

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
CGS Administrators, LLC	DME MAC	18003 - DME MAC	J-C	Alabama Arkansas Colorado Florida Georgia Louisiana Mississippi New Mexico North Carolina Oklahoma Puerto Rico South Carolina Tennessee Texas Virgin Islands Virginia West Virginia
Noridian Healthcare Solutions, LLC	DME MAC	16013 - DME MAC	J-A	Connecticut Delaware District of Columbia Maine Maryland Massachusetts New Hampshire New Jersey New York - Entire State Pennsylvania Rhode Island Vermont

CONTRACTOR NAME	CONTRACT TYPE	CONTRACT NUMBER	JURISDICTION	STATE(S)
Noridian Healthcare Solutions, LLC	DME MAC	19003 - DME MAC	J-D	Alaska American Samoa Arizona California - Entire State Guam Hawaii Idaho Iowa Kansas Missouri - Entire State Montana Nebraska Nevada North Dakota Northern Mariana Islands Oregon South Dakota Utah Washington Wyoming

LCD Information

Document Information

LCD ID

L33611

Original Effective Date

For services performed on or after 10/01/2015

LCD Title

Oral Appliances for Obstructive Sleep Apnea

Revision Effective Date

For services performed on or after 01/01/2020

Proposed LCD in Comment Period

N/A

Revision Ending Date

N/A

Source Proposed LCD

N/A

Retirement Date

N/A

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Notice Period Start Date

N/A

Notice Period End 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 practitioner prior to the sleep test to assess the beneficiary for obstructive sleep apnea testing. Refer to the ICD-10 code list in the LCD-related Policy Article for applicable diagnoses.
- 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 practitioner determines that the use of a PAP device is contraindicated.
- C. The device is ordered by the treating practitioner following a review of the report of the sleep test. (The practitioner 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, treating practitioner refers to a licensed MD, DO, nurse practitioner, clinical nurse specialist, or physician's assistant working within their scope of practice. The term treating practitioner 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 practitioner 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 practitioner 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 practitioner 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 practitioner 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 Standard Written Order (SWO) must be communicated to the supplier before a claim is submitted. If the supplier bills for an item addressed in this policy without first receiving a completed SWO, the claim shall be denied as not reasonable and necessary.

For Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) base items that require a Written Order Prior to Delivery (WOPD), the supplier must have received a signed SWO before the DMEPOS item is delivered to a beneficiary. If a supplier delivers a DMEPOS item without first receiving a WOPD, the claim shall be denied as not reasonable and necessary. Refer to the LCD-related Policy Article, located at the bottom of this policy under the Related Local Coverage Documents section.

For DMEPOS base items that require a WOPD, and also require separately billed associated options, accessories, and/or supplies, the supplier must have received a WOPD which lists the base item and which may list all the associated options, accessories, and/or supplies that are separately billed prior to the delivery of the items. In this scenario, if the supplier separately bills for associated options, accessories, and/or supplies without first receiving a completed and signed WOPD of the base item prior to delivery, the claim(s) 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.

Summary of Evidence

NA

Analysis of Evidence (Rationale for Determination)

NA

Coding Information

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:

CODE	DESCRIPTION
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

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 treating practitioner'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:

- SWO
- 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
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

N/A

Bibliography

NA

Revision History Information

REVISION HISTORY DATE	REVISION HISTORY NUMBER	REVISION HISTORY EXPLANATION	REASON(S) FOR CHANGE
01/01/2020	R6	<p>Revision Effective Date: 01/01/2020</p> <p>CODING INFORMATION: Removed: Field titled "Bill Type" Removed: Field titled "Revenue Codes" Removed: Field titled "ICD-10 Codes that Support Medical Necessity" Removed: Field titled "ICD-10 Codes that DO NOT Support Medical Necessity" Removed: Field titled "Additional ICD-10 Information"</p> <p><i>As required by CR 10901, the ICD-10 information has been moved to all Policy Articles. There is no change in coverage.</i></p>	<ul style="list-style-type: none"> Other

REVISION HISTORY DATE	REVISION HISTORY NUMBER	REVISION HISTORY EXPLANATION	REASON(S) FOR CHANGE
01/01/2020	R5	<p>Revision Effective Date: 01/01/2020 COVERAGE INDICATIONS, LIMITATIONS AND/OR MEDICAL NECESSITY: Revised: "physician" to "treating practitioner" Removed: Statement to refer to ICD-10 Codes that are Covered section in the LCD-related PA Added: Statement to refer to ICD-10 code list in the LCD-related Policy Article GENERAL: Revised: Order information as a result of Final Rule 1713 DOCUMENTATION REQUIREMENTS: Revised: "physician's" to "treating practitioner's" GENERAL DOCUMENTATION REQUIREMENTS: Revised: "Prescriptions (orders)" to "SWO"</p> <p><i>02/13/2020: Pursuant to the 21st Century Cures Act, these revisions do not require notice and comment because they are due to non-discretionary coverage updates reflective of CMS FR-1713.</i></p>	<ul style="list-style-type: none"> • Provider Education/Guidance
01/01/2019	R4	<p>Revision Effective Date: 01/01/2019 COVERAGE INDICATIONS, LIMITATIONS, AND/OR MEDICAL NECESSITY: Removed: Statement to refer to diagnosis code section below Added: Refer to Covered ICD-10 Codes in the LCD-related Policy Article ICD-10 CODES THAT SUPPORT MEDICAL NECESSITY: Moved: Diagnosis code to the LCD-related Policy Article diagnosis code section per CMS instruction ICD-10 CODES THAT DO NOT SUPPORT MEDICAL NECESSITY: Moved: Statement about noncovered diagnosis codes moved to LCD-related Policy Article noncovered diagnosis code section per CMS instruction</p>	<ul style="list-style-type: none"> • Other (ICD-10 code relocation per CMS instruction)
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:</p>	<ul style="list-style-type: none"> • Provider Education/Guidance

REVISION HISTORY DATE	REVISION HISTORY NUMBER	REVISION HISTORY EXPLANATION	REASON(S) FOR CHANGE
		<p>Removed: Standard Documentation Language Added: General Documentation Requirements Added: New reference language and directions to Standard Documentation Requirements</p> <p>POLICY SPECIFIC DOCUMENTATION REQUIREMENTS: Removed: Standard Documentation Language Added: Direction to Standard Documentation Requirements</p> <p>Removed: Supplier manual reference from Miscellaneous Removed: PIM reference under Appendices</p> <p>RELATED LOCAL COVERAGE DOCUMENTS: Added: LCD-related Standard Documentation Requirements article</p>	
07/01/2016	R2	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.	<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</p> <p>COVERAGE INDICATIONS, LIMITATIONS AND/OR MEDICAL NECESSITY: Revised: Standard Documentation Language to add covered prior to a beneficiary's Medicare eligibility</p> <p>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</p> <p>POLICY SPECIFIC DOCUMENTATION REQUIREMENTS: Added: Diagnosis code reference</p>	<ul style="list-style-type: none"> Provider Education/Guidance

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 02/13/2020 with effective dates 01/01/2020 - N/A

Updated on 02/07/2020 with effective dates 01/01/2020 - N/A

Updated on 03/29/2019 with effective dates 01/01/2019 - 12/31/2019

Some older versions have been archived. Please visit the MCD Archive Site to retrieve them.

Keywords

N/A

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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Noridian Healthcare Solutions, LLC	DME MAC	16013 - DME MAC	J-A	Connecticut Delaware District of Columbia Maine Maryland Massachusetts New Hampshire New Jersey New York - Entire State Pennsylvania Rhode Island

CONTRACTOR NAME	CONTRACT TYPE	CONTRACT NUMBER	JURISDICTION	STATE(S)
				Vermont
Noridian Healthcare Solutions, LLC	DME MAC	19003 - DME MAC	J-D	Alaska American Samoa Arizona California - Entire State Guam Hawaii Idaho Iowa Kansas Missouri - Entire State Montana Nebraska Nevada North Dakota Northern Mariana Islands Oregon South Dakota Utah Washington Wyoming

Article Information

General Information

Article ID

A52512

Original Effective Date

10/01/2015

Original ICD-9 Article ID

[A50417](#)

[A50449](#)

[A50413](#)

[A50695](#)

Revision Effective Date

04/03/2020

Revision Ending Date

N/A

Article Title

Oral Appliances for Obstructive Sleep Apnea - Policy Article

Retirement Date

N/A

Article Type

Article

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Statement

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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.

REQUIREMENTS FOR SPECIFIC DMEPOS ITEMS PURSUANT TO Final Rule 1713 (84 Fed. Reg Vol 217)

Final Rule 1713 (84 Fed. Reg Vol 217) requires a face-to-face encounter and a Written Order Prior to Delivery (WOPD) for specified HCPCS codes. CMS and the DME MACs provide a list of the specified codes, which is periodically updated. The link will be located here once it is available.

Claims for the specified items subject to Final Rule 1713 (84 Fed. Reg Vol 217) that do not meet the face-to-face encounter and WOPD requirements specified in the LCD-related Standard Documentation Requirements Article (A55426) will be denied as not reasonable and necessary.

If a supplier delivers an item prior to receipt of a WOPD, it will be denied as not reasonable and necessary. If the WOPD is not obtained prior to delivery, payment will not be made for that item even if a WOPD is subsequently obtained by the supplier. If a similar item is subsequently provided by an unrelated supplier who has obtained a WOPD, it will be eligible for coverage.

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.

Treating practitioners 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 a full arch, negative impression of the beneficiary's teeth, either using appropriate materials or digital images, from which a positive model is created. Basic materials are then cut, bent, and molded using the positive model in order to construct the final oral appliance. 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).

Code E0467 (HOME VENTILATOR, MULTI-FUNCTION RESPIRATORY DEVICE, ALSO PERFORMS ANY OR ALL OF THE ADDITIONAL FUNCTIONS OF OXYGEN CONCENTRATION, DRUG NEBULIZATION, ASPIRATION, AND COUGH STIMULATION, INCLUDES ALL ACCESSORIES, COMPONENTS AND SUPPLIES FOR ALL FUNCTIONS) describes a ventilator that integrates the function of multiple types of equipment into a single device. Code E0467 combines the function of a ventilator with those of any combination or all of the following:

- Oxygen equipment
- Nebulizer and compressor
- Aspirator (suction device)
- Cough stimulator (multiple products)
- Positive airway pressure devices (PAP and RAD)
- Custom fabricated oral appliances

The following HCPCS code for individual items are included in the functionality of code E0467:

- HCPCS code E0486

For E0467 claims with dates of service before April 3, 2020:

Claims for any of the HCPCS code listed above that are submitted on the same claim or that overlap any date(s) of service for E0467 is considered to be unbundling.

In addition, any claim for repair (HCPCS code K0739 for labor and any HCPCS code for replacement items) of beneficiary-owned equipment identified by HCPCS code listed above is considered as unbundling if the date(s) of service for the repair overlaps any date(s) of service for code E0467.

Claims for code E0467 with a date(s) of service that overlaps date(s) of service for any of the following scenarios are considered as a claim for same or similar equipment when the beneficiary:

- Is currently in a rental month for any of the items listed above
- Owns any of the equipment listed above that has not reached the end of its reasonable useful lifetime.

For E0467 claims with dates of service on or after April 3, 2020:

Any claim for repair (HCPCS code K0739 for labor and any HCPCS code for replacement items) of beneficiary-owned equipment identified by HCPCS codes listed above is considered as unbundling if the date(s) of service for the repair overlaps any date(s) of service for code E0467.

Claims for code E0467 with a date(s) of service that overlaps date(s) of service in a rental month for any of the items listed above are considered as a claim for same or similar equipment.

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

Coding Information

CPT/HCPCS Codes

N/A

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 LCD section on "**Coverage Indications, Limitations, and/or Medical Necessity**" for other coverage criteria and payment information.

Group 1 Codes:

ICD-10 CODE	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

Additional ICD-10 Information

N/A

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

Revision History Information

REVISION HISTORY DATE	REVISION HISTORY NUMBER	REVISION HISTORY EXPLANATION
04/03/2020	R6	<p>Revision Effective Date: 04/03/2020 CODING GUIDELINES: Revised: Guidance for billing HCPCS code E0467 based on DOS</p> <p><i>07/16/2020: At this time 21st Century Cures Act applies to new and revised LCDs which require comment and notice. This revision is to an article that is not a local coverage determination.</i></p>
01/01/2020	R5	<p>Revision Effective Date: 01/01/2020 REQUIREMENTS FOR SPECIFIC DMEPOS ITEMS PURSUANT TO FINAL RULE 1713 (84 Fed. Reg Vol 217): Added: Section and related information based on Final Rule 1713 POLICY SPECIFIC DOCUMENTATION REQUIREMENTS: Revised: "Physicians" to "Treating practitioners" ICD-10 CODES THAT SUPPORT MEDICAL NECESSITY: Revised: Section header "ICD-10 Codes that are Covered" updated to "ICD-10 Codes that Support Medical Necessity" ICD-10 CODES THAT DO NOT SUPPORT MEDICAL NECESSITY: Revised: Section header "ICD-10 Codes that are Not Covered" updated to "ICD-10 Codes that DO NOT Support Medical Necessity"</p> <p><i>02/13/2020: At this time 21st Century Cures Act applies to new and revised LCDs which require comment and notice. This revision is to an article that is not a local coverage determination.</i></p>
01/01/2019	R4	<p>Revision Effective Date: 01/01/2019 CODING GUIDELINES: Added: E0467 Coding Guidelines Revised: Language for custom fabricated oral appliance (E0486) ICD-10 CODES THAT ARE COVERED: Added: Diagnosis code formerly listed in the LCD ICD-10 CODES THAT ARE NOT COVERED: Added: Notation excluding all unlisted diagnosis codes from coverage</p>

REVISION HISTORY DATE	REVISION HISTORY NUMBER	REVISION HISTORY EXPLANATION
		<i>04/04/2019: At this time 21st Century Cures Act applies to new and revised LCDs which require comment and notice. This revision is to an article that is not a local coverage determination.</i>
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. RELATED LOCAL COVERAGE DOCUMENTS: Added: LCD-related Standard Documentation Requirements Language Article
07/01/2016	R2	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.
10/01/2015	R1	Revision Effective Date: 01/01/2015 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

Associated Documents

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

Rules and Regulations URL(s)

N/A

CMS Manual Explanations URL(s)

N/A

Other URL(s)

N/A

Public Version(s)

Updated on 07/09/2020 with effective dates 04/03/2020 - N/A

Updated on 02/07/2020 with effective dates 01/01/2020 - N/A

Updated on 03/29/2019 with effective dates 01/01/2019 - N/A

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Keywords

N/A