Subject: Oral Devices for Obstructive Sleep Apnea

Background: 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 the quality of life for the patient.

Policy and Coverage Criteria: Harvard Pilgrim Health Care (HPHC) considers FDA-approved, physician-ordered mandibular oral devices medically necessary for members with a diagnosis of mild to moderate OSA who meet all the following:

- OSA is confirmed by appropriate sleep testing;
- Device is ordered by the physician treating the member for OSA (PCP or specialist);
- Failed trial or documented intolerance of CPAP or BiPAP;
- Possesses adequate dentition to support the device;
- Has at least 7 mm of protrusive jaw movement from a position of maximum intercuspation;
- Has a patent nasal airway;
- No TMJ restriction, painful or loud TMJ noises, or local sites of severe joint or muscle tenderness

Exclusions: Harvard Pilgrim Health Care (HPHC) considers oral devices for the treatment of OSA as not medically necessary when the above criteria are not met. HPHC does not cover over-the-counter oral devices.

Supporting Information: There are numerous nonsurgical devices, aside from continuous positive airway pressure (CPAP) devices, that have been proposed and are used to treat OSA, including: tongue-retaining devices and mandibular advancement devices. Mandibular advancement devices work by positioning the mandibular forward which moves the tongue forward and also changes the hyoid bone position modifying the lower airway space below the level of the base of the tongue. Tongue-retaining devices hold the tongue in a forward position, preventing it from being drawn downward by the negative pressure of inspiration.

Mandibular Advancement Devices:
Johal et al. (2015) conducted an analysis of existing systematic reviews concerning the management of OSA with mandibular advancement splint therapy. The analysis showed that mandibular advancement splint therapy is effective in improving OSA.

Randerath et al. (2011) conducted an evaluation of the scientific literature on the use of alternative treatment methods in OSA. The authors reported that the use of mandibular advancement devices was supported by the evidence in mild to moderate OSA.

Ferguson et al. (2006) conducted an evidence-based review of literature on the use of oral appliances in the treatment of snoring and OSA. 87 articles were included in the evidence base, including 15 Level I to II randomized controlled trials and 5 of these trials with placebo-controlled treatment. The efficacy of OAs was established for controlling OSA in some but not all patients with success achieved in an average of 52% of treated patients. In comparison to CPAP, OAs are less efficacious in reducing the apnea hypopnea index, but OAs appear to be used more, and in many studies were preferred over CPAP when the treatments were compared.

Naismith et al. (2005) conducted a randomized controlled crossover study to assess the efficacy of a custom-made mandibular advancement splint for the treatment of OSA in 73 patients with at least 2 symptoms of OSA and an apnea hypopnea index >/= 10/hour. Mandibular advancement splint treatment results in improvements in...
self-reported sleepiness, fatigue/energy levels and vigilance/psychomotor speed in patients with obstructive sleep apnea.

Cistulli et al. (2004) reported in their review that the efficacy of mandibular repositioning appliances has been rigorously proven in a significant proportion of patients with varying disease severity. The authors reported that short-term side-effects are common but typically transient and there have been reports of long-term permanent adverse effects on the dentition and occlusion.

Gotsopoulos et al. (2004) conducted a randomized, controlled crossover trial to investigate the short-term effect of oral appliance therapy for OSA on blood pressure. The study included 61 patients diagnosed with OSA on polysomnography who received a mandibular advancement splint and control oral appliance for 4 weeks each. The patients showed a 50% reduction in mean apnea hypopnea index with mandibular advancement splint compared with the control and a significant improvement in both minimum oxygen saturation and arousal index. There was a significant reduction with the mandibular advancement splint in mean 24-hour diastolic blood pressure compared with the control, but not in 24-hour systolic blood pressure. The authors concluded that oral appliance therapy for OSA over 4 weeks results in a reduction in blood pressure, similar to that reported with CPAP therapy.

Gotsopoulos et al. (2002) conducted a randomized crossover study to evaluate the effect of a mandibular advancement splint (MAS) on daytime sleepiness and other symptoms in OSA. Patients received 4 weeks of treatment with MAS and a control device, with a 1-week washout. At the end of each treatment period, patients were assessed by questionnaire, polysomnography, and multiple sleep latency test. Fifty-nine men and 14 women with experienced significantly improved mean sleep latency on the multiple sleep latency test and Epworth sleepiness scale score with the MAS compared with the control device after 4 weeks. The proportion of patients with normal subjective sleepiness was significantly higher with the MAS than with the control device, but not for objective sleepiness. Other OSA symptoms were controlled in significantly more patients with the MAS than with the control device. The authors concluded that MAS therapy improves a range of symptoms associated with OSA.

Mehta et al. (2001) conducted a randomized, controlled three-period crossover study consisting of 24 patients with OSA to investigate the efficacy of a novel mandibular advancement splint. Subjective improvements with the mandibular advancement splint were reported by 96% of patients. There were significant improvements in Apnea/Hypopnea Index, MinSa(O(2)), and arousal index with mandibular advancement splint compared with the control. The authors concluded that mandibular advancement splint is an effective treatment in some patients with OSA, including those patients with moderate or severe OSA.

Coding:

Codes are listed below for informational purposes only, and do not guarantee member coverage or provider reimbursement. The list may not be all-inclusive. Deleted codes and codes which are not effective at the time the service is rendered may not be eligible.

<table>
<thead>
<tr>
<th>HCPCS® Code</th>
<th>Description</th>
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<tr>
<td>E0486</td>
<td>Oral device/ appliance used to reduce upper airway collapsibility, adjustable or nonadjustable, custom fabricated, includes fitting and adjustment.</td>
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Billing Guidelines:

Member’s medical records must document that services are medically necessary for the care provided. Harvard Pilgrim Health Care maintains the right to audit the services provided to our members, regardless of the participation status of the provider. All documentation must be available to HPHC upon request. Failure to produce the requested information may result in denial or retraction of payment.

References:


Summary of Changes

<table>
<thead>
<tr>
<th>Date</th>
<th>Revisions</th>
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</thead>
<tbody>
<tr>
<td>4/19</td>
<td>Annual review; no changes</td>
</tr>
<tr>
<td>5/17</td>
<td>Reissued</td>
</tr>
<tr>
<td>4/17</td>
<td>Removed Benchmarks</td>
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Approved by Medical Policy Committee: 4/9/19
Approved by Clinical Policy Operational Committee: 8/15; 4/17, 6/17, 4/19
Policy Effective Date: 4/19
Initiated: 8/15