

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

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

Contractor Name	Contract Type	Contract Number	Jurisdiction	State(s)
				Rhode Island 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

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N/A

Article TitleOral Appliances for Obstructive Sleep Apnea -
Policy Article**Article Type**

Article

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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.

No aspect of a home sleep test, 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 or to tests conducted in facility-based sleep laboratories.

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 in-person 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 of related LCD)

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 "Coverage Indications, Limitations, 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 Product Classification List (PCL).

If a product is billed to Medicare using a HCPCS code that requires written coding verification review, but the product is not on the PCL for that particular HCPCS code, then the claim line will be denied as incorrect coding.

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 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

Revision History Information

Revision History Date	Revision History Number	Revision History Explanation
xx/xx/xxxx	R7	<p>Revision Effective Date: xx/xx/xxxx</p> <p>NON-MEDICAL NECESSITY COVERAGE AND PAYMENT RULES: Added: Language regarding no aspect of a HST may be performed by a DME supplier previously noted in the LCD</p> <p>POLICY SPECIFIC DOCUMENTATION REQUIREMENTS: Revised: "Face-to-face" to "in-person" Revised: History elements of the treating practitioners evaluation by separating the "sleep hygiene inventory" from the "duration of symptoms" bullet</p> <p>MODIFIERS: Revised: The reference to the coverage criteria within the "Coverage Indications, Limitations, and/or Medical Necessity" section of the LCD</p> <p>CODING GUIDELINES: Revised: Coding Verification Review statement for E0486 by removing "appropriate" prior to "Product Classification List" Revised: Removed language related to the use of HCPCS code A9270 when coding verification was not received and replaced with incorrect coding statement</p> <p><i>xx/xx/xxxx: 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>
04/03/2020	R6	<p>Revision Effective Date: 04/03/2020</p> <p>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>

Revision History Date	Revision History Number	Revision History Explanation
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> <p><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></p>
01/01/2017	R3	<p>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</p>
07/01/2016	R2	<p>Effective July 1, 2016 oversight for DME MAC Articles is the responsibility of CGS Administrators, LLC 18003 and 17013 and</p>

Revision History Date	Revision History Number	Revision History Explanation
10/01/2015	R1	<p>Noridian Healthcare Solutions, LLC 19003 and 16013. No other changes have been made to the Articles.</p> <p>Revision Effective Date: 01/01/2015</p> <p>CODING GUIDELINES:</p> <p>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</p>

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)

N/A

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