
33. 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.
34. Masa JF, Jimenez A, Duran J, et al. Alternative methods of titrating continuous positive airway pressure. A large multicenter study. *Am J Respir Crit Care Med.* 2004; 170:1218-1224.
35. Messner Anna H. Treating pediatric patients with obstructive sleep disorders: An update. *Otolaryngologic Clinics of North America*, June 2003, Vol. 36, No. 3.
36. McEvoy RD, Antic NA, Heeley E, et al. CPAP for prevention of cardiovascular events in obstructive sleep apnea. *N Engl J Med.* Sep 8 2016; 375(10):919-931.
37. 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.
38. Mulgrew AT, Fox N, Ayas NT, et al. Diagnosis and initial management of obstructive sleep apnea without polysomnography: a randomized validation study. *Ann Int Med.* 2007; 146(3):157-166.
39. 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.
40. National Institute for Health and Clinical Excellence (NICE). Continuous positive airway pressure for the treatment of obstructive sleep apnea/hypopnea syndrome [TA139]. 2008; www.nice.org.uk/nicemedia/pdf/TA139Guidance.pdf Accessed October 6, 2016.
41. 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.* Oct 1 2013; 159(7):471-483.
42. Ramar K, Dort LC, Katz SG, et al. Clinical practice guideline for the treatment of obstructive sleep apnea and snoring with oral appliance therapy: An update for 2015. *Journal of Clinical Sleep Medicine* 2015; 11(7):773-6.
www.aasmnet.org/practiceparameters.aspx?cid=102.
43. Respiroics[®], Inc. Suggested protocol for initiation of the BiPAP[®] S/T-D 30 Ventilatory Support System, March 27, 1998.
44. Riaz M, Certal V, Nigam G, et al. Nasal expiratory positive airway pressure devices (Provent) for OSA: a systematic review and meta-analysis. *Sleep Disord.* 2015; 2015:734798.
45. 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.
46. Schmidt-Nowara, Wolfgang Lowe Alan, et al. Oral appliances for the treatment of snoring and obstructive sleep apnea: a review. *SLEEP*, 1995; 18(6):501-510.
47. Schwab R J, Kim C, Siegel L C, et al. Mechanism of action of a novel device using oral pressure therapy (OPT) for the treatment of OSA. *Am J Respir Crit Care Med* 185; 2012:A6811.

48. Simantirakis EN, Schiza SE, et al. Atrial overdrive pacing for the obstructive sleep apnea-hypopnea syndrome. *NEJM*, December 2005; 353(24): 2568-2577.
49. 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. *JACC* 2008; 52: 686-717.
50. 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.
51. Stammnitz A, Jerrentrup A, Penzel T, et al. Automatic CPAP titration with different self-setting devices in patients with obstructive sleep apnea. *Eur Respir J*. Aug 2004; 24(2):273-278.
52. 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.
53. Thorpy Michael, Chesson Andrew, et al. Practice parameters for the treatment of snoring and obstructive sleep apnea with oral appliances. *SLEEP*, 1995; 18:511-13.
54. U.S. Preventive Services Task Force, Bibbins-Domingo K, Grossman DC, et al. Screening for obstructive sleep apnea in adults: US Preventive Services Task Force Recommendation Statement. *JAMA*. Jan 24 2017; 317(4):407-414.
55. Vanderveken OM, Boudewyns A, Kashyap B et al. Cardiovascular Implications in the Treatment of Obstructive Sleep Apnea. *J of Cardiovas. Transl. Res*. 2011; 4: 53-60.
56. Vanderveken OM, Devolder A, Marklund M, et al. Comparison of a custom-made and a thermoplastic oral appliance for the treatment of mild sleep apnea. *American Journal of Respiratory and Critical Care Medicine* 2008, Vol. 178, pp. 197-202.
57. Vicini C, Dallan I, et al. Surgery vs. ventilation in adult severe obstructive sleep apnea syndrome. *Am J Otolaryngol*, Jan-Feb 2010; 31(1): 14-20.
58. Victor Lyle D. Obstructive sleep apnea. *American Family Physician*, November 15, 1999, Vol. 60, No. 8.
59. Woodson BT, Steward DL, Weaver EM and Javaheri S. A randomized trial of temperature-controlled radiofrequency, continuous positive airway pressure, and placebo for obstructive sleep apnea syndrome. *Otolaryngol Head Neck Surg*, June 2003; 128(6): 848-861.

POLICY HISTORY:

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Medical Policy Group, July 2005

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Medical Policy Group, August 2019
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This medical policy is not an authorization, certification, explanation of benefits, or a contract. Eligibility and benefits are determined on a case-by-case basis according to the terms of the member's plan in effect as of the date services are rendered. All medical policies are based on (i) research of current medical literature and (ii) review of common medical practices in the treatment and diagnosis of disease as of the date hereof. Physicians and other providers are solely responsible for all aspects of medical care and treatment, including the type, quality, and levels of care and treatment.

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