

Local Coverage Determination (LCD): Oral Appliances for Obstructive Sleep Apnea (L33611)

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Contractor Information

Contractor Name	Contract Type	Contract Number	Jurisdiction	State(s)
CGS Administrators, LLC	DME MAC	17013 -	DME MAC J-B	Illinois Indiana Kentucky Michigan Minnesota Ohio Wisconsin Alabama Arkansas Colorado Florida Georgia Louisiana Mississippi North Carolina New Mexico Oklahoma Puerto Rico South Carolina Tennessee Texas Virginia Virgin Islands West Virginia Connecticut District of Columbia Delaware Massachusetts Maryland Maine New Hampshire New Jersey New York - Entire State Pennsylvania Rhode Island Vermont Alaska American Samoa Arizona California - Entire State Guam Hawaii Iowa Idaho Kansas Missouri - Entire State Montana North Dakota Nebraska Nevada Oregon South Dakota
CGS Administrators, LLC	DME MAC	18003 -	DME MAC J-C	
Noridian Healthcare Solutions, LLC	DME MAC	16013 -	DME MAC J-A	
Noridian Healthcare Solutions, LLC	DME MAC	19003 -	DME MAC J-D	

LCD Information

Document Information

LCD ID L33611	Original Effective Date For services performed on or after 10/01/2015
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Original ICD-9 LCD ID L28603 L28620 L28601 L28606	Revision Effective Date For services performed on or after 01/01/2017
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	Revision Ending Date N/A
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LCD Title Oral Appliances for Obstructive Sleep Apnea	Retirement Date N/A
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CMS National Coverage Policy N/A

Coverage Guidance

Coverage Indications, Limitations, 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.

The purpose of a Local Coverage Determination (LCD) is to provide information regarding "reasonable and necessary" criteria based on Social Security Act § 1862(a)(1)(A) provisions.

In addition to the "reasonable and necessary" criteria contained in this LCD there are other payment rules, which are discussed in the following documents, that must also be met prior to Medicare reimbursement:

- The LCD-related Standard Documentation Requirements Article, located at the bottom of this policy under the Related Local Coverage Documents section.
- The LCD-related Policy Article, located at the bottom of this policy under the Related Local Coverage Documents section.
- Refer to the Supplier Manual for additional information on documentation requirements.
- Refer the DME MAC web sites for additional bulletin articles and other publications related to this LCD.

For the items addressed in this LCD, the "reasonable and necessary" criteria, based on Social Security Act § 1862(a)(1)(A) provisions, are defined by the following coverage indications, limitations and/or medical necessity.

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

Refer to the NONMEDICAL NECESSITY COVERAGE AND PAYMENT RULES section of the Policy Article for information about coverage for appliances that achieve their effect through positioning of the tongue (A9270).

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. Projections of AHI or RDI based upon shorter testing times and/or fewer events are not acceptable for use in determining eligibility for payment.

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. 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, or other home sleep

studies). 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.

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

1. 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,
2. Type III device – Monitors and records a minimum of four (4) channels: respiratory movement/effort, airflow, ECG/heart rate and oxygen saturation; or,
3. Type IV device - Monitors and records a minimum of three (3) channels, one of which is airflow; or,
4. 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. Beneficiary 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), Accreditation Commission for Health Care (ACHC) or The Joint Commission (formerly the Joint Commission on Accreditation of Healthcare Organizations – JCAHO).

No aspect of a 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.

GENERAL

A Detailed Written Order (DWO) (if applicable) 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 a completed DWO, the claim shall be denied as not reasonable and necessary.

An item/service is correctly coded when it meets all the coding guidelines listed in CMS HCPCS guidelines, LCDs, LCD-related Policy Articles, or DME MAC articles. Claims that do not meet coding guidelines shall be denied as not reasonable and necessary/incorrectly coded.

Proof of delivery (POD) is a Supplier Standard and DMEPOS suppliers are required to maintain POD documentation in their files. Proof of delivery documentation must be made available to the Medicare contractor upon request. All services that do not have appropriate proof of delivery from the supplier shall be denied as not reasonable and necessary.

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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.

N/A

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.

N/A

CPT/HCPCS Codes

Group 1 Paragraph: 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

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:

Group 1 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-10 Codes that Support Medical Necessity

Group 1 Paragraph: The presence of an ICD-10 code listed in this section is not sufficient by itself to assure coverage. Refer to the section on Coverage Indications, Limitations and/or Medical Necessity for other coverage criteria and payment information.

Group 1 Codes:

ICD-10 Codes	Description
G47.33	Obstructive sleep apnea (adult) (pediatric)

ICD-10 Codes that DO NOT Support Medical Necessity

Group 1 Paragraph: All ICD-10 codes that are not specified in the preceding section.

Group 1 Codes: N/A

ICD-10 Additional Information

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General Information

Associated 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 beneficiary's medical records will reflect the need for the care provided. The beneficiary'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.

GENERAL DOCUMENTATION REQUIREMENTS

In order to justify payment for DMEPOS items, suppliers must meet the following requirements:

- Prescription (orders)
- Medical Record Information (including continued need/use if applicable)
- Correct Coding
- Proof of Delivery

Refer to the LCD-related Standard Documentation Requirements article, located at the bottom of this policy under the Related Local Coverage Documents section for additional information regarding these requirements.

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

Refer to the DME MAC web sites for additional bulletin articles and other publications related to this LCD.

POLICY SPECIFIC DOCUMENTATION REQUIREMENTS

Items covered in this LCD have additional policy-specific requirements that must be met prior to Medicare reimbursement.

Refer to the LCD-related Policy article, located at the bottom of this policy under the Related Local Coverage Documents section for additional information.

MISCELLANEOUS

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
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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 Coverage Indications, Limitations and/or Medical Necessity

Sources of Information and Basis for Decision

N/A [Back to Top](#)

Revision History Information

Revision History Date	Revision History Number	Revision History Explanation	Reason(s) for Change
01/01/2017	R3	<p>Revision Effective Date: 01/01/2017 COVERAGE INDICATIONS, INDICATIONS, LIMITATIONS AND/OR MEDICAL NECESSITY: Removed: Standard Documentation Language Added: New reference language and directions to Standard Documentation Requirements Added: General Requirements DOCUMENTATION REQUIREMENTS: Removed: Standard Documentation Language Added: General Documentation Requirements Added: New reference language and directions to Standard Documentation Requirements POLICY SPECIFIC DOCUMENTATION REQUIREMENTS: Removed: Standard Documentation Language Added: Direction to Standard Documentation Requirements Removed: Supplier manual reference from Miscellaneous Removed: PIM reference under Appendices RELATED LOCAL COVERAGE DOCUMENTS: Added: LCD-related Standard Documentation Requirements article</p>	<ul style="list-style-type: none">• Provider Education/Guidance
07/01/2016	R2	<p>Effective July 1, 2016 oversight for DME MAC LCDs is the responsibility of CGS Administrators, LLC 18003 and 17013 and Noridian Healthcare Solutions, LLC 19003 and 16013. No other changes have been made to the LCDs.</p>	<ul style="list-style-type: none">• Change in Assigned States or Affiliated Contract Numbers
10/01/2015	R1	<p>Revision Effective Date: 10/31/2014 COVERAGE INDICATIONS, LIMITATIONS AND/OR MEDICAL NECESSITY: Revised: Standard Documentation Language to add covered prior to a beneficiary's Medicare eligibility DOCUMENTATION REQUIREMENTS: Added: Continued Medical Need/ Continued Use sections Revised: Standard Documentation Language to add who can enter date of delivery date on the POD Added: Instructions for equipment retained from a prior payer Added: Repair/Replacement section POLICY SPECIFIC DOCUMENTATION REQUIREMENTS: Added: Diagnosis code reference</p>	<ul style="list-style-type: none">• Provider Education/Guidance

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Associated Documents

Attachments N/A

Related Local Coverage Documents Article(s) [A52512 - Oral Appliances for Obstructive Sleep Apnea - Policy Article A55426 - Standard Documentation Requirements for All Claims Submitted to DME MACs](#)

Related National Coverage Documents N/A

Public Version(s) Updated on 04/28/2017 with effective dates 01/01/2017 - N/A [Updated on 06/07/2016 with effective dates 07/01/2016 - 12/31/2016](#) [Updated on 03/27/2015 with effective dates 10/01/2015 - 06/30/2016](#) [Updated on 04/04/2014 with effective dates 10/01/2015 - N/A](#) [Back to Top](#)

Keywords

N/A Read the [LCD Disclaimer](#) [Back to Top](#)

END OF LOCAL COVERAGE DETERMINATION

Per the Code of Federal Regulations, 42 C.F.R § 426. 325, only those portions of the currently effective Local Coverage Determination (LCD) that are based on section 1862(a)(1)(A) of the Social Security Act, may be challenged through an acceptable complaint as described in 42 C.F.R § 426.400. Also, per 42 C.F.R § 426.325 items that are not reviewable, and therefore cannot be challenged, include the Policy Article. Please note the distinction of the documents when reviewing the materials.

Local Coverage Article: Oral Appliances for Obstructive Sleep Apnea - Policy Article (A52512)

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Contractor Information

Contractor Name	Contract Type	Contract Number	Jurisdiction	State(s)
CGS Administrators, LLC	DME MAC	17013 -	DME MAC J-B	Illinois Indiana Kentucky Michigan Minnesota Ohio Wisconsin Alabama Arkansas Colorado Florida Georgia Louisiana Mississippi North Carolina New Mexico Oklahoma Puerto Rico South Carolina Tennessee Texas Virginia Virgin Islands West Virginia Connecticut District of Columbia Delaware Massachusetts Maryland Maine New Hampshire New Jersey New York - Entire State Pennsylvania Rhode Island Vermont Alaska American Samoa Arizona California - Entire State Guam Hawaii
CGS Administrators, LLC	DME MAC	18003 -	DME MAC J-C	Iowa Idaho Kansas Missouri - Entire State Montana North Dakota Nebraska Nevada
Noridian Healthcare Solutions, LLC	DME MAC	16013 -	DME MAC J-A	
Noridian Healthcare Solutions, LLC	DME MAC	19003 -	DME MAC J-D	

Article Information

General Information

Article ID

A52512

Original Article Effective Date

10/01/2015

Original ICD-9 Article ID

[A50417](#)[A50449](#)[A50413](#)[A50695](#)**Revision Effective Date**

01/01/2017

Revision Ending Date

N/A

Article Title

Oral Appliances for Obstructive Sleep Apnea - Policy Article

Retirement Date

N/A

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Article Guidance

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 (OSA) 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 appliances generally are classified as dental devices and are not classified as durable medical equipment. The following items (not all-inclusive) are considered to be dental devices and will be denied as non-covered, not DME:

- Oral occlusal appliances used to treat temporomandibular joint (TMJ) disorders
- Tongue retaining devices used to treat OSA and/or snoring
- All oral appliances used only to treat snoring without a diagnosis of OSA
- Oral appliances used to treat other dental conditions
- Oral appliances that require repeated fitting and/or adjustments, beyond the first 90-days, in order to maintain fit and/or effectiveness

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 non-covered prior to the expiration of the 5-year RUL.

POLICY SPECIFIC DOCUMENTATION REQUIREMENTS

In addition to policy specific documentation requirements, there are general documentation requirements that are applicable to all DMEPOS policies. These general requirements are located in the DOCUMENTATION REQUIREMENTS section of the LCD.

Refer to the LCD-related Standard Documentation Requirements article, located at the bottom of this Policy Article under the Related Local Coverage Documents section for additional information regarding GENERAL DOCUMENTATION REQUIREMENTS and the POLICY SPECIFIC DOCUMENTATION REQUIREMENTS discussed below.

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)

MODIFIERS

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 the related LCD 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.

CODING GUIDELINES

Oral appliances are used to reposition oral and pharyngeal tissues in an effort to create and maintain a beneficiary'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 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.

A custom fabricated oral appliance (E0486) is one that is uniquely made for an individual beneficiary. It involves taking an impression of the beneficiary's teeth and making a positive model of plaster or equivalent material. Basic materials are cut, bent, and molded using 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 meet all of the criteria below:

- Have a fixed mechanical hinge (see below) at the sides, front or palate; and,
- Be able to protrude the individual beneficiary's mandible beyond the front teeth when adjusted to maximum protrusion; and,

- Incorporate a mechanism that allows the mandible to be easily advanced by the beneficiary in increments of one millimeter or less; and,
- Retain the adjustment setting when removed from the mouth; and,
- Maintain the adjusted mouth position during sleep; and,
- 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 (see below)

A fixed hinge is defined as a mechanical joint, containing an inseparable pivot point. Interlocking flanges, tongue and groove mechanisms, hook and loop or hook and eye clasps, elastic straps or bands, mono-block articulation, traction-based articulation, compression-based articulation, etc. (not all-inclusive) do not meet this requirement.

Items that require repeated adjustments and modification beyond the initial 90-day fitting and adjustment period in order to maintain fit and/or effectiveness are not eligible for classification as DME. These items are considered as dental therapies, which are not eligible for reimbursement, by Medicare under the DME benefit. They must not be coded using E0486.

Custom fabricated mandibular advancement devices that do not incorporate all of the criteria above must use HCPCS code A9270 (NON-COVERED ITEM OR SERVICE). Do not use HCPCS code E0486.

Tongue positioning appliances are coded A9270.

Oral appliances used to treat snoring without a diagnosis of OSA established with a sleep test as described in the LCD are coded A9270 (NON-COVERED ITEM OR SERVICE).

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 for which a written Coding Verification Review has been made by the Pricing, Data Analysis and Coding (PDAC) Contractor and subsequently published on the appropriate Product Classification List.

All custom fabricated mandibular advancement devices that have not received a written PDAC Verification Review must use HCPCS code A9270 (NON-COVERED ITEM OR SERVICE).

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

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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 article does not apply to that Bill Type. Complete absence of all Bill Types indicates that coverage is not influenced by Bill Type and the article should be assumed to apply equally to all claims.

N/A

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 article, 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 article should be assumed to apply equally to all Revenue Codes.

N/A

CPT/HCPCS Codes N/A

ICD-10 Codes that are Covered N/A

ICD-10 Codes that are Not Covered N/A

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[Revision History Information](#)

Revision History Date	Revision History Number	Revision History Explanation
01/01/2017	R3	Revision Effective Date: 01/01/2017 POLICY SPECIFIC DOCUMENTATION REQUIREMENTS: Added: Face to Face clinical evaluation, Modifier requirements CODING GUIDELINES: Revised: Examples of articulations that do not meet the requirement of a fixed hinge.
07/01/2016	R2	RELATED LOCAL COVERAGE DOCUMENTS: Added: LCD-related Standard Documentation Requirements Language Article Effective July 1, 2016 oversight for DME MAC Articles is the responsibility of CGS Administrators, LLC 18003 and 17013 and Noridian Healthcare Solutions, LLC 19003 and 16013. No other changes have been made to the Articles. Revision Effective Date: 01/01/2015
10/01/2015	R1	CODING GUIDELINES: Revised: Coding Guidelines based on DME MAC article: "Correct Coding for Oral Appliances for the Treatment of Obstructive Sleep Apnea (E0486)" - Effective July, 01, 2012

[Back to Top](#) **Related Local Coverage Document(s)** Article(s) [A55426 - Standard Documentation Requirements for All Claims Submitted to DME MACs](#) LCD(s) [L33611 - Oral Appliances for Obstructive Sleep Apnea](#)

Related National Coverage Document(s) N/A

Statutory Requirements URL(s) N/A

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CMS Manual Explanations URL(s) N/A

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