Reimbursement Fast Facts

This tool will assist you in understanding Medicare coding and coverage for oral appliance therapy to treat obstructive sleep apnea (OSA).

Oral appliances, also referred to as mandibular repositioning devices (MRDs), are indicated for patients with OSA. ResMed’s Narval™ CC MRD is designed to optimize patient compliance and treatment efficacy.

<table>
<thead>
<tr>
<th>Device</th>
<th>Description</th>
<th>HCPCS</th>
<th>Medicare Jurisdiction D 2011 rate: $1290.63¹</th>
<th>Priced by each DME Medicare Administrative Contractor (DME MAC).</th>
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<tbody>
<tr>
<td>Narval CC</td>
<td>Oral device/appliance used to reduce upper airway collapsibility, adjustable or non-adjustable, custom fabricated, includes fitting and adjustment</td>
<td>E0486 Note: Follow-up care, fitting, adjustments, modifications, professional services (not all-inclusive) required during first 90 days after provision of oral appliance are included in payment for the device.</td>
<td>Medicare Jurisdiction D 2011 rate: $1290.63¹</td>
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<td>FDA cleared under K113201</td>
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**Billing Criteria**

Medicare has specific criteria for coverage of oral appliances for treatment of OSA. Please refer to the local coverage policy for additional details.²

Please note to bill for E0486, the provider must enroll in Medicare as a DMEPOS supplier to be eligible for Medicare reimbursement for billing a custom fabricated oral appliance.

**Key Coverage Criteria for Oral Appliances**

A custom fabricated mandibular advancement oral appliance (E0486) used to treat OSA is covered if criteria A–D are met.

A. The patient has a face-to-face clinical evaluation by the treating physician prior to the sleep test to assess the patient for OSA.

B. The patient has a Medicare-covered sleep test that meets one of the following criteria (1–3):

1. 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

2. The AHI or RDI is greater than or equal to 5 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

3. If the AHI>30 or the RDI>30 and meets either of the following (a or b):
   a. The patient 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 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). A written signed and dated order must be received by the supplier before a claim is submitted. If the supplier bills for an item without first receiving the completed order, the item will be denied as not medically necessary.

**Qualifications for an E0486:**

Code E0486 may only be used for custom fabricated mandibular advancement devices. The only products which may be billed using code E0486 are those products for which a written coding verification has been made by the Pricing, Data Analysis and Coding (PDAC) contractor.

To be coded as E0486, custom fabricated mandibular advancement devices must:

1. have a fixed mechanical hinge³ at the sides, front or palate; and
2. be able to protrude the individual beneficiary’s mandible beyond the front teeth when adjusted to maximum protrusion; and
3. incorporate a mechanism that allows the mandible to be easily advanced by the beneficiary in increments of one millimeter or less; and
4. retain the adjustment setting when removed from the mouth; and
5. maintain the adjusted mouth position during sleep; and
6. remain fixed in place during sleep so as to prevent dislodging the device; and
7. require no return dental visits beyond the initial 90-day fitting and adjustment period to perform ongoing modification and adjustments in order to maintain effectiveness.
Key Definitions
Per Medicare policy, physician refers to a licensed MD, DO, nurse practitioner, clinical nurse specialist or physician's assistant working within their scope of practice. The term physician does not include a dentist (DDS or DMD).

Apnea is defined as the cessation of airflow for at least 10 seconds.

Hypopnea is defined as an abnormal respiratory event lasting at least 10 seconds associated with at least a 30% reduction in thoracoabdominal movement or airflow as compared to baseline, and with at least a 4% decrease in oxygen saturation.

The AHI is defined as the average number of episodes of apnea and hypopnea per hour of sleep without the use of a PAP device.

The RDI is defined as the average number of apneas plus hypopneas per hour of recording without the use of a PAP device. For purposes of this policy, respiratory effort related arousals (RERAs) are not included in the calculation of the RDI. The RDI is reported in Type III, Type IV and other home sleep studies.

If the AHI or RDI is calculated based on less than two hours of sleep or recording time, the total number of recorded events used to calculate the AHI or RDI (respectively) must be at least the number of events that would have been required in a two-hour period (ie, must reach ≥30 events without symptoms or ≥10 events with symptoms).

A Medicare-covered sleep test must be either a polysomnogram (PSG) performed in a facility-based laboratory (Type I study) or a home sleep test (HST) (Types II, III, IV or other). All sleep tests must be interpreted by a physician who holds either (required as of 11/1/08 for interpretation of HST and as of 1/1/10 for facility-based tests):

1. Current certification in sleep medicine by the American Board of Sleep Medicine (ABSM); or
2. Current subspecialty certification in sleep medicine by member board of American Board of Medical Specialists (ABMS); or
3. Completed training by ABMS member board and completed all requirements for subspecialty certification in sleep except exam itself; or
4. Active staff of a sleep center or lab accredited by the American Academy of Sleep Medicine (AASM), Accreditation Commission for Health Care (ACHC) or The Joint Commission.

No aspect of HST, including, but not limited to, delivery and/or pickup of the device, may be performed by a DME supplier.

Q & A
Q: Will prefabricated oral appliances or tongue repositioning devices be covered by Medicare?
Custom fabricated appliances that achieve their effect through positioning of the tongue (E1399) and are a prefabricated oral appliance (E0485) will both be denied as not reasonable and necessary.

Q: Does Medicare cover other dental conditions?
No, oral appliances used to treat other dental conditions are not covered by Medicare. Oral occlusal appliances used to treat temporomandibular joint (TMJ) disorders are considered dental-related items and are not covered by Medicare.

Q: What qualifies a product as an E0486?
Custom fabricated mandibular advancement devices must receive a written coding verification from the PDAC contractor.

Q: What additional information will be needed with each submitted claim?
The ICD-9 diagnosis code that justifies the need for the item must be included on the claim, and suppliers must add a KX modifier to a code only if all of the criteria in the coverage policy have been met. If the requirements for the KX modifier are not met, the KX modifier must not be used.

Q: What is billable past the initial 90 days?
After the initial 90-day period, adjustments, modifications and follow-up visits are not eligible for coverage under the Medicare DME benefit and are therefore not within the jurisdiction of the DME MAC.

Q: When can an oral appliance be replaced according to Medicare?
Oral appliances are eligible for replacement at the end of their five-year reasonable useful lifetime (RUL). These items may be replaced prior to the end of the five-year RUL in cases of loss, theft or irreparable damage. Irreparable damage refers to a specific accident or to a natural disaster (eg, fire, flood). Replacement due to wear and tear as the result of everyday use will be denied as statutorily non-covered prior to the expiration of the five-year RUL.