

CONTINUOUS POSITIVE AIRWAY PRESSURE (CPAP) THERAPY FOR OBSTRUCTIVE SLEEP APNEA (OSA) (NCD 240.4)

Guideline Number: MPG061.06

Approval Date: September 9, 2020

[Terms and Conditions](#) ⓘ

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Related Medicare Advantage Policy Guidelines

- [Durable Medical Equipment Reference List \(NCD 280.1\)](#)
- [Routine Costs in Clinical Trials \(NCD 310.1\)](#)
- [Sleep Testing for Obstructive Sleep Apnea \(OSA\) \(NCD 240.4.1\)](#)

Related Medicare Advantage Coverage Summary

- [Sleep Apnea: Diagnosis and Treatment](#)

POLICY SUMMARY

See [Purpose](#) ⓘ

Overview

Continuous Positive Airway Pressure (CPAP) is a non-invasive technique for providing single levels of air pressure from a flow generator, via a nose mask, through the nares. This is to prevent the collapse of the oropharyngeal walls and the obstruction of airflow during sleep, which occurs in obstructive sleep apnea (OSA).

The apnea hypopnea index (AHI) is equal to the average number of episodes of apnea and hypopnea per hour. The respiratory disturbance index (RDI) is equal to the average number of respiratory disturbances per hour.

Apnea is defined as a cessation of airflow for at least 10 seconds. Hypopnea is defined as an abnormal respiratory event lasting at least 10 seconds with at least a 30% reduction in thoracoabdominal movement or airflow as compared to baseline, and with at least a 4% oxygen desaturation.

The AHI and/or RDI may be measured by polysomnography (PSG) in a facility-based sleep study laboratory, or by a Type II home sleep test (HST) monitor, a Type III HST monitor, or a Type IV HST monitor measuring at least 3 channels.

Guidelines

Nationally Covered Indications

The Centers for Medicare & Medicaid Services (CMS) determines that CPAP therapy when used in adult patients with OSA is considered reasonable and necessary under the following situations:

1. The use of CPAP is covered when used in adult patients with OSA. Coverage of CPAP is initially limited to a 12-week period to identify beneficiaries diagnosed with OSA as subsequently described who benefit from CPAP. CPAP is subsequently covered only for those beneficiaries diagnosed with OSA who benefit from CPAP during this 12-week period.
2. The provider of CPAP must conduct education of the beneficiary prior to the use of the CPAP device to ensure that the beneficiary has been educated in the proper use of the device. A caregiver, for example a family member, may be compensatory, if consistently available in the beneficiary's home and willing and able to safely operate the CPAP device.
3. A positive diagnosis of OSA for the coverage of CPAP must include a clinical evaluation and a positive:
 - a. attended PSG performed in a sleep laboratory; or
 - b. unattended HST with a Type II home sleep monitoring device; or
 - c. unattended HST with a Type III home sleep monitoring device; or
 - d. unattended HST with a Type IV home sleep monitoring device that measures at least 3 channels
4. The sleep test must have been previously ordered by the beneficiary's treating physician and furnished under appropriate physician supervision.

5. An initial 12-week period of CPAP is covered in adult patients with OSA if either of the following criterion using the AHI or RDI are met:
 - a. AHI or RDI greater than or equal to 15 events per hour, or
 - b. AHI or RDI greater than or equal to 5 events and less than or equal to 14 events per hour with documented symptoms of excessive daytime sleepiness, impaired cognition, mood disorders or insomnia, or documented hypertension, ischemic heart disease, or history of stroke.
6. The AHI or RDI is calculated on the average number of events of per hour. If the AHI or RDI is calculated based on less than 2 hours of continuous recorded sleep, the total number of recorded events to calculate the AHI or RDI during sleep testing must be at a minimum the number of events that would have been required in a 2-hour period.
7. Apnea is defined as a cessation of airflow for at least 10 seconds. Hypopnea is defined as an abnormal respiratory event lasting at least 10 seconds with at least a 30% reduction in thoracoabdominal movement or airflow as compared to baseline, and with at least a 4% oxygen desaturation.
8. **Coverage with Evidence Development (CED):** Medicare provides the following limited coverage for CPAP in adult beneficiaries who do not qualify for CPAP coverage based on criteria 1-7 above. A clinical study seeking Medicare payment for CPAP provided to a beneficiary who is an enrolled subject in that study must address one or more of the following questions:
 - a. In Medicare-aged subjects with clinically identified risk factors for OSA, how does the diagnostic accuracy of a clinical trial of CPAP compare with PSG and Type II, III & IV HST in identifying subjects with OSA who will respond to CPAP?
 - b. In Medicare-aged subjects with clinically identified risk factors for OSA who have not undergone confirmatory testing with PSG or Type II, III & IV HST, does CPAP cause clinically meaningful harm?

The study must meet the following additional standards:

 - c. The principal purpose of the research study is to test whether a particular intervention potentially improves the participants' health outcomes.
 - d. The research study is well-supported by available scientific and medical information or it is intended to clarify or establish the health outcomes of interventions already in common clinical use.
 - e. The research study does not unjustifiably duplicate existing studies.
 - f. The research study design is appropriate to answer the research question being asked in the study.
 - g. The research study is sponsored by an organization or individual capable of executing the proposed study successfully.
 - h. The research study is in compliance with all applicable Federal regulations concerning the protection of human subjects found at 45 CFR Part 46. If a study is Food and Drug Administration-regulated, it also must be in compliance with 21 CFR Parts 50 and 56.
 - i. All aspects of the research study are conducted according to the appropriate standards of scientific integrity.
 - j. The research study has a written protocol that clearly addresses, or incorporates by reference, the Medicare standards.
 - k. The clinical research study is not designed to exclusively test toxicity or disease pathophysiology in healthy individuals. Trials of all medical technologies measuring therapeutic outcomes as one of the objectives meet this standard only if the disease or condition being studied is life-threatening as defined in 21 CFR § 312.81(a) and the patient has no other viable treatment options.
 - l. The clinical research study is registered on the ClinicalTrials.gov Web site by the principal sponsor/investigator prior to the enrollment of the first study subject.
 - m. The research study protocol specifies the method and timing of public release of all pre-specified outcomes to be measured, including release of outcomes if outcomes are negative or study is terminated early. The results must be made public within 24 months of the end of data collection. If a report is planned for publication in a peer-reviewed journal, then that initial release may be an abstract that meets the requirements of the International Committee of Medical Journal Editors. However, a full report of the outcomes must be made public no later than 3 years after the end of data collection.
 - n. The research study protocol must explicitly discuss subpopulations affected by the treatment under investigation, particularly traditionally underrepresented groups in clinical studies, how the inclusion and exclusion criteria affect enrollment of these populations, and a plan for the retention and reporting of said populations in the trial. If the inclusion and exclusion criteria are expected to have a negative effect on the recruitment or retention of underrepresented populations, the protocol must discuss why these criteria are necessary.
 - o. The research study protocol explicitly discusses how the results are or are not expected to be generalizable to the Medicare population to infer whether Medicare patients may benefit from the intervention. Separate discussions in the protocol may be necessary for populations eligible for Medicare due to age, disability, or Medicaid eligibility.

Nationally Non-covered Indications

Other diagnostic tests for the diagnosis of OSA, other than those noted above for prescribing CPAP, are not sufficient for the coverage of CPAP.

OSA and Respiratory Assist Devices

Initial Coverage OSA

In this policy, the term PAP (positive airway pressure) device will refer to both a single-level continuous positive airway pressure device (E0601) and a bi-level respiratory assist device without back-up rate (E0470) when it is used in the treatment of obstructive sleep apnea.

1. An E0601 device is covered for the treatment of obstructive sleep apnea (OSA) if criteria A – C are met:
 - a. The beneficiary has a face-to-face clinical evaluation by the treating practitioner prior to the sleep test to assess the beneficiary for obstructive sleep apnea.
 - b. The beneficiary has a sleep test (as defined below) that meets either of the following criteria (1 or 2):
 1. The apnea-hypopnea index (AHI) or Respiratory Disturbance Index (RDI) is greater than or equal to 15 events per hour with a minimum of 30 events; or,
 2. The AHI or RDI is greater than or equal to 5 and less than or equal to 14 events per hour with a minimum of 10 events and documentation of:
 - Excessive daytime sleepiness, impaired cognition, mood disorders, or insomnia; or,
 - Hypertension, ischemic heart disease, or history of stroke.
 - c. The beneficiary and/or their caregiver has received instruction from the supplier of the device in the proper use and care of the equipment.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.
2. An E0470 device is covered for those beneficiaries with OSA who meet criteria a - c above, in addition to the following criterion:
 - a. An E0601 device has been tried and proven ineffective based on a therapeutic trial conducted in either a facility or in a home setting. Ineffective is defined as documented failure to meet therapeutic goals using an E0601 during the titration portion of a facility-based study or during home use despite optimal therapy (i.e., proper mask selection and fitting and appropriate pressure settings).

If E0470 is billed for a beneficiary with OSA and all criteria above are not met, it will be denied as not reasonable and necessary.

A bi-level positive airway pressure device with back-up rate (E0471) is not reasonable and necessary if the primary diagnosis is OSA. If an E0471 is billed with a diagnosis of OSA, it will be denied as not reasonable and necessary.

If an E0601 device is tried and found ineffective during the initial facility-based titration or home trial, substitution of an E0470 does not require a new initial face-to-face clinical evaluation or a new sleep test.

If an E0601 device has been used for more than 3 months and the beneficiary is switched to an E0470, a new initial face-to-face clinical evaluation is required, but a new sleep test is not required. A new 3 month trial would begin for use of the E0470.

Initial Coverage Respiratory Assist Devices

For an E0470 or an E0471 Respiratory Assist Device to be covered, the treating practitioner must fully document in the beneficiary's medical record symptoms characteristic of sleep-associated hypoventilation, such as daytime hypersomnolence, excessive fatigue, morning headache, cognitive dysfunction, dyspnea, etc.

Respiratory Assist Device (E0470, E0471) is covered for those beneficiaries with one of the following clinical disorders: restrictive thoracic disorders (i.e., neuromuscular diseases or severe thoracic cage abnormalities), severe chronic obstructive pulmonary disease (COPD), Central Sleep Apnea or Complex Sleep Apnea, or hypoventilation syndrome, as described in **L33800 Respiratory Assist Devices**.

Continued Coverage Beyond the First Three Months of Therapy for PAP and OSA

Continued coverage of a PAP device (E0470 or E0601) beyond the first three months of therapy requires that, no sooner than the 31st day but no later than the 91st day after initiating therapy, the treating practitioner must conduct a clinical re-evaluation and document that the beneficiary is benefiting from PAP therapy. Documentation of clinical benefit is demonstrated by:

1. Face-to-face clinical re-evaluation by the treating practitioner with documentation that symptoms of obstructive sleep apnea are improved; and,
2. Objective evidence of adherence to use of the PAP device, reviewed by the treating practitioner.

Adherence to therapy is defined as use of PAP \geq 4 hours per night on 70% of nights during a consecutive thirty (30) day period anytime during the first three (3) months of initial usage.

If the above criteria are not met, continued coverage of a PAP device and related accessories will be denied as not reasonable and necessary.

If the practitioner re-evaluation does not occur until after the 91st day but the evaluation demonstrates that the beneficiary is benefiting from PAP therapy as defined in criteria 1 and 2 above, continued coverage of the PAP device will commence with the date of that re-evaluation. See **L33718 Positive Airway Pressure (PAP) Devices for the Treatment of Obstructive Sleep Apnea** for detailed guidelines.

Continued Coverage Criteria for E0470 and E0471 Devices Beyond the First Three Months of Therapy: RAD

Beneficiaries covered for the first three months of an E0470 or an E0471 device must be re-evaluated to establish the medical necessity of continued coverage by Medicare beyond the first three months. While the beneficiary may certainly need to be evaluated at earlier intervals after this therapy is initiated, the re-evaluation upon which Medicare will base a decision to continue coverage beyond this time must occur no sooner than 61 days after initiating therapy by the treating practitioner. Medicare will not continue coverage for the fourth and succeeding months of therapy until this re-evaluation has been completed.

There must be documentation in the beneficiary's medical record about the progress of relevant symptoms and beneficiary usage of the device up to that time. Failure of the beneficiary to be consistently using the E0470 or E0471 device for an average of 4 hours per 24 hour period by the time of the re-evaluation (on or after 61 days after initiation of therapy) would represent non-compliant utilization for the intended purposes and expectations of benefit of this therapy. This would constitute reason for Medicare to deny continued coverage as not reasonable and necessary.

A signed and dated statement completed by the treating practitioner no sooner than 61 days after initiating use of the device, declaring that the beneficiary is compliantly using the device (an average of 4 hours per 24 hour period) and that the beneficiary is benefiting from its use must be obtained by the supplier of the device for continued coverage beyond three months.

If the above criteria are not met, continued coverage of an E0470 or an E0471 device and related accessories will be denied as not reasonable and necessary. See **L33800 Respiratory Assist Devices** for detailed guidelines.

APPLICABLE CODES

The following list(s) of codes is provided for reference purposes only and may not be all inclusive. Listing of a code in this guideline does not imply that the service described by the code is a covered or non-covered health service. Benefit coverage for health services is determined by the member specific benefit plan document and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment. Other Policies and Guidelines may apply.

Coding Clarification: CMS, as part of the National Coverage Determination (NCD) may determine coverage of an item or service only in the context of a clinical study. The clinical trial identifier number is required for all items/services provided in relation to participation in a clinical trial, clinical study, or registry that may result from Coverage with Evidence Development (CED). Specifically, include the clinical trial identifier number if:

- The beneficiary is enrolled in an approved clinical trial; **and**
- The claim is for the investigational item or service, **and/or**,
- The costs are related to the investigational item or service, **and/or**
- The costs are related to routine care for the condition in the clinical trial.

HCPCS Code	Description
Devices	
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)
E0601	Continuous positive airway pressure (CPAP) device
Accessories	
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

HCPCS Code	Description
Accessories	
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, nondisposable, 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, nonheated, used with positive airway pressure device
E0562	Humidifier, heated, used with positive airway pressure device

Modifier	Description
KX	Requirements specified in the medical policy have been met
NU	New equipment (Not covered)
RR	Rental (use the RR modifier when DME is to be rented)

CED Only	
Q0	Investigational clinical service provided in a clinical research

Coding Clarification: Inclusion of an ICD-10 diagnosis code within any of the following grids does not always imply coverage. The entire policy must be read to determine applicable coverage indications. In addition, indications may have variable effective dates. Claims with dates of service prior to the effective date for the diagnosis code are not eligible to be overridden and paid. The diagnosis code effective dates within a policy or National Coverage Determination (NCD) are based on the date of service, not the claim transaction date.

ICD-10 Diagnosis Code	Description
G47.33	Obstructive sleep apnea (adult) (pediatric)
CED Only	
Z00.6	Encounter for examination for normal comparison and control in clinical research program (In any position)

DEFINITIONS

BiPAP: Bi-level Positive Airway Pressure

CPAP: Continuous Positive Airway Pressure

OSA: Obstructive Sleep Apnea

PAP: Positive Airway Pressure

RAD: Respiratory Assist Devices

QUESTIONS AND ANSWERS

1	Q:	Have you verified the CPT/HCPCS code(s) on your claim may have limited coverage under CED (Coverage with Evidence Development)?
	A:	If no, clinical trial number, modifier Q0 and diagnosis code Z00.6 should not be submitted. If yes, the three requirements listed above are required. Claims without the required information will be denied.

PURPOSE

The Medicare Advantage Policy Guideline documents are generally used to support UnitedHealthcare Medicare Advantage claims processing activities and facilitate providers' submission of accurate claims for the specified services. The document can be used as a guide to help determine applicable:

- Medicare coding or billing requirements, and/or
- Medical necessity coverage guidelines; including documentation requirements.

UnitedHealthcare follows Medicare guidelines such as LCDs, NCDs, and other Medicare manuals for the purposes of determining coverage. It is expected providers retain or have access to appropriate documentation when requested to support coverage. Please utilize the links in the [References](#) section below to view the Medicare source materials used to develop this resource document. This document is not a replacement for the Medicare source materials that outline Medicare coverage requirements. Where there is a conflict between this document and Medicare source materials, the Medicare source materials will apply.

REFERENCES

CMS National Coverage Determinations (NCDs)

[NCD 240.4 Continuous Positive Airway Pressure \(CPAP\) Therapy for Obstructive Sleep Apnea \(OSA\)](#)

Reference NCDs: [NCD 240.4.1 Sleep Testing for Obstructive Sleep Apnea \(OSA\)](#), [NCD 280.1 Durable Medical Equipment Reference List](#), [NCD 310.1 Routine Costs in Clinical Trials](#)

CMS Local Coverage Determinations (LCDs) and Articles

LCD	Article	Contractor	DME MAC
L33718 (Positive Airway Pressure (PAP) Devices for the Treatment of Obstructive Sleep Apnea)	A52467 (Positive Airway Pressure (PAP) Devices for the Treatment of Obstructive Sleep Apnea – Policy Article)	CGS	AL, AR, CO, FL, GA, IL, IN, KY, LA, MI, MN, MS, NC, NM, OH, OK, PR, SC, TN, TX, VA, VI, WI, WV
		Noridian	AL, AS, AZ, CA, CT, DC, DE, GU, HI, IA, ID, KS, MA, MD, ME, MO, MT, ND, NE, NH, NJ, NV, NY, OR, PA, RI, SD, UT, VT, WA, WY, MP
L33800 (Respiratory Assist Devices)	A52517 (Respiratory Assist Devices – Policy Article)	CGS	AL, AR, CO, FL, GA, IL, IN, KY, LA, MI, MN, MS, NC, NM, OH, OK, PR, SC, TN, TX, VA, VI, WI, WV
		Noridian	AL, AS, AZ, CA, CT, DC, DE, GU, HI, IA, ID, KS, MA, MD, ME, MO, MT, ND, NE, NH, NJ, NV, NY, OR, PA, RI, SD, UT, VT, WA, WY, MP
N/A	A55426 (Standard Documentation Requirements for All Claims Submitted to DME MACs)	CGS	AL, AR, CO, FL, GA, IL, IN, KY, LA, MI, MN, MS, NC, NM, OH, OK, PR, SC, TN, TX, VA, VI, WI, WV
		Noridian	AL, AS, AZ, CA, CT, DC, DE, GU, HI, IA, ID, KS, MA, MD, ME, MO, MT, ND, NE, NH, NJ, NV, NY, OR, PA, RI, SD, UT, VT, WA, WY, MP

CMS Benefit Policy Manual

[Chapter 6; § 50 Sleep Disorder Clinics](#)

[Chapter 15; § 70 Sleep Disorder Clinics, § 110 Durable Medical Equipment – General](#)

CMS Claims Processing Manual

[Chapter 32; § 210 Billing Requirements for Continuous Positive Airway Pressure \(CPAP\) for Obstructive Sleep Apnea \(OSA\)](#)

CMS Transmittals

[Transmittal 96, Change Request 6048, Dated 10/15/2008, Continuous Positive Airway Pressure \(CPAP\) Therapy for Obstructive Sleep Apnea \(OSA\)](#)

[Transmittal 103, Change Request 6534, Dated 07/10/2009, Sleep Testing for Obstructive Sleep Apnea \(OSA\)](#)

[Transmittal 672, Change Request 9741, Dated 09/19/16 Documentation for DMEPOS Claims for Replacement of Essential Accessories for Beneficiary Owned CPAP and RADs](#)

MLN Matters

[Article MM3843, Continuous Positive Airway Pressure \(CPAP\) Therapy for Obstructive Sleep Apnea \(OSA\)](#)

[Article MM6094, July 2008 Update of the Hospital Outpatient Prospective Payment System \(OPPS\)](#)

[Article MM6534, Sleep Testing for Obstructive Sleep Apnea \(OSA\)](#)

[Article MM8304, Detailed Written Orders and Face-to-Face Encounters](#)

UnitedHealthcare Commercial Policies

[Attended Polysomnography for Evaluation of Sleep Disorders](#)

[Durable Medical Equipment, Orthotics, Ostomy Supplies, Medical Supplies and Repairs/Replacements](#)

Others

[Continuous Positive Airway Pressure \(CPAP\) Therapy for Obstructive Sleep Apnea \(OSA\) – JA6048, Job Aid 6048](#)

[Provider Inquiry Assistance, CMS Website](#)

GUIDELINE HISTORY/REVISION INFORMATION

Revisions to this summary document do not in any way modify the requirement that services be provided and documented in accordance with the Medicare guidelines in effect on the date of service in question.

Date	Action/Description
09/09/2020	Supporting Information <ul style="list-style-type: none">Updated <i>References</i> section to reflect the most current informationArchived previous policy version MPG061.05

TERMS AND CONDITIONS

The Medicare Advantage Policy Guidelines are applicable to UnitedHealthcare Medicare Advantage Plans offered by UnitedHealthcare and its affiliates.

These Policy Guidelines are provided for informational purposes, and do not constitute medical advice. Treating physicians and healthcare providers are solely responsible for determining what care to provide to their patients. Members should always consult their physician before making any decisions about medical care.

Benefit coverage for health services is determined by the member specific benefit plan document* and applicable laws that may require coverage for a specific service. The member specific benefit plan document identifies which services are covered, which are excluded, and which are subject to limitations. In the event of a conflict, the member specific benefit plan document supersedes the Medicare Advantage Policy Guidelines.

Medicare Advantage Policy Guidelines are developed as needed, are regularly reviewed and updated, and are subject to change. They represent a portion of the resources used to support UnitedHealthcare coverage decision making. UnitedHealthcare may modify these Policy Guidelines at any time by publishing a new version of the policy on this website. Medicare source materials used to develop these guidelines include, but are not limited to, CMS National Coverage Determinations (NCDs), Local Coverage Determinations (LCDs), Medicare Benefit Policy Manual, Medicare Claims Processing Manual, Medicare Program Integrity Manual, Medicare Managed Care Manual, etc. The information presented in the Medicare Advantage Policy Guidelines is believed to be accurate and current as of the date of publication, and is provided on an "AS IS" basis. Where there is a conflict between this document and Medicare source materials, the Medicare source materials will apply.

You are responsible for submission of accurate claims. Medicare Advantage Policy Guidelines are intended to ensure that coverage decisions are made accurately based on the code or codes that correctly describe the health care services provided. UnitedHealthcare Medicare Advantage Policy Guidelines use Current Procedural Terminology (CPT®), Centers for Medicare and Medicaid Services (CMS), or other coding guidelines. References to CPT® or other sources are for definitional purposes only and do not imply any right to reimbursement or guarantee claims payment.

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*For more information on a specific member's benefit coverage, please call the customer service number on the back of the member ID card or refer to the [Administrative Guide](#).