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## Regional Medical Review Policies (RMRPs)

### 14.11 Continuous Positive Airway Pressure System (CPAP)

#### HCPCS Codes

The appearance of a code in this section does not necessarily indicate coverage.

#### Equipment

E0601 Continuous positive airway pressure (CPAP) device

#### Accessories

K0183 Nasal application device, used with positive airway pressure device

K0184 Nasal pillows/seals, replacement for nasal application device, pair or single piece interface

K0185 Headgear, used with positive airway pressure device

K0186 Chin strap, used with positive airway pressure device

K0187 Tubing, used with positive airway pressure device

K0188 Filter, disposable, used with positive airway pressure device

K0189 Filter, non-disposable, used with positive airway pressure device

K0268 Humidifier, non-heated, used with positive airway pressure device

K0531 Humidifier, heated, used with positive airway pressure device

#### HCPCS Modifiers

KX Specific required documentation on file.

#### Benefit Category

Durable Medical Equipment

#### Reference

Coverage Issues Manual 60-17

#### Definitions

A continuous positive airway pressure (CPAP) device (E0601) delivers a constant level of positive air pressure (within a single respiratory cycle) by way of tubing and a noninvasive interface (such as a nasal, oral, or facial mask) to assist spontaneous respiratory efforts and supplement the volume of inspired air into the lungs.

A respiratory cycle is defined as an inspiration, followed by an expiration. Polysomnography is the continuous and simultaneous monitoring and recording of various physiological and pathophysiological parameters of sleep with physician review, interpretation, and report. It must include sleep staging, which is defined to include a 1-4 lead electroencephalogram (EEG), and electro-oculogram (EOG),

and a submental electromyogram (EMG). It must also include at least the following additional parameters of sleep: airflow, respiratory effort, and oxygen saturation by oximetry. It may be performed as either a whole night study for diagnosis only or as a split night study to diagnose and initially evaluate treatment.

Apnea is defined as the cessation of airflow for at least 10 seconds documented on a polysomnogram.

Hypopnea is defined as an abnormal respiratory event lasting at least 10 seconds associated with at least a 30% reduction in thoracoabdominal movement or airflow as compared to baseline, and with at least a 4% decrease in oxygen saturation.

The apnea-hypopnea index (AHI) (also referred to as a respiratory disturbance index [RDI]) is defined as the average number of episodes of apnea and hypopnea per hour and must be based on a minimum of 2 hours of sleep reported by polysomnography using actual recorded hours of sleep (i.e., the AHI may not be extrapolated or projected).

### Coverage and Payment Rules

For any item to be covered by Medicare, it must: 1) be eligible for a defined Medicare benefit category, 2) 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) meet all other applicable Medicare statutory and regulatory requirements. For the items addressed in this medical policy, "reasonable and necessary" is defined by the following coverage and payment rules.

#### Initial Coverage

A single level continuous positive airway pressure (CPAP) device (E0601) is covered if the patient has a diagnosis of obstructive sleep apnea (OSA) documented by an attended, facility-based polysomnogram and meets either of the following criteria (1 or 2):

- 1) The AHI is  $\geq 15$  events per hour, or
- 2) The AHI is from 5 to 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 2 hours of recorded sleep and must be calculated using actual recorded hours of sleep (i.e. the AHI may not be an extrapolated or a projected calculation).

If a continuous positive airway pressure device (E0601) is provided and the criteria above have not been met, it will be denied as not medically necessary.

For the purpose of this policy, polysomnographic studies must be performed in a facility based sleep study laboratory, and not in the home or in a mobile facility. These labs must be qualified providers of Medicare services and comply with all applicable state regulatory requirements.

For the purpose of this policy, polysomnographic studies must not be performed by a DME supplier. This prohibition does not extend to the results of studies conducted by hospitals certified to do such tests.

If there is discontinuation of 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.

### Continued Coverage Beyond The First Three Months of Therapy

Continued coverage of an E0601 device beyond the first three months of therapy requires that, no sooner than the 61<sup>st</sup> day after initiating therapy, the supplier ascertain from either the beneficiary or the treating

physician that the beneficiary is continuing to use the CPAP device.

If the above criterion is not met, continued coverage of an E0601 device and related accessories will be denied as not medically necessary.

### Accessories

Accessories used with an E0601 device are covered when the coverage criteria for the device are met. Accessories are separately reimbursable at the time of initial issue and when replaced.

The following table represents the usual maximum amount of accessories expected to be medically necessary:

K0183	1 per 3 months
K0184	2 per 1 month
K0185	1 per 6 months
K0186	1 per 6 months
K0187	1 per 1 month
K0188	2 per 1 month
K0189	1 per 6 months

Claims for more than the usual maximum replacement amount will be denied as not medically necessary unless the claim is accompanied by documentation, which justifies a larger quantity in the individual case.

Either a non-heated (K0268) or heated (K0531) humidifier is covered when ordered by the treating physician for use with a covered E0601 device.

### **Coding Guidelines**

For auto-titrating CPAP devices use HCPCS code E0601.

Suppliers should contact the Statistical Analysis Durable Medical Equipment Regional Carrier (SADMERC) for guidance on the correct coding of these devices.

### **Documentation**

Section 1833(e) of the Social Security Act precludes payment to any provider of services unless "there has been furnished such information as may be necessary in order to determine the amounts due such provider" (42 U.S.C. §1395l(e)). It is expected that the patient's medical records will reflect the need for the care provided. The patient's medical records include the physician's office records, hospital records, nursing home records, home health agency records, records from other healthcare professionals and test reports. This documentation must be available to the DMERC upon request.

An order for all equipment and accessories must be signed and dated by the treating physician, be kept on file by the supplier and made available to the DMERC upon request.

Proper use of the KX modifier is discussed below. The KX modifier must not be used on claims submitted to the DMERC until the requirements outlined in the documentation section have been met.

#### Initial Coverage (First Three Months)

On claims for the first through third months, suppliers must add a KX modifier to codes for equipment (E0601) and accessories only if all of the criteria in the Coverage and Payment Rules section of this policy ("Initial Coverage") have been met. If the 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.

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**Continued Coverage Beyond The First Three Months of Therapy**

On the fourth month's 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" criteria and the "Continued Coverage" criteria in the Coverage and Payment Rules section of this policy 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 obtain information 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 added. However, if the supplier chooses to hold claims for the fourth and succeeding months until they determine that the beneficiary is continuing to use the device, those claims may then be submitted with the KX modifier.

Refer to the Supplier Manual for further information on orders, medical records and supplier documentation.

**Effective Date**

Claims with dates of service on or after July 1, 2002.

This is a revision to a previously published policy.