UnitedHealthcare®

Reimbursement Policy

Continuous Positive Airway Pressure (CPAP) Therapy For Obstructive Sleep Apnea (OSA) (NCD 240.4) and other Respiratory Assist Devices (RAD)

Policy Number	240.4	Approved By	UnitedHealthcare Medicare Reimbursement Policy Committee	Current Approval Date	08/13/2014

IMPORTANT NOTE ABOUT THIS REIMBURSEMENT POLICY

This policy is applicable to UnitedHealthcare Medicare Advantage Plans offered by UnitedHealthcare and its affiliates.

You are responsible for submission of accurate claims. This reimbursement policy is intended to ensure that you are reimbursed based on the code or codes that correctly describe the health care services provided. UnitedHealthcare reimbursement policies 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.

This reimbursement policy applies to all health care services billed on CMS 1500 forms and, when specified, to those billed on UB04 forms (CMS 1450). Coding methodology, industry-standard reimbursement logic, regulatory requirements, benefits design and other factors are considered in developing reimbursement policy.

This information is intended to serve only as a general resource regarding UnitedHealthcare's reimbursement policy for the services described and is not intended to address every aspect of a reimbursement situation. Accordingly, UnitedHealthcare may use reasonable discretion in interpreting and applying this policy to health care services provided in a particular case. Further, the policy does not address all issues related to reimbursement for health care services provided to UnitedHealthcare enrollees. Other factors affecting reimbursement may supplement, modify or, in some cases, supersede this policy. These factors may include, but are not limited to: legislative mandates, the physician or other provider contracts, and/or the enrollee's benefit coverage documents. Finally, this policy may not be implemented exactly the same way on the different electronic claims processing systems used by UnitedHealthcare due to programming or other constraints; however, UnitedHealthcare strives to minimize these variations.

UnitedHealthcare may modify this reimbursement policy at any time by publishing a new version of the policy on this Website. However, the information presented in this policy is accurate and current as of the date of publication.

Table of Contents

Continuous Positive Airway Pressure (CPAP) Therapy For Obstructive Sleep Apnea (OSA) (NCD 240.4) and other Respiratory Assist Devices (RAD)

Application

This reimbursement policy applies to services reported using the Health Insurance Claim Form CMS-1500 or its electronic equivalent or its successor form, and services reported using facility claim form CMS-1450 or its electronic equivalent or its successor form. This policy applies to all products, all network and non-network physicians, and other health care professionals.

The HCPCS/CPT code(s) may be subject to Correct Coding Initiative (CCI) edits. This policy does not take precedence over CCI edits. Please refer to the CCI for correct coding guidelines and specific applicable code combinations prior to billing UnitedHealthcare. It is not enough to link the procedure code to a correct, payable ICD-9-CM diagnosis code. The diagnosis must be present for the procedure to be paid. Compliance with the provisions in this policy is subject to monitoring by pre-payment review and/or post-payment data analysis and subsequent medical review. The effective date of changes/additions/deletions to this policy is the committee meeting date unless otherwise indicated.

Summary

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. The purpose 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.

Reimbursement Guidelines

Nationally Covered Indications

Effective for claims with dates of service on and after March 13, 2008, 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 under Medicare 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

Effective for claims with dates of services on and after March 13, 2008, other diagnostic tests for the diagnosis of OSA, other than those noted above for prescribing CPAP, are not sufficient for the coverage of CPAP.

Respiratory Assist Devices

Initial Coverage

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.

I. 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 physician 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:

a. Excessive daytime sleepiness, impaired cognition, mood disorders, or insomnia; or,

b. 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.

II. An E0470 device is covered for those beneficiaries with OSA who meet criteria A-C above, in addition to criterion D:

D. An E0601 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 criteria A-D 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.

Continued Coverage Beyond the First Three Months of Therapy

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 physician must conduct a clinical re-evaluation and document that the beneficiary is benefiting from PAP therapy.

For PAP devices with initial dates of service on or after November 1, 2008, documentation of clinical benefit is demonstrated by:

1. Face-to-face clinical re-evaluation by the treating physician 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 physician.

Adherence to therapy is defined as use of PAP ≥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 physician 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.

Beneficiaries who fail the initial 12 week trial are eligible to re-qualify for a PAP device but must have both:

1. Face-to-face clinical re-evaluation by the treating physician to determine the etiology of the failure to respond to PAP therapy; and,
2. Repeat sleep test in a facility-based setting (Type 1 study).This may be a repeat diagnostic, titration or split-night study.

If an E0601 device is tried and found ineffective during the initial facility-based titration or home trial, substitution of an E0470 does not change the length of the trial unless there is less than 30 days remaining in the trial period. If more than 30 days remain in the trial period, the clinical re-evaluation would still occur between the 31st and 91st day following the initiation of an E0601 and objective documentation of adherence on the E0470 would need to occur prior to the 91st day following initiation of the E0601. If less than 30 days remain in the trial period, the clinical re-evaluation and objective documentation of adherence must occur before the 120th day following the initiation of the E0601.

If an E0601 device was used for more than 3 months and the beneficiary was then switched to an E0470, the clinical re-evaluation must occur between the 31st and 91st day following the initiation of the E0470. There would also need to be documentation of adherence to therapy during the 3 month trial with the E0470.

If there is discontinuation of usage of a PAP device at any time, the supplier is expected to ascertain this and stop billing for the equipment and related accessories and supplies.

Continuous Positive Airway Pressure (CPAP) Therapy For Obstructive Sleep Apnea (OSA) (NCD 240.4) and other Respiratory Assist Devices (RAD)

CPT / HCPCS Codes

Code	Description
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 airway pressure (CPAP) device
95808	Polysomnography; any age, sleep staging with 1-3 additional parameters of sleep, attended by a technologist (See NCD 240.4.1 Sleep Testing for Obstructive Sleep Apnea (OSA))
95810	Polysomnography; age 6 years or older, sleep staging with 4 or more additional parameters of sleep, attended by a technologist (See NCD 240.4.1 Sleep Testing for Obstructive Sleep Apnea (OSA))
G0398	Home sleep study test (HST) with type II portable monitor, unattended; minimum of 7 channels: EEG, EOG, EMG, ECG/heart rate, airflow, respiratory effort and oxygen saturation (See NCD 240.4.1 Sleep Testing for Obstructive Sleep Apnea (OSA))
G0399	Home sleep test (HST) with type III portable monitor, unattended; minimum of 4 channels: 2 respiratory movement/airflow, 1 ECG/heart rate and 1 oxygen saturation (See NCD 240.4.1 Sleep Testing for Obstructive Sleep Apnea (OSA))
G0400	Home sleep test (HST) with type IV portable monitor, unattended; minimum of 3 channels (See NCD 240.4.1 Sleep Testing for Obstructive Sleep Apnea (OSA))

Modifiers

Code	Description
EY	No physician or other licensed health care provider order for this item or service
GZ	Item or service expected to be denied as not reasonable and necessary
KX	Requirements specified in the medical policy have been met
NU	New equipment
RR	Rental (use the RR modifier when DME is to be rented)

Questions and Answers

1	**Q:**	Do HCPCS E0470, E0471 and E0601 require Prior Notification?
	A:	Yes, all are on the Durable Medical Equipment (DME) - greater than $1000 prior notification list. Retail purchase cost or a cumulative rental cost over $1,000.

References Included (but not limited to):

CMS NCD(s)

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 LCD(s)

Numerous LCDs

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CMS Article(s)

Numerous Articles

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)

UnitedHealthcare Medicare Advantage Coverage Summaries

Sleep Apnea – Diagnosis and Treatment

UnitedHealthcare Reimbursement Policies

Durable Medical Equipment Reference List (NCD 280.1)

Routine Costs in a Clinical Trial (NCD 310.1)

Sleep Testing for Obstructive Sleep Apnea (OSA) (NCD 240.4.1)

UnitedHealthcare Medical Policies

Attended Polysomnography for Evaluation of Sleep Disorders

Durable Medical Equipment, Orthotics, Ostomy Supplies, Medical Supplies and Repairs/Replacements

Obstructive Sleep Apnea Treatment

MLN Matters

Article MM6534, Sleep Testing for Obstructive Sleep Apnea (OSA)

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

Article MM8304, Detailed Written Orders and Face-to-Face Encounters

History

Date	Revisions
09/10/2014	Administrative updates
08/13/2014	• Annual review • Added HCPCS codes E0470 and E0471 including CMS coverage criteria for BiPAP Bi-level Positive Airway Pressure and Respiratory Assist Devices (RAD) • Added EY, GZ, KX modifiers
02/13/2013	Administrative updates
02/08/2012	Administrative updates