


MEDICAL POLICY	Temporary Policy Emergency Provisions for: Sleep Disorder Treatment: Positive Airway Pressure (Medicare Only)
Effective Date: 7/1/2022	Medical Policy Number: 53
 7/1/2022	Medical Policy Committee Approved Date: 1/18; 1/19; 12/19; 7/2020; 9/2020; 11/2020; 1/2021; 04/2021; 12/2021; 3/2022
Medical Officer	Date

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: 5/27/2020; 7/22/2020; 9/23/2020; 11/30/2020; 2/3/2021; 3/31/2021; 6/1/2021; 12/8/2021; 7/20/2022**
- 5. Termination Date: 9/30/2022**
- 6. Next Reassessment Date determined at Companies sole discretion: 9/28/2022, 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.).

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“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

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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	
<p>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.</p>	
Service	Medicare Guidelines
<p><i>Continuous Positive Airway Pressure (CPAP) Therapy for Obstructive Sleep Apnea (OSA) – General Coverage Guidance</i></p>	<p>General medical necessity criteria for continuous positive airway pressure (CPAP) therapy when used for OSA:</p> <ul style="list-style-type: none"> National Coverage Determination (NCD): Continuous Positive Airway Pressure (CPAP) Therapy for Obstructive Sleep Apnea (240.4) <p><i>Note: The NCD provides more detailed criteria on the sleep testing requirements for the OSA diagnosis (see criterion B.3. and B.4.)</i></p> <p>The LCD below supplements this NCD, providing the same coverage criteria, as well as providing further clarifying details.</p>
<p><i>All PAP Devices for OSA – Supplemental Information – Initial Provision and Replacement</i></p>	<p>Supplemental information, including clarifications regarding criteria (single level CPAPs and bi-level [BiPAP] machines), coding, and documentation requirements and accessories when used to treat OSA:</p>

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	<ul style="list-style-type: none"> Local Coverage Determination (LCD): Positive Airway Pressure (PAP) Devices for the Treatment of Obstructive Sleep Apnea (L33718) <p>See "Policy Guidelines" below for additional information regarding equipment replacement.</p>
<i>Positive Airway Pressure for non-OSA Breathing Disorders (e.g., restrictive thoracic disorders, severe chronic obstructive pulmonary disease [COPD], central sleep apnea) – Initial Provision and Replacement</i>	<p>General medical necessity criteria for respiratory assist devices (RAD) used for non-OSA disorders:</p> <ul style="list-style-type: none"> LCD: Respiratory Assist Devices (L33800) <p>See "Policy Guidelines" below for additional information regarding equipment replacement.</p>
<i>Replacement of PAP Accessories</i>	<ul style="list-style-type: none"> Local Coverage Article (LCA): Positive Airway Pressure (PAP) Devices for the Treatment of Obstructive Sleep Apnea (A52467) LCA: Respiratory Assist Devices - Policy Article (A52517)

POLICY GUIDELINES

Replacement of Positive Airway (PAP) Devices and Respiratory Assist Devices (RAD)

The reasonable useful lifetime (RUL) for PAP and RAD equipment is 5 years. Replacement of this equipment **prior to** the 5-year RUL is eligible for coverage only in select situations (e.g., lost, stolen, irreparably damaged). Replacement when the 5-year RUL **ends** may be eligible for coverage when it is determined that the member continues to use and benefit from the device.

Accessories are not subject to the 5-year RUL and replacement of these items may be warranted sooner.

Replacement of items that are not irreparably worn or damaged and which continue to provide necessary therapeutic benefit for the member would not be considered medically reasonable or necessary because the replacement serves essentially the same purpose as equipment already available to the beneficiary, even if the minimum 5-year reasonable useful lifetime (RUL) for an item is met.^{1,2} Therefore, an individual simply having a particular piece of PAP or RAD equipment for 5-years does not automatically warrant or justify replacement. It must be determined that the existing equipment does not sufficiently meet the therapeutic needs for the member.

Replacement of PAP or RAD equipment **prior to** the 5-year RUL period being reached:

If due to **irreparable wear**:

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- Medicare expects *rented* equipment to remain in good working order for the entire RUL of the equipment. Therefore, if the equipment does not last for the entire 5-year RUL, the supplier must replace the equipment at no charge.
- For *member-owned* equipment, coverage for replacement equipment is not allowed prior to the 5-year RUL for irreparable *wear* per Medicare statute.

If due to **change in patient medical condition**:

- Replacement of rented or member-owned equipment may be warranted if:
 1. The current item(s) can no longer meet the patient's therapeutic medical needs; **and**
 2. It is the least costly option to replace the equipment in order to meet the patient's medical needs (rather than repair or reconfigure with available options).

Replacement of PAP or RAD equipment **after** the 5-year RUL period is reached due to irreparable *wear* **OR replacement at any time** due to *theft, loss*, or irreparable *damage*:

- If the 5-year RUL of the equipment is reached, replacement must still be medically reasonable and necessary:
 - The member must be regularly using the equipment as prescribed; and,
 - The equipment continues to provide the needed therapeutic benefit.
 - For irreparably *worn* devices, documentation must support the current device no longer meets the therapeutic medical needs of the member and cannot be repaired to a state where it can provide the needed therapeutic benefit (e.g., it is not cost effective to repair the current device).
 - For lost, stolen, or irreparably *damaged* devices, documentation of the specific incident of irreparable damage or a written explanation regarding the loss (e.g., details around circumstances of the loss, a police report for stolen items, etc.).

To safeguard member financial liabilities, it is recommended the member be advised of and understands that provision of a replacement item may will result in new member financial liability (e.g., new rental period starts over or the re-purchase of an item).

Accessories or replacement components of PAP or RAD equipment are not subject to the 5-year RUL and may be replaced prior to the end of the RUL period.

BILLING GUIDELINES

General

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

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- LCA: Positive Airway Pressure (PAP) Devices for the Treatment of Obstructive Sleep Apnea ([A52467](#))
- LCA: Respiratory Assist Devices - Policy Article ([A52517](#))

Multi-Function Home Ventilation Systems

If a member is on a multi-function home ventilation system (HCPCS E0467), no separate reimbursement is made for RAD or PAP devices. (LCA A52467)

HCPCS CODES

Medicare Only	
No Prior Authorization Required	
E0470	Respiratory assist device, bi-level pressure capability, without backup rate feature, used with noninvasive interface, e.g., nasal or facial mask (intermittent assist device with continuous positive airway pressure device)
E0471	Respiratory assist device, bi-level pressure capability, with back-up rate feature, used with noninvasive interface, e.g., nasal or facial mask (intermittent assist device with continuous positive airway pressure device)
E0472	Respiratory assist device, bi-level pressure capability, with backup rate feature, used with invasive interface, e.g., tracheostomy tube (intermittent assist device with continuous positive airway pressure device)
E0601	Continuous positive airway pressure (cpap) device

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

REFERENCES

1. Medicare Benefit Policy Manual, Chapter 15 – Covered Medical and Other Health, §110.2 - Repairs, Maintenance, Replacement, and Delivery, C. Replacement; Last Updated: 07/06/2015; Available at: <https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/bp102c15.pdf> [Last cited 02/08/2022]
2. Medicare Benefit Policy Manual, Chapter 15 – Covered Medical and Other Health, §110.1 - Definition of Durable Medical Equipment; Last Updated: 11/08/2021; Available at: <https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/bp102c15.pdf> [Last cited 02/08/2022]