Medicare Medical Policy

Sleep Disorder Treatment: Oral and Sleep Position Appliances

MEDICARE MEDICAL POLICY NUMBER: 45

Effective Date: 4/1/2024

Last Review Date: 3/2024

Next Annual Review: 4/2024

INSTRUCTIONS FOR USE: Company Medicare Medical Policies serve as guidance for the administration of plan benefits and do not constitute medical advice nor a guarantee of coverage. Company Medicare Medical Policies are reviewed annually to guide the coverage or non-coverage decision-making process for services or procedures in accordance with member benefit contracts (otherwise known as Evidence of Coverage or EOCs) and Centers of Medicare and Medicaid Services (CMS) policies, manuals, and other CMS rules and regulations. In the absence of a CMS coverage determination or specific regulation for a requested service, item or procedure, Company policy criteria or applicable utilization management vendor criteria may be applied. These are based upon published, peer-reviewed scientific evidence and evidence-based clinical practice guidelines that are available as of the last policy update. Coverage decisions are made on the basis of individualized determinations of medical necessity and the experimental or investigational character of the treatment in the individual case. In cases where medical necessity is not established by policy for specific treatment modalities, evidence not previously considered regarding the efficacy of the modality that is presented shall be given consideration to determine if the policy represents current standards of care.

The Company reserves the right to determine the application of Medicare Medical Policies and make revisions to these policies at any time. Any conflict or variance between the EOC and Company Medical Policy will be resolved in favor of the EOC.

SCOPE: Providence Health Plan, Providence Health Assurance, and Providence Plan Partners as applicable (referred to individually as “Company” and collectively as “Companies”).

PRODUCT AND BENEFIT APPLICATION

☒ Medicare Only

MEDICARE COVERAGE CRITERIA

IMPORTANT NOTE: More than one Centers for Medicare and Medicaid Services (CMS) reference may apply to the same health care service, such as when more than one coverage policy is available (e.g., both an NCD and LCD exist). All references listed should be considered for coverage decision-making. The Company uses the most current version of a Medicare reference available at the time of publication; however, these websites are not maintained by the Company, so Medicare references and their corresponding hyperlinks may change at any time. If there is a conflict between the Company Medicare Medical Policy and CMS guidance, the CMS guidance will govern.

Note: Prior to May 11, 2023, there were temporary provisions in place for this Medicare medical policy during the COVID-19 public health emergency. See **Policy Guidelines** below for information regarding these emergency provisions.

Service	Medicare Guidelines
Oral Appliance Therapy for Obstructive Sleep Apnea	Local Coverage Determination (LCD): Oral Appliances for Obstructive Sleep Apnea (L33611) *See "Billing Guidelines" below for additional information regarding appropriate coding of custom fabricated and electronic oral appliances.*
Neuromuscular Electrical Stimulation of the Tongue Muscle, Controlled by Phone Application (eXciteOSA®)	National Coverage Determination (NCD): Neuromuscular Electrical Stimulation (NMES) (160.12) See also the Medicare Benefit Policy Manual, Chapter 15, §110.8 – DMEPOS Benefit Category Determinations, which states the following for these devices: "No DMEPOS Benefit Category—The component that performs the medically necessary function of the device is a smartphone which is useful to an individual in the absence of an illness or injury." **NOTE:** This NCD provides only two indications for which NMES may be considered medically necessary by Medicare (muscle atrophy and patients with spinal cord injuries). Other uses of NMES would not meet NCD criteria for Medicare coverage, making the eXciteOSA® device **not medically necessary**.

IMPORTANT NOTICE: While some services or items may appear medically indicated for an individual, they may also be a direct exclusion of Medicare or the member's benefit plan. Such excluded services or items by Medicare and member EOCs include, but are not limited to, services or procedures considered to be cosmetic, not medical in nature, or those considered not medically reasonable or necessary under *Title XVIII of the Social Security Act, §1862(a)(1)(A).* If there is uncertainty regarding coverage of a service or item, please review the member EOC or submit a pre-service organization

determination request. Note that the Medicare Advance Beneficiary Notice of Noncoverage (ABN) form **cannot** be used for Medicare Advantage members. *(Medicare Advance Written Notices of Non-coverage. MLN006266 May 2021)*

POLICY CROSS REFERENCES

- Sleep Disorder Testing, MP57
- Sleep Disorder Treatment: Positive Airway Pressure, MP53
- Sleep Disorder Treatment: Surgical, MP244

The full Company portfolio of Medicare Medical Policies is available online and can be accessed here.

POLICY GUIDELINES

NEED AND DURATION OF EMERGENCY PROVISIONS

1. **Need for the temporary Provisions:** COVID-19 public health emergency
2. **Documents or source relied upon:**
    a. Rural Crosswalk: CMS Flexibilities to Fight COVID-19: https://www.cms.gov/files/document/omh-rural-crosswalk-5-21-21.pdf
    b. Noridian Article CMS Issues Interim Final Rules with Comment (CMS-1744-IFC & CMS-5531-IFC) – COVID-19 Public Health Emergency – Revised; *[Last updated 07/14/2021]*
    c. CMS Final Rule: CMS-5531-IFC for Medicare and Medicaid Programs, Basic Health Program, and Exchanges; Additional Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency and Delay of Certain Reporting Requirements for the Skilled Nursing Facility Quality Reporting Program
    d. CMS Final Rule: CMS-1744-IFC for Medicare and Medicaid Programs; Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency
    e. CMS COVID-19 Frequently Asked Questions (FAQs) on Medicare Fee-for-Service (FFS) Billing document [Last updated 11/17/2021]
3. **Initial Effective Date: 3/1/2020**
4. **Re-review dates: 2/3/2021; 3/31/2021; 6/1/2021; 12/8/2021; 7/20/2022; 10/4/2022; 12/16/2022; 1/30/2023**
5. **Termination Date: 5/11/2023**
6. **Reassessment Date determined at Companies sole discretion: 5/10/2023, or sooner if regulations or clinical practice guidelines change.**

POLICY ADDENDUM

COVID-19 Public Health Emergency

Since March 2020, Medicare has released various final rules on the CMS response to the COVID-19 public health emergency (PHE). Some of these final rules apply to enforcement of certain requirements for select durable medical equipment (DME) and supplies (e.g., face-to-face or in-person encounters or provider specialty requirements when required by NCD/LCD, etc.).

"For the duration of this PHE for the COVID-19 PHE, it is in the best interest of patients, health care professionals and suppliers to limit face-to-face encounters and avoid exposure of vulnerable Medicare beneficiaries to COVID-19. Therefore, on an interim basis, we are finalizing that to the extent an NCD or LCD (including policy articles) would otherwise require a face-to-face or in-person encounter for evaluations, assessments, certifications or other implied face-to-face services, those requirements would not apply during the COVID-19 PHE."[1]

Thus, telehealth (telemedicine) visits would satisfy any face-to-face or in-person requirements when noted in an NCD, LCD, or LCA.

"Effective for claims with dates of service on or after March 1, 2020 and for the duration of this COVID-19 PHE, clinical indications for coverage found in respiratory, infusion pump, and therapeutic continuous glucose monitor NCDs or LCDs will not be enforced. These NCDs and LCDs include:

- *Home Oxygen (NCD 240.2)*
- *Infusion Pumps (NCD 280.14)*
- *Continuous Positive Airway Pressure for Obstructive Sleep Apnea (NCD 240.4)*
- *Intrapulmonary Percussive Ventilator (NCD 240.5)*
- *Durable Medical Equipment Reference List (NCD 280.1) – Only clinical indications for ventilators are not enforced*
- *Oxygen and Oxygen Equipment (L33797)*
- *Positive Airway Pressure Devices for the Treatment of Obstructive Sleep Apnea (L33718)*
- ***Oral Appliances for the Treatment of Obstructive Sleep Apnea (L33611)***
- *Respiratory Assist Devices (L33800)*
- *Mechanical In-exsufflation Devices (L33795)*
- *High Frequency Chest Wall Oscillation (L33785)*
- *Nebulizers (L33370)*
- *Suction Pumps (L33612) – Only clinical indications for respiratory suction pumps (E0600) are not enforced*
- *Glucose Monitors (L33822) – Only clinical indications for Therapeutic Continuous Glucose Monitors (CGM) are not enforced*
- *External Infusion Pumps (L33794)"*[1]

Treating practitioners and suppliers must still:

- Provide a standard written order (SWO) for all items.
- Ensure that the items or services are reasonable and necessary;
- Continue documenting the medical necessity for all services and the medical record must be sufficient to support payment for the services billed (i.e., the services were actually provided, were provided at the level billed, and were medically necessary);
- Make documentation available, upon request.[1]

While prior authorization and review will not be required for the items addressed by this medical policy, the CMS-5531-IFC clarifies that the lack of enforcement of certain elements of NCDs and LCDs does **not** mean medical necessity requirements for items and services are waived during this PHE. This final rule

serves to *"remind physicians, practitioners and suppliers that most items and services must be reasonable and necessary for the diagnosis or treatment of an illness or injury or to improve the functioning of a malformed body member to be paid under Part A or Part B of Title XVIII. Physicians, practitioners, and suppliers are required to continue documenting the medical necessity for all services. Accordingly, the medical record must be sufficient to support payment for the services billed..."*

MEDICARE AND MEDICAL NECESSITY

Only medically reasonable and necessary services or items which treat illness or injury are eligible for Medicare coverage, as outlined in *Title XVIII of the Social Security Act, §1862(a)(1)(A)*.

Medicare provides coverage guidance for most oral appliances used in the treatment of sleep disorders. However, as of this policy update, the eXciteOSA® device, which is a tongue neuromuscular electrical stimulation device intended to treat mild obstructive sleep apnea (OSA), is not included in the oral appliance LCDs. However, the national coverage determination (NCD) for Neuromuscular Electrical Stimulation (NMES) (160.12) provides only two indicates for which NMES may be allowed by Medicare (muscle atrophy and patients with spinal cord injuries). Since OSA is not included as a covered indication for NMES, then this device is non-covered by Medicare at this time.

REGULATORY STATUS

U.S. FOOD & DRUG ADMINISTRATION (FDA)

While clearance by the Food and Drug Administration (FDA) is a prerequisite for Medicare coverage, the 510(k) premarket clearance process does not in itself establish medical necessity. Medicare payment policy is determined by the interaction of numerous requirements, including but not limited to, the availability of a Medicare benefit category and other statutory requirements, coding and pricing guidelines, as well as national and local coverage determinations and clinical evidence.

BILLING GUIDELINES AND CODING

GENERAL

See associated local coverage article (LCA) for related billing and coding guidelines:

- LCA: Oral Appliances for Obstructive Sleep Apnea (A52512)

CODING FOR CUSTOM FABRICATED ORAL APPLIANCES

According to LCA A52512, in order for a device to be coded using HCPCS code E0486, Medicare requires that the device in question have, among other things, a fixed hinge.

HCPCS CODES E0490, E0491 K1027-K1029

HCPCS codes E0490 and E0491 are new codes as of October 1, 2023.

HCPCS code K1027 was a new code as of October 1, 2021 and is used to represent oral devices that do **not** have a fixed hinge, and thus, would not be eligible for coding using HCPCS code E0486. As of the date of this policy update, devices reported with HCPCS code K1027 include the following:

- O2Vent Optima and O2Vent Optima Mini (Oventus Medical)
- Prosomnus Evo Sleep and Snore Device (Prosomnus Sleep Technologies)
- Slow Wave DS8 (Slow Wave)

HCPCS codes E0492 and E0493 are new codes as of January 1, 2024 and are used to report the eXciteOSA device (Signifier Medical Technologies) (HCPCS codes K1028 and K1029 were used between April 1, 2022 and December 31, 2023).

Prior to the development of these codes, most of these devices were coded by the Medicare Pricing, Data and Coding Contractor (PDAC) with HCPCS code A9270, which means these devices were – and continue to be – non-covered by Medicare.

HCPCS CODE E0486

In addition, the only products which may be billed using HCPCS code E0486 are those for which a written coding verification review (CVR) has been performed by the PDAC contractor and published on the PDAC Product Classification List (PCL) website. If a product is billed HCPCS code E0486, but that product is not listed on the PCL for E0486, then that device will be considered improper coding and coverage will not be allowed. *(LCA A52512)*

CODING FOR ELECTRONIC POSITIONAL OSA DEVICES

HCPCS code HCPCS code K1001 was a new code as of January 1, 2020. As of the date of this policy update, devices reported with HCPCS code E0530 (previously K1001) include the following:

- Lunoa System (Philips Respironics)
- NightBalance (Respironics Inc.)

Note that some items may need to be reported using HCPCS code A9270 and these items are not covered benefits.

CODES*		
CPT	21085	Impression and custom preparation; oral surgical splint
HCPCS	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
	E0490	Power source and control electronics unit for oral device/appliance for neuromuscular electrical stimulation of the tongue muscle, controlled by hardware remote

	E0491	Oral device/appliance for neuromuscular electrical stimulation of the tongue muscle, used in conjunction with the power source and control electronics unit, controlled by hardware remote, 90-day supply
	E0492	Power source and control electronics unit for oral device/appliance for neuromuscular electrical stimulation of the tongue muscle, controlled by phone application
	E0493	Oral device/appliance for neuromuscular electrical stimulation of the tongue muscle, used in conjunction with the power source and control electronics unit, controlled by phone application, 90-day supply
	E0530	Electronic positional obstructive sleep apnea treatment, with sensor, includes all components and accessories, any type
	E1399	Durable medical equipment, miscellaneous
	~~K1001~~	**TERMED 12/31/2023** ~~Electronic positional obstructive sleep apnea treatment, with sensor, includes all components and accessories, any type~~
	K1027	Oral device/appliance used to reduce upper airway collapsibility, without fixed mechanical hinge, custom fabricated, includes fitting and adjustment
	~~K1028~~	**TERMED 12/31/2023** ~~Power source and control electronics unit for oral device/appliance for neuromuscular electrical stimulation of the tongue muscle, controlled by phone application~~
	~~K1029~~	**TERMED 12/31/2023** ~~Oral device/appliance for neuromuscular electrical stimulation of the tongue muscle, used in conjunction with the power source and control electronics unit, controlled by phone application, 90-day supply~~
	K1037	Docking station for use with oral device/appliance used to reduce upper airway collapsibility

***Coding Notes:**

- The code list above is provided as a courtesy and may not be all-inclusive. Inclusion or omission of a code from this policy neither implies nor guarantees reimbursement or coverage. Some codes may not require routine review for medical necessity, but they are subject to provider contracts, as well as member benefits, eligibility and potential utilization audit. According to Medicare, "presence of a payment amount in the MPFS and the Medicare physician fee schedule database (MPFSDB) does not imply that CMS has determined that the service may be covered by Medicare." The issuance of a CPT or HCPCS code or the provision of a payment or fee amount by Medicare does **not** make a procedure medically reasonable or necessary or a covered benefit by Medicare. *(Medicare Claims Processing Manual, Chapter 23 - Fee Schedule Administration and Coding Requirements, §30 - Services Paid Under the Medicare Physician's Fee Schedule, A. Physician's Services)*
- All unlisted codes are reviewed for medical necessity, correct coding, and pricing at the claim level. If an unlisted code is submitted for non-covered services addressed in this policy then it will be **denied as not covered**. If an unlisted code is submitted for potentially covered services addressed in this policy, to avoid post-service denial, **prior authorization is recommended**.
- **See the non-covered and prior authorization lists on the Company Medical Policy, Reimbursement Policy, Pharmacy Policy and Provider Information website for additional information.**
- HCPCS/CPT code(s) may be subject to National Correct Coding Initiative (NCCI) procedure-to-procedure (PTP) bundling edits and daily maximum edits known as "medically unlikely edits" (MUEs) published by the Centers for Medicare and Medicaid Services (CMS). This policy does not take precedence over NCCI edits or MUEs. Please refer to the CMS website for coding guidelines and applicable code combinations.

REFERENCES

1. Medicare Benefit Policy Manual, Chapter 15 – Covered Medical and Other Health Services, §110.8 – DMEPOS Benefit Category Determinations; Available at: https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/bp102c15.pdf

POLICY REVISION HISTORY

DATE	REVISION SUMMARY
7/2022	Annual review (converted to new format 2/2023)
7/2023	Annual review
10/2023	Q4 2023 code updates
1/2024	Q1 2024 code updates
4/2024	Q2 2024 code updates