Harvard Pilgrim Health Care | TUFTS Health Plan

Point32Health companies

Medical Necessity Guidelines:

Custom Fabricated Oral Appliances for Obstructive Sleep Apnea (OSA)

Effective: September 1, 2026

Prior Authorization Required If REQUIRED, submit supporting clinical documentation (electronically recommended or by fax)	Yes ☒ No ☐
Notification Required	Yes ☐ No ☒

Applies to:

- Harvard Pilgrim Health Care Commercial products
- Tufts Health Plan Commercial products
- Tufts Health Direct
- Tufts Health Together
- Tufts Health RITogether
- Tufts Health One Care

We recommend submitting prior authorization electronically. If you opt to submit prior authorization requests via fax, please refer to this reference chart for the appropriate fax number (varies by product).
For details on all our products, please visit the Our Plans page on our provider website. For additional Prior Authorization and Notification details on other lines of business not listed on our Medical Necessity Guidelines page, please also reference our Prior Authorization Resources page.

Note: While you may not be the provider responsible for obtaining prior authorization or notifying Point32Health, as a condition of payment you will need to ensure that any necessary prior authorization has been obtained and/or Point32Health has received proper notification. If notification is required, providers may additionally be required to provide updated clinical information to qualify for continued service.

For Harvard Pilgrim Health Care Members:

This policy utilizes InterQual® criteria and/or tools, which Harvard Pilgrim may have customized. You may request authorization and complete the automated authorization questionnaire via HPHConnect at www.harvardpilgrim.org/providerportal. In some cases, clinical documentation may be required to complete a medical necessity review. Please submit required documentation as follows:

- Clinical notes/written documentation – via HPHConnect Clinical Upload or secure fax (800-232-0816)

Providers may view and print the medical necessity criteria and questionnaire via HPHConnect for providers (Select Researched and the InterQual® link) or contact the commercial Provider Service Center at 800-708-4414. (To register for HPHConnect, follow the instructions here). Members may access materials by logging into their online account (visit www.harvardpilgrim.org, click on Member Login, then Plan Details, Prior Authorization for Care, and the link to clinical criteria) or by calling Member Services at 888-333-4742.

For Tufts Health Plan Members:

Please submit clinical documentation pertinent to service request to the FAX numbers below:

- Tufts Health Plan Commercial products; Fax: 617.972.9409
  - CareLinkSM – Refer to CareLink Procedures, Services and Items Requiring Prior Authorization
- Tufts Health Direct – A Massachusetts Qualified Health Plan (QHP) (a commercial product); Fax: 888-415-9055
- Tufts Health Together – MassHealth MCO Plan and Accountable Care Partnership Plans; Fax: 888-415-9055
- Tufts Health RITogether – A Rhode Island Medicaid Plan; Fax: 857-304-6404
- Tufts Health One Care – A dual-eligible product; Fax: 857-304-6304

Overview

Obstructive sleep apnea (OSA), the most common form of sleep apnea, is the collapse of the upper airway leading to the reduction or cessation of airflow during sleep. These episodes may be associated with oxygen desaturation. There are three different forms of sleep apnea, obstructive, central, and mixed. The Apnea Hypopnea Index (AHI) represents the average number of apneas and hypopneas experienced each hour during sleep and is a diagnostic used to tool determine the presence and severity of obstructive sleep apnea.

Oral devices are used to treat obstructive sleep apnea (OSA) by restoring airway competence. The restoration of airway competence is intended to reduce morbidity and mortality by reversing hypoxia, hypercapnia, and acidosis as well as improving quality of life.

Clinical Guideline Coverage Criteria

The Plan uses guidance from the Centers for Medicare and Medicaid Services (CMS) and MassHealth for coverage determinations for its Dual Product Eligible plan members. CMS National Coverage Determinations (NCDs), Local Coverage Determinations (LCDs), Local Coverage Articles (LCAs) and documentation included in the Medicare manuals and MassHealth Medical Necessity Determinations are the basis for coverage determinations where available. For **Tufts Health One Care** plan members the following criteria is used: Oral Appliances for Obstructive Sleep Apnea LCD L33611

For Harvard Pilgrim Health Care Commercial Members

The Plan requires the use of the following InterQual® Subsets or SmartSheets to obtain prior authorization for custom fabricated oral appliances:

1. Mandibular Advancement Oral Appliance, Adjustable, Custom Fabricated Mandibular Advancement Oral Appliance

In addition, the Member must be aware of the following:

1. Positive airway pressure (PAP) is superior at improving the AHI and oxyhemoglobin saturation. Oral appliance therapy may not provide optimal improvement in oxygenation
2. Possible side effects with oral appliance treatment, including complications of TMJ

For Tufts Health Plan Members:

NOTE: Request for custom fabricated oral appliance must be submitted by a certified sleep specialist.

The Plan may authorize the coverage of an FDA-approved (custom fabricated only) oral appliance/device when **ALL** the following criteria are met:

1. Recent face-to-face clinical evaluation with a sleep specialist certified by an approved specialty board of the American Board of Medical Specialties (e.g., ABIM); **and**
2. Recent documentation of a facility based or home approved sleep study; **and**
3. Clinical documentation submitted by certified sleep specialist does not suggest a change in clinical status (e.g., change in cardiac, pulmonary, neuromuscular condition, substantial weight loss, upper airway surgery) since previous sleep study; **and**
4. There is evidence of obstructive sleep apnea established by a previous sleep study documenting:
    a. An AHI or respiratory disturbance index (RDI) of ≥ 5 and <15 and documentation of one or more of the following: Excessive daytime sleepiness, impaired cognition, mood disorder, insomnia, hypertension, ischemic heart disease or history of stroke. Excessive daytime sleepiness must be assessed using the Epworth Sleepiness Scale. An Epworth score ≥10 is required to confirm excessive daytime sleepiness; **or**
    b. An Apnea Hypopnea Index (AHI) or RDI of ≥15 and ≤ 30 **or**
    c. An Apnea Hypopnea Index (AHI) or (RDI) >30;
5. There is documentation from a sleep specialist certified by an approved specialty board of the American Board of Medical Specialties (e.g., ABIM), that the Member has had a previous trial of positive airway pressure (PAP) that failed or was not tolerated for the following reasons:
    a. Significant clinical improvement was not demonstrated with a trial of PAP; **or**
    b. The device trialed could not be tolerated because of claustrophobia, inability to breathe through nose, pain or increasing levels of discomfort; **or**
    c. Documentation of continued complaint of pressure discomfort which precludes proper use of CPAP and is unable to be resolved (e.g., pressure and interface adjustments); **and**
    d. Attempts to resolve reason(s) for PAP failure/intolerance, including but not limited to poor mask fit, excessive leak, adjustments in humidification and improper treatment settings, have failed;
6. The following information has been discussed with the Member by certified sleep specialist:
    a. Positive airway pressure (PAP) is superior at improving the AHI and oxyhemoglobin saturation. Oral

appliance therapy may not provide optimal improvement in oxygenation; **and**

b. Possible side effects with oral appliance treatment, including complications of TMJ

Authorization of a Replacement of or Repair to Custom Oral Appliance

The Plan may authorize replacement or repair of oral appliance when the following criteria are met:

1) Equipment in use ≥ 5 years; **or**
2) Member benefits from and is adherent to use of current/previous
3) For One Care Members only: replacement is necessary due to theft, loss, or irreparable damage

Limitations

The Plan does not cover custom oral appliances when:

1. The Member is less than 18 years of age
2. The requested oral appliance is available over the counter or is not custom-made
3. The Member has a diagnosis of central sleep apnea
4. The oral appliance is being requested for snoring without documentation of OSA
5. The oral appliance is being requested to treat central sleep apnea
6. Facility PAP titration study and unattended auto-titration of PAP (APAP) do not qualify as a trial of PAP
7. Convenience item (e.g., for travel)
8. Nasal dilators are not considered appliances for OSA
9. Distributed/interrupted sleep of spouse/partner
10. Replacement devices necessary due to loss, theft, negligence, or willful damage

Mandibular Anterior Repositioning Appliances/Devices

Mandibular Anterior Repositioning Devices should only be constructed by a dentist with experience in this type of appliance. Compliance and efficacy will be dependent upon the comfort and fit of this appliance

The Plan does not cover "Morning Repositioner" as this device is considered investigational. Refer to Noncovered Investigational Services Medical Necessity Guidelines.

Codes

The following code(s) require prior authorization:

Table 1: CPT/HCPCS Codes

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

The following codes are considered *not* medically necessary

Table 2: CPT/HCPCS Codes

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

References:

1. Ramar K, Dort LC, Katz SG, et al. Clinical Practice Guideline for the Treatment of Obstructive Sleep Apnea and Snoring with Oral Appliance Therapy: An Update for 2015. J Clin Sleep Med. 2015;11(7):773-827. Published 2015 Jul 15. doi:10.5664/jcsm.4858. Accessed June 11, 2026.
2. Centers for Medicare and Medicaid Services. Local Coverage Determination (LCD): Oral Appliances for Obstructive Sleep Apnea (L33611). Accessed May 13, 2026. LCD - Oral Appliances for Obstructive Sleep Apnea (L33611) (cms.gov)
3. Kapur VK, Auckley DH, Chowdhuri S, et al. Clinical Practice Guideline for Diagnostic Testing for Adult Obstructive Sleep Apnea: An American Academy of Sleep Medicine Clinical Practice Guideline. J Clin Sleep Med. 2017;13(3):479-504. Published 2017 Mar 15. doi:10.5664/jcsm.6506.

4. Ruehland WR, Rochford PD, O'Donoghue FJ, Pierce RJ, Singh P, Thornton AT. The new AASM criteria for scoring hypopneas: impact on the apnea hypopnea index. Sleep. 2009;32(2):150-157. doi:10.1093/sleep/32.2.150.
5. Cistulli PA. Oral appliances in the treatment of obstructive sleep apnea in adults. Accessed June 1, 2026 by subscription only Oral appliances in the treatment of obstructive sleep apnea in adults – UpToDate
6. Spicuzza L, Caruso D, Di Maria G. Obstructive sleep apnoea syndrome and its management. Ther Adv Chronic Dis. 2015;6(5):273-285. doi:10.1177/2040622315590318

Approval And Revision History

May 20, 2020: Reviewed by IMPAC, renewed without changes

Subsequent endorsement date(s) and changes made:

- July 21, 2021: Reviewed at IMPAC. Expansion of initial coverage to include diagnosed severe OSA (AHI or RDI >30). Language clarification regarding complaint of pressure discomfort.
- November 17, 2021: Reviewed at IMPAC. Diagnosed severe OSA (AHI or RDI >30) added to guidelines for authorization of replacement/repair of oral appliance.
- May 18, 2022: Reviewed by Medical Policy Approval Committee (MPAC), renewed without changes
- August 17, 2022: Reviewed by Medical Policy Approval Committee (MPAC) for integration purposes between Harvard Pilgrim Health Care and Tufts Health Plan with an effective date of December 1, 2022. Update to definition of OSA. Clarification of board certification requirement. Update language regarding oral appliance O2 saturation effectiveness. Update to replacement criteria.
- November 16, 2022. Reviewed by MPAC. Effective January 1, 2023, Providers prescribing custom fabricated oral appliances for Tufts Health Plan Commercial product members are no longer required to utilize SomnoMed® for manufacturing of appliance
- May 17, 2023: Reviewed by MPAC, limitations updated regarding over-the-counter appliances
- June 21, 2023: Reviewed by MPAC, renewed without changes
- November 2023: Rebranded Unify to One Care and updated One Care criteria effective January 1, 2024
- December 1, 2023: Reviewed and approved by UM Committee effective January 1, 2024
- May 15, 2024: Reviewed by MPAC, E0486 added to prior authorization for public plans effective September 1, 2024
- June 13, 2024: Reviewed and approve by UM Committee, adding E0486 to PA and InterQual 2024 updates effective September 1, 2024
- June 20, 2024: Reviewed by MPAC for 2024 InterQual Upgrade, effective September 1, 2024
- April 16, 2025: Reviewed by MPAC for clarification of limitation, effective June 1, 2025
- May 21, 2025: Reviewed by MPAC for 2025 InterQual update, effective July 1, 2025
- June 18, 2025: Reviewed by MPAC, annual review no changes, effective August 1, 2025
- May 20, 2026: Reviewed by MPAC for 2026 InterQual Update, effective July 1, 2026
- July 15, 2026: Reviewed by MPAC, annual review, renewed without changes. Effective September 1, 2026

Background, Product and Disclaimer Information

Medical Necessity Guidelines are developed to determine coverage for benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. We make coverage decisions using these guidelines, along with the Member's benefit document, and in coordination with the Member's physician(s) on a case-by-case basis considering the individual Member's health care needs.

Medical Necessity Guidelines are developed for selected therapeutic or diagnostic services found to be safe and proven effective in a limited, defined population of patients or clinical circumstances. They include concise clinical coverage criteria based on current literature review, consultation with practicing physicians in our service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. We revise and update Medical Necessity Guidelines annually, or more frequently if new evidence becomes available that suggests needed revisions.

For self-insured plans, coverage may vary depending on the terms of the benefit document. If a discrepancy exists between a Medical Necessity Guideline and a self-insured Member's benefit document, the provisions of the benefit document will govern. For Tufts Health Together (Medicaid), coverage may be available beyond these guidelines for pediatric members under age 21 under the Early and Periodic Screening, Diagnostic and Treatment (EPSDT) benefits of the plan in accordance with 130 CMR 450.140 and 130 CMR 447.000, and with prior authorization.

Treating providers are solely responsible for the medical advice and treatment of Members. The use of this guideline is not a guarantee of payment or a final prediction of how specific claim(s) will be adjudicated. Claims payment is subject to eligibility and benefits on the date of service, coordination of benefits, referral/authorization, utilization management guidelines when applicable, and adherence to plan policies, plan procedures, and claims editing logic.