



BlueCross BlueShield
of Alabama

Name of Blue Advantage Policy:

Medical Management of Obstructive Sleep Apnea Syndrome

Policy #: 065

Latest Review Date: June 2023

Category: DME

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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:

For dates of service on or after November 1, 2023:

For CPAP, APAP, Bi-PAP, and BiPap S/T, refer to NCD 240.4, LCD L33718 and Article A52467.

For oral appliances, refer to LCD L33611 and Article A52512.

For nasal expiratory airway pressure (EPAP) (e.g. PROVENT[®], Winx[™]), use of a sleep positioning trainer with vibration and use of daytime electrical stimulation of the tongue, refer to [CMS Manual 100-02, Chapter 16-General Exclusions from Coverage](#).

For dates of service prior to November 1, 2023:

For CPAP, APAP, Bi-PAP, and BiPap S/T, refer to NCD 240.4, LCD L33718 and Article A52467.

For oral appliances, refer to LCD L33611 and Article A52512.

Blue Advantage will treat nasal expiratory airway pressure (EPAP) (e.g. PROVENT[®], Winx[™]) as a **non-covered benefit** and as **investigational**.

Blue Advantage will treat the **use of a sleep positioning trainer with vibration** as a **non-covered benefit** and as **investigational**.

Blue Advantage will treat the **use of daytime electrical stimulation of the tongue** as a **non-covered benefit** and as **investigational**.

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. 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 (EPAP) and oral pressure therapy.

Obstructive Sleep Apnea

Obstructive sleep apnea (OSA) syndrome is characterized by repetitive episodes of upper airway obstruction due to the collapse of the upper airway during sleep. This causes a drop in blood oxygenation and brief arousal and can occur as frequently as every minute throughout the night. The main risk factors for OSA include obesity, male sex, older age, large neck size, instability of the respiratory control system, and craniofacial dysmorphisms; additional factors include cardiovascular disease, diabetes, and metabolic syndrome. Since disorders linked to OSA are more common in ethnic minority groups, there are data supporting an increased risk of OSA in African Americans and American Indians.

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

The hallmark of OSA is snoring. The snoring abruptly ceases during the apneic episodes and during the brief period of patient arousal and then resumes when the patient again falls asleep. The sleep fragmentation associated with repeated sleep disruption can lead to impairment of daytime activity. Adults with OSA-associated daytime somnolence are thought to be at higher risk for collisions involving motorized vehicles (i.e., cars, trucks, heavy equipment), while OSA in children may result in neurocognitive impairment and behavioral problems.

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

Diagnosis

Definitions of terms and scoring criteria for OSA are presented in Table 1. Obstructive sleep apnea is widely underdiagnosed with up to 95% of individuals with clinically significant OSA reporting no prior OSA diagnosis. Moreover, under diagnosis is particularly prevalent in Black patients. The criterion standard for a diagnosis of sleep disorders is a polysomnogram performed in a sleep laboratory. A standard polysomnogram includes electroencephalogram (EEG), submental electromyogram, and electrooculogram (to detect rapid eye movement sleep) for sleep staging. Polysomnography (PSG) also typically includes electrocardiography and monitoring of respiratory airflow and effort, snoring, oxygen desaturation, and sleep position. An attended study ensures that the electrodes and sensors are functioning adequately and do not dislodge during the night. In addition, an attendant is able to identify severe OSA in the first part of the

night and titrate continuous positive airway pressure (CPAP) in the second part of the night, commonly known as a "split-night" study. If successful, this strategy eliminates the need for additional PSG for CPAP titration.

A variety of devices have also been developed specifically to evaluate OSA at home. They range from portable full PSG 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.

Table 1. Definitions of Terms and Scoring Criteria for OSA

| Terms | Definition |
|-----------------------------|--|
| Respiratory Event | |
| Apnea | The frequency of apneas and hypopneas is measured from channels assessing oxygen desaturation, respiratory airflow, and respiratory effort. In adults, apnea is defined as a drop in airflow by 90% or more of pre-event baseline for at least 10 seconds. Due to faster respiratory rates in children, pediatric scoring criteria define an apnea as 2 or more missed breaths, regardless of its duration in seconds. |
| Hypopnea | Hypopnea in adults is scored when the peak airflow drops by at least 30% of pre-event baseline for at least 10 seconds in association with either at least 4% arterial oxygen desaturation or an arousal. Hypopneas in children are scored by a 50% or greater drop in nasal pressure and either a 3% or more decrease in oxygen saturation or 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. |

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|---|--|
| 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 | <p>In adults: AHI or RDI of 5 to <15</p> <p>In children: AHI \geq1.0 to < 5</p> |
| <ul style="list-style-type: none"> Moderate OSA | AHI or RDI of 15 to < 30. Children: AHI of \geq 5 to <10 |
| <ul style="list-style-type: none"> Severe OSA | <p>Adults: AHI or RDI \geq30</p> <p>Children: AHI of \geq10</p> |
| UARS | Upper airway resistance syndrome is characterized by a partial collapse of the airway and results in increased resistance to airflow. The increased respiratory effort is associated with multiple sleep fragmentations, as measured by very short alpha EEG arousals. |
| Positive airway pressure | |
| APAP | Auto-adjusting positive airway pressure may be used either to provide treatment or to determine the most effective pressure for CPAP |
| PAP | PAP may be continuous (CPAP) or auto-adjusting (APAP) or bi-level (bi-PAP). CPAP is a more familiar abbreviation for delivery of positive airway pressure. |
| <ul style="list-style-type: none"> PAP failure | Usually defined as an AHI >20 events per hour while using CPAP |
| <ul style="list-style-type: none"> PAP 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.

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 (PAP) therapy (i.e., fixed CPAP, bilevel PAP, or auto-adjusting positive airway pressure [APAP]) during sleep. This evidence review addresses established and novel devices including the Daytime-Nighttime Appliance (BioModeling Solutions), the mandibular Repositioning Nighttime Appliance (BioModeling Solutions), eXciteOSA (Signifier Medical Technologies), NightBalance Sleep Position Trainer (Phillips), Provent, and Winx. Provent is a single-use nasal expiratory resistance valve device containing valves inserted into the nostrils and secured with adhesive. The Winx system uses oral pressure therapy to treat OSA.

Surgical management of OSA (i.e., adenotonsillectomy, uvulopalatopharyngoplasty, orthognathic surgery) is discussed in medical policy #621 (Surgical Treatment of Snoring and Obstructive Sleep Apnea).

Risk Factors for OSA

Although not an exclusive list, patients with all 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.

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. In addition, the first-line treatment in children is usually adenotonsillectomy. Continuous positive airway pressure (CPAP) is an option for children who are not candidates for surgery or who have an inadequate response to surgery.

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.

KEY POINTS:

The most recent update and literature review was performed through May 9, 2023.

Summary of Evidence:

For individuals who have OSA who receive PAP devices, the evidence includes RCTs and systematic reviews of RCTs, and a cohort study. 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 continuous PAP (CPAP) during sleep. A diagnostic sleep study may be followed by a trial of APAP to evaluate the efficacy and adjust pressure. Studies have suggested that both CPAP and APAP are associated with improvements in sleep architecture. Additionally, 11-year follow-up of obese patients with severe OSA from the Sleep Heart Health Study found a reduction in all-cause mortality with PAP use which appeared after 6 to 7 years. If the patient is intolerant of CPAP, APAP or bilevel PAP may also be indicated. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have OSA who use oral appliances, the evidence includes RCTs and systematic reviews of RCTs. Relevant outcomes are symptoms, functional outcomes, and QOL. Conventional medical management of OSA includes weight loss, avoidance of stimulants, body position adjustment, oral appliances, and use of CPAP during sleep. Oral appliances are an accepted therapy for mild-to-moderate OSA. A 2015 and 2022 meta-analysis demonstrated the efficacy of oral appliances for measures of OSA, but they were generally less effective than CPAP. Conflicting data exists on if custom-made oral devices demonstrate superior impact on symptoms and QOL outcomes compared to ready-made oral devices, based on available RCTs. Oral appliances may be an appropriate alternative in patients who refuse or cannot tolerate PAP devices. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have OSA who receive novel OSA treatments (e.g., palate expansion, EPAP, oral pressure therapy, tongue stimulation, supine vibration), the evidence includes RCTs, prospective single-arm studies, and a meta-analysis of case series. Relevant outcomes are symptoms, functional outcomes, and QOL. The evidence on palate and mandible expansion devices includes a few small series. Further study with well-designed trials is needed to evaluate this treatment. The evidence on nasal EPAP devices in patients with OSA has been reported in prospective case series, an industry-sponsored RCT, smaller RCTs, and a systematic review that did not include the industry-sponsored RCT. The main finding of the industry-sponsored RCT was a decrease in the AHI, with a minor impact on oxygenation, and a decrease in ESS. One small RCT with 22 patients found no benefit of an oral EPAP therapy device when added to an oral appliance. One nonrandomized comparative trial with historical controls and a retrospective chart review evaluated a daytime sleep procedure (PAP-NAP) to reduce resistance to CPAP

titration or use. Additional study is needed to evaluate the efficacy of this intervention. Single-arm studies suggest that daytime tongue stimulation may improve snoring, but the effect on OSA is uncertain. Several RCTs, observational studies, and a meta-analysis have been published with a sleep positioning device that vibrates when the individual is in a supine position. Drop-out rates were high and long-term compliance is unknown. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Practice Guidelines and Position Statements:

American Academy of Otolaryngology-Head and Neck Surgery

In 2021, the American Academy of Otolaryngology-Head and Neck Surgery updated its position statement on the treatment of OSA. The academy states that adenotonsillectomy is the first line treatment in pediatric OSA. In most adults, CPAP is the first-line treatment. Surgical procedures may be considered when positive airway pressure (PAP) therapy is inadequate.

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 updated the AAP's 2002 guidelines. Adenotonsillectomy was recommended as the first-line 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 was recommended if adenotonsillectomy was not performed or if OSA persisted postoperatively. Weight loss was 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 Academy of Sleep Medicine

The American Academy of Sleep Medicine (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).

Treatment with positive airway pressure (PAP)

- CPAP is indicated for patients with moderate to severe OSA (Standard) and mild OSA (Option).
- Bilevel PAP can be considered in CPAP-intolerant patients (Consensus).
- Autotitrating positive airway pressure (APAP) can be considered in CPAP-intolerant patients (Consensus).

Treatment with oral appliances (OA) is indicated for "patients with mild to moderate OSA, who prefer OAs to CPAP, or who do not respond to CPAP, or are not appropriate candidates for CPAP, or who fail CPAP ... (Guideline)."

- Mandibular repositioning appliance covers the upper and lower teeth.

- Tongue-retaining device holds the tongue in a forward position.

The AASM (2019) also published a clinical practice guideline on the treatment of OSA with PAP that was based on a systematic review of the evidence. "A STRONG (i.e., "We recommend...") recommendation is one that clinicians should follow under most circumstances. A CONDITIONAL recommendation (i.e., "We suggest...") reflects a lower degree of certainty regarding the outcome and appropriateness of the patient-care strategy for all patients."

The AASM provided strong recommendations for the following use of PAP therapy in adults:

- Use of PAP to treat OSA in adults with excessive sleepiness.
- That PAP therapy be initiated at home using APAP or in-laboratory PAP titration in adults with no significant morbidities.
- Use of CPAP or APAP for ongoing treatment of OSA.
- That clinicians provide educational interventions with the initiation of PAP.
- The AASM provided conditional recommendations (suggest) for the following use of PAP therapy in adults:
 - Use of PAP to treat OSA in adults with impaired sleep-related quality of life (QOL).
 - Use of PAP to treat OSA in adults with comorbid hypertension.
 - Use CPAP or APAP over Bilevel PAP in the routine treatment of OSA.
 - That behavioral and/or troubleshooting interventions be given during the initial period of PAP therapy.
 - That clinicians use telemonitoring during the initial period of PAP therapy.

The AASM and the American Academy of Dental Sleep Medicine (2015) published guidelines on the treatment of OSA and snoring with OA therapy.²⁰ The 2 societies provided a recommendation of "standard" that sleep physicians consider prescription of OA, rather than no treatment, for adults with OSA who are intolerant of CPAP therapy or prefer alternative therapy. The quality of evidence was rated as moderate. "Guideline" recommendations were provided for the use of custom, titratable appliance over noncustom oral devices, that qualified dentists provide oversight, that sleep physicians conduct follow-up sleep testing to improve or confirm treatment efficacy, and that patients return for periodic office visits with a qualified dentist and a sleep physician.

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 Heart Association

In 2021, the American Heart Association (AHA) published a scientific statement on OSA and cardiovascular disease.

The treatment options for OSA and eligibility for their use are described in the statement and briefly summarized below:

- CPAP: "The Centers for Medicare & Medicaid Services cover CPAP on the basis of an AHI [apnea/hypopnea index] or REI [respiratory event index] ≥ 15 events per hour or AHI (or REI) ≥ 5 with documented symptoms of excessive daytime sleepiness, impaired cognition, mood disorders or insomnia, or documented comorbidities (i.e., hypertension, ischemic heart disease, or history of stroke)."
- APAP: "Same as CPAP."
- Bilevel PAP: "Patients intolerant of CPAP pressure or who require additional ventilatory support."
- Positional therapy: "Indicated for positional sleep apnea defined by breathing events only (isolated) or predominantly in the supine posture often considered as supine AHI at least double the lateral AHI."
- Oral appliances: "Alternative to CPAP for mild to moderate OSA or in patients who do not tolerate CPAP."

The statement also notes the following with regard to treatment:

"All patients with OSA should be considered for treatment, including behavioral modifications and weight loss as indicated. Continuous positive airway pressure should be offered to patients with severe OSA, whereas oral appliances can be considered for those with mild to moderate

OSA or for continuous positive airway pressure–intolerant patients. Follow-up sleep testing should be performed to assess the effectiveness of treatment."

National Institute for Health and Care Excellence

NICE provides guidance on medical management in individuals with varying degrees of OSA.

They recommend offering fixed-level CPAP in those with mild OSA when symptoms affect QOL and usual daytime activities if lifestyle changes alone have been unsuccessful or are considered inappropriate. They recommend APAP as an alternative to fixed-level CPAP in those unable to tolerate CPAP. In individuals who cannot tolerate or refuse CPAP, they recommend offering a customized mandibular advancement device. In individuals with moderate to severe OSA, CPAP is recommended as a treatment option, with APAP offered as an alternative in those unable to tolerate CPAP. Similarly, a customized mandibular advancement device may be used if an individual refuses PAP or is unable to tolerate PAP. NICE also states that a positional modifier may be considered for those with mild to moderate positional OSA if other treatments are unsuitable or not tolerated, but this should not be a first-line treatment option.

American Thoracic Society

The American Thoracic Society (2016) published a research statement on the long-term effects and treatment of mild OSA in adults. The Society'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

None.

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®, tongue stimulation, supine vibration, eXciteOSA, NightBalance, Sleep Position Trainer, Slow Wave DS8

APPROVED BY GOVERNING BODIES:

A variety of oral appliances have been cleared for marketing by the U.S. Food and Drug Administration (FDA) through the 510(k) process for treatment of snoring and mild-to-moderate OSA, including the Narval™ CC, Lamberg Sleep Well Smartrusion, 1st Snoring Appliance, Full

Breath Sleep Appliance, PM Positioner, Snorenti, Snorex, Osap, DeSRA, Elastomeric Sleep Appliance, Snoremaster Snore Remedy, Snore-noMore, Napa, Snoar™ Open Airway Appliance, and The Equalizer Airway Device.

Various PAP devices have been cleared by the FDA through the 510(k) process since 1977. Bilevel positive airway pressure devices were first cleared for marketing in 1996.

Table 2. Novel devices for OSA Diagnosis and Treatment

| Device | Manufacturer | Description | 510 (K) Number | FDA Product Code | Year |
|---------------------------|--------------------------------|--|----------------|------------------|------|
| Treatment | | | | | |
| Provent® | Ventus Medical | Nasal expiratory resistance valve | K102404 | OHP | 2010 |
| Winx™ | Apnicure, Inc. | Nasal expiratory resistance valve | K122130 | OZR | 2012 |
| mRNA Appliance® | BioModeling Solutions | Expandable oral appliance for the treatment of snoring and mild-to-moderate OSA | K130067 | LRK | 2014 |
| NightBalance Lunoa System | Philips | The positional sleep trainer is worn with an elasticized chest strap, and is intended to keep patients with positional obstructive sleep apnea from sleeping in the supine position. | K180608 | MYB | 2018 |
| eXciteOSA® | Signifier Medical Technologies | The device delivers neuromuscular stimulation during the day to strengthen the tongue in order to reduce snoring and mild sleep apnea. It is used for 20 minutes once a day for a period of 6-weeks, and once a week thereafter. | K223446 | QNO | 2021 |
| Respire Clear | Respire | The device is an oral | K214096 | LQZ, | 2022 |

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|--|--------------|--|--|-----|--|
| | Medical, LLC | appliance used in the treatment of mild to moderate OSA. It helps move a patient's jaw forward, thus opening their airways, and allowing them to breathe more easily throughout the night. | | LRK | |
|--|--------------|--|--|-----|--|

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

BENEFIT APPLICATION:

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

CURRENT CODING:

CPT:

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

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|-------|--|
| A4604 | Tubing with integrated heating element for use with positive airway pressure device |
| 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 |
| A7030 | Full face mask used with positive airway pressure device, each |
| A7031 | Face mask interface, replacement for full face mask, each |
| A7032 | Cushion for use on nasal mask interface, replacement only, each |
| A7033 | Pillow for use on nasal cannula type interface, replacement only, pair |
| A7034 | Nasal interface (mask or cannula type) used with positive airway pressure device, with or without head strap |

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| 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 |
| A7044 | Oral interface used with positive airway pressure device, each |
| A7045 | Exhalation port with or without swivel used with accessories for positive airway devices, replacement only |
| A7046 | Water chamber for humidifier, used with positive airway pressure device, replacement, each |
| A7047 | Oral interface used with respiratory suction pump, each |
| A7049 | Expiratory positive airway pressure intranasal resistance valve |
| 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 |

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|-------|---|
| E0490 | Power source and control electronics unit for oral device/appliance for neuromuscular electrical stimulation of the tongue muscle, controlled by hardware remote |
| E0491 | Oral device/appliance for neuromuscular electrical stimulation of the tongue muscle, used in conjunction with the power source and control electronics unit, controlled by hardware remote, 90-day supply |
| 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 | Durable medical equipment, miscellaneous |
| K1001 | Electronic positional obstructive sleep apnea treatment, with sensor, includes all components and accessories, any type |
| K1027 | Oral device/appliance used to reduce upper airway collapsibility, without fixed mechanical hinge, custom fabricated, includes fitting and adjustment |
| K1028 | Power source and control electronics unit for oral device/appliance for neuromuscular electrical stimulation of the tongue muscle controlled by phone application |
| K1029 | Oral device/appliance for neuromuscular electrical stimulation of the tongue muscle, used in conjunction with the power source and control electronics unit, controlled by phone application, 90-day supply |

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POLICY HISTORY:

Adopted for Blue Advantage, March 2005

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Medical Policy Group, July 2005

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 Medical Policy Group, July 2017
 Medical Policy Group, July 2018 **(6)**: Updates to Description, Key Points and Practice Guidelines.
 Medical Policy Group, August 2019
 Medical Policy Group, June 2020: Added HCPCS A7027.
 Medical Policy Group, June 2021
 Medical Policy Group, September 2021
 Medical Policy Group, March 2022: Quarterly Coding Update. Added HCPCS K1028/K1029 to Current Coding section.
 Medical Policy Group, June 2022
 Medical Policy Group, March 2023: Quarterly Coding Update. Added HCPCS A7049 to Current Coding section.
 Medical Policy Group, June 2023
 Medical Policy Group, July 2023: Updated Current Coding to include A4604, A7029, A7030, A7031, A7032, A7033, A7044, A7045, A7046.
 Medical Policy Group, September 2023: Quarterly HCPCS Coding Update. K1028 description revised, added E0490-E0491 to Current Coding section.

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.