

## Oral Appliances for Obstructive Sleep Apnea

**Policy** REIMB-015

**Origination Date:** 11/20/2019

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**Current Effective Date:** 07/10/2023

### Disclaimer:

1. Policies are subject to change in accordance with State and Federal notice requirements.
2. Policies outline coverage determinations for U of U Health Plans Commercial and Healthy U (Medicaid) plans. Refer to the "Policy" section for more information.
3. Services requiring prior-authorization may not be covered, if prior-authorization is not obtained.
4. **This Medical Policy does not guarantee coverage or payment of the service. The service must be a benefit in the member's plan and the member must be eligible for coverage at the time of service. Additional payment guidelines may be applied that are not included in this policy.**

### Description:

Obstructive Sleep apnea (OSA) is a common disorder in which a patient will have one or more pauses in breathing or shallow breaths while they sleep due to collapse of upper airway tissues blocking the airway during sleep. Breathing pauses can last from a few seconds to minutes. They often occur 30 times or more an hour.

There are multiple invasive and noninvasive therapies which are used to treat this problem. The 'gold standard' therapy remains continuous positive airway pressure (CPAP) or bi-level positive airway pressure (BiPAP). Some patients do not optimally respond to this therapy, have disease mild enough that alternative therapies are considered reasonable, or do not tolerate noninvasive airway therapy. In those instances many other invasive and noninvasive therapy choices are considered depending on the patient's characteristics. One choice often selected for individuals with mild to moderate disease is mandibular advancement therapy using an oral appliance. This appliance advances the jaw and is intended to open the airway in treatment of the airway obstruction.

Oral appliances impact the airway by repositioning the mandible in a vertical (open) position and anterior position. The exact mechanism by which mandibular repositioning impacts the airway is not fully understood, but it is believed to affect the musculature of the tongue and muscles that support the upper airway. It has been demonstrated that the upper airway is narrower during sleep in patients with OSA compared with those without apnea and that improvements in the lateral aspect of the upper airway play an important role in the management of patients with OSA.

The net effect of an oral device on the upper airway is mediated by its impact on the musculature that involves the tongue and soft tissues of the airway. With mandibular repositioning, the airway and tongue are stabilized; this prevents collapse, narrowing, and obstruction of the upper airway that can be seen with OSA and snoring. Mandible repositioning also has a beneficial effect on the velopharyngeal area. This is most likely related to changes in the palatopharyngeus muscle, which enhances the ability of the patient to breathe nasally. In addition, with the mandible repositioned, there is increased tension on the soft palate, which, in turn, reduces its potential for collapse. Improvement in nasal breathing and diminished soft palatal collapse both increase the efficacy of oral devices in managing OSA.

There are 2 primary types of oral appliances, prefabricated and custom. A prefabricated oral appliance (E0485) is one, which is manufactured in quantity without a specific beneficiary in mind. A prefabricated oral appliance may be trimmed, bent, molded (with or without heat), or otherwise modified for use by a specific beneficiary (i.e., custom fitted). Any appliance that does not meet the definition of a custom fabricated oral appliance is considered prefabricated. E0485 is used for all prefabricated oral appliances used for the treatment of OSA including, but not limited to, mandibular advancement devices, tongue positioning appliances, etc.

The second type is a custom fabricated oral appliance (E0486) that is uniquely made for an individual beneficiary. It involves taking a full arch, negative impression of the beneficiary's teeth, either using appropriate materials or digital images, from which a positive model is created. Basic materials are then cut, bent, and molded using the positive model in order to construct the final oral appliance. A custom fabricated oral appliance may include a prefabricated component with modifications specific to the individual intended to use the device.

## **Policy Statement and Criteria**

### **1. Commercial Plans**

**U of U Health Plans covers custom fabricated oral appliances as monotherapy using HCPCS code E0486 for the treatment of obstructive sleep apnea when coverage criteria are met.**

**U of U Health Plans does not cover any oral appliances as they are a benefit exclusion and are therefore non-covered for obstructive sleep apnea (OSA) in the following circumstances:**

- 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.

**U of U Health Plans does not cover E0485, Oral device/appliance used to reduce upper airway collapsibility, adjustable or nonadjustable, prefabricated, includes fitting and adjustments.** These are considered a non-covered benefit as they are available over the counter without a prescription.

**Elements considered bundled into E0486 include all time, labor, materials, professional services, and radiology and lab costs necessary to provide and fit the device. 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 as these are considered dental related and thus excluded from coverage under the medical 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 sleep specialist.**

**Evaluation, measurement and impressions, instruction on use, and postfabrication adjustments are considered part of the global fee for the appliance and are not reimbursed as separate services.**

**CPT/HCPCS codes considered bundled into E0486 include the following:**

- **21085** - Impression and custom preparation; oral surgical splint
- **21089** - Unlisted maxillofacial prosthetic procedure
- **21110** - Application of interdental fixation device for conditions other than fracture or dislocation, includes removal
- **70350** - Cephalogram, orthodontic
- **70355** - Orthopantomogram (eg, panoramic x-ray)
- **70486** - Computed tomography, maxillofacial area; without contrast material
- **70487** - Computed tomography, maxillofacial area; with contrast material(s)

- **70488** - Computed tomography, maxillofacial area; without contrast material, followed by contrast material(s) and further section
- **76497** - Unlisted computed tomography procedure (eg, diagnostic, interventional) Code used for Cone Beam CT
- **99201-99205, 99211-99215** – Evaluation/Management codes

## 2. Medicaid Plans

Coverage is determined by the State of Utah Medicaid program; if Utah State Medicaid has no published coverage position and InterQual criteria are not available, the U of U Health Plans Commercial criteria will apply. For the most up-to-date Medicaid policies and coverage, please visit their website at: <https://medicaid.utah.gov/utah-medicaid-official-publications/> or the [Utah Medicaid code Look-Up tool](#)

CPT/HCPCS codes covered by Utah State Medicaid may still require further evaluation to determine medical necessity for coverage.

## Applicable Coding

### HCPCS Codes

**E0486** Oral device/appliance used to reduce upper airway collapsibility, adjustable or non-adjustable, custom fabricated, includes fitting and adjustment

### Non-covered codes

**E0485** Oral device/appliance used to reduce upper airway collapsibility, adjustable or non-adjustable, prefabricated, includes fitting and adjustment

### Bundled services, these services are not payed separately in addition to the appliance

**21085** Impression and custom preparation; oral surgical splint

**21089** Unlisted maxillofacial prosthetic procedure

**21110** Application of interdental fixation device for conditions other than fracture or dislocation, includes removal

**70350** Cephalogram, orthodontic

**70355** Orthopantomogram (eg, panoramic x-ray)

**70486** Computed tomography, maxillofacial area; without contrast material

**70487** Computed tomography, maxillofacial area; with contrast material(s)

**70488** Computed tomography, maxillofacial area; without contrast material, followed by contrast material(s) and further section

- 76497** Unlisted computed tomography procedure (eg, diagnostic, interventional) (*Used for Cone Beam CT*)
- 99202-99205** Office or other outpatient visit for the evaluation and management of a new patient,
- 99211-99215** Office or other outpatient visit for the evaluation and management of an established patient, that may not require the presence of a physician or other qualified health care professional

**References:**

1. <https://aasm.org/>
2. <https://www.cms.gov/medicare-coverage-database/details/article-details.aspx?articleId=52512&ver=22&LCDId=33611&DocID=L33611&bc=gAAAABABAAAA&>
3. <https://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?LCDId=33611&ver=14&DocID=L33611&bc=gAAAABABAAAA&>

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