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Origination Date	06/01/2024
Originated Department	Medical Management

Standard Operating Procedure (SOP) – Oral Appliances for Obstructive Sleep Apnea

Audience
Medical Management, Claims

Purpose
<p>Medical policies provide general support for applying Mountain Health Co-Op member policy document coverage decisions, and the member-specific benefit plan document must be referenced. The terms of the member-specific Policy document may differ from the standard benefit plan based on this medical policy. If there is a conflict between a member-specific policy document and the Mountain Health Co-Op medical policy, the document supersedes this policy. Any person(s) applying this medical policy must identify member eligibility, the member-specific policy document, and related policies or guidelines before applying this medical policy, including the existence of any state or federal guidance. Mountain Health Co-Op medical policies are designed for informational purposes only and are not an authorization, explanation of benefits, or contract. Receipt of benefits is subject to the satisfaction of all terms and conditions of the member-specific policy document coverage. Mountain Health Co-Op reserves the sole discretionary right to modify all policies and guidelines at any time.</p>

Definition
<p>Obstructive Sleep apnea (OSA) is a common disorder in which a patient has one or more pauses in breathing or shallow breaths while they sleep due to the collapse of upper airway tissues blocking the airway during sleep. Breathing pauses can last from a few seconds to minutes and often occur 30 times or more an hour.</p> <p>Multiple invasive and noninvasive therapies are used to treat this problem. The ‘gold standard’ therapy remains continuous positive airway pressure (CPAP) or bi-level positive airway pressure (BiPAP). Some patients do not optimally respond to this therapy, have a disease mild enough that alternative therapies are considered reasonable, or do not tolerate noninvasive</p>

airway therapy. Many other invasive and noninvasive therapy choices are considered depending on the patient's characteristics. One option often selected for individuals with mild to moderate disease is mandibular advancement therapy using an oral appliance. This appliance advances the jaw and is intended to open the airway to treat airway obstruction.

Oral appliances impact the airway by repositioning the mandible in vertical (open) and anterior positions. The exact mechanism by which mandibular repositioning impacts the airway is not fully understood. Still, it is believed to affect the musculature of the tongue and muscles that support the upper airway. It has been demonstrated that the upper airway is narrower during sleep in patients with OSA compared with those without apnea and that improvements in the lateral aspect of the upper airway play an essential role in managing patients with OSA.

The net effect of an oral device on the upper airway is mediated by its impact on the musculature that involves the tongue and soft tissues of the airway. With mandibular repositioning, the airway and tongue are stabilized; this prevents collapse, narrowing, and obstruction of the upper airway, which can be seen with OSA and snoring. Mandible repositioning also has a beneficial effect on the velopharyngeal area. This is most likely related to changes in the palatopharyngeus muscle, which enhances the ability of the patient to breathe nasally. In addition, with the mandible repositioned, there is increased tension on the soft palate, reducing its potential for collapse. Improvement in nasal breathing and diminished soft palatal collapse increase the efficacy of oral devices in managing OSA.

There are two primary types of oral appliances: prefabricated and custom. A prefabricated oral appliance (E0485) is one that is manufactured in quantity without a specific beneficiary in mind. A prefabricated oral appliance may be trimmed, bent, molded (with or without heat), or otherwise modified for use by a specific beneficiary (i.e., custom-fitted). Any appliance that does not meet the definition of a custom-fabricated oral appliance is considered prefabricated. E0485 is used for all prefabricated oral appliances used for the treatment of OSA, including, but not limited to, mandibular advancement devices, tongue positioning appliances, etc.

The second type is a custom-fabricated oral appliance (E0486) uniquely made for an individual beneficiary. It involves taking an entire arch, a negative impression of the beneficiary's teeth using appropriate materials or digital images, from which a positive model is created. Basic materials are then cut, bent, and molded using the positive model to construct the final oral appliance. A custom-fabricated oral appliance may include a prefabricated component with modifications specific to the individual intended to use the device.

Policy/Procedure

Mountain Health, Co-Op Health Plans, covers custom fabricated oral appliances as monotherapy using HCPCS code E0486 for treating obstructive sleep apnea when coverage criteria are met.

Mountain Health Co-op Plans does not cover any oral appliances as they are a benefit exclusion and are therefore non-covered for obstructive sleep apnea (OSA) in the following circumstances:

- Oral appliances that are available over the counter;
- Oral appliances that are prefabricated;
- Oral appliances used as a treatment for snoring without a diagnosis of OSA;
- Oral appliances used to treat dental conditions such as bruxism;
- Concurrent coverage of an oral appliance and a CPAP or BIPAP to treat OSA as duplicate therapies when intended only for personal comfort or convenience.

Mountain Health Co-op Plans does not cover E0485, oral device/appliance used to reduce upper airway collapsibility, adjustable or nonadjustable, prefabricated, and includes fitting and adjustments. These are considered a non-covered benefit as they are available over the counter without a prescription.

Elements considered bundled into E0486 include all time, labor, materials, professional services, and radiology and lab costs necessary to provide and fit the device. All fittings, adjustments, modifications, and professional services required during the first 90 days after the provision of the oral appliance are also considered to be included in the payment for the device.

After the initial 90-day period, adjustments, modifications, and follow-up visits are not eligible for coverage under the DME benefit as these are considered dental-related and thus excluded from coverage under the medical benefit.

Repairs are covered for items that meet the coverage criteria. To repair means to fix or mend and to put the item back in good condition after damage or wear. Repairs are covered when necessary to make the item serviceable. If the repair expense exceeds the estimated cost of purchasing another item, no payment can be made for the excess.

A qualified dentist or physician sleep specialist may perform evaluation, measurement, and impressions for and instruction on using these devices.

Evaluation, measurement and impressions, instruction on use, and post-fabrication adjustments are considered part of the global fee for the appliance and are not reimbursed as separate services.

CPT/HCPCS codes considered bundled into E0486 include the following:

- **21085** - Impression and custom preparation; oral surgical splint
- **21089** - Unlisted maxillofacial prosthetic procedure
- **21110** - Application of interdental fixation device for conditions other than fracture or dislocation, includes removal
- **70350** - Cephalogram, orthodontic
- **70355** - Orthopantomogram (eg, panoramic x-ray)
- **70486** - Computed tomography, maxillofacial area; without contrast material
- **70487** - Computed tomography, maxillofacial area; with contrast material(s)
- **70488** - Computed tomography, maxillofacial area; without contrast material, followed by contrast material(s) and further section

- **76497** - Unlisted computed tomography procedure (eg, diagnostic, interventional) Code used for Cone Beam CT
- **99202-99205, 99211-99215** – Evaluation/Management codes

Applicable Coding

HCPCS Codes

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

Non-covered codes

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

Bundled services, these services are not payed separately in addition to the appliance

21085 Impression and custom preparation; oral surgical splint 21089 Unlisted maxillofacial prosthetic procedure

21110 Application of interdental fixation device for conditions other than fracture or dislocation, includes removal

70350 Cephalogram, orthodontic

70355 Orthopantomogram (eg, panoramic x-ray)

70486 Computed tomography, maxillofacial area; without contrast material

70487 Computed tomography, maxillofacial area; with contrast material(s)

70488 Computed tomography, maxillofacial area; without contrast material, followed by contrast material(s) and further section

76497 Unlisted computed tomography procedure (eg, diagnostic, interventional) (Used for Cone Beam CT)

99202-99205 Office or other outpatient visit for the evaluation and management of a new patient,

99211-99215 Office or other outpatient visit for the evaluation and management of an established patient, that may not require the presence of a physician or other qualified health care professional

References

1. <https://aasm.org/>
2. <https://www.cms.gov/medicare-coverage-database/details/article/details.aspx?articleId=52512&ver=22&LCDId=33611&DocID=L33611&bc=gAAAAABABAAAA&>

3. <https://www.cms.gov/medicare-coverage-database/details/lcddetails.aspx?LCDId=33611&ver=14&DocID=L33611&bc=gAAAAABABAAAA&>

Vendors

- Health Plan Services (HPS)

Review/Revision/Approval History

Date	Description
06/01/2024	New Policy

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The codes for treatments and procedures applicable to this policy are included for informational purposes. Including or excluding a procedure, diagnosis, or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as they apply to an individual member.

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