Oral Appliance Therapy - US

Key Points

1. Dentists CANNOT diagnose obstructive sleep apnea (OSA)
   The treating physician must render a diagnosis for OSA.

2. Dentists CANNOT prescribe/order oral appliance therapy (OAT)
   Dentists must have a written order from the treating physician on file before delivering the oral appliance to the patient and submitting the claim.

3. The written order for the OAT must contain:
   a. Beneficiary’s name
   b. Physician’s name, legible signature, NPI number, and signature date
   c. Date of the order and start date, if start date is different from the date of the order
   d. Detailed description of the item (narrative description or brand name/model number)

4. There is no dental insurance code for OAT
   OAs used for the treatment of OSA are billed to either medical insurance or Medicare because the dentist is treating the patient for a medical condition, and not a dental condition.

5. OAT billing guidelines based on the patient’s AHI
   a. AHI < 5: No coverage
   b. AHI 5-15 (Mild OSA): pre-authorization will need to include the patient’s co-morbidities (e.g. history of ischemic heart disease, stroke, hypertension, impaired cognition or mood disorders); if there are none, the Epworth Sleepiness Scale (ESS) must be greater than 11
   c. AHI 16-30 (Moderate OSA): OAT seen as first-line therapy therefore the pre-authorization does not need to include co-morbidities or the ESS
   d. AHI > 30 (Severe OSA): CPAP intolerance has to be shown before an oral appliance will be covered

HCPCS Codes Used in OAT Claim Submission

1. The most commonly used HCPCS (Healthcare Common Procedure Coding System) codes:
   a. **E0485** - Oral device/appliance used to reduce upper airway collapsibility, adjustable or non-adjustable, prefabricated, includes fitting and adjustment
   
   *Note: In most cases, insurance carriers and Medicare will not pay for prefabricated oral appliances as they see these types of appliances as not reasonable and necessary.*
b. **E0486** - Oral device/appliance used to reduce upper airway collapsibility, adjustable or non-adjustable, custom fabricated, includes fitting and adjustment

*Note*: Payment for the device using E0486 includes: follow-up care, fitting, adjustments, modifications, professional services (not all inclusive) required during the first 90 days after provision of the oral appliance.

Many insurance carriers will reimburse dentists for the initial patient evaluation separately (including X-ray imaging) and adjustment visits however, Medicare will not separately reimburse dentists for the initial evaluation.

**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:

i. Have a fixed mechanical hinge at the sides, front or palate; and

ii. Be able to protrude the individual beneficiary’s mandible beyond the front teeth when adjusted to maximum protrusion; and

iii. Incorporate a mechanism that allows the mandible to be easily advanced by the beneficiary in increments of one millimeter or less; and

iv. Retain the adjustment setting when removed from the mouth; and

v. Maintain the adjusted mouth position during sleep; and

vi. Remain fixed in place during sleep so as to prevent dislodging the device; and 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.

2. Other billable but not payable codes are:
   a. **A9270** - non covered items or services (i.e. for those appliances not on the PDAC list for E0486)
   b. **E1399** - miscellaneous DME. Can be used for custom fabricated appliances that achieve their effect through positioning of the tongue.

**HCPCS Codes Used in OAT Claim Submission**

1. **Diagnoses Supporting OAT as Medically Necessary**
   a. OSA (ICD-10-CM diagnostic code G47.33) – most frequently used to support OAT and must be included on the claim
   b. Upper Airway Resistance Syndrome (UARS) – only covered by some insurers if certain comorbidities exist and the RDI > 5
   c. Snoring – not covered by insurers when snoring is the primary diagnosis
2. Code Modifiers

<table>
<thead>
<tr>
<th>Modifier</th>
<th>Definition</th>
<th>When to Use the Modifier</th>
</tr>
</thead>
<tbody>
<tr>
<td>NU</td>
<td>Purchase of new and unused durable medical equipment; oral appliance is custom made for the patient</td>
<td>On every claim</td>
</tr>
<tr>
<td>KX</td>
<td>Requirements specified in the medical policy have been met</td>
<td>Only if all of the coverage criteria (A-D) have been met</td>
</tr>
<tr>
<td>GA</td>
<td>Item or service expected to be denied as not reasonable and necessary</td>
<td>Only if all the coverage criteria have NOT been met A valid ABN has been issued and is on file</td>
</tr>
<tr>
<td>GZ</td>
<td>Item or service expected to be denied as not reasonable and necessary</td>
<td>Only if all the coverage criteria have NOT been met No ABN has been issued</td>
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Note: Requirements for the use of modifiers vary from insurer to insurer.

Codes for Appliance Repair or Replacement

1. **K0739** – for repair of an oral appliance; to support such claims, the dentist must maintain detailed records describing the need, justification, and nature of all repairs

2. **Replacement** – a written order from the treating physician is required for confirm medical necessity and reasonableness of replacing the oral appliance

   Note: For Medicare, oral appliances are eligible for replacement at the end of their 5-year reasonable useful lifetime (RUL). In case of loss, theft and irreparable damage (i.e. accidents or natural disaster), appliances may be replaced before the end of the 5-year RUL.

Documentation Required to Support OAT Claims

1. Medical record of face-to-face exam of patient by treating physician
2. Diagnostic sleep study dated with the last 5 years
3. Written order (prescription) from treating physician for OAT
4. Patient’s medical records (includes Epworth Sleepiness Scale, AHI score, CPAP intolerance affidavit, alternate therapy, Narrative report of Questionnaires/clinical exam notes/referral forms (i.e. Medical Necessity forms)
5. FDA 510(k) approval of oral appliance
6. Correct coding
7. Proof of device delivery

Note: Documentation criteria for claims submission vary from insurer to insurer. A face-to-face exam may not be required by all insurers but it is mandatory for Medicare patients (i.e the patient must have a face-to-face clinical evaluation by the treating physician prior to the sleep test to assess the patient for OSA).
MEDICAL INSURANCE

Medical Insurance FACTS

1. Some medical insurance providers require dentists to have a Medicare Durable Medical Equipment (DME) supplier license to get reimbursement
2. On average, medical insurance covers between $800-$5000 for OAT
   Note: Since many insurance carriers will reimburse dentists for the initial patient evaluation separately, these visits can be billed using evaluation and management (E/M) codes: E/M codes 99201-99205 for new patients; E/M codes 99211-99215 for established patients.

3. To avoid claim rejection, dentists can become an In-Network Provider
4. OAT claims should be submitted after delivery of the appliance
5. If claims are denied, patient pays upfront in cash and gets reimbursement by private insurance

Becoming a Network Provider

1. Some, but not all, medical insurance carriers will allow dentists to become In-Network Providers of OAT for patients diagnosed with OSA
2. The dentist should contact the most commonly used medical insurance companies in their area to find out if OAT provider networks exist, and to request an application to participate
3. If there are other dentists In-Network in your area, you may lose the patient if you are Out-of-Network
4. Sometimes being In-Network for dental insurance, automatically includes In-Network for medical insurance

<table>
<thead>
<tr>
<th>IN-Network Provider</th>
<th>Out-of-Network Provider</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dentist has to take what the insurance carrier allows</td>
<td>Dentist can charge what they want</td>
</tr>
<tr>
<td>Can’t balance bill</td>
<td>Patient makes up the difference; take upfront payment prior to starting treatment</td>
</tr>
<tr>
<td>Out-of-pocket expenses for patients at the time of treatment may be as low as their co-pay and dental offices get reimbursed the difference within weeks</td>
<td>Can be different percentages and deductibles</td>
</tr>
</tbody>
</table>
Network Gap Exception

1. Designed to compensate for gaps in an insurance plan’s network of contracted providers (i.e. there are no In-Network Providers of OAT within a specific geographical area)
2. Many insurers provide a gap exception so that the subscriber can use an Out-of-Network Provider; this helps to reduce the patient’s out-of-pocket costs
3. The Out-of-Network Provider is paid the same rate as the In-Network provider
4. The dentist who is providing OAT must first submit a formal request to the medical insurance carrier for gap exception; documentation should include OAT delivery time-frame, list of In-Network providers near patient's location, explanation regarding why patient cannot be treated by those In-Network providers, and that you provide a nonsurgical, conservative and effective treatment for OSA

Note: Gap exceptions are not granted immediately and approved gap exceptions are only valid for a specific time frame.

Preapproval for OAT

1. The dentist must contact the insurers in their area to find out if preapproval is necessary
2. If preapproval is required, the steps are as follows:
   a. Precertification: process of confirming whether or not OAT is a service covered by the insurer
   b. Preauthorization: process of confirming whether the insurer considers OAT as medically necessary for the patient
   c. Predetermination: process of confirming the amount that the insurer will reimburse for OAT

MEDICARE

Medicare FACTS

1. Medicare is the federal health insurance program for people who are 65 years or older and is the largest medical insurer in the US
2. Medicare has certain criteria for coverage of custom made oral appliances for the treatment of OSA (i.e. the oral appliance needs to be on the P-DAC list)
3. All dentists, even those who are not enrolled in the Medicare program, must submit claims to Medicare for providing OAT to Medicare beneficiaries. There are 2 exceptions to this rule:
   a. The dentist formally opts out of the Medicare program
   b. The patient signs an Advanced Beneficiary Notice (ABN) of non-coverage electing the option that directs the dentist not to submit his or her claim to Medicare
4. The patient must sign a proof of delivery form when the appliance is received
**Medicare Billing Criteria**

1. To bill Medicare for DME items, a dental practice must enroll as a DME supplier. To enroll in the Medicare program, the dentist is required to complete the following actions:
   a. Obtain a National Provider Identifier (NPI) number
   b. Submit the CMS-855s application to the National Supplier Clearinghouse
   c. Submit form CMS-460 (Participating physician or supplier agreement)
   d. Submit form CMS-588 (Electronic funds transfer authorization agreement)

5. Dentists have the choice to enroll as a participating or a non-participating DME supplier
   a. A Participating DME Supplier - must accept the allowed Medicare amount as payment in full
   b. A Non-participating DME Supplier - can bill patients for difference between what Medicare covers vs. their fee

   **Note:** The allowed Medicare amount is 5% less for a non-participating DME supplier compared to a participating DME supplier.

6. Each claim must be submitted with modifier NU, and either modifier KX, GA or GZ or the claim will be rejected as missing information

7. **NEW** (as of Nov 2018): Dentists must now carry a Surety Bond in order to provide DME services to Medicare beneficiaries
   a. Surety Bond must provide $50,000 coverage minimum per practice location
   b. The dentist will have 60 calendar days form the date on the notification letter to obtain the Surety Bond
   c. The dentist can obtain a Surety Bond from their current general liability insurance company
   d. If the information is not provided within the allotted time frame, the dentist’s Medicare Plan will be deactivated. Once deactivated, the dentist will not be able to provide Medicare DME services, and will need to reapply

**Medicare Coverage Criteria**

1. The coverage criteria is different for mild, moderate and severe OSA
2. A custom made oral appliance (E0486) used to treat OSA is covered if criteria A–D are met

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

   **Note:** The physician who performs the evaluation prior to the sleep test does not necessarily have to be the same physician who writes the order (i.e. prescription) for the oral appliance in the dental practice.
B. The patient has a Medicare-covered sleep test that meets one of the following criteria (1–3):

01. 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
02. 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:
   iii. Excessive daytime sleepiness, impaired cognition, mood disorders, or insomnia; or
   iv. Hypertension, ischemic heart disease, or history of stroke; or
   v. If the AHI>30 or the RDI>30 and meets either of the following (a or b):
      vi. The patient is not able to tolerate a positive airway pressure (PAP) device; or
      vii. The treating physician determines that the use of a PAP device is contraindicated.

C. The oral appliance is ordered by the treating physician following review of the report of the sleep test.

   Note: 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 oral appliance can only be provided and billed for by a licensed dentist (DDS or DMD).

   Note: 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.

   Oral occlusal appliances used to treat temporomandibular joint (TMJ) disorders are considered dental-related items and are not covered by Medicare.

Medicare Jurisdictions

3. Each of the four Medicare DME Jurisdictions (A, B, C, D) have their own Medical Local Coverage Determination (LCD)
4. Medicare pays 80% of allowable amount (minus 2% sequestration fee)
5. Patient or secondary insurance pays 20% and sometimes up to the billed amount

<table>
<thead>
<tr>
<th>Medicare Jurisdiction</th>
<th>Allowable</th>
<th>Paid Amount</th>
<th>Patient 2nd insurance</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>$1,814.98</td>
<td>$1,422.94</td>
<td>$363.00</td>
</tr>
<tr>
<td>B</td>
<td>$1,354.87</td>
<td>$1,062.22</td>
<td>$270.97</td>
</tr>
<tr>
<td>C</td>
<td>$1,069.98</td>
<td>$838.86</td>
<td>$214.00</td>
</tr>
<tr>
<td>D</td>
<td>$1,369.74</td>
<td>$1,073.87</td>
<td>$273.95</td>
</tr>
</tbody>
</table>
Medicare Opt-out

1. The Dentist must file an affidavit with their Medicare jurisdiction
2. Lasts for a period of two years with an option to renew for subsequent two-year periods
3. The Dentist must enter into private contracts with all Medicare beneficiaries to whom the dentist renders services that would otherwise be covered by Medicare. By signing the private contract, the patient agrees to give up Medicare payment for services rendered by the dentist and pay the dentist without regard to any limits on the amount of the charges (the patient cannot submit the bill themselves to Medicare for services rendered).
4. Dentists who opt out cannot elect to opt out for some Medicare beneficiaries but not others, or for some services and not others
5. Only individuals can opt out, not group practices or organizations

Not Enrolling in Medicare

1. When a dentist does not enroll in the Medicare program, he/she is still obligated to submit claims to Medicare on the beneficiary’s behalf
2. In this case, prior to rendering the item or service that is usually covered by Medicare, the dentist is required to provide the Medicare beneficiary an Advance Beneficiary Notice of Noncoverage (ABN)

Advance Beneficiary Notice of Noncoverage (ABN)

1. ABNs are effective for 1 year; must be retained for 5 years
2. Informs beneficiary that Medicare is likely to deny payment for the specific claim, and that if Medicare denies the claim, the beneficiary will be liable for the full charge for the item or service
3. The ABN allows the beneficiary to make an informed decision as to whether to accept an item or service for which he/she may have to pay out-of-pocket or through medical insurance
4. If ABN is not issued, and Medicare denies the claim, then the dentist is liable for treatment and may not charge the beneficiary
5. Mandatory use of the ABN is indicated when:
   a. Dentist is not enrolled in the Medicare program
   b. The oral appliance is not a PDAC-approved device
6. OAT is not considered medically reasonable and necessary
7. Voluntary use of the ABN is seen as a courtesy to the Medicare beneficiary to forewarn them of potential financial obligations. In this case, the dentist is not required to adhere to the issuance guidelines (i.e. the beneficiary is not required to select an option or sign the document).
8. To avoid being subject to this and other Medicare rules and regulations, the dentist needs to opt out of the Medicare program entirely
Same or Similar (for Medicare patients in Jurisdiction A and D only)

<table>
<thead>
<tr>
<th>Days on CPAP</th>
<th>Eligibility for OAT</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt; 90</td>
<td><strong>Eligible</strong></td>
</tr>
<tr>
<td></td>
<td>• Patient must return CPAP and cease receiving (billing for) DME supplies</td>
</tr>
<tr>
<td></td>
<td>• A receipt for CPAP return should be obtained</td>
</tr>
<tr>
<td>&gt;= 90</td>
<td><strong>May be Eligible</strong></td>
</tr>
<tr>
<td></td>
<td>• Patient must return CPAP if still in rental period (obtain receipt)</td>
</tr>
<tr>
<td></td>
<td>• Patient must cease receiving (billing for) DME supplies</td>
</tr>
<tr>
<td></td>
<td>• The attending physician must complete a CPAP intolerance form and treatment for OAT (this will likely be denied)</td>
</tr>
<tr>
<td></td>
<td>• The physician must provide relevant documentation to support why OAT is reasonable and necessary (i.e. intolerance form, etc.)</td>
</tr>
<tr>
<td>&gt; 5 Years</td>
<td><strong>Eligible</strong></td>
</tr>
<tr>
<td></td>
<td>• Patient must cease receiving (billing for) DME supplies</td>
</tr>
</tbody>
</table>

Disclaimer: This information is intended to provide general background only. Coverage varies from state-to-state and payer-to-payer. Payer policy, billing, and coding guidelines change on a regular basis and it is the provider’s responsibility to seek specific directions and guidelines from their third party payers. Use of the information in these documents does not guarantee coverage or prior-authorization approval. Zephyr Sleep Technologies, Inc. will not be held liable for any denials, unpaid claims or loss of income that may result from a provider referencing this information.