Medicare Medical Policy

Sleep Disorder Treatment with Oral and Sleep Position Appliances

MEDICARE MEDICAL POLICY NUMBER: 45

Effective Date: 7/1/2025

Last Review Date: 6/2025

Next Annual Review: 4/2026

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.

Service	Medicare Guidelines
*Oral Appliance Therapy for Obstructive Sleep Apnea (Includes custom oral appliance **with** a fixed hinge, reported with HCPCS E0486, as well as prefabricated oral appliances [E0485])*	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®) (HCPCS E0492, E0493)	National Coverage Determination (NCD): Neuromuscular Electrical Stimulation (NMES) (160.12) **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**. In addition, see also the Medicare Benefit Policy Manual, Chapter 15, §110.8 – DMEPOS Benefit Category Determinations, which states these devices were determined to have "**No DMEPOS Benefit Category,**" and thus not eligible for coverage.
Neuromuscular Electrical Stimulation of the Tongue Muscle, Controlled by Hardware Remote (eXciteOSA®) (HCPCS E0490, E0491)	National Coverage Determination (NCD): Neuromuscular Electrical Stimulation (NMES) (160.12) **NOTE:** Same note as above, uses of NMES other than those called out as medically necessary in the NCD would not meet NCD criteria for Medicare coverage, making the device **not medically necessary** as well.

Medicare Coverage Criteria: "MA organizations may create publicly accessible internal coverage criteria… when coverage criteria are not fully established in applicable Medicare statutes, regulations, NCDs or LCDs." *(§ 422.101(b)(6) – see Policy Guidelines below*) • **Medicare Coverage Manuals:** Medicare does not have criteria for oral appliances, for any indication, in a coverage manual. • **National Coverage Determination (NCD):** Medicare does not have an NCD for oral appliances • **FOR ORAL APPLIANCE DEVICES: Noridian J-D DMEPOS Local Coverage Determination (LCD)/Local Coverage Article (LCA):** As of the most recent policy review, while there is an LCD for oral appliances to treat obstructive sleep apnea (OSA), it is limited to E0485 and E0486. Neither DME Medicare Administrative Contractor (MAC) has an LCD or LCA applicable to the oral appliances/devices noted below. • **FOR BITE DEPROGRAMMERS: Noridian J-F Local Coverage Determination (LCD)/Local Coverage Article (LCA):** As of the most recent policy review, no Medicare Administrative Contractors (MACs) have LCDs for a bite deprogrammer (or custom-made splint; CPT 21085). • Therefore, in the absence of **fully established** Medicare coverage criteria in a manual, NCD, LCD, or other regulatory guidance for the health plan's service area, Company criteria below are applied for medical necessity decision-making. In this case, Medicare coverage criteria are considered "not fully established" as defined under CFR § 422.101(6)(i)(B) as the available Medicare coverage policies provide flexibility for coverage decisions beyond the LCD, since the available oral appliance LCD doesn't address the specific devices or services listed below. • ***NOTE:*** *The summary of evidence, as well as the list of citations/references used in the development of the Company's internal coverage criteria, are publicly available and can be found using the Company medical policy link below [CFR § 422.101(6)(ii)(A) and (B)].*	
Other Oral Appliances Not Otherwise Addressed *Examples:* • *Bite deprogrammer (CPT 21085) (e.g., AM Align, Morning Repositioner)* • *Electronic Positional OSA or Sleep Position Trainer Devices (e.g., NightBalance by Respironics Inc., Lunoa System by Philips Respironics) (HCPCS E0530)* • *Oral Appliance **Without** Fixed Hinge (e.g., the EVO® Sleep and Snore Device, by (ProSomnus® Sleep Technologies) (HCPCS K1027, K1037)*	Company medical policy for Sleep Disorder Treatment with Oral and Sleep Position Appliances I. These services are considered **not medically necessary** for Medicare based on the Company medical policy. *See Policy Guidelines below.*

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 Surgery, MP244

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

POLICY GUIDELINES

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.

When the eXciteOSA® device is used with a **phone app**, the Medicare Benefit Policy Manual, Chapter 15, §110.8 – DMEPOS Benefit Category Determinations, makes the following statement: "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." Thus, these devices are not eligible for DME coverage for Medicare or Medicare Advantage plans when used with a phone app.

However, when the eXciteOSA® device is used with a **hardware remote**, even though the Medicare Benefit Policy Manual, Chapter 15, states this use of the device could be considered durable medical equipment or DME, all items and services must still be considered medically reasonable and necessary, and thus Medicare coverage criteria for NMES is applied. 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.

Other Devices and Services

According to Medicare Final Rulings, MA organizations (MAOs) make medical necessity determinations based on coverage and benefit criteria, current standards of care, the member's unique personal medical history (e.g., diagnoses, conditions, functional status, co-morbidities, etc.), physician recommendations, and clinical notes, as well as involvement of a plan medical director, where appropriate. *(§ 422.101(c)(1))*

> "MA organizations may create publicly accessible internal coverage criteria that are based on current evidence in widely used treatment guidelines or clinical literature when coverage criteria are not fully established in applicable Medicare statutes, regulations, NCDs or LCDs. Current, widely-used treatment guidelines are those developed by organizations representing clinical medical specialties, and refers to guidelines for the treatment of specific diseases or conditions. Acceptable clinical literature includes large, randomized controlled trials or prospective cohort studies with clear results, published in a peer-reviewed journal, and specifically designed to answer the relevant clinical question, or large systematic reviews or meta-analyses summarizing the literature of the specific clinical question." *(§ 422.101(b)(6) and Medicare Managed Care Manual, Ch. 4, §90.5)*

The Plan's Medicare policy for *PHA Medicare Medical Policy Development and Application* (MP50) provides details regarding Medicare's definition of medical necessity and the hierarchy of Medicare references and resources during the development of medical policies, as well as the Plan's use of evidence-based processes for policy development.

Since there are not fully established coverage criteria for oral appliances or surgical splints/bite deprogrammers available in applicable Medicare statutes, regulations, NCDs or LCDs, then Company medical policy criteria will be applied. See the Medicare Coverage Criteria table above for more information regarding the use of internal coverage criteria when Medicare coverage criteria are not fully established.

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.

There are several devices that have been approved by the U.S. Federal Drug & Administration (FDA). Examples of these are included in the table below. Note, the list below is not all-inclusive.

Table 2: Description of Table Contents

Device/Product Name	Manufacturer/Distributer	PDAC-Assigned HCPCS code (Date)

AirVata	Gelb Practice Solutions	K1027 (6/19/2024)
Clear Sleep®	Space Maintainers Lab	K1027 (1/17/2025)
Elevate	Serena Sleep Solutions	K1027 (3/2/2022)
EMA® - Fixed Hinge	Serena Sleep Solutions	K1027 (5/10/2023)
EMA® 3D	Apex Dental Sleep Lab	K1027 (9/7/2024)
Flex	Serena Sleep Solutions	K1027 (9/13/2023)
Hushd Pro Avera	Good Sleep Co Usa Llc	K1027 (11/7/2024)
Lamberg Sleep Well	Space Maintainers Lab	K1027 (11/1/2022)
Morpheus	Hallmark Dental Laboratory	K1027 (6/22/2023)
Noa Sleep Apnea and Snoring Device	Apex Dental Sleep Lab	K1027 (10/25/2024)
O2vent Optima	Oventus Medical Ltd	K1027 (10/30/2021)
O2vent Optima	Open Airway Dental Solutions Ltd	K1027 (8/22/2023)
O2vent Optima Connect	Open Airway Dental Solutions Ltd	K1027 (4/23/2024)
O2vent Optima Mini	Oventus Medical Ltd	K1027 (1/22/2022)
O2vent Optima Mini	Open Airway Dental Solutions Ltd	K1027 (8/22/2023)
O2vent Optima Mini Connect	Open Airway Dental Solutions Ltd	K1027 (4/23/2024)
Oasys Oral/Nasal Airway System	Dream Systems Dental Lab	K1027 (2/7/2024)
Panthera D-Sad X3	Panthera Dental Inc	K1027 (10/15/2022)
Prosomnus [Ca] Sleep and Snore Device	Prosomnus Sleep Technologies	K1027 (7/12/2024)
Prosomnus EVO Sleep and Snore Device	Prosomnus Sleep Technologies	K1027 (12/9/2021)
Respire Blue + Hard, Hard/Soft, EF (Models SBP000US, SBP020US, & SPB030US)	Respire Medical	K1027 (9/29/2022)
Silent Nite 3d Sleep Appliance	Prismatik Dentalcraft Inc	K1027 (10/8/2024)
Slow Wave Ds8	Slow Wave	K1027 (10/1/2021)
Snorehook Splint	Boyd Research Inc	K1027 (10/1/2024)
SnorehookPRO	Boyd Research Inc	K1027 (1/28/2025)
SnorehookPRO-Elite	Boyd Research Inc	K1027 (1/28/2025)
Somnodent Avant	Somnomed Inc	K1027 (5/17/2023)
Somnomed Mas Flex "S"	Somnomed Inc	K1027 (1/7/2025)
The Slide	Leblanc Dental Products	K1027 (4/1/2024)
The Slide	Biotex Inc	K1027 (9/30/2022)
Versa	Serena Sleep Solutions	K1027 (9/13/2023)
Vivos DNA Appliance	Vivos Therapeutics Inc	K1027 (4/1/2024)
Vivos mRNA Appliance	Vivos Therapeutics Inc	K1027 (4/1/2024)
Prosomnus EVO™ Docking Station/Power Supply	Prosomnus Sleep Technologies	K1037 (4/1/2024)

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	0964T	Impression and custom preparation of jaw expansion oral prosthesis for obstructive sleep apnea, including initial adjustment; single arch, without mandibular advancement mechanism
	0965T	Impression and custom preparation of jaw expansion oral prosthesis for obstructive sleep apnea, including initial adjustment; dual arch, with additional mandibular advancement, non-fixed hinge mechanism
	0966T	Impression and custom preparation of jaw expansion oral prosthesis for obstructive sleep apnea, including initial adjustment; dual arch, with additional mandibular advancement, fixed hinge mechanism
	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
	K1027	Oral device/appliance used to reduce upper airway collapsibility, without fixed mechanical hinge, custom fabricated, includes fitting and adjustment
	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
5/2024	Annual review; no change to criteria, but update to title
5/2025	Annual review
7/2025	Q3 2025 code updates