



BlueCross BlueShield of Vermont

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Oral Appliances for Obstructive Sleep Apnea Corporate Medical Policy

File name: Oral Appliances for Obstructive Sleep Apnea

File Code: UM.OSA.02

Origination: 8/2011

Last Review: 11/2017

Next Review: 11/2018

Effective Date: 08/01/2018

Description/Summary

Oral Appliances, sometimes called dental appliances, are intended to treat Obstructive Sleep Apnea (OSA) and Upper Airway Resistance Syndrome by keeping the airway open in one of three ways; by pushing the lower jaw forward with a mandibular advancement device (MAD), by preventing the tongue from falling back over the airway with a tongue-retaining device (TRD), or, by combining both mechanisms. Oral appliances are typically more effective for people with mild OSA and for non-obese people but can, for some, be effective for moderate and severe OSA.

The most common type of oral appliance, a MAD, is often adjustable so that the dentist can move the jaw further or reduce the advancement as necessary. The goal is to find the most comfortable and effective position for the patient. Some examples of these appliances are Tongue Retaining Devices, Non-Adjustable Mandibular Repositioning Devices, Adjustable Mandibular Repositioning Appliances, Combined Mandibular Repositioners and CPAP Attachment.

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

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, Snore Remedy, Snore-no-More, Napa, Snoar™ Open

Airway Appliance, and The Equalizer Airway Device. FDA product code: LQZ.

Palatal implants are intended to stiffen and change the airflow characteristics of the soft palate tissue. The change is intended to reduce the severity of snoring and the incidence of airway obstructions for individuals with mild to moderate obstructive sleep apnea (OSA). The devices are cylindrical shaped segments of braided polyester filaments. A delivery tool comprised of a handle and needle assembly allows for positioning and placement of three implants submucosally in the soft palate. The procedure is performed under local anesthetic in an outpatient setting.

Palate and mandibular expansion devices: The Daytime Nighttime Appliance (DNA Appliance, Biomodeling Solutions) and the mandibular Repositioning Nighttime Appliance (mRNA Appliance, Biomodeling Solutions) are customized palate and mandible expanding devices. In addition to the upper-jaw device that is common to both the DNA Appliance and the mRNA Appliance (worn both during the day and night), the mRNA Appliance moves the mandible forward and is worn during sleep. The DNA Appliance and mRNA Appliance systems use 3- dimensional axial springs which are proposed to expand the upper and lower jaw and airway gradually to treat and eliminate mild-to-moderate OSA eventually.

Policy

Coding Information

Click the links below for attachments, coding tables & instructions.

[Attachment I](#)

When a service may be considered medically necessary

Intraoral appliances (tongue-retaining devices or mandibular advancing/positioning devices) may be considered **medically necessary** in adult patients with clinically significant OSA when **ALL** of the following conditions have been met:

- OSA, defined by an AHI of at least 15 per hour or an AHI of at least 5 events per hour in a patient with excessive daytime sleepiness or unexplained hypertension, 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

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

- Two different oral appliances may be needed, and each considered **medically**

necessary for the treatment of co-occurring TMJ and OSA. *For oral appliance to treat temporomandibular joint (TMJ) disorders refer to the separate BCBSVT medical policy, **Temporomandibular Joint Disease**.

- Concurrent coverage of an oral appliance and a CPAP or BIPAP to treat OSA may be considered **medically necessary** for those with a diagnosis of severe OSA.
- Replacement appliances to treat OSA are covered at three-year intervals and repairs are considered **medically necessary** according to the "Medical Equipment and Supplies" policy, which states the following:

When a service is considered not medically necessary

An oral appliance to treat OSA is considered **not medically necessary** when the above criteria are not met.

- For an AHI less than 5
- For an AHI between 5 and 15 without documented excessive daytime sleepiness or unexplained hypertension.
- When there is no history of failure of a CPAP trial or contraindication to a CPAP.

When a service is considered investigational

The following oral devices are considered investigational

- Nasal expiratory positive airway pressure and oral pressure therapy devices
- Palatal implants for the treatment of obstructive sleep apnea or snoring
- Palate and mandible expansion devices (DNA Appliance or mRNA Appliance by Biomodeling Solutions)
- Oral pressure therapy

When a service is considered a benefit exclusion and therefore not covered.

Oral appliances considered a **benefit exclusion and therefore non-covered** for obstructive sleep apnea (OSA):

- Oral appliances that are available over the counter.
- Oral appliances that are prefabricated.
- Oral appliances used as a treatment for snoring without a diagnosis of OSA.
- Oral appliances used to treat dental conditions such as bruxism.
- Concurrent coverage of an oral appliance and a CPAP or BIPAP to treat OSA as duplicate therapies when intended only for personal comfort or convenience.

Replacement of lost, stolen or destroyed Durable Medical Equipment

We will replace one lost, stolen or destroyed Durable Medical Equipment, prosthetic or orthotic per Plan Year if not covered by an alternative entity (including but not limited to homeowners insurance and automobile insurance) if:

- the Durable Medical Equipment, prosthetic or orthotic's absence would put the member at risk of death, disability or significant negative health consequences such as a hospital admission;
- the Durable Medical Equipment is still under warranty.

Note: In order to replace a stolen item we require you to submit documentation, such as a police report, with the request.

Exclusions

We do not cover the replacement of a lost, stolen or destroyed Durable Medical Equipment, prosthetic or orthotic:

- if the criteria above have not been met; and
- for more than one lost, stolen or destroyed Durable Medical Equipment, prosthetic or orthotic per Plan Year.

Policy Guidelines

Payment for a custom fabricated device includes all time, labor, materials, professional services, and radiology and lab costs necessary to provide and fit the device. Oral appliance therapy is a process that involves gradual mandibular advancement typically over a number of months. All fitting, adjustments, modifications, professional services required during the first 90 days after provision of the oral appliance are also considered to be included in the payment for device.

After the initial 90-day period, adjustments, modifications and follow-up visits are not eligible for coverage under the DME benefit. Repairs are covered for items that meet the coverage criteria. To repair means to fix or mend and to put the item back in good condition after damage or wear. Repairs are covered when necessary to make the item serviceable. If the expense for repairs exceeds the estimated expense of purchasing another item, no payment can be made for the excess.

Evaluation, measurement and impressions for, and instruction on the use of these devices may be performed by a qualified dentist or physician. Evaluation, measurement and impressions, instruction on use, and post fabrication adjustments are considered part of the global fee for the appliance and are not reimbursed as separate services.

Dental rehabilitation services (dentures, bridgework, dental implants, etc.) as treatment for (or part of treatment for) OSA are not available benefits under standard BCBSVT plans. Members should review their dental benefits plan, if any. (Please refer to BCBSVT medical policy on Dental Services)

Rationale/Scientific Background

Oral Appliance Therapy

A systematic review of the evidence on the treatment of OSA with oral appliance therapy was performed for a 2015 update of clinical practice guidelines by the American Academy of Sleep Medicine (AASM) and the American Academy of Dental Sleep Medicine.⁴⁰ Meta-analysis showed that oral appliances reduced AHI score, arousal index, and oxygen desaturation index, and increase oxygen saturation. However, oral appliances had no significant effect on sleep architecture and sleep efficiency. Meta-analysis found CPAP to

be more effective than oral appliances in reducing the AHI score, arousal index, and oxygen desaturation index, and improving oxygen desaturation, supporting the use of CPAP as a first-line therapy for treating OSA. One of the studies included in the systematic review was a 2013 randomized crossover trial by Phillips et al, who found similar health outcomes after 1 month of CPAP or oral appliance therapy (OAT) in 126 patients (82% with moderate to severe OSA, AHI ≥ 15).⁴¹ CPAP was more effective than mandibular advancement therapy in reducing AHI (CPAP AHI=4.5, OAT AHI=11.1), but patient-reported compliance was higher with OAT (6.5 vs 5.2 hours/night). Neither treatment improved the primary outcome of 24-hour ambulatory blood pressure, except in a subgroup of patients who were initially hypertensive. The 2 treatments resulted in similar improvements in sleepiness (improvement, 1.6-1.9), FOSQ (improvement, 1.0), some measures on driving simulator performance, and disease-specific quality of life. OAT was superior to CPAP in 4 domains on the SF-36.

Palate and Mandibular Expansion Devices

The Daytime Nighttime Appliance (DNA Appliance, Biomodeling Solutions) and the mandibular Repositioning Nighttime Appliance (mRNA Appliance, Biomodeling Solutions) are customized palate and mandible expanding devices. In addition to the upper-jaw device that is common to both the DNA Appliance and the mRNA Appliance (worn both during the day and night), the mRNA Appliance moves the mandible forward and is worn during sleep. The DNA Appliance and mRNA Appliance systems use 3-dimensional axial springs which are proposed to expand the upper and lower jaw and airway gradually to treat and eliminate mild-to-moderate OSA eventually.

Nasal EPAP

One randomized controlled trial and several prospective case series have been published with the PROVENT device. In 2011, Berry et al reported an industry-sponsored multicenter double-blind randomized sham-controlled trial of nasal EPAP. Two hundred fifty patients with OSA and an AHI of 10 or more per hour were randomized to nasal EPAP (n=127) or a sham device (n=123) for 3 months. PSG was performed on 2 nights (device-on, device off, in a random order) at week 1 (92% follow-up) and after 3 months of treatment (78% follow-up). EPAP reduced the AHI from a median of 13.8 to 5.0 (-52.7%) at week 1 and from 14.4 to 5.6 (-42.7%) at 3 months. This was a significantly greater reduction in AHI than the sham group (-7.3% at week 1, -10.1% at 3 months). Over 3 months, the decrease in ESS was statistically greater in the EPAP group (from 9.9 to 7.2) than in the sham group (from 9.6 to 8.3), although the clinical significance of a 1 point difference in the ESS is unclear. Treatment success and oxygenation data were presented only for the 58% of per-protocol patients who had an AHI of 5 or more per hour on the device off PSG night. The oxygenation results (oxygenation desaturation index and percent of total sleep time with SpO₂ <90%) showed small but statistically significant decreases at 1 week and 3 months. Treatment success, defined as a 50% or greater reduction in the AHI or an AHI reduced to less than 10 (if device-off AHI was ≥ 10), was greater in the EPAP group at 1 week (62% vs 27.2%) and 3 months (50.7% vs 22.4%). Device-related adverse events were reported by 45% of patients in the EPAP group and 34% of patients in the sham group, with 7% of patients in the EPAP group discontinuing the study due to adverse events. Overall, the validity of these results is limited by the high dropout rate, and the clinical significance of the results

is uncertain. An open-label extension of the 2011 randomized study by Berry et al evaluated 12-month safety and durability of the treatment response in patients who had an initial favorable response to EPAP.⁴³ Included were 41 patients (32% of 127) in the EPAP arm of the study who used the device for an average of at least 4 hours per night on at least 5 nights per week during months 1 and 2 and had at least a 50% reduction in AHI, or reduction to less than 10 events per hour, compared to the device-off PSG. Of the 51 patients (40% of 127) eligible, 41 enrolled in the extension study, and 34 (27% of 127) were still using the EPAP device at the end of 12 months. Median AHI was reduced from 15.7 to 4.7 events per hour; the percentage of patients who met criteria for success was not reported. The arousal index was modestly decreased (from 23.9 to 19.0). Over 12 months of treatment, the ESS decreased from 11.1 to 6.0. The median percentage of reported nights used (entire night) was 89.3%. Device-related adverse events were reported by 42% of patients, and the most frequently reported adverse events were difficulty exhaling, nasal discomfort, dry mouth, headache, and insomnia. This open-label extension study is limited by the inclusion of responders only and by the potential for a placebo effect on the ESS. However, the data suggest that some patients may respond to this device, and the patient compliance data might indicate a positive effect on daytime sleepiness that leads to continued use of the device in about 1 in 4 patients. Additional controlled studies are needed to distinguish between these alternatives.

Kureshi et al reported a small (N=14) double-blind, pilot, crossover RCT on EPAP in children to evaluate efficacy and compliance with this new treatment. PSG with EPAP or a placebo device showed a significant mean improvement in Obstructive Apnea Index with EPAP (index of 0.6 vs 4.2, $p=0.01$), but responses were variable (3 did not improve, 2 worsened). No other measures were statistically significant in this small study. For the responders who used the devices at home for 30 days, adherence was 83% of nights. ESS scores improved from 11 to 7 ($p=0.031$) and Obstructive Sleep Apnea-18 questionnaire scores improved from 50 to 39 ($p=0.028$). Other outcome measures did not improve significantly.

Oral Pressure Therapy

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

Summary of Evidence

The evidence for the novel OSA treatments (including expiratory positive airway pressure [EPAP] and oral therapy) in patients who have OSA includes 1 RCT, 1 nonrandomized controlled study, and case series. Relevant outcomes are symptoms, morbid events, functional outcomes, and quality of life. CPAP is the primary treatment for OSA. The evidence on EPAP devices in patients with OSA has been reported in several prospective case series and 1 industry-sponsored RCT. The main finding of the RCT was a decrease in Apnea/Hypopnea Index score with minor impact on oxygenation and Epworth Sleepiness Scale score. One comparative trial with historical controls was identified on use of a PAP-NAP study for patients with complex insomnia who are resistant to CPAP titration or use. Additional study is needed to evaluate the efficacy of this intervention with greater certainty. No evidence was identified on the oral therapy device. The evidence is insufficient to determine the effects of the technology on health outcomes.

Reference Resources

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Related Policies

Sleep Disorders Diagnosis and Treatment
Medical Equipment and Supplies
Dental Services
Temporomandibular Joint Disorder (TMJ)

Document Precedence

Blue Cross and Blue Shield of Vermont (BCBSVT) Medical Policies are developed to provide clinical guidance and are based on research of current medical literature and review of common medical practices in the treatment and diagnosis of disease. The applicable group/individual contract and member certificate language, or employer's benefit plan if an ASO group, determines benefits that are in effect at the time of service. Since medical practices and knowledge are constantly evolving, BCBSVT reserves the right to review and revise its medical policies periodically. To the extent that there may be any conflict between medical policy and contract/employer benefit plan language, the member's contract/employer benefit plan language takes precedence.

Audit Information

BCBSVT reserves the right to conduct audits on any provider and/or facility to ensure compliance with the guidelines stated in the medical policy. If an audit identifies instances of non-compliance with this medical policy, BCBSVT reserves the right to recoup all non-compliant payments.

Administrative and Contractual Guidance

Benefit Determination Guidance

Prior approval is required and benefits are subject to all terms, limitations and conditions of the subscriber contract.

Incomplete authorization requests may result in a delay of decision pending submission of missing information. To be considered complete, see policy guidelines above.

An approved referral authorization for members of the New England Health Plan (NEHP) is required. A prior approval for Access Blue New England (ABNE) members is required. NEHP/ABNE members may have different benefits for services listed in this policy. To confirm benefits, please contact the customer service department at the member's health plan.

Federal Employee Program (FEP): Members may have different benefits that apply. For further information please contact FEP customer service or refer to the FEP Service Benefit Plan Brochure. It is important to verify the member's benefits prior to providing the service to determine if benefits are available or if there is a specific exclusion in the member's benefit.

Coverage varies according to the member's group or individual contract. Not all groups are required to follow the Vermont legislative mandates. Member Contract language takes precedence over medical policy when there is a conflict.

If the member receives benefits through an Administrative Services Only (ASO) group, benefits may vary or not apply. To verify benefit information, please refer to the

member’s employer benefit plan documents or contact the customer service department. Language in the employer benefit plan documents takes precedence over medical policy when there is a conflict.

Policy Implementation/Update information

10/2016	Input received from external providers, updated criteria per providers and BCBSA – removed exclusion criteria of TMJ and AHI>41, added language related to inclusive billing and replacement of the device
11/2017	<p>General Summary: Removed old coding table and replaced with new coding table. Added D7881 for adjustments, Deleted 21076, moved E0485 from requiring PA to BE this is for a prefabricated appliance. D9940 from not medically necessary to contract exclusion. Added language for lost/stolen equipment.</p> <p>Changed benefit statement from not medically necessary to align with certificate language for the following: Oral appliances considered a benefit exclusion and therefore non-covered for obstructive sleep apnea (OSA):</p> <ul style="list-style-type: none"> • Oral appliances that are available over the counter. • Oral appliances that are prefabricated. • Oral appliances used as a treatment for snoring without a diagnosis of OSA. • Oral appliances used to treat dental conditions such as bruxism.

Eligible Providers

Qualified healthcare professionals practicing within the scope of their license(s).

Medical Doctor (MD) Doctor
of Osteopathy (DO)
Dentist or Oral Surgeon (DDS or DMD)

Approved by BCBSVT Medical Directors Date Approved

Gabrielle Bercy-Roberson, MD, MPH, MBA
Senior Medical Director
Chair, Health Policy Committee

Joshua Plavin, MD, MPH, MBA
Chief Medical Officer

Attachment I

Code Type	Number	Description	Policy Instructions
The following codes will be considered as medically necessary when applicable criteria have been met.			
HCPCS	E0486	Oral device/appliance used to reduce upper airway collapsibility, adjustable or nonadjustable, custom fabricated, includes fitting and adjustment	Requires PA
CDT®	D7881	Occlusal orthotic device adjustment	Refer to TMJ policy
The following codes will be denied as Not Medically Necessary, Non-Covered, Contract Exclusions or Investigational			
CDT®	D9940	Occlusal guard, by report; Removable dental appliances, which are designed to minimize the effects of bruxism (grinding) and other occlusal factors.	Deny Benefit Exclusion/ Non-Covered
HCPCS	E0485	Oral device/appliance used to reduce upper airway collapsibility, adjustable or nonadjustable, prefabricated, includes fitting and adjustment	Deny Benefit Exclusion/ Non-Covered
The following codes are not covered, and will default to provider liability, if billed in conjunction with HCPCS E0486 as they are considered be inclusive of HCPCS E0486			
CPT®	70350	Cephalogram, orthodontic	Inclusive to E0486
CPT®	70355	Orthopantomogram (eg, panoramic x-ray)	Inclusive to E0486