Medicare Medical Policy

Sleep Disorder Treatment: Positive Airway Pressure

MEDICARE MEDICAL POLICY NUMBER: 53

Effective Date: 5/1/2023

Last Review Date: 4/2023

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, Providence Plan Partners, and Ayin Health Solutions 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
Continuous Positive Airway Pressure (CPAP) Therapy for Obstructive Sleep Apnea (OSA) – General Coverage Guidance	**General medical necessity criteria** for **continuous positive airway pressure (CPAP)** therapy **when used for OSA**: • National Coverage Determination (NCD): Continuous Positive Airway Pressure (CPAP) Therapy for Obstructive Sleep Apnea (240.4) *Note: The NCD provides more detailed criteria on the sleep testing requirements for the OSA diagnosis (see criterion B.3. and B.4.)* The LCD below supplements this NCD, providing the same coverage criteria, as well as providing further clarifying details.
All PAP Devices for OSA – Supplemental Information – Initial Provision and Replacement	**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:** • Local Coverage Determination (LCD): Positive Airway Pressure (PAP) Devices for the Treatment of Obstructive Sleep Apnea (L33718) *See "Policy Guidelines" below for additional information regarding equipment replacement, as well as non-coverage information regarding the ULTepap™ System.*
Positive Airway Pressure for non-OSA Breathing Disorders	**General medical necessity criteria** for **respiratory assist devices** (RAD) used for **non-OSA disorders**:

(e.g., restrictive thoracic disorders, severe chronic obstructive pulmonary disease [COPD], central sleep apnea) – Initial Provision and Replacement	• LCD: Respiratory Assist Devices (L33800) *See "Policy Guidelines" below for additional information regarding equipment replacement.*
Replacement of PAP Accessories	• Local Coverage Article (LCA): Positive Airway Pressure (PAP) Devices for the Treatment of Obstructive Sleep Apnea (A52467) • LCA: Respiratory Assist Devices - Policy Article (A52517)

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: 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: 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; 10/4/2022; 12/16/2022; 1/30/2023**
5. **Termination Date: 5/11/2023**
6. **Next 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…"*

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***:

- 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.

ULTepap™ System

The ULTepap™ System "is a single-patient, reusable Expiratory Positive Airway Pressure (EPAP) device for the treatment of mild to moderate obstructive sleep apnea marketed as ULTepap™. The ULTepap™ System received the Food and Drug Administration's (FDA's) 510(k) clearance on January 24, 2020. The device is comprised of a pair of bi-resistance cartridges which are designed and warrantied for a 3-year expected service life. The ULTepap™ System includes a headgear and appropriate size nasal pillow for the patient. These accessory items are similar in design and performance to currently available products."[3]

According to CMS, this item does not meet Medicare requirements to be classified as DME. Specifically, it does not meet the requirement for "repeated use."[3]

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 coding and billing guidance:

- 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)*

ULTepap™ System

HCPCS code A7049 represents the ULTepap™ System and is a new code as of April 1, 2023.

CODES*		
CPT	None	
HCPCS	A7049	Expiratory positive airway pressure intranasal resistance valve
	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

***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, §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]
3. Centers for Medicare and Medicaid Services (CMS) HCPCS Application Summary; Available at: https://www.cms.gov/files/document/2022-hcpcs-application-summary-biannual-2-2022-non-drug-and-non-biological-items-and-services.pdf

POLICY REVISION HISTORY

DATE	REVISION SUMMARY
7/2022	Annual review (converted to new format 2/2023)
4/2023	Q2 2023 code updates
5/2023	Annual review; no changes