

Local Coverage Determination (LCD) for Oral Appliances for Obstructive Sleep Apnea (L28603)

Contractor Information

Contractor Name

NHIC, Corp.

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Contractor Number

16003

Contractor Type

DME MAC

LCD Information

Document Information**LCD ID Number**

L28603

LCD Title

Oral Appliances for Obstructive Sleep Apnea

Contractor's Determination Number**AMA CPT/ADA CDT Copyright Statement**

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Primary Geographic Jurisdiction

Connecticut
District of Columbia
Delaware
Massachusetts
Maryland
Maine
New Hampshire
New Jersey
New York - Entire State
Pennsylvania
Rhode Island
Vermont

Oversight Region

Region I

DME Region LCD Covers

Jurisdiction A

Original Determination Effective Date

For services performed on or after 01/03/2011

Original Determination Ending Date**Revision Effective Date**

For services performed on or after 09/01/2011

Revision Ending Date**CMS National Coverage Policy****Indications and Limitations of Coverage and/or Medical Necessity**

For any item to be covered by Medicare, it must 1) be eligible for a defined Medicare benefit category, 2) be reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member, and 3) meet all other applicable Medicare statutory and regulatory requirements. For the items addressed in this medical policy, the criteria for "reasonable and necessary" are defined by the following indications and limitations of coverage and/or medical necessity.

For an item to be covered by Medicare, a written signed and dated order must be received by the supplier before a claim is submitted. If the supplier bills for an item addressed in this policy without first receiving the completed order, the item will be denied as not reasonable and necessary.

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

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

Custom fabricated appliances that achieve their effect through positioning of the tongue (E1399) will be denied as not reasonable and necessary. There is insufficient evidence to show that these items are effective therapy for OSA.

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.

Definitions

As used in this 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 apnea-hypopnea index (AHI) is defined as the average number of episodes of apnea and hypopnea per hour of sleep without the use of a positive airway pressure device. For purposes of this policy, respiratory effort related arousals (RERAs) are not included in the calculation of the AHI. Sleep time can only be measured in a Type I (facility-based polysomnogram) or Type II sleep study (see descriptions below).

The respiratory disturbance index (RDI) is defined as the average number of apneas plus hypopneas per hour of recording without the use of a positive airway pressure 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 2 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 2-hour period (i.e., must reach ≥ 30 events without symptoms or ≥ 10 events with symptoms).

Sleep Tests

Coverage and Payment rules for sleep tests may be found in the local coverage determinations (LCDs) for the applicable Medicare Part A or Part B contractor. There may be differences between those LCDs and the DME MAC LCD. For the purposes of coverage of oral appliances used to treat OSA, the DME MAC coverage, coding and payment rules take precedence.

Coverage of an oral appliance for the treatment of OSA is limited to claims where the diagnosis of OSA is based upon a Medicare-covered sleep test (Type I, II, III, IV, Other). A Medicare-covered sleep test must be either a polysomnogram performed in a facility-based laboratory (Type I study) or a home sleep test (HST) (Types II, III, IV, Other). The test must be ordered by the beneficiary's treating physician and conducted by an entity that qualifies as a Medicare provider of sleep tests and is in compliance with all applicable state regulatory requirements.

A Type I sleep test is the continuous and simultaneous monitoring and recording of various physiological and pathophysiological parameters of sleep with physician review, interpretation, and report. It is facility-based and must include sleep staging, which is defined to include a 1-4 lead electroencephalogram (EEG), and electro-oculogram (EOG), submental electromyogram (EMG) and electrocardiogram (ECG). It must also include at least the following additional parameters of sleep: airflow, respiratory effort, and oxygen saturation by oximetry. It may be performed as either a whole night study for diagnosis only or as a split night study to diagnose and initially evaluate treatment.

An HST is performed unattended in the beneficiary's home using a portable monitoring device. A portable monitoring device for conducting an HST must meet one of the following criteria:

- A. Type II device – Monitors and records a minimum of seven (7) channels: EEG, EOG, EMG, ECG/heart rate, airflow, respiratory movement/effort and oxygen saturation; or,
- B. Type III device – Monitors and records a minimum of four (4) channels: respiratory movement/effort, airflow, ECG/heart rate and oxygen saturation; or,

- C. Type IV device - Monitors and records a minimum of three (3) channels, one of which is airflow; or,
- D. Other - Devices that monitor and record a minimum of three (3) channels that include actigraphy, oximetry and peripheral arterial tone and for which there is substantive clinical evidence in the published peer-reviewed medical literature that demonstrates that the results accurately and reliably correspond to an AHI or RDI as defined above. This determination will be made on a device-by-device basis (WatchPAT (Itamar Medical) is currently the only approved device in this category).

All beneficiaries who undergo a HST must, prior to having the test, receive instruction on how to properly apply a portable sleep monitoring device. This instruction must be provided by the entity conducting the HST and may not be performed by a DME supplier. Patient instruction may be accomplished by either:

- 1. Face-to-face demonstration of the portable sleep monitoring device's application and use; or,
- 2. Video or telephonic instruction, with 24-hour availability of qualified personnel to answer questions or troubleshoot issues with the device.

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

- 1. Current certification in Sleep Medicine by the American Board of Sleep Medicine (ABSM); or,
- 2. Current subspecialty certification in Sleep Medicine by a member board of the American Board of Medical Specialties (ABMS); or,
- 3. Completed residency or fellowship training in a program approved by an ABMS member board 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,
- 4. Active staff membership of a sleep center or laboratory accredited by the American Academy of Sleep Medicine (AASM) or The Joint Commission (formerly the Joint Commission on Accreditation of Healthcare Organizations – JCAHO).

No aspect of an HST, including but not limited to delivery and/or pickup of the device, may be performed by a DME supplier. This prohibition does not extend to the results of studies conducted by hospitals certified to do such tests.

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Coding Information

Bill Type Codes:

Contractors may specify Bill Types to help providers identify those Bill Types typically used to report this service. Absence of a Bill Type does not guarantee that the policy does not apply to that Bill Type. Complete absence of all Bill Types indicates that coverage is not influenced by Bill Type and the policy should be assumed to apply equally to all claims.

Revenue Codes:

Contractors may specify Revenue Codes to help providers identify those Revenue Codes typically used to report this service. In most instances Revenue Codes are purely advisory; unless specified in the policy services reported under other Revenue Codes are equally subject to this coverage determination. Complete absence of all Revenue Codes indicates that coverage is not influenced by Revenue Code and the policy should be assumed to apply equally to all Revenue Codes.

CPT/HCPCS Codes

GroupName

HCPCS MODIFIERS:

The appearance of a code in this section does not necessarily indicate coverage.

EY - No physician or other licensed health care provider order for this item or service.

GA - Waiver of liability statement issued, as required by payer policy.

GZ - Item or service expected to be denied as not reasonable and necessary.

KX -Requirements specified in the medical policy have been met.

HCPCS CODES:

A9270	NON-COVERED ITEM OR SERVICE
E0485	ORAL DEVICE/APPLIANCE USED TO REDUCE UPPER AIRWAY COLLAPSIBILITY, ADJUSTABLE OR NON-ADJUSTABLE, PREFABRICATED, INCLUDES FITTING AND ADJUSTMENT
E0486	ORAL DEVICE/APPLIANCE USED TO REDUCE UPPER AIRWAY COLLAPSIBILITY, ADJUSTABLE OR NON-ADJUSTABLE, CUSTOM FABRICATED, INCLUDES FITTING AND ADJUSTMENT
E1399	DURABLE MEDICAL EQUIPMENT, MISCELLANEOUS

ICD-9 Codes that Support Medical Necessity

327.23	OBSTRUCTIVE SLEEP APNEA (ADULT) (PEDIATRIC)
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Diagnoses that Support Medical Necessity

All diagnosis that are specified in the preceding section.

ICD-9 Codes that DO NOT Support Medical Necessity

All ICD-9 codes that are not specified in the preceding section.

ICD-9 Codes that DO NOT Support Medical Necessity Asterisk Explanation

Diagnoses that DO NOT Support Medical Necessity

All diagnoses that are not specified in the preceding section.

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General Information

Documentations Requirements

Section 1833(e) of the Social Security Act precludes payment to any provider of services unless "there has been furnished such information as may be necessary in order to determine the amounts due such provider". It is expected that the patient's medical records will reflect the need for the care provided. The patient's medical records include the physician's office records, hospital records, nursing home records, home health agency records, records from other healthcare professionals and test reports. This documentation must be available upon request.

An order for each item billed must be signed and dated by the treating physician, kept on file by the supplier, and made available upon request. Items billed before a signed and dated order has been received by the supplier must be submitted with an EY modifier added to each affected HCPCS code.

The ICD-9 code that justifies the need for these items must be included on the claim.

Suppliers must add a KX modifier to a code only if all of the criteria in the "Indications and Limitations of Coverage and/or Medical Necessity" section of this policy have been met. If the requirements for the KX modifier are not met, the KX modifier must not be used.

If all of the coverage criteria have not been met, the GA or GZ modifier must be added to a claim line for the oral appliance. When there is an expectation of a medical necessity denial, suppliers must enter the GA modifier on the claim line if they have obtained a properly executed Advance Beneficiary Notice (ABN) or the GZ modifier if they have not obtained a valid ABN. Claim lines billed without a GA, GZ, or KX modifier will be rejected as missing information.

Physicians shall document the face-to-face clinical evaluation in a detailed narrative note in their charts in the format that they use for other entries. The report would commonly document pertinent information about the following elements, but may include other details. Each element would not have to be addressed in every evaluation.

History

- Signs and symptoms of sleep disordered breathing including snoring, daytime sleepiness, observed apneas, choking or gasping during sleep, morning headaches;
- Duration of symptoms
- Validated sleep hygiene inventory such as the Epworth Sleepiness Scale (see Appendices)

Physical Exam

- Focused cardiopulmonary and upper airway system evaluation
- Neck circumference
- Body mass index (BMI)

Refer to the Supplier Manual for additional information on documentation requirements.

Appendices EPWORTH SLEEPINESS SCALE

How likely are you to doze off or fall asleep in the following situations, in contrast to feeling just tired? This refers to your usual way of life in recent times. Even if you have not done some of these things recently try to work out how they would have affected you.

Use the following scale to choose the most appropriate number for each situation:

0 = would *never* doze or sleep

1 = *slight* chance of dozing or sleeping

2 = *moderate* chance of dozing or sleeping

3 = *high* chance of dozing or sleeping

Situation	Chance of Dozing or Sleeping
Sitting and reading	_____
Watching TV	_____
Sitting inactive in a public place	_____
Being a passenger in a motor vehicle for an hour or more	_____
Lying down in the afternoon	_____
Sitting and talking to someone	_____
Sitting quietly after lunch (no alcohol)	_____
Stopped for a few minutes in traffic while driving	_____

Total score (add the scores up) (This is your Epworth score)	
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0-9 - Average score, normal population

Epworth Sleepiness Scale reprinted with permission of the Associated Professional Sleep Societies (Johns MW; A New Method for Measuring Daytime Sleepiness: The Epworth Sleepiness Scale. *SLEEP* 1991;14(6):540-545).

Utilization Guidelines Refer to Indications and Limitations of Coverage and/or Medical Necessity.

**Sources of Information and Basis for Decision
Advisory Committee Meeting Notes**

Start Date of Comment Period 09/18/2008

End Date of Comment Period 11/03/2008

Start Date of Notice Period 11/18/2010

Revision History Number OAOSA1

Revision History Explanation Revision Effective Date:09/01/2011

INDICATIONS AND LIMITATIONS OF COVERAGE:

Revised: Correct coding denial to reflect PDAC review requirement for E0486

Removed: References

INDICATIONS AND LIMITATIONS OF COVERAGE:

Revision Effective Date: 01/03/2011

INDICATIONS AND LIMITATIONS OF COVERAGE:

Corrected: Clerical error in the coverage criterion for Severe OSA (Was listed as criterion C. Should have been B 3)

Revision Effective Date: 09/18/2008

Sources of Information:
Activated web addresses.

Reason for Change

Related Documents

Article(s)

LCD Attachments

There are no attachments for this LCD.

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All Versions

Updated on 05/20/2011 with effective dates 09/01/2011 - N/A

[Updated on 02/10/2011 with effective dates 02/11/2011 - 08/31/2011](#)

[Updated on 11/12/2010 with effective dates 01/03/2011 - N/A](#)

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Local Coverage Article for Oral Appliances for Obstructive Sleep Apnea-Policy Article-Effective September 2011 (A50417)

Contractor Information

Contractor Name

NHIC, Corp.

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16003

Contractor Type

DME MAC

Article Information

General Information**Article ID Number**

A50417

Article Type

Article

Key Article

No

Article Title

Oral Appliances for Obstructive Sleep Apnea-Policy Article-Effective September 2011

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Primary Geographic Jurisdiction

Connecticut
District of Columbia
Delaware
Massachusetts
Maryland
Maine
New Hampshire
New Jersey
New York - Entire State
Pennsylvania
Rhode Island
Vermont

DME Region Article Covers

Jurisdiction A

Original Article Effective Date

01/03/2011

Article Revision Effective Date

09/01/2011

Article Text**NON-MEDICAL NECESSITY COVERAGE AND PAYMENT RULES**

For any item to be covered by Medicare, it must 1) be eligible for a defined Medicare benefit category, 2) be reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member, and 3) meet all other applicable Medicare statutory and regulatory requirements. Information provided in this policy article relates to determinations other than those based on Social Security Act §1862(a)(1)(A) provisions (i.e. "reasonable and necessary").

Oral appliances used to treat obstructive sleep apnea are covered under the Durable Medical Equipment benefit (SSA 1861(s) (6)). In order for a beneficiary's equipment to be eligible for reimbursement the reasonable and necessary (R&N) requirements set out in the related Local Coverage Determination must be met. In addition, there are specific statutory payment policy requirements, discussed below, that must be met.

Oral occlusal appliances used to treat temporomandibular joint (TMJ) disorders jaw are considered dental-related items and are noncovered by Medicare.

Oral appliances used to treat other dental conditions are noncovered by Medicare.

Oral appliances used to treat snoring without a diagnosis of OSA are noncovered by Medicare.

All follow-up care, including fitting, adjustments, modifications, professional services (not all-inclusive) required during the first 90 days after provision of the oral appliance are considered to be included in the payment for device. Claims for these will be denied as not separately payable.

After the initial 90-day period, adjustments, modifications and follow-up visits are not eligible for coverage under the DME benefit and are therefore not within the jurisdiction of the DME MAC.

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 expense for repairs exceeds the estimated expense of purchasing another item, no payment can be made for the excess.

Oral appliances are eligible for replacement at the end of their 5-year reasonable useful lifetime (RUL). These items may be replaced prior to the end of the 5-year RUL in cases of loss, theft, or irreparable damage. Irreparable damage refers to a specific accident or to a natural disaster (e.g., fire, flood). Replacement due to wear-and-tear as the result of everyday use will be denied as statutorily noncovered prior to the expiration of the 5-year RUL.

CODING GUIDELINES

Oral appliances are used to reposition oral and pharyngeal tissues in an effort to create and maintain a patient's airway during sleep.

Mandibular advancement devices reposition the mandible in a forward position.

Tongue positioning devices reposition the tongue through the use of a vacuum-bulb or other mechanism such as bars, prongs or extensions (not all-inclusive) in a depressed and/or more anterior position.

A prefabricated oral appliance (E0485) is one, which is manufactured in quantity without a specific patient in mind. A prefabricated oral appliance may be trimmed, bent, molded (with or without heat), or otherwise modified for use by a specific patient (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.

A custom fabricated oral appliance (E0486) is one which is individually and uniquely made for an individual patient. It involves taking an impression of the patient's teeth and making a positive model of plaster or equivalent material. Basic materials are cut, bent, and molded over the positive model. It requires more than trimming, bending, or making other modifications to a substantially prefabricated item. A custom fabricated oral appliance may include a prefabricated component (e.g., the joint mechanism).

Code E0486 may only be used for custom fabricated mandibular advancement devices. To be coded as E0486, custom fabricated mandibular advancement devices must:

1. Have a mechanism that is hinged or jointed at the sides, front or palate, and
2. Have a mechanism that allows the mandible to be advanced, and
3. Be able to protrude the mandible beyond the front teeth at maximum protrusion, and

4. Be adjustable by the beneficiary in increments of one millimeter or less, and
5. Retain their adjustment setting when removed.

Custom fabricated mandibular advancement devices that do not incorporate all of the criteria (1-5) above must not be coded as E0486 and must be coded as E1399.

Custom fabricated tongue positioning appliances are coded E1399.

Oral appliances used to treat snoring without a diagnosis of OSA established with a sleep test as described in the LCD are coded A9270.

Oral occlusal appliances used to treat temporomandibular joint (TMJ) disorders are coded D7880 - occlusal orthotic appliance. Claims for these devices should not be submitted to the DME MACs.

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. Information concerning the documentation that must be submitted to the PDAC for a Coding Verification Request can be found on the PDAC web site or by contacting the PDAC. A Product Classification List with products which have received a coding verification can be found on the PDAC web site.

Suppliers should contact the PDAC contractor for guidance on the correct coding of these items.

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Coding Information

No Coding Information has been entered in this section of the article.

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Other Information

Revision History Explanation

Revision Effective Date: 09/01/2011

NONMEDICAL NECESSITY COVERAGE AND PAYMENT RULES:

Added: Preamble

Added: Benefit category statement

CODING GUIDELINES:

Added: PDAC review requirement for E0486

Related Document(s)

LCD(s)

[L28603 - Oral Appliances for Obstructive Sleep Apnea](#)

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All Versions

Updated on 05/20/2011 with effective dates 09/01/2011 - N/A

[Updated on 11/18/2010 with effective dates 01/03/2011 - N/A](#)

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