

# Oral Appliances for Sleep Apnea

For any item to be covered by The Health Plan, it must:

1. Be eligible for a defined Medicare or The Health Plan benefit category
2. Be reasonable and necessary for the diagnosis or treatment of an illness or injury or to improve the functioning of a malformed body member
3. Meet all other applicable Medicare and/or The Health Plan statutory and regulatory requirements

For the items addressed in this medical policy, the criteria for "reasonable and necessary" are defined by the following indications and limitations of coverage and/or medical necessity. *Please refer to individual product lines certificates of coverage for possible exclusions of benefit.*

For an item to be covered by The Health Plan, the supplier must receive a written, signed, and dated order before a claim is submitted to The Health Plan. If the supplier bills for an item addressed in this policy without first receiving the completed order, the item will be denied as not reasonable and necessary.

Suppliers are to follow The Health Plan requirements for precertification as applicable.

Oral sleep appliances require precertification.

<b>National Coverage Determination Policy</b>	CMS Publication 100-3, Medicare National Coverage Determinations Manual, Chapter 1, Section 280.1
<b>Local Coverage Determination Policy</b>	J-B/C
<b>Effective Date</b>	For services performed on or after 07/01/12
<b>Revision/Review Date</b>	01/19, 10/30/18, 06/05/2018, 07/01/17, 06/01/16, 10/01/13
<b>The Health Plan</b>	The Health Plan will follow Oversight Region V Coverage Determination posted on the National Government Services website unless otherwise indicated in sections of this policy or contractual agreement

## DESCRIPTION

Oral appliances are small plastic devices that fit in the mouth during sleep, like a sports mouth guard or orthodontic retainer. They are used to reposition oral and pharyngeal tissues in an effort to create and maintain a member’s airway during sleep. Oral appliances help prevent the collapse of the tongue and soft tissues in the back of the throat, keeping the airway open during sleep and promoting adequate air intake. They may be used alone or in combination with other treatments for sleep-related breathing disorders, such as weight management, surgery, or CPAP.

## COVERAGE GUIDELINES

An oral appliance (E0486) is covered for treatment of obstructive sleep apnea (OSA) if criteria A - D are met:

- A. The member has a face-to-face clinical evaluation by the treating physician (MD, DO) prior to the sleep test to assess the member for obstructive sleep apnea testing.
- B. The member has a Medicare-covered sleep test that meets one of the following criteria (1 - 3):
  1. The apnea-hypopnea index (AHI) or respiratory disturbance index (RDI) is greater than or equal to 15 events per hour with a minimum of 30 events or,
  2. The AHI or RDI is greater than or equal to five and less than or equal to 14 events per hour with a minimum of 10 events and documentation of:
    - a. Excessive daytime sleepiness, impaired cognition, mood disorders, or insomnia or,
    - b. Hypertension, ischemic heart disease, or history of stroke or,
  3. If the AHI > 30 or the RDI > 30 and meets either of the following (a or b):
    - a. The member is not able to tolerate a positive airway pressure (PAP) device or
    - b. The treating physician (MD/DO) determines that the use of a PAP device is contraindicated. Must provide contraindication with precertification
- C. The device is ordered by the treating physician (MD/DO) following review of the report of the sleep test. The physician (MD/DO) who provides the order for the oral appliance could be different from the one who performed the clinical evaluation in criterion A. The referred to treating or ordering physician above does not include DDS/DMD.
- D. The device is provided and billed for by a licensed dentist (DDS or DMD).
- E. No aspect of the sleep test may be performed by the supplier of the device.
- F. For **commercial and self-funded** plans please indicate why the prefabricated device (E0485) would be contraindicated and ineffective.

If the above criteria is not met the custom fabricated oral appliance (E0486) will be denied as not reasonable and necessary.

Providers may refer to coverage policy on PAP devices for definitions for apnea, hypopnea, RDI and AHI, and appropriate guidelines for sleep testing. Epworth sleepiness scale is available online.

Repairs are covered if required to make the device serviceable. If the cost of the repair exceeds the cost of the device, no payment will be made for the excess.

## NONCOVERAGE STATEMENT

Oral Device/Appliances for sleep apnea (E0485, E0486) are not covered by West Virginia Medicaid per their Internet Manual, list of Non-Covered Codes.

Medicare does not cover the prefabricated oral appliance (E0485), as there is insufficient evidence to show that these items are effective therapy for OSA. The Health Plan is following this across all lines of business.

Custom fabricated mandibular advancement devices do not meet the requirements by the PDAC as shown below will be denied as not reasonable and necessary.

Most oral appliances are considered dental devices and not DME covered under a medical benefit.

The following items (not all-inclusive) are considered to be dental devices and will be denied as noncovered, not DME.

- Oral occlusal appliances used to treat temporomandibular joint (TMJ) disorders
- Tongue retaining devices used to treat OSA and/or snoring
- All oral appliances used only to treat snoring without a diagnosis of OSA
- Oral appliances used to treat other dental conditions
- Oral appliances that require repeated fitting and/or adjustments, beyond the first 90 days, in order to maintain fit and/or effectiveness.

Oral appliances used to treat snoring without a diagnosis of OSA established with a sleep test as described in the PAP policy are coded A9270.

Oral occlusal appliances used to treat temporomandibular joint (TMJ) disorders are coded D7880 - occlusal orthotic appliance. Check individual benefits for coverage.

Oral appliances and oral occlusal appliances are not covered for treatment of TMJ or other dental conditions, unless specifically indicated in the benefit document.

Oral appliance for the diagnosis of snoring alone is not covered. These devices should be coded A9270.

Custom fabricated tongue positioning appliances are coded A9270.

Device being provided does not meet PDAC guidelines.

Items that require repeated adjustments and modification beyond the initial 90-day fitting and adjustment period in order to maintain fit and/or effectiveness are not eligible for classification as DME. These items are considered as dental therapies, which are not eligible for reimbursement, by Medicare under the DME benefit. They must not be coded using E0486.

The only products, which may be billed using code E0486, are those for which a written Coding Verification Review has been made by the Pricing, Data Analysis and Coding (PDAC) Contractor and subsequently published on the appropriate Product Classification List.

All custom fabricated mandibular advancement devices that have not received a written PDAC Verification Review must use HCPCS code A9270 (NON-COVERED ITEM OR SERVICE).

#### **REPAIR, REPLACEMENT, AND REASONABLE USEFUL LIFETIME**

After the initial 90-day period, adjustments, modifications, and follow-up visits are not covered under the DME benefit and will be subject to specific contract and allowance guidelines.

Oral appliances are eligible for replacement at the end of their five year reasonable useful lifetime (RUL). These items may be replaced prior to the end of the five year RUL in cases of loss, theft, or irreparable damage. Irreparable damage refers to a specific accident or to a natural disaster (e.g., fire, flood). Replacement due to wear-and-tear as the result of everyday use will be denied as statutorily noncovered prior to the expiration of the five year RUL.

**CODING INFORMATION**

**CPT/HCPCS codes: The appearance of a code in this section does not necessarily indicate coverage.**

**HCPCS MODIFIERS**

<b>EY</b>	NO PHYSICIAN OR OTHER LICENSED HEALTH CARE PROVIDER ORDER FOR THIS ITEM OR SERVICE
<b>GA</b>	WAIVER OF LIABILITY ISSUED AS REQUIRED BY PAYER POLICY, IN INDIVIDUAL CASE
<b>GZ</b>	ITEM OR SERVICE EXPECTED TO BE DENIED AS NOT REASONABLE AND NECESSARY
<b>KX</b>	REQUIREMENTS SPECIFIED IN THE MEDICAL POLICY HAVE BEEN MET

**HCPCS CODES**

<b>CODE</b>	<b>DESCRIPTION</b>
<b>A9270</b>	NONCOVERED ITEM OR SERVICE
<b>E0485</b>	ORAL DEVICE/APPLIANCE USED TO REDUCE UPPER AIRWAY COLLAPSIBILITY, ADJUSTABLE OR NON-ADJUSTABLE, PREFABRICATED, INCLUDES FITTING AND ADJUSTMENT
<b>E0486</b>	ORAL DEVICE/APPLIANCE USED TO REDUCE UPPER AIRWAY COLLAPSIBILITY, ADJUSTABLE OR NON-ADJUSTABLE, CUSTOM FABRICATED, INCLUDES FITTING AND ADJUSTMENT
<b>E1399</b>	DURABLE MEDICAL EQUIPMENT, MISCELLANEOUS

**ICD-10 CODES THAT SUPPORT MEDICAL NECESSITY**

<b>G47.33</b>	OBSTRUCTIVE SLEEP APNEA (ADULT) (PEDIATRIC)
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**DOCUMENTATION REQUIREMENTS**

For the purposes of this policy, it is expected that the medical record will support the need for the care provided. It is generally understood that the medical record includes the physician's office records, hospital records, nursing home records, home health agency records, records from other healthcare professionals and test reports.

This documentation must be available with precertification.

Medicare has made changes to its requirements for dispensing orders, detailed written orders, and proof of delivery. The Health Plan will require the following:

1. Physician detailed written order. Order must include the following:

- a. Member's name
- b. Date
- c. Description of item. The medical record must contain the information that supports the request for each item, and must be submitted with the precertification if the item requires precertification, or with the claim, if no precertification was required
- d. Order must include diagnosis code
- e. Physician signature with date. Date stamps are not appropriate
- f. Quantity of items required and duration. A new order is required if there is an increase in the quantity of the supply and/or the type of supply used

The supplier is to contact The Health Plan in this instance to update referral

2. There must be documentation in the supplier's records to support the medical necessity of that item. This information must be available upon request usually with precertification per The Health Plan policy.
3. Physicians face-to-face. Documented as a detailed narrative note, that is part of the medical record present in the member's chart. It must include the following:
  - a. History of signs and symptoms of sleep disordered breathing including snoring, daytime sleepiness, observed apneas, choking or gasping during sleep, morning headaches, duration of symptoms, validated sleep hygiene, i.e., Epworth Sleepiness Scale
  - b. Physical exam, BMI, neck circumference, cardiopulmonary and upper airway system evaluation
  - c. Sleep study and PAP titration results
4. Proof of delivery to be kept on file by the provider of the item.

**Note:** If templates or forms are submitted, (i.e., a Medicare Certificate of Medical Necessity, and/or a provider created form), and all of the required information is not included, The Health Plan reserves the right to request the medical record, that may include, but not limited to, the physician office notes, hospital and nursing facility records, and home health records.

**Note:** Template provider forms, prescriptions, and attestation letters are not considered part of the medical record, even if signed by the ordering physician.

### ORAL SLEEP APPLIANCE PROVIDED WHILE MEMBER IN PART A FACILITY

Separate reimbursement for oral sleep appliance provided to a member while the member is covered in a Part A facility will be based on facility contract and intended use of device. A precertification will be required for review.

In order for it to be billed separately, it must meet the above guidelines and be medically necessary for home use.

### BILLING GUIDELINES

Billing for OAOSA item is all-inclusive, once the decision has been made to provide the device. Reimbursement for these items includes all time, labor, materials, professional services, radiology, and

lab costs necessary to provide and fit the device. It also includes all costs associated with follow-up, fitting, and any adjustments after the item are provided within the first 90 days. Claims for this service will be denied as not separately payable.

For OAOSA (E0486), the unit of service is for the entire, complete item. Some items have multiple components. Each component is not separately billable. For example, billing E0486 (two units) for a two-piece appliance, top and bottom and E0486 (one unit) for the piece that holds the tongue back, for three units of service is not correct. One unit of service should be billed for the entire device, inclusive of all components.

Providers are responsible to make sure the device provided meets the definition of oral appliance for sleep apnea per the PDAC contractor prior to submitting to The Health Plan for precertification. Only those manufacturers found on the PDAC website will be eligible for reimbursement.

**The Health Plan requires that in order for a provider to supply this service/appliance, they must be contracted with The Health Plan or one of The Health Plan networks, or can show that they are authorized as a Medicare DME supplier.** Information about enrolling as a DME supplier is available from the National Supplier Clearinghouse at, [palmettogba.com/nsc](http://palmettogba.com/nsc) or by calling, 1.866.238.9652.

### **KX, GA, and GZ MODIFIERS**

Suppliers may submit a claim with a KX modifier only if all the criteria for that item are met.

If coverage criteria are not met, the GA or GZ modifier must be used. When there is an expectation of a medical denial, suppliers must enter the GA modifier on the claim line if they have obtained a properly executed Advance beneficiary Notice (ABN) or the GZ modifier if they have not obtained a valid (ABN).

### **ADVANCED BENEFICIARY NOTICE**

The Health Plan expects providers to follow the Medicare policy on ABN across all Medicare, Medicaid, and Commercial plans.

**NOTE:** Providers may be held financially responsible if they furnish the above items without notifying the member, verbally and in writing, that the specific service being provided is not covered. This must be done prior to the dispensing of the device. The provider must submit the waiver or ABN to The Health Plan with the claim showing the member agreed to pay for the device. Generalized statements on waivers or ABN are not acceptable.

### **PRICING, DATA ANALYSIS, AND CODING (PDAC)**

The Health Plan has implemented use of Medicare's PDAC contractor for review of authorizations. Please refer to PDAC website for the appropriate product classification list. [dmepdac.com/](http://dmepdac.com/)

The PDAC DME and supplies coding verification application required for these products is located on the PDAC website at [dmepdac.com/review/apps\\_check.html](http://dmepdac.com/review/apps_check.html). Coding decisions are updated frequently. Suppliers should refer to the product classification list often to ensure that items billed have been coded by the PDAC. The product classification list in DMECS is located on the PDAC website at [dmepdac.com/](http://dmepdac.com/)

For questions about correct coding, contact the PDAC Contact Center at 1.877.735.1326 during the hours of 8:30 a.m. to 4:00 p.m. CT, Monday through Friday, or email the PDAC by completing the DME PDAC contact form located on the PDAC website at dmepdac.com.

## MEDICARE DEFINITIONS AND DESCRIPTION

**Mandibular advancement devices** reposition the mandible in a forward position.

**Tongue positioning devices** reposition the tongue through the use of a vacuum-bulb or other mechanism such as bars, prongs or extensions (not all inclusive) in a depressed and/or more anterior position.

A **prefabricated oral appliance (E0485)** is one, which is manufactured in quantity without a specific member in mind. A prefabricated oral appliance may be trimmed, bent, molded (with or without heat), or otherwise modified for use by a specific member (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.

A **custom fabricated oral appliance (E0486)** is one which is individually and uniquely made for an individual member. It involves taking an impression of the member's teeth and making a positive model of plaster or equivalent material. Basic materials are cut, bent, and molded over the positive model. It requires more than trimming, bending, or making other modifications to a substantially prefabricated item. A custom fabricated oral appliance may include a prefabricated component (e.g., the joint mechanism).

Code **E0486** may only be used for custom fabricated mandibular advancement devices. To be coded as E0486, custom fabricated mandibular advancement devices must:

1. Have a fixed mechanism that is hinged or jointed at the sides, front or palate
2. Have a mechanism that allows the mandible to be advanced at increments of one millimeter or less
3. Be able to protrude the mandible beyond the front teeth at maximum protrusion
4. Be adjustable by the beneficiary in increments of one millimeter or less
5. Retain their adjustment setting when removed
6. Maintain mouth position during sleep
7. Require no return dental visits beyond the initial 90-day fitting and adjustment period to perform ongoing modification and adjustments in order to maintain effectiveness

**Custom fabricated mandibular advancement devices that do not incorporate all of the criteria (1-7) above must not be coded as E0486 and must be coded as A9720.**

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#### INTERNET LINKS AND SOURCES

National Government Services website. [Oral Appliances - Response to Comments - November 2010](#). Last accessed 10/30/18. Retrieved from <http://ngsmedicare.com>

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