


<p align="center">MEDICAL POLICY</p>	<p align="center">Temporary Policy Emergency Provisions for:</p> <p align="center">Sleep Disorder Treatment: Oral and Sleep Position Appliances</p> <p align="center">(Medicare Only)</p>
<p>Effective Date: 05/01/2021 for Annual Review</p> <p>60 day effective period for temporary policy provisions beginning 4/1/2021</p>  <p align="right">5/1/2021</p>	<p align="center">Medical Policy Number: 45</p> <p>Medical Policy Committee Approved Date: 1/18; 1/19; 12/19; 11/2020; 1/2021; 04/2021</p>
<p>Medical Officer Date</p>	

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:** [Centers for Medicare & Medicaid Services \(CMS\) final rules in response to the COVID-19 Public Health Emergency](#) and [Noridian CMS Interim Final Rules](#)
3. **Initial Effective Date:** 3/1/2020
4. **Re-review dates:** 2/3/2021; 3/31/2021
5. **Termination Date:** 6/1/2021
6. **Reassessment Date determined at Companies sole discretion:** 05/26/2021

POLICY ADDENDUM

COVID-19 Public Health Emergency

On March 30th, 2020, the Centers for Medicare & Medicaid Services (CMS) released “[Centers for Medicare & Medicaid Services \(CMS\) final rules in response to the COVID-19 Public Health Emergency](#)”. These rules state:

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)

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- *Intrapulmonary Percussive Ventilator (NCD 240.5)*
- *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)*
- *Glucose Monitors (L33822) - Only clinical indications for Therapeutic Continuous Glucose Monitors (CGM) are not enforced*
- *External Infusion Pumps (L33794);*

Treating practitioners and suppliers must still:

- *Provide a standard written order (SWO) for all items. For PMDs, the treating practitioner must document and communicate to the DMEPOS supplier that the treating practitioner has had a face-to-face encounter with the beneficiary within the 6 months preceding the date of the written order/prescription, per section 1834(a)(1)(E)(iv) of the Act;*
- *Ensure that the items or services are reasonable and necessary;*
- *Continue documenting the medical necessity for all services. Accordingly, the medical record must be sufficient to support payment for the services billed (that is, the services were actually provided, were provided at the level billed, and were medically necessary);*
- *Make documentation available, upon request.*
- *This enforcement discretion will only apply during the COVID-19 PHE. At the conclusion of the COVID-19 PHE, the DME MACs will return to enforcement of the clinical indications for coverage.*

SCOPE:

Providence Health Plan, Providence Health Assurance, Providence Plan Partners, and Aycin 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.

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Service	Medicare Guidelines
<i>Oral Appliance Therapy for Obstructive Sleep Apnea</i>	<ul style="list-style-type: none"> Local Coverage Determination (LCD): Oral Appliances for Obstructive Sleep Apnea (L33611)¹ Local Coverage Article (LCA): Oral Appliances for Obstructive Sleep Apnea (A52512)² LCA: Standard Documentation Requirements for All Claims Submitted to DME MACs (A55426)³

CPT/HCPCS CODES

Medicare Only	
Prior Authorization Required	
E0486	Oral device/appliance used to reduce upper airway collapsibility, adjustable or non-adjustable, custom fabricated, includes fitting and adjustment
21085	Impression and custom preparation; oral surgical splint
Not Covered	
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
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.

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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)
- Sleep Disorder Testing (Medicare Only)
- Sleep Disorder Treatment: Oral Appliances (All Lines of Business Except Medicare)
- Sleep Disorder Treatment: Positive Airway Pressure (All Lines of Business Except Medicare)
- Sleep Disorder Treatment: Positive Airway Pressure (Medicare Only)
- Sleep Disorder Treatment: Surgical (All Lines of Business Except Medicare)
- Sleep Disorder Treatment: Surgical (Medicare Only)

REFERENCES

1. Centers for Medicare & Medicaid Services Local Coverage Determination (LCD): Oral Appliances for Obstructive Sleep Apnea (L33611). Revision Effective Date: For services performed on or after 01/01/2020. <https://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?lcdid=33611>. Accessed 02/10/2021.
2. Centers for Medicare & Medicaid Services Local Coverage Article: Oral Appliances for Obstructive Sleep Apnea - Policy Article (A52512). Revision Effective Date: 04/03/2020. <https://www.cms.gov/medicare-coverage-database/details/article-details.aspx?articleId=52512>. Accessed 2/10/2021.
3. Centers for Medicare & Medicaid Services Local Coverage Article: Standard Documentation Requirements for All Claims Submitted to DME MACs (A55426). Revision Effective Date: 04/06/2020. <https://www.cms.gov/medicare-coverage-database/details/article-details.aspx?articleId=55426>. Accessed 2/10/2021.