Medicare Medical Policy

Sleep Disorder Treatment with Positive Airway Pressure

MEDICARE MEDICAL POLICY NUMBER: 53

Effective Date: 6/1/2025

Last Review Date: 5/2025

Next Annual Review: 5/2026

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
NOTE: 1. **See Policy Guidelines below for a Coverage Quick Guide.** 2. For the purposes of this policy, the term PAP (positive airway pressure) device will refer to: • Single-level continuous positive airway pressure (CPAP) device (HCPCS E0601) • Bi-level respiratory assist (BiPAP or BPap) device (HCPCS E0470, E0471, E0472) • Expiratory positive airway pressure (EPAP) device (HCPCS A7049).	
Continuous Positive Airway Pressure (CPAP) Therapy (E0601) 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 (both **CPAP and 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) **NOTE:** See "Policy Guidelines" below for additional information regarding equipment replacement. According to LCD L33718,

	HCPCS code E0471 is **not medically necessary** for a primary diagnosis of OSA.
BiPAP Devices for non-OSA Breathing Disorders (e.g., restrictive thoracic disorders, severe chronic obstructive pulmonary disease [COPD], central sleep apnea) – Initial Provision and Replacement	LCD L33718 states, "Coverage, coding and documentation requirements for the use of E0470 and E0471 for diagnoses other than OSA are addressed in the Respiratory Assist Devices (RAD) Local Coverage Determination (LCD) and related Policy Article (PA)." Therefore, **general medical necessity criteria** for **respiratory assist devices** (RAD) used for **non-OSA disorders** are found in the following reference: • 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)
Expiratory positive airway pressure intranasal resistance valve (ULTepap™ System) (HCPCS A7049)	Medicare Benefit Policy Manual, Chapter 15 – Covered Medical and Other Health Services, §110.8 – DMEPOS Benefit Category Determinations *(Search for "Expiratory positive airway pressure" within this CMS reference)* **NOTE:** Expiratory positive airway pressure (EPAP) devices (A7049) do not meet the CMS requirements to be classified as DME, meaning there is no Medicare benefit available for them. Therefore, these items will be denied as **not medically necessary**.

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 Surgery, MP244

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

POLICY GUIDELINES

COMMON ACRONYMS USED IN THIS POLICY

Bilevel positive airway pressure: BIPAP

Central Sleep Apnea: CSA

Chronic Obstructive Pulmonary Disease: COPD

Complex Sleep Apnea: CompSA

Continuous Positive Airway Pressure: CPAP

Obstructive Sleep Apnea: OSA

BACKGROUND

CPAP and BiPAP machines are both forms of positive airway pressure (PAP) therapy, which uses compressed air to open and support the upper airway during sleep. As implied by their name, CPAP devices apply a constant (or continuous), **single** level of air pressure. BiPAP devices offer **two** pressure settings (aka, two levels of pressure), and can switch between an inhalation pressure and a lower exhalation pressure.

Interfaces

There are two different types of interfaces used to provide respiratory support with a PAP or RAD device.

- **Invasive** interface is provided by either an endotracheal tube or tracheostomy tube.
- **Noninvasive** interface options include items such as a nasal, oral, or facial mask.

Coverage of Positive Airway Pressure (PAP) Devices and Respiratory Assist Devices (RAD)

Table 1: Coverage Quick Guide

EQUIPMENT	HCPCS	CONDITION/INDICATION & CRITERIA REFERENCE				
		OSA	CSA	CompSA	COPD	Restrictive Thoracic Disorders
Continuous positive airway pressure (CPAP)	***E0601***	NCD 240.4 & LCD L33718	*Not covered. Both NCD and LCD criteria include diagnosis of OSA for coverage. LCD L33718 states, "If a claim for an E0601 is submitted and all of the criteria above have not been met, it will be denied as not reasonable and necessary." Therefore, CPAP for condition* ***other than*** *OSA is* ***not medically necessary****.*			
Bi-level positive airway pressure device without back-up rate	***E0470***	LCD L33718	LCD L33800	LCD L33800	LCD L33800	LCD L33800

Bi-level positive airway pressure device <u>with</u> back-up rate (<u>non</u>-invasive interface)	***E0471***	LCD L33718 *(Not covered)*	LCD L33800	LCD L33800	LCD L33800	LCD L33800
Bi-level positive airway pressure device <u>with</u> back-up rate (invasive interface)	***E0472***	*Medicare does not provide specific coverage criteria for E0472. The coverage criteria noted for E0471 will be applied to E0472.*				

REPLACEMENT OF PAP DEVICES AND RADS

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 <u>*rented*</u> 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 <u>*wear* ***OR replacement at any time***</u> due to <u>*theft*</u>, <u>*loss*</u>, or irreparable <u>***damage***</u>:

- 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)

BI-LEVEL PRESSURE RESPIRATORY ASSIST DEVICE WITH BACKUP RATE (E0471)

While many of the codes in this policy are not subject to regular review for medical necessity, according to LCD L33718, HCPCS E0471 is not covered for a primary diagnosis of OSA.

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.

MONITORING DEVICES

"Monitoring devices (integrated or modular) are capable of tracking data generated by a RAD or PAP device, which can be subsequently downloaded for further analysis by a healthcare provider, DME supplier, or beneficiary. Such technologies include, but are not limited to:

- Smart cards and readers
- USB/Thumb drive accessories
- Wired telephonic transmission modules
- Wireless modems" *(LCA A52467)*

These devices are to be reported with HCPCS code A9279, which describes any type of monitoring technology.

ACCESSORIES

In addition to the monitoring devices mentioned above, additional accessories for PAP and RAD devices include, but may not be limited to, the following:

A4604 *Tubing with integrated heating element for use with positive airway pressure device*
A7027 *Combination oral/nasal mask, used with continuous positive airway pressure device, each*
A7028 *Oral cushion for combination oral/nasal mask, replacement only, each*
A7029 *Nasal pillows for combination oral/nasal mask, replacement only, pair*
A7030 *Full face mask used with positive airway pressure device, each*
A7031 *Face mask interface, replacement for full face mask, each*
A7032 *Cushion for use on nasal mask interface, replacement only, each*

A7033 *Pillow for use on nasal cannula type interface, replacement only, pair*
A7034 *Nasal interface (mask or cannula type) used with positive airway pressure device, with or without head strap*
A7035 *Headgear used with positive airway pressure device*
A7036 *Chinstrap used with positive airway pressure device*
A7037 *Tubing used with positive airway pressure device*
A7038 *Filter, disposable, used with positive airway pressure device*
A7039 *Filter, non disposable, used with positive airway pressure device*
A7044 *Oral interface used with positive airway pressure device, each*
A7045 *Exhalation port with or without swivel used with accessories for positive airway devices, replacement only*
A7046 *Water chamber for humidifier, used with positive airway pressure device, replacement, each*
E0561 *Humidifier, non-heated, used with positive airway pressure device*
E0562 *Humidifier, heated, used with positive airway pressure device*

Accessories used with a PAP device are covered when the coverage criteria for the base PAP device are met. If the coverage criteria are not met and the PAP device is not medically necessary, accessories will also be denied as not medically necessary. While accessories do not require routine review for medical necessity, usage may be reviewed on audit to ensure appropriate Medicare-established frequency utilization is as expected.

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: 7/6/2015; Available at: https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/bp102c15.pdf. Accessed 4/2/2024.
2. Medicare Benefit Policy Manual, Chapter 15 – Covered Medical and Other Health, §110.1 - Definition of Durable Medical Equipment; Last Updated: 11/8/2021; Available at: https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/bp102c15.pdf. Accessed 4/2/2024.
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. Accessed 4/2/2024.

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
8/2024	Annual review; add EPAPs to criteria table, add notation that bi-level with backup rate for primary diagnosis of OSA is not medically necessary
6/2025	Annual review; no changes