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Oral Appliances for Obstructive Sleep Apnea
Corporate Medical Policy

File Name: Oral Appliances for Obstructive Sleep Apnea
File Code: 10.01.VT206
Origination: 08/2011
Last Review: 10/2020
Next Review: 10/2021
Effective Date: 10/01/2021 (Adaptive Maintenance Cycle)

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/BPAP 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 is considered medically necessary

For adult patients, clinically significant mild to moderate OSA is defined as:

- An AHI, RDI, or REI ≥ 15 but ≤ 30; **OR**
- An AHI or RDI ≥ 5 and ≤ 14; **AND**
  - Any of the following documented symptoms:
    - Excessive daytime sleepiness
    - Impaired cognition
    - Mood disorders
    - Insomnia
    - 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 trial of CPAP/APAP/BPAP has failed **or** an assessment has been performed by a board-certified sleep medicine specialist in an accredited sleep

center showing that the patient either has a contraindication to or is not anatomically appropriate for CPAP/APAP/BPAP; **AND**
- The device is prescribed by a treating qualified healthcare professional; **AND**
- The device is custom fitted by qualified dental personnel

Adult patients with clinically severe OSA (AHI/RDI/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/BPAP as first line therapy.

Intraoral appliances may be considered **medically necessary** in adult patients with clinically significant severe OSA when **ALL** of the following conditions have been met:
- A trial of CPAP/APAP/BPAP has failed **or** an assessment has been performed by a board-certified sleep medicine specialist in an accredited sleep center showing that the patient either has a contraindication to or is not anatomically appropriate for CPAP/APAP/BPAP; **AND**
- The device is prescribed by a treating qualified healthcare professional; **AND**
- The device is custom-fitted by qualified dental personnel

Note:
- Concurrent coverage of an oral appliance and CPAP, APAP or BPAP 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.

When a service is considered not medically necessary

- For an AHI < 5
- For an AHI or RDI ≥ 5 and ≤ 15 without a documented symptom as listed above
- When there is no documentation of failure of a CPAP/APAP/BPAP trial or documentation of contraindication to CPAP/APAP/BPAP.
- Oral appliances for obstructive sleep apnea, used to treat dental conditions such as bruxism.

When a service is 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 that are available over the counter.
- Oral appliances used as a treatment for snoring without a diagnosis of OSA.
- Concurrent coverage of an oral appliance and a CPAP/APAP or BPAP 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)

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 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

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	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.
11/2018	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 BPAP and CPAP devices. Code D9940 deleted effective 01/01/2019 replaced with D9944, D9945 & D9946. Updated references.

07/2019	External input received, language updated around clinical trials when CPAP/APAP/BPAP have failed or are contraindicated. Code D7881 is included in code E0486.
10/2020	Policy reviewed, changes to policy statement language, references updated. Treatment of dental conditions changed to not medically necessary.
10/2021	Adaptive Maintenance effective 10/01/2021 added code K1027 to coding table as requiring prior approval.

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, MBA, FAAP
Senior Medical Director

Attachment I
Coding & Policy Instructions

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
HCPCS	K1027	Oral device/appliance used to reduce upper airway collapsibility, without fixed mechanical hinge, custom fabricated, includes fitting and adjustment	Requires PA
The following codes will be denied as Not Medically Necessary, Non-Covered, Contract Exclusions or Investigational			
CDT®	D7881	Occlusal orthotic device adjustment	Included in E0486

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
CDT®	D9945	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.	Deny Benefit Exclusion/ Non-Covered
CDT®	D9946	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.	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