MEDICAL POLICY	
Policy Name:	Custom-Made Oral Appliances in the Treatment of Obstructive Sleep Apnea (OSA)
Policy Number:	MP-039-MD-DE
Responsible Department(s):	Medical Management
Provider Notice Date:	08/15/2019; 04/01/2019; 04/15/2018; 04/01/2017
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Products:	Highmark Health Options
Application:	All participating hospitals and providers
Page Number(s):	1 of 12

DISCLAIMER

Highmark Health Options medical policy is intended to serve only as a general reference resource regarding coverage for the services described. This policy does not constitute medical advice and is not intended to govern or otherwise influence medical decisions.

POLICY STATEMENT

Highmark Health Options may provide coverage under the Durable Medical Equipment (DME) benefits of the Company's Medicaid products for medically necessary oral appliances in the treatment of Obstructive Sleep Apnea (OSA) when specific criteria are met.

This policy is designed to address medical necessity guidelines that are appropriate for the majority of individuals with a particular disease, illness or condition. Each person's unique clinical circumstances warrant individual consideration, based upon review of applicable medical records.

The qualifications of the policy will meet the standards of the National Committee for Quality Assurance (NCQA) and the Delaware Department of Health and Social Services (DHSS) and all applicable state and federal regulations.

DEFINITIONS

Prior Authorization Review Panel – A panel of representatives from within the Pennsylvania Department of Human Services who have been assigned organizational responsibility for the review, approval and denial of all PH-MCO Prior Authorization policies and procedures.

Oral Appliances – A generic term used for devices that are inserted into the mouth to modify the structures of the upper airway (mandible, tongue, and other structures in the upper airway) for the purpose of relieving snoring and sleep apnea.

Tongue-Retaining Devices (TRD) – One of the two forms of oral appliances that uses a suction cavity to reposition the tongue. Most often used with edentulous patients and patients with snoring issues.

Mandibular Advancement Device (MAD) – The second of two oral appliances that are the most common forms of appliance. These appliances are anchored to the dental arches causing mandibular advancement. The mandibular advancement manipulates the anatomical structure of the airway, relieving collapse of the upper airway during sleep.

Apnea – Cessation of airflow for at least 10 seconds.

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

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.

Custom-Fabricated Oral Appliance – An oral appliance that is specifically created for the individual patient. It involves taking an impression of the patient's teeth and making a positive model of plaster or equivalent material. The basic materials are cut, bent, and molded using the positive model. Further trimming, bending, or other modifications may be required. A custom-fabricated oral appliance may include a prefabricated component (e.g., the joint mechanism).

Obstructive Sleep Apnea - As defined by the American Academy of Sleep Medicine, a sleep related breathing disorder that involves a decrease or complete halting airflow despite an ongoing effort to breathe.

Respiratory Disturbance Index (RDI) – This is the number of apneas, the number of hypopneas and the number of respiratory effort related arousals multiplied by 60 and then divided by total sleep time.

PROCEDURES

1. **In order for a custom-made oral appliance (E0486) to be considered an eligible service, the following medical necessity criteria must be met:**

   A. The patient is 18 years of age or older; AND

   B. The patient must have a face-to-face clinical evaluation by the treating physician prior to sleep test to assess the patient for obstructive sleep apnea. A dentist is not the treating physician in the context of this clinical examination; AND

   C. The patient has had a sleep study test and meets one of the following criteria:

      i. An apnea-hypopnea index (AHI) or respiratory disturbance index (RDI) is greater than or equal to 15 events per hour with a minimum of 30 events; OR

      ii. The AHI or RDI is greater than or equal to 5 events and less than or equal to 14 events per hour with a minimum of 10 events AND documentation of:

         a. Excessive daytime sleepiness (documented by either Epworth score of greater than 10 or MSL less than 6), impaired cognition, mood disorder, or insomnia; OR

         b. Hypertension, ischemic heart disease, or history of stroke; OR

      iii. If the AHI or the RDI is greater than 30 and meets either of the following:

         a. The patient is not able to tolerate a positive airway pressure device (e.g., the patient is unwilling or fail to adhere to the use CPAP/BiPAP, patient does not respond to PAP devices, the patient exhibits side effects affecting the nose or pharynx, or the patient's perceived lack of benefit of using PAP devices); OR

         b. The treating provider determines that the use of the positive pressure device is contraindicated (e.g., patients with CHF or COPD, patients expected to experience nocturnal arterial oxyhemoglobin desaturation due to conditions other than OSA [obesity hypoventilation syndrome], patients with inability to maintain a patent airway or adequately clear secretions, history of allergy or sensitivity to mask materials, recent facial, oral or skull surgery or trauma);

         OR

      iv. All sleep tests must be interpreted by a physician who holds either:

         a. Current certification in Sleep Medicine by the American Board of Sleep Medicine (ABSM); OR

         b. Current subspecialty certification in Sleep Medicine by a member of the American Board of Medical Specialists (ABMS); OR

         c. Completed a residency or fellowship training in a program approved by an ABMS board member and has completed all the requirements for subspecialty certification in sleep medicine except the examination itself and only until the time of reporting of the first examination for which the physician is eligible; OR

         d. An active staff membership of a sleep center or laboratory accredited by the American Academy of Sleep Medicine (AASM), Accreditation Commission for Health Care (ACHC) or the Joint Commission (formerly the Joint Commission on Accreditation of Healthcare Organizations [JCAHO]);

         AND

      v. Only the treating physician may order an oral appliance; AND

      vi. The patient must be under multidisciplinary care of a qualified dentist and a medical

practitioner for baseline evaluation, device selection, and titration, as well as outcome monitoring in order to achieve the best patient outcomes; AND

vii. The custom-made device must have a mechanism that is hinged or jointed on the sides, front, or palate and have a mechanism that allows for the mandible to be advanced; the device must be able to protrude the patient's mandible beyond the front teeth when adjusted to its maximum protrusion; the device must retain the adjustment setting when removed from the mouth; the device must maintain the adjusted mouth position during sleep and remain in a fixed place during sleep to prevent dislodging the device; AND

viii. Patients with OSA being treated with an oral appliance should return for periodic follow-up visits with the order provider. The purpose of the follow-up visits is to assess the patient for signs and symptoms of worsening OSA; AND

ix. Patients with OSA being treated with an oral appliance should undergo polysomnography or an attended cardio-respiratory sleep study with the oral appliance in place after final adjustments of fit have been performed. Repeat sleep study testing can be performed twice a year for follow-up.

Note: Oral appliances are considered medically necessary for the treatment of Obstructive Sleep Apnea Syndrome (OSAS) in children with craniofacial anomalies.

2. Contraindications

A. Temporomandibular joint dysfunction

B. Periodontal disease

C. Severe Sleep Apnea (RDI ≥ 40)

3. When the oral appliances are not covered

A. Oral appliances are considered experimental/investigational for conditions other than those listed because the scientific evidence has not been established. These conditions may include and are not limited to: treatment of snoring without a diagnosis of OSA, appliances used to treat other dental conditions, and appliances used to treat temporomandibular joint (TMJ) disorder. Services are considered not medically necessary.

B. Over-the-counter appliances and prefabricated oral appliances are not covered, therefore not medically necessary.

C. Oral appliances or functional orthopedic appliances in the treatment of children with Obstructive Sleep Apnea Syndrome (OSAS) are considered experimental/investigational and therefore not medically necessary.

4. Post-payment Audit Statement

The medical record must include documentation that reflects the medical necessity criteria and is subject to audit by Gateway Health℠ at any time pursuant to the terms of your provider agreement.

5. Place of Service

The place of service for oral appliances is outpatient.

6. Length of Coverage

An oral appliance is eligible for replacement at the end of its five-year reasonable useful lifetime. Oral appliances may be replaced prior to the end of this time frame in cases of loss, theft, or irreparable damage. Examples of irreparable damage include damage that is the result of a specific accident or a natural disaster.

GOVERNING BODIES APPROVAL

A number of oral appliances have received clearance through the 501(k) pathway of the FDA for the treatment of snoring and mild-to-moderate sleep apnea. A few examples include: Narval CC™, Lamberg Sleep Well-Smarttrusion, 1st Snoring Appliance, Full Breath Sleep Appliance, PM Positioner, Snorenti, Snorex, Osap, Desra, Elastomeric Sleep Appliance, Snoremaster Snore Remedy, Snore-no-More, Napa, Snoar™, Open Airway Appliance, Equalizer Airway Device, SomnoDent, Saud, Kealway, Herbst, Tap, Tap™, E.M.A., Silencer, MPowRx™.

Additional information is available at:
http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/IVDRegulatoryAssistance/ucm1241 05.htm.

Medicare
No National Coverage Determination is documented.

There are several Local Coverage Determinations regarding medically necessary oral appliances in the treatment of obstructive sleep apnea.

Noridian LCD 33611
A custom-fabricated mandibular advancement oral appliance (E0486) used to treat obstructive sleep apnea (OSA) is covered if criteria A - D are met:

A. The beneficiary has a face-to-face clinical evaluation by the treating physician prior to the sleep test to assess the beneficiary for obstructive sleep apnea testing.

B. The beneficiary has a Medicare-covered sleep test that meets one of the following criteria (1 - 3):
    i. The apnea-hypopnea index (AHI) or Respiratory Disturbance Index (RDI) is greater than or equal to 15 events per hour with a minimum of 30 events; or
    ii. The AHI or RDI is greater than or equal to 5 events and less than or equal to 14 events per hour with a minimum of 10 events and documentation of:
        a. Excessive daytime sleepiness, impaired cognition, mood disorders, or insomnia; or
        b. Hypertension, ischemic heart disease, or history of stroke; or
    iii. If the AHI > 30 or the RDI > 30 and meets either of the following (a. or b.):
        a. The beneficiary is not able to tolerate a positive airway pressure (PAP) device; or
        b. The treating physician determines that the use of a PAP device is contraindicated.

C. The device is ordered by the treating physician following a review of the report of the sleep test. (The physician who provides the order for the oral appliance could be different from the one who performed the clinical evaluation in criterion A.)

D. The device is provided and billed for by a licensed dentist (DDS or DMD).

If all of these criteria (A-D) are not met, the custom-fabricated oral appliance (E0486) will be denied as not reasonable and necessary.

A prefabricated oral appliance (E0485) will be denied as not reasonable and necessary. There is insufficient evidence to show that these items are effective therapy for OSA.

Custom-fabricated mandibular advancement devices that have not received a written coding verification from the Pricing, Data Analysis, and Coding (PDAC) contractor will be denied as not reasonable and necessary.

CODING REQUIREMENTS

Procedure Codes

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

Non-covered Procedure Code

HCPCS Code	Description
E0485	Oral device/appliance used to reduce upper airway collapsibility, adjustable or nonadjustable, prefabricated, includes fitting and adjustment.

Diagnosis Codes

ICD-10 Codes	Description
G47.33	Obstructive sleep apnea (adult) (pediatric) [OSAS]
M26.00	Unspecified anomalies of jaw size (craniofacial anomalies that obstruct the upper airway)
M26.01	Maxillary hyperplasia
M26.02	Maxillary hypoplasia
M26.03	Mandibular hyperplasia
M26.04	Mandibular hypoplasia
M26.05	Macrogenia
M26.06	Microgenia
M26.07	Excessive tuberosity of the jaw
M26.09	Other specified anomalies of the jaw size
M26. 10	Unspecified anomaly of the jaw-cranial base relationship
M26.11	Maxillary asymmetry
M26.12	Other jaw asymmetry
M26.13	Other specified anomalies of jaw-cranial base relationship

REIMBURSEMENT

Participating facilities will be reimbursed per their Highmark Health Options contract.

SUMMARY OF LITERATURE

Obstructive sleep apnea (OSA) is a common condition in which the airway becomes obstructed during sleep which causes periods of apnea and hypopnea due to repetitive collapse of the upper airway during sleep. Recent studies have indicated that 1 in 4 adults in the United States (31% of all men and 21% of all women over age 18) are at high risk for developing OSA (National Sleep Foundation, 2005).
Complications from OSA include excessive daytime sleepiness, mental impairment, metabolic dysfunction, cardiovascular problems, heart attack, stroke, diabetes, impotence, acid reflux, and even death if untreated.

OSA occurs at one or more levels of the nasopharyngo-tracheal airway. Type I disease involves narrowing or collapse of the retropalatal region. Type II disease involves collapse in the retrolingual area (tongue base). Type III disease involves narrowing or collapse of both the retropalatal and retrolingual areas. Major OSA is usually a multi-level disorder, with tissues of the soft palate, lateral pharyngeal walls, and tongue base all contributing to airway impingement. Intra-nasal tissue, adenoids, and tonsils may also play a role (AASM, 2008).

Management of OSA is based on symptomatology, the severity of the disease, and patient education regarding the risk factors and associated outcomes of OSA. Management begins with appropriate diagnostic testing to confirm OSA diagnosis. Several behavior modifications are recommended for patients with OSA and a modifiable risk factor. These include education, weight loss and exercise, sleep positioning, alcohol avoidance, and concomitant medications.

The desired outcome of all OSA treatment modalities (Kryger & Malhotra, 2016) is the resolution of signs and symptoms of OSA and the normalization of sleep quality, the apnea hypopnea index (AHI), and oxyhemoglobin levels.

Mechanical treatment measures include positive airway pressure with a CPAP or bi-level positive airway pressure (BiPAP) device and oral appliance (OA) therapy. CPAP is the standard treatment option for OSA and generally can reverse this condition quickly with the appropriate titration of devices.

OAs are indicated for (1) patients with mild-to-moderate OSA who prefer oral appliances to CPAP devices; (2) patients with mild-to-moderate OSA who do not respond to CPAP therapy; and (3) patients with mild- to-moderate OSA for whom treatment attempts with CPAP devices fail. They should not be considered effective therapy for patients with severe OSA.

In 2013, the American College of Physicians (ACP) reviewed treatment options for OSA. The guidelines do not support surgical treatment since the evidence is insufficient, and there are risks. This organization prefers weight loss if needed and the use of CPAP. In situations in which the patient will not use the CPAP device, the ACP guidelines suggest the use of a mandibular advancement device as an alternative treatment option.

The American Academy of Sleep Medicine (AASM) has published practice parameters and a review of the use of OAs in persons with OSA. These parameters include the following recommendations:

- The presence or absence of OSA must be determined before treatment with OAs is started in order to identify patients at risk because of complications of sleep apnea and to provide a baseline to establish the effectiveness of subsequent treatment.
- For patients with OSA, the desired outcome of treatment includes resolution of the clinical signs and symptoms of OSA and normalization of the patient's AHI and oxyhemoglobin saturation.
- Although OA therapy is not as effective as CPAP, OAs are indicated for use in patients with mild- to-moderate OSA who prefer OAs to CPAP, those whose condition does not respond to CPAP, those who are not appropriate candidates for CPAP, and those in whom attempted CPAP or behavioral measures (e.g., weight loss, changing sleeping positions) fail.
- Patients with severe OSA should receive an initial trial of nasal CPAP because CPAP is more effective than OA therapy. Upper airway surgery may also supersede the use of OAs in patients for whom these operations are predicted to be highly effective in treating sleep apnea.
- To ensure satisfactory therapeutic benefit from OAs, patients with OSA should undergo polysomnography or an attended cardiorespiratory (type 3) sleep study with the OA in place after final adjustment of fit is performed.

According to the standards and guidelines listed above, the major role for OA therapy appears to be the treatment of patients with mild-to-moderate OSA who cannot tolerate CPAP (and BiPAP) therapy. These devices are relatively unlikely to benefit patients with severe OSA. Clinicians and patients prefer a titratable device, such as a mandibular repositioner, because it can be adjusted to improve both effectiveness and comfort.

AHI may increase with OA treatment. A change in AHI may be due to weight change between the first study and the final OA titration, not always due to the OA appliance itself. Also recognize that the AHI may vary from night to night because of the degree of severity of the obstructive sleep apnea itself; persons with mild-to-moderate obstructive sleep apnea have higher AHI variability compared with those who have more severe obstructive sleep apnea; OA therapy is not typically used in patients with more severe obstructive sleep apnea.

A review of the literature by the American Sleep Disorders Association (ASDA) indicated the following findings:

- Overall, 51% of patients studied achieved an RDI of less than 10 with OA therapy.
- Of patients who had a pretreatment RDI of greater than 20, 39% continued to have an RDI above this level despite OA therapy. At least one randomized controlled trial demonstrated that OAs have better success rates in patients with mild OSA (81%) than in those with moderate (60%) or severe (25%) OSA.
- Continuous adjustment or replacement, as needed, improves success rates with OAs in the long term.
- No patient characteristics predicted success with OA therapy.
- No particular OA had any advantages over the others studied.
- Some patients have an increase in AHI with OA treatment.
- Endpoints assessed in the studies of OAs varied and included an RDI of less than 10, an RDI of less than 20, or a greater than 50% reduction in the AHI. This variation made the comparison of results difficult. Furthermore, many studies did not stratify patients by severity of OSA.
- OAs were more likely to be successful in patients with low BMIs, at a young age, with a small neck circumference, with a short soft palate, or with a small oropharynx and in treating positional OSA, as based on retrospective data analysis.

In a randomized one-month crossover trial involving both CPAP and mandibular advancement devices (MAD), the effects of treatment on cardiovascular and neurobehavioral outcomes were compared (Phillips, 2013). Cardiovascular measurements (24-hour blood pressure and arterial stiffness) and neurobehavioral findings (subjective sleepiness, driving simulator performance), and quality of life were compared between the two treatments. There were 126 trial participants with moderate to severe OSA who were randomly assigned to a treatment order. There were a total of 108 who completed the trial. CPAP was more effective than MAD in reducing AHI, however, there was higher compliance with the MAD. The 24-hour mean arterial pressure was not inferior on treatment with MAD compared to CPAP. Overall, neither treatment improved blood pressure. On the other hand, sleepiness, driving simulator performance, and disease-specific quality of life improved on both treatments by similar amounts. It was reported that MAD was superior to CPAP for improving four general quality-of-life domains. The author concluded that health outcomes were similar after one month of optimal MAD and CPAP treatment in patients with moderate to severe OSA.

An Agency for Healthcare Research and Quality (AHRQ) comparative effectiveness report states that despite no evidence or weak evidence on clinical outcomes, given the large magnitude of effect on the important intermediate outcomes of apnea-hypopnea index (AHI), Epworth Sleepiness Scale (ESS), and other sleep study measures, overall, the strength of evidence is moderate that mandibular advancement devices (MAD) are an effective treatment for OSA in patients without comorbidities (including periodontal disease) or excessive sleepiness. However, the strength of evidence is insufficient to address which patients might benefit most from treatment. The strength of evidence is insufficient regarding comparisons of different oral devices. Despite no evidence or weak evidence on clinical outcomes, overall the strength of evidence is moderate that the use of CPAP is superior to MAD. However, the strength of evidence is insufficient to address which patients might benefit most from either treatment. Comparative studies focusing on long-term follow-up and clinical outcomes are needed (Balk et al., 2011).

Bratton et al. (2015) compared the association of CPAP, MADs and inactive control groups (placebo or no treatment) with changes in systolic blood pressure and diastolic blood pressure in patients with OSA. A network meta-analysis was used to estimate pooled differences between each intervention. Of the 51 randomized studies included in the analysis (n=4888), 44 compared CPAP with an inactive control, 3 compared MADs with an inactive control, 1 compared CPAP with an MAD and 3 compared CPAP, MADs, and an inactive control. Both CPAP and MADs were associated with reductions in blood pressure. Network meta-analysis did not identify statistically significant differences among the blood pressure outcomes associated with these therapies.

The Epworth Sleepiness Scale

The Epworth Sleepiness Scale is widely used in the field of sleep medicine as a subjective measure of a patient's sleepiness. The test is a list of eight situations in which you rate your tendency to become sleepy on a scale of 0, no chance of dozing, to 3, high chance of dozing. When you finish the test, add up the values of your responses. Your total score is based on a scale of 0 to 24. The scale estimates whether you are experiencing excessive sleepiness that possibly requires medical attention.

How Sleepy Are You?
How likely are you to doze off or fall asleep in the following situations? You should rate your chances of dozing off, not just feeling tired. Even if you have not done some of these things recently try to determine how they would have affected you. For each situation, decide whether or not you would have:

- No chance of dozing = 0
- Slight chance of dozing = 1
- Moderate chance of dozing = 2
- High chance of dozing = 3

Write down the number corresponding to your choice in the right-hand column. Total your score below.

Situation	Chance of Dozing
Sitting and reading	
Watching TV	
Sitting inactive in a public space (e.g., theater or a meeting)	
As a passenger in a car for an hour without a break	
Lying down to rest in the afternoon when circumstances permit	
Sitting and talking to someone	
Sitting quietly after a lunch without alcohol	
In a car, stopped for a few minutes in traffic	
Total Score:	

Analyze Your Score

Interpretation

0-7: It is unlikely that you are abnormally sleepy.
8-9: You have an average amount of daytime sleepiness.
10-15: You may be excessively sleepy depending on the situation. You may want to consider seeking medical attention.
16-24: You are excessively sleepy and should consider seeking medical attention.

Reference: Johns MW. A new method for measuring daytime sleepiness: The Epworth Sleepiness Scale. Sleep. 1991; 14(6):540-5. Located at: https://www.slhn.org/docs/pdf/neuro-epworthsleepscale.pdf

POLICY SOURCE(S)

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Policy History

Date	Activity
11/01/2016	Initial policy developed
03/14/2017	QI/UM Committee Approval
05/01/2017	Provider effective date
08/09/2017	Added Disclaimer Statement in opening of medical policy. EHS Revisions: Added Issue Date to opening policy box; Added 'Covered' to procedure code table in Attachment B and diagnosis codes in Attachment C; Added Noncovered Procedure Code E0485 in separate table under Attachment C; Added 'Informational' to Table D.
12/20/2017	Annual Review: Added patient age to criteria under Procedures and Operational Guidelines for clarification.
03/13/2018	QI/UM Committee Review Approval
04/25/2018	Revision: Removed the word 'Covered' from the procedure and diagnosis code tables in Attachments B & C
05/15/2018	New Provider Effective Date
07/26/2018	Removed the word 'Covered' from the procedure and diagnosis code tables in Attachments B & C; Clarified Operational Guidelines related to E0485 & E0486.
03/12/2019	Annual review: No criteria changes; added two new definitions for OSA and RDI; included conditions that are considered not covered under Section 3; removed the hyperlinks from all references. Corrected typographical error in Dx Codes: change M26.13 to M26.19.
03/12/2019	QI/UM Committee Review Approval
05/06/2019	Provider effective date
07/10/2019	Revision: Criteria was added to C.3.a. and C.3.b. due to internal operations
07/16/2019	QI/UM Committee Review Approval
09/16/2019	Provider Effective Date