

**Contractor Information**

**Contractor Name**

[Tricenturion](#)

**Contractor Number**

77011

**Contractor Type**

DMERC

**LCD Information**

**LCD ID Number**

L11528

**LCD Title**

Continuous Positive Airway Pressure System (CPAP)

**Contractor's Determination Number**

CPAP20060101

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**CMS National Coverage Policy**

CMS Pub. 100-03, (Medicare National Coverage Determinations Manual), Chapter 1, Section 240.4

**Primary Geographic Jurisdiction**

Connecticut  
Delaware  
Massachusetts  
Maine  
New Hampshire  
New Jersey  
New York - Entire State  
Pennsylvania  
Rhode Island  
Vermont

**Oversight Region**

Region III

**CMS Consortium**

Northeast

**DMERC Region LCD Covers**

Region A

**Original Determination Effective Date**

For services performed on or after 10/01/1993

**Original Determination Ending Date****Revision Effective Date**

For services performed on or after 01/01/2006

**Revision Ending Date****Indications and Limitations of Coverage and/or Medical Necessity**

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, the criteria for "reasonable and necessary" are defined by the following indications and limitations of coverage and/or medical necessity.

For an item to be covered by Medicare, a written signed and dated order must be received by the supplier before a claim is submitted to the DMERC. If the supplier bills for an item addressed in this policy without first receiving the completed order, the item will be denied as not medically necessary.

**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 greater than or equal to 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.

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 61st 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. If the coverage criteria are not met, the accessories will be denied as not medically necessary.

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

- A4604 – 1 per 3 months
- A7030 – 1 per 3 months
- A7031 – 1 per 1 month
- A7032 - 2 per 1 month
- A7033 – 2 per 1 month
- A7034 - 1 per 3 months
- A7035 - 1 per 6 months
- A7036 - 1 per 6 months
- A7037 - 1 per 1 month
- A7038 - 2 per 1 month
- A7039 - 1 per 6 months
- A7046 – 1 per 6 months

Quantities of supplies greater than those described in the policy as the usual maximum amounts, in the absence of documentation clearly explaining the medical necessity of the excess quantities, will be denied as not medically necessary.

Either a non-heated (E0561) or heated (E0562) humidifier is covered when ordered by the treating physician for use with a covered E0601 device.

**Coverage Topic**

Durable Medical Equipment

**Coding Information**

**CPT/HCPCS Codes**

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

**HCPCS MODIFIERS:**

**EY - No physician or other licensed health care provider order for this item or service.**

**KX - Specific required documentation on file.**

**EQUIPMENT**

E0601 CONTINUOUS AIRWAY PRESSURE (CPAP) DEVICE

**ACCESSORIES**

A4604 TUBING WITH INTEGRATED HEATING ELEMENT FOR USE WITH POSITIVE AIRWAY PRESSURE DEVICE

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

#### **ICD-9 Codes that Support Medical Necessity**

Not specified.

#### **Diagnoses that Support Medical Necessity**

Not specified.

#### **ICD-9 Codes that DO NOT Support Medical Necessity**

Not specified.

#### **ICD-9 Codes that DO NOT Support Medical Necessity Asterisk Explanation**

#### **Diagnoses that DO NOT Support Medical Necessity**

Not specified.

### **General Information**

#### **Documentation Requirements**

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. section 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 each item billed must be signed and dated by the treating physician, kept on file by the supplier, and made available to the DMERC upon request. Items billed to the DMERC before a signed and dated order has been received by the supplier must be submitted with an EY modifier added to each affected HCPCS code.

When billing for quantities of supplies greater than those described in the policy as the usual maximum amounts, documentation supporting the medical necessity for the higher utilization must be available to the DMERC on 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 "Indications and Limitations of Coverage and/or Medical Necessity" 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.

#### 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 "Indications and Limitations of Coverage and/or Medical Necessity" 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.

#### **Appendices**

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) 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 without the use of a positive airway pressure device, reported by polysomnography using actual recorded hours of sleep

(i.e., the AHI may not be extrapolated or projected).

### **Utilization Guidelines**

Refer to Indications and Limitations of Coverage and/or Medical Necessity.

### **Sources of Information and Basis for Decision**

Reserved for future use.

### **Advisory Committee Meeting Notes**

### **Start Date of Comment Period**

04/30/1993

### **End Date of Comment Period**

06/14/1993

### **Start Date of Notice Period**

08/01/1993

### **Revision History Number**

CPAP009

### **Revision History Explanation**

Revision Effective Date: 01/01/2006

HCPCS CODES:

Added: A4604

Revised: A7032, A7033

INDICATIONS AND LIMITATIONS OF COVERAGE:

Accessories:

Added frequency guideline for A4604, A7030 and A7046

Added clarification regarding Full Face Mask Seals (A7031)

DOCUMENTATION:

Revised requirements for documenting excess quantities of supplies.

APPENDICES:

Revised definition of apnea-hypopnea index (AHI) to reflect NCD.

Revision Effective Date: 01/01/2005

HCPCS CODES AND MODIFIERS:

Added code A7045

APPENDICES:

Clerical correction to move definitions from Policy Article to LCD Clarified calculation of AHI

Revision Effective Date: 07/01/2004

LMRP converted into LCD and Policy Article

INDICATIONS AND LIMITATIONS OF COVERAGE AND/OR MEDICAL NECESSITY:

Clarified how accessories are denied when medical necessity is not met.

Revision Effective Date: 01/01/2004

HCPCS CODES AND MODIFIERS:

Crosswalked codes K0268 and K0531 to E0561 and E0562, respectively. Added new code A7046

OTHER COMMENTS:

Revised the definition of AHI to require a minimum of two hours of recording time without the use of the device rather than two hour of recorded sleep.

Revision Effective Date: 04/01/2003

HCPCS CODES AND MODIFIERS:

Added: A7030 – A7039, A7044, EY

Discontinued: K0183 – K0189

**INDICATIONS AND LIMITATIONS OF COVERAGE:**

Adds standard language concerning coverage of items without an order.

Updated utilization table to incorporate new A codes which were crosswalked from K codes.

Removed reference to RDI in definitions section.

**DOCUMENTATION REQUIREMENTS:**

Adds standard language concerning use of EY modifier for items without an order.

The revision dates listed below are the dates the revisions were published and not necessarily the effective dates for the revisions.

07/01/2002 – Revised language regarding who is a qualified provider of polysomnographic studies.

04/01/2002 – Updated Coverage and Payment Rules section to reflect National Coverage Decision to cover CPAP based on apnea-hypopnea index. Eliminated Certificate of Medical Necessity requirement. Added KX modifier to indicate coverage criteria met. Revised verbiage of HCPCS code K0184. Allowed coverage of either heated or non-heated humidifier with a covered CPAP device.

10/01/1995 – Added HCPCS codes for accessories.

12/01/1993 – Corrected typo from HAO to HA0 in the Documentation section.

11/26/2005 - The description for CPT/HCPCS code A7032 was changed in group 2

11/26/2005 - The description for CPT/HCPCS code A7033 was changed in group 2

**Last Reviewed On Date**

**Related Documents**

**Article(s)**

[A19815 - Continuous Positive Airway Pressure \(CPAP\) Devices – Policy Article – Effective January 2006](#)

**LCD Attachments**

There are no attachments for this LCD

**Article for Continuous Positive Airway Pressure (CPAP) Devices – Policy Article – Effective January 2006 (A19815)**

**Contractor Information**

**Contractor Name**

[Tricenturion](#)

**Contractor Number**

77011

**Contractor Type**

DMERC

**Article Information**

**Article ID Number**

A19815

**Article Type**

Article

**Key Article**

Yes

**Article Title**

Continuous Positive Airway Pressure (CPAP) Devices – Policy Article – Effective January 2006

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**Primary Geographic Jurisdiction**

Connecticut  
Delaware  
Massachusetts  
Maine  
New Hampshire  
New Jersey  
New York - Entire State  
Pennsylvania  
Rhode Island  
Vermont

**DMERC Region Article Covers**

Region A

**Original Article Effective Date**

07/01/2004

### **Article Revision Effective Date**

01/01/2006

### **Article Text**

#### **CODING GUIDELINES**

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.

For auto-titrating CPAP devices use HCPCS code E0601.

Accessories are separately reimbursable at the time of initial issue and when replaced.

A4604 describes tubing used with a heated humidifier which and has a heated wire running the length of the tubing. It is designed for use with a positive airway pressure device and a non-invasive interface – i.e., nasal or face mask, nasal cannula, or oral interface.

Code A7032 is used for a replacement nasal mask interface that goes around the nose, but not into the nostrils. The unit of service for this code is "each".

Code A7033 is used for a replacement nasal cannula-type interface. This interface extends a short distance into the nostrils. The unit of service for this code is "pair". For some products, there are two physically separate cushions or "pillows" – one for each nostril. Two cushions/ pillows equals one unit of service of A7033. For other products, the interface is a single piece with two protrusions that extend into the nostrils. One of these interfaces equals one unit of service of A7033.

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

### **Coverage Topic**

Durable Medical Equipment

## **Other Information**

### **Other Comments**

Revision Effective Date: 01/01/2006

CODING GUIDELINES:

Added definitions for tubing with a heated wire (A4604) and replacement nasal interfaces (A7032, A7033).

Revision Effective Date: 01/01/2005

Clerical correction to move definitions from Policy Article to LCD

Revision Effective Date: 07/01/2004

LMRP converted into LCD and Policy Article

### **Related Documents**

#### **LCD(s)**

[L11528 - Continuous Positive Airway Pressure System \(CPAP\)](#)