BlueCross BlueShield Federal Employee Program.

FEP Medical Policy Manual

FEP 8.01.67 Medical Management of Obstructive Sleep Apnea Syndrome

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Related Policies:

7.01.101 - Surgical Treatment of Snoring and Obstructive Sleep Apnea Syndrome

Medical Management of Obstructive Sleep Apnea Syndrome

Description

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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.

OBJECTIVE

The objective of this evidence review is to evaluate the evidence for established and novel methods of treating obstructive sleep apnea.

POLICY STATEMENT

Auto-adjusting positive airway pressure (APAP) may be considered **medically necessary** for the titration of pressure in individuals with clinically significant obstructive sleep apnea (OSA) defined as those who have:

- An Apnea/Hypopnea Index (AHI), Respiratory Disturbance Index (RDI), or Respiratory Event Index (REI) of at least 15 events per hour, OR
- An AHI, RDI, or REI of at least 5 events per hour in an individual with 1 or more signs or symptoms associated with OSA (eg, excessive daytime sleepiness, hypertension, cardiovascular heart disease, or stroke); OR
- If there is a significant change in weight or change in symptoms suggesting that continuous positive airway pressure (CPAP) should be retitrated or possibly discontinued.

CPAP may be considered **medically necessary** in adult or pediatric individuals with clinically significant OSA.

Clinically significant OSA in adults is:

- An AHI, RDI, or REI ≥15, OR
- An AHI, RDI, or REI ≥5 in an individual with 1 or more signs or symptoms associated with OSA (e.g., excessive daytime sleepiness, hypertension, cardiovascular heart disease, or stroke).

Clinically significant OSA in pediatric individuals is:

- An AHI or RDI ≥5 OR
- An AHI or RDI ≥1.5 in an individual with excessive daytime sleepiness, behavioral problems or hyperactivity.

Bilevel positive airway pressure (PAP) or APAP may be considered **medically necessary** in individuals with clinically significant OSA who have failed a prior trial of CPAP or for whom bilevel PAP is found to be more effective in the sleep lab.

Intraoral appliances (tongue-retaining devices or mandibular advancing/positioning devices) may be considered **medically necessary** in adults with clinically significant OSA under the following conditions:

OSA, defined by an AHI, RDI, or REI of at least 15 events per hour or an AHI, RDI, or REI of at least 5 events per hour in an individual with 1 or more signs or symptoms associated with OSA (e.g., excessive daytime sleepiness, hypertension, cardiovascular heart disease, or stroke), 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 individuals with severe OSA, because oral appliances have been shown to be less efficacious in individuals with severe OSA than in individuals with mild-to-moderate OSA. Therefore, it is particularly important that individuals with severe OSA 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.

The use of CPAP, bi-level PAP, APAP, and intraoral appliances that do not meet the above criteria is considered **investigational** for the treatment of OSA.

The use of an abbreviated daytime sleep session for acclimation to CPAP (PAP-NAP) is considered **investigational**.

The use of a sleep positioning trainer with vibration is considered **investigational** for the treatment of positional OSA.

The use of daytime electrical stimulation of the tongue is considered **investigational** for the treatment of OSA.

Palate and mandible expansion devices are considered **investigational** for the treatment of OSA.

Nasal expiratory positive airway pressure (EPAP) and oral pressure therapy devices are considered **investigational**.

POLICY GUIDELINES

Specialist Training

Treatment of individuals diagnosed with obstructive sleep apnea (OSA) should be initiated and monitored by a professional trained in sleep medicine. It is important to monitor symptoms and adherence to positive airway pressure (PAP) treatment (e.g., review of symptoms and device utilization at 90 days with a minimum of 4 hours per night for at least 5 nights per week).

Risk Factors for Obstructive Sleep Apnea

Although not an exclusive list, individuals with all of the following symptoms are considered to be at high risk for OSA:

- habitual snoring;
- observed apneas;
- excessive daytime sleepiness;
- a body mass index (BMI) greater than 35 kg/m^2.

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

The STOP-BANG questionnaire, a method developed for nonsleep specialists, assesses the signs and symptoms of OSA (Snore, Tired, Observed apnea, blood Pressure, BMI, Age, Neck, Gender), and has been shown to have 97% sensitivity and 96% negative predictive value (specificity, 33%) for the identification of individuals with severe OSA (Apnea/Hypopnea Index [AHI] >30 events per hour). Overnight oximetry has been used by some sleep specialists as a component of the risk assessment but is inadequate for the diagnosis of OSA. Therefore, a follow-up polysomnography (PSG) or home sleep apnea test would still be required to confirm or exclude a diagnosis of OSA.

Obstructive Sleep Apnea 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.

BENEFIT APPLICATION

Experimental or investigational procedures, treatments, drugs, or devices are not covered (See General Exclusion Section of brochure).

Weight Loss Programs

Weight loss is frequently recommended for obese individuals with obstructive sleep apnea (OSA). Plans may want to review their policies on weight loss programs in general and determine whether such policies should apply to individuals with OSA. In some instances, continuous positive airway pressure (CPAP) may also be recommended while the individual is in a weight loss program; if the weight loss program is successful, further therapy may be unnecessary. If the weight loss program is unsuccessful, and the individual does not tolerate CPAP (or auto-adjusting positive airway pressure or bilevel positive airway pressure), surgical therapy may be considered.

FDA REGULATORY STATUS

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 the treatment of snoring and mild-to-moderate OSA, including the Narval™ CC, Lamberg Sleep Well Smartrusion, 1st Snoring Appliance, Full Breath Sleep Appliance, PM Positioner, Snorenti, Snorex, Osap, DeSRA, Elastomeric Sleep Appliance, Snoremaster Snore Remedy, Snore-no-More, Napa, Snoar™ Open Airway Appliance, and The Equalizer Airway Device.
FDA product code: LQZ.

Various PAP devices have been cleared by the FDA through the 510(k) process since 1977. Bilevel PAP devices were first cleared for marketing in 1996.
FDA product codes: BZD, MNT.

Novel devices for OSA diagnosis and treatment are described in Table 1.

Table 1. Novel Devices for OSA Diagnosis and Treatment

Device	Manufacturer	Description	510(K) Number	FDA Product Code	Year
Diagnosis					
SleepImage System	MyCardio	Software as a medical device that provides automated analysis of sleep data from a single photoplethysmogram sensor to aid in the evaluation of sleep disorders.	K163696	MNR	2017
Treatment					
Provent	Ventus Medical	Nasal expiratory resistance valve.	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 Medical, LLC	The device is an oral appliance used in the treatment of mild tomoderate OSA. It helps move a patient's jaw forward, thus opening their airways, and allowing them to breathe more easily throughout the night.	K214096	LRK; LQZ	2022

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

RATIONALE

Summary of Evidence

For individuals who have obstructive sleep apnea (OSA) who receive positive airway pressure (PAP) devices, the evidence includes randomized controlled trials (RCTs), systematic reviews of RCTs, and a cohort study. Relevant outcomes are symptoms, functional outcomes, and quality of life (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 Auto-adjusting positive airway pressure (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 (eg, palate expansion, expiratory positive airway pressure [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 apnea/hypopnea index (AHI), with a minor impact on oxygenation, and a decrease in Epworth Sleepiness Score (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.

SUPPLEMENTAL INFORMATION

Practice Guidelines and Position Statements

Guidelines or position statements will be considered for inclusion in 'Supplemental Information' if they were issued by, or jointly by, a US professional society, an international society with US representation, or National Institute for Health and Care Excellence (NICE). Priority will be given to guidelines that are informed by a systematic review, include strength of evidence ratings, and include a description of management of conflict of interest.

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.[42,] 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.[43,44,] 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.[45,] 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 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.[4,5,] "A STRONG (ie, "We recommend...") recommendation is one that clinicians should follow under most circumstances. A CONDITIONAL recommendation (ie, "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 Heart Association

In 2021, the American Heart Association (AHA) published a scientific statement on OSA and cardiovascular disease.[46,] 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 (ie, 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 regards 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."

American Society of Metabolic and Bariatric Surgery

The American Society of Metabolic and Bariatric Surgery (2012) published guidelines on the perioperative management of OSA (reviewed in October 2015).[47,] The guidelines noted that while some reports in the literature have recommended routine screening for OSA prior to bariatric surgery, other reports have suggested 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 PSG, but do not make this a routine preoperative test prior to bariatric surgery. The Society provided, based on the evidence in the literature to date, the following guidelines on OSA in the bariatric surgery patient and its perioperative management:

1. "OSA is highly prevalent in the bariatric patient population....

4. [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.

7. 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 [intensive care unit] setting.

8. No clear guidelines exist upon which to base recommendations for retesting for OSA following bariatric surgery...."

American Thoracic Society

The American Thoracic Society (2016) published a research statement on the long-term effects and treatment of mild OSA in adults.[48,] The Society's systematic review concluded:

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

National Institute for Health and Care Excellence

NICE provides guidance on medical management in individuals with varying degrees of OSA.[49,] 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.

U.S. Preventive Services Task Force Recommendations

None.

Medicare National Coverage

In 2001, the Centers for Medicare & Medicaid Services published a decision memorandum on CPAP that addressed how to define moderate-to-severe OSA as a guide to a coverage policy for CPAP. This review of the literature suggested there is a risk of hypertension with an AHI greater than 15 events per hour, and thus treatment would be warranted for these patients without any additional signs and symptoms. For patients with an AHI between 5 and 15 events per hour and associated symptoms, CMS concluded that the data from 3 randomized controlled trials demonstrated improved daytime somnolence and functioning in those treated with CPAP.

In 2008, CMS expanded coverage of CPAP to include those beneficiaries with a diagnosis of OSA made with a combination of clinical evaluation and unattended home sleep monitoring using a device with at least 3 channels.[50,51,] There is variability in the published medical literature about the definition of the events that constitute a respiratory disturbance, and, for the purposes of this national coverage decision, a respiratory disturbance was defined in the context of the sleep test technology of interest and, for portable monitoring devices that do not measure AHI or Respiratory Disturbance Index (RDI) directly, does not require direct measurement of airflow.

Effective in March 2008, CMS determined that CPAP therapy, when used in adults with OSA, would be considered reasonable and necessary in 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 clinical evaluation and a positive:
    1. attended PSG performed in a sleep laboratory; or
    2. unattended HST [home sleep test] with a Type II home sleep monitoring device; or
    3. unattended HST with a Type III home sleep monitoring device; or
    4. unattended HST 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:
    1. AHI or RDI greater than or equal to 15 events per hour, or

2. 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 (CED): Medicare provides the following limited coverage for CPAP in adult beneficiaries who do not qualify for CPAP coverage based on criteria 1-7 above. A clinical study seeking Medicare payment for CPAP provided to a beneficiary who is an enrolled subject in that study must address 1 or more of the following questions:

    1. 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 & IV HST in identifying subjects with OSA who will respond to CPAP?

    2. In Medicare aged subjects with clinically identified risk factors for OSA who have not undergone confirmatory testing with PSG or Types II, III & IV HST, does CPAP cause clinically meaningful harm?"

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POLICY HISTORY - THIS POLICY WAS APPROVED BY THE FEP® PHARMACY AND MEDICAL POLICY COMMITTEE ACCORDING TO THE HISTORY BELOW:

Date	Action	Description
September 2022	New policy	Policy created with literature review through April 16, 2022. Relevant information was moved from 2.01.18 (Diagnosis and Medical Management of Obstructive Sleep Apnea Syndrome); references added. Policy statements unchanged.
September 2023	Replace policy	Policy updated with literature review through May 9, 2023; references added. Policy statements unchanged.