RESPIRONICS®
www.respironics.com

Reimbursement Services
HELPFUL HINTS FOR FILING
Continuous Positive Airway Pressure Device (CPAP)
HCPCS Code E0601

Overview

The following information describes coverage and payment information regarding continuous positive airway pressure (CPAP) devices and accessories. Coding, coverage, payment and documentation guidelines are listed on the following pages. This is to be used as a guide. For an item to be covered by Medicare, the following conditions apply: (1) item must be eligible for a defined Medicare benefit category; (2) item must be reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member; and (3) the item must meet all applicable Medicare statutory and regulatory requirements.[1] *Please contact your Supplier Manual, local carrier or your DMERC medical director for specific instructions.*

CPAP, Auto CPAP, and CPAP with C-Flex™ devices are classified in the payment policy category "Capped Rental Items." Accessories required for items in the "Capped Rental Items" category are reimbursed separately by Medicare unless specifically noted otherwise.

General Coverage Guidelines

The Centers for Medicare and Medicaid Services (CMS) issued a revised National Coverage Decision on continuous positive airway pressure (CPAP) devices for the treatment of obstructive sleep apnea (OSA), effective April 1, 2002, broadening the coverage criteria for CPAP devices. Under a national coverage policy established in 1987, Medicare provided for coverage of CPAP in beneficiaries with moderate to severe OSA. With the revision of the national coverage policy, Medicare lowered the threshold for coverage eligibility and will cover CPAP even in beneficiaries who have mild, symptomatic OSA.

Definitions

- **Continuous Positive Airway Pressure device (CPAP) –** A device which provides a flow of positive pressure air at a constant level to the upper airway by way of tubing and a noninvasive interface to splint the airway open during sleep.
- **Nasal Application Device –** Nasal, nasal/oral, or facial mask.
- **Obstructive Sleep Apnea (OSA) –** Frequent and prolonged episodes in which breathing stops during sleep. Diagnosis is confirmed by monitoring the patient during sleep for periods of apnea and lowered blood oxygen levels. *Obstructive* sleep apnea results from the obstruction of the upper airways.
- **Sleep Study –** Continuous and simultaneous recording of physiological and pathophysiological parameters of sleep for six or more hours with physician review, interpretation, and report. The recorded parameters are ventilation, respiratory effort, ECG or heart rate, and oxygen saturation.[2]
- **Polysomnography (PSG) –** A polysomnography is distinguished from a sleep study by the inclusion of sleep staging. Sleep staging is defined to include a 1-4 lead electroencephalogram (EEG), an electro-oculogram (EOG), and a submental electromyogram (EMG). This study may either be conducted as a whole-night or split-night study.[2]
- **Apnea –** A cessation of airflow for at least 10 seconds.
- **Hypopnea –** 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.
- **Apnea-Hypopnea Index (AHI) –** Average number of episodes of apnea and hypopnea per hour based on a minimum of two hours of recording time, without the use of a positive airway pressure device, reported by polysomnography (i.e., the AHI may not be extrapolated or projected).

[1] Section 1862 (a)1(A) of Title XVIII of the Social Security Act.
[2] CPT codes, descriptions, and material only ©2004 American Medical Association (AMA).

General Coverage Guidelines

For the purpose of the policy, polysomnographic studies must:

- Be performed in a facility-based sleep laboratory, and not in a home or mobile facility. The laboratory must be a qualified Medicare provider and comply with all applicable state regulatory requirements.
- Not be performed by a DME supplier or any entity with a significant financial relationship to the DME supplier. This exclusion does not apply to results of studies from hospitals certified to perform such tests.

If a patient discontinues usage of an E0601 device at any time, the supplier is expected to ascertain this, and stop billing for the equipment and related accessories and supplies.

Clinical Coverage Guidelines

Initial coverage for the use of CPAP devices is covered under Medicare when ordered and prescribed by the licensed treating physician to be used in adult patients with OSA if either of the following criteria using the Apnea-Hypopnea Index (AHI) are met:

- **AHI ≥ 15 events per hour, or**
- **AHI ≥ 5 and ≤ 14 events per hour with documented symptoms of**
  - **a) excessive daytime sleepiness, impaired cognition, mood disorders or insomnia, or**
  - **b) hypertension, ischemic heart disease or history of stroke**

The AHI must be calculated based on a minimum of two hours of recording time without the use of a positive airway pressure device, recorded by polysomnography (i.e., the AHI may not be extrapolated or projected).

Continued coverage beyond the first three months of therapy requires the supplier to verify, with either the physician or the beneficiary, continued usage of the CPAP device no sooner than the 61st day after initiating therapy. Findings must be documented and kept on file by the supplier. Continued coverage of the CPAP device and related accessories will be denied as not medically necessary if this criterion is not met.

Billing for CPAP Accessories

All accessories associated with E0601 will use the "NU" modifier. The modifier should appear after the HCPCS code (e.g., A7034-NU). Accessories are separately reimbursable at the time of initial issue and when replaced.

HCPCS Code	Description	Payment Category/Max Replacement Allowance
A7030	Full Face Mask used with positive airway pressure device, each	*Not specified in current DMERC policy*
A7031	Face Mask Interface, Replacement for Full Face Mask, each	*Not specified in current DMERC policy*
A7032	Replacement Cushion for Nasal Application Device, each	2 per 1 month
A7033	Replacement Pillows for Nasal Application Device, pair	2 per 1 month
A7034	Nasal Interface (mask or cannula type), used with positive airway pressure device, with or without head strap	1 per 3 months
A7035	Headgear	1 per 6 months
A7036	Chinstrap	1 per 6 months
A7037	Tubing	1 per 1 month
A7038	Filter, disposable	2 per 1 month
A7039	Filter, non-disposable	1 per 6 months
A7045	Exhalation port with or without swivel, replacement only	*Not specified in current DMERC policy*
A7046	Water chamber for humidifier, replacement, each	*Not specified in current DMERC policy*
E0561	Humidifier, non-heated	N/A purchase
E0562	Humidifier, heated	N/A purchase
A9900	Miscellaneous DME supply/accessory; component of another HCPCS code	N/A
A9999	Miscellaneous DME supply/accessory	N/A

*Quantities of supplies greater than those outlined in DMERC policy as the usual maximum amounts will be denied as not medically necessary, in the absence of clear documentation supporting the medical necessity for the higher utilization. This information must be attached to a hard copy claim or entered into the narrative field of an electronic claim. Documentation in the patient record must corroborate the order and medical necessity of the items and quantities billed.

Humidifier Coverage

Either a non-heated (E0561) or heated (E0562) humidifier is covered when ordered by the treating physician for use with a covered CPAP device.

Suggestions:

- Document medical necessity and maintain in patient file.
- Candidates for heated humidity may include:
  - Patients prone to mouth leaks
  - Patients with chronic nasal symptoms (including conditions existing prior to initiation of CPAP treatment)
  - Elderly patients: As a person ages, the likelihood of nasal complaints, increased nasal resistance, and/or impairment of the mucociliary function of the nose increases
  - Patients taking medications that may result in dryness of the nasal mucosa (i.e., antihypertensives, antidepressants)

Documentation Requirements

A Certificate of Medical Necessity (CMN) is not required for CPAP claims. However, the supplier is required to keep appropriate documentation on file including:

- An order for all equipment and accessories signed and dated by the treating physician.
- Documentation of medical necessity.

-EY Modifier

Claims for CPAPs and accessories submitted to the DMERC before a signed and dated order is on file with the supplier must include an **-EY modifier** attached to each affected HCPCS code.

-KX Modifier

The CPAP policy requires a supplier to use a **-KX modifier** to indicate that the coverage and payment rules for CPAP have been met. The -KX modifier:

- Should be used when a DMERC local medical review policy directs the use of a modifier to indicate "specific required documentation on file."
- Applies to both the HCPCS code E0601 and accessories.

Initial Coverage (First Three Months)

For claims 1-3 months, suppliers must add a -KX modifier to codes for equipment (E0601) and accessories only if the initial coverage criteria have been met.

- When requirements for the -KX modifier are not met, the supplier may submit additional documentation with the claim to justify coverage, but the -KX modifier must not be used.

Continued Coverage (Beyond First Three Months)

For the month 4 claim (and any month thereafter), the supplier must add a -KX modifier to codes for equipment (E0601) and accessories only if both the initial coverage and continued coverage criteria have been met. Suppliers must maintain documentation in their records that these criteria have been met and this must be available to the DMERC upon request.

- If the supplier does not verify and document that the beneficiary is continuing to use the CPAP device in time for submission of the fourth or succeeding months' claims, the supplier may still submit the claims, but a -KX modifier must not be used.
- Claims may be held for the fourth and succeeding months until the supplier determines that the beneficiary is continuing to use the device, and then be submitted with the -KX modifier.

Note: Inclusion or exclusion of a code for a specific product or supply does not imply any health insurance coverage or reimbursement policy. All referenced information and codes were taken from HCPCS. Please refer to DMEPOS Supplier Manual for complete explanations.

FOR MORE INFORMATION FROM RESPIRONICS CONCERNING		
Reimbursement	**Contact**	**Website/Phone**
Information & Fee Schedules	Respironics Website	www.respironics.com
Educational Materials & Questions (coding, coverage and payment)	Customer Service	1-800-345-6443; listen to the instructions and follow prompts to select the Insurance Reimbursement Information option

RESPIRONICS®
www.respironics.com
Customer Service: 1-800-345-6443 • 724-387-4000
Respironics Europe: +33-1-55-60-19-80
Respironics Asia Pacific: +81-3-5280-9611

PTch - SB 2/28/05
mci 4100199 PN 1015456