

## Medical Necessity Guidelines: Custom Fabricated Oral Appliances for Obstructive Sleep Apnea (OSA)

Effective: May 20, 2020

<b>Prior Authorization Required</b>	<b>Yes <input checked="" type="checkbox"/> No <input type="checkbox"/></b>
If <u>REQUIRED</u> , submit supporting clinical documentation pertinent to service request.	
<b>Applies to:</b> <b>COMMERCIAL Products</b> <input checked="" type="checkbox"/> Tufts Health Plan Commercial products; Fax: 617.972.9409 <input checked="" type="checkbox"/> Tufts Health Freedom Plan products; Fax: 617.972.9409 • CareLink <sup>SM</sup> – Refer to <a href="#">CareLink Procedures, Services and Items Requiring Prior Authorization</a> <b>TUFTS HEALTH PUBLIC PLANS Products</b> <input checked="" type="checkbox"/> Tufts Health Direct – A Massachusetts Qualified Health Plan (QHP) (a commercial product); Fax: 888.415.9055 <input checked="" type="checkbox"/> Tufts Health Together – MassHealth MCO Plan and Accountable Care Partnership Plans; Fax: 888.415.9055 <input checked="" type="checkbox"/> Tufts Health RITogether – A Rhode Island Medicaid Plan; Fax: 857.304.6404 <input checked="" type="checkbox"/> Tufts Health Unify* – OneCare Plan (a dual-eligible product); Fax: 857.304.6304 *The MNG applies to Tufts Health Unify members unless a less restrictive LCD or NCD exists. <b>SENIOR Products</b> • Tufts Health Plan Senior Care Options (SCO), (a dual-eligible product) – Refer to the <a href="#">Tufts Health Plan SCO Prior Authorization List</a> • Tufts Medicare Preferred HMO, (a Medicare Advantage product) – Refer to the <a href="#">Tufts Medicare Preferred HMO Prior Authorization and Inpatient Notification List</a>	

**Note:** While you may not be the provider responsible for obtaining prior authorization, as a condition of payment you will need to make sure that prior authorization has been obtained.

### OVERVIEW

Sleep apnea means cessation of breath. Of the three different forms of sleep apnea (obstructive, central, or mixed), obstructive sleep apnea (OSA) is the most common. Typically, patients who have OSA have repeat occurrences of upper airway obstruction during sleep, which may be accompanied by a decrease in blood oxygen saturation level. Upper airway obstruction usually includes relaxation and collapse of the airway muscles during sleep. The structure of the jaw and airway can also be a factor in sleep apnea. The Apnea Hypopnea Index (AHI) is a common summary measure used to describe respiratory disturbances during sleep. The AHI is the total number of episodes of apnea and hypopnea during sleep divided by the hours of sleep time<sup>23</sup>.

### CLINICAL COVERAGE CRITERIA

**Note:** For Commercial Products, SomnoMed<sup>®</sup> is the Tufts Health Plan provider for custom fabricated oral appliances. Refer to the [Sleep Studies Payment Policy](#) for more information.

**To Initiate the Prior Authorization Process**, it is necessary for prescribing providers to contact SomnoMed<sup>®</sup> via their [website](#) or call 888.447.6673 (option 6).

### Initial Authorization

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

- There is evidence of obstructive sleep apnea established by a previous sleep study documenting:
  - An Apnea Hypopnea Index (AHI) of  $\geq 15$  per hour with a minimum of 30 events;

**OR**

  - An AHI of  $\geq 5$  and  $\leq 14.9$  with a minimum of 10 events **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  $\geq 10$  is required to confirm excessive daytime sleepiness.

- Documentation of a current sleep study will be required if:
  - Previous sleep study is not available **or**
  - Clinical documentation suggests a change in clinical status (e.g. change in cardiac, pulmonary, neuromuscular condition, substantial weight loss, upper airway surgery) since previous sleep study
- There is documentation from a physician sleep specialist, board certified by the American Board of Internal Medicine (ABIM), that the member **has had a previous trial of positive airway pressure (PAP)** that failed or was not tolerated for the following reasons:
  - Significant clinical improvement was not demonstrated with trial of PAP  
or
  - The device trialed could not be tolerated because of claustrophobia, inability to breathe through nose, pain or increasing levels of discomfort  
or
  - The Member, at levels of PAP > 10cm water, had complaints of pressure discomfort

**AND**

- 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

**AND**

- The following information must have been discussed with the patient:
  - Oral appliances do not raise the minimum O2 saturation level significantly, as does PAP
  - Up to 25% of patients do not respond to treatment with an oral appliance
  - Possible side effects with oral appliance treatment, including complications of TMJ

**Authorization of a Replacement or Repair**

Requests for replacement or repair of an oral appliance that has previously been authorized by Tufts Health Plan must include the following:

- A statement verifying the efficacy of and adherence to use of previous appliance
- Date the appliance was obtained
- Reason for repair or replacement

Requests for replacement or repair of an oral appliance that has not been previously authorized by Tufts Health Plan must include ALL the following:

- Diagnosis of obstructive sleep apnea established by a prior sleep study which documents an Apnea Hypopnea Index (AHI) greater than 15 per hour with a minimum of 30 events

**OR**

An AHI of  $\geq 5$  and  $\leq 14$  with a minimum of 10 events **and** documentation of any one or more of the following: Excessive daytime sleepiness, impaired cognition, mood disorders, 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

- A statement verifying the efficacy of and adherence to use of previous appliance
- Date the appliance was obtained
- Reason for repair or replacement

**LIMITATIONS**

Tufts Health Plan may not authorize an oral appliance in the following circumstances:

- The Member is less than 18 years of age
- The requested oral appliance is available over-the-counter or not custom-made
- The Member has a diagnosis of central sleep apnea
- The oral appliance is being requested for snoring without documentation of OSA
- The oral appliance is being requested to treat central sleep apnea
- Facility PAP titration study and unattended auto-titration of PAP (APAP) do not qualify as a trial of PAP
- Convenience item (e.g., for travel)
- Nasal Dilators are not considered appliances for OSA
- Disturbed/interrupted sleep of spouse /partner

### **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.

Tufts Health Plan does not cover "Morning Repositioner" as this device is considered investigational. Refer to [Noncovered Investigational Services Medical Necessity Guidelines](#).

#### **CODES**

The following HCPCS code requires prior authorization:

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

#### **REFERENCES**

1. Partinen, M. Epidemiology of obstructive sleep apnea syndrome. *Current Opinion in Pulmonary Medicine* 1995, Nov; 1 (6): 482-7. Update search March 23, 2018.
2. Fischer J, Raschke F. Economic and medical significance of sleep-related breathing disorders. *Respiration*. 1997; 64 Suppl 1:39-44. Update search March 23, 2018.
3. Silverberg, D.S., Iaina, A., Ocksenberg, A. Sleep-related breathing disturbances: their pathogenesis and potential interest to the nephrologist. *Nephro Dial Transplant* 1997 Apr; 12 (4):680-3. Update Search March 23, 2018.
4. Man, Godfrey C.W.. Obstructive sleep apnea: Diagnosis and treatment. *Medical Clinics of North America*. 1 July 1996, 80(4): 803-820. Abstract last accessed March 23, 2018.
5. Schrand, J.R. Is sleep apnea a predisposing factor for tobacco use? *Med Hypotheses*.1996; Dec 47(6):443-8. Update search March 23, 2018.
6. Bliwise, D.L. Is sleep apnea a cause of reversible dementia in old age? *J Am Geriatr Soc*. 1996, Nov; 44(11) 1407-9.
7. Johns, M.W. A new method for measuring daytime sleepiness: The Epworth Sleepiness Scale. *Sleep*. 14:540-545. Update search March 23, 2018.
8. Marklund, M. et al. The effect of a mandibular advancement device on apneas and sleep in patients with obstructive sleep apnea. *Chest*. 1998; 113:707-13. Update search March 23, 2018.
9. Chesson, Jr, A. Beyond apnea and narcolepsy. *Sleepiness*. May 1998:33-38. Indications and standards for use of nasal continuous positive airway pressure (CPAP) in sleep apnea syndromes. *American Journal of Respiratory and Critical Care Medicine*. 1994; 150:1738-45.
10. Schmidt-Nowara W et al. Oral appliances for the treatment of snoring and obstructive sleep apnea: a review. *Sleep*. 1995 Jul 18(6): 501-10. Update search March 23, 2018.
11. Flemons, W.Ward et al. Quality of life consequences of sleep-disordered breathing. *Journal of Allergy and Clinical Immunology*. Volume 99, Issue 2, S750-S756. Update search March 23, 2018.
12. Hudgel, David.W. Availability of a meta-analysis of the surgical treatment of obstructive sleep apnea. (Editorial) *Chest*. 1997; Volume 111, Issue 2, 265-266. Last accessed March 23, 2018.
13. American Sleep Disorders Association Report. Practice parameters for the treatment of obstructive sleep apnea in adults. The efficacy of surgical modification of the upper airway. *Sleep*. 1996(2)152. Updated 2010. *SLEEP* 2010;33(10):1408-1413. Last accessed Mar 23, 2018.
14. Strobel RJ, Rosen RC. Obesity and weight loss in obstructive sleep apnea: a critical review. *Sleep* 1996;19:104-115. Update search March 23, 2018.
15. Low, A.A., et al. Cephalometric and computed tomographic predictors of obstructive sleep apneas severity. *American Journal of Orthodontics and Dental Facial Orthopedics*. 107 (106) 589-595.
16. Ball, E.M. et al. Diagnosis of sleep apnea within the community. *Archives of Internal Medicine*. Feb 1997; 419-424.
17. Pradhin, P.S. et al. Screening of obstructive sleep apnea in patients presenting for snoring surgery. *Laryngoscope*. Jan 1997; 107 (1): 149.
18. Finkelstine, Y. et al. Uvulopalatopharyngoplasty vs. laser-assisted uvulopalatoplasty: anatomic considerations. *Archives of Otolaryngology and Head & Neck Surgery*. Mar 1997; 123 (3): 265-76. Update search March 23, 2018.

19. Dundar. A. et al. Patient selection and surgical results in sleep apnea. *European Archives of Otolaryngology. Supplement*; 1:S157-61.
20. Sher, A.E. Update on upper airway surgery for obstructive sleep apnea. *Current Opinions in Pulmonary Medicine*. Nov 1995; 1(6): 504-11. Update Search March 23, 2018.
21. Strollo, P.J., Rogers, R.M. Obstructive sleep apnea. *Current Concepts*. (2) 1996, 99-104.
22. Sher, A. et al. The efficiency of surgical modifications of the upper airway in adults with obstructive sleep apnea syndrome. *Sleep*. 19: 2 156 1998.
23. Beers MH, Berkow R, editors. Obstructive sleep apnea. *The Merck manual of diagnosis and therapy*, 17th ed. Retrieved on February 5, 2007 from: [merck.com/mrkshared/mmanual/section12/chapter149/149h.jsp](http://merck.com/mrkshared/mmanual/section12/chapter149/149h.jsp). Update search: Last full review/revision May 2015 by Kingman P. Strohl, MD accessed July 13, 2016. Update search: Last full review/revision February 2017 by Kingman P. Strohl, MD accessed March 23, 2018.
24. Li W. et al. The comparison of CPAP and oral appliances in treatment of patients with OSA: a systemic review and meta-analysis. *Respiratory Care*. 2013 July; 58(7):1184-95
25. Sutherlank K. et al. Oral appliance treatment for obstructive sleep apnea: An update. *Journal of Clinical Sleep Medicine*, Vol 10 NO2, 2014
26. Remar K. et al. American Academy of Sleep Medicine. Clinical practice guideline for the treatment of obstructive sleep apnea and snoring with oral appliance therapy: An update for 2015. *Journal of Clinical Sleep Medicine*, Vol. 11, No. 7, 2015: 773-827.
27. Sharples L. et al. Meta-analysis of randomized controlled trials of oral mandibular advancement devices and continuous positive airway pressure for obstructive sleep apnea-hypopnea. *Sleep Medicine Review*. May 2015.
28. Qaseem A, Holty JE, Owens K, et al.: Clinical Guidelines Committee of the American College of Physicians. Management of obstructive sleep apnea in adults: a clinical practice guideline From the American College of Physicians. *Annals of Internal Medicine*. 1 October 2013. Last accessed March 23, 2018
29. Hayes, Winifred S. Directory Report. Mandibular Advancement Devices for Sleep Apnea. August 17, 2010. Available at: <http://www.hayesinc.com>. Last accessed March 23, 2018.
30. Hayes, Winifred S. Directory Report. Mandibular Advancement Devices for Sleep Apnea. August 17, 2010. Update Search: Hayes Annual Review July 14, 2014. Last accessed March 23, 2018.
31. Hayes, Winifred S. Search and Summary Report. The Morning Repositioner (SomnoMed) to Restore Proper Mandibular Alignment After Use of Overnight Sleep Apnea Appliance. June 27, 2018. Accessed July 29, 2018.
32. Johns MW. A New Method for Measuring Daytime Sleepiness: The Epworth Sleepiness Scale. *Sleep*. 1991;14(6):540-545. doi:10.1093/sleep/14.6.540.
33. Freedman N. When CPAP Fails: Treatment Options Beyond CPAP Therapy for Obstructive Sleep Apnea. Accessed on April 17, 2019 @ <https://www.acc.org/latest-in-cardiology/articles/2014/07/22/08/27/when-cpap-fails-treatment-options-beyond-cpap-therapy-for-obstructive-sleep-apnea>.
34. Kushida C, Morgenthaler T, Littner M, et al. Practice parameters for the treatment of snoring and Obstructive Sleep Apnea with oral appliances: An update for 2005.. *Sleep* 2006;29:240-43.
35. Epstein LJ, Kristo D, et.al. Clinical Guideline for the Evaluation, Management and Long-term Care of Obstructive Sleep Apnea in Adults. *Journal of Clinical Sleep Medicine* 2009; 5(3):263-276.
36. Kushida CA, Littner MR, et.al. Practice Parameters for the Indications for Polysomnography and Related Procedures: An Update for 2005. *SLEEP* 2005; 28(4):499-521.
37. Kapur VK, Auckley DH, Chowdhuri S, Kuhlmann DC, Mehra R, Ramar K, Harrod CG. 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.
38. The Link between Obesity and Obstructive Sleep Apnea/Provider Fact Sheet. American Academy Of Sleep Medicine/ Provider Fact sheet. [j2vjt3dnbra3ps7ll1clb4q2-wpengine.netdna-ssl.com/wp-content/uploads/2018/09/ProviderFS\\_Obesity\\_18.pdf](https://www.aasm.org/wp-content/uploads/2018/09/ProviderFS_Obesity_18.pdf). Accessed February 18, 2019.

## APPROVAL HISTORY

January 1999: Reviewed by the Clinical Coverage Criteria Committee.

Subsequent endorsement date(s) and changes made:

- October 2000: Renewed
- November 2001: Renewed
- May 2002: Renewed, RDI decreased from 20 to 15

- October 30, 2003: Reviewed and renewed, updated to new format, limitations clarified
- November 8, 2004: Reviewed and renewed
- November 4, 2005: Reviewed and renewed
- November 17, 2006: Reviewed and renewed without changes
- February 15, 2007: References to the Respiratory Distress Index (RDI) removed from criteria, required measurement changed to Apnea Hypopnea Index (AHI) only
- April 18, 2008: Complications of oral devices for OSA clarified
- March 16, 2009: Reviewed and renewed without changes
- October 7, 2009 for an effective date of November 1, 2009: Oxygen saturation levels removed from coverage criteria
- December 2009: Replacement of device language added
- April 14, 2010: Reviewed and renewed without changes
- March 2011: Reviewed by Medical Specialty Policy Advisory Committee (MSPAC), no changes
- February 8, 2012: Reviewed by Integrated Medical Policy Advisory Committee (IMPAC), no changes.
- March 13, 2013: Reviewed by IMPAC, sleep study time frame requirements changed to within the past 3 years, documentation of CPAP failure from a physician who is a board-certified sleep specialist is required, limitations related to age and weight clarified.
- December 11, 2013: Reviewed by IMPAC, renewed without changes.
- June 11, 2014: Reviewed by IMPAC, HCPCS codes for oral devices and language with guidelines for repair or replacement of the device were added to the MNG for an effective date of October 1, 2014.
- September 17, 2014: Adopted by Tufts Health Plan – Network Health Commercial Plans and Tufts Health Plan – Network Health Medicaid Plans.
- December 10, 2014: Reviewed by IMPAC, renewed without changes.
- March 11, 2015: Reviewed by IMPAC, renewed without changes.
- September 2015: Branding and template change to distinguish Tufts Health Plan products in "Applies to" section. Added Tufts Health Freedom Plan products, effective January 1, 2016.
- March 9, 2016: Reviewed by IMPAC, wording changes for clarification of oral cavity tissues.
- July 20, 2016: Reviewed by IMPAC, AHI criteria clarified by adding 'An Apnea Hypopnea Index (AHI) is  $\geq 15$  per hour with a minimum of 30 events; OR the AHI is  $\geq 5$  and  $\leq 14$  with a minimum of 10 events AND additional documentation of associated listed comorbid(s).
- August 10, 2016: Reviewed by IMPAC. Under the Limitations section the following were removed: BMI, neck size, TMJ, oral, teeth, hypoxemia, and nasal passage language; the following were added: not custom made/adjustable/OTC, snoring without OSA, central sleep apnea, nasal dilators and convenience items. Under 'Requests for replacement or repair': the criterion for sleep study changed from 12 months to 24 months. Coding updated: removal of HCPCS code E0485 from coverage as it is prefabricated. Effective 1/1/17.
- January 11, 2017. Reviewed by IMPAC, format and wording changes. Effective March 15, 2017, for Commercial Products, providers prescribing custom fabricated oral appliances for Tufts Health Plan Members must utilize SomnoMed® to manufacture the appliance and initiate the prior authorization process.
- March 15, 2017: Reviewed by IMPAC, sleep specialist clarified.
- April 2017: Added RITogether Plan product to template. For MNGs applicable to RITogether, effective date is August 1, 2017.
- February 14, 2018: Reviewed by IMPAC, renewed without changes.
- August 22, 2018: Reviewed by IMPAC. For effective date August 22, 2018, Morning Repositioner device added to limitations section. For effective date January 1, 2019, MNG is applicable to RITogether.
- October, 2018: Template and disclaimer updated
- April 17, 2019: Reviewed at IMPAC. Effective October 1, 2019, an Epworth score  $>10$  is required to confirm excessive daytime sleepiness.
- May 15, 2019: Reviewed at IMPAC. For effective date October 1, 2019, documentation of attempts to resolve reason(s) for PAP failure and/or intolerance is required. A documented sleep study performed within a timeframe of 12 months for initial appliance and 24 months for replacement appliance is removed. Added criteria requires documentation of a current sleep study if a previous sleep study is not available or if clinical documentation suggests a change in clinical status (e.g., change in cardiac, pulmonary, neuromuscular condition, substantial weight

loss, upper airway surgery) since a previous sleep study. Facility PAP titration study and unattended auto-titration of PAP (APAP) do not qualify as a trial of PAP and are added to the limitations section. Disturbed/interrupted sleep of spouse /partner is added to limitations section.

- September 18, 2019: Reviewed at IMPAC. Criteria allowing coverage of a custom fabricated oral appliance for treatment of obstructive sleep apnea for an AHI of  $\geq 5$  and  $\leq 14$  has been changed to allow coverage for an AHI of  $\geq 5$  and  $\leq 14.9$ .
- March 18, 2020: Reviewed at IMPAC. Epworth score requirement for confirmation of excessive daytime sleepiness changed from  $>10$  to  $\geq 10$ .
- March 18, 2020: Unify fax number updated
- May 20, 2020: Reviewed by IMPAC, renewed without changes

#### **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.

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.