MEDICAL POLICY	**Temporary Policy Emergency Provisions for:** **Sleep Disorder Treatment: Oral and Sleep Position Appliances** **(Medicare Only)**
Effective Date: 7/1/2022  7/1/2022 Medical Officer Date	Medical Policy Number: 45 Medical Policy Committee Approved Date: 1/18; 1/19; 12/19; 11/2020; 1/2021; 04/2021; 9/2021; 12/2021; 3/2022

See Policy HCPCS CODE section below for any prior authorization requirements

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**
5. **Termination Date: 12/31/2022**
6. **Reassessment Date determined at Companies sole discretion: 12/30/2022, 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]

MEDICAL POLICY	Sleep Disorder Treatment: Oral and Sleep Position Appliances (Medicare Only)

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..."*

SCOPE:

Providence Health Plan, Providence Health Assurance, Providence Plan Partners, and Ayin Health Solutions as applicable (referred to individually as "Company" and collectively as "Companies").

APPLIES TO:

Medicare only

MEDICARE POLICY CRITERIA

The following Centers for Medicare & Medicaid Service (CMS) guidelines should be utilized for medical necessity coverage determinations. Click the link provided in the table below to access applicable medical necessity criteria. All listed guidelines apply.

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.*

BILLING GUIDELINES

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 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 K1028 and K1029 are new codes as of April 1, 2022 and are used to report the eXciteOSA device (Signifier Medical Technologies).

Prior to the development of codes K1027, K1028, and K1029, 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.

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 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.

CPT/HCPCS CODES

Medicare Only	
Prior Authorization Required	
21085	Impression and custom preparation; oral surgical splint

No Prior Authorization Required	
E0486	Oral device/appliance used to reduce upper airway collapsibility, adjustable or non-adjustable, custom fabricated, includes fitting and adjustment
Not Covered	
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
K1001	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	Power source and control electronics unit for oral device/appliance for neuromuscular electrical stimulation of the tongue muscle for the reduction of snoring and obstructive sleep apnea, controlled by phone application
K1029	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
Unlisted Codes All unlisted codes will be reviewed for medical necessity, correct coding, and pricing at the claim level. If an unlisted code is billed related to services addressed in this policy then **prior-authorization is required.**	
E1399	Durable medical equipment, miscellaneous

INSTRUCTIONS FOR USE

Company Medical Policies serve as guidance for the administration of plan benefits. Medical policies do not constitute medical advice nor a guarantee of coverage. Company Medical Policies are reviewed annually and are based upon published, peer-reviewed scientific evidence and evidence-based clinical practice guidelines that are available as of the last policy update. The Companies reserve the right to determine the application of Medical Policies and make revisions to Medical Policies at any time. Providers will be given at least 60-days notice of policy changes that are restrictive in nature.

The scope and availability of all plan benefits are determined in accordance with the applicable coverage agreement. Any conflict or variance between the terms of the coverage agreement and PHA Medical Policy will be resolved in favor of the coverage agreement.

REGULATORY STATUS

Mental Health Parity Statement

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.

MEDICAL POLICY CROSS REFERENCES

- Sleep Disorder Testing (All Lines of Business Except Medicare), MP60
- Sleep Disorder Testing (Medicare Only), MP57
- Sleep Disorder Treatment: Oral Appliances (All Lines of Business Except Medicare), MP46
- Sleep Disorder Treatment: Positive Airway Pressure (All Lines of Business Except Medicare), MP56
- Sleep Disorder Treatment: Positive Airway Pressure (Medicare Only), MP53
- Sleep Disorder Treatment: Surgical (All Lines of Business Except Medicare), MP179
- Sleep Disorder Treatment: Surgical (Medicare Only), MP244