Oral Appliances for Obstructive Sleep Apnea
Corporate Medical Policy

File Name: Oral Appliances for Obstructive Sleep Apnea
File Code: UM.OSA.02
Origination: 08/2011
Last Review: 11/2018
Next Review: 11/2019
Effective Date: 04/01/2019

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 Respositioners and CPAP /APAP/BIPAP 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) though 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 rRNA 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 - Coding & Policy Instructions**

When a service may be considered medically necessary

For adult patients with clinically significant mild to moderate OSA defined as:
- An AHI, RDI, or REI≥15 but REI <30, OR
- AHI or RDI greater than or equal to 5 events and less than or equal to 14 events per hour
  **AND**
- documented symptoms of one of the following symptoms:
  - excessive daytime sleepiness
  - impaired cognition
  - mood disorders or insomnia
  - documented hypertension
  - ischemic heart disease,
  - history of stroke

Intraoral appliances (tongue-retaining devices or mandibular advancing/positioning devices) may be considered **medically necessary** in adult patients with clinically significant mild to moderate OSA when **ALL** of the following conditions have been met:
- Mild to moderate OSA, as defined above, **AND**
- A clinical trial of CPAP/APAP has failed or is contraindicated, **AND**
- The device is prescribed by a treating qualified healthcare professional, **AND**
The device is custom-fitted by qualified dental personnel

For adult patients with clinically severe OSA (REI>30), severe oxyhemoglobin desaturation (large magnitude or prolonged), Temporomandibular joint disease, periodontal disease, insufficient dentition to support appliance retention in the mouth, inadequate range of motion of the jaw, or limited capacity for mandibular protrusion (<6mm) should be treated with CPAP/APAP/BIPAP as first line therapy. An intraoral appliance may be considered medically necessary in adult patients with clinically significant severe OSA when ALL of the following conditions have been met:

- A trial with CPAP/APAP/BIPAP has failed, or is contraindicated, AND
- The device is prescribed by a treating qualified healthcare professional, AND
- The device is custom-fitted by qualified dental personnel
- Concurrent coverage of an oral appliance and a CPAP/APAP 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:

An oral appliance to treat OSA is considered not medically necessary:

- 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/APAP/BIPAP trial or contraindication to a CPAP/APAP/BIPAP.

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 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/APAP 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

A systematic review of the evidence on the treatment of OSA with oral appliance therapy was performed by Ramar et al. (2015), as part of an update of practice guidelines by American Academy of Sleep Medicine and the American Academy of Dental Sleep Medicine. Meta-analysis showed that oral appliances reduced the AHI, arousal index, and Oxygen Desaturation Index, and increase oxygen saturation. However, oral appliances had no significant effect on sleep architecture or sleep efficiency. The meta-analysis found CPAP to be more effective than oral appliances in reducing the AHI, arousal index, and Oxygen Desaturation Index, and in improving oxygen desaturation, supporting the use of CPAP as a first-line therapy for treating OSA.

In the AHRQ report (2011) on the diagnosis and treatment of OSA in adults, the strength of the evidence that mandibular advancement devices improve sleep apnea signs and symptoms was rated moderate.

Oral Appliances Custom oral appliances, which may include mandibular repositioning or tongue-retaining devices, are an accepted therapy for mild-to-moderate OSA. A 2015 meta-analysis found efficacy of oral appliances for measures of OSA, but they were less effective than CPAP. The strength of evidence for mandibular repositioning devices was rated as moderate by AHRQ.

Novel OSA Treatments such as palate and mandible expansion, EPAP and PAP-NAP devices either do not have sufficient evidence available to evaluate them as treatments, or do not have sufficient evidence for clinical improvement to warrant efficacy of treatment based on scientific evidence.

Reference Resources

1. Blue Cross and Blue Shield Association Policy MPRM 2.01.18 Last Reviewed June 2018.
2. Highmark Medicare Services, LCD # S-129 Treatment of Obstructive Sleep Apnea, retired 10/14/02
3. Highmark Medicare Services, LCD Article # S-129B- Treatment of Obstructive Sleep Apnea, retired 10/1/05.
4. Regence Medical Policy # 08 Positive Airway Pressure Systems and Oral Appliances for Treatment of Sleep Disordered Breathing, effective 1/1/08.
7. Oral Appliance Practitioners: Ferguson, KA, Cartwright R., Rogers RR et al. Oral appliances for snoring and obstructive sleep apnea: a review. Sleep 2006;29,244-262[ISI][Medline]
Medical Page 24.


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 compete, see policy guidelines above.

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

<table>
<thead>
<tr>
<th>Date</th>
<th>Information</th>
</tr>
</thead>
<tbody>
<tr>
<td>10/2016</td>
<td>Input received from external providers, updated criteria per providers and BCBSA - removed exclusion criteria of TMJ and AHI&gt;41, added language related to inclusive billing and replacement of the device</td>
</tr>
<tr>
<td>11/2017</td>
<td>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. 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): - 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.</td>
</tr>
</tbody>
</table>
External provider input reviewed and language revision to oral appliance statements clarified. Policy reviewed and definitions of mild and severe sleep apnea clarified. Language revision with regard to oral appliances. Language aligned with BCBSA MPRM 2.01.18. Added APA to BiPAP and CPAP devices. Code D9940 deleted effective 01/01/2019 replaced with D9944, D9945 & D9946. Updated references.

### Eligible Providers

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

**Approved by BCBSVT Medical Directors**  
**Date Approved**

Joshua Plavin, MD, MPH, MBA  
Chief Medical Officer

Kate McIntosh, MD, FAAP  
Senior Medical Director

---

### Attachment I

#### Coding & Policy Instructions

<table>
<thead>
<tr>
<th>Code Type</th>
<th>Number</th>
<th>Description</th>
<th>Policy Instructions</th>
</tr>
</thead>
<tbody>
<tr>
<td>HCPCS</td>
<td>E0486</td>
<td>Oral device/appliance used to reduce upper airway collapsibility, adjustable or nonadjustable, custom fabricated, includes fitting and adjustment</td>
<td>Requires PA</td>
</tr>
<tr>
<td>CDT®</td>
<td>D7881</td>
<td>Occlusal orthotic device adjustment</td>
<td>Refer to TMJ policy</td>
</tr>
</tbody>
</table>

The following codes will be considered as medically necessary when applicable criteria have been met.

| CDT®      | D9944  | Occlusal guard- hard appliance, full arch; Removable dental appliance designed to minimize the effects of bruxism or other occlusal factors. Not to be reported for any type of sleep apnea, snoring or TMD appliances. | Deny Benefit Exclusion/Non-Covered |

The following codes will be denied as Not Medically Necessary, Non-Covered, Contract Exclusions or Investigational
<table>
<thead>
<tr>
<th>Code Type</th>
<th>Number</th>
<th>Description</th>
<th>Policy Instructions</th>
</tr>
</thead>
<tbody>
<tr>
<td>CDT®</td>
<td>D9945</td>
<td>Occlusal guard- soft appliance, full arch; Removable dental appliance designed to minimize the effects of bruxism or other occlusal factors. Not to be reported for any type of sleep apnea, snoring or TMD appliances.</td>
<td>Deny Benefit Exclusion/Non-Covered</td>
</tr>
<tr>
<td>CDT®</td>
<td>D9946</td>
<td>Occlusal guard- hard appliance, partial arch; Removable dental appliance designed to minimize the effects of bruxism or other occlusal factors. Not to be reported for any type of sleep apnea, snoring or TMD appliances.</td>
<td>Deny Benefit Exclusion/Non-Covered</td>
</tr>
<tr>
<td>HCPCS</td>
<td>E0485</td>
<td>Oral device/appliance used to reduce upper airway collapsibility, adjustable or nonadjustable, prefabricated, includes fitting and adjustment</td>
<td>Deny Benefit Exclusion/Non-Covered</td>
</tr>
</tbody>
</table>