



18 September 2008

Dear Physician, Supplier, Specialty Group:

The Centers for Medicare and Medicaid Services (CMS) assigned to the Durable Medical Equipment Medicare Administrative Contractors (DME MACs) the task of developing and updating medical policies for the purpose of processing and reviewing Medicare claims for Durable Medical Equipment, Prostheses, Orthoses and Supplies (DMEPOS). The DME MACs are proposing a new policy for **Oral Appliances for Obstructive Sleep Apnea**.

We are soliciting comments on this draft policy from physicians, manufacturers, suppliers and other professionals involved in the ordering or provision of these items. We recommend that you send this draft policy to selected members of your organization for review and comment. If you disagree with any aspect of the policy, you should be very specific and, if possible, offer an alternative indication, guideline, etc. You should provide a clinical rationale for your position including references from the published clinical literature (e.g. standard textbooks, peer-reviewed journals, etc.). We would also encourage a written response if you agree with this policy.

When comments of this policy have been received, they will be reviewed and revisions to the policy will be considered. The revised policy will be published in the CMS Medicare Coverage Database and on individual DME MAC websites, allowing for adequate notice before the policy's effective date.

Please submit your comments to each DME MAC medical director by mail at the addresses below no later than November 3, 2008. Comments may also be submitted via e-mail through each DME MAC's web site. In addition, a public meeting for receiving comments will be conducted by each of the DME MACs. Information regarding submission of email comments and the open meeting may be obtained from the DME MAC web sites.

Thank you for your participation in our policy development process.

Sincerely yours,

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A CMS CONTRACTOR

9 September 2008

DRAFT 9

LCD for Oral Appliances for Obstructive Sleep Apnea

Contractor Information

Contractor Name

Contractor Number

Contractor Type

DME MAC

LCD Information

LCD ID Number

LCD Title

Oral Appliances for Obstructive Sleep Apnea

Contractor's Determination Number

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CMS National Coverage Policy

None

Primary Geographic Jurisdiction

Oversight Region

CMS Consortium

DMERC Region LCD Covers

Original Determination Effective Date

For services performed on or after xxxxxxxxxxxxxxxx

Original Determination Ending Date

Revision Effective Date

Revision Ending Date

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 medically necessary.

An oral appliance (E0485, E0486) is covered if it is used to treat obstructive sleep apnea (OSA) and if criteria A - D are met.

- A The patient has a face-to-face clinical evaluation by the treating physician (MD or DO) prior to the sleep test to assess the patient for obstructive sleep apnea.
- B The patient has a Medicare-covered sleep test that meets either of the following criteria (1 or 2):
 - 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.
- C The patient is not able to tolerate a positive airway pressure (PAP) device or the treating physician determines that the use of a PAP device is contraindicated.
- D The device is provided by a licensed dentist (DDS or DMD).

If all of these criteria are not met, the oral appliance will be denied as not medically necessary.

A custom fabricated oral appliance (E0486) is covered only if there is an anatomical abnormality of the mouth, jaw, or throat that cannot be accommodated by a prefabricated appliance (E0485). If this criterion is not met but the general coverage criteria (A-D above) are met, payment will be based on the allowance for the least costly medically appropriate alternative, E0485.

Definitions

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.

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.

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 PAP therapy, 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). 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, or IV). 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 that allow direct calculation of an AHI or RDI as defined above. Devices that record channels that do not allow direct calculation of an AHI or RDI may be considered as acceptable alternatives if 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. This determination will be made on a device-by-device basis. Currently there is no device that indirectly measures AHI or RDI that meets this criterion.

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 HSTs (Type II, III, or IV) 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).

For oral appliances with dates of service on or after January 1, 2010, physicians interpreting facility-based polysomnograms (Type I) must meet one of the requirements listed above (1-4) for credentialing.

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

Coverage Topic

DME

Coding Information

CPT/HCPCS Codes

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

HCPCS MODIFIERS:

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

KX - Specific required documentation on file.

HCPCS CODES:

A9270 Noncovered 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)

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.

General Information

Documentation 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.

Physicians shall document the face-to-face clinical evaluations 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)	_____

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

1. Krishnan V, et al. An Evaluation of a Titration Strategy for Prescription of Oral Appliances for Obstructive Sleep Apnea. *Chest*. 2008;133(5).
2. Randerath WJ, et al. An Individually Adjustable Oral Appliance vs Continuous Positive Airway Pressure in Mild-to-Moderate Obstructive Sleep Apnea Syndrome. *Chest*. 2002;122:569-575.
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4. Vanderveken OM, et al. Comparison of a Custom-made and a Thermoplastic Oral Appliance for the Treatment of Mild Sleep Apnea. *American Journal of Respiratory and Critical Care Medicine*. 2008;178:197-202.
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8. Cook V, Schoof M. Oral Appliances for Obstructive Sleep Apnea? *Am Fam Physician*. 2006;73(5):802-803.
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10. United Healthcare. Treatment of Obstructive Sleep Apnea for Medicare Plans. 2008. Available at: https://www.oxhp.com/secure/policy/treatment_sleep_apnea_oma_808.html [Accessed August 16, 2008].
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Med. 2002;166:743-748.

12. Ferguson KA; Cartwright R; Rogers R et al. Oral Appliances for Snoring and Obstructive Sleep Apnea: A Review. *Sleep*. 2006;29(2):244-262.

13. Regence BCBS. Positive Airway Pressure Systems and Oral Appliances for Treatment of Sleep Disordered Breathing. 2007. Available at: <http://blue.regence.com/trgmedpol/dme/dme08.html> [Accessed August 18, 2008].

14. Kushida CA; Morgenthaler TI; Littner MR et al. Practice Parameters for the Treatment of Snoring and Obstructive Sleep Apnea with Oral Appliances: An Update for 2005. *Sleep*. 2006;29(2):240-243.

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

Revision History Number

Revision History Explanation

Last Reviewed On Date

Related Documents

Article(s)

Oral Appliances for Obstructive Sleep Apnea – Policy Article – Draft

LCD Attachments

Contractor Information

Contractor Name

Contractor Number

Contractor Type

DME MAC

Article Information

Article ID Number

Article Type

Article

Key Article

Yes

Article Title

Oral Appliances for Obstructive Sleep Apnea – Policy Article Draft

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Primary Geographic Jurisdiction

DMERC Region Article Covers

Original Article Effective Date

09/18/2008

Article Revision Effective Date

Article Text

This is a draft Policy Article intended to accompany a Draft LCD. You should take no action based upon the information in this article. A final

Article will be prepared and published concurrently with the release of the final LCD.

NON-MEDICAL NECESSITY COVERAGE AND PAYMENT RULES

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.

CODING GUIDELINES

The oral appliances billed with codes E0485 and E0486 must meet the following criteria:

1. They meet the general coverage requirements for durable medical equipment, and
2. They are hinged or jointed at the back, and.
3. They have a mechanism that allows the mandible to be advanced.

A prefabricated oral appliance 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.

A custom fabricated oral appliance is one, which is individually made for a specific patient. It involves taking an impression of the patient's teeth and making a positive model of plaster or equivalent material. Basic materials (e.g., sheets of plastic, etc.) 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).

Oral appliances used to treat snoring without a diagnosis of OSA are coded A9270.

Oral appliances for other non-dental conditions are coded E1399.

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.

Suppliers should contact the Pricing, Data Analysis, and Coding (PDAC)

contractor for guidance on the correct coding of these items.

Coverage Topic

DME

Coding Information

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

Other Information

Revision History Explanation

Related Documents

LCD(s)