Regence

Medical Policy Manual Allied Health, Policy No. 36

Prefabricated Oral Appliances for Obstructive Sleep Apnea

Effective: July 1, 2024

Next Review: May 2025
Last Review: May 2024

IMPORTANT REMINDER

Medical Policies are developed to provide guidance for members and providers regarding coverage in accordance with contract terms. Benefit determinations are based in all cases on the applicable contract language. To the extent there may be any conflict between the Medical Policy and contract language, the contract language takes precedence.

PLEASE NOTE: Contracts exclude from coverage, among other things, services or procedures that are considered investigational or cosmetic. Providers may bill members for services or procedures that are considered investigational or cosmetic. Providers are encouraged to inform members before rendering such services that the members are likely to be financially responsible for the cost of these services.

DESCRIPTION

Oral appliances may be used to treat sleep apnea. The treatment goal for oral appliances is to increase the size of the upper airway by moving the jaw forward. Prefabricated oral appliances are not custom fit to the patient.

MEDICAL POLICY CRITERIA

Note: Prefabricated oral appliances should be reported with HCPCS code E0485. This policy does not address fabricated oral appliance devices (HCPCS code E0486) which may be considered medically necessary.

Prefabricated oral appliance devices (HCPCS code E0485) are considered **investigational** as a treatment of obstructive sleep apnea.

NOTE: A summary of the supporting rationale for the policy criteria is at the end of the policy.

CROSS REFERENCES

1. Administrative Guidelines to Determine Dental vs Medical Services, Allied Health, Policy No. 35
2. Orthognathic Surgery, Surgery, Policy No. 137

3. Surgeries for Snoring, Obstructive Sleep Apnea Syndrome, and Upper Airway Resistance Syndrome, Surgery, Policy No. 166
4. Hypoglossal Nerve Stimulation, Surgery, Policy No. 215

BACKGROUND

OBSTRUCTIVE SLEEP APNEA (OSA)

Obstructive sleep apnea syndrome is associated with increased risk of heart failure and potential increase in overall morbidity and mortality.[1] OSA is defined as repeated periods of complete airway obstruction (apnea) lasting at least 10 seconds during sleep. Hypopnea, partial airway obstruction with at least 30% reduction in airflow for 10 seconds or more, may also be present. When the sequence of breaths does not meet criteria for an apnea or hypopnea, but lasts at least 10 seconds and is characterized by either increasing respiratory effort or an arousal from sleep, this is scored as a respiratory event related arousal (RERA). Inadequate oxygen intake during these episodes results in a drop-in oxygen saturation, which stimulates a brief awakening that is usually accompanied by gasping until the oxygen saturation rises. This cycle usually repeats throughout the night.

ORAL APPLIANCES

There are several treatment options for sleep apnea. A standard of care for nonsurgical treatment of OSA is continuous positive airway pressure (CPAP) therapy; however, many patients find this device to be intolerable and compliance rates are relatively low. Oral appliances (e.g., jaw advancing device, mandibular advancement device) may be used as a substitute for CPAP or surgery. There are many kinds of oral appliances but in general the goal is to increase the size of the upper airway by moving the jaw forward. Fabricated oral appliance (OA) devices are custom made to minimize or alleviate airway obstruction by repositioning the mandible and tongue forward which increases upper airway dimensions.[2] According to the American Academy of Sleep Medicine, “mandibular repositioning appliances (MRA) cover the upper and lower teeth and hold the mandible in an advanced position with respect to the resting position. Tongue retaining devices (TRD) only hold the tongue in a forward position with respect to the resting position, without mandibular repositioning.”[2] More recently, prefabricated oral appliances have been developed to treat OSA or as a transition device for patients waiting to receive a custom OA. These OAs are not custom fitted to the patient.

REGULATORY STATUS

Several prefabricated oral appliance devices have received marketing clearance through the U.S. Food and Drug Administration’s (FDA) 510(k) process.

EVIDENCE SUMMARY

Evaluating the safety and effectiveness of prefabricated oral appliance devices require large comparative studies comparing prefabricated appliances to custom-fit prefabricated oral appliances or other treatments for obstructive sleep apnea (OSA).

SYSTEMATIC REVIEWS

Tallamraju (2021) published a systematic review (SR) with meta-analysis that evaluated factors that predict adherence to oral appliance therapy in adults treated for OSA.[3] A total of

31 studies were included consisting of eight randomized controlled trials (RCTs), two controlled clinical trials, seven prospective cohort studies, and 11 retrospective cohort studies. Across the studies included in the meta-analysis, increased adherence with custom-made appliances was found, with a pooled mean difference of -1.34 (-2.02 to -0.66b) and low levels of heterogeneity ($I^2 = 0\%$). Weak correlations were found between adherence to oral appliance therapy and patient and disease characteristics including age, sex, obesity, apnea-hypopnea index (AHI), daytime sleepiness.

Johal and Agha (2018) published a SR that compared ready-made mandibular advancement appliances (MAAs) to custom-made MAAs, for patients with obstructive sleep apnea.[4] Three randomized controlled trials (RCTs) with low risk of bias were evaluated. The analysis outcome determined that custom-made MAAs showed a mean difference in the apnea-hypopnea index (-3.2; 95% confidence interval -5.18, -1.22; p=0.004), daytime sleepiness (-0.98; 95% confidence interval -1.97, 0.01; p=0.05), functional outcomes of sleep questionnaire scores (0.76; 95% confidence interval 0.14, 1.38; p =0.02), self-reported adherence (6.4-7 nights per week and 5-6.3 hours per night), and expressed preference ($p \leq 0.001$) when measured against the ready-made MAAs. The authors stated custom-made appliances clearly demonstrated advantages for clinical outcomes, patient preference, and commitment to wear the appliance.

RANDOMIZED CONTROLLED TRIALS

Johal (2017) published a randomized controlled trial (RCT) that compared custom-made mandibular repositioning devices to ready-made devices for patients with obstructive sleep apnea.[5] Patients received either a custom-made or ready-made device, for three months. Then, had a two-week wash-out period prior to cross-over to the other device. Twenty-five patients completed both trial arms. Complete treatment response with the custom-made appliance was 64% versus 24% with the ready-made appliance. In addition, the custom-made appliance improved health outcomes more than the ready-made appliance for daytime sleepiness and quality of life. Patient compliance and tolerance was better with the custom-made appliance. However, this study was short-term and limited in size.

Vanderveken (2008) published results of a small randomized controlled cross-over trial (n=35) which compared thermoplastic OAs to custom-made devices as a treatment of sleep apnea.[6] This RCT was included in the 2018 SR by Johal and Agha. At a four-month follow-up, results indicated that apnea-hypopnea index (AHI) score were only reduced in the custom device group. The overall success rate was better in the custom device group compared to the thermoplastic device group (60 vs. 31%; p=0.02), including snoring reduction. In addition, one-third of patients in the thermoplastic group had compliance failure due to insufficient overnight retention. These study result suggest superiority of custom-fit devices compared to thermoplastic prefabricated OAs; however, limitations of this study include small sample size which limits the conclusions that can be drawn.

NONRANDOMIZED STUDIES

Friedman (2012) published a case series of 180 patients with obstructive sleep apnea-hypopnea syndrome (OSAHS) comparing the efficacy of titratable thermoplastic devices (TPD) compared to custom-made mandibular advancement devices (MAD).[7] Of the 180 patients included in the review, 123 had TPD and 57 had custom fit devices. Patients were followed for 6 months and improvement was defined as ≥ 50% apnea-hypopnea index (AHI) reduction plus posttreatment AHI <20, and cure was defined as AHI <5. Both improvement and cure rates were significantly better with custom fit MADs compared to TPDs (91.2%/71.9% vs

77.2%/52.0%, =0.024/0.012). Adherence was also better in the MAD group compared to the TPD group. Authors concluded that custom-fit OAs were superior at treating OSAHA compared to prefabricated thermoplastic devices.

PRACTICE GUIDELINE SUMMARY

AMERICAN ACADEMY OF SLEEP MEDICINE

The 2009 American Academy of Sleep Medicine (AASM) guidelines on the evaluation, management, and long-term care of obstructive sleep apnea in adults recommend the use of custom oral appliances as a method for improving upper airway patency in patients with "mild to moderate OSA who prefer OAs to CPAP, or who do not respond to CPAP, are not appropriate candidates for CPAP, or who fail CPAP or behavioral measures such as weight loss or sleep position change."[2] Prefabricated OAs are not specifically addressed.

AMERICAN ACADEMY OF SLEEP MEDICINE AND AMERICAN ACADEMY OF DENTAL SLEEP MEDICINE

The AASM and the American Academy of Dental Sleep Medicine published a clinical practice guideline in 2015 for the treatment of obstructive sleep apnea and snoring with oral appliance therapy.[8] The guideline recommends that sleep physicians prescribe oral appliances, rather than no therapy, for adult patients who request treatment of primary snoring (without obstructive sleep apnea). The guideline further recommends that when oral appliance therapy is prescribed by a sleep physician for an adult patient with obstructive sleep apnea, that a qualified dentist use a custom, titratable appliance over non-custom oral devices. This recommendation is consistent with a 2019 update from the American Academy of Sleep Medicine regarding the definition of an effective oral appliance for the treatment of obstructive sleep apnea and snoring, which states "an oral appliance is custom fabricated using digital or physical impressions and models of an individual patient's oral structures and physical needs."[5]

AMERICAN COLLEGE OF PHYSICIANS

The 2013 American College of Physicians (ACP) guidelines for the management of OSA recommend custom mandibular advancement devices as an alternative therapy to CPAP treatment.[9] However, prefabricated OAs are not specifically addressed.

SUMMARY

There is not enough research to show an improvement in health outcomes with the use of prefabricated oral appliance devices as a treatment of obstructive sleep apnea (OSA). In addition, no evidence-based practice guidelines recommend prefabricated devices as a treatment of OSA. Therefore, prefabricated oral appliance devices are considered investigational as a treatment of obstructive sleep apnea.

REFERENCES

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CODES

NOTE: Prefabricated oral appliances used in the treatment of obstructive sleep apnea (OSA) should be reported with HCPCS code E0485. Codes 20999, 21085, 21110, or similar surgical CPT codes should not be used to report this device. In addition, HCPCS code E0486 should not be used because this code is specific to custom fabricated oral appliances. Finally, HCPCS codes specific to oral devices designed to treat other medical conditions (e.g., temporomandibular joint [TMJ] disorders, bruxism, fractures, etc.) should not be used to code for OSA devices/appliances.

Codes	Number	Description
CPT	None	
HCPCS	E0485	Oral device/appliance used to reduce upper airway collapsibility, adjustable or nonadjustable, prefabricated, includes fitting and adjustment

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