



## Oral Appliances for Obstructive Sleep Apnea Clinical Coverage Criteria

### Overview

Obstructive sleep apnea (OSA) is a common, widely under diagnosed condition that is associated with significant morbidity and mortality. Due to intermittent anatomical blockage of the upper airway, reduction or cessation of airflow occurs during sleep, resulting in recurrent oxygen desaturation and sympathetic neural activation, with resultant nighttime hypertension and cortical arousal. This cycle results in sleep fragmentation and limits the amount of time spent in deeper sleep stages. Common symptoms include snoring, restless sleep, daytime fatigue, and morning headaches. If not treated, OSA is associated with an increased risk of cardiac, respiratory, and metabolic conditions, including hypertension, stroke, congestive heart failure, and sudden death.

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 most likely causes 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.

### Definitions

**Apnea:** The cessation of airflow for at least 10 seconds.

**Continuous Positive Airway Pressure (CPAP):** A device consisting of a mask which is placed over the mouth and nose. Pressure delivers air to keep the airway open during sleep.

**Hypopnea:** An abnormal respiratory event lasting at least 10 seconds associated with at least a 30% reduction in thoracoabdominal movement or airflow as compared to baseline, and with at least a 4% decrease in oxygen saturation.

**Polysomnography and sleep studies:** The continuous and simultaneous monitoring and recording of various physiological and pathophysiological parameters of sleep for 6 or more hours with physician review, interpretation and report. The studies are performed to diagnose a variety of sleep disorders and to evaluate a plan member's response to therapies such as continuous positive airway pressure (CPAP).

**The apnea-hypopnea index (AHI):** The average number of episodes of apnea and hypopnea per hour of sleep without the use of a positive airway pressure device.

**The respiratory disturbance index (RDI):** The average number of apneas plus hypopneas per hour of recording without the use of a positive airway pressure device.

## Policy

This Policy applies to the following Fallon Health products:

- Fallon Medicare Plus, Fallon Medicare Plus Central (Medicare Advantage)
- MassHealth ACO
- NaviCare HMO SNP (Dual Eligible Medicare Advantage and MassHealth)
- NaviCare SCO (MassHealth-only)
- PACE (Summit Eldercare PACE, Fallon Health Weinberg PACE)
- Community Care (Commercial/Exchange)

Prior authorization is required for oral appliances for obstructive sleep apnea.

### Medicare Advantage

Fallon Health complies with CMS's national coverage determinations (NCDs), local coverage determinations (LCDs) of Medicare Contractors with jurisdiction for claims in the Plan's service area, and applicable Medicare statutes and regulations when making medical necessity determinations for Medicare Advantage members. When coverage criteria are not fully established in applicable Medicare statutes, regulations, NCDs or LCDs, Fallon Health may create internal coverage criteria under specific circumstances described at § 422.101(b)(6)(i) and (ii).

Medicare statutes and regulations do not have coverage criteria for oral appliances for obstructive sleep apnea. Medicare does not have an NCD Oral Appliances for Obstructive Sleep Apnea. Noridian Healthcare Solutions, LLC has an LCD for Oral Appliances for Obstructive Sleep Apnea (L33611), Revision Effective Date: For services performed on or after 08/08/2021 (Medicare Coverage Database search 07/22/2024).

Coverage criteria for oral appliances for obstructive sleep apnea are fully established by Medicare.

Link: Noridian Healthcare Solutions, LLC has an [LCD Oral Appliances for Obstructive Sleep Apnea \(L33611\)](#), Revision Effective Date: For services performed on or after 08/08/2021

### MassHealth ACO

Fallon Health follows Medical Necessity Guidelines published by MassHealth when making medical necessity determinations for MassHealth members. In the absence of Medical Necessity Guidelines published by MassHealth, Fallon Health may create clinical coverage criteria in accordance with the definition of Medical Necessity in 130 CMR 450.204.

MassHealth does not have Guidelines for Medical Necessity Determination for oral appliances for obstructive sleep apnea (MassHealth website search 07/22/2024), therefore, the Plan's coverage criteria are applicable.

### NaviCare HMO SNP, NaviCare SCO

For plan members enrolled in NaviCare, Fallon Health first follow's CMS's national coverage determinations (NCDs), local coverage determinations (LCDs) of Medicare Contractors with jurisdiction for claims in the Plan's service area, and applicable Medicare statutes and regulations when making medical necessity determinations.

When coverage criteria are not fully established in applicable Medicare statutes, regulations, NCDs or LCDs, or if the NaviCare member does not meet coverage criteria in applicable Medicare statutes, regulations, NCDs or LCDs, Fallon Health then follows Medical Necessity Guidelines published by MassHealth when making necessity determinations for NaviCare members.

## **PACE (Summit Eldercare PACE, Fallon Health Weinberg PACE)**

Each PACE plan member is assigned to an Interdisciplinary Team. PACE provides participants with all the care and services covered by Medicare and Medicaid, as authorized by the interdisciplinary team, as well as additional medically necessary care and services not covered by Medicare and Medicaid. With the exception of emergency care and out-of-area urgently needed care, all care and services provided to PACE plan members must be authorized by the interdisciplinary team.

## **Fallon Health Clinical Coverage Criteria**

Fallon Health Clinical Coverage Criteria apply to Community Care and MassHealth ACO members. For Medicare Advantage, NaviCare and PACE members refer to criteria in Policy section above.

Fallon Health covers a custom fabricated mandibular advancement oral appliance (HCPCS code E0486) when all of the following medical necessity criteria are met:

1. The plan member is 18 years of age or older.
2. The plan member has had a face-to-face clinical evaluation by the treating physician prior to the sleep study. The treating physician shall document the face-to-face clinical evaluation in a detailed narrative note in the medical record. The evaluation should include information about the following elements but may include other details.

### History

- 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 inventory such as the Epworth Sleepiness Scale
  - (see Appendices)
  - Physical Exam
  - Focused cardiopulmonary and upper airway system evaluation
  - Neck circumference
  - Body mass index (BMI)
3. The plan member has had a covered sleep study and meets one of the following criteria (Mild, Moderate, Severe):

Mild sleep apnea: the apnea-hypopnea index (AHI) or Respiratory Disturbance Index (RDI) is greater than or equal to 5 and less than or equal to 14 events per hour with a minimum of 10 events and documentation of:

- Excessive daytime sleepiness, impaired cognition, mood disorders, or insomnia, or
- Hypertension, ischemic heart disease, or history of stroke.
- The patient is not able to tolerate a positive airway pressure (PAP) device as demonstrated in a trial/failure PAP treatment or the treating physician determines that the use of a PAP device is contraindicated.

Moderate sleep apnea: the AHI or RDI is greater than or equal to 15 events per hour with a minimum of 30 events

- If the AHI or RDI is calculated based on less than 2 hours of sleep or recording time, the total number of recorded events used to calculate the AHI or RDI (respectively) must be at least the number of events that would have been required in a 2 hour period (i.e., must reach  $\geq 30$  events without symptoms or  $\geq 10$  events with symptoms).
- The patient is not able to tolerate a positive airway pressure (PAP) device as demonstrated in a trial/failure PAP treatment or the treating physician determines that the use of a PAP device is contraindicated.

Severe sleep apnea: the AHI  $> 30$  or the RDI  $> 30$  and either one of the following:

- The patient is not able to tolerate a positive airway pressure (PAP) device as demonstrated in a trial/failure PAP treatment or the treating physician determines that the use of a PAP device is contraindicated.
4. The oral appliance is ordered by the treating physician following review of the report from the covered sleep study. A written order (signed and dated) must be sent to the supplier and available to Fallon Health upon request.

Oral Appliances for the treatment of severe sleep apnea additionally require a trial and failure of CPAP treatment in order to be covered.

Oral appliances are eligible for replacement at the end of their 5-year reasonable useful lifetime. These items may be replaced prior to the end of the 5-year reasonable useful lifetime in cases of loss, theft, or irreparable damage. Irreparable damage refers to a specific accident or to a natural disaster (e.g., fire, flood). An ordering physician must submit documentation supporting irreparable damages. Replacement due to wear-and-tear as the result of everyday use will be denied as not covered prior to the expiration of the 5-year reasonable useful lifetime.

## Exclusions

- Prefabricated oral appliances (E0485) are considered experimental and investigational for the treatment of OSA.
- Palatal implants (HCPCS code C9727) are considered experimental/investigational for the treatment of OSA and all other indications because its effectiveness for this and other indications has not been established.
- The AIRvance System (formerly The Repose™ System) a tongue base suspension.
- Adjunctive dental care is that dental care which is medically necessary in the treatment of an otherwise covered medical (not dental) condition; is an integral part of the treatment of such medical condition; or is required in preparation for, or as the result of treatment for a medical condition. Fallon Health does not cover adjunctive dental care.
- Oral appliances 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 under the DME benefit. They must not be coded using E0486.

## Coding

The following codes are included below for informational purposes only; inclusion of a code does not constitute or imply coverage or reimbursement.

The ICD-10 diagnosis code for oral appliances for obstructive sleep apnea is G47.33. A diagnosis of obstructive sleep apnea is not sufficient to qualify for coverage for oral appliances. Oral appliances for obstructive sleep apnea require prior authorization and the coverage criteria listed above must be met.

Code	Description
E0485	Oral device/appliance used to reduce upper airway collapsibility, adjustable or non-adjustable, prefabricated, includes fitting and adjustment
E0486	Oral device/appliance used to reduce upper airway collapsibility, adjustable or non-adjustable, custom fabricated, includes fitting and adjustment

A prefabricated oral appliance (E0485) is one, which is manufactured in quantity without a specific patient in mind. A prefabricated oral appliance may be trimmed, bent, molded (with or without heat), or otherwise modified for use by a specific patient (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. This is not covered as there is limited evidence of its clinical effectiveness.

A custom fabricated oral appliance (E0486) is one which is individually and uniquely made for an individual patient. It involves taking an impression of the patient'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.

A custom fabricated mandibular advancement devices must:

- Have a mechanism that is hinged or jointed at the sides, front or palate, and
- Have a mechanism that allows the mandible to be advanced, and
- Be able to protrude the mandible beyond the front teeth at maximum protrusion, and
- Be adjustable by the beneficiary in increments of one millimeter or less, and
- Retain their adjustment setting when removed.

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.

## References

1. Noridian Healthcare Solutions, LLC Local Coverage Determination (LCD) L33611 for Oral Appliances for Obstructive Sleep Apnea. Original Effective Date: For services performed on or after 08/08/2021. Revision Effective Date: For services performed on or after 08/08/2021.
2. Noridian Healthcare Solutions, LLC Local Coverage Article (LCA) for Oral Appliances for Obstructive Sleep Apnea (A52512). Original Effective Date: 10/1/2015. Revision Effective Date: 08/08/2021.
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7. Lam B, Sam K, Mok WY, et al. Randomised study of three non-surgical treatments in mild to moderate obstructive sleep apnoea. *Thorax.* 2007;62(4):354-359.

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14. Haviv Y, Kamer L, Sheinfeld R, Almozino G, Bachar G. Successful Treatment of Extremely Severe Obstructive Sleep Apnea with a Dental Appliance. *Isr Med Assoc J*. 2018 Jul;20(7):429-432.
15. Sutherland K, Cistulli PA. Oral Appliance Therapy for Obstructive Sleep Apnoea: State of the Art. *J Clin Med*. 2019 Dec 2;8(12).
16. Dieltjens M, Vanderveken O. Oral Appliances in Obstructive Sleep Apnea. *Healthcare (Basel)*. 2019 Nov 8;7(4):141.

## Policy history

Origination date:	12/27/2011
Review/Approval(s):	Technology Assessment Committee: 09/27/2011, 12/27/2011, 08/28/2013, 01/28/2015 (updated template, references, added exclusion of coverage for severe apnea), 06/03/2015 (removed exclusion of coverage for severe apnea) 05/25/2016 (updated references), 05/24/2017 (updated references), 05/15/2018 (updated references), 01/23/2019 (clarified trial/failure of CPAP is required for all levels of sleep apnea, updated references), 01/22/2020 (updated references), 06/25/2021 (Added clarifying language related to Medicare Advantage, NaviCare and PACE under policy section), 07/23/2024 (annual review; no changes to coverage criteria).

*Not all services mentioned in this policy are covered for all products or employer groups. Coverage is based upon the terms of a member's particular benefit plan which may contain its own specific provisions for coverage and exclusions regardless of medical necessity. Please consult the product's Evidence of Coverage for exclusions or other benefit limitations applicable to this service or supply. If there is any discrepancy between this policy and a member's benefit plan, the provisions of the benefit plan will govern. However, applicable state mandates take precedence with respect to fully-insured plans and self-funded non-ERISA (e.g., government, school boards, church) plans. Unless otherwise specifically excluded, federal mandates will apply to all plans.*